Georgia Rules and Regulations
Administrative Bulletin for March 2023

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290. RULES OF DEPARTMENT OF HUMAN SERVICES	290-9-2-.01, 290-9-2-.04, 290-9-2-.07	amended	Feb. 20, 2023	Mar. 12
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Department 110. RULES OF GEORGIA DEPARTMENT OF COMMUNITY AFFAIRS

Chapter 110-38. GEORGIA STATE SMALL BUSINESS CREDIT INITIATIVE 2.0 PROGRAM

Subject 110-38-1. GEORGIA STATE SMALL BUSINESS CREDIT INITIATIVE 2.0 PROGRAM REGULATIONS

110-38-1-.01 Name

The name of this program is the Georgia State Small Business Credit Initiative 2.0. This program is divided into five sub-programs as follows: the Georgia Loan Participation Program, the Georgia Small Business Credit Guarantee Program, the Georgia CDFI Program, the Georgia Venture Capital Program, and the Georgia Equity Direct Program.

Cite as Ga. Comp. R. & Regs. R. 110-38-1-.01

AUTHORITY: O.C.G.A. §§ 50-8-3**,** 50-8-8**.**

HISTORY: Original Rule entitled "Name" adopted. F. Mar. 20, 2023; eff. Apr. 9, 2023.

110-38-1-.02 General Scope and Purpose

(1) The American Rescue Plan Act of 2021 (ARPA) reauthorized and amended the Small Business Jobs Act of 2010, codified at 12 U.S.C. §5701 et seq., to provide $10 billion to fund the State Small Business Credit Initiative (SSBCI) as a response to the economic effects of the COVID-19 pandemic. SSBCI is a federal program administered by the Department of Treasury (Treasury) that was created to strengthen capital programs that support private financing to small businesses. Pursuant to ARPA, Treasury allocated a potential funding amount of $199,616,860 to the State of Georgia for SSBCI 2.0.

(a) On November 4, 2022, Treasury approved the State's application with an executed SSBCI Allocation Agreement (Allocation Agreement), which included proposals for five programs. The Georgia Department of Community Affairs (DCA) through the Georgia Housing and Finance Authority's (GHFA)[1] economic development powers and GHFA Economic Development Financing, Inc. (GHFA EDFI) plan to use the $199,616,860 in SSBCI funds (the Allocated Funds) in five state administered SSBCI Programs. Treasury approved the Georgia Loan Participation Program (GA LPP) for $70,000,000, the Georgia Small Business Credit Guarantee Program (SBCG) for $19,616,860, the Georgia CDFI Program (GA CDFI) for $60,000,000, the Georgia Venture Capital Program for $30,000,000 and the Georgia Equity Direct Program for $20,000,000.

(b) Operation of the five programs under the Georgia State Small Business Credit Initiative is subject to the U.S. Treasury SSBCI Capital Program Policy Guidelines, SSBCI Capital Program National Compliance Standards, SSBCI Capital Program Reporting Guidance, the Treasury- approved Georgia SSBCI application, and the Allocation Agreement between Treasury and Georgia. The last annual reporting date with Treasury is March 31, 2028, which may be extended by Treasury. The Secretary of Treasury shall complete all disbursements and remaining obligations before September 30, 2023, according to the SSBCI 2.0 statute under ARPA.

(c) DCA, as the lead SSBCI-designated implementing entity authorized pursuant to the Allocation Agreement, shall be responsible for overseeing the five approved programs and ensuring compliance of the programs with all Treasury requirements. The approved Contracted Entities under the Allocation Agreement are Georgia Housing and Finance Authority, GHFA Economic Development Financing, Inc. and IG Fund, LLC (Invest Georgia). Invest

Georgia will operate under a memorandum of agreement with DCA and GHFA EDFI to administer the two venture capital programs - the Georgia Venture Capital Program and the Georgia Equity Direct Program.

(d) Pursuant to 12 U.S.C. §5702(c)(1), each state that is approved for participation in the SSBCI will receive its allocation of main capital funds in three disbursements (tranches) as follows: 33 percent, 33 percent, and 34 percent. The transfer of the first 33 percent occurs promptly following the receipt of the fully signed Allocation Agreement. As a precondition to receipt of the second and third disbursements, each state must, among other things, certify to Treasury that the state has expended, transferred, or obligated 80 percent or more of the prior disbursement of allocated funds to or for the account of one or more approved programs that have delivered loans or investments to eligible businesses.

(e) SSBCI is expected to, in conjunction with new small business financing, create billions of dollars in lending and investments to small businesses that are not getting the support they need to expand and create jobs. ARPA provided for a $6.5 billion main capital allocation, $1.5 billion allocation for business enterprises owned and controlled by socially and economically disadvantaged individuals (SEDI-owned businesses), $1.0 billion incentive allocation for SEDI- owned businesses, $500 million allocation for very small businesses (VSBs), and $500 million allocation for technical assistance funding. The $199,616,860 funding allocated to Georgia included $109,140,449 from the main capital allocation, $8,678,471 from the VSBs allocation, $53,346,483 from the SEDI allocation and $28,451,457 from the incentive allocation for SEDI-owned businesses. Each state's SEDI allocation must be expended for SEDI-owned businesses. Georgia was not required to create a separate program for SEDI-owned businesses. However, Georgia must maintain records of the total amounts of its SSBCI funds that are expended for SEDI-owned businesses for loans, investments, or other credit support. States that demonstrate "robust support" for SEDI-owned businesses will be able to access their incentive allocation for SEDI-owned businesses in the second and third tranches. Each state should aspire to expend a certain percentage (the SEDI Objective) of its SSBCI funds for meeting the needs of the SEDI-owned businesses within its jurisdiction. Georgia's SEDI Objective is 53.48%.

(f) Under Georgia's three SSBCI loan programs, credit facilities are extended to eligible small businesses in Georgia by lenders (banks, credit unions and CDFIs). Lenders will undergo a review process to ensure adequate commercial lending experience, financial and managerial capacity, and operational skills.

(2) **Scope and Purpose of the Georgia Loan Participation (GA LPP) Program.** The Georgia Loan Participation Program is designed to increase lending to eligible small businesses by lenders to diversify their risk through shared exposure with the State. Lenders approved for participation in GA LPP will sign a Master Loan Participation Agreement with GHFA Economic Development Financing, Inc. GHFA EDFI is a wholly owned subsidiary of GHFA and dedicated to economic development.

(a) GA LPP will utilize SSBCI funds to purchase up to 25% of a loan originated by a participating lender to an eligible small business borrower. Underwriting is performed by the primary lender, then shared with the Department of Community Affairs (DCA) to streamline the approval process of the purchased participation. The GA LPP can purchase up to 30% of a loan originated by a CDFI depository lending institution or a minority depository institution (MDI). A written commitment letter is executed between the primary lender and GHFA EDFI; the lender closes the loan and sells the position to GHFA/DCA. The primary lender performs debt servicing and shares proportional debt payments with DCA. Interest rates, maturity, collateral, and other loan terms are negotiated with the borrower and determined by the lender. GHFA/DCA will be in a subordinate lien position, and the primary lender will have first claim to all recoveries until its losses are covered.

(3) **Scope and Purpose of the Small Business Credit Guarantee (SBCG) Program.** Under the SBCG Program, credit facilities are extended to eligible small businesses by lenders that have entered into a Lender Program Participation Agreement (PPA) with GHFA EDFI. The PPA provides that qualifying lenders may enroll a qualified credit to an eligible small business in the credit guarantee program for eligible business purposes that meet the eligibility criteria described in 110-31-.03. The SBCG Program will reimburse from SSBCI funds 50% of losses incurred on an enrolled credit by a lender that is not in material default of the PPA. Guarantee funds will generally be available to lenders on a first-come, first-served basis.

(4) **Scope and Purpose of the Georgia CDFI Program (GA CDFI).** The GA CDFI Program is a companion loan program among the non-depository Community Development Financial Institutions (CDFIs) and the private lending

institutions. The program is designed to provide access to capital to small businesses in order to create job opportunities in low- to moderate-income, minority and other underserved communities. CDFIs will provide access to capital to the borrowers, gap financing for the banks, low interest rates and attractive terms. Georgia businesses will be able to receive significant incentive to start projects, expand operations, improve facilities, purchase equipment or access working capital. CDFIs are encouraged to participate in projects with a private leverage of 10:1, with no less than a private leverage of 1:1.

(a) Invest Georgia will administer the two venture capital programs as a Contracted Entity under a Memorandum of Agreement with DCA and GHFA EDFI. Invest Georgia is an instrumentality of the State of Georgia and has authority under O.C.G.A. § 10-10-10 to operate venture capital programs intended to increase the amount of private investment capital available for Georgia-based businesses.

(5) **Scope and Purpose of the Georgia Venture Capital Program (GA VC Program).** The GA VC Program will help grow venture capital for small businesses at the earliest stages of development, which Invest Georgia will operate as a multi-fund program. The Memorandum of Agreement with Invest Georgia will highlight the objectives of the GA VC Program including improving regional entrepreneurial and investment ecosystems that support economic growth, innovation development and job creation.

(6) **Scope and Purpose of the Georgia Equity Direct Program.** The Georgia Equity Direct Program will provide an attractive source of capital for investments in startups and eligible businesses. Investments will be made alongside diverse venture funds, non-profit seed funds, angel funds and other investors that present a compelling economic development case. Invest Georgia will manage the co-investment program, which will provide flexibility for supporting a diverse portfolio of small businesses.

Footnote:
The Department of Community Affairs (DCA) was created as a Department of the Executive Branch of state government. The Georgia Housing and Finance Authority is an instrumentality of the State of Georgia and a public corporation performing an essential governmental function. GHFA is assigned to DCA, and all operations are performed by the personnel of DCA. GHFA is listed as a Contracted Entity on the Georgia SSBCI Application.

Cite as Ga. Comp. R. & Regs. R. 110-38-1-.02

AUTHORITY: O.C.G.A. §§ 50-8-3**,** 50-8-8**.**

HISTORY: Original Rule entitled "General Scope and Purpose" adopted. F. Mar. 20, 2023; eff. Apr. 9, 2023.

110-38-1-.03 Eligible Applicants and Activities

Each lender or investor must obtain an assurance from the borrower affirming:

(1) The loan or investment proceeds must be used for a "business purpose." A business purpose includes, but is not limited to, start-up costs, working capital, franchise fees, and acquisition of equipment, inventory, or services used in the production, manufacturing, or delivery of a business's goods or services, or in the purchase, construction, renovation, or tenant improvements of an eligible place of business that is not for passive real estate investment purposes. SSBCI funds may be used to purchase any tangible or intangible assets except goodwill. The term "business purpose" excludes acquiring or holding passive investments in real estate; the purchase of securities except as permitted in certification (2)(d) below; and lobbying activities (as defined in Section 3 (7) of the Lobbying Disclosure Act of 1995, P.L. 104-65, as amended (2 U.S.C. §1602(7)).

(2) The loan or investment proceeds will not be used to:

(a) repay delinquent federal or state income taxes unless the borrower or investee has a payment plan in place with the relevant taxing authority; or

(b) repay taxes held in trust or escrow, e.g., payroll or sales taxes; or

(c) reimburse funds owed to any owner, including any equity investment or investment of capital for the business' continuance; or

(d) purchase any portion of the ownership interest of any owner of the business, except for the purchase of an interest in an employee stock ownership plan qualifying under section 401 of the Internal Revenue Code, worker cooperative, or related vehicle, provided that the transaction results in the employee stock ownership plan or other employee-owned entity holding a majority interest (on a fully diluted basis) in the business.

(3) For a borrower participating in the loan/credit program only, the borrower is not:

(a) an executive officer, director, or principal shareholder of the lender;

(b) a member of the immediate family of an executive officer, director, or principal shareholder of the lender: or

(c) related interest or immediate family of an executive officer, director, or principal shareholder of the lender.

(4) The borrower or investee is not:

(a) a business engaged in speculative activities that profit from fluctuations in price, such as wildcatting for oil and dealing in commodities futures, unless those activities are incidental to the regular activities of the business and part of a legitimate risk management strategy to guard against price fluctuations related to the regular activities of the business through the normal course of trade; or

(b) a business that earns more than half of its annual net revenue from lending activities; unless the business is (1) a CDFI that is not a depository institution or a bank holding company; or (2) a Tribal enterprise lender that is not a depository institution or a bank holding company; or

(c) a business engaged in pyramid sales, where a participant's primary incentive is based on the sales made by an ever-increasing number of participants; or

(d) a business engaged in activities that are prohibited by federal law or, if permitted by federal law, applicable law in the jurisdiction where the business is located or conducted (this includes businesses that make, sell, service, or distribute products or services used in connection with illegal activity, unless such use can be shown to be completely outside of the business's intended market); this category of businesses includes direct and indirect marijuana businesses, as defined in SBA Standard Operating Procedure 50 10 6; or

(e) a business deriving more than one-third of gross annual revenue from legal gambling activities.

(5) For an investee participating in a venture capital/equity program:

(a) The investee is compliant with the venture capital program conflict of interest standards set forth in section VIII.f of the SSBCI Capital Program Policy Guidelines. Briefly, these standards provide that no SSBCI insider, or a family member or business partner of an SSBCI insider, has a personal financial interest in the investee unless an exception specified in Section VIII.f of the SSBCI Capital Program Policy Guidelines applies. The terms "SSBCI insider," "family member," "business partner," and "personal financial interest" have the meaning set forth in Section VIII.f of the SSBCI Capital Program Policy Guidelines.

(b) No principal of the investee has been convicted of a sex offense against a minor (as such terms are defined in 34 U.S.C. §20911). For the purposes of this certification, "principal" is defined as if a sole proprietorship, the proprietor; if a partnership, each managing partner and each partner who is a natural person and holds 50 percent or more ownership interest of any class of the partnership interests; if a corporation, limited liability company, association, development company, or other entity, each director, each of the five most highly compensated executives or officers of the entity, and each natural person who is a direct or indirect holder of 50 percent or more of any class of equity interest in the entity; and if a partnership where the managing partner is a corporation, limited liability company, association, development company, or other entity, each director and each of the five most highly compensated executives or officers of the entity.

(6) No principal of the borrowing entity has been convicted of a sex offense against a minor (as such terms are defined in 34 U.S.C. §20911). For the purposes of this certification, "principal" is defined as if a sole proprietorship, the proprietor; if a partnership, each partner; if a corporation, limited liability company, association, development company, or other entity, each director, each of the five most highly compensated executives, officers, or employees of the entity, and each direct or indirect holder of 20 percent or more of the ownership stock or stock equivalent of the entity.

Cite as Ga. Comp. R. & Regs. R. 110-38-1-.03

AUTHORITY: O.C.G.A. §§ 50-8-3**,** 50-8-8**.**

HISTORY: Original Rule entitled "Eligible Applicants and Activities" adopted. F. Mar. 20, 2023; eff. Apr. 9, 2023.

110-38-1-.04 Terms and Conditions

The following are the general terms and conditions of the five programs for the Georgia State Small Business Credit Initiative.

(1) Georgia Loan Participation Program (GA LPP)

(a) A Master Loan Participation Agreement is executed between an approved participating lender and GHFA EDFI.

(b) The approved participating lender originates the loan. DCA/GHFA EDFI through GA LPP may purchase up to 25% on loans up to $5 million and may purchase up to 30% on loans from a CDFI depository lending institution and minority depository institutions (MDIs) up to $5 million. There is a concentration limit of $5 million to any one borrower.

(c) Underwriting is performed by the primary lender and shared with DCA to streamline the approval process of the purchased participation.

(d) A written commitment letter is executed between the primary lender and GHFA EDFI.

(e) The lender closes the loan and sells the position to DCA/GHFA EDFI.

(f) The lender keeps all its standard fees.

(g) Loan servicing is performed by the primary lender, which shares proportional debt payments with DCA/GHFA EDFI.

(h) DCA/GHFA EDFI will be in a subordinate lien position, and the primary lender will have first claim to all recoveries until its losses are covered.

(i) Rates, fees, and terms are determined by the primary lender. There are no additional fees to use the GA LPP.

(j) DCA/GHFA EDFI may provide a lower interest rate than the primary lender for a limited period of time in order to improve the borrower's debt coverage ratio.

(k) The primary lender has the unconditional right to repurchase the participation sold in the original loan to DCA/GHFA EDFI at any time.

(l) GA LPP will target businesses with an average borrower size of 500 employees or less, but credit cannot be extended to businesses with more than 750 employees. Average projected loan size is between $100,000 and $5,000,000.

(2) Georgia Small Business Credit Guarantee (SBCG) Program

(a) A Lender Program Participation Agreement is executed between an approved participating lender and GHFA EDFI.

(b) The SBCG Program will provide a 50% loan guarantee on a lender's loan. Each loan covered under the SBCG Program will stand alone with a maximum guarantee of 50%.

(c) Underwriting is performed by the primary lender and shared with DCA to streamline the approval process.

(d) Lenders will pay a processing fee as determined by DCA for all loans submitted for enrollment.

(e) The SBCG Program will charge a flat fee of 1% upfront of the guarantee amount on lines of credit with a two-year term and a flat fee of 2% of the guarantee amount on term loans with a maturity of five years. For all loans, the fee will be paid at the time of the loan closing. The fee structure may be modified in response to program sustainability or market conditions.

(f) The maximum individual loan amount eligible for the SBCG guarantee is $1,000,000 with a 50% maximum guarantee of $500,000. DCA/GHFA EDFI may consider loans greater than the $1,000,000 maximum; however, the maximum amount of the guarantee will remain at $500,000.

(g) Lender Concentration Limit - The maximum guarantees that may be set aside at any time with respect to a single borrower is $5,000,000.

(h) The maximum term for SBCG guarantee on lines of credit will generally be 24 months.

(i) The maximum term for SBCG guarantee on amortizing loans will generally be 60 months.

(j) The SBCG is a deficiency guarantee; lenders must first liquidate collateral before claiming the guarantee.

(k) SBCG will target businesses with an average borrower size of 500 employees or less, but credit cannot be extended to businesses with more than 750 employees.

(3) Georgia CDFI Program (GA CDFI)

(a) Qualified non-profit, non-depository CDFIs will be able to participate in the GA CDFI Program.

(b) Each CDFI approved to participate as a lender will enter into a performance-based contract arrangement with DCA/GHFA EDFI.

(c) The CDFI will receive and review eligible loan requests, then forward appropriate paperwork to DCA for final review and approval.

(d) Funds will be advanced to the CDFIs on a loan-by-loan basis, and the CDFI, in turn, will then make the loan to the eligible business. The CDFI will be deemed the lender and holder of the loans for purposes of its books and records. All principal and other payments from the loan may be retained by the CDFI to be used for additional eligible loans under the GA CDFI Program. Interest earned may be used to pay for SSBCI-related expenses in accordance with Treasury Guidelines.

(e) Loans may be for working capital, equipment, real estate, and other eligible activities under Treasury Guidelines.

(f) CDFIs are encouraged to offer lower interest rates than those of their participating lending institutions. There are no fees to the CDFIs or the borrowers from DCA for the of the GA CDFI Program.

(g) There is not a minimum loan amount for the GA CDFI Program. The maximum loan amount is $1,250,000 with a loan term no longer than 10 years.

(h) DCA will set aside initial reserves in increments of $2 million for each approved CDFI for lending purposes. CDFIs will request funding for their loans from their reserves and may request additional reserves upon deployment of their initial respective $2 million in reserve.

(4) Georgia Venture Capital (GA VC) Program

(a) The GA VC Program is a multi-fund program administered by Invest Georgia as a Contracted Entity.

(b) Invest Georgia will invest capital in multiple funds as a limited partner, and each separate fund will manage the full processes of investing in high-potential Georgia-based small businesses.

(c) Invest Georgia will target "seed" and "early stage" venture capital funds.

(d) Invest Georgia, along with LCG Associates (investment consultant), will perform due diligence and select venture capital funds to invest and will monitor investment.

(e) SSBCI capital will be legally obligated to venture capital funds as a limited partner through contractual agreements (subscription agreements) prior to these funds expending capital with investments in small businesses.

(f) The minimum investment amount will be $1,000,000 with a maximum investment amount of $3 million in private venture capital funds. At the discretion of DCA and Invest Georgia, investment amounts may be raised to no more than $5 million to invest in larger venture capital funds or special opportunities.

(g) SSBCI venture capital program investments may be used for most business purposes unless prohibited under Treasury Guidelines.

(h) Invest Georgia will take a seat on the Limited Partner Advisory Committee of each venture capital fund receiving a SSBCI investment.

(i) SSBCI capital investments will generally be limited to 10% of a venture capital fund.

(j) The GA VC Program will require a minimum of 1:1 capital match at the fund level.

(k) Invest Georgia and DCA will identify funds with SEDI characteristics to participate in the GA VC Program.

(5) Georgia Equity Direct Program

(a) The Georgia Equity Direct Program will be a direct co-investment program administered by Invest Georgia as a Contracted Entity.

(b) A special emphasis will be placed on reaching SEDI businesses.

(c) SSBCI funds will flow from DCA/GHFA EDFI to Invest Georgia to a limited liability company (LLC) to be created by Invest Georgia. The LLC will act as the equity owner in eligible businesses.

(d) Invest Georgia will oversee due diligence, and under the direction of a Direct Investment Advisory Committee will select the co-investment opportunities. This Advisory Committee will be formed by Invest Georgia to help manage the full process of due diligence, selection, and investment into high-potential Georgia-based businesses.

(e) The minimum investment amount will be $250,000 with a maximum investment amount of $1 million alongside angel investors, non-profit seed funds, emerging funds, SEDI or rural funds and other investors.

(f) SSBCI venture capital program investments may be used for most business purposes unless prohibited under Treasury Guidelines.

(g) The Georgia Equity Direct Program will require a minimum of 1:1 capital match at the company level.

(h) SEDI-owned businesses will be targeted for investments in the Georgia Equity Direct Program.

(i) Direct investments through the Georgia Equity Direct Program are intended to incentivize ("cause") additional investment into promising young Georgia-based companies.

(6) Other Terms and Conditions applicable to Georgia SSBCI Programs

(a) Each of the five Georgia SSBCI Programs will cause and result in $1 of new private credit. It is anticipated the private leverage ratio will exceed 10:1 over a 10-year period when all of Georgia's five SSBCI Programs are measured together.

(b) The Georgia SSBCI Programs are required (1) to target an average borrower or investee size of 500 employees or less, (2) not to extend credit or investment support to borrowers or investees that have more than 750 employees, (3) to target support towards loans or investments with an average principal or investment amount of $5 million or less, and (4) not to provide credit or investment support if a given transaction exceeds $20 million.

(c) The SSBCI Capital Program Policy Guidelines require certifications in various circumstances from lenders, investors, and small business borrowers and investees participating in SSBCI capital programs. Certifications include Borrower/Investee Use of Proceeds and Conflict of Interest Certification, Lender/Investor Use of Proceeds and Conflict of Interest Certification, Sex Offender Lender/Borrower Certification, Sex Offender Investor/Investee Certification, Borrower/Investee Certification Related to Business Enterprises Owned and Controlled by Socially and Economically Disadvantaged Individuals and Certification Regarding Venture Capital Fund Services to Portfolio Companies.

(d) No principal of the investor has been convicted of a sex offense against a minor (as such terms are defined in 34 U.S.C. §20911). For the purposes of this certification, "principal" is defined as if a sole proprietorship, the proprietor; if a partnership, each managing partner and each partner who is a natural person and holds 50 percent or more ownership interest of any class of the partnership interests; if a corporation, limited liability company, association, development company, or other entity, each director, each of the five most highly compensated executives or officers of the entity, and each natural person who is a direct or indirect holder of 50 percent or more of any class of equity interest in the entity; and if a partnership where the managing partner is a corporation, limited liability company, association, development company, or other entity, each director and each of the five most highly compensated executives or officers of the entity.

(e) For a SSBCI-supported venture capital or equity investment, the investment complies with the venture capital program conflict of interest standards as set forth in Section VIII.f of the SSBCI Capital Program Policy Guidelines.

(f) The State must obtain an assurance from the lender affirming:

(f.i) The SSBCI-supported loan is not being made in order to place under the protection of the approved program prior debt that is not covered under the approved program and that is or was owed by the borrower to the financial institution lender or to an affiliate of the financial institution lender.

(f.ii) If the SSBCI-supported loan is a refinancing, it complies with all applicable SSBCI restrictions and requirements in Sections VIII.f and VIII.f of the SSBCI Capital Program Policy Guidelines regarding refinancing and new extensions of credit, including that the SSBCI-supported loan is not a refinancing of a loan previously made to the borrower by the lender or an affiliate of the lender.

(f.iii) No principal of the lender has been convicted of a sex offense against a minor (as such terms are defined in 34 U.S.C. §20911). For the purposes of this certification, "principal" is defined as if a sole proprietorship, the proprietor; if a partnership, each partner; if a corporation, limited liability company, association, development company, or other entity, each director, each of the five most highly compensated executives, officers, or employees of the entity, and each direct or indirect holder of 20 percent or more of the ownership stock or stock equivalent of the entity.

(f.iv) The private entity receiving SSBCI funds and financial institution lender will make available to the Treasury Inspector General and the Government Accountability Office all books and records related to the use of the SSBCI funds, subject to applicable privacy laws, including but not limited to 12 U.S.C. §3401 *et seq.*, including detailed loan and investment records, as applicable.

(f.v) The financial institution lender is in compliance with the requirements of 31 C.F.R. §1020.220, regarding customer identification programs.

(g) Monthly and Quarterly Reporting Requirements: All lenders in the Georgia SSBCI program are required to submit monthly and quarterly reports to DCA. Details on the deadlines and format of these reports are available from DCA directly. The reporting requirements of the two venture capital programs are detailed in the Memorandum of Agreement between DCA/GHFA EDFI and Invest Georgia.

(h) Lender Approval Criteria: Each lender seeking participation in the State of Georgia's SSBCI Programs will undergo a thorough review process by the State to ensure that the lender has the adequate commercial lending experience, financial and managerial capacity, and operational skills. Regulated financial institutions must meet certain criteria established by their regulators to maintain their charters. DCA will work with the Georgia Department of Banking and Finance on the selection process for participating financial institutions including banks and credit unions. Principal evaluation factors of lenders will include capital adequacy, asset quality, management, earnings, liquidity, and sensitivity to market risk.

(i) Georgia's SSBCI Programs may not enroll the unguaranteed portions of SBA-guaranteed loans. This prohibition also applies to the unguaranteed portion of other federally generated loans.

(j) Underserved Markets. Georgia's SSBCI Programs will strive to reach underserved markets including women- and minority-owned businesses as well as small businesses in low- and moderate-income communities, in minority communities, and in other underserved communities.

Cite as Ga. Comp. R. & Regs. R. 110-38-1-.04

AUTHORITY: O.C.G.A. §§ 50-8-3**,** 50-8-8**.**

HISTORY: Original Rule entitled "Terms and Conditions" adopted. F. Mar. 20, 2023; eff. Apr. 9, 2023.

Department 111. RULES OF DEPARTMENT OF COMMUNITY HEALTH

Chapter 111-1. ADMINISTRATION

Subject 111-1-1. REGULATIONS FOR PETITION FOR PROMULGATION

111-1-1-.01 Definitions

In these rules, unless the content otherwise requires, the terms set forth, herein shall mean the following;

(1) "Department" means the Department of Community Health, any division, section, or unit of the Department, and any agency attached to the Department for administrative purposes.

(2) "Person" means any individual, partnership, corporation, association, governmental subdivision, or public or private organization of any character other than an agency.

(3) "Petition" means a petition for promulgation, amendment, or repeal of rules made by an interested person pursuant to O.C.G.A. § 50-13-9.

(4) "Rule" means each Department regulation, standard, or statement of general applicability that implements, interprets, or prescribes law or policy or describes the organization, procedure, or practice requirements of the Department. The term includes the amendment or repeal of a prior rule but does not include the following:

(a) Statements concerning only the internal management of the Department and not affecting private rights or procedures available to the public;

(b) Declaratory rulings issued pursuant to O.C.G.A. § 50-13-11;

(c) Intra-Department memoranda;

(d) Statements of policy or interpretations that are made in the decision of a contested case;

(e) Rules which relate to the acquiring, sale, development, and management of the property, both real and personal, of the state or of the Department;

(f) Rules which relate to contracts for the purchases and sales of goods and services by the state or of the Department;

(g) Rules which relate to the employment, compensation, tenure, terms, retirement, or regulation of the employees of the state or of the Department;

(h) Rules relating to loans, grants, and benefits by the state or of the Department; or

(i) The approval or prescription for the future of rates or prices.

Cite as Ga. Comp. R. & Regs. R. 111-1-1-.01

AUTHORITY: O.C.G.A. §§ 50-13-4**,** 50-13-9**,** 31-2-1 ***et seq*****.**

HISTORY: Original Rule entitled "Definitions" adopted. F. Mar. 15, 2023; eff. Apr. 4, 2023.

111-1-1-.02 Petition by Interested Person

(1) Form of Petition. Each petition for promulgation, amendment, or repeal of rules made pursuant to O.C.G.A. § 50-13-9 shall be submitted in writing to the Department's Commissioner and General Counsel. The petition shall include:

(a) The name, address, telephone number, and email address of the petitioner;

(b) The full text of the rule requested to be promulgated, or the full text of the rule desired to be amended or repealed, including strike through of any text of an existing rule the petitioner seeks to remove by amendment;

(c) A statement of the reason(s) such rule should be promulgated, amended, or repealed, including a statement of all pertinent facts which relate to petitioner's interest in the matter;

(d) Citations of legal authority which authorize, support, or require the action requested by petition;

(e) A notarized verification by the petitioner stating that petitioner has reviewed the petition and that the statement of pertinent facts is true to the best of petitioner's information and belief.

(2) Department's Action on the Petition. Upon receipt of the Petition, the Department shall determine what action, if any, is required by the petition.

(a) The Department is only required to take action regarding petitions which include all requirements of Ga. Comp. R. & Regs. r. 111-1-1-.02(1).

(b) Within thirty (30) days after submission of a petition in conformance with the requirements of Ga. Comp. R. & Regs. r. 111-1-1-.02(1), the Department shall either deny the petition in writing, stating its reasons for denial, or shall initiate rule-making proceedings in accordance with O.C.G.A. § 50-13-4. Petitions submitted which fail to conform with the requirements of Ga. Comp. R. & Regs. r. 111-1-1-.02(1) shall be denied without further action required by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-1-1-.02

AUTHORITY: O.C.G.A. §§ 50-13-4**,** 50-13-9**,** 31-2-1 ***et seq*****.**

HISTORY: Original Rule entitled "Petition by Interested Person" adopted. F. Mar. 15, 2023; eff. Apr. 4, 2023.

Department 111. RULES OF DEPARTMENT OF COMMUNITY HEALTH

Chapter 111-2. HEALTH PLANNING

Subject 111-2-2. CERTIFICATE OF NEED

111-2-2-.01 Definitions

As used in these Rules, the term:

(1) "Acquisition of an existing health care facility" means to come into possession or control of a health care facility by purchase, gift, merger of corporations, lease, purchase of stock, inheritance, or by any other legal means.

(2) "Acquisition of diagnostic, therapeutic, or other imaging equipment":

(a) as it relates to a diagnostic, treatment, or rehabilitation center, means to come into possession, or control of, or to otherwise use diagnostic, therapeutic, or other imaging equipment by purchase, gift, donation, lease, transfer, or by any other legal means by or on behalf of the diagnostic, treatment, or rehabilitation center; and

(b) as it relates to a health care facility, means to come into possession or control of diagnostic, therapeutic, or other imaging equipment by purchase or lease by or on behalf of the health care facility.

(3) "Ambulatory surgery" means surgical procedures that include but are not limited to those recognized by the Centers for Medicare and Medicaid Services ("CMS"), by the Georgia Division of Medical Assistance ("DMA"), by the State Health Benefit Plans, or by any successor entities as reimbursable ambulatory surgery procedures. Ambulatory surgery is provided only to patients who are admitted to a facility which offers ambulatory surgery and which does not admit patients for treatment that normally requires stays that are overnight or exceed 24 hours and which does not provide accommodations for treatment of patients for periods of twenty-four hours or longer.

(4) "Ambulatory surgical or obstetrical facility", as defined at O.C.G.A. § 31-6-2(1), means a public or private facility, not a part of a hospital, which provides surgical or obstetrical treatment performed under general or regional anesthesia in an operating room environment to patients not requiring hospitalization.

(5) "Applicant" means the owner or lessee of an existing health care facility or the person who would be the owner or lessee of a proposed facility, as named in the application. An applicant may also be multiple owners or lessees of existing health care facilities who share common ownership or corporate affiliation and wish to submit an application to the Department for a single Certificate of Need for certain non-clinical health services, for example, but not limited to, parking decks, infrastructure improvement or replacement, and capital renovation expenditures.

(6) "Application", as defined at O.C.G.A. § 31-6-2(2), means a written request for a Certificate of Need made to the Department, containing such documentation and information as the Department may require.

(7) "Approved date" means the date that the Department issues a Certificate of Need to an applicant.

(8) "Associated with and simultaneously developed or proposed" means that if the Department determines that a single project or the substantial equivalent of a single project is divided into separate components which are associated and which are developed or planned simultaneously, so that the project or the substantial equivalent of a project or any component thereof does not require a total capital expenditure in excess of the capital expenditure or diagnostic, therapeutic, or other imaging equipment threshold, the Department shall combine the components for purposes of computing the amount of the total capital expenditure or expense and shall treat the combined components as a single project or substantial equivalent of a project. The Department shall include items and

expenditures which are related and which occur simultaneously in computing an applicable threshold regardless of whether the items or expenditures individually may otherwise be below the threshold or may be otherwise unreviewable exclusive of the items exempted from review by Ga. Comp. R. & Regs. r. 111-2-2-.03(1)-(3) and Ga. Comp. R. & Regs. r. 111-2-2-.03(5)-(19);

(a) The Department may determine that activities, services, expenditures, and items are associated if they share a relationship or association based on law, regulation, definition, function, procedure, or process; and

(b) The Department shall determine that expenditures related to activities, services, and items are simultaneously developed or planned if such expenditures occur within a 6-month period. The 6-month period shall run from operation of the activity, service or item to initial capital expenditure on the second activity or item or from operation of the activity or item to operation of the second activity or item. For services, the date of operation shall be the date that the service is actually offered. If applicable, for facilities, the date of operation shall be the date a Certificate of Occupancy is issued.

(9) **Reserved.**

(10) "Basic perinatal services" means providing basic inpatient care for pregnant women and newborns without complications; managing perinatal emergencies; consulting with and referring to specialty and subspecialty hospitals; identifying high-risk pregnancies; providing follow-up care for new mothers and infants; and providing public/community education on perinatal health.

(11) "Bed capacity", as defined at O.C.G.A. § 31-6-2(4), means space used exclusively for inpatient care, including space designed or remodeled for inpatient beds even though temporarily not used for such purposes. The number of beds to be counted in any patient room shall be the maximum number for which adequate square footage is provided as established by Rules of the Department, except that single beds in single rooms shall be counted even if the room contains inadequate square footage.

(12) "By or on behalf of" means any expenditures made by a health care facility, a political subdivision of the State, a diagnostic, treatment, or rehabilitation center, or a hospital authority, itself as well as capital expenditures made by other persons or related entities to assist the facility, subdivision, center, or authority, directly or indirectly, to offer services to its patients or residents. Related entities include entities that are associated or affiliated with, have control over or are controlled by, or have any direct financial interest in, the health care facility, political subdivision of the State, diagnostic, treatment, or rehabilitation center, or hospital authority, including, without limitation, an underwriter, guarantor, parent organization, sister organization, subsidiary or sub-entity, foreign corporation, joint venturer, partner, general partner, or building lessor, as applicable.

(13) "Capital expenditure" in relation to a proposed modification, renovation, or addition to a health care facility or to a diagnostic, treatment, or rehabilitation center, or acquisition of equipment, means an expenditure by or on behalf of a health care facility or diagnostic, treatment, or rehabilitation center that, under generally accepted accounting principles, is not properly chargeable as an expense of operation or maintenance. Any series of capital expenditures, each less than a threshold, but which when taken together are in excess of a threshold, directed toward the accomplishment of a single project, requires a Certificate of Need. Any series of capital expenditures, which are associated and simultaneously developed or proposed, will be presumed to be a single project. In calculating the capital expenditure for modifications, additions, or renovations "capital expenditure" is the amount per construction bid or total amount of invoices or purchase orders for the single project excluding diagnostic, therapeutic, or other imaging equipment.

(14) "Certificate of Need" or "CON", as defined at O.C.G.A. § 31-6-2(6), means an official finding by the Department, evidenced by certification issued pursuant to an application, that the action proposed in the application satisfies and complies with the criteria contained in the Statute and Rules promulgated pursuant thereto.

(15) **Reserved.**

(16) "Clinical health services", as defined at O.C.G.A. § 31-6-2(8), means diagnostic, treatment, or rehabilitative services provided in a health care facility and includes, but is not limited to, the following: radiology and diagnostic

imaging, such as magnetic resonance imaging and positron emission tomography (PET); radiation therapy; biliary lithotripsy; surgery; intensive care; coronary care; pediatrics; gynecology; obstetrics; general medical care; medical-surgical care; inpatient nursing care, whether intermediate, skilled or extended care; cardiac catheterization; open heart surgery; inpatient rehabilitation; and alcohol, drug abuse, and mental health services.

(17) "Consumer", as defined at O.C.G.A. § 31-6-2(10), means a person who is not employed by any health care facility or provider and who has no financial or fiduciary interest in any health care facility or provider.

(18) "Cost estimate" means an estimate of the total cost of a project's development and construction prepared by a licensed architect or engineer within sixty days prior to the date of submittal of an application.

(19) "Defined location", as it relates to the approved location of a project or substantial equivalent of a project, means the address of the project, or in the case of a health care facility or diagnostic, treatment, or rehabilitation center with multiple addresses, the campus of such health care facility or diagnostic, treatment, or rehabilitation center. However, in no case shall a campus be considered a single defined location if varying locations and facilities of such campus are more than 3 miles apart or within more than one county.

(20) "Destination cancer hospital" means an institution with a licensed bed capacity of fifty (50) or less which provides diagnostic, therapeutic, treatment, and rehabilitative care services to cancer inpatients and outpatients, by or under the supervision of physicians, and whose proposed annual patient base is composed of a minimum of sixty-five percent (65%) of patients who reside outside of the State of Georgia.

(21) "Develop", as defined at O.C.G.A. § 31-6-2(14), with reference to a project, means constructing, remodeling, installing, or proceeding with a project, or any part of a project, or a capital expenditure project, the cost estimate for which exceeds $10 million. Notwithstanding the provisions of this paragraph, the expenditure or commitment or incurring an obligation for the expenditure of funds to develop Certificate of Need applications, studies, reports, schematics, preliminary plans and specifications, or working drawings, or to acquire, develop, or prepare sites shall not be considered to be the developing of a project.

(22) "Diagnostic imaging" means magnetic resonance imaging, computed tomography (CT) scanning, positron emission tomography (PET) scanning, positron emission tomography/computed tomography, and other advanced imaging services as defined by the Department by rule, but such term shall not include X-rays, fluoroscopy, or ultrasound services.

(23) "Diagnostic, treatment, or rehabilitation center", as defined at O.C.G.A. § 31-6-2(16), means any professional or business undertaking, whether for profit or not for profit, which offers or proposes to offer any clinical health service in a setting which is not part of a hospital; provided, however, that any such diagnostic, treatment, or rehabilitation center that offers or proposes to offer surgery in an operating room environment and to allow patients to remain more than twenty-three (23) hours shall be considered a hospital for purposes of O.C.G.A. § 31-6 et seq.

(24) "Effective date" means:

(a) for approved projects that have not been appealed pursuant to the appeal provisions of the Rules of the Certificate of Need Appeal Panel, the approved date;

(b) for projects, which are appealed pursuant to the appeal provisions of the Rules of the Certificate of Need Appeal Panel, the date of the final resolution of any such administrative appeal if the resolution results in the approval of the project; or

(c) for projects which undergo judicial review, the effective date shall be the date referenced in (b) above, unless the Department, pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.07(2)(h), or the reviewing court stays the effective date of the project pending the outcome of the judicial review. If the Department or the reviewing court stays the effective date, the effective date shall be the date of the final resolution of any such judicial review if the resolution results in approval of the project.

(25) "Expiration date" is the date upon which a Certificate of Need expires and becomes null and void.

(26) "Functionally related diagnostic, therapeutic, or other imaging equipment" means that pieces of diagnostic, therapeutic, or other imaging equipment are interdependent to the extent that one piece of equipment is unable to function in the absence of or without the functioning piece or equipment, or that pieces of equipment are normally used together in the provision of a single health care facility or diagnostic, treatment, or rehabilitation center service.

(27) "General cancer hospital" means an institution which was an existing and approved destination cancer hospital as of January 1, 2019; has obtained final Certificate of Need approval for conversion from a destination cancer hospital to a general cancer hospital in accordance with O.C.G.A. § 31-6-40.3; and offers inpatient and outpatient diagnostic, therapeutic, treatments, and rehabilitative cancer care service or other services to diagnose or treat co-morbid medical conditions or diseases of cancer patients so long as such services do not result in the offering of any new or expanded clinical health service that would require a Certificate of Need under this chapter unless a Certificate of Need or letter of determination has been obtained for such new or expanded services.

(28) "Health care facility", as defined at O.C.G.A. § 31-6-2(17), means hospitals; destination cancer hospitals; other special care units, including but not limited to podiatric facilities; skilled nursing facilities; intermediate care facilities; personal care homes; ambulatory surgical or obstetrical facilities; freestanding emergency departments or facilities not located on a hospital's primary campus; health maintenance organizations; home health agencies; diagnostic, treatment, or rehabilitation centers, but only to the extent that O.C.G.A. § 31-6-40(a)(3) or (7) or both are applicable thereto.

(29) "Health maintenance organization", as defined at O.C.G.A. § 31-6-2(18), means a public or private organization organized under the laws of this state which:

(a) provides or otherwise makes available to enrolled participants health care services, including at least the following basic health care services: usual physicians' services, hospitalization, laboratory, X-ray, emergency and preventive services, and out-of-area coverage;

(b) is compensated, except for co-payments, for the provision of the basic health care services listed in subparagraph (a) of this paragraph to enrolled participants on a predetermined periodic rate basis; and

(c) provides physicians' services primarily:

1. directly through physicians who are either employees or partners of such organization; or

2. through arrangements with individual physicians organized on a group practice or individual practice basis.

(30) "Home health agency", as defined at O.C.G.A. § 31-6-2(20), means a public agency or private organization, or a subdivision of such an agency or organization, which is primarily engaged in providing to individuals who are under a written plan of care of a physician, on a visiting basis in the places of residence used as such individuals' homes, part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse, and one or more of the following services:

(a) physical therapy;

(b) occupational therapy;

(c) speech therapy;

(d) medical social services under the direction of a physician; or

(e) part-time or intermittent services of a home health aide.

(31) "Hospital", as defined at O.C.G.A. § 31-6-2(21), means an institution which is primarily engaged in providing to inpatients, by or under the supervision of physicians, diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons or rehabilitation services for the rehabilitation of

injured, disabled, or sick persons. Such term includes public, private, psychiatric, rehabilitative, geriatric, osteopathic, micro-hospitals, general cancer hospitals, and other specialty hospitals.

(32) "Incur a financial obligation", in relation to the offering of a new institutional health service, means that, within time periods described in Ga. Comp. R. & Regs. r. 111-2-2-.02(5) and (6) of these Rules, the applicant has fulfilled the following performance requirements.

(a) With regard to new construction or renovation:

1. has acquired title, an option to purchase or a leasehold to an appropriate site;

2. has filed with the Department the complete set of plans, drawings, and specifications for the project in the electronic format designated by the Department;

3. has obtained a firm commitment for adequate capital financing; and

4. has entered into a construction contract that provides for a specific date for commencement, and completion of construction within a reasonable time span.

With regard to equipment not associated with a construction project;

1. a purchase or lease agreement has been entered into or, if acquired by a comparable arrangement, the applicant has possession of the equipment.

(33) **Reserved.**

(34) "Intermediate care facility", as defined at O.C.G.A. § 31-6-2(22), means an institution which provides, on a regular basis, health related care and services to individuals who do not require the degree of care and treatment which a hospital or skilled nursing facility is designed to provide but who, because of their mental or physical condition, require health related care and services beyond the provision of room and board.

(35) "Joined applications" means two or more applications which involve similar projects in the same service area or overlapping service areas all of which have been declared complete within thirty days of the date the first application was declared complete, and whose time limits are scheduled to run from the latest date that any one of the joined applications was declared complete for review.

(36) "Joint venture ambulatory surgical center" means a freestanding ambulatory surgical center that is jointly owned by a hospital in the same county as the center or a hospital in a contiguous county if there is no hospital in the same county as the center and a single group of physicians practicing in the center and that provides surgery in a single specialty as defined by the Department; provided, however, that general surgery, a group practice which includes one or more physiatrists who perform services that are reasonably related to the surgical procedures performed in the center, and a group practice in orthopedics which includes hand surgeons with a certificate of added qualifications in Surgery of the Hand from the American Board of Plastic and Reconstructive Surgery shall be considered a single specialty. The ownership interest of the hospital shall be no less than thirty percent (30%) and the collective ownership of the physicians or group of physicians shall be no less than thirty percent (30%).

(37) "Life plan community" means an organization, whether operated for profit or not, whose owner or operator undertakes to provide shelter, food, and either nursing care or personal services, whether such nursing care or personal services are provided in the facility or in another setting, and other services, as designated by agreement, to an individual not related by consanguinity or affinity to such owner or operator providing such care pursuant to an agreement for a fixed or variable fee, or for any other remuneration of any type, whether fixed or variable, for the period of care, payable in a lump sum, lump sum and monthly maintenance charges or in installments. Agreements to provide continuing care include agreements to provide care for any duration, including agreements that are terminable by either party.

(38) "Medical use rights" means rights or interests in real property in which the owner of the property has agreed not to sell or lease such real property for identified medical uses or purposes.

(a) It shall be unlawful for any health care facility to purchase, renew, extend, lease, maintain, or hold medical use rights.

(39) "Micro-hospital" means a hospital in a rural county which has at least two and not more than seven inpatient beds and which provides emergency services seven days per week and 24 hours per day.

(40) "Mobile unit" means an object with the ability by structure, function or design to move or be moved from one site to another, such that upon arriving at a site the object is not permanently fixed but is temporarily secured for the purpose of providing a service to individuals.

(41) "New and emerging health care service" means a health care service or utilization of medical equipment which has been developed and has become acceptable or available for implementation or use but which has not yet been addressed under the Rules and regulations promulgated, adopted and included within and hereto.

(42) "New institutional health service", as defined at O.C.G.A. § 31-6-40(a) means:

(a) the construction, development, or other establishment of a new, expanded, or relocated health care facility, except as otherwise provided in O.C.G.A. § 31-6-47;

(b) any expenditure by or on behalf of a health care facility in excess of $10 million, which amount shall be adjusted annually as provided by law, and which, under generally accepted accounting principles consistently applied, is a capital expenditure, except expenditures for acquisition of an existing health care facility. See the definition of "threshold" below for expenditures that shall be counted to calculate the threshold;

(c) any increase in the bed capacity of a health care facility, regardless of whether a capital expenditure is made, which increases the total bed capacity. An exception to this Rule will be made in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.03(14);

(d) clinical health services that are offered in or through a health care facility, which were not offered on a regular basis in or through such health care facility within the twelve (12) month period prior to the time such services would be offered;

(e) any conversion or upgrading of any general acute care hospital to a specialty hospital or of a facility such that it is converted from a type of facility not covered by these Rules to any of the types of health care facilities which are covered by these Rules;

(f) the purchase or lease by or on behalf of a health care facility of diagnostic or therapeutic equipment except as otherwise provided in O.C.G.A. § 31-6-47 and Ga. Comp. R. & Regs. r. 111-2-2-.03 and Ga. Comp. R. & Regs. r. 111-2-2-.10;

(g) clinical health services which are offered in or through a diagnostic, treatment, or rehabilitation center which were not offered on a regular basis in or through that center within the twelve (12) month period to the time such services would be offered, but only if the clinical health services are any of the following:

1. Radiation therapy;

2. Biliary lithotripsy;

3. Surgery in an operating room environment, including but not limited to ambulatory surgery; and

4. Cardiac catheterization.

(h) The conversion of a destination cancer hospital to a general cancer hospital.

(43) "Nonclinical health services", as defined at O.C.G.A. § 31-6-2(25), means services or functions provided or performed by a health care facility, and the parts of the physical plant where they are located in a health care facility that are not diagnostic, therapeutic, or rehabilitative services to patients and are not clinical health services as defined in this chapter.

(44) "Offer", as defined at O.C.G.A. § 31-6-2(26), means that the health care facility is open for the acceptance of patients or performance of services and has qualified personnel, equipment, and supplies necessary to provide specified clinical health services.

(45) "Operating room environment", as defined at O.C.G.A. § 31-6-2(27), means an environment which meets the minimum physical plant and operational standards specified in the applicable administrative rules of the state which shall consider and use the design and construction specifications as set forth in the Guidelines for Design and Construction of Health Care Facilities published by the American Institute of Architects.

(46) "Pediatric cardiac catheterization" means the performance of angiographic, physiologic, and as appropriate, therapeutic cardiac catheterization on children fourteen (14) years of age or younger.

(47) "Person", as defined at O.C.G.A. § 31-6-2(29), means any individual, trust, or estate, partnership, limited liability company or partnership, corporation (including associations, joint-stock companies and insurance companies), state, political subdivision, hospital authority, or instrumentality (including a municipal corporation) of a state as defined in the laws of this State. This term shall include all related parties, including individuals, business corporations, general partnerships, limited partnerships, limited liability companies, limited liability partnerships, joint ventures, nonprofit corporations, or any other for profit or not for profit entity that owns or controls, is owned or controlled by, or operates under common ownership or control with a person.

(48) "Personal Care Home", as defined at O.C.G.A. § 31-6-2(30), means a residential facility that is certified as a provider of medical assistance for Medicaid purposes pursuant to Article 7 of Chapter 4 of Title 49 having at least twenty-five (25) beds and providing, for compensation, protective care and oversight of ambulatory, non-related persons who need a monitored environment but who do not have injuries or disabilities which require chronic or convalescent care, including medical, nursing, or intermediate care. Personal care homes including those facilities which monitor daily residents' functioning and location, have the capability for crisis intervention, and provide supervision in areas of nutrition, medication, and provision of transient medical care. Such term does not include:

(a) Old age residences which are devoted to independent living units with kitchen facilities in which residents have the option of preparing and serving some or all of their own meals; or

(b) Boarding facilities that do not provide personal care.

(49) "Primary campus" means the building at which the majority of a hospital's or a remote location of a hospital's licensed and operational inpatient hospital beds are located, and includes the health care facilities of such hospital within 1,000 yards of such building. Any health care facility operated under a hospital's license prior to July 1, 2019, but not on the hospital's primary campus shall remain part of such hospital but shall not constitute such hospital's primary campus unless otherwise meeting the requirements of this paragraph.

(50) "Project", as defined at O.C.G.A. § 31-6-2(31), means a proposal to take an action for which Certificate of Need review is required under these Rules. A project or proposed project may refer to the proposal from its earliest planning stages up through the point at which the new institutional health service is offered. In accordance with the definition of "associated with and simultaneously developed or proposed", the Department shall consider simultaneous activities, including, but not limited to, construction, remodeling, development, and acquisitions, unless expressly not included by other provisions of these Rules, which are determined by the Department to be associated with one another, to be a single project.

(51) "Remote location of a hospital" means a hospital facility or organization that is either created by, or acquired by, a hospital that is the main provider for the purpose of furnishing inpatient hospital services under the name, ownership, and financial and administrative control of the main provider.

(52) "Rural county" means a county having a population of less than 50,000 according to the United States decennial census of 2010 or any future such census.

(53) "Service-specific Rule" means those rules that are part of Ga. Comp. R. & Regs. r. 111-2-2 that regard specific clinical health care services as outlined at Ga. Comp. R. & Regs. r. 111-2-2-.20 et seq.

(54) "Single specialty ambulatory surgical center" means an ambulatory surgical center where surgery is performed in the offices of an individual private physician or single group practice of private physicians if such surgery is performed in a facility that is owned, operated, and utilized by such physicians who are also of a single specialty; provided, however, that general surgery, a group practice which includes one or more physiatrists who perform services that are reasonably related to the surgical procedures performed in the center, and a group practice in orthopedics which includes plastic hand surgeons with a certificate of added qualifications in Surgery of the Hand from the American Board of Plastic and Reconstructive Surgery shall be considered a single specialty.

(55) "Skilled nursing facility", as defined at O.C.G.A. § 31-6-2(34), means a public or private institution or a distinct part of an institution which is primarily engaged in providing inpatient skilled nursing care and related services for patients who require medical or nursing care or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

(56) "Specialty hospital" means a hospital that is primarily or exclusively engaged in the care and treatment of one of the following: patients with a cardiac condition, patients with an orthopedic condition, patients receiving a surgical procedure, or patients receiving any other specialized category of services defined elsewhere in these Rules. A "specialty hospital" does not include a destination cancer hospital or a general cancer hospital.

(57) "State health plan", as defined at O.C.G.A. § 31-6-2(36), means a comprehensive program based on recommendations by the Health Strategies Council and the board, approved by the Governor, and implemented by the State of Georgia for the purpose of providing adequate health care services and facilities throughout the State. The State Health Plan is divided into a series of component plans modified from time to time as needed.

(58) "Substantial equivalent of a project" means a proposal to take an action for which a letter of determination is sought under these Rules. A substantial equivalent of a project may refer to the proposal from its earliest planning stages up through the point at which the service is offered. In accordance with the definition of "associated with and simultaneously developed or proposed", the Department shall consider simultaneous activities, including, but not limited to, construction, remodeling, development, and acquisitions, unless expressly not included by other provisions of these Rules, which are determined by the Department to be associated with one another, to be a single substantial equivalent of a project.

(59) "Threshold" means the dollar amount of capital expenditures for which, when exceeded, a Certificate of Need is required.

(a) In calculating the dollar amounts of a proposed project for purposes of 111-2-2-.01(42)(b) and (42)(f), and 111-2-2-.01(54) and (36) of these Rules, the capital costs of all items subject to review by these Rules and items not subject to review by these Rules associated with and simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop Certificate of Need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites;

(b) The following threshold amounts are effective as of July 1, 2019:

1. The capital expenditure threshold of Ga. Comp. R. & Regs. r. 111-2-2-.01(42)(b), is $10 million;

2. The equipment threshold of Ga. Comp. R. & Regs. r. 111-2-2-.03(30) is $3 million;

3. The physician-owned, single-specialty, office-based ambulatory surgery center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.01(54) is $2.5 million;

4. The joint venture ambulatory surgical center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.01(36) is $5 million;

With respect to (b)1., above, beginning on July 1, 2019, and with respect to (b)3., and 4. above, beginning on July 1, 2009, the Department shall update or adjust this CON threshold amount by the annual percentage of change in an appropriate composite price index that, in the judgment of the Department, represents national construction prices for the preceding calendar year such as those published by the Department of Commerce of the United States government or other government agency;

With respect to (b)2. above, beginning on July 1, 2010, the Department shall update or adjust this CON threshold amount by the annual percentage of change in an appropriate consumer price index, or its successor or appropriate replacement index, for the preceding calendar year, such as those published by the United States Department of Labor or other United States government agency. However, diagnostic or other imaging services that are not offered in a hospital or in the offices of an individual private physician or single group practice of physicians exclusively for use on patients of that physician or group practice shall be deemed to be a new institutional health service regardless of the cost of the equipment. Also, however, this amount or threshold figure shall not include build out costs, as defined in Ga. Comp. R. & Regs. r. 111-2-2-.10(3)(c), but shall include all functionally related equipment, software, and any warranty and services contract costs for the first five (5) years.

(c) For purposes of computing the capital expenditure threshold of Ga. Comp. R. & Regs. r. 111-2-2-.01(42)(b) and Ga. Comp. R. & Regs. r. 111-2-2-.01(21) and the physician-owned, single specialty ambulatory surgical center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.03(21) and the joint venture ambulatory surgical center threshold of Ga. Comp. R. & Regs. r. 111-2-2-.03(22), the Department shall include, but not be limited to, the following guidelines:

1. Pursuant to the definition of "associated with and simultaneously developed or proposed", the total cost of all associated capital expenditures for items to be obligated for or purchased within a six (6) month period for a single program, service, plan, or project, regardless of whether or not the cost of any individual item is in excess of the capital expenditure threshold and regardless of whether or not the expenditure or item is otherwise reviewable under these Rules or the CON Statute, is included in the computation;

2. The cost of depreciable equipment that is not used for diagnosis or treatment, such as office equipment, usual business equipment, and office and waiting room furniture, is included in the computation, if such items are associated with and simultaneously developed or proposed with the project. If such furnishing and equipment are used, the cost that shall be used in calculating the threshold shall be the depreciated value or current market value of the furnishings or equipment, whichever is greater;

3. The cost of normal inventories of supplies, such as glassware, chemicals, drugs, linens, and paper, is exempt from the computation as an operating expense;

4. The value of the facilities to be acquired by lease, gift, donation or other means is based on a current (within six (6) months) appraisal of the facility, except that the value of newly constructed facilities shall be based on the actual square footage cost to construct the facility;

5. For facilities that are acquired by lease, the computation of value shall be based on the rentable square footage of the facility and not the useable square footage. Notwithstanding this Rule, lease payments shall be considered to be operating expenses for leases other than capital leases;

6. For facilities that are only partly occupied by a person, the computation shall include a pro-rata share of the value of the common space, unless the rentable square footage is provided as required by 5. above and that rentable square footage already includes an allocation for common space, as documented by the lease agreement; and

7. In the case of a gift or donation, the value of equipment, furnishings or facilities is the fair market value of the equipment, furnishings, or facilities;

(d) For purposes of computing the equipment threshold of Ga. Comp. R. & Regs. r. 111-2-2-.01(59)(b)(2) and Ga. Comp. R. & Regs. r. 111-2-2-.01(42)(f), the Department shall include, but not be limited to, the following guidelines:

1. The cost of diagnostic, therapeutic, or other imaging equipment includes all capital costs, expenditures, charges, fees and assessments which are reasonably necessary to put the equipment into use for the purposes for which the equipment was intended, including but not limited to the following expenses:

(i) Any expense incurred for the purchase of a warranty on the diagnostic, therapeutic, or other imaging equipment from the manufacturer or vendor for the first five years of operation;

(ii) Any expense incurred for operator training;

(iii) Any expense incurred for installation and assembly of the equipment;

(iv) Any expense incurred for transportation and insurance costs pertaining to the purchase and/or delivery of the equipment;

(v) Any expense incurred for functionally related diagnostic, therapeutic or other imaging equipment, such as, but not limited to, water chillers, surge protectors, laser cameras, computer workstations, etc.

(vi) Any expense incurred for any options, extra packages, or accessories to be used in the operation of the equipment;

(vii) Any expense incurred for RF shielding, lead shielding, magnetic shielding necessary to protect patients or staff in the operation of the equipment;

(viii) Any dollar amount attributable to service contracts for the first five (5) years of operation;

(ix) Any dollar amount attributable to volume or bulk purchase discounts given to the party requesting a letter of determination by the manufacturer or vendor of the equipment;

(x) For mobile units of equipment, expenditures and values associated with the motor coach, trailer, van, rig, or other form of modular or transitional housing shall be included in the computation of the threshold;

2. The acquisition by whatever means of one or more items of functionally related diagnostic, therapeutic, other imaging equipment shall be considered as one project. The acquisition of functionally related accessories shall also be counted. Pursuant to the definition of "functionally related diagnostic, therapeutic, or other imaging equipment", any individual components or pieces of diagnostic, therapeutic, or other imaging equipment, which depend on one another in order to function and that are purchased within a six (6) month period, shall be considered in the aggregate in calculating the threshold;

3. Diagnostic, therapeutic, or other imaging equipment shall include single and multiple units of equipment, if such units are associated with and simultaneously developed or proposed with one another. Pursuant to the definition of "associated with and simultaneously developed or proposed", the Department may determine that individual pieces or units of diagnostic, therapeutic, or other imaging equipment are associated with one another if such pieces or units of equipment are used for the same or similar health services and if such pieces or units of equipment are developed, proposed, or acquired simultaneously. Such associated and simultaneous units purchased within a six (6) month period shall be aggregated to calculate the threshold;

4. Purchase or lease shall include purchases, contracts, encumbrances of funds, lease arrangements, conditional sales or a comparable arrangements that purport to be a transfer of ownership in whole or in part;

5. In the case of a lease, loan, or gift, the value of the diagnostic, therapeutic, or other imaging equipment is the fair market value of the diagnostic, therapeutic, or other imaging equipment, as evidenced by documentation from a reputable vendor or manufacturer.

(60) "Uncompensated indigent or charity care" means the dollar amount of "net uncompensated indigent or charity care after direct and indirect (all) compensation" as defined by, and calculated in accordance with, the Department's Hospital Financial Survey and related instructions.

(61) "Urban county" means a county having a population equal to or greater than 50,000 according to the United States decennial census of 2010 or any future such census.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.01

AUTHORITY: O.C.G.A. §§ 31-2 **et seq., 31-6 et seq.**

HISTORY: Original Rule entitled "Definitions" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Oct. 19, 2018; eff. Nov. 8, 2018.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.01, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.02 Nature of Certificate of Need

(1) **Purpose**. The purpose of the Certificate of Need evaluation process is to ensure that adequate health care services and facilities are developed in an orderly and economical manner and are made available to all Georgians and that only those health care services that are found to be in the public interest shall be provided in the State. The goals are to:

(a) Review proposed health care services;

(b) Contain health costs;

(c) Promote economic value;

(d) Ensure compatibility of health care services with the needs of various areas and populations of Georgia; and

(e) Prevent unnecessary duplication or services.

(2) **Contents.** The certificate, or attachments, shall specify, but not be limited to:

(a) the scope of the project;

(b) the defined location of the project;

(c) the person to whom the certificate was issued;

(d) the maximum capital expenditure, if any, which may be obligated under the certificate;

(e) the service area of the project;

(f) the valid dates;

(g) the schedule of time periods to be followed in making the service or equipment available or in completing the project;

(h) the services or units of services, which have been approved; and

(i) when the progress reporting requirements under Ga. Comp. R. & Regs. r. 111-2-2-.04(2) and Ga. Comp. R. & Regs. r. 111-2-2-.02(5) are due.

(3) **Validity.** A Certificate of Need shall be valid only for the defined scope, physical location, cost, service area, and person named in the application as the applicant.

(4) **Non-transferability.** A Certificate of Need shall not be transferable or assignable, nor shall a project for which a Certificate of Need has been issued be transferred from or assigned by one person to another, except under the following circumstances:

(a) the death of the holder of the Certificate, provided the transfer is solely from the estate of the holder to his or her heirs; or

(b) an existing licensed health care facility to which a Certificate has been issued is acquired by another person, in which instance the Certificate shall be valid for the person who acquires the facility and for the scope, location, cost, and service area previously approved by the Department.

(5) **Effective Period.** Unless otherwise provided by a service-specific rule, or unless the Department in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.02(7) has extended the effective period, the effective period of a Certificate of Need shall be as follows:

(a) Certificates involving neither construction nor equipment acquisition shall be effective for twelve (12) months;

(b) Certificates solely involving acquisition of equipment shall be effective for twelve (12) months, by which date the applicant must be in possession of the equipment; and

(c) Certificates for projects involving construction shall be effective based on a reasonable, phased timetable presented in the application, which may be amended during the review cycle, as planned, developed, proposed, and submitted by the applicant. In determining the reasonableness of the proposed phases and time periods, the Department will be guided by the applicable horizon year for the project. However, in appropriate circumstance, the Department may approve an effective period in excess of the applicable horizon year. The approved and valid phases and effective period shall be included in the Certificate of Need. When the Department extends the effective period pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.02(7) or when, due to an appeal of a project, a project's effective date is not the approved date, the Department will update the effective period, including the horizon year, of the project accordingly.

(6) **Initial 12-month Implementation Period for Projects Involving Construction.** Unless otherwise provided in a service-specific rule or unless the Department in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.02(7) has extended the initial 12-month implementation period, all projects involving construction regardless of the dollar amount must, within twelve (12) months of the effective date of the certificate, demonstrate, as evidenced by a progress report (as described at Ga. Comp. R. & Regs. r. 111-2-2-.04(2)) and supporting documentation, substantial performance in beginning the project. Substantial performance shall be demonstrated by the following:

(a) The construction plans have been approved by the Department's Architect;

(b) The construction contract has been signed and specifically indicates beginning and completion dates; and

(c) Construction materials and equipment are on site.

(7) Extension of Time Periods. The Department may, upon written request of the certificate holder, grant an extension of the effective period of a Certificate of Need or of the initial 12-month implementation period if the applicant's request is received by the Department 30 days prior to expiration of the Certificate of Need or of the initial 12-month implementation period, as applicable.

(a) A request for an extension of the initial 12-month implementation period, or any extension thereof, shall demonstrate:

1. that failure to perform as required is caused by circumstances beyond the control of the certificate holder. Occurrences that may justify an extension of the initial 12-month implementation period may include, without limitation, fire, flood, explosion, catastrophic weather conditions, riots or other civil disturbances, work stoppages or strikes, zoning or permitting changes, and similar occurrences. Ordinarily, lack of adequate or accurate planning, uncertainty as to reimbursement and/or financial difficulties will not justify an extension of the implementation period;

2. that the certificate holder has made substantial and timely progress in implementing the project. In order to show substantial and timely progress in implementing the project, the certificate holder must show that the project was on schedule and could reasonably have been implemented during the initial 12-month implementation period or extension thereof, but for the occurrence or circumstance beyond the certificate holder's control;

(b) A request for an extension of the effective period of a Certificate of Need, or any phase or extension thereof, shall:

1. demonstrate that failure to perform as required is caused by circumstances beyond the control of the certificate holder. Occurrences that may justify an extension of the effective period, or any phase or extension thereof, may include, without limitation, fire, flood, explosion, catastrophic weather conditions, riots or other civil disturbances, work stoppages or strikes, zoning or permitting changes, and similar occurrences.

2. demonstrate that but for the circumstance beyond the control of the certificate holder, the project, or phase thereof, would have been completed within the effective period;

3. demonstrate that the certificate holder has made substantial and timely progress in completing the project, or phase thereof;

4. indicate the expected completion date of the project, or phase thereof, as applicable; and

5. affirm that the project, or phase thereof, will be completed within the requested extension period.

(c) The length of an extension of the effective period or of the initial 12-month implementation period of a Certificate of Need shall be determined by the Department and shall be reasonable and consistent with the circumstances. In no case, shall the Department extend the initial 12-month implementation period of a Certificate of Need beyond an additional 12 months.

(d) In circumstances where the certificate holder is precluded from normal progression due to litigation involving the Certificate or where the method of financing is precluded by litigation, the Department may, at its discretion, suspend any or all of the time periods specified herein until the litigation has been resolved.

(8) **Expiration and Cancellation**. If, within the effective period specified in Ga. Comp. R. & Regs. r. 111-2-2-.02(5) and initial 12-month implementation period specified in Ga. Comp. R. & Regs. r. 111-2-2-.02(6), as applicable, the required performance standards are not met, the Certificate will be deemed to have expired unless an extension has been obtained from the Department pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.02(7). Unless the certificate holder demonstrated good cause not to deem the Certificate to have expired, which shall be determined by the Department, the Certificate will be canceled and notifications of same issued to the applicant, local governing authorities, Regional Development Center, and a newspaper of general circulation in the area where the application originated. An applicant whose Certificate has expired may not resubmit an application for the same or a substantially similar project until at least 120 days after expiration of the Certificate.

(9) **Modification by Operation of Law of Certificate for Failure to Complete**. Upon expiration of the effective period, if a certificate holder has not completed all activities or has not implemented all services or units of services granted in the Certificate of Need issued on the approved date (or if appealed, the effective date), the Certificate shall be modified upon such expiration to include and be valid for only those activities, services, or units of services, which have been completed and implemented as of the date of expiration.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.02

AUTHORITY: O.C.G.A. §§ 31-2 **et seq., 31-6 et seq.**

HISTORY: Original Rule entitled "Nature of Certificate of Need" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.02, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.03 Exemptions from Review

The following shall not be subject to Certificate of Need review and shall be exempted from the provisions of these Rules regarding Certificate of Need Review except as otherwise provided:

(1) infirmaries operated by educational institutions for the sole and exclusive benefit of students, faculty members, officers, or employees thereof;

(2) infirmaries or facilities operated by businesses for the sole and exclusive benefit of officers or employees thereof, provided that such infirmaries or facilities make no provision for overnight stay by persons receiving their services;

(3) institutions operated exclusively by the federal government or by any of its agencies;

(4) offices of private physicians or dentists, as determined in the sole discretion of the Department, whether for individual or group practice except as otherwise provided in Ga. Comp. R. & Regs. r. 111-2-2-.01(54) and Ga. Comp. R. & Regs. r. 111-2-2-.01(42)(f). Simple ownership of a facility by a practitioner or a group of practitioners of the healing arts does not, in and of itself, exempt such facility from the scope of these Rules. Seeking licensure of a place, building, or facility as a health care institution is inconsistent with an assertion that such place, building, or facility is being occupied exclusively as the office of private physicians or dentists. Therefore, any person who seeks licensure as a health care facility must secure a Certificate of Need if a new institutional health service is being offered or developed;

(5) Religious, nonmedical health care institutions as defined in 42 U.S.C. Section 1395x(ss)(1), listed and certified by a national accrediting organization;

(6) site acquisitions for health care facilities or preparation or development costs for such sites prior to filing a Certificate of Need application**;**

(7) expenditures related to adequate preparation and development of an application for a Certificate of Need;

(8) the commitment of funds conditioned upon the obtaining of a Certificate of Need;

(9) transfers from one health care facility to another such facility of major medical equipment previously approved under or exempted from Certificate of Need review, except where such transfer results in the institution of a new

clinical health service for which a Certificate of Need is required in the facility acquiring said equipment, provided that such transfers are recorded at net book value of the medical equipment as recorded on the books of the transferring facility;

(10) expenditures for the restructuring or acquisition of existing health care facilities by stock or asset purchase, merger, consolidation, or other lawful means;

(11) the purchase of a closing hospital or of a hospital that has been closed for no more than twelve (12) months by a hospital in a contiguous county to repurpose the facility as a micro-hospital;

(12) capital expenditures otherwise covered by this Chapter required solely to eliminate or prevent safety hazards as defined by federal, state or local fire, building, environmental occupational health, or life safety codes of regulations, to comply with licensing requirements of the Healthcare Facility Regulation Division, or to comply with accreditation standards of the Joint Commission or another nationally recognized health care accreditation body;

(13) except as otherwise provided in this subsection, all cost overruns are excluded from prior Certificate of Need review and approval. For purposes of this subsection, a cost overrun that is subject to prior Certificate of Need review and approval (i.e., a reviewable cost overrun) is defined as meaning any cost overrun which is in excess of the current capital or diagnostic, therapeutic, or other imaging equipment threshold, or in excess of ten percent (10%) of the approved capital expenditure amount, whichever is less. However, in no event shall an additional expenditure of less than $300,000 be deemed a reviewable cost overrun. Reviewable cost overruns will be reviewed by the Department in accordance with the following provisions:

(a) A reviewable cost overrun associated with ongoing construction or renovation activity which has not been incurred prior to a Certificate of Need approval and is solely related to an unanticipated engineering, major fixed equipment or other construction problem, or federal, state or local fire requirements which were adopted or became effective after the issuance of the Certificate of Need but prior to the completion of construction or renovation, will receive favorable review consideration if the applicant demonstrates that the overrun will have no impact or a minimal impact on costs and/or charges per patient day or procedure; and

(b) A reviewable cost overrun which is the result of subsequent project bidding prior to any contractual obligation for construction and/or renovation work will not receive favorable review consideration by the Department but will require the entire project to be reviewed as an entirely new project subject to all the applicable criteria, standards and plans; and

(c) A reviewable cost overrun which is due to delays of project construction and/or renovation activity resulting from an appeal proceeding, when such delay has been in excess of one year, and where the Department has suspended the time periods until the issues are resolved, will be given favorable consideration as long as the project has not changed in scope, square footage, services or number of new beds proposed.

(d) For projects involving either construction or renovation, but not both, a reviewable cost overrun which increases the square footage beyond five percent (5%) of the originally approved project's total new square footage will require the entire project to be submitted as a new application and the new application will be subject to all the applicable criteria, standards and plans.

(e) For projects involving construction and renovation, a reviewable cost overrun which increases the square footage beyond five percent (5%) of the sum of the new construction square footage and renovated square footage will require the entire project to be submitted as a new application and the new application will be subject to all the applicable criteria, standards and plans.

(f) Regardless of cost, during implementation of the project, any increase in the scope of the original project or any change in the number of beds (i.e., the subtraction, addition, replacement or conversion of different number of beds than authorized in the original Certificate of Need) will invalidate the original project and the Department will deem the original project to have been withdrawn unless prior written approval is obtained from the Department;

(14) increases in the bed capacity of a hospital up to ten beds or ten percent (10%) of capacity, whichever is greater, in any consecutive two-year period, in a hospital that has maintained an overall occupancy rate greater than seventy-five percent (75%) (exclusive of any skilled nursing units or comprehensive inpatient rehabilitation units) for the previous twelve (12) month period;

(15) expenditures of less than $870,000.00 for any minor or major repair or replacement of equipment by a health care facility that is not owned by a group practice of physicians or a hospital and that provides diagnostic imaging services if such facility received a letter of non-reviewability from the Department prior to July 1, 2008. This paragraph shall not apply to such facilities in rural counties;

(16) except as provided in paragraph (15) of this subsection, expenditures for the minor or major repair of a health care facility or a facility that is exempt from the requirements of these Rules, parts thereof or services provided or equipment used therein; or the replacement of equipment, including but not limited to CT scanners, magnetic resonance imaging, positron emission tomography (PET), and positron emission tomography/computed tomography previously approved for a Certificate of Need.

(a) To qualify for this exemption, the replaced equipment must have received prior CON review and approval, or have been grandfathered, and the replaced equipment must be removed entirely from the premises and not be used in tandem with the replacement equipment, unless authorized in writing by the Department. Replacement equipment must be placed in the same defined location as the replaced equipment.

1. The Department may authorize in writing the retention of certain functionality of the equipment to be replaced if such retained functionality is not used in tandem with the replacement equipment and if the retained functionality would not otherwise result in the provision of a new institutional health service. The fair market value of the retained functionality must not exceed the applicable equipment threshold at the time of replacement.

(b) Expenditures associated with activities essential to acquiring and making operational the replacement equipment shall also be exempted from review. "Activities essential to acquiring and making operational the replacement equipment" means those activities that are indispensable and requisite, absent which the replacement equipment could not be acquired or made operational.

(c) Replacement equipment shall be comparable diagnostic or therapeutic equipment in relation to the replaced equipment. "Comparable diagnostic or therapeutic equipment" means equipment which is functionally similar and which is used for the same or similar diagnostic or treatment purposes. Replacement equipment is comparable to the equipment being replaced if it is functionally similar and is used for the same or similar diagnostic, therapeutic, or treatment purposes as the equipment currently in use and is not used to provide a new health service;

(17) new institutional health services offered by or on behalf of a Health Maintenance Organization, or a health facility controlled, directly or indirectly, by a Health Maintenance Organization or a combination of Health Maintenance Organizations, provided specific and detailed documentation is provided to the Department that one of the following conditions are met:

(a) that seventy-five percent (75%) of the patients who can reasonably be expected to use the service will be individuals enrolled in a Health Maintenance Organization certified by the State of Georgia;

(b) that the service is needed by the Health Maintenance Organization in order to operate efficiently and economically and that it is not otherwise readily accessible to the Health Maintenance Organization because:

1. existing similar services are not available under a contract of reasonable duration;

2. full and equal staff privileges are not available in existing facilities; or

3. arrangements with existing facilities are not administratively feasible;

(18) capital expenditures for a project otherwise requiring a Certificate of Need if those expenditures are for a project to remodel, renovate, replace, or any combination thereof, a medical-surgical hospital and all the following conditions are met:

(a) the hospital has a bed capacity of not more than fifty (50) beds;

(b) the hospital is located in a county in which no other medical-surgical hospital is located;

(c) the hospital has at any time been designated as a disproportionate share hospital by the Department;

(d) the hospital has at least forty-five percent (45%) of its patient revenues derived from Medicare, Medicaid, or any combination thereof, for the immediately preceding three years;

(e) the project has at least eighty percent (80%) of its capital expenditures financed by proceeds of a special purpose county sales and use tax imposed pursuant to Article 3 of Chapter 8 of Title 48;

(f) the proposed replacement hospital is located within a three (3) mile radius of and within the same county as the hospital's existing facility; and

(g) the project does not result in any of the following:

1. the offering of any new clinical health services;

2. any increase in bed capacity;

3. any redistribution of existing beds among existing clinical health services; and

4. any increase in the capacity of existing clinical health services;

(19) Expenditures for nonclinical projects, including parking lots, parking decks, and other parking facilities; computer systems, software, and other information technology; medical office buildings; administrative office space; conference rooms; education facilities; lobbies; common spaces; clinical staff lounges and sleep areas; waiting rooms; bathrooms; cafeterias; hallways; engineering facilities; mechanical systems; roofs; grounds; signage; family meeting or lounge areas; other nonclinical physical plant renovations or upgrades that do not result in new or expanded clinical health services; and state mental health facilities;

(20) Life plan communities, provided that the skilled nursing component of the facility is for the exclusive use of residents of the life plan community and that a written exemption is obtained from the Department; provided, however, that new sheltered nursing home beds may be used on a limited basis by persons who are not residents of the life plan community for a period up to five years after the date of issuance of the initial nursing home license, but such beds shall not be eligible for Medicaid reimbursement. For the first year, the life plan community sheltered nursing facility may utilize not more than fifty percent (50%) of its licensed beds for patients who are not residents of the life plan community. In the second year of operation, the life plan community shall allow not more than forty percent (40%) of its licensed beds for new patients who are not residents of the life plan community. In the third year of operation, the life plan community shall allow not more than thirty percent (30%) of its licensed beds for new patients who are not residents of the life plan community. In the fourth year of operation, the life plan community shall allow not more than twenty percent (20%) of its licensed beds for new patients who are not residents of the life plan community. In the fifth year of operation, the life plan community shall allow not more than ten percent (10%) of its licensed beds for new patients who are not residents of the life plan community. At no time during the first five (5) years shall the life plan community sheltered nursing facility occupy more than fifty percent (50%) of its licensed beds with patients who are not residents under contract with the life plan community. At the end of the five (5) year period, the life plan community sheltered nursing facility shall be utilized exclusively by residents of the life plan community and at no time shall a resident of a life plan community be denied access to the sheltered nursing facility. At no time shall any existing patient be forced to leave the life plan community to comply with this paragraph. The Department is authorized to promulgate rules and regulations regarding the use and definition of "sheltered nursing facility" in a manner consistent with this Code section. Agreements to provide

continuing care include agreements to provide care for any duration, including agreements that are terminable by either party;

(21) Any single specialty ambulatory surgical center that:

(a) 1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health services which do not exceed $2.5 million; or

2. Is the only single specialty ambulatory surgical center in the county owned by the group practice and has two (2) or fewer operating rooms; provided, however, that a center exempt pursuant to this paragraph shall be required to obtain a certificated of need in order to add any additional operating rooms;

(b) Has a hospital affiliation agreement with a hospital within a reasonable distance from the facility or the medical staff at the center has admitting privileges or other acceptable documented arrangements with such hospital to ensure the necessary backup for the center for medical complications. The center shall have the capability to transfer a patient immediately to a hospital within a reasonable distance from the facility with adequate emergency room services. Hospitals shall not unreasonably deny a transfer agreement or affiliation agreement to the center;

(c) 1. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

2. If the center is not a participant in Medicaid or the PeachCare for Kids® Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue; provided, however, single specialty ambulatory surgical centers owned by physicians in the practice of ophthalmology shall not be required to comply with this subparagraph; and

(d) Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70.

Noncompliance with any condition of this paragraph shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70 after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index. In calculating the dollar amounts of a proposed project for purposes of this paragraph, the costs of all items subject to review by this chapter and items not subject to review by this chapter associated with an simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop Certificate of Need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites;

(22) Any joint venture ambulatory surgical center that:

(a) Has capital expenditures associated with the construction, development, or other establishment of the clinical health service which do not exceed $5 million;

(b) 1. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

2. If the center is not a participant in Medicaid or the PeachCare for Kids® Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue; and

(c) Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70. Noncompliance with any condition of this paragraph shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70 after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index. In calculating the dollar amounts of a proposed project for purposes of this paragraph, the costs of all items subject to review by this chapter and items not subject to review by this chapter associated with and simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop Certificate of Need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites;

(23) Expansion of services by an imaging center based on a population needs methodology taking into consideration whether the population residing in the area served by the imaging center has a need for expanded services, as determined by the Department in accordance with its rules and regulations, if such imaging center:

(a) Was in existence and operational in this state on January 1, 2008;

(b) Is owned by a hospital or by a physician or a group of physicians comprising at least eighty percent (80%) ownership who are currently board certified in radiology;

(c) Provides three (3) or more diagnostic and other imaging services;

(d) Accepts all patients regardless of ability to pay; and

(e) Provides uncompensated indigent and charity care in an amount equal to or greater than the amount of such care provided by the geographically closest general acute care hospital; provided, however, this paragraph shall not apply to an imaging center in a rural county;

(24) Diagnostic cardiac catheterization in a hospital setting on patients fifteen (15) years of age and older;

(25) Therapeutic cardiac catheterization in hospitals selected by the Department prior to July 1, 2008, to participate in the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Study and therapeutic cardiac catheterization in hospitals that, as determined by the Department on an annual basis, meet the criteria to participate in the C-PORT Study but have not been selected for participation; provided, however, that if the criteria requires a transfer agreement to another hospital, no hospital shall unreasonably deny a transfer agreement to another hospital;

(a) The standards for therapeutic cardiac catheterization, pursuant to the exemption in subsection (24) for hospitals who have not been selected for participation in the C-PORT Study shall be as follows:

A hospital that wishes to receive authorization to perform therapeutic cardiac catheterization procedures must:

1. submit a request for a letter of determination on the required form with the proper filing fee between May 1 and May 15 of each year, beginning with calendar year 2009; the sufficiency of the information submitted in the request shall be determined within the administrative discretion of the Department;

2. provide documentation which demonstrates it can perform a minimum of two hundred (200) percutaneous cardiac interventions (PCI) per year by the beginning of the third year of operation of a program, including both elective and primary PCI, with a minimum of thirty-six (36) primary PCI per year beginning the third year of operation;

3. provide documentation to support the criteria referenced in subsection 2 above that includes substantive information on the number of diagnostic cardiac catheterization procedures performed at the hospital, or referred to existing PCI providers by the hospital, in or out of the state of Georgia, in the two (2) calendar years immediately preceding the request;

4. provide documentation that it will have, prior to beginning a PCI program, on active medical staff, at least one (1) interventional cardiologist who will meet the American College of Cardiology (ACC) and American Heart Association (AHA) competency standards, including the performance of at least seventy-five (75) PCI procedures per year;

5. provide documentation that the interventional cardiologist is board certified, or is in the process at the time of the request, of obtaining board certification in Interventional Cardiology from the American Board of Internal Medicine;

6. provide documentation of access to at least one (1) other interventional cardiologist who meets the criteria of subsections 4. and 5. above, to participate in its program on an as-needed basis as determined by the hospital;

7. agree to report annually the data on number of PCI procedures, type, and outcomes to the National Cardiovascular Data Registry Cath/PCI registry;

8. provide documentation to show that one (1) or more interventional cardiologist(s), as qualified in subsections 4., 5. and 6. above, are available to perform primary PCI procedures twenty-four (24) hours a day, seven (7) days a week, three hundred sixty-five (365) days a year;

9. provide documentation one (1) or more interventional cardiologist(s) are required to respond to a call, within the calendar availability specified in subsection 8. above, within sixty (60) minutes;

10. provide documentation that competent and trained nursing and technical cardiac catheterization staff are available at all times and are required to respond in a manner determined by the hospital in conjunction with the interventional cardiologists;

11. provide documentation of a transfer agreement with a tertiary medical facility that has an open heart surgery service to which a patient can be transferred when necessary within a period of sixty (60) minutes, by any means of transportation as chosen by the hospital, from the time the need for transfer is identified;

(i) if the provider of an open heart surgery service within the travel time parameters of this subsection refuses to enter into a transfer agreement with the requesting hospital, the hospital may submit documentation on the reasons given for the denial, and the Department may consider these reasons;

(ii) the Department may allow a requesting hospital to submit a transfer agreement with a provider of an open heart surgery service that is beyond the travel time parameters in this subsection if the reasons given for the denial of a transfer agreement by the tertiary provider are determined by the Department to be unreasonable;

(iii) if the Department determines the reasons for the denial of a transfer agreement by the tertiary provider within the time travel parameters in this subsection are reasonable, the Department may require the requesting hospital to address the reasons for the denial and enter into further negotiations for a transfer agreement prior to receiving a favorable determination from the Department;

12. provide documentation of an agreement with an ambulance service capable of advanced life support and intra aortic balloon pump services and that guarantees a thirty (30) minute or less response time;

13. agree to provide accurate and timely data, including outcomes analysis and formal periodic external and internal case review as required by the Department;

14. provide documentation to show that guidelines for determining patients appropriate for PCI procedures in a setting without on-site open heart backup consistent with C-PORT and ACC standards will be developed and maintained;

15. provide documentation to show the cardiac catheterization laboratory(s) at the requesting hospital is equipped in a manner consistent with C-PORT and ACC guidelines;

16. agree to participate in an elective and primary PCI Development Program at its expense, the successful completion of which will be verified by the Department through the use of an identified third-party; and

17. affirmatively agree authorization to begin a therapeutic cardiac catheterization program is expressly contingent upon successful completion of the development program as referenced in subsection 16. above.

(b) Any hospital approved to perform therapeutic cardiac catheterization procedures as a result of a request submitted between May 1 and May 15 of any calendar year after the adoption of this rule, must, between May 1 and May 15, of each subsequent year, submit a request which documents its compliance with the standards of this Rule, and the Department must re-affirm the hospital's current compliance in writing in order for the hospital to continue its therapeutic cardiac catheterization program.

(c) Any administrative proceeding held pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.10(6), in opposition to a Department approval of a request from a hospital to perform therapeutic cardiac catheterization procedures in accordance with the standards established in this section, or in opposition to a Department decision to deny a hospital request to perform therapeutic cardiac catheterization procedures, shall not conduct a de novo review of the Department decision, and such decision shall only be reversed by an administrative hearing officer upon a showing the Department's action was without reason, arbitrary, or capricious;

(26) Infirmaries of facilities operated by, on behalf of, or under contract with the Department of Corrections or the Department of Juvenile Justice for the sole and exclusive purpose of providing health care services in a secure environment to prisoners within a penal institution, penitentiary, prison, detention center, or other secure correctional institution, including correctional institutions operated by private entities in this state which house inmates under the Department of Corrections or the Department of Juvenile Justice;

(27) The relocation of any skilled nursing facility, intermediate care facility, or micro-hospital within the same county, any other health care facility in a rural county within the same county, and any other health care facility in an urban county within a three-mile radius of the existing facility so long as the facility does not propose to offer any new or expanded clinical health services at the new location;

(28) Facilities which are devoted to the provision of treatment and rehabilitative care for periods continuing for twenty-four (24) hours or longer for persons who have traumatic brain injury, as defined in O.C.G.A. § 37-3-1;

(29) The renovation, remodeling, refurbishment, or upgrading of a health care facility, so long as the project does not result in any of the following:

(a) The offering of any new or expanded clinical health services;

(b) Any increase in inpatient bed capacity;

(c) Any redistribution of existing beds among existing clinical health services; or

(d) A capital expenditure exceeding the threshold contained in paragraph (2) of subsection (a) of O.C.G.A. § 31-6-40;

(30) Other than for equipment used to provide positron emission tomography (PET) services, the acquisition of diagnostic, therapeutic, or other imaging equipment with a value of $3,000,000.00 or less, by or on behalf of:

(a) A hospital; or

(b) An individual private physician or single group practice of physicians exclusively for use on patients of such private physician or single group practice of physicians and such private physician or member of such single group practice of physicians is physically present at the practice location where the diagnostic or other imaging equipment is located at least seventy-five percent (75%) of the time that the equipment is in use.

The amount specified in this paragraph shall not include build-out costs, as defined by the Department, but shall include all functionally related equipment, software, and any warranty and services contract costs for the first five years. The acquisition of one or more items of functionally related diagnostic or therapeutic equipment shall be considered as one project. The dollar amount specified in this paragraph and in paragraph (15) of this subsection shall be adjusted annually by an amount calculated by multiplying such dollar amounts (as adjusted for the preceding year) by the annual percentage of change in the consumer price index, or its successor or appropriate replacement index, if any, published by the United States Department of Labor for the preceding calendar year, commencing on July 1, 2010; and

(31) A capital expenditure of $10 million or less by a hospital at such hospital's primary campus for:

(a) The expansion or addition of the following clinical health services: operating rooms, other than dedicated outpatient operating rooms; medical-surgical services; gynecology; procedure rooms; intensive care; pharmaceutical services; pediatrics; cardiac care or other general hospital services; provided, however, that such expenditure does not include the expansion or addition of inpatient beds or the conversion of one type of inpatient bed to another type of inpatient bed; or

(b) The movement of clinical health services from one location on the hospital's primary campus to another location on such hospital's primary campus.

Pursuant to O.C.G.A. § 31-6-40(c)(1), any person who had a valid exemption granted or approved by the former Health Planning Agency or the Department of Community Health prior to July 1, 2008, shall not be required to obtain a Certificate of Need in order to continue to offer those previously offered services.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.03

AUTHORITY: O.C.G.A. §§ 31-2 et seq., 31-6 et seq.

HISTORY: Original Rule entitled "Exemptions from Review" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. May 1, 2009; eff. May 21, 2009.

Amended: F. Oct. 19, 2018; eff. Nov. 8, 2018.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.03, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.04 Periodic Reports

The availability of accurate, current data is critical for adequate health planning and for the review process. Therefore, all inpatient and outpatient health care facilities and services subject to Certificate of Need review will be required to provide complete and accurate data, in a timely manner, as required by the Department. Pursuant to

O.C.G.A. § 31-6-70(a), this reporting requirement shall also apply, beginning July 1, 2008, to all ambulatory surgical centers and imaging centers, whether or not exempt from obtaining a Certificate of Need under O.C.G.A. § 31-6 et seq. and these Rules.

(1) **Annual and Special Questionnaires.**

(a) All CON-regulated facilities and services, as well as all ambulatory surgical centers and imaging centers, whether or not exempt from obtaining a Certificate of Need under these Rules, shall complete and submit certain surveys annually and periodically to the Department, as deemed necessary by the Department.

(b) Any facility offering ambulatory surgery pursuant to the exclusion designated on June 30, 2008, as division (14)(G)(iii) of O.C.G.A. § 31-6-2; any diagnostic, treatment, or rehabilitation center offering diagnostic imaging or other imaging services in operation and exempt prior to July 1, 2008; or any facility operating pursuant to a letter of non-reviewability and offering diagnostic imaging services prior to July 1, 2008, shall:

1. Provide notice to the Department of the name, ownership, location, single specialty, and services provided in the exempt facility; and

2. Beginning on January 1, 2009, provide annual reports in the same manner and in accordance with the provisions of this Rule.

(c) The Department shall publish a notice giving a date when the information responsive to subsection (b)1. of this Rule by December 30, 2008, or the Department does not receive the annual report referenced in subsection (a), and subsection (b)2., of this Rule from a health care facility requiring a Certificate of Need or an ambulatory surgical center or imaging center, whether or not exempt from obtaining a Certificate of Need under these Rules, on or before the date such report is due or receives a timely but incomplete report, the Department shall notify the health care facility or center regarding the deficiencies and shall be authorized to fine such health care facility or center an amount not to exceed $500.00 per day for every day up to thirty (30) days and $1,000.00 per day for every day over thirty (30) days for every day the Department has not received a report or an incomplete report has not been sufficiently corrected based on the Department's notice of deficiencies.

(d) Survey notices will be mailed or electronically transmitted by the Department to each such facility. The accurately and fully completed survey, covering the report period indicated, shall be filed with the Department within the time frame specific in the notice. The Survey shall be filed with the Department in the electronic format designated by the Department in the Survey Notice or on the Department's website. The survey shall include an electronic signature as authorized by law, of the chief executive officer or principal administrator of the facility, who shall attest to the accuracy and completeness of the information provided.

(e) Reporting requirements shall also apply to new health facilities and services approved through Certificate of Need review. Generally, new facilities and services will be required to report if approved for operation or occupancy for sixty (60) days or more of the report period.

(f) Surveys submitted to the Department pursuant to these Rules and any service-specific Rules shall not be available for public review until after the deadline for submission for all surveys of that type;

(g) Required surveys submitted for a given period of time may not be revised by the facility or service after the survey filing deadline unless the request for revision is approved by the Department at its sole discretion.

(h) If the Department does not receive an annual report from a health care facility within one hundred eighty (180) days following the date such report was due or receives a timely but incomplete report which is not sufficiently completed within such one hundred eighty (180) days, the Department shall be authorized to revoke the Certificate of Need of the health care facility in accordance with O.C.G.A. § 31-6-45 and Ga. Comp. R. & Regs. r. 111-2-2-.05.

(i) The Department shall make publicly available all annual reports submitted pursuant to O.C.G.A. § 31-6-70 on the Department website. The Department shall also provide a copy of such annual reports to the Governor, the President

of the Senate, the Speaker of the House of Representatives, and the chairpersons of the House Committee on Health and Human Services and the Senate Health and Human Services Committee.

(j) All health care facilities, ambulatory surgical centers, and imaging centers required to submit an annual report pursuant to O.C.G.A. § 31-6-70(a) shall make such annual reports publicly available on their websites.

(2) **Post-Approval Reporting.**

(a) All entities receiving a Certificate of Need shall maintain a valid and accurate mailing and electronic mail address with the Department. Any notification, notice, or letter required by these Rules is deemed to be received by the certificate holder when the Department sends such notification, notice, or letter to the mailing or electronic mail address on file with the Department.

(b) Persons holding Certificates for construction projects shall, within twelve (12) months of the effective date of the Certificate, i.e., at the end of the implementation period, provide a progress report to the Department including documentation of the following:

1. that the construction plans have been approved by the Department;

2. that a construction contract has been signed, specifically indicating beginning and completion dates;

3. that construction materials and equipment are on the site and construction of the project has actually begun.

(c) The Department shall monitor the Certificate of Need holder's progress in completing the project and phases thereof, as applicable, within the effective period as specified at Ga. Comp. R. & Regs. r. 111-2-2-.02(5). Each Certificate of Need issued requires a regular reporting of the different stages of development to completion. All projects approved as presented with phases shall submit a progress report within forty-five (45) days of the completion of each phase. All Certificate of Need projects must satisfy the pertinent reporting requirements or the Certificate shall be subject to revocation. These reports shall include information as to the total dollar amount of capital expenditures that have been obligated under the certificate, and any changes in amounts of proposed or previously obligated capital expenditures or changes to the timing of phases, if approved by the Department in advance. These reports will be made on a form provided by the Department on its website and will be due on the date or dates indicated by the Department on attachments to the Certificate of Need and in subsequent correspondence.

(d) The Department may also request additional reports as often as necessary in order to determine:

1. if the timetable specified in the certificate is being met;

2. if the scope of the project is being completed as described on the certificate and in the application for the Certificate of Need;

3. if the amount of the capital expenditure or expenditures obligated under the certificate has exceeded or can be expected to exceed the maximum under the certificate; and

4. if the condition(s) of approval, if any, have been satisfactorily met.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.04

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq.***

HISTORY: Original Rule entitled "Periodic Reports" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.04, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.05 Enforcement

(1) Revocation

(a) In the event that the Department has cause to consider revocation of a Certificate, in whole or in part, the Department shall provide notice to the holder of the Certificate and shall hold a hearing to determine whether the holder has:

1. Intentionally provided false information to the Department;

2. Failed to incur a financial obligation in accordance with the Certificate as granted;

3. Failed to implement the project in accordance with the specific purpose(s) for which the certificate was granted or failed to meet the initial twelve (12) month performance standards or failed to request an extension of such standards. For certificates issued on or after July 1, 2008, failed to implement the services or units of services for which the Certificate of Need was issued, and that were outlined in or on the certificate granted, in a timely manner as also outlined in or on the certificate granted, as provided by O.C.G.A. § 31-6-45(a.1);

4. Transferred controlling ownership in the facility before completion of the project without prior written approval of the Department, except as authorized by Ga. Comp. R. & Regs. r. 111-2-2-.02(4);

6. Changed the defined location of the project except as allowed by O.C.G.A. § 31-6-45(a) authorizing change in location under certain conditions;

7. Failed to comply with any and all requirements or conditions of the Certificate;

8. Failed to submit a timely or complete periodic report within 180 days following the date the report is due pursuant to O.C.G.A. § 31-6-70 and as otherwise required by Ga. Comp. R. & Regs. r. 111-2-2-.04;

9. Failed repeatedly to pay any fines or moneys due to the Department;

10. Failed to maintain minimum quality of care standards that are outlined within the Certificate as granted; or

11. Failed to participate as a provider of medical assistance for Medicaid purposes if made a condition of the Certificate as granted pursuant to O.C.G.A. § 31-6-45.2(a).

(b) In the event that there is sufficient evidence to justify revocation of a Certificate, the Department shall provide written notification to the holder, which shall be effective as of the postmark date on the notification letter. Notice shall also be provided to the public, to the county or municipal authority and to the appropriate Regional Development Center. Any person whose Certificate is revoked under this Rule is entitled to judicial review, pursuant to O.C.G.A. § 50-13 et seq.

(c) A person whose Certificate of Need has been revoked or denied may not reapply for a Certificate of Need for the same or substantially similar project for at least one hundred twenty (120) days from the date that the revocation or denial becomes final, at which time the person may submit a new application. For purposes of this subparagraph, a decision revoking or denying a Certificate of Need shall become final when the time for appealing that decision expires without an appeal of such decision having been timely filed. If an appeal is timely filed, the decision is not final until the resolution of the administrative appeal, if any.

(d) A person holding a Certificate of Need may voluntarily request revocation of the Certificate without prejudice by submitting such request to the Department in writing.

(e) A health care facility which has a Certificate of Need or is otherwise authorized to operate pursuant to this chapter shall have such Certificates of Need or authority to operate automatically revoked by operation of law without any action by the Department when that facility's permit to operate pursuant to O.C.G.A. § 31-7-4 is finally revoked by order of the Healthcare Facility Regulation Division. For purposes of this subsection, the date of such final revocation shall be as follows:

1. When there is no appeal of the order pursuant to O.C.G.A. § 31-5, the one hundred and eightieth (180th) day after the date upon which expires the time for appealing the revocation order without such an appeal being filed; or

2. When there is an appeal of the order pursuant to O.C.G.A. § 31-5, the date upon which expires the time to appeal the last administrative or judicial order affirming or approving the revocation or revocation order without such appeal being filed.

The Department may become a party to any judicial proceeding to review a decision by the Healthcare Facility Regulation Division to revoke such a permit.

(f) A certificate shall be subject to revocation for the following failures, without limitation:

1. Failure to incur a project-specific capital expenditure, within the initial twelve (12) month implementation period specified at Ga. Comp. R. & Regs. r. 111-2-2-.02(6) and in the Certificate itself or within an extension implementation period granted by the Department, through initiation of substantial project above-ground construction or lease or purchase of the proposed equipment;

2. Failure to file the required Progress Report(s);

3. Failure to meet the conditions on the face of the Certificate; or

4. Failure to pay any penalty assessed pursuant to O.C.G.A. § 31-6-40.1.

(2) **Sanctions.**

(a) Any health care facility offering a new institutional health service without having obtained a Certificate of Need and which has not been previously licensed as a health care facility shall be denied a license to operate by the Healthcare Facility Regulation Division.

(b) In the event that a new institutional health service is knowingly offered or developed without having obtained a Certificate of Need as required by O.C.G.A. § 31-6 et seq., or by these Rules, or the Certificate of Need for such service is revoked according to the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.05(1), a facility or person may be fined an amount not to exceed $5,000.00 per day up to thirty (30) days, $10,000.00 per day from thirty-one (31) days through sixty (60) days, and $25,000.00 per day after sixty (60) days for each day that the violation of these Rules and O.C.G.A. § 31-6 et seq. has existed and knowingly and willingly continues; provided however, that the expenditure or commitment of or incurring an obligation for the expenditure of funds to take or perform actions not subject to this chapter or to acquire, develop or prepare a health care facility site for which a Certificate of Need application is denied, shall not be a violation of this Chapter and shall not be subject to such a fine. The Commissioner or his designee shall determine, after notice and a hearing if requested, whether the fines provided in the Code section shall be levied.

(c) Any person who acquires a health care facility by stock or asset purchase, merger, consolidation, or other lawful means shall notify the Department of such acquisition, the date thereof, and the names and address of the acquiring person. Such notification shall be made in writing to the Commissioner or his designee within forty-five (45) days following the acquisition and the acquiring person may be fined by the Department in the amount of $500.00 for each day that such notification is late.

(d) The Department may require that any applicant for a Certificate of Need commit to provide a specified amount of clinical health services to indigent or charity, Medicare, Medicaid, PeachCare, and similar patients as a condition for the grant of a Certificate of Need. A grantee or successor in interest of a Certificate of Need or authorization to operate under O.C.G.A. § 31-6 et seq. which violates such an agreement, whether made before or after July 1, 1991, shall be liable to the Department for a monetary penalty in the amount of the difference between the amount of services so agreed to be provided and the amount actually provided. Penalties authorized under this Code section shall be subject to the same notices and hearing for the levy of fines under Ga. Comp. R. & Regs. r. 111-2-2-.05(2)(b).

(e) All hearings under this Section shall be in accordance with the Georgia Administrative Procedure Act. Any person so penalized under this Rule is entitled to judicial review, pursuant to O.C.G.A. § 50-13 et seq.

(f) If the person assessed fails to pay the amount of the assessment to the Department within thirty (30) days after notice of assessment is postmarked to him, or within such longer period, not to exceed ninety (90) days, as the Department may specify, the Department may institute a civil action to recover the amount of the assessment or may revoke the Certificate of Need. The Department may add reasonable interest to the assessment.

(g) For purposes of this Rule, the State of Georgia, acting by and through the Department or any other interested person, shall have standing in any court of competent jurisdiction to maintain an action for injunctive or other appropriate relief to enforce the provisions of this Rule.

(3) **Department's Right to Inspect and Audit**. The Department or an authorized representative or employee designated by the Department shall have the right to inspect and audit any facility, site, location, book, document, paper, files, or other record of the holder of the Certificate of Need or letter of non-reviewability or other determination that is related to any project authorized by the Certificate of Need or letter of non-reviewability or other determination, in order to monitor and evaluate the person's compliance with the terms of issuance of the Certificate of Need or the letter of non-reviewability or other determination. The Department shall have the authority to make public or private investigations or examinations inside or outside of the state of Georgia to determine whether all provisions of O.C.G.A. § 31-6-2 et seq. or any other law, rule, regulation, or formal order relating to the provisions of O.C.G.A. § 31-6-40 in particular, has been violated. Such investigations may be initiated at any time in the discretion of the Department and may continue during the pendency of any action initiated by the Department pursuant to section (1)(a) of this Rule. For the purpose of conducting any investigation or inspection pursuant to this subsection, the Department shall have the authority, upon providing reasonable notice, to require the production of any books, records, or other information related to any Certificate of Need issue.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.05

AUTHORITY: O.C.G.A. §§ 31-2 et seq., 31-6 et seq.

HISTORY: Original Rule entitled "Enforcement" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.05, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.06 Application for Certificate of Need

(1) **Letter of Intent.** Beginning July 15, 2008, all persons who wish to submit an application for a Certificate of Need for a new institutional health service or health care facility, as provided in O.C.G.A. § 31-6-40(a) and (b), must submit a letter of intent notifying the Department of their intent to do so at least thirty (30) days prior to submission

of the Certificate of Need application. The notice must be in writing, must be submitted via the Department's web portal, and must contain the following information:

(a) Name and address of the legal applicant;

(b) Person to whom inquiries must be addressed;

(c) Name, address of facility, if different from legal applicant;

(d) Proposed project site location with specificity;

(e) Brief summary description of proposal;

(f) Proposed service area; and

(g) Cost of the project.

The Department will not accept any notices of intent submitted by either telephone, facsimile, or electronic mail, pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.06(6). Beginning with the date referenced above, no Certificate of Need application will be accepted without a previously filed letter of intent. The Certificate of Need application must be submitted no later than thirty (30) calendar days after the letter of intent has been received by the Department. In the event that the thirtieth (30th) calendar day falls either on a weekend or a legal holiday, the thirtieth (30th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday. If a Certificate of Need application is not submitted as provided herein, it will not be accepted and an applicant filing an application beyond the time period specified will be required to submit a new letter of intent in the manner specified above.

(2) **Contents of Application.** Applications shall contain all relevant data, information and assurances required by the Department. The Department will provide application forms on request, and all applications must be on the form supplied by the Department or a copy thereof, and comply with the content requirements specified thereon. Applications shall provide information including, but not necessarily limited to, the following categories as they relate to the proposed projects:

(a) identification of the applicant;

(b) ownership;

(c) site identification;

(d) compliance with State and local codes and ordinances, including flood hazards;

(e) a detailed and complete description of proposed project;

(f) project justification, including specific documentation of the need (utilizing the Department's data and methodology) that the population to be served has for the project;

(g) staffing and operation;

(h) financial information, which shall include positive evidence of ability to obtain financing, the source of financing, and maximum interest rates, which will be paid to the lender. Applications submitted for or on behalf of a health care institution shall include one copy of the latest audit report (or internal financial statement for investor-owned facilities). Also submitted shall be all pro forma financial data requested in the application;

(i) cost containment and quality of care considerations;

(j) project design and construction schedule including as applicable:

1. Schematic Design Documents meeting the standards defined by the American Institute of Architects in section 2.4.2 of the Standard AIA Contract Language. These Schematic Design Documents shall establish the conceptual design of the Project illustrating the scale and relationship of the Project components. The Schematic Design Documents shall also include a conceptual site plan, if appropriate, and preliminary building plans, sections and elevations. Preliminary selections of major building systems and construction materials shall be noted on the drawings or described in writing;

2. A written summary of the Architect's evaluation and planning findings and recommendations meeting the standards defined by the American Institute of Architects in section 2.3 of the Standard AIA Contract Language. This summary shall include, as applicable, an evaluation of the Applicants program and schedule requirements and budget for the Cost of the Work, each in terms of the other, a preliminary evaluation of the Applicants site for the Project based on the information provided by the Applicant of site conditions, and the Applicants program, schedule and budget for the Cost of the Work, and an evaluation of the applicants proposed method of contracting for construction services; and

3. A detailed description of the proposed timeline and phases for project completion.

(k) a cost estimate prepared by a licensed architect or engineer within the sixty (60) days immediately preceding submission of the application;

(l) documentation from the Healthcare Facility Regulation Division of no uncorrected licensure operational standards in the applicants facility, if applicable.

(3) **Submittal of Applications.**

(a) Using the Departments web portal, Applicants should submit one (1) copy of the application signed by the applicant or the legal representative of the applicant. Failure to do so will result in non-acceptance of the application.

(b) Applications received after 3:00 p.m. on any business day will be considered to have been received on the next business day. Receipt of the application will be acknowledged in writing by the Department.

(4) **Filing Fee Required.**

(a) Each application for a Certificate of Need review shall be accompanied by a fee, except for the provisions covered in Ga. Comp. R. & Regs. r. 111-2-2-.06(4)(d) and Ga. Comp. R. & Regs. r. 111-2-2-.06(4)(e), the amount of which shall be determined by the following schedule:

1. for applications with a total project cost from zero to $1,000,000.00, the fee shall be $1,000.00; and

2. for applications with a total project cost greater than $1,000,000.00, the fee shall be one-tenth of one percent (.001) of the total cost but not to exceed $50,000.00; and

3. for the review of cost overruns the fee shall be computed as shown above for the amount of the overrun only.

(b) For any project, which is to be accomplished by lease, gift or other means of acquisition, the dollar value for purposes of computing the fee will be based on the value of the major medical equipment or facilities to be acquired. The value of the major medical equipment is the expenditure, which would be required for purchase. The value of the facilities to be acquired is based on a current (within six (6) months of the submittal of the Certificate of Need application) appraisal of the property.

(c) Payment of the fee shall be by credit/debit card via the Departments website, certified check, or money order made payable to the State of Georgia and must be received by the Department before an application will be accepted for review. Failure to provide payment of the appropriate fee will result in non-acceptance of the application. Fee payments are collected as general State revenue.

(d) State-owned institutions shall be exempt from payment of a filing fee.

(e) The Department may waive payment of a filing fee, or any portion thereof, for certain hospital authority facilities and for certain public non-profit providers when the Department determines that financial circumstances exist, which would justify such action. A party requesting a waiver must make such request at the time the application is submitted to the Department.

(f) Subject to the Rules in (a) through (e) above, applicants shall submit an additional filing fee for additional information or amendments provided during the review period that increase the cost of the project. For such supplementary information which increases the cost of the project, the amount that shall be submitted is an amount equal to the difference between the calculation of the filing fee based on the total amended project costs as outlined in (a) and the filing fee paid at the time of application, except that in no case shall the amount submitted be less than $500.00. Should such supplementary information decrease the costs associated with a project, the filing fee shall not be reduced or refunded. The Department shall not issue decisions on applications for which such supplementary information has been provided where an applicant has not submitted the additional filing fee, as applicable.

(5) **Review for Completeness**.

(a) Upon receipt of an application, the Department shall determine whether the application is complete. No application shall be reviewed until it has been determined by the Department to be complete in accordance with information requirements specified in this Section.

(b) An application will be determined to be incomplete if any of the following were not either provided with the application or as may be specified in this Section, submitted previously to the Department:

1. all the required data, information and assurances provided on the correct forms, including but not limited to the following:

(i) detailed description of the proposed project as required by Ga. Comp. R. & Regs. r. 111-2-2-.06(2)(e);

(ii) financial program to meet the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.06(2)(h);

(iii) documentation of necessary financing for the project, such as a letter of credit, etc.;

(iv) financial pro forma to meet the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.06(2)(h); and

(v) most recent audited financial statements, or personal financial statements if audited statements are not available (tax returns would meet this requirement for unaudited entities and individuals);

(vi) for projects invoking service-specific Rules, as outlined in Ga. Comp. R. & Regs. r. 111-2-2-.20 et seq., the appropriate service-specific review considerations;

(vii) for projects involving construction, renovation, and/or expansion, schematic plans and cost estimates certified by an architect, engineer, or general contractor, as appropriate and as required by Ga. Comp. R. & Regs. r. 111-2-2-.06(2)(j) and (k);

(viii) for projects involving the acquisition of equipment, purchase orders or invoices, as appropriate;

2. signature of the applicant;

3. payment of the filing fee, as described in Ga. Comp. R. & Regs. r. 111-2-2-.06(4);

4. the most recent three (3) years of all required surveys, as may be previously submitted to the Department, including the Annual Hospital Questionnaire, Annual Nursing Home Questionnaire, survey of home health agencies, or other data-gathering instruments required by the Department for any health care facilities and services owned or operated by the applicant, to include data requested pursuant to O.C.G.A. § 31-6-70. In order for an application to be

deemed complete, such surveys and data-gathering instruments shall be complete and accurate, as determined by the Department. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation have submitted completed questionnaires with the Department;

5. written verification certifying entitlement to any necessary real estate property or leasehold as described by the applicant in the application. Verification of entitlement shall include, but not be limited to, deeds, contracts, lease arrangements, conditional sales agreements or a comparable arrangement that purports to be a transfer of ownership in whole or in part. If an unsigned lease arrangement is submitted, the Applicant shall also submit an original letter documenting both the lessors and lessees commitment to participate in the lease once the CON is approved;

6. authorization to conduct business, including but not limited to, as appropriate:

(i) if the applicant is an entity requiring authorization by the Secretary of State to become a legal entity entitled to do business in the State of Georgia, such documentation;

(ii) by-laws, articles of incorporation, or articles of organization; and

(iii) if the applicant is an existing and licensed or permitted entity, a copy of such license or permit.

7. The applicant shall file one copy of the application with the office of the County Commissioner of the county in which the project exists or is proposed. The applicant shall submit with the application an exact copy of the letter addressed and submitted to the County Commission that accompanied the submittal of the application to the County Commission;

8. all post-approval reporting requirements as mandated at Ga. Comp. R. & Regs. r. 111-2-2-.04(2) for all previously approved projects, as may be previously submitted to the Department. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation have met the said post-approval reporting requirements for all previously approved projects with the Department;

9. the written vendor lobbyist certification required by Ga. Comp. R. & Regs. r. 111-1-2-.03(2);

10. In order to be determined complete, an applicant must be current will all indigent and charity care commitments, if any, made to the Department as a condition or requirement for past approval of a project. Further, an application submitted by a component of an entity which owns or operates other health care facilities will be determined to be incomplete unless all health care facilities under the same ownership or operation are current with any and all indigent and charity care commitments made to the Department; and

11. In order to be determined complete, an applicant must be current with any and all fines, if any, levied by the Department for violation of these Rules.

12. No applicant for a new Certificate of Need, a modification to an existing Certificate of Need, or a conversion of a Certificate of Need that has any outstanding amounts owed to the state including fines, penalties, fees, or other payments for noncompliance with any requirements contained in O.C.G.A. §§ 31-6-40.1, 31-6-45.2, 31-6-70, 31-7-280, or 31-8-179.2 shall be eligible to receive a new Certificate of Need or a modification to an existing Certificate of Need unless such applicant pays such outstanding amounts to the state. Any such fines, penalties, fees, or other payments for noncompliance shall be subject to the same notices and hearing for the levy of fines under O.C.G.A. § 31-6-45.

(c) The Department shall notify the applicant within ten (10) business days following receipt of the application that the application is complete as submitted or that additional information is required to complete the application. If additional information is required, the notice shall include a statement of the specific additional information required. Notice shall be effective the date it is sent electronically by the Department.

(d) The Department shall notify the applicant no later than ten business days following receipt of the additional information whether such information is sufficient to complete the application. If it is not sufficient, the notice shall include a specific statement of the information which needs clarification or which does not adequately respond to the original request.

(e) The Department will deem an application to be withdrawn if the applicant fails to provide the Department with information requested on a notice of incompleteness within two (2) calendar months after the date of the original letter notifying the applicant of the information necessary for completeness.

(f) In addition to the provisions of a paragraph (b) above, additional requirements shall be in effect where the application involves the acquisition of a hospital owned or operated by or on behalf of a political subdivision, any combination of such subdivisions, or by or on behalf of a hospital authority. These requirements shall be as follows:

1. in the event that a health care facility, which has been assisted at any time during the past twenty years through a grant of State funds, is proposed to be acquired by a non-grant-eligible entity, the Department, in accordance with O.C.G.A. §§ 31-7-53(c) and 31-7-57(d), is required to recover the funds granted by the State. A commitment regarding return to the State of such monies consistent with the Code should be forwarded to the Department no later than the end of the review period.

2. there shall be submitted a written agreement between the parties containing the following commitments:

(i) that the purchaser or lessee will annually allocate funds for the purpose of providing indigent/charity care. The funds allocated will be no less than three percent (3%) of the gross revenues of the hospital after provisions for bad debt and Medicaid and Medicare contractual adjustments have been deducted. The funds allocated will be based on the previous years financial records, except the first year of operation following an acquisition the three percent (3%) will be based on the gross revenues of the hospital after provisions for bad debt and Medicaid and Medicare adjustments have been deducted. For purposes of this Rule; gross revenues will include all income derived from all sources;

(ii) that the purchaser will agree that no resident of the county in which the hospital resides will be denied emergency care (including emergency obstetrical care) due to inability to pay;

(iii) that the purchaser will participate in the Medicaid and Medicare programs and the State Health Benefit Plan, if authorized by the Department.

(6) **Submission of Information and Documents.**

For the purposes of meeting any deadlines imposed by either these Rules or O.C.G.A. § 31-6, the Department will not accept any information or documents that are submitted either via telephone or facsimile. In order to meet any of the above referenced deadlines, it will be necessary to submit the information or documents via the Departments web portal or as otherwise directed by these Rules. Except as otherwise provided, information and documents received after 5:00 p.m. on any business day will be considered to have been received on the next business day. Except as otherwise provided by these Rules, all documents required and described in these Rules, except for the periodic reports described in Ga. Comp. R. & Regs. r. 111-2-2-.04, including, but not limited to, applications, opposition letters, supplementary information, requests for determinations, and opposition to determinations, shall be submitted via the Departments web portal.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.06

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq.***

HISTORY: Original Rule entitled "Application for Certificate of Need" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

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Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.06, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.08 Alternative Application and Review Procedures

(1) **Batching Review Process**

(a) Pursuant to O.C.G.A. § 31-6-43(e), the Department may limit the time periods during which it will accept applications for the following health care facilities and/or services: skilled nursing facilities; intermediate care facilities; home health agencies, open heart surgical services, pediatric cardiac catheterization and open heart services, perinatal services, freestanding birthing centers, psychiatric and substance abuse services, comprehensive inpatient physical rehabilitation services, ambulatory surgical services, positron emission tomography services, and megavoltage radiation therapy services. Limitation of the time periods shall be to only such times after the Department has determined there is an unmet need for such facilities and/or services, or will accept applications pursuant to any service-specific need standard exceptions. The Department shall make a determination as to whether or not there is an unmet need for each type of facility at least every six (6) months and shall notify those requesting such notification of that determination. No application for the services listed above will be accepted for review by the Department except as provided for pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.08(1). For purposes of batching only, the applications entered into the one hundred twenty (120) day review period shall be evaluated according to the data used to publish the unmet need, or to accept applications pursuant to any service-specific need standard exceptions, for the particular service at issue, for those services listed above, and not the latest available data at the time of decision, as is the case with all non-batched applications.

(b) Upon the determination of an unmet need for a particular facility/service in a given service area, the Department shall provide notice indicating which applications will be considered in that particular batching cycle to all interested parties requesting notice of that determination. It shall be the sole and exclusive responsibility of the interested party to notify the Department in writing of that party's desire to be informed of the Departments unmet need determination(s) for batching purposes. The Departments notice shall contain the unmet need for the type of facility/service in the given service area(s) and shall also contain the pertinent time frames and deadlines for submission of notices of intent to apply, for submission of applications, and the review of such applications.

(c) All parties interested in applying for the particular unmet need in a given service area must notify the Department of that party's intent to apply.

1. The notice must be in writing, submitted via the Departments web portal, and must address specifically the type of unmet need and service area(s) for which the applicant intends to apply.

2. The notice of intent must be received by the Department no later than the close of business on the thirtieth (30th) calendar day following the date that the Department publishes the determination of unmet need. In the event that the thirtieth (30th) calendar day falls on either a weekend or a legal holiday, the thirtieth (30th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday.

3. Notwithstanding any other relevant provisions within this Rule, the notice of intent to apply must be received by the Department either before or simultaneously with the submission of the actual application in accordance with the notice of intent deadline.

4. In the event that the Department fails to receive the notice of intent to apply by the stated deadline, the interested party shall be disqualified automatically from applying during that batching cycle.

(d) Subject to the proper submission of a notice of intent to apply, any interested party shall use the Departments web portal to submit an application no later than 12:00 P.M. on the sixtieth (60th) calendar day following the date that the Department publishes the determination of unmet need. In the event that the sixtieth (60th) calendar day falls either on a weekend or a legal holiday, the sixtieth (60th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday. For purposes of batching only, all properly submitted applications will be deemed received on the sixtieth (60th) day, regardless of the actual date of submission.

(e) For the purposes of batching only, an application which has been deemed received according to (d) above, will only be deemed properly submitted and complete if the following requirements, in addition to the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.06(5), are met:

1. The appropriate Certification Statement (an applicable service-specific related checklist) is submitted simultaneously with the original application; and

2. All of the items addressed in the Certification Statement are provided, as certified, with the original application.

(f) In the event that an application is deemed in receipt by (d) above, but is not deemed to be properly submitted and complete by (e) above by 12:00 PM on the sixtieth (60th) calendar day following the date that the Department publishes the determination of unmet need (in the event that the sixtieth (60th) calendar day falls either on a weekend or a legal holiday, the sixtieth (60th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday), the application will be disqualified from the batching review.

(g) The batching review cycle will be conducted in the following manner:

1. The batching review cycle shall be one hundred and twenty (120) days in duration. As a result, no party participating in the batching review process, including the Department, shall either request or be granted an extension of time past the one hundred and twentieth (120th) day.

2. The first day of the batching review cycle shall be the day upon which all properly submitted applications are deemed to be received. [See Ga. Comp. R. & Regs. r. 111-2-2-.08(1)(d) above.]

3. On or before the sixtieth (60th) day of the batching review cycle, the Department shall provide the applicant(s) an opportunity to meet with the Department. The Department will describe any issues with the application and provide an opportunity to the applicant(s) to amend or withdraw the application or to submit additional information. Any and all additional information must be submitted on or before the seventy-fifth (75th) day of the batching review cycle. The sixty (60) day meeting with the applicant(s) is restricted to the Department and the applicant(s). Parties opposing an application(s) may not attend or participate in an applicant sixty (60) day meeting.

4. Any party who is opposed to one or more applications submitted during a batching cycle must submit a notice of opposition via the Departments web portal, on the form provided by the Department, no later than the sixtieth (60th) day of the batching review cycle. The notice must contain the information specified by the form. The notice of opposition form submission shall also include one signed original of the written vendor lobbyist certification required by Ga. Comp. R. & Regs. r. 111-1-2-.03(2). The notice of opposition must not contain the substantive arguments against a particular application.

Those parties who are opposed to an application will be given an opportunity to meet with the Department at a time and place specified by the Department after a review of the opposition notices. The opposition meeting, provided for by O.C.G.A. § 31-6-43(h), shall be held no earlier than the ninetieth (90th) day of the batching review cycle. The applicant(s) shall be entitled to attend the opposition meeting. Only one designated person on behalf of each party opposed to a particular application will be allowed to speak on behalf of the opposition to said application at the opposition meeting. The time period provided for that opposition spokesperson shall be determined in the sole discretion of the Department. The applicant(s) will not be allowed to speak in rebuttal of the opposition remarks at the opposition meeting. The Department shall make no formal substantive comments regarding the review of the application(s) at the opposition meeting. The opposition parties shall submit via the Departments web portal, substantive written comments and arguments regarding the nature of their opposition to the particular project. The opposition parties must provide one copy of the substantive opposition comments to the applicant at the opposition

meeting. In order for an opposing party to have standing to appeal an adverse decision pursuant to O.C.G.A. § 31-6-44, such party must attend and participate in an opposition meeting. Substantive opposition comments must pertain to only one application and one applicant. In no case shall the Department accept substantive opposition comments that concerns multiple applicants or applications.

Letters of support for a particular application must be submitted pursuant to and in compliance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6) via the Departments web portal and can be submitted no later than the one hundredth (100th) day of the batching review cycle.

5. Applicants shall be given the opportunity to respond to the substantive opposition comments made orally and submitted in writing at the opposition meeting. The last day for the applicant(s) to submit final amendments to the application and/or to respond to the opposition meeting comments, shall be the one hundred and tenth (110th) day of the batching review cycle. The Department reserves the right, but is not required to, ask the applicant(s) for information in response to the substantive opposition comments. If the Department asks the applicant for information as a result of the comments provided at the opposition meeting, the applicant must submit the information requested no later than the one hundred and tenth (110th) day of the batching review cycle.

6. No later than the one hundred and twentieth (120th) day of the batching review cycle, the Department shall provide written notification of its decision to issue or deny a Certificate of Need to the pertinent applicant(s).

(h) In evaluating batched applications, if any or all of the batched applications equally meet the statutory considerations, priority consideration will be given to a comparison of the applications with regard to:

1. The past and present records of the facility, and other existing facilities in Georgia, if any, owned by the same parent organization, regarding the provision of service to all segments of the population, particularly including Medicare, Medicaid, minority patients and those patients with limited or no ability to pay;

2. Specific services to be offered;

3. Appropriateness of the site, i.e., the accessibility to the population to be served, availability of utilities, transportation systems, adequacy of size, cost of acquisition, and cost to develop;

4. Demonstrated readiness to implement the project, including commitment of financing;

5. Patterns of past performance, if any, of the applicants in implementing previously approved projects in a timely fashion;

6. Past record, if any, of the applicant facility, and other existing facilities owned by the same parent organization, if any, in meeting licensure requirements and factors relevant to providing accessible, quality health care;

7. Evidence of attention to factors of cost containment, which do not diminish the quality of care or safety of the patient, but which demonstrate sincere efforts to avoid significant costs unrelated to patient care; and

8. Past compliance, if any, with survey and post-approval reporting requirements and indigent and charity care commitments.

(i) In the event of a favorable decision, the Departments notification letter shall serve as the Certificate of Need. The date of the decision shall be the date on the notification letter of the Department. The decision shall be to approve or deny the application(s) as submitted or as amended by the applicant(s) during the course of the batching review cycle, whichever is applicable. The effective date of the Certificate shall be the decision or approval date if not appealed. If administratively appealed in a timely fashion, the effective date of the Certificate shall be the date of final resolution of any administrative hearing. The Department may stay the effective date of a project appealed through judicial process at the request of any party to such appeal or upon the Departments own initiative. Any determination by the Department to stay the effective date will be based upon sound health planning principles. If the Department stays the effective date of a project appealed through judicial process, the effective date shall be the date of final resolution of any judicial appeal.

(j) The decision letter shall contain at least the following:

1. A detailed statement of the findings related to each applicable consideration and standard relevant to the decision to issue or deny a Certificate of Need; and

2. Information pertaining to the availability of an appeal hearing.

(k) A copy of the notification letter shall be sent to the applicant(s), to the appropriate Regional Development Center and to the chief elected official of the applicable county and municipal government, if any. The Departments decision shall be subject to the provisions of the Open Records Act.

(l) Appeals of the Decision of the Department shall be in accordance with the Rules promulgated by the Certificate of Need Appeal Panel found in Ga. Comp. R. & Regs. Chapter 274.

(2) **Alternative Healthcare Models**

(a) **Applicability**

1. For Certificate of Need purposes, Alternative Healthcare Models are defined as new and/or innovative models of providing new or existing institutional health services delivered in a proposed or existing healthcare facility.

2. For Certificate of Need purposes, the applicant for an Alternative Healthcare Model CON will be as follows:

(i) If the service(s) will be provided within a single healthcare facility, the owner of that facility will be the applicant;

(ii) If the service(s) will be provided within two or more healthcare facilities that are part of a healthcare services network, the owner(s) of the facility(ies) in which the service(s) will be provided will be the co-applicant(s).

3. The Department shall evaluate the performance of the Alternative Healthcare Model according to the scope as defined by the Department decision and the standards set forth in these Rules. If after a review the Department determines that the Alternative Healthcare Model does not meet the defined scope or expected standards, the Department may either immediately revoke the Certificate of Need or grant a specified time period during which the Alternative Healthcare Model must meet the defined scope and the expected standards or lose its Certificate of Need.

(b) **Definitions**

1. "Alternative healthcare model" means a new and/or innovative model of providing new or existing institutional health service(s) delivered in or through a healthcare facility(ies) and/or healthcare services networks.

2. "Authorized service" means a Department sanctioned Alternative Healthcare Model, which is either existing or approved. An existing service is an authorized service, which has become operational, and an approved service is an authorized service, which has not yet become operational.

3. "Board" means the Board of Community Health.

4. "Health care facility", as defined at O.C.G.A. § 31-6-2(17), means hospitals; destination cancer hospitals; other special care units, including but not limited to podiatric facilities; skilled nursing facilities; intermediate care facilities; personal care homes of at least twenty-five (25) beds; ambulatory surgical or obstetrical facilities; freestanding emergency departments or facilities not located on a hospitals primary campus; health maintenance organizations; home health agencies; diagnostic, treatment, or rehabilitative centers, but only to the extent that O.C.G.A. § 31-6-40(a)(3) or (7) or both are applicable thereto.

5. "Healthcare services network" means a collaborative arrangement that consists of at least one healthcare facility plus one or more physician groups and/or one or more third party payers, or a collaborative arrangement that includes at least two or more healthcare facilities.

6. "Most recent year" means the most recent calendar year prior to submission of an application.

7. "Official inventory" means the inventory of all authorized Alternative Healthcare Models maintained by the Department based on CON approval and official Department records.

8. "Official state component plan" means the most recent document(s) that is/are most closely related to those services being provided by the Alternative Healthcare Model. The most recent document(s) will have been developed by the Department and approved by the Board.

9. "State health policies" means the most recent policies developed by the Board, which provide a framework for the service-specific policies included within each component of the State Health Plan. These state health policies include health promotion, financial accessibility, least restrictive care, regionalization, cost containment, health planning and citizen participation, healthcare personnel, and healthcare data and information networks.

(c) **Requests for Proposals**

1. Within the period of April 1 through May 31 of each year, the Board may accept abstracts describing potential Alternative Healthcare Models, based on the recommendation of the Department. The Board will review these abstracts, if any are solicited for that year, by August 31 of that year and select a list of those categories for which Alternative Healthcare Model Certificate of Need applications may be submitted.

2. Within thirty (30) days of the determination by the Board of the particular categories under which Alternative Healthcare Model Certificate of Need applications may be submitted, the Department shall provide notice of these categories to all interested parties. The notice shall contain:

(i) the listing of category(ies) related goals and desired outcomes and the probable scope of services;

(ii) the pertinent time frames and deadlines for submission of notices of intent to apply for Alternative Healthcare Model Certificate of Need;

(iii) the pertinent time frames and deadlines for submission of CON applications; and

(iv) the pertinent time frames and deadlines for the review of such applications, and any related criteria for review.

(d) **Intent to Apply**

1. All parties wanting to apply for Alternative Healthcare Model Certificates of Need under the selected categories must notify the Department of that party’s intent to apply.

2. This notice must be:

(i) in writing, submitted via the Departments web portal, and must address specifically the particular category under which the applicant intends to apply;

(ii) received by the Department no later than the close of business on the sixtieth (60th) calendar day following the date that the Department publishes the notice of the selected categories. In the event that the sixtieth (60th) calendar day falls on either a weekend or a legal holiday, the sixtieth (60th) calendar day shall become automatically the next business day that is neither a weekend nor a legal holiday;

(iii) must be received by the Department either before or simultaneously with the submission of the actual application; and

(iv) in the event that the Department fails to receive the notice of intent to apply by the stated deadline, the interested party automatically shall be disqualified from applying during that particular review cycle.

(e) **Application Process**

1. Certificate of Need applications pertaining to the selected categories will be submitted via the Departments web portal on or before 3:00 p.m. June 1 of the year following the year in which the categories were selected by the Board. (Although applications may be submitted prior to 3:00 p.m. June 1, all application will be deemed received on June 1.) In the event that June 1 falls either on a weekend or a legal holiday, the day of submission shall become automatically the next business day that is neither a weekend nor a legal holiday;

2. Alternative Healthcare Model Certificate of Need applications must comply with the requirements in Ga. Comp. R. & Regs. r. 111-2-2-.06(2) and (3).

3. For the purposes of Alternative Healthcare Model Certificate of Need applications, an application will be deemed properly submitted if the following requirements are met:

(i) a summary of the Certificate of Need application is included to be used as information for the Board and general public;

(ii) a Certification Statement of Completeness is included designating under which category the application is being submitted; and

(iii) all items addressed in the Certification Statement of Completeness are provided with the application.

(f) **The Review Cycle**

1. The review cycle shall be automatically one hundred and twenty (120) days in duration. As a result, no party participating in the review process, including the Department, shall either request or be granted an extension of time past the one hundred and twentieth (120th) day;

2. The first day of the review cycle shall be the day upon which all properly submitted applications are deemed to be received as specified in Ga. Comp. R. & Regs. r. 111-2-2-.08(2)(e)3.

3. No later than the thirtieth (30th) day of the review cycle, the Department shall, if deemed necessary, submit a written request to any and all pertinent applicants for clarifying and/or supplemental information. This written request may be distributed within a meeting of the applicant(s). The purpose of the request for clarifying and/or supplemental information shall be to obtain information from the applicant(s) that clarifies or supplements the initial information submitted with the original application.

4. No later than the forty-fifth (45th) day of the review cycle, the applicant(s) shall, if deemed necessary by the Department, submit their clarifying and/or supplemental information. Failure to submit the required clarifying and/or supplemental information by the forty-fifth (45th) day may be grounds for denial of the application.

5. If, by the forty-fifth (45th) day, the review indicates potential for denial of the application(s), the Department, on or before the sixtieth (60th) day of the review cycle, shall provide the applicant(s) an opportunity to meet with the Department. The problems with the application(s) will be described and an opportunity offered to amend or withdraw the application or to submit additional information. Any and all additional information and amendments must be submitted on or before the seventy-fifth (75th) day of the review cycle.

6. The last day for interested parties (including, but not limited to, competing applicant(s) and/or existing competing health care facilities) to submit letters of support or opposition addressing the underlying merits, or lack thereof, of any pending application(s) shall be the eighty-fifth (85th) day of the review cycle and must be submitted via the Departments web portal. Any letters of support and/or opposition that are received after the eighty-fifth (85th) day of the review cycle shall not be considered by the Department in its review of the pertinent application(s) and the letter(s) shall not become part of the master file compiled for the pertinent application(s).

7. The last day for applicant(s) to submit final amendments and responses to letters of opposition shall be the one hundred and tenth (110th) day of the review cycle.

8. No later than the one hundred and twentieth (120th) day of the review cycle, the Department shall provide a written letter notifying the applicant of their decision to issue or deny a Certificate of Need to the pertinent applicant(s).

9. In the event of a favorable decision, this letter shall serve as the Certificate of Need. The date of the decision shall be the date on the notification letter from the Department. The decision shall be to approve or deny the application(s) as submitted or as amended by the applicant(s) during the course of the review cycle, whichever is applicable.

10. The decision letter shall contain at least the following:

(i) a detailed statement of the findings related to each applicable consideration and standard relevant to the decision to issue or deny a Certificate of Need; and

(ii) information pertaining to the availability of an appeal hearing.

11. A copy of the notification letter shall be sent to the applicant(s), to the appropriate Regional Development Center and to the chief elected official of the applicable county and municipal government, if any. The Departments decision shall be subject to the provisions of the Open Records Act.

12. Appeals of the decision of the Department shall be in accordance with the Rules promulgated by the Certificate of Need Appeal Panel.

(g) **Standards**

1. An Alternative Healthcare Model must be consistent with the State Health Policies adopted by the Board.

2. An Alternative Healthcare Model must clearly define its target population/community.

3. An Alternative Healthcare Model must:

(i) include a hypothesis(es) to be tested within a time-limited period not to exceed five (5) years;

(ii) demonstrate, as applicable, how it will support research, new service development, health professional education and training, and/or affiliation with an academic center of higher learning; and

(iii) demonstrate that the community supports the Alternative Healthcare Model.

4. An applicant for an Alternative Healthcare Model CON shall demonstrate the feasibility of operating the Alternative Healthcare Model in Georgia, based on a review of the experience in other states including the impact on health professionals of other healthcare programs or facilities and how the project is impacted by payers and regulatory entities.

5. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to reduce healthcare costs to consumers, third party payors and the system as a whole.

6. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to maintain or improve the standards of healthcare quality in some measurable fashion.

7. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to provide increased choices or access for consumers to a continuum of services within the target community.

8. An applicant for an Alternative Healthcare Model CON shall demonstrate the potential of the Alternative Healthcare Model to meet existing or emerging health status and/or health system needs.

9. For any applicant that meets the requirements of this Rule the Department may waive all or part of otherwise applicable service-specific Ga. Comp. R. & Regs. r. 111-2-2-.20 et seq.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.08

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq.***

HISTORY: Original Rule entitled "Alternative Application and Review Procedures" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.08, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.09 General Review Considerations

(1) **General Considerations**. The burden of proof for producing information and evidence that an application is consistent with the applicable considerations and review policies, which follow, shall be on the applicant. In conducting review and making findings for Certificates of Need, the Department will consider whether:

(a) the proposed new institutional health services is reasonably consistent with the relevant general goals and objectives of the State Health Plan. The goals and objectives related to issues and addressed in the State Health Plan, which are relevant to the Certificate of Need proposal, will be considered in the review. It should be recognized that the goals of the State Health Plan express the ideal and, in some respects, may be incompatible with the concept of cost containment. The statutes and Rules represent the final authority for review decisions and the content of the Plan, or any component thereof shall not supersede the Rules in such determination;

(b) the population residing in the area served, or to be served, by the new institutional health service has a need for such services;

1. Population projections used by the Department will be resident population figures prepared or approved by the Office of Planning and Budget or other official figures that may be applicable as determined by the Department.

2. Updated resident population projections will be utilized upon the official effective date as stated by the Department, pursuant to these Rules, replacing and superseding the older data.

3. The projection period or horizon year for need determinations will be five years for hospital services and three years for all other services, unless otherwise provided by the Rules for the specified service. The projection period or horizon year will be advanced to the next projection year or horizon year on or about April 1 of each year.

4. Inpatient facilities will be inventoried on the basis of bed capacity approved, grandfathered, or authorized through the Certificate of Need process regardless of the number of beds in operation at any given time or which may be licensed by the Healthcare Facility Regulation Division.

5. Data sources to be utilized by the Department to evaluate need, population characteristics, referral patterns, seasonal variations, utilization patterns, financial feasibility, and future trends will include, but not be limited to, the following:

(i) any surveys required by the Department, including but not limited to those for hospitals, nursing facilities, home health agencies, specialized services, and ambulatory surgery facilities;

(ii) Cost reports submitted to fiscal intermediaries and the Department;

(iii) periodic special studies or surveys, as produced or formally adopted or used by the Department;

(iv) the United States Census and other studies conducted by the Census and other Federal and State agencies and bureaus, including but not limited to, the Department of Labor; and

(v) such other data sources utilized by the Department for measurement of community health status. Such data may include information submitted by the applicant pursuant to Ga. Comp. R. & Regs. 111-2-2-.06(2)(f), which may be necessary for the Department to ensure that the project is consistent with applicable general consideration provisions.

6. All data used by the Department in a Certificate of Need review will be available to the applicant on request, in accordance with Department policies on requested information. The most recent data reported and validated will be used in the analysis of a proposal.

(c) existing alternatives for providing services in the service area the same as the new institutional health service proposed are neither currently available, implemented, similarly utilized, nor capable of providing a less costly alternative, or no Certificate of Need to provide such alternative services has been issued by the Department and is currently valid

1. The Department supports the concept of regionalization of those services for which a service-specific Rule exists.

2. The Department shall consider economies of scale where need exists for additional services or facilities.

3. Utilization of existing facilities and services similar to a proposal to initiate services shall be evaluated to assure that unnecessary duplication of services is avoided. Where there exists significant unused capacity, initiating a similar service in another health care facility would require strong justification under other criteria.

(d) the project can be financed adequately and is in the immediate and long term, financially feasible;

(e) the effects of the new institutional health service on payors for health services, including governmental payors, are reasonable;

(f) the costs and methods of a proposed construction project, including the costs and methods of energy provision and conservation, are reasonable and adequate for quality health care. Construction plans will be reviewed in detail to assure that space is designed economically. Space shelled-in for some future use will not be accepted unless the applicant demonstrates that the shelled-in space will not be directly related to the provision of any clinical health service;

(g) the new institutional health service proposed is reasonably financially and physically accessible to the residents of the proposed service area and will not discriminate by virtue of race, age, sex, handicap, color, creed or ethnic affiliation;

1. In accordance with the provision found in O.C.G.A. § 31-6-42(7), the Department will evaluate the extent to which each applicant applying for a Certificate of Need participates in a reasonable share of the total community burden of care for those unable to pay. This provision shall not apply to applicants for life plan communities, skilled nursing facilities or units, and to projects that are reviewed by the Department on an emergency basis in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.07(1)(k). In all other instances, the following indicators will be evaluated:

(i) administrative policies and directives related to acceptance of indigent, medically indigent, and Medicaid patients;

(ii) policies relating medical staff privileges, if applicable, to reasonable acceptance of emergency referrals of Medicaid and PeachCare patients and all other patients who are unable to pay all or a portion of the cost of care;

(iii) evidence of specific informational efforts targeted toward patients regarding arrangements for satisfying charges;

(iv) documented records of refunds, if any, received from the Federal, State, county, city, philanthropic agencies, donations, and any other source of funds other than from direct operations, such as indigent care trust fund distributions and disproportionate share payments, if applicable;

(v) the applicants commitment to participate in the Medicare/Medicaid and PeachCare programs; to provide legitimate emergency care, if applicable, regardless of ability to pay; and to provide indigent and charity care; and

(vi) documented records of care provided to patients unable to pay, Medicare and Medicaid contractual adjustment, Hill-Burton payments (if applicable), other indigent care, and other itemized deductions from revenue including bad debt. Such records shall demonstrate that the levels of care provided correspond to a reasonable proportion of those persons who are medically or financially indigent and those who are eligible for Medicare or Medicaid within the service area.

2. The evaluation in 1. above is in addition to satisfaction of a minimum indigent and charity care commitment required by prior CON(s), if any.

(h) the proposed new institutional health service has a positive relationship to the existing health care delivery system in the service area;

(i) the proposed new institutional health service encourages more efficient utilization of the health care facility proposing such service;

(j) the proposed new institutional health service provides, or would provide a substantial portion of its services to individuals not residing in its defined service area or the adjacent service area;

(k) the proposed new institutional health service conducts biomedical or behavioral research projects or new service development that is designed to meet a national, regional, or statewide need;

(l) the proposed new institutional health service meets the clinical needs of health professional training programs;

(m) the proposed new institutional health service fosters improvements or innovations in the financing or delivery of health services; promotes health care quality assurance that can be documented with outcomes greater than those which are generally in keeping with accepted clinical guidelines, peer review programs and comparable state rates for similar populations; promotes cost effectiveness; or fosters improvements or innovations in the financing or delivery of health services; or fosters competition that is shown to result in lower patient costs without a significant deterioration in the quality of care;

(n) the proposed new institutional health service fosters the special needs and circumstances of Health Maintenance Organizations;

(o) the proposed new institutional health service meets the Departments minimum quality standards, including, but not limited to, standards relating to accreditation, minimum volumes, quality improvements, assurance practices, and utilization review procedures;

(p) the proposed new institutional health service can obtain the necessary resources, including health care management personnel; and

(q) the proposed new institutional health service is an underrepresented health service, as determined annually by the Department. The Department shall, by rule, provide for an advantage to equally qualified applicants that agree to provide an underrepresented service in addition to the services for which the application was originally submitted.

(2) **Destination Cancer Hospitals**. In the case of Certificate of Need applications for the construction, development, or establishment of a destination cancer hospital, the applicable general considerations as to the need for such service shall not include paragraphs (a), (b), (c), (g), (h), (j), (k), and (n) of Section (1) of Ga. Comp. R. & Regs. r. 111-2-2-.09, but shall include:

(a) Paragraphs (d), (e), (f), (i), (l), (m), (o), (p), and (q) of Section (1) of Ga. Comp. R. & Regs. r. 111-2-2-.09;

(b) That the proposed new destination cancer hospital can demonstrate, based on historical data from the applicant or its affiliated entities, that its annual patient base shall be composed of a minimum of sixty-five percent (65%) of patients who reside outside of the State of Georgia;

(c) The proposed new destination cancer hospital states its intent to provide uncompensated indigent and charity care which shall meet or exceed three percent (3%) of its adjusted gross revenues and provide care to Medicaid beneficiaries;

(d) That the proposed new destination cancer hospital shall conduct biomedical or behavioral research projects or service development which is designed to meet a national or regional need;

(e) That the proposed new destination cancer hospital shall be reasonable financially and physically accessible;

(f) That the proposed new destination cancer hospital shall have a positive relationship to the existing health care delivery system on a regional basis;

1. That the proposed new destination cancer hospital shall enter into a hospital transfer agreement with one or more hospitals within a reasonable distance from the destination cancer hospital or the medical staff at the destination cancer hospital has admitting privileges or other acceptable documented arrangements with such hospital or hospitals to ensure necessary backup for the destination cancer hospital for medical complications. The destination cancer hospital shall have the capability to transfer a patient immediately to a hospital within a reasonable distance from the destination cancer hospital with adequate emergency room services. Hospitals shall not unreasonable deny a transfer agreement with the destination cancer hospital. In the event that a destination cancer hospital and another hospital cannot agree to the terms of a transfer agreement as required by this paragraph, the Department shall mediate between such parties for a period of no more than forty-five (45) days. If an agreement is still not reached within such forty-five (45) day period, the parties shall enter into binding arbitration conducted by the Department.

(g) That an applicant for a new destination cancer hospital shall document in its application that the new facility is not predicted to be detrimental to existing hospitals within the planning area. Such demonstration shall be made by providing an analysis in such application that compares current and projected changes in market share and payor mix for such applicant and such existing hospitals within the planning area. Impact on an existing hospital shall be determined to be adverse if, based on the utilization projected by the applicant, such existing hospital would have a total decrease of ten percent (10%) or more in its average annual utilization, as measured by patient days for the two most recent and available preceding calendar years of data; and

(h) That the destination cancer hospital shall express its intent to participate in medical staffing work force development activities.

(3) **General Cancer Hospital**

(a) On and after July 1, 2019, a destination cancer hospital may apply for a letter of determination in accordance with O.C.G.A. § 31-6-40(a)(8).

(b) Upon its receipt of a complete application for a destination cancer hospital to convert to a general cancer hospital, the Department shall issue such determination within 60 days.

(c) Upon the conversion of a destination cancer hospital to a general cancer hospital:

1. The general cancer hospital may continue to provide all institutional health care services and other services it provided as of the date of such conversion, including but not limited to inpatient beds, outpatient services, surgery, radiation therapy, imaging, and positron emission tomography (PET) scanning, without any further approval from the Department;

2. The destination cancer hospital shall be classified as a general cancer hospital under this chapter and shall be subject to all requirements and conditions applicable to hospitals under this article, including but not limited to, indigent and charity care and inventories and methodologies to determine need for additional providers or services; and

3. The hospitals inpatient beds, operating rooms, radiation therapy equipment, and imaging equipment existing on the date of conversion shall not be counted in the inventory by the Department for purposes of determining need for additional providers or services, except that any inpatient beds, operating rooms, radiation therapy equipment, and imaging equipment added after the date of conversion shall be counted in accordance with the Departments rules and regulations.

(d) In the event that a destination cancer hospital does not convert to a general cancer hospital, it shall remain subject to all requirements and conditions applicable to destination cancer hospitals under this article.

(4) In the case of applications for basic perinatal services in counties where:

(a) Only one civilian health care facility or health system is currently providing basic perinatal services; and

(b) There are not at least three (3) different health care facilities in a contiguous county providing basic perinatal services, the Department shall not apply the consideration contained in paragraph (b) of section (1) of this Rule.

(5) **Osteopathic Considerations**. When an application is made for a Certificate of Need to develop or offer a new institutional health service or health care facility for osteopathic medicine, the need for such facility shall be determined on the basis of the need and availability in the community for osteopathic services and facilities. Nothing in this Chapter shall, however, be construed as recognizing any distinction between allopathic and osteopathic medicine.

(6) **Minority-Administered Hospital Considerations**. If the denial of an application for a Certificate of Need for a new institutional health service proposed to be offered or developed by a minority-administered hospital serving a socially and economically disadvantaged minority population in an urban setting, or by a minority-administered hospital utilized for the training of minority medical practitioners, would adversely impact upon the facility and population served by said facility, the special needs of such hospital facility and the population to be served by said facility for the new institutional health service shall be given extraordinary consideration by the Department in making its determination of need. The term "minority-administered" means a hospital controlled or operated by a governing body or administrative staff composed predominantly of members of a minority race. The Department shall have the authority to vary or modify strict adherence to the provisions of Code Chapter 31-6-42(c) and this Chapter in considering the special needs of said facility and its population served and to avoid an adverse impact on the facility and the population served thereby.

(7) **Considerations for Joined Applications**.

(a) In evaluating joined applications, if the services proposed are found to be needed, and if any or all applications equally meet the statutory considerations, priority consideration will be given to a comparison of the applications with regard to:

1. the past and present records of the facility, and other existing facilities in Georgia, if any, owned by the same parent organization, regarding the provision of service to all segments of the population, particularly including Medicare, Medicaid, minority patients and those patients with limited or no ability to pay;

2. specific services to be offered;

3. appropriateness of the site, i.e., the accessibility to the population to be served, availability of utilities, transportation systems, adequacy of size, cost of acquisition, and cost to develop;

4. demonstrated readiness to implement the project, including commitment of financing;

5. patterns of past performance, if any, of the applicants in implementing previously approved projects in timely fashion;

6. past record, if any, of the applicant facility, and other existing facilities owned by the same parent organization, if any, in meeting licensure requirements and factors relevant to providing accessible, quality health care;

7. evidence of attention to factors of cost containment, which do not diminish the quality of care or safety of the patient, but which demonstrate sincere efforts to avoid significant costs unrelated to patient care;

8. past compliance, if any, with survey and post-approval reporting requirements and indigent and charity care commitments;

9. hospital and physician collaborations that promote greater cost efficiency to patients, ensure greater quality assurance outcomes and foster positive relationships within the existing healthcare delivery network which benefits both providers and members within the impacted service area population; and

10. proposed services that include or involve a clinical healthcare service that is or has been underrepresented in the proposed service area for more than twelve (12) months as evidenced by geographical barriers to the service, insufficient staffing to provide the service and/or recent termination of the service in the proposed planning area.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.09

AUTHORITY: O.C.G.A. §§ 31-2 **et seq., 31-6 et seq.**

HISTORY: Original Rule entitled "General Review Considerations" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

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Note: Rule 111-2-2-.09, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.10 Determinations

(1) **General Provisions Relating to Determinations**

(a) Determinations are conclusions of the Department that are based on specific facts and are limited to the specific issues addressed in the request for determination, as applicable. Therefore, the conclusions of a specific

determination shall have no binding precedent in relation to parties not subject to the request and to other facts or factual situations that are not presented in the request.

(b) This Rule shall not be construed as providing an administrative remedy for decisions made by the Department pursuant to O.C.G.A. § 31-6-43, which involve the approval or denial of applications for certificates of need.

(c) A person requesting a determination shall make such a request in writing and shall specify in detail all relevant facts, which relate to the proposed action or course of conduct. The request shall be directed to the General Counsel or his designee. The General Counsel or his designee shall respond to the request in writing. The request shall include, at a minimum, the following components:

1. a statement citing by appropriate reference the statutory provision or other authority under which the request is to be granted by the Department.

2. the exact legal name of each person whose rights are affected and who is requesting a determination and the address or principal place of business of each such person. A request may be submitted by an attorney or other party on behalf of such person, but the request must include the information required by this subsection relating to the person whose rights are affected;

3. The name, title, address, telephone number, facsimile telephone number and electronic mail address of the attorney or other person, if any, to whom correspondence or communications in regard to the request shall be addressed; and

4. An explanation of any unusual circumstances involved in the request which the Department will be expected to direct its particular attention, including the existence of emergency conditions.

(d) Requests for determination shall address only one matter per request.

(e) Requests for determination shall be submitted pursuant to and in compliance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6). Such requests shall also include one signed original of the written vendor lobbyist certification required by Ga. Comp. R. & Regs. r. 111-1-2-.03(2).

(f) Requests for determination shall include payment of a request fee. Payment of the fee shall be by credit/debit card via the Departments website, certified check, or money order made payable to the State of Georgia Department of Community Health and must be received by the Department before a determination request will be reviewed. Failure to provide payment of the appropriate fee will result in non-acceptance of the request.

1. The request fee for determination shall be $250.00;

2. State-owned institutions shall be exempt from payment of these fees; and

3. The Department may waive payment of these fees for certain hospital authority facilities and for certain public non-profit providers when the Department determines that financial circumstances exist, which would justify such action. Such requests for waiver must be received at the time of the initial request.

(2) **Letters of Determination**. Pursuant to O.C.G.A. § 31-6-47, if a person believes or has reason to believe that the application of a Department Rule or statutory provision may directly affect or impair the legal rights of that person as to some proposed action or course of conduct being considered by that person, including, but not limited to, determinations regarding reviewability, grandfathering decisions, and relocation or replacement determinations, such person may request a written determination from the Department regarding the application of such Department Rule or statutory provision upon that persons proposed action or course of conduct. A determination request is distinguished from a general question as a determination does not address general issues relating to policy and procedure.

Any person proposing an activity that would make it a health care facility unless exempted from prior CON review and approval pursuant to O.C.G.A. § 31-6-47, or any other part of the CON statute at O.C.G.A. § 31-6 et seq. shall

be required to, pursuant to O.C.G.A. § 31-6-47.1, submit a request for a letter of determination from the Department. The Departments written response which confirms that the proposed activity is exempt from review shall act as the official confirmation of exemption provided in this Code section. A party is not authorized to commence or undertake the activity in question which it believes to fall within any one or more of the statutory exemptions in O.C.G.A. § 31-6-47 until written approval is issued by the Department in response to a request for a letter of determination as provided in this Rule.

In reviewing a determination request pursuant to this Rule to relocate all or a portion of an existing skilled nursing facility, intermediate care facility, or intermingled nursing facility, pursuant to O.C.G.A. § 31-6-47(a)(24) and Ga. Comp. R. & Regs. r. 111-2-2-.03(27), the Department may allow such facility to divide into two or more such facilities if the Department determines that the proposed division is financially feasible and would be consistent with quality patient care. Under no circumstances will the Department allow, via a favorable determination, a facility as listed above to relocate as one facility, or divide into more than one facility, with more than the total number of beds authorized in the facilitys location prior to any relocation and/or division.

(a) No person shall be entitled to request a determination that relates to an actual or proposed action or course of conduct which has been taken or which would be taken by a third party; and

(b) In addition to the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.10(1), a determination request shall include a concise and explicit iteration of the facts on which the Department is expected to rely in granting the determination.

(c) The Department shall establish timeframes, forms, and criteria to request a letter of determination that an activity is properly exempt or excluded under this chapter prior to its implementation.

1. If no objection to a request for determination is filed within 30 days of the Departments receipt of such request for Determination, the Department shall have 60 days from the date of the Departments receipt of such request to review the request and issue a letter of determination.

2. Where conditions exist which make it impractical to complete a review in 60 days, the Department may, on notification to the requester, extend the time limit another 30 days to 90 days.

(d) The Department shall publish notice of all requests for letters of determination regarding exempt activity and opposition to such request.

(e) In addition to the requirements of Ga. Comp. R. & Regs. r. 111-2-2-.10(1) and pursuant to the meaning of threshold as defined at Ga. Comp. R. & Regs. r. 111-2-2-.01(59), the Department applies the following Rules as they concern requests for determinations that the value of certain diagnostic, therapeutic, or other imaging equipment does not exceed the Departments equipment threshold, pursuant to O.C.G.A. § 31-6-47(a)(28) and therefore that such equipment is not subject to prior CON review and approval.

1. The party who requests the letter of determination must submit a manufacturers or vendors price quotation or purchase order for the diagnostic, therapeutic, or other imaging equipment. This requirement applies even if the equipment is to be leased.

2. The party who requests the letter of determination must submit a sworn affidavit affirmed by a person capable of making a binding commitment on behalf of the manufacturer or vendor of the diagnostic, therapeutic, or other imaging equipment for which a determination containing the following affirmations:

(i) that the affiant is capable of making a binding commitment on behalf of the manufacturer or vendor; and

(ii) that the price shown on the price quotation or purchase order is the total expense the requesting party is incurring for the equipment shown and the total dollar amount that the manufacturer or vendor is receiving for the exact unit shown on the quotation or purchase order; or

(iii) In the case of a lease or other means of acquisition, that the price shown is the total dollar amount that would have been expended had the equipment been purchased.

(3) **Requests for Letters of Determination for Below Threshold Diagnostic, Therapeutic, or Other Imaging Equipment**. A party requesting a letter of determination for the acquisition of diagnostic, therapeutic, or other imaging equipment with a value below the equipment threshold must submit with the request a sworn affidavit from a person capable of making a binding commitment on behalf of the party containing the following affirmations:

(a) that the affiant is:

1. a hospital; or

2. an individual private physician or single group practice of physicians and is

(i) acquiring the equipment exclusively for use on patients of such private physician or single group practice of physicians; and

(ii) such private physician or member of such single group practice of physicians is physically present at the practice location where the diagnostic or other imaging equipment is located at least seventy-five percent (75%) of the time that the equipment is in use.

3. that the affiant is capable of making a binding commitment on behalf of the party;

4. that no acquisition of additional items not listed on a Line Item Valuation Sheets or the Aggregate Valuation Sheet, to be added to or used with the operational configuration of the particular diagnostic, therapeutic, or other imaging equipment at issue to include functionally related equipment, will be made or will take place for a period of six (6) months from the date of installation of the equipment that would put the total expenditure incurred on the diagnostic, therapeutic, other imaging equipment or its operational configuration over the Departments equipment threshold;

5. that no acquisition of additional equipment reasonably related to or associated with the general type of service provided by the equipment to be acquired not listed on a Line Item Valuation Sheet or the Aggregate Valuation Sheet will occur within a period of six (6) months, that is that such expenditure for associated, but not functionally related equipment, regardless of modality, shall occur simultaneously;

6. that no construction not listed on a Line Item Valuation Sheet or the Aggregate Valuation Sheet that can reasonably be determined to be associated with the equipment to be acquired will occur within a period of six (6) months;

7. that the Line Item Valuation Sheets and the Aggregate Valuation Sheet included in the request are accurate, reflect all of the expenses required by Ga. Comp. R. & Regs. r. 111-2-2-.10(2)(e), and reflects the true cost of acquiring the exact same equipment and any and all associated and simultaneous items and activities; and

8. that the price shown on the price quotation(s) or purchase order(s) reflects the exact amount of the total expense that will be incurred and paid to the manufacturer or vendor for the exact same equipment listed on the price quotation or purchase order; or

9. in the case of a lease or other acquisition, that the price shown on the purchase order(s) or quote(s) is the total dollar amount that would have been expended had the equipment been purchased.

(b) The request for a letter of determination must include an Equipment Line Item Valuation Sheet, generated by the party requesting a letter, listing all dollar amounts attributable to each category listed below of items the Department will evaluate for purposes of determining if the value of the diagnostic, therapeutic, or other imaging equipment is below the equipment threshold dollar amount. If an item is not applicable, the requesting party should include the item on the Line Item Valuation Sheet and indicate the dollar amount as $0. For each simultaneous and associated

unit of equipment, as outlined at Ga. Comp. R. & Regs. r. 111-2-2-.10(3)(e) below, a separate line item valuation sheet must be submitted.

1. The dollar amount of the base price of the unit before adding any of the following items;

2. Any expense incurred for the purchase of a warranty on the diagnostic, therapeutic, or other imaging equipment from the manufacturer or vendor for the first five (5) years of operation;

3. Any expense incurred for operator training;

4. Any expense incurred for installation and assembly of the equipment;

5. Any expense incurred for transportation and insurance costs pertaining to the purchase and/or delivery of the equipment;

6. Any expense incurred for functionally related diagnostic, therapeutic or other imaging equipment, such as, but not limited to, water chillers, surge protectors, laser cameras, computer workstations, etc.;

7. Any expense incurred for any options, extra packages, or accessories to be used in the operation of the equipment;

8. Any expense incurred for RF shielding, lead shielding, magnetic shielding necessary to protect patients or staff in the operation of the equipment;

9. Any dollar amount attributable to service contracts for the first five (5) years of operation;

10. Any dollar amount attributable to volume or bulk purchase discounts given to the party requesting a letter of determination by the manufacturer or vendor of the equipment;

11. For mobile equipment, any expense incurred for a mobile coach, trailer, or van in which the equipment will be operated; and

12. The final line of the Line Item Valuation Sheet should reflect the total of the preceding eleven (11) items.

(c) The value of diagnostic, therapeutic, or other imaging equipment for which a letter of determination is requested shall not include build out costs. Build out costs are defined as expenditures made for items such as electrical, plumbing, masonry such as concrete pads, construction of modular buildings, and renovation of the space that will actually house the equipment, such as the room where an MRI unit would be used. Build out costs shall also include expenditures for new construction for a building to house the equipment or to renovate a building or structure to house the equipment, or expenditures for administrative office space unrelated to the actual functionality of the equipment, related equipment, or software necessary to operate the equipment.

(d) A party acquiring functionally related equipment or items, including those items and expenses listed in Ga. Comp. R. & Regs. r. 111-2-2-.10(3)(b) within a six (6) month period, which when added to the values of the items submitted for approval would exceed the threshold applicable at the time of approval, will be considered to be offering a new institutional health service without Certificate of Need authorization;

(e) All simultaneously acquired and associated diagnostic, therapeutic, and other imaging equipment regardless of modality shall be aggregated. See the definition of "associated with and simultaneously developed or proposed." If additional diagnostic, therapeutic, and other imaging equipment is to be acquired, the party must submit price quotations for each piece of simultaneously acquired diagnostic, therapeutic, and other imaging equipment;

(f) A letter of determination for the acquisition of diagnostic, therapeutic, or other imaging equipment shall be valid only for the defined equipment, physical location, cost, and entity or person named in the request as the acquirer and operator of the equipment and only to the pertinent facts that were disclosed in the request, except that cost may exceed the amount approved by the Department as long as the actual final expenditures do not exceed the equipment

threshold. Such letters are non-transferable and may not be acquired. If the facts pertinent to the letter of determination change in any way, the letter is no longer valid;

(g) Upon completion of the acquisition of the equipment, the party requesting a determination shall submit a final statement of the total costs of the equipment. In addition, if the if the equipment and associated activities are not completed within one hundred and eighty (180) days of the issuance of the determination, the party requesting a determination shall submit an interim statement within two weeks of the end of that one hundred and eighty (180) day period and within two weeks of the end of each succeeding ninety (90) day period until the final statement is submitted upon completion of the facility. Each of the interim statements shall disclose the expenses incurred to date, and any good faith estimates of the percentage of completion and the amount of costs expected to be incurred to complete. The accuracy and completeness of the interim and final statements shall be verified by sworn affidavits from an authorized owner or officer of the party requesting a determination. Failure to comply with the provisions of this subsection may result in the rescission of the determination issued.

(4) **Requests for Letters of Determination for Exempt Single Specialty or Joint Venture Ambulatory Surgical Centers**.

(a) When the Department receives a request for a letter of determination for the establishment of a physician-owned, single specialty, office-based ambulatory surgery facility, or a joint venture ambulatory surgical center, pursuant to O.C.G.A. § 31-6-2(33), (23), and O.C.G.A. § 31-6-47(a)(18), (19), the party requesting such a letter must comply with the following:

1. Identify the name and address of the proposed ambulatory surgery facility, including the principal business address of the sole physician or group practice that will own the facility.

2. Identify the individual private physician, or all owners (e.g. stockholders, partners, members) of the single group practice of private physicians who are also on the same single specialty, that will own, operate, and utilize the proposed facility. All members of the single group practice must be of the same specified surgical specialty. Physicians who perform procedures within the single specialty ambulatory surgical center must own at least eighty-five percent (85%) of the group practice and the surgery center. The Department will issue a determination, if all other criteria are met, to a single group practice which utilized the services of employee physicians of the same specialty in the surgery center if these employee physicians are not a member or employee of any other medical practice. All employee physicians must be identified, and an affirmative statement with regard to their practice affiliation must be included. The Department will allow no more than fifteen percent (15%) non-physician ownership in the physician(s) practice requesting a determination, and/or the surgery center in a single specialty ambulatory surgical center. Evidence of non-physician ownership, including the percentage of such ownership, must be provided with the determination request. For a joint venture ambulatory surgical center, the ownership interest of the hospital shall be no less than thirty percent (30%) and the collective ownership of the physicians or group of physicians shall be no less than thirty percent (30%). Any evidence of non-hospital or non-physician or group of physicians ownership in a joint venture ambulatory surgical center must be provided with the determination request.

3. All physicians must be licensed to practice in the state of Georgia, and must submit a copy of such license; should any physician members of a single group practice perform procedures in the ambulatory surgery facility created by the issuance of a determination lose their license to practice medicine in Georgia, the determination shall be revoked, unless within sixty (60) days of such physician losing their license, the group practice submits new evidence documenting that the physician ownership of the facility by the group practice does not include the physician who lost their license.

4. Submit evidence of the sole physician professional corporation or the entity comprising the single group practice of private physicians, to include authorizing and governing documents such as articles of incorporation, by-laws, operating agreements, partnership agreements, etc. Submit a sworn affidavit, signed by the owners, which lists all owners of the sole or group practice and the proposed surgery facility.

5. The physician(s) must show evidence of ownership by warranty deed or lease of the space housing the ambulatory surgery facility including the clinical office space.

6. Provide a detailed description of the proximity of the physicians or the group practices clinical offices to the ambulatory surgery facility. The Department will only grant a determination to those proposed ambulatory surgical facilities, which are deemed to be in reasonable proximity to the clinical offices of the sole physician or single group practice that will own the proposed facility. Reasonable proximity will be determined on a case-by-case basis. Example of reasonable proximity include those ambulatory surgical facilities on the same floor and physically attached to the clinical offices; surgical suites on a different floor of the same building as the clinical offices with one public entrance to the proposed facility.

7. State the number of operating rooms in the proposed ambulatory surgery facility.

8. State the total square footage in the proposed ambulatory surgery facility. This total includes the square footage associated with all operating suites, reception and waiting areas, business offices, pre and post-operation areas, all building common areas including a pro rata share of the common areas of buildings utilized by multiple tenants, which are new and/or renovated and involve expenditures to be incurred in the development, construction and establishment of the proposed surgery facility.

9. List costs attributable to new construction or renovation of the total area comprising the ambulatory surgery facility. Documentation of the total costs of constructing, developing, and establishing the proposed ambulatory surgical facility, and the costs of all items associated with or simultaneously developed with the project, including, but not limited to, fixed equipment not included in the construction contract, moveable equipment, architectural and engineering fees, legal and administrative fees, interim financing (interest during construction), and underwriting costs. The documentation of construction and renovation costs must be in the form of a letter from a licensed Georgia architect verifying the estimated construction costs of the proposed ambulatory surgery facility. With regard to the construction of a new building (or a new wing including space devoted to services other than the surgery center) to house an ambulatory surgery facility, a pro-rata portion of the building shell costs, including all building common areas, must be allocated to the costs of the proposed ambulatory surgery facility. Other costs to be included are:

(i) The cost of new space (even if the space will be leased) based on the construction cost of the new space. Appropriate documentation from an architect licensed in Georgia must be submitted. A copy of all leases must be submitted;

(ii) The cost of all equipment (medical and non-medical) purchases for the ambulatory surgery facility.

(iii) The present value of any equipment to be leased for the surgery facility.

(iv) The Department must have a line item breakdown of all amounts attributable to new construction, renovation, furnishings, leases, and items of equipment in accordance with the provisions outlined above, including new expenditures for furnishings for non-patient care areas such as waiting areas, reception areas, and business offices.

The Department will require a sworn affidavit that no party associated with the practice or physicians requesting a determination, by virtue of ownership or employment, has incurred any expenditure for equipment of any kind to be utilized in the surgery center that has been subsequently donated to the practice for use in the surgery center and the cost of that equipment, whether purchased or leased, was not included in the dollar threshold applicable to the surgery center.

10. A schematic floor plan must be provided to the Department. This documentation must be clear and readable. The floor plan must clearly show all areas of the proposed ambulatory surgery facility.

11. Pursuant to O.C.G.A. § 31-6-2(14), list the cost of all other items, regardless whether they are independently subject to Certificate of Need review, that are associated and to be simultaneously developed with the proposed ambulatory surgery facility, except for the expenditure or commitment of funds to develop studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites.

12. The Department will not issue a determination to any sole physician or single specialty group practice of physicians proposing to bill a professional fee through a larger multi-specialty group practice in which the single

specialty group practice requesting the determination remains a part of. For purposes of these Rules, this provision does not preclude the issuance of a determination to a physician(s), which utilizes a larger group practice for the sole purpose of billing services under the provider number of the sole physician or single group practice.

13. The Department will not issue a determination to any physician(s) who is a member of more than one single group practice, pursuant to O.C.G.A. § 43-1B-3(5) of the Georgia Patient Self-Referral Law.

14. The Department will not issue a determination to any group practice of physicians if any members of that group practice are also members of a multi-specialty clinical practice. For purposes of these Rules a multi-specialty clinical group practice does not mean any volume purchasing association or managed care network whose function is managed care contracting in which the physician or group practice participates.

15. The Department will not issue a determination to any party proposing to share operating rooms or common space in a proposed ambulatory surgical facility between more than one group practice of the same specialty or between more than one surgical group practice of different specialties, or between more than one sole physician of the same or different specialties who are not members of the same medical practice.

16. Provide a sworn affidavit, signed by the physician(s) owners, that the party requesting a determination will not incur any additional capital expenditures involving new construction or renovation of physical space or the addition or replacement of equipment within three (3) years after the issuance of the determination, which, when coupled with prior expenditures, would exceed the threshold amount applicable to the statutory exemption for this type of facility unless it first secures a Certificate of Need. A party holding a determination issued by the Department may request, in writing, a waiver from this provision for expenditures for equipment involving newly recognized and innovative medical technologies (FDA approved) present in the marketplace. Any such expenditure will be applied to the original threshold amount unless the written consent of the Department is obtained prior to the expenditure.

17. Upon completion of construction of the ambulatory surgery facility, the party requesting a determination shall submit a final statement of the total costs of the facility, including a separate line item completed project cost sheet with the same detail and documentation as required in subsection (4)(a)11. above. In addition, if the proposed ambulatory surgery facility is not completed within one hundred and eighty (180) days of the issuance of a determination, the party requesting a determination shall submit an interim statement within two weeks of the end of that one hundred and eighty (180) day period and within two weeks of the end of each succeeding ninety (90) day period until the final statement is submitted upon completion of the facility. Each of the interim statements shall disclose the cost of the facility incurred to date, and any good faith estimates of the percentage of completion of the facility and the amount of costs expected to be incurred to complete the facility. The accuracy and completeness of the interim and final statements shall be verified by sworn affidavits from an authorized owner or officer of the party requesting a determination and from the general contractor. Failure to comply with the provisions of this subsection may result in the rescission of the determination issued.

18. The determination is not transferable to a purchaser of the sole physician or single group practice, which originally received a determination. This provision is not intended to limit the transferability of a sole physician practice or a group practice but is intended to put the new physician owners on notice that they must request a new determination as new owners of that practice. Such a new request will be evaluated based on the determination criteria applicable at the time of the new request, and the acquisition costs of the practice will not be a part of the applicable capital expenditure threshold.

(b) A single specialty ambulatory surgical center that requests a letter of determination shall provide documentation, in addition to the requirements outlined in section (1) of this Rule above, to show that it:

1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health service which do not exceed $2,500,000.00; or

2. Is the only single specialty ambulatory surgical center in the county owned by the group practice and has two or fewer operating rooms; provided, however, that a center exempt pursuant to this provision shall be required to obtain a Certificate of Need in order to add any additional operating rooms;

3. Has a hospital affiliation agreement with a hospital within a reasonable distance from the facility or the medical staff at the center has admitting privileges or other acceptable documented arrangements with such hospital to ensure the necessary backup for the center for medical complications. The center shall have the capability to transfer a patient immediately to a hospital within a reasonable distance from the facility with adequate emergency room services. A party requesting a letter of determination must provide documentation to support an assertion that a hospital, pursuant to this requirement, has unreasonable denied a transfer agreement or affiliation agreement to the center;

4. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

5. If the center is not a participant in Medicaid or the PeachCare for KidsT Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue; provided, however, single specialty ambulatory surgical centers owned by physicians in the practice of ophthalmology shall not be required to comply with this subparagraph; and

6. Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and Ga. Comp. R. & Regs. r. 111-2-2-.04.

Noncompliance with any condition of subsections 4. and 5. of Section (4)(b) of this Rule shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70, and subsection 6. of section (4)(b) of this Rule, after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index.

(c) Any joint venture ambulatory surgical center that requests a letter of determination shall provide documentation, in addition to the requirements outlined in section (1) of this Rule above, to show that it:

1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health service which do not exceed $5,000,000.00;

2. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

3. If the center is not a participant in Medicaid or the PeachCare for Kids® Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue; and

4. Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and Ga. Comp. R. & Regs. r. 111-2-2-.04.

Noncompliance with any condition of subsections 2. and 3. of section (4)(c) of this Rule shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70, and subsection 4. of section (4)(c) of this Rule, after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph

shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index.

(c) Any joint venture ambulatory surgical center that requests a letter of determination shall provide documentation, in addition to the requirements outlined in section (1) of this Rule above, to show that it:

1. Has capital expenditures associated with the construction, development, or other establishment of the clinical health service which do not exceed $5,000,000.00;

2. Provides care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries and provides uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

3. If the center is not a participant in Medicaid or the PeachCare for Kids® Program, provides uncompensated care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue; and

4. Provides annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and Ga. Comp. R. & Regs. r. 111-2-2-.04.

Noncompliance with any condition of subsections 2. and 3. of section (4)(c) of this Rule shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fines or moneys due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70, and subsection 4. of section (4)(c) of this Rule, after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the composite index of construction material prices, or its successor or appropriate replacement index, if any, published by the United States Department of Commerce for the preceding calendar year, commencing on July 1, 2009, and on each anniversary thereafter of publication of the index.

(5) **Requirements Applicable to Valid Holders of Ambulatory Surgery or Diagnostic or Therapeutic Equipment Exemptions Prior to July 1, 2008.**

(a) Any facility offering ambulatory surgery pursuant to the exclusion designated on June 30, 2008, as division (14)(G)(iii) of O.C.G.A. § 31-6-2; any diagnostic, treatment, or rehabilitation center offering diagnostic imaging or other imaging services in operation and exempt prior to July 1, 2008; or any facility operating pursuant to a letter of nonreviewability and offering diagnostic imaging services prior to July 1, 2008, shall:

1. Provide annual reports in the same manner and in accordance with O.C.G.A. § 31-6-70 and in accordance with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.04(1)(b)2.

(b) If, on or after July 1, 2008, any facility referenced in subsection (5)(a) above that, makes a capital expenditure associated with the construction, development, expansion, or other establishment of a clinical health service or the acquisition or replacement of diagnostic or therapeutic equipment with a value in excess of $800,000.00 over a two-year period; builds a new operating room; or chooses to relocate in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.03, it shall:

1. Provide care to Medicaid beneficiaries and, if the facility provides medical care and treatment to children, to PeachCare for Kids® beneficiaries and provide uncompensated indigent and charity care in an amount equal to or greater than two percent (2%) of its adjusted gross revenue; or

2. If the facility is not a participant in Medicaid or the PeachCare for Kids® Program, provide uncompensated care for Medicaid beneficiaries and, if the facility provides medical care and treatment to children, for PeachCare for Kids® beneficiaries, uncompensated indigent and charity care, or both in an amount equal to or greater than four percent (4%) of its adjusted gross revenue.

Noncompliance with any condition of subsection (b)1. and 2. above shall result in a monetary penalty in the amount of the difference between the services which the center is required to provide and the amount actually provided and may be subject to revocation of its exemption status by the Department for repeated failure to pay any fees or monies due to the Department or for repeated failure to produce data as required by O.C.G.A. § 31-6-70 after notice to the exemption holder and a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act. The dollar amount specified in this paragraph shall be adjusted annually by an amount calculated by multiplying such dollar amount (as adjusted for the preceding year) by the annual percentage of change in the consumer price index, or its successor or appropriate replacement index, if any, published by the United States Department of Labor for the preceding calendar year, commencing on July 1, 2009. In calculating the dollar amounts of a proposed project for the purposes of this paragraph, the costs of all items subject to review by this chapter and items not subject to review by this chapter associated with and simultaneously developed or proposed with the project shall be counted, except for the expenditure or commitment of or incurring an obligation for the expenditure of funds to develop Certificate of Need applications, studies, reports, schematics, preliminary plans and specifications or working drawings, or to acquire sites. Subsections (b)1. and 2. of section (5) of this Rule, shall not apply to facilities offering ophthalmic ambulatory surgery pursuant to the exclusion designated on June 30, 2008, as division (14)(G)(iii) of O.C.G.A. § 31-6-2 that are owned by physicians in the practice of ophthalmology.

(6) **Administrative Remedies for Adverse Determinations**.

When the Department makes a determination or decision pursuant to Ga. Comp. R. & Regs. r. 111-2-2-.10(1) through (5) of this Rule or any other determination or decision over which the Certificate of Need Appeal Panel lacks subject matter jurisdiction, the person who requests and receives the determination or decision may appeal to the Commissioner or his designee for an administrative hearing pursuant to the Administrative Procedures Act if such person is aggrieved by the Departments determination or decision. Such request for a hearing must be made in writing and must be received by the Department within thirty (30) days of the date of the Departments determination or decision. If such written request is not received by the Department within thirty (30) days, the Departments determination or decision shall become final upon the thirty-first (31st) day.

The Department shall publish notice of all requests for letters of determination regarding exempt activity and opposition to such request, whether pursuant to O.C.G.A. § 31-6-47 or any other provision of Code Section 31-6 and these Rules. Persons opposing a request for approval of an exempt activity, whether pursuant to an express statutory exemption or any other provision of the health planning statute or these Rules, shall be entitled to file a written objection with the Department and the Department shall consider any filed objection when determining whether an activity is exempt. A person who wishes to file a written objection to an exemption determination request, including requests for letters of determination for a single specialty ambulatory surgical center or a joint venture ambulatory surgical center, must do so no later than thirty (30) days after the date of Department receipt of the initial request for the exemption determination. Such written opposition should be submitted via the Departments web portal. The opposition shall be submitted in accordance with Ga. Comp. R. & Regs. r. 111-2-2-.06(6).

If no objection to a request for determination is filed within 30 days of the Departments receipt of such request for Determination, the Department shall have 60 days from the date of the Departments receipt of such request to review the request and issue a letter of determination. The Department may adopt rules for deciding when it is not practicable to provide a determination in 60 days and may extend the review period upon written notice to the requestor but only for an extended period of no longer than an additional 30 days.

After the issuance of an approval to a response to the request for an exemption determination, including requests for letters of determination for a single specialty ambulatory surgical center or a joint venture ambulatory surgical center, a person in opposition that has complied with the provisions outlined above, shall have the right to a fair hearing pursuant to Chapter 13 of Title 50, the Georgia Administrative Procedure Act, and judicial review of a final decision in the same manner and under the same provisions as in O.C.G.A. § 31-6-44.1 and Ga. Comp. R. & Regs. r. 274-1 et seq. A person who requested and received the exemption determination shall have automatic standing to

participate in any such administrative proceeding to defend the approved exemption determination. The Department may also participate to defend its decision. A person who opposes an exemption determination request that is denied, and who has complied with the written opposition submission requirements provided above, shall have standing to participate in any administrative proceeding requested by the person denied an approved exemption determination. If the written opposition is not submitted in accordance with the provisions outlined above, the Department shall not consider the opposition, and the rights to an administrative hearing, and/or any participation in any proceeding as outlined above, will not adhere to the opposing person.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.10

AUTHORITY: O.C.G.A. §§ 31-2 *et seq.*, 31-6 *et seq.*

HISTORY: Original Rule entitled "Determinations and Letters of Non-Reviewability" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Aug. 28, 2006; eff. Sept. 17, 2006.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Nov. 14, 2008; eff. Dec. 4, 2008.

Amended: New title, "Determinations." F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.10, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.11 Service-Specific Review Considerations Generally

(1) The Department has adopted the following service-specific requirements and review considerations:

(a) Acute Care and Acute Care-Related Rules:

1. Short-Stay General Hospital Services, Ga. Comp. R. & Regs. r. 111-2-2-.20;

2. Adult Cardiac Catheterization Services, Ga. Comp. R. & Regs. r. 111-2-2-.21;

3. Open Heart Surgical Services, Ga. Comp. R. & Regs. r. 111-2-2-.22;

4. Pediatric Cardiac Catheterization and Open Heart Services, Ga. Comp. R. & Regs. r. 111-2-2-.23;

5. Perinatal Services, Ga. Comp. R. & Regs. r. 111-2-2-.24;

6. Freestanding Birthing Center Services, Ga. Comp. R. & Regs. r. 111-2-2-.25; and

7. Psychiatric and Substance Abuse Inpatient Services, Ga. Comp. R. & Regs. r. 111-2-2-.26;

(b) Long-Term Care Rules:

1. Skilled Nursing and Intermediate Care Facility Services, Ga. Comp. R. & Regs. r. 111-2-2-.30;

2. Personal Care Home Services, Ga. Comp. R. & Regs. r. 111-2-2-.31;

3. Home Health Services, Ga. Comp. R. & Regs. r. 111-2-2-.32;

4. Life Plan Community ("LPC") Sheltered Nursing Facilities, Ga. Comp. R. & Regs. r. 111-2-2-.33;

5. Traumatic Brain Injury Services, Ga. Comp. R. & Regs. r. 111-2-2-.34; and

6. Comprehensive Inpatient Physical Rehabilitation Services, Ga. Comp. R. & Regs. r. 111-2-2-.35;

7. Long Term Care Hospitals, Ga. Comp. R. & Reg. R. 111-2-2-.36

(c) Special and Other Health Services:

1. Ambulatory Surgical Services, Ga. Comp. R. & Regs. r. 111-2-2-.40;

2. Positron Emission Tomography, Ga. Comp. R. & Regs. r. 111-2-2-.41; and

3. Radiation Therapy Services, Ga. Comp. R. & Regs. r. 111-2-2-.42.

(2) The review considerations and standards that are promulgated in service-specific rules are considerations and standards that apply to specific services in addition to the general considerations in Ga. Comp. R. & Regs. r. 111-2-2-.09. Any conflict between the meaning or application of a service-specific requirement and the general considerations shall be interpreted in favor of the service-specific consideration, unless a general consideration specifically indicates that it supersedes any and all service-specific considerations.

(3) The meaning of words as they are defined in a particular service-specific rule only applies to that service-specific rule unless a specific citation is made to another service-specific rule.

(4) Numerical Need Calculations.

(a) The numerical need calculations, which shall apply to an application for a clinical health service for which service-specific rules exist, shall be the calculated need in effect on the date the application is deemed complete for review less any subsequently approved units and services during the review period. This provision does not apply to batching reviews as the need applicable to batching decisions is the need stated in the batching notice.

(b) In the instance of joined projects where one project is reviewed as an exception based on utilization and the other is reviewed as need-based, the approval of the utilization exception shall not preclude an approval based on a numerical need projection should, prior to the approval of any of the joined projects, the numerical need projection indicates a need for the clinical health service.

(c) Approved projects that affect service-specific numerical need calculations shall be added to the Departments service-specific inventories and the numerical need projections shall be adjusted as of the approved date of the project.

(d) Approved projects that are reversed through administrative and/or judicial appeal final resolution shall be subtracted from the Departments service-specific inventories and the numerical need projections shall be adjusted as of the date of such final resolution.

(5) Service-specific component plans provide general background on specific considerations that were undertaken in developing service-specific rules. The service-specific rules shall supersede a component plan.

(6) If any provision of these service-specific rules, or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the particular service-specific rule in question or of the service-specific rules in general which can be given effect without the invalid provision or application, and to this end the provisions of these service-specific rules are severable.

(7) The commissioner shall be authorized, with the approval of the board, to place a temporary moratorium of up to six (6) months on the issuance of certificates of need for new and emerging health care services. Any such

moratorium placed shall be for the purpose of promulgating service-specific rules and regulations regarding such new and emerging health care services. A moratorium may be extended one time for an additional three (3) months if circumstances warrant, as approved by the board. In the event that final service-specific rules and regulations are not promulgated within the time period allowed by the moratorium, any applications received by the Department for a new and emerging health care service shall be reviewed under existing general statutes and regulations relating to certificates of need. Upon the identification by the Department of a new and emerging health care service as defined by Ga. Comp. R. & Regs. r. 111-2-2-.01(41), and the request for and receipt of approval by the board of a moratorium as provided in this subsection, the Department shall publish notice of the moratorium and the identified service in a manner used in the normal course for other Certificate of Need information and announcements.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.11

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq*****.**

HISTORY: Original Rule entitled "Service-Specific Review Considerations Generally" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Dec. 14, 2007; eff. Jan. 3, 2008.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.11, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.20 Specific Review Considerations for Short-Stay General Hospital Beds

(1) **Applicability.**

(a) A Certificate of Need will be required prior to the establishment of a new hospital, replacement of an existing hospital, or expansion of an existing hospital.

(b) The provisions in these Rules do not apply to the following situations:

1. bed replacements in existing hospital facilities which do not require a capital or equipment expenditure over the applicable dollar threshold; or

2. changing the physical location of existing beds within an existing facility regardless of cost; provided, however, that any project in excess of the applicable capital expenditure or equipment dollar threshold must be reviewed in accordance with the review considerations set forth in Ga. Comp. R. & Regs. r. 111-2-2-.09; or

3. projects that are otherwise exempt from review pursuant to O.C.G.A. § 31-6-47(a)(15).

(c) An existing hospital seeking an expansion to be used for new institutional health services, including perinatal services, rehabilitation services, or psychiatric and substance abuse services, must meet the applicable service-specific Rules found in this Chapter and, as a threshold matter, meet the need standards set forth in Ga. Comp. R. & Regs. r. 111-2-2-.20(3)(b)(3) but shall not be required to meet the other requirements in Ga. Comp. R. & Regs. r. 111-2-2-.20.

(d) A hospital that has been approved through the Certificate of Need process to use a certain number of short-stay hospital beds for long-term acute care ("LTAC") beds shall have such LTAC beds removed from the official inventory of available short-stay beds once the LTAC is certified by Medicare; provided, however, that such beds

will revert to the hospital's official inventory of available short-stay beds at any point that the LTAC ceases operation or is no longer certified by Medicare. An application to use existing short-stay hospital beds for LTAC beds shall not be subject to the guidelines in Ga. Comp. R. & Regs. r. 111-2-2-.20.

(2) **Definitions.**

(a) "Age cohorts" for purposes of these Rules refers to the following age groups: persons zero (0) to seventeen (17); persons eighteen (18) to sixty-four (64); and persons sixty-five (65) and older.

(b) "Available beds" or "CON approved beds" means the total number of beds authorized for use by a hospital or group of hospitals based on capacity approved or authorized through the Certificate of Need process.

(c) "Children's hospital" means a hospital in which ninety percent (90%) or more of the patients served by the hospital are seventeen (17) or less years of age.

(d) "Critical Access Hospital" means a hospital designated as a critical access hospital pursuant to the state's rural health plan and the guidelines of the Medicare Rural Hospital Flexibility Program authorized by section 4201 of the Balanced Budget Act of 1997.

(e) "Destination cancer hospital" means an institution with a licensed bed capacity of fifty (50) or less which provides diagnostic, therapeutic, treatment, and rehabilitative care services to cancer inpatients and outpatients, by or under the supervision of physicians, and whose proposed annual patient base is composed of a minimum of sixty-five percent (65%) of patients who reside outside the State of Georgia.

(f) "Expansion" means the addition of available beds or CON approved beds for an existing hospital.

(g) "Health planning area" or "planning area" means the twelve (12) state service delivery regions as defined in O.C.G.A. § 50-4-7.

(h) "Horizon year" means the last year of a five (5) year projection period for need determinations.

(i) "Optimal Occupancy Rate" means a target or expected level of use of available beds as calculated based on the annual patient days divided by the available beds multiplied by three hundred sixty-five (365). The optimal occupancy rate is variable based on the following:

1. for hospitals located in a rural county, sixty-five percent (65%);

2. for hospitals located in a non-rural county, seventy-five percent (75%); and

3. for teaching or children's hospitals, seventy percent (70%).

(j) "Patient days" means the number of days of inpatient services based on the most recent full year of hospital discharge data or the annual hospital questionnaire.

(k) "Replacement" means new construction to substitute another facility for an existing facility. New construction may be considered a replacement only if the replacement site is located three (3) miles or less from the facility being replaced or, in the case of the facility proposing a replacement site beyond the three (3) mile limit, if the replacement site is located within the same county and would serve substantially the same patient population, based on patient origin by zip code and payer mix, as the existing facility.

(l) "Rural county" means a county with a population of 35,000 or less based on the most recent decennial census, as defined in O.C.G.A. § 31-7-94.1(c)(3).

(m) "Safety net hospital" is defined as a hospital that meets at least two (2) of following criteria:

1. the hospital is a children's hospital or a teaching hospital;

2. the hospital is designated by the Healthcare Facility Regulation Division as a trauma center;

3. Medicaid and Peach Care inpatient admissions constitute twenty percent (20%) or more of the total hospital inpatient admissions;

4. Uncompensated charges for indigent patients constitute six percent (6%) or more of hospital adjusted gross revenue; or

5. Uncompensated charges for indigent and charity patients constitute ten percent (10%) or more of hospital adjusted gross revenue.

(n) "Short stay hospital" or "hospital" is defined as a facility with an average length of stay of less than thirty (30) days.

(o) "Target service area population" means the total populations of all counties, which are in part or in whole, within a ten (10) mile radius of the planned location of a new, expanded, or replacement hospital.

(p) "Teaching hospital" means a hospital designated as a teaching hospital by the Georgia Board for Physician Workforce, which serves as a sponsoring or major participating hospital for a program of graduate medical education accredited by the Accreditation Council for Graduate Medical Education (ACGME) or the American Osteopathic Association (AOA) and maintains a written affiliation agreement with an accredited medical school located in Georgia or is owned and operated by an accredited medical school in Georgia.

(3) **Standards.**

(a) A new hospital must be at least fifty (50) beds in size if located in a rural county and at least one hundred (100) beds in size if located in a county other than a rural county.

(b) The need for a new, replacement or expanded hospital shall be determined through application of an appropriate numerical need methodology designed to assess need for the specific purpose sought in the application.

1. The numerical need for a new hospital shall be determined through application of a demand-based forecasting model. The model is outlined in the steps below:

(i) Calculate the use rate for current hospital services in the target service area population by dividing the patients days for each age cohort by the population for each age cohort for same year as patient days were calculated.

(ii) Project the horizon year use rate for hospital services in the target service area population by multiplying the use rate for current hospital services by age cohort by the horizon year population by age cohort.

(iii) Divide the results of the calculations in Step (ii) by 365 and sum these numbers to determine a baseline bed need.

(iv) Adjust the baseline bed need by adding a factor to account for use of the hospital services located within the target service area population by persons from out of state. The factor shall be determined by calculating the patient days for the hospitals in the target service area that may be attributed to persons from out of state as a percentage of total patient days, and then dividing that percentage into the baseline bed need. In addition, if the target service area population includes any county or counties outside the state of Georgia, the projected bed need of the out-of-state counties should be calculated by applying the projected rate of beds needed per 1,000 for in-state counties in the target service area population to the prorated portion of population in out-of-state counties.

(v) Divide the baseline bed need by the optimal occupancy rate, as determined by the size of the proposed new facility, to project the total number of beds needed for the target service area population.

(vi) Calculate the number of available beds for the target service area population by adding all of the short stay beds located in the counties, including those outside of Georgia if applicable, which are in part or in whole within a ten (10) mile radius of the planned location of the new hospital.

(vii) Subtract the number of available beds from the total number of beds needed for the target service area population to determine the net number of beds needed.

2. A new hospital shall be approved only if the total target service area population is at least 50,000 persons.

3. The numerical need for a replacement or expanded hospital shall be determined through application of a demand-based forecasting model. The model is outlined in the steps below:

(i) Calculate the county use rate for the current hospital's services by dividing the patients days for Georgia residents by county within each age cohort by the population by county for each age cohort for the same year as patient days were calculated.

(ii) Project the horizon year use rate for the hospital's services by multiplying each county use rate by age cohort by the horizon year population of each county by age cohort.

(iii) Sum the number of patients resulting from Step (ii) and divide by three hundred and sixty-five (365) to determine a baseline bed need rate.

(iv) Adjust the baseline bed need rate by adding a factor to account for use of the hospital's services by persons from out of state. The factor shall be determined by calculating the patient days for the hospital that may be attributed to persons from out of state as a percentage of total patient days, and then dividing that number into the baseline bed need.

(v) Divide by optimal occupancy rate, as determined by the size of the proposed facility, to project the total number of beds needed for the replacement or expanded hospital.

(vi) Compare the results of Step (v) with the number of beds requested for the replacement or expanded hospital and, if appropriate, the number of available beds to determine whether the proposed replacement or expanded hospital meets the need standards.

(c) The Department may allow an exception to need and adverse impact standards outlined in Ga. Comp. R. & Regs. r. 111-2-2-.20(3)(b) and (d) for a facility meeting any one of the following criteria:

1. The facility is an existing facility designated by the Department of Public Health as a trauma center;

2. The facility is an existing teaching hospital;

3. The facility is a sole community provider and more than twenty percent (20%) of the capital cost of any new, replacement or expanded facility is financed by the county governing authority, as defined in O.C.G.A. § 1-3-3(7), of the home county or the county governing authorities of a group of counties; or

4. The facility is a designated critical access hospital and is seeking replacement of its existing facility at a size not to exceed twenty-five (25) CON approved beds.

(d) 1. An applicant for a new, replacement or expanded hospital shall demonstrate the expected effects of the proposed services on other hospitals within the target service area population, including how any enhanced competition will have a positive impact upon the cost, quality, and access to the services proposed; and in the case of applications for a new, replacement or expanded hospital where competition between providers will not have a favorable impact on cost, quality and access, the applicant shall be required to document that its application will not have an adverse impact.

2. An applicant for a new, replacement or expanded hospital shall document in its application that the new, replacement or expanded facility is not predicted to be detrimental to safety net hospitals within the planning area. Such demonstration shall be made by providing an analysis in the application that compares current and projected changes in market share and payer mix for the applicant and any safety net hospitals. Impact on an existing safety net hospital shall be determined to be adverse if, based on the utilization projected by the applicant, any existing safety net hospital would have a total decrease of ten percent (10%) or more in its average annual utilization, as measured by patient days for the two most recent and available preceding calendar years of data.

3. An applicant for a new, replacement or expanded hospital shall document in its application that the new, replacement or expanded facility is not predicted to be detrimental to any teaching hospitals in the state. Such demonstration shall be made by providing an analysis in the application that compares current and projected changes in market share and payer mix for the applicant and any teaching hospitals. Impact on an existing teaching hospital shall be determined to be adverse if, based on the utilization projected by the applicant, any existing teaching hospital would have a total decrease of five percent (5%) or more in its average annual utilization, as measured by patient days for the two most recent and available preceding calendar years of data.

(e) In considering applications joined for review, the Department may give favorable consideration to whichever of the applicants historically has provided the higher annual percentage of unreimbursed care to indigent and charity patients and the higher annual percentage of services to Medicare, Medicaid and Peach Care patients.

(f) An applicant for a new, replacement or expanded hospital shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, sex, creed, religion, disability or the patient's ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard that meets or exceeds three percent (3%) of annual, adjusted gross revenues for the hospital;

3. providing a written commitment to participate in the Medicare, Medicaid and Peach Care programs;

4. providing a written commitment to participate in any other state health benefits insurance programs for which the hospital is eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients.

(g) 1. An applicant for a replacement or expanded hospital shall document that the hospital is fully accredited by the Joint Commission or another nationally recognized accrediting body, and also shall provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and/or Medicaid certification deficiencies in the past three (3) years and has no outstanding licensure and Medicare and/or Medicaid certification deficiencies. In the event that the hospital is not accredited by the Joint Commission or another nationally recognized health care accreditation body and relies solely on state licensure, the applicant should provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and/or Medicaid certification deficiencies in the past five (5) years and has no outstanding licensure and Medicare and/or Medicaid certification deficiencies.

2. An applicant for a new, replacement or expanded hospital shall:

(i) provide a written commitment that the applicant presently participates, or in the case of a new hospital, will participate, in a statewide or national external reporting and peer review process related to patient safety and control of medical errors;

(ii) provide evidence of the availability of resources, including health care providers, management personnel and funds for capital and operating needs, for the provision of the hospital services; and

(iii) document a plan for obtaining and maintaining staff and service quality standards necessary to promote effective patient care and clinical outcomes.

(h) 1. An applicant for a new, replacement or expanded hospital shall document a plan to operate an emergency room licensed by the Healthcare Facility Regulation Division.

2. An applicant for a new, replacement or expanded hospital shall provide a description of the proposed service area for the hospital and document a community planning process that addresses primary care relationships and the range of transfer and referral activities across the range of care levels. The descriptions and community planning process should address:

(i) Estimated geographic boundaries of primary and secondary service areas and the primary and outpatient providers in these areas;

(ii) Demographic and income characteristics of the service area by age, gender and racial compositions;

(iii) Anticipated payer sources by population totals and percentages to include public payers and indigent and charity care services;

(iv) Patient access to the full continuum of care, including discharge planning and long-term care options;

(v) The projected financial and economic impact that the project will have on the community;

(vi) Strategies related to physician recruitment and medical staffing to include the hospital's plan to ensure that the care provided by physicians and other clinicians is made available to patients without regard for ability to pay;

(vii) The manner in which the facility coordinates or will coordinate with the existing health care system;

(viii) The manner(s) in which the hospital will make available the necessary ancillary and support services; and

(ix) The manner in which the hospital will support the operation of any affiliated critical access hospitals, if applicable.

3. An applicant for a new, replacement or expanded hospital shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the hospital.

4. An applicant for a new, replacement or expanded hospital shall demonstrate that proposed charges for services shall compare favorably with charges for other similar hospital services in the planning area when adjusted for annual inflation. When determining the accuracy of an applicant's projected charges for hospital services, the Department may compare the applicant's history of charges if applicable, with other hospitals in the planning area(s) previously served by the applicant or its parent company.

(i) 1. To respond to changes in the health care delivery system and to promote improved efficiency, access and cost-containment, the Department may authorize the consolidation of two or more hospitals located in one rural county or in contiguous rural counties. A proposal to consolidate hospitals into a single, new consolidated hospital requires a Certificate of Need and must comply with the following criteria.

2. Two or more existing facilities, each of which are operational at the time of approval and each of which are located in the same rural county or in contiguous rural counties, may seek a consolidation to create a single consolidated facility at an existing site or a new site within the same rural county or one of the same rural counties. The applicant or applicants for such a consolidated facility must be able to meet the following conditions:

(i) The available beds for the proposed consolidated facility must not exceed the total number of available beds of the existing facilities proposed for consolidation;

(ii) The applicant(s) for the proposed consolidated facility must show, using patient origin data, that the proposed new facility and/or location is reasonably projected to continue to meet the utilization needs of those populations that historically utilized the existing facilities;

(iii) The applicant(s) must explain the impact of consolidation on the service area's health care delivery system and show that any negative impacts on existing and approved providers will be outweighed by the benefits of the proposal;

(iv) The applicant must submit documentation demonstrating that the consolidation will promote the most efficient handling of patient needs; improve the ability to update medical technology infrastructure; maximize efficiency for capital and physical plant needs; and improve consumer access to enhanced quality and depth of services; and

(v) The applicant(s) must comply with all other provisions of this Rule with exception of the need and adverse impact standards set forth in Ga. Comp. R. & Regs. r. 111-2-2-.20(3)(b) and (d).

(j) 1. To respond to changes in the health care delivery system and to promote improved efficiency, access and cost-containment, the Department may authorize the consolidation of two or more hospitals located in one non-rural county. A proposal to consolidate hospitals into a single, new consolidated hospital requires a Certificate of Need and must comply with the following criteria.

2. Two or more existing facilities, each of which are operational at the time of approval and each of which are located in the same non-rural county, may seek a consolidation to create a single consolidated facility at an existing site or a new site within the same non-rural county. The consolidating facilities must apply as co-applicants. The applicant or applicants for such a consolidated facility must be able to meet the following conditions:

(i) The available beds sought for the proposed consolidated facility must not exceed the sum of the total number of beds for which each of the consolidating facilities would be authorized, at the time the application is filed, pursuant to the demand-based forecasting model for determining need set forth in Ga. Comp. R. & Regs. r. 111-2-2-.20(3)(b)3.

(ii) The applicant(s) for the proposed consolidated facility must show, using patient origin data by zip code, that the proposed new facility and/or location is reasonably projected to continue to meet the utilization needs of those populations that historically utilized the existing facilities;

(iii) The applicant(s) must explain the impact of consolidation on the facilities to be consolidated existing service area(s) health care delivery system and show that any negative impacts on existing and approved providers will be outweighed by the benefits of the proposal;

(iv) The applicant must submit documentation demonstrating that the consolidation will promote the most efficient handling of patient needs; improve the ability to update medical technology infrastructure; maximize efficiency for capital and physical plant needs; and improve consumer access to enhanced quality and depth of services; and

(v) The consolidating facilities must not seek to offer in a consolidation application any new clinical health service at the proposed new site not offered in each or all of the facilities to be consolidated.

(k) 1. A Certificate of Need will be issued to an applicant for a destination cancer hospital if it meets the following standards and under the following conditions.

2. An applicant for a destination cancer hospital must document that it meets the criteria described in the definition in Section (2)(e).

3. An applicant for a destination cancer hospital must:

(i) Document that the destination cancer hospital itself and all affiliated facilities are within twenty-five (25) miles of a commercial airport in the State of Georgia with five (5) or more runways;

(ii) Document that the services to be offered by the facility are solely related to the treatment of cancer patients;

(iii) Document the services to be offered within and by the facility that would otherwise be considered a separate new institutional health service. Such services will not be required to obtain separate Certificate of Need authorization, or be reviewed under any service-specific need methodology or rules other than those for a destination cancer hospital if included in the initial Certificate of Need application reviewed under the Rules outlined in section (k) of these Rules;

(iv) Document that the destination cancer hospital will not offer services that are not reasonable related to the diagnosis and treatment of cancer such as, but not limited to, open heart surgery, perinatal services, and cardiac catheterization;

(v) Document that at least sixty-five percent (65%) of its projected annual patient base will be composed of persons who reside outside of the State of Georgia;

(vi) Agree to provide uncompensated indigent and charity care for residents of the State of Georgia which meets or exceeds three percent (3%) of the applicant's adjusted gross revenue;

(vii) Agree to provide care to Medicaid beneficiaries;

(viii) Document that the applicant for a destination cancer hospital will comply with the criteria found in the General Review Considerations of these Ga. Comp. R. & Regs. r. at Section 111-2-2-.09(2).

4. A destination cancer hospital that does not meet an annual patient base composed of a minimum of sixty-five percent (65%) of patients who reside outside the State of Georgia in a calendar year shall be fined $2,000,000.00 for the first year of noncompliance, $4,000,000.00 for the second consecutive year of noncompliance, and $6,000,000.00 for the third consecutive year of noncompliance. Such fine amount shall reset to $2,000,000.00 after any year of compliance. In the event that a destination cancer hospital does not meet an annual patient base composed of a minimum of sixty-five percent (65%) of patients who reside outside of the State of Georgia for three (3) calendar years in a five (5) year period, such hospital shall be fined an additional amount of $8,000,000.00. All revenues collected from any such fine may be dedicated and deposited by the Department into the Indigent Care Trust Fund created pursuant to O.C.G.A. § 31-8-152. The Department, pursuant to O.C.G.A. § 31-6-45(a)(7), may revoke the Certificate of Need of a destination cancer hospital, in whole, or in part, after notice and an opportunity for a hearing, for failure to meet an annual patient base composed of a minimum of sixty-five percent (65%) of patients who reside outside of the State of Georgia for three calendar years in any five-year period.

5. After commencing operations upon receipt of a Certificate of Need pursuant to these Rules, a destination cancer hospital seeking to add an additional new institutional health service, shall apply for and obtain an additional Certificate of Need under the applicable statutory provisions and the Rules in this section. Any such application shall only be granted if the patient base of the destination cancer hospital is composed of at least sixty-five percent (65%) of patients who reside outside of the State of Georgia for two consecutive years.

6. The Department may apply the Rules in section (k) of these Rules to an application from a destination cancer hospital for a Certificate of Need for services and equipment required for it to meet federal or state laws applicable to a hospital.

7. If a destination cancer hospital cannot show a patient base of a minimum of sixty-five percent (65%) of persons who reside outside of the State of Georgia, the application for a Certificate of Need for any new institutional health service shall be evaluated under the specific statutes and Rules applicable to that particular service.

8. If a destination cancer hospital applies for a Certificate of Need to add an additional new institutional health service before commencing operations or completing two (2) consecutive years of operation, the applicant may rely on historical data from its affiliated entities.

9. The number of beds, services, and equipment used in and by a destination cancer hospital shall not be counted as part of the Department's inventory when determining the need for those beds, services, or equipment for other providers in other Certificate of Need applications not involving destination cancer hospitals.

10. No person shall be issued more than one Certificate of Need for a destination cancer hospital.

11. The Department will not accept an application for a Certificate of Need for a destination cancer hospital on or after January 1, 2010; however, an existing destination cancer hospital may avail itself of all applicable Certificate of Need provisions regarding the upgrade, purchase, or replacement of diagnostic or therapeutic equipment.

12. An applicant for a destination cancer hospital shall agree to provide information related to the operation of and services provided by the facility in the time frame and manner requested by the Department. In addition, a destination cancer hospital shall submit an annual statement, in accordance with the timeframes and format specified by the Department, affirming that the hospital has met an annual patient based composed of a minimum of sixty-five percent (65%) of patients who reside outside the State of Georgia. The chief executive officer of the destination cancer hospital shall certify under penalty of perjury that the statement as prepared accurately reflects the composition of the annual patient base. The Department shall have the authority to inspect any books, records, papers, or other information of the destination cancer hospital to confirm the information provided on such statement or any other information required of the destination cancer hospital. The report required by this sub-section shall not be construed to require the release of any information that would violate the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.20

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq.***

HISTORY: Original Rule entitled "Specific Review Considerations for Short-Stay General Hospital Beds" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

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Note: Rule 111-2-2-.20, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.21 Specific Review Considerations for Adult Cardiac Catheterization Services

(1) **Applicability.**

(a) For Certificate of Need purposes, Adult Cardiac Catheterization Services is classified as a specialized service and is defined as a new institutional health service which must be delivered in a permanently fixed location in either an acute care hospital or in a diagnostic, treatment, or rehabilitation center ("DTRC"). A Certificate of Need will be required prior to the establishment of a new or expanded adult cardiac catheterization service, if not exempt as provided by O.C.G.A. § 31-6-47(a)(21) and Ga. Comp. R. & Regs. r. 111-2-2-.03(24).

(b) If the service will be provided within a licensed acute care hospital, the hospital shall be the applicant.

(c) If cardiac catheterization services will be provided in a DTRC, the organizational entity that develops the service shall be the applicant.

(d) Seeking and receiving approval from the Department under the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(f)3. shall neither be considered a new adult cardiac catheterization service nor an expanded service. Additionally, the issuance of such an approval shall not be construed to be anything other than a time-limited approval to participate in the particular medical research trial specified in Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(f)(3).

(2) **Definitions.**

(a) "Adjacent acute care hospital" means an acute care hospital which is physically connected to another acute care hospital in a manner that emergency transport of a patient by a stretcher or gurney can be achieved rapidly, conveniently, and effectively without the use of motorized vehicles.

(b) "Adult" means a person fifteen (15) years of age and over.

(c) "Authorized service" means an adult cardiac catheterization service that is either existing or approved. An existing service is an authorized service that has become operational, and an approved service is an authorized service that has not yet become operational.

(d) "Capacity" means 1300 adult cardiac catheterization procedure equivalents per dedicated and multipurpose room per year. In the computation of the use rate (percent of capacity) of authorized adult cardiac catheterization rooms, each adult diagnostic cardiac catheterization and other cardiac catheterizations of similar complexity shall equal a 1.0 procedure equivalent, each coronary angioplasty procedure shall equal 1.5 procedure equivalents, and each electrophysiological (EP) study shall equal 2.0 procedure equivalents. If pediatric catheterizations are performed in a room in which adult cardiac catheterizations are performed, each pediatric procedure shall equal 2.0 procedure equivalents.

(e) "Cardiac catheterization" means a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in the patient; subsequently, the free end of the catheter is manipulated by the physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aids in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures on the heart or its vessels.

(f) "Cardiac catheterization service" means an organized program which serves inpatients and/or outpatients of an acute care hospital or diagnostic, treatment and rehabilitation center (DTRC) with a room or a suite of rooms, with equipment to perform angiographic, physiologic, and as appropriate, therapeutic cardiac catheterization procedures. An authorized adult cardiac catheterization service is prohibited from performing coronary angioplasty procedures unless the acute care hospital where the service is located meets the requirements identified in Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(f).

(g) "Coronary angioplasty" means a cardiac catheterization procedure to treat coronary artery disease by utilizing a catheter with a balloon, laser, laser-assisted device, rotational device, stent placement or other mechanical means to unblock an occluded coronary artery.

(h) "Diagnostic cardiac catheterization" means the performance of cardiac catheterization for the purpose of detecting and identifying defects in the great arteries or veins of the heart, or abnormalities in the heart structure, whether congenital or acquired. Post-operative evaluation of the effectiveness of prostheses (e.g. heart valves or vein grafts) also can be accomplished through use of diagnostic cardiac catheterization.

(i) "Diagnostic, treatment, or rehabilitation center (DTRC)" means any professional or business undertaking, whether for profit or not for profit, which offers or proposes to offer any clinical health service in a setting that is not part of a hospital.

(j) "Expanded Service" or "Expansion" means an adult cardiac catheterization service that undertakes any capital renovation or construction project in and to the physical space within the hospital where the cardiac catheterization services are or will be offered, the cost of which exceeds the capital expenditure threshold at that time; or that acquires a piece of diagnostic or therapeutic equipment with a value above the equipment threshold at that time which is to be utilized in the provision of cardiac catheterization services; or that seeks the addition of a new catheterization laboratory or room regardless of cost. Replacement or repair of existing diagnostic or therapeutic equipment utilized in the provision of such services is not an expansion for purposes of these Rules.

(k) "Horizon year" means the last year of a five-year projection period for need determinations for any adult cardiac catheterization services.

(l) "Official inventory" means the Department's inventory of all authorized hospital-based and diagnostic, treatment, or rehabilitation center (DTRC) adult cardiac catheterization laboratories or any other authorized laboratory approved for operation at the time of adoption of these Rules.

(m) "Official state component plan" means the document related to specialized cardiovascular services developed by the Department adopted by the Health Strategies Council and approved by the Board of Community Health.

(n) "Procedure" means a cardiac catheterization study or treatment or combination of studies and/or treatments performed in a single session on a single patient who appears for cardiac catheterization.

(o) "Planning area" means each of the planning areas designated in the official State Component Plan.

(p) "Therapeutic cardiac catheterization" means the performance of cardiac catheterization for the purpose of ameliorating certain conditions that have been determined to exist in the heart or great arteries or veins of the heart.

(3) **Standards.**

(a) The need for new or expanded adult cardiac catheterization services shall be determined through application of a numerical need method and an analysis of service demand based on an assessment of the aggregate utilization rate of existing services;

1. the numerical need for new or expanded adult cardiac catheterization services shall be determined by a population-based formula which includes current usage patterns and projected population as follows:

(i) calculate the current state adult cardiac catheterization rate for the most recent year of reported survey or hospital and outpatient discharge data by dividing the total number of adult cardiac catheterizations performed on Georgia residents by the total state adult Resident population;

(ii) determine the projected adult cardiac catheterization procedures for the horizon year by multiplying the state rate by the adult Resident population for the planning area for the horizon year;

(iii) adjust the projected adult cardiac catheterization procedures for the planning area by adding the out-of-state hospital-based catheterizations for the most recent year based on the percentage of total procedures performed on out-of-state patients by hospitals in each planning area;

(iv) convert projected adult cardiac catheterization procedures to procedure equivalents by multiplying the projected procedures by the statewide rate of equivalents per catheterization; and

(v) determine the projected net surplus or deficit for adult cardiac catheterization capacity, expressed in terms of rooms/laboratories, in the planning area by subtracting the rooms/laboratories needed for the total projected procedure equivalents calculated in steps (i) through (iv) from the total capacity (1300 procedure equivalents per room/laboratory) based on the official inventory.

2. before a new or expanded adult cardiac catheterization service will be approved in any planning area, the aggregate utilization rate of all adult cardiac catheterization services in that planning area shall be eighty-five percent (85%) or more during the most recent year;

(b) 1. The Department may allow an exception to Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(a) in the following circumstances:

(i) actual utilization in the applicant's existing service has exceeded ninety percent (90%) of capacity over the past two (2) years;

(ii) to remedy an atypical barrier to adult cardiac catheterization services based on cost, quality, financial access, or geographic accessibility. The types of atypical barriers outlined below are intended to be illustrative and not exclusive.

(I) An atypical barrier to services based on cost may include the failure of existing providers of adult cardiac catheterization services to provide services at reasonable cost, as evidenced by the providers' charges and/or reimbursement being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other providers in the state and/or planning area.

(II) An atypical barrier to services based on quality may include the failure of existing providers of adult cardiac catheterization services to provide services with outcomes generally in keeping with accepted clinical guidelines of the American College of Cardiology, peer review programs and comparable state rates for similar populations.

(III) An atypical barrier to services based on financial access may include the repeated failure, as exhibited by a documented pattern over two or more years prior to the submission of the application, of existing providers of services within the community to provide services to indigent, charity, and Medicaid patients.

(IV) An atypical barrier to services based on geographic accessibility may include a planning area which has an adult cardiac catheterization rate significantly less than the state rate (two or more standard deviations from the mean), a cardiovascular disease rate as projected through death and hospital discharge data which is significantly higher than the state rate (two or more standard deviations from the mean), and other demographic risk factors which can be documented through research and clinical studies.

(V) An applicant seeking approval for a new or expanded adult cardiac catheterization service solely for the purpose of providing cardiac electrophysiological studies may apply for consideration under the terms of an atypical barrier; provided, however, that any such applicant if approved shall be restricted to the provision of electrophysiological studies.

2. The Department may allow an exception to Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(a) and (3)(c) for any cardiac catheterization service seeking an expansion, other than the addition of another laboratory or room; provided the applicant complies with the general considerations and policies of Ga. Comp. R. & Regs. r. 111-2-2-.09 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(d),(e),(f),(g),(h),(j),(k) and (l).

(c) An applicant for a new or expanded adult cardiac catheterization service shall document that authorized cardiac catheterization services which could be adversely impacted by the establishment of the new or expanded service are not predicted to perform less than eighty percent (80%) of capacity as a result of the establishment of the new or expanded service. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application.

(d) An applicant for a new or expanded adult catheterization service shall demonstrate a plan whereby the service and its medical staff agree to provide a full array of cardiovascular services to the community, including, but not limited to, education and outreach, prevention and screening, diagnosis and treatment, and rehabilitation.

(e) An applicant for a new or expanded adult cardiac catheterization services shall:

1. demonstrate the ability to meet the optimal clinical and physical environment standards established in the most recent American College of Cardiology/American Heart Association's Guidelines for Cardiac Catheterization and Cardiac Catheterization Laboratories. These standards include, but are not limited to, physical facility requirements, staffing, training, quality assurance, patient safety, screening patients for appropriate settings, and linkages with supporting emergency services;

2. document the availability of, or shall present a plan for recruiting, at least two board-certified cardiologists with training and qualification in cardiac catheterization, and, if applicable with training and qualification in coronary intervention, who will reside within one hour drive of the service site; and

3. document a plan for obtaining a sufficient number of clinical, professional and technical staff to safely and effectively operate the service.

(f) An authorized adult cardiac catheterization service shall not perform catheterization procedures requiring open heart surgery backup as part of its service unless the acute care hospital where the service is located:

1. operates an existing adult open heart surgery service;

2. has a Department approved written agreement for open heart surgery backup with an adjacent acute care hospital as defined by these Rules; or

3. has been accepted as a participant in a randomized medical research trial comparing patient outcomes after non-primary Percutaneous Coronary Intervention (PCI) in hospitals with and without cardiac surgery on-site, which also requires the performance of Primary PCI and has a parallel Primary PCI Registry, and which is coordinated by the Atlantic Cardiovascular-Patient Outcomes Research Team (Atlantic C-PORT). The authorized adult cardiac catheterization service must receive such Atlantic C-PORT acceptance and also must obtain written approval from the Department to perform such procedures, except that the Department may approve no more than ten (10) existing and authorized hospital services for participation, regardless of the number of such services that are accepted by Atlantic C-PORT.

(i) Any request for such Departmental approval must be submitted to the Department no later than June 30, 2005 in writing on a form developed by the Department for such purposes. Prior to final approval to participate by the Department, the requesting authorized service must provide written proof it has been accepted by Atlantic C-PORT as a participant in said trial under all applicable protocols;

(ii) In reviewing and approving such requests, the Department shall take into consideration such factors including, but not limited to, rural, suburban or urban location of the service, mix of patients to be treated, whether the service has the capability of performing a minimum of 100 PCIs (elective and primary combined) during the first year of such approval, 200 PCIs (elective and primary combined) during the second year of such approval unless a lower number, but not below 150 PCIs, is approved for specific reasons by both the Department and the trial chairperson, and 200 PCIs (elective and primary combined) during the third year of such approval, and whether the service has on its staff physicians and support staff with training and experience in both therapeutic and diagnostic cardiac catheterizations;

(iii) The selection of an authorized service for participation pursuant to this Rule will be made at the sole discretion of the Department; however, the Department shall consult with medical experts in the fields of cardiology and percutaneous coronary intervention when making the decision to approve or not approve a particular service for participation in such trial;

(iv) Any approval obtained from the Department in this regard shall only be valid for as long as the health care facility receiving such approval is an active participant in the trial; however, in no case shall such approval continue to be valid upon Atlantic C-PORT declaring the trial concluded, or under no circumstance for a period in excess of three (3) years from the time the authorized service's first procedure is conducted under the authority of the Department's approval and Atlantic C-PORT's acceptance to begin active participation in the trial; whichever event occurs first; and

(v) As any such Departmental approval is conditioned on being an active participant in the trial, should an authorized service which has received approval under the provisions of this Rule be expelled or otherwise lose the approval of Atlantic C-PORT to continue participation, the Department's approval will be simultaneously withdrawn without said service's or facility's right to an appeal of the Department's withdrawal of its approval to participate in such trial.

(g) Catheterization procedures requiring open heart surgery backup include coronary angioplasty and the following:

1. catheter atherectomy;

2. catheter endomyocardial biopsy;

3. left ventricular puncture;

4. percutaneous transluminal coronary angioplasty;

5. percutaneous catheter balloon valvuloplasty; and

6. transeptal catheterization.

(h) An applicant for a new or expanded adult cardiac catheterization service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to cardiac catheterization services for all segments of the population in the documented and proposed service area of the applicant. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area; and

2. propose a heart disease prevention and clinical intervention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

(i) A clinical intervention program for all catheterization patients that shall provide for the following in a comprehensive, systematic way:

(I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

(II) Assessment of risk factors and referral for appropriate care in first-degree relatives; and

(III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended including preventive therapies.

(ii) The program, if not operated by a facility with an existing Open Heart Surgical Service, shall submit a written affiliation agreement with at least one Open Heart Surgical Service that provides, at a minimum, for:

(I) a plan to transplant and handle acute cardiac emergencies;

(II) a plan to facilitate referral of patients for whom surgery or angioplasty may be indicated without unnecessarily repeating diagnostic studies; and

(III) a plan for ongoing communications between representatives of the Open-Heart Surgical Service and the proposed applicant, to allow for review of pre-operative and post-operative processes and specific cases.

(iii) The program shall provide for annual support and participation in at least three (3) professional education programs targeted to community-based health professionals, related to heart disease risk assessment, diagnostic procedures, disease management in clinical settings, and case finding and referral strategies.

(iv) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources to target at-risk populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors.

3. propose a system of outcome monitoring and quality improvement and identify at least five clinical outcomes that the applicant proposes to monitor for performance on a regular basis.

(i) An applicant for a new or expanded adult cardiac catheterization service must project and, if approved, shall document that the proposed service will be performing a minimum of 1040 adult cardiac catheterization procedure equivalents within three (3) years of initiation of the service and annually thereafter within the authorized guidelines for such services. Such projections, at a minimum, shall include consideration of patient origin data for catheterization services, the use rate of existing services, referral data and market patterns for existing hospital and DTRC services in the community, and cardiovascular disease incidence rates and related health indicators. An applicant seeking approval solely for the purpose of providing electrophysiological (EP) studies shall not be required to document a projected performance minimum but shall be required to document compliance with guidelines for EP studies issued by the American College of Cardiology.

(j) An applicant for a new or expanded adult cardiac catheterization service shall provide documentation that the service is fully accredited by the Joint Commission or another nationally recognized health care accreditation body, in the case of an applicant proposing a new facility location, shall provide a written commitment to secure full accreditation by the Joint Commission or another nationally recognized health care accreditation body within eighteen (18) months of initiating operation.

(k) An applicant for a new or expanded adult cardiac catheterization service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant to include disease prevention and intervention services outlined in Ga. Comp. R. & Regs. r. 111-2-2-.21(3)(h), that such services shall be provided regardless of race, age, sex, creed, religion, disability or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the adult cardiac catheterization service, or the applicant may request that the Department consider allowing the commitment for services to indigent and charity to patients to be applied to the entire facility;

3. providing a written commitment to accept any patient within the facility's service area, without regard to the patient's ability to pay, unless such patient is clinically inappropriate;

4. providing a written commitment to participate in the Medicaid, PeachCare and Medicare programs and to accept any Medicaid-, PeachCare- and/or Medicare-eligible patient for services unless such patient is clinically inappropriate;

5. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

6. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(l) An applicant for a new or expanded adult cardiac catheterization service must agree in writing to the following conditions:

1. establishment and maintenance of a system of continuity of care and coordination of service, as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs;

2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital or DTRC as well as a national, state or multi-program system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital or DTRC;

3. development of procedures to ensure that cardiologists and any other physicians providing care in the cardiac catheterization service or related services shall be required to accept Medicaid, PeachCare and Medicare payment for services without discrimination;

4. commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;

5. provision of all required data and survey information to the Department as requested; and

6. commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.

(m) The Department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.21

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq*****.**

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111-2-2-.22 Specific Review Considerations for Adult Open Heart Surgery Services

(1) **Applicability.** A Certificate of Need will be required prior to the establishment of a new or, subject to certain stipulations, expanded adult open heart surgical service.

(2) **Definitions.**

(a) "Adult" means persons 15 years of age and over.

(b) "Authorized service" means an adult open heart surgery service that is either existing or approved. An existing service is an authorized service that has become operational, and an approved service is an authorized service that has not become operational.

(c) "Coronary Angioplasty" means a cardiac catheterization procedure to treat coronary heart disease by utilizing a catheter with a balloon, laser, laser-assisted device, rotational device, stent placement or other mechanical means to unblock an occluded coronary artery.

(d) "Expanded Service" or "Expansion" means an adult open heart surgery service that undertakes any capital renovation or construction project in and to the physical space within the hospital where the adult open heart surgery service is or will be offered, the costs of which exceed the capital expenditure threshold at that time; or that acquires a piece of diagnostic or therapeutic equipment with a value above the equipment threshold at that time which is to be utilized in the provision of open heart surgery services; or, for any service a full four (4) years or more following implementation of an approved Certificate of Need, that increases adult open heart surgery volume to a level resulting in a twenty-five percent (25%) or more increase in procedures being performed by the service over the higher annual number of procedures having been performed during the most recent prior two calendar years. Replacement or repair of existing diagnostic or therapeutic equipment utilized in the provision of such service is not an expansion for purposes of these Rules.

(e) "Official State Component Plan" means the document related to specialized cardiovascular services developed by the Department established by the Health Strategies Council, and adopted by the Board of Community Health.

(f) "Open heart surgery" means surgery performed directly on the heart or its associated veins or arteries during which a heart and lung by-pass machine (extracorporeal pump) may be used to perform the work of the heart and lungs.

(g) "Open heart surgery service" means an organized surgical program that serves inpatients of a hospital that has a suitable operating room or suite of operating rooms, equipment, staff, intensive care unit, and all support services required to perform adult open-heart surgery. The adult open heart surgery service shall be located in an acute care hospital that has an authorized adult cardiac catheterization service.

(h) "Procedure" means an adult open heart surgery operation or combination of operations performed in a single session on a single patient who appears for open heart.

(3) **Standards.**

(a) 1. An application for new adult open heart surgery services shall be considered by the Department only if each and all of the following conditions are met:

(i) an applicant must have operated an existing adult cardiac catheterization service which is located in an acute care hospital setting for at least three (3) years prior to the date of application; and

(ii) an applicant shall document, based on actual service data of the applicant, survey data provided to the Department and other supporting research and documentation, that the hospital's existing adult cardiac catheterization service generated a minimum of 250 or more adult open heart surgery procedures in each of the two (2) calendar years immediately prior to submittal of the application; and

(iii) an applicant shall project and, if approved, shall document that the proposed adult open heart surgery service will be performing a minimum of 300 adult open heart surgery procedures per year within three years of initiation of

the service. Such projections, at a minimum, shall include consideration of patient origin data for open heart and catheterization services, the use rate of existing services, and referral data and market patterns for existing hospital services, and cardiovascular disease incidence rates and related health indicators; and

(iv) an applicant shall document that existing and approved adult open heart surgery services in the state are not predicted to be adversely impacted as a result of the establishment of the new service. Impact on an existing or approved service shall be determined to be adverse if, based on the number of cases projected to be performed by the applicant, any of the existing or approved services would have either a decrease in volume equal to or greater than ten percent (10%) of the average annual service volume in the preceding two calendar years or a decrease of less than ten percent (10%) of the annual service volume in the preceding two calendar years but which would result in such service falling below a minimum of 200 open heart surgical procedures annually. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application. An existing service that has been operational for four or more years and has not performed a minimum of 200 open heart surgical procedures in at least one of the past four years shall be excluded from a determination of adverse impact; and

(v) if multiple applications are joined or comparatively reviewed, the Department shall determine whether the individual impact of the establishment of each proposed service or the cumulative impact of the establishment of two or more proposed services would adversely impact an existing or approved service or any of the proposed services if established.

2. The Department may allow an exception to the need standard and adverse impact requirements in Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(a)1. of this paragraph to remedy an atypical barrier to open heart surgery services based on cost, quality, financial access, or geographic accessibility. The types of atypical barriers outlined below are intended to be illustrative and not exclusive.

(i) An atypical barrier to services based on cost may include the failure of existing providers of open-heart surgical services to provide services at reasonable cost, as evidenced by the providers' charges and/or reimbursement being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other providers in the state.

(ii) An atypical barrier to services based on quality may include the failure of existing providers of open-heart surgical services to provide services with outcomes generally in keeping with accepted clinical guidelines, peer review programs and comparable state rates for similar populations.

(iii) An atypical barrier to services based on financial access may include the repeated failure as exhibited by a documented pattern over two or more years prior to the submission of the application, of an existing provider or group of providers of open-heart surgical services within the community to provide services to indigent, charity and Medicaid patients.

(b) 1. An existing adult open heart surgery service seeking an expansion or expanded service due to a capital or equipment expenditure shall be approved if the applicant complies with the general considerations and policies of Ga. Comp. R. & Regs. r. 111-2-2-.09 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c),(d),(e),(g),(h) and (j).

2. Any existing service seeking an expansion or expanded service based on an increase in procedures pursuant to the definition in Ga. Comp. R. & Regs. r. 111-2-2-.22(2)(d) may request a determination from the Department that the service is fully in compliance with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c),(d),(e),(g),(h) and (j). The Department may issue a determination that the service is in compliance. If the Department issues such a determination, the service will not be required to apply for a Certificate of Need. If the Department determines that the service is not in compliance with the above referenced conditions, the service will be required to submit a Certificate of Need application.

(c) An applicant requesting a new or expanded adult open heart surgery service shall comply with the following three requirements:

1. Document that the open-heart surgery service shall have the capability to implement circulatory assist devices such as intra-aortic balloon assist and prolonged cardiopulmonary procedures, including at a minimum:

(i) repair and replacement of heart valves;

(ii) cardiac revascularization;

(iii) treatment of cardiac trauma;

(iv) repair of congenital defects in adults; and

(v) repair of acute aortic dissection.

2. Document that the applicant has available to the open-heart surgery service a full range of hospital-based diagnostic, ancillary, and support services, including the following organizational departments or services:

(i) medicine: cardiology, hematology, nephrology;

(ii) radiology: diagnostic, nuclear medicine;

(iii) surgery: cardiovascular, thoracic;

(iv) pathology: anatomic, clinical, blood bank, coagulation laboratory;

(v) anesthesiology: inhalation therapy; echocardiology in the operating room;

(vi) neurology;

(vii) special laboratories: cardiac catheter/angiographic;

(viii) clinical dietary;

(ix) cardiac surgical intensive care unit;

(x) pacemaker therapy;

(xi) cardiac rehabilitation services;

(xii) renal dialysis; and

(xiii) social services.

3. Document that the service shall be available for elective procedures as needed, at least eight hours per day, five days a week, and shall document the capability to rapidly mobilize surgical and medical support teams for emergency cases 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

(d) An applicant for a new or expanded adult open heart surgery service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to cardiac surgical services for all segments of the population in the documented and proposed service area of the facility and service. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area;

2. propose a heart disease prevention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

(i) Clinical intervention for cardiac patients (any inpatient or outpatient with a principal diagnosis of ischemic heart disease). These patients are at high risk for development of adverse cardiovascular events and the program shall provide for the following in a comprehensive, systematic way:

(I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

(II) Assessment of risk factors and referral for appropriate care in first-degree relatives;

(III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended; and

(IV) Establishment and maintenance of systems to assist in tracking and follow-up to determine attendance at referred services and status of risk management.

(ii) Clinical intervention for non-cardiac patients (any inpatient or outpatient whose principal diagnosis is not ischemic heart disease). For these patients, the program shall encourage the following:

(I) Assessment of risk factors including, hypertension, hypercholesterolemia, smoking, obesity, sedentary lifestyle, and history of diabetes;

(II) Provision of appropriate counseling and referral for diagnostic evaluation, treatment and risk factor modification; and

(III) Establishment and maintenance of record systems to assist in documenting risk factors identified, referrals made, and other follow-up action taken.

(iii) The program shall assure access to cardiac rehabilitation services, provided either by the hospital itself or through formal referral agreements.

(iv) The program shall provide for annual support and participation in at least three professional education programs targeted to community-based health professionals, related to heart disease risk assessment, disease management in clinical settings, and case finding and referral strategies.

(v) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources for target populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors; and

(3) **Standards.**

(a) 1. An application for new adult open heart surgery services shall be considered by the Department only if each and all of the following conditions are met:

(i) an applicant must have operated an existing adult cardiac catheterization service which is located in an acute care hospital setting for at least three (3) years prior to the date of application; and

(ii) an applicant shall document, based on actual service data of the applicant, survey data provided to the Department and other supporting research and documentation, that the hospital's existing adult cardiac catheterization service generated a minimum of 250 or more adult open heart surgery procedures in each of the two (2) calendar years immediately prior to submittal of the application; and

(iii) an applicant shall project and, if approved, shall document that the proposed adult open heart surgery service will be performing a minimum of 300 adult open heart surgery procedures per year within three years of initiation of the service. Such projections, at a minimum, shall include consideration of patient origin data for open heart and catheterization services, the use rate of existing services, and referral data and market patterns for existing hospital services, and cardiovascular disease incidence rates and related health indicators; and

(iv) an applicant shall document that existing and approved adult open heart surgery services in the state are not predicted to be adversely impacted as a result of the establishment of the new service. Impact on an existing or approved service shall be determined to be adverse if, based on the number of cases projected to be performed by the applicant, any of the existing or approved services would have either a decrease in volume equal to or greater than ten percent (10%) of the average annual service volume in the preceding two calendar years or a decrease of less than ten percent (10%) of the annual service volume in the preceding two calendar years but which would result in such service falling below a minimum of 200 open heart surgical procedures annually. In the case of an approved service, service volume should be projected in accordance with the volume projections in the approved application. An existing service that has been operational for four or more years and has not performed a minimum of 200 open heart surgical procedures in at least one of the past four years shall be excluded from a determination of adverse impact; and

(v) if multiple applications are joined or comparatively reviewed, the Department shall determine whether the individual impact of the establishment of each proposed service or the cumulative impact of the establishment of two or more proposed services would adversely impact an existing or approved service or any of the proposed services if established.

2. The Department may allow an exception to the need standard and adverse impact requirements in Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(a)1. of this paragraph to remedy an atypical barrier to open heart surgery services based on cost, quality, financial access, or geographic accessibility. The types of atypical barriers outlined below are intended to be illustrative and not exclusive.

(i) An atypical barrier to services based on cost may include the failure of existing providers of open-heart surgical services to provide services at reasonable cost, as evidenced by the providers' charges and/or reimbursement being significantly higher (one or more standard deviations from the mean) than the charges and/or reimbursement for other providers in the state.

(ii) An atypical barrier to services based on quality may include the failure of existing providers of open-heart surgical services to provide services with outcomes generally in keeping with accepted clinical guidelines, peer review programs and comparable state rates for similar populations.

(iii) An atypical barrier to services based on financial access may include the repeated failure as exhibited by a documented pattern over two or more years prior to the submission of the application, of an existing provider or group of providers of open-heart surgical services within the community to provide services to indigent, charity and Medicaid patients.

(b) 1. An existing adult open heart surgery service seeking an expansion or expanded service due to a capital or equipment expenditure shall be approved if the applicant complies with the general considerations and policies of Ga. Comp. R. & Regs. r. 111-2-2-.09 and submits an application that demonstrates the applicant's compliance with or documents a plan and agreement to comply with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c),(d),(e),(g),(h) and (j).

2. Any existing service seeking an expansion or expanded service based on an increase in procedures pursuant to the definition in Ga. Comp. R. & Regs. r. 111-2-2-.22(2)(d) may request a determination from the Department that the service is fully in compliance with the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(c),(d),(e),(g),(h) and (j). The Department may issue a determination that the service is in compliance. If the Department issues such a determination, the service will not be required to apply for a Certificate of Need. If the Department determines that the service is not in compliance with the above referenced conditions, the service will be required to submit a Certificate of Need application.

(c) An applicant requesting a new or expanded adult open heart surgery service shall comply with the following three requirements:

1. Document that the open-heart surgery service shall have the capability to implement circulatory assist devices such as intra-aortic balloon assist and prolonged cardiopulmonary procedures, including at a minimum:

(i) repair and replacement of heart valves;

(ii) cardiac revascularization;

(iii) treatment of cardiac trauma;

(iv) repair of congenital defects in adults; and

(v) repair of acute aortic dissection.

2. Document that the applicant has available to the open-heart surgery service a full range of hospital-based diagnostic, ancillary, and support services, including the following organizational departments or services:

(i) medicine: cardiology, hematology, nephrology;

(ii) radiology: diagnostic, nuclear medicine;

(iii) surgery: cardiovascular, thoracic;

(iv) pathology: anatomic, clinical, blood bank, coagulation laboratory;

(v) anesthesiology: inhalation therapy; echocardiology in the operating room;

(vi) neurology;

(vii) special laboratories: cardiac catheter/angiographic;

(viii) clinical dietary;

(ix) cardiac surgical intensive care unit;

(x) pacemaker therapy;

(xi) cardiac rehabilitation services;

(xii) renal dialysis; and

(xiii) social services.

3. Document that the service shall be available for elective procedures as needed, at least eight hours per day, five days a week, and shall document the capability to rapidly mobilize surgical and medical support teams for

emergency cases 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

(d) An applicant for a new or expanded adult open heart surgery service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to cardiac surgical services for all segments of the population in the documented and proposed service area of the facility and service. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area;

2. propose a heart disease prevention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

(i) Clinical intervention for cardiac patients (any inpatient or outpatient with a principal diagnosis of ischemic heart disease). These patients are at high risk for development of adverse cardiovascular events and the program shall provide for the following in a comprehensive, systematic way:

(I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

(II) Assessment of risk factors and referral for appropriate care in first-degree relatives;

(III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended; and

(IV) Establishment and maintenance of systems to assist in tracking and follow-up to determine attendance at referred services and status of risk management.

(ii) Clinical intervention for non-cardiac patients (any inpatient or outpatient whose principal diagnosis is not ischemic heart disease). For these patients, the program shall encourage the following:

(I) Assessment of risk factors including, hypertension, hypercholesterolemia, smoking, obesity, sedentary lifestyle, and history of diabetes;

(II) Provision of appropriate counseling and referral for diagnostic evaluation, treatment and risk factor modification; and

(III) Establishment and maintenance of record systems to assist in documenting risk factors identified, referrals made, and other follow-up action taken.

(iii) The program shall assure access to cardiac rehabilitation services, provided either by the hospital itself or through formal referral agreements.

(iv) The program shall provide for annual support and participation in at least three professional education programs targeted to community-based health professionals, related to heart disease risk assessment, disease management in clinical settings, and case finding and referral strategies.

(v) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide

programs and services. The objective of this consortium is to mobilize and coordinate resources for target populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors; and

3. propose a system of outcome monitoring and quality improvement and identify at least five clinical outcomes that the applicant proposes to monitor for performance on a regular basis.

(e) An applicant for a new or expanded adult open heart surgery service shall foster an environment which assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant to include disease prevention and intervention services outlined in Ga. Comp. R. & Regs. r. 111-2-2-.22(3)(d), that such services shall be provided regardless of race, age, sex, creed, religion, disability, or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the adult open heart surgery service, or the applicant may request that the Department allow the commitment for services to indigent and charity to patients to be applied to the entire facility;

3. providing a written commitment to accept any patient without regard to the patient's ability to pay, unless such patient is clinically inappropriate;

4. providing a written commitment to participate in the Medicaid, PeachCare and Medicare programs and to accept any Medicaid-, PeachCare- and/or Medicare-eligible patient for services unless such patient is clinically inappropriate;

5. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

6. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(f) In considering applications joined for review for new adult open heart surgery services, the Department may give favorable consideration to an applicant which historically has provided a higher annual percentage of unreimbursed services to indigent and charity patients and a higher annual percentage of services to Medicare and Medicaid patients.

(g) An applicant for a new or expanded adult open heart surgery service shall comply with the following three requirements:

1. Demonstrate the intent to achieve the optimal standards established by the American College of Surgeons and the Advisory Council for Cardiothoracic Surgery of the American College for evaluating the clinical and physical environments of cardiac surgical services and covering professional qualifications and responsibilities, staffing requirements, support services, physical plant, and equipment.

2. Document the availability of; or shall present a plan for recruiting, a qualified surgeon certified by the American Board of Thoracic Surgery with special qualifications in cardiac surgery.

3. Document a plan for obtaining a sufficient number of professional and technical staff; including cardiac intensive care nurses, for the size of the adult open heart surgery program proposed and document that the operating room

team necessary for an adult open heart surgical procedure shall be available, including a cardiovascular surgeon who is board certified by the American Board of Thoracic Surgery; a second physician who is a cardiovascular or thoracic surgeon or surgical resident; a board-certified anesthesiologist trained in open heart surgery; a circulating nurse or scrub nurse (RN); an operating room technician or registered nurse trained in cardiac procedures; and one or two pump technicians, with one being certified and one qualified.

(h) An applicant for a new or expanded adult open heart surgery service shall provide documentation that the hospital is fully accredited by the Joint Commission or another nationally recognized health care accreditation body, and also shall provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and/or Medicaid certification deficiencies in the past three years and has no outstanding licensure and Medicare and/or Medicaid certification deficiencies.

(i) An applicant for a new adult open heart surgery service shall demonstrate that charges and/or reimbursement rates for the service shall compare favorably with charges and/or reimbursement rates in existing adult open heart surgery services in the state when adjusted for annual inflation. When determining the accuracy of an applicant's projected charges for adult open heart surgery procedures, the Department may compare the applicant's history of charges and/or reimbursement rates for cardiac catheterization procedures and other treatments and/or interventions for disorders of the circulatory system and for open heart procedures, if applicable, with such charges and/or reimbursement rates in other similar hospitals.

(j) An applicant for a new or expanded adult open heart surgery service must agree in writing to the following conditions:

1. establishment and maintenance of a system of continuity of care and coordination of service, as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs; and

2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital as well as a national, state or multi-hospital system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital;

3. development of procedures to ensure that any surgeon authorized to perform open heart surgery for the hospital shall be required to perform at least 100 procedures on annual basis across his or her various practice settings, and shall be required to accept Medicaid or Medicare payment for services without discrimination;

4. commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;

5. provision of all required data and survey information to the Department as requested; and

6. commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.

(k) The Department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.22

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq*****.**

HISTORY: Original Rule entitled "Specific Review Considerations for Adult Open Heart Surgery Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.22, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.23 Specific Review Considerations for Pediatric Cardiac Catheterization and Open-Heart Surgery

(1) **Definitions.**

(a) "Authorized service" means a pediatric cardiac catheterization service or pediatric cardiac surgery service that is either existing or approved. An existing service is an authorized service that has become operational, and an approved service is an authorized service that has not become operational.

(b) "Capacity" means:

1. for a pediatric catheterization service:

(i) in considering applications for a new pediatric cardiac catheterization service, 750 procedures per year per authorized service regardless of the number of rooms used; or

(ii) in considering applications for expansion of an existing service, 750 pediatric cardiac catheterization procedures per dedicated room per year in the existing service (3 per day per room, 5 days per week, 50 weeks per year) and for each multipurpose room in the existing service, 750 procedures (special procedures and pediatric cardiac catheterization procedures) per year. If adult and pediatric cardiac catheterization are performed in the same room in a service seeking to expand, the capacity of the room shall be equivalent to 750 pediatric procedures with adult procedures performed in the room weighted in proportion to pediatric procedures as being 0.50 for each adult cardiac catheterization or special procedure, except for each adult coronary angioplasty, which shall be 0.75, in order to determine the service's use rate; or

2. for a pediatric cardiac surgery service, the number of pediatric cardiac surgery procedures which could be performed annually as reported by each hospital with an authorized service and based on survey and other reported data. In determining capacity, a hospital must consider factors such as available operating rooms which can be used for pediatric cardiac surgery, cardiac surgical intensive care beds and other pediatric intensive care beds available for pediatric patients, general bed capacity, and any other factors which impact the determination.

(c) "Cardiac catheterization" means a medical diagnostic or therapeutic procedure during which a catheter is inserted into a vein or artery in the patient; subsequently, the free end of the catheter is manipulated by the physician to travel along the course of the blood vessel into the chambers or vessels of the heart. X-rays and an electronic image intensifier are used as aids in placing the catheter tip in the desired position. When the catheter is in place, the physician is able to perform various diagnostic studies and/or therapeutic procedures on the heart or its vessels.

(d) "Closed heart surgery" means an operation performed directly on the heart or its associated veins or arteries that does not require use of a heart and lung bypass machine (extracorporeal pump) to perform the work of the heart and lungs. Such operations often require the bypass machine to be available on standby for use if the surgery needs to be changed to open heart with the machine then performing the work of the heart and lungs.

(e) "Official State Component Plan" means the document related to specialized cardiovascular services developed by the Department, established by the Health Strategies Council, and adopted by the Board of Community Health.

(f) "Open heart surgery" means surgery performed directly on the heart or its associated veins or arteries during which a heart and lung bypass machine (extracorporeal pump) is used to perform the work of the heart and lungs.

(g) "Pediatric" refers to children 14 years of age and under.

(h) "Pediatric cardiac catheterization service" means an organized program which serves pediatric patients of a hospital which has a room or suite of rooms with the equipment, staff, and all support services required to perform angiographic, physiologic, and, as appropriate, therapeutic cardiac catheterization procedures. The pediatric cardiac catheterization service shall be located in a pediatric tertiary hospital. Procedures may be performed in a room dedicated to cardiac catheterization and/or in a special procedures or multipurpose room not exclusively used for cardiac catheterization.

(i) "Pediatric cardiac surgery" means an operation performed directly on a pediatric patient's heart or its associated veins or arteries, including open heart and closed heart surgery procedures but excluding surgical procedures for the closure of neonatal patent ductus arteriosus.

(j) "Pediatric cardiac surgery service" means an organized surgical program which serves pediatric inpatients of a hospital which has a suitable operating room or suite of operating rooms, equipment, staff, and all support services required to perform closed heart and open-heart operations for pediatric patients. The pediatric cardiac surgery service shall be located in a pediatric tertiary hospital.

(k) "Pediatric tertiary hospital" means a teaching center, specialty medical or large community hospital characterized by serving pediatric patients from a large region or the entire state with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients.

(l) "Procedure" means a cardiac catheterization study or treatment or combination of studies and/or treatments performed in a single session on a single patient who appears for cardiac catheterization or a pediatric open or closed heart operation or combination of operations performed in a single session on a single patient who appears for pediatric cardiac surgery.

(m) "Service area", for pediatric cardiac catheterization and pediatric cardiac surgery means the State of Georgia.

(2) **Standards**.

(a) An applicant for new pediatric cardiac catheterization and pediatric cardiac surgery services must be a pediatric tertiary hospital. Due to the highly specialized nature of pediatric cardiac catheterization and pediatric cardiac surgery services, applicants for these services must propose to provide both pediatric cardiac catheterization and pediatric cardiac surgery. Only those projects that meet all applicable standards for both services will be approved.

(b) New pediatric cardiac catheterization services shall be approved in the state only if each and all of the following conditions are met:

1. the combined use rate for all existing and approved pediatric cardiac catheterization services in the state has been at or above eighty percent (80%) of capacity for the past two (2) years as documented through surveys submitted to the Department;

2. an applicant must project that the proposed service will be operating at a minimum of one-hundred fifty (150) procedures per year within three (3) years of initiation of the service in order to maintain and strengthen skills. Such projection at a minimum shall include consideration of patient origin data and the use rate of existing services; and

3. an applicant must show that authorized pediatric cardiac catheterization services that would be impacted by the establishment of the new service are not predicted to perform less than the minimum quality level of one-hundred fifty (150) procedures annually as a result of the establishment of the new service.

(c) An application for expansion of an existing pediatric cardiac catheterization service which exceeds the capital expenditure threshold shall be approved in the state only if the applicant's existing service has operated at a use rate of at least eighty percent (80%) of capacity for each of the past two (2) years and the applicant can project a

minimum of one-hundred fifty (150) additional pediatric procedures per year within three (3) years of initiation of the service expansion and the applicant demonstrates compliance with or documents a plan and agreement to comply with the applicable provisions of Ga. Comp. R. & Regs. r. 111-2-2-.23(2)(f) through (o).

(d) New pediatric cardiac surgery services shall be approved in the state only if each and all of the following conditions are met:

1. the combined use rate of all authorized pediatric cardiac surgery services in the state has been at or above eighty percent of (80%) capacity for the past two (2) years as documented through surveys submitted to the Department;

2. an applicant must project that the proposed service will be operating at a minimum of one hundred (100) pediatric cardiac surgery procedures per year, of which at least fifty (50) are open heart operations, within three years of initiation of the service in order to maintain and strengthen skills. Such projections at a minimum shall include consideration of patient origin data and the use rate of existing services; and

3. an applicant must show that authorized pediatric cardiac surgery services which would be impacted by the establishment of the new services are not predicted to perform less than the minimum quality level of one hundred (100) procedures annually, of which at least fifty (50) are open heart operations, as a result of the establishment of the new service.

(e) An application for expansion of an existing pediatric cardiac surgery service which exceeds the capital expenditure threshold shall be approved in the state only if the applicant's existing service has operated at a use rate of at least eighty percent (80%) of capacity for each of the past two years and the applicant can project a minimum of one hundred 100 additional pediatric cardiac surgery procedures, of which at least fifty (50) are open heart operations, within three (3) years of initiation of the service expansion and the applicant demonstrates compliance with or documents a plan and agreement to comply with the applicable provisions of Ga. Comp. R. & Regs. r. 111-2-2-.23(2)(f) through (o).

(f) An applicant for a new or expanded pediatric cardiac catheterization service shall:

1. document that the applicant is a pediatric tertiary hospital, which serves pediatric patients from a large region or the entire state, with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients; and

2. document that, in addition to the basic requirements described for adult cardiac catheterization services, the hospital shall have support services and equipment necessary for the diagnosis and treatment of infants and children as specified by the American College of Cardiology and the American Academy of Pediatrics.

(g) An applicant for a new or expanded pediatric cardiac surgery service shall:

1. document that the applicant is a pediatric tertiary hospital, which serves pediatric patients from a large region or the entire state, with sophisticated technology and support services to provide highly specialized medical and surgical care for unusual and complex medical problems of pediatric patients; and

2. document that, in addition to the basic requirements described for adult open-heart surgery, the hospital shall have support services and equipment necessary for surgery on infants and children as specified by the American College of Cardiology and the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers. This includes a complete pediatric cardiology unit, a neonatal intensive care unit, a pediatric intensive care unit, and a general pediatric unit with pediatric sub-specialists in hematology, endocrinology, pulmonary neurology, and radiology.

(h) An applicant for a new or expanded pediatric cardiac catheterization service or for a new or expanded pediatric cardiac surgery service shall document that the service shall be available for the performance of procedures as needed at least eight hours per day, five days per week, and shall document the capability to rapidly mobilize the surgical and medical support teams for emergency procedures 24 hours per day, seven days per week, including a plan for utilizing this capability when needed to perform emergency procedures.

(i) An applicant for a new or expanded pediatric cardiac catheterization service and/or pediatric cardiac surgery service shall:

1. submit a written plan to the Department which, when implemented, will ensure access to services for all segments of the population in the documented and proposed service area of the applicant. Such plan shall provide a detailed strategy to reach patients not currently served within the service area, ensure continuity of care for patients transferred between facilities and shall promote planning for a continuum of cardiac services within the service area;

2. propose a heart disease prevention and clinical intervention program to be provided by the applicant or through formal referral agreements which, when implemented, shall include:

(i) A clinical intervention program for all patients that shall provide for the following in a comprehensive, systematic way:

(I) Assessment of risk factors including lipid disorders, hypertension, diabetes, obesity, cigarette smoking, and sedentary lifestyle;

(II) Assessment of risk factors and referral for appropriate care in first-degree relatives; and

(III) Assure risk management including modification of lipid disorders by diet/exercise/drugs, modification of blood pressure level by diet/exercise/drugs, control of blood glucose level by diet/exercise/drugs, dietary counseling aimed at reduced caloric and fat intake and appropriate weight management, smoking cessation, and exercise prescription. Patients should be referred to their primary care provider with documentation of treatments provided and actions recommended including preventive therapies.

(ii) The program shall provide for annual support and participation in at least three professional education programs targeted to community-based health professionals, related to heart disease risk assessment, diagnostic procedures, disease management in clinical settings, and case finding and referral strategies.

(iii) Community based heart health promotion:

(I) The program shall provide for organization of or participation in a consortium of community-based organizations to complete an assessment of heart disease risk factors in the community as well as resources available to provide programs and services. The objective of this consortium is to mobilize and coordinate resources to target at-risk populations in the community; and

(II) Organization of or participation in at least one major community-based campaign each year related to major heart disease risk factors; and

3. propose a system of outcome monitoring and quality improvement and identify at least five (5) clinical outcomes that the applicant proposes to monitor for performance on a regular basis.

(j) An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall foster an environment which assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant regardless of race, age, sex, creed, religion, disability or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the pediatric cardiac catheterization and surgical services, or the applicant may request that the Department consider allowing the commitment for services to indigent and charity to patients to be applied to the entire facility;

3. providing a written commitment to accept any patient within the facility's service area, without regard to the patient's ability to pay, unless such patient is clinically inappropriate;

4. providing a written commitment to participate in the Medicaid and PeachCare programs and to accept any Medicaid- and/or PeachCare-eligible patient for services unless such patient is clinically inappropriate;

5. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

6. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(k) An applicant for a new or expanded pediatric cardiac catheterization service shall:

1. demonstrate the intent to achieve the optimal standards established by the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers for evaluating the clinical and physical environments of cardiac catheterization services and covering professional qualifications and responsibilities, staffing requirements, supporting services, physical plant, and equipment;

2. document the availability of, or shall present a plan for recruiting, a qualified service director who is a physician, board-certified in pediatrics, with subspecialty training and board eligibility in pediatric cardiology and who is competent to perform physiologic and angiographic procedures or both; and

3. document a plan for obtaining a sufficient number of professional and technical staff for the size of the pediatric cardiac catheterization service proposed, including a pediatric nurse, radiologic technologist, cardiopulmonary technician, and darkroom technician and document that the staff required for most procedures shall be available, including two physicians, one nurse, and two technicians, with the nurse and technicians cross trained to cover technical responsibility of the monitoring and recording technicians.

(l) An applicant for a new or expanded pediatric cardiac surgery service shall comply with the following three requirements:

1. Demonstrate the intent to achieve the optimal standards established by the Advisory Council for Cardiothoracic Surgery of the American College of Surgeons, and the American Academy of Pediatrics, Guidelines for Pediatric Cardiology Diagnostic and Treatment Centers for evaluating the clinical and physical environments of cardiac surgical services and covering professional qualifications and responsibilities, staffing requirements, supporting services, physical plant, and equipment.

2. Document the availability of, or shall present a plan for recruiting, a qualified pediatric cardiac surgery director who is a pediatric cardiovascular surgeon, board-certified in thoracic surgery, with special emphasis and experience in surgery for congenital heart disease.

3. Document a plan for obtaining a sufficient number of professional and technical staff, including pediatric cardiac intensive care nurses, for the size of the pediatric cardiac surgery service proposed, including at least two board-qualified cardiac surgeons on the staff of the hospital and a cardiovascular surgical team which includes a neonatologist, a pediatric anesthesiologist, a pediatric radiologist, a pediatric cardiologist, a nurse clinician, and backup of medical social services.

(m) An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall provide documentation that the hospital is fully accredited by the Joint Commission or another nationally recognized health care accreditation body and also shall provide sufficient documentation that the hospital has no history of significant licensure deficiencies and no history of conditional level Medicare and Medicaid certification

deficiencies in the past three (3) years and has no outstanding licensure and Medicare and Medicaid certification deficiencies.

(n) An applicant for new or expanded pediatric cardiac catheterization and pediatric cardiac surgery services shall demonstrate that the applicant's charges and/or reimbursement for pediatric cardiac catheterization and pediatric cardiac surgery services shall compare favorably with charges and/or reimbursement in existing pediatric cardiac catheterization and pediatric cardiac surgery services in the state, when adjusted for annual inflation.

(o) An applicant for new or expanded pediatric cardiac catheterization and/or pediatric cardiac surgery services must agree in writing to the following conditions:

1. establishment and maintenance of a system of continuity of care and coordination of service, as evidenced by regular and ongoing planning and quality improvement sessions with community health providers and advocacy programs;

2. participation in a data reporting, quality improvement, outcome monitoring, and peer review system within the applicant hospital as well as a national, state or multi-hospital system which benchmarks outcomes based on national norms and which shall be named in the application and which provides for peer review between and among professionals practicing in facilities and programs other than the applicant hospital;

3. development of procedures to ensure that any surgeon or cardiologists authorized to perform pediatric cardiac services for the hospital shall be required to accept Medicaid and PeachCare payment for services without discrimination;

4. commitment that charges for services shall be reasonable and comparable to other providers in the state and the service area;

5. provision of all required data and survey information to the Department as requested; and

6. commitment to act in good faith to fulfill all provisions and commitments documented in the application for a new or expanded service.

(p) The Department may revoke a Certificate of Need after notice to the holder of the certificate and a fair hearing pursuant to the Georgia Administrative Procedure Act for failure to comply with the defined scope, location, cost, service area, and person named in an application as approved by the Department and for the intentional provision of false information to the Department by an applicant in that applicant's application.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.23

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq.***

HISTORY: Original Rule entitled "Specific Review Considerations for Pediatric Cardiac Catheterization and Open Heart Surgery" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: New title, "Specific Review Considerations for Pediatric Cardiac Catheterization and Open-Heart Surgery." F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.23, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.24 Specific Review Considerations for Perinatal Services

(1) **Applicability.** For Certificate of Need purposes, Basic Perinatal Services, Neonatal Intermediate Care Services (Specialty/Level II), and Neonatal Intensive Care Services (Subspecialty/Level III) shall be defined as new institutional health services.

(2) **Definitions.**

(a) "Basic Perinatal Services (Level I)" means providing basic inpatient care for pregnant women and newborns without complications; managing perinatal emergencies; consulting with and referring to specialty and subspecialty hospitals; identifying high-risk pregnancies; providing follow-up care for new mothers and infants; and providing public/community education on perinatal health.

(b) "Most recent year" means the most current twelve-month period within a month of the date of completion of an application or within a month of the date of completion of the first application when applications are joined. If the Department has conducted a survey within six (6) months of the date of completion of the first application when applications are joined, the Department may consider the most recent year to be the report period covered by the prior survey.

(c) "Neonatal Intensive Care Service (Subspecialty/Level III)" means a hospital service that meets the requirements for a Neonatal Newborn Care Service and meets the definition of a Subspecialty Perinatal Hospital Service as contained in the most recent edition of the Recommended Guidelines for Perinatal Care in Georgia, as published by the Council on Maternal & Infant Health.

(d) "Neonatal Intermediate Care Service (Specialty/Level II)" means a hospital service that meets the requirements for a Neonatal Newborn Care Service and meets the definition of a Specialty Perinatal Hospital Service as contained in the most recent edition of the Recommended Guidelines for Perinatal Care in Georgia, as published by the Council on Maternal & Infant Health.

(e) "Neonatal Newborn Care Service (Basic/Level I)" means a hospital service which meets the minimum standards contained in Chapter 111-8-40 of the Rules of the Healthcare Facility Regulation Division, such chapter being entitled "Newborn Service. Amended."

(f) "Obstetric Service" means a hospital service that meets the minimum standards contained in Chapter 111-8-40 of the Rules of the Healthcare Facility Regulation Division, such chapter being entitled "Maternity and Obstetric Service. Amended."

(g) "Official Inventory" means the inventory for each hospital of Basic Perinatal Service and Neonatal Intermediate and Intensive Care Service beds maintained by the Department based upon responses to the Annual Hospital Questionnaire (AHQ) and/or its Perinatal Addendum and any Certificate of Need approved beds after the period covered by the AHQ and with the following provisions:

1. the official inventory for each facility will remain unchanged for the year following the last day of the report period on each hospital's completed AHQ and/or its Perinatal Addendum unless the Department approves a change of bed capacity through the Certificate of Need process; and

2. the capacity of existing freestanding birthing centers will not be counted as part of the official inventory of available services when computing unmet numerical need for Basic Perinatal Services in a planning area.

(h) "Perinatal physician training program" refers to obstetrics and gynecology, family practice and pediatrics disciplines.

(i) "Planning Areas" means fixed sub-state regions for reviewable services as defined in the State Health Component Plan for Perinatal Services.

(j) "Regional Perinatal Center" (RPC) means those hospitals designated by the Department of Public Health to serve a defined geographic area to provide the highest level of comprehensive perinatal health care services for pregnant women, their fetuses and neonates of all risk categories. The RPC accepts patients in need of these services from its

region regardless of race, creed, religion, ability to pay, or funding source. The RPC provides consultation and transport for patients requiring special services; coordination and assurance of follow-up medical care for maternal and neonatal patients requiring special care; educational support to ensure quality care in institutions involved in perinatal health care; compilation, analysis, and evaluation of perinatal data from the center and referring hospitals and coordination of perinatal health care within the region.

(k) "Urban County" means a county with a projected population for the horizon year of 100,000 or more and a population density for that year of 200 or more people per square mile. All other counties are "rural."

(3) **Standards.**

(a) The need for a new or expanded Obstetric Service, Neonatal Intermediate Care Service and Neonatal Intensive Care Service shall be determined through application of a Numerical Need method and an assessment of the aggregate occupancy rate of existing services.

1. The numerical need for a new or expanded Obstetric Service in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:

(i) Calculate the average obstetric utilization rate (UR) by dividing the obstetric days (OBDays) reported by hospitals for the two most recent 12-month reporting periods of the Annual Hospital Questionnaire and/or its Perinatal Addendum by the female population ages 15 to 44 (FP) for the corresponding years:

$$UR = \frac{OBDays_1 + OBDays_2}{FP_{YR}1 + FP_{YR}2}$$

(ii) Multiply the obstetric utilization rate by the projected female population ages 15 to 44 (PFP) for the horizon year to determine the number of projected obstetric days (POBDays):

$$POBDays = URxPFP$$

(iii) Calculate the number of projected obstetric beds (POBBeds) by dividing the number of projected obstetric days by 273.75 (the result of 365 days multiplied by the occupancy standard of seventy-five percent (75%)) with any fraction rounded up to a whole bed:

$$POBBeds = \frac{POBDays}{273.75}$$

(iv) Determine the net numerical unmet need (UN) for new or additional obstetric beds by subtracting the number of beds in the Official Inventory (OI) from the number of projected obstetric beds:

$$UN = POBBeds - OI$$

2. The numerical need for a new or expanded Level II Neonatal Intermediate Care Service in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps below, and all data elements relate to each planning area:

(i) Calculate the average resident live-birth rate (ABR) using the sum of the resident live births (RB) for the three most recent calendar years available from the Department of Public Health or other official source divided by the corresponding years' female population ages 15 to 44 (FP):

$$ABR = \frac{RB_1 + RB_2 + RB_3}{FP_{YR}1 + FP_{YR}2 + FP_{YR}3}$$

(ii) Determine the number of projected resident live births (PRB) for the horizon year by multiplying the average resident live-birth rate by the estimated female population ages 15 to 44 (PFP) for the horizon year:

$$PRB = ABRxPFP$$

(iii) Calculate the projected number of neonatal intermediate care patient days (PN2Days) in the horizon year by multiplying the average number of patient days (N2Days) in neonatal intermediate care beds reported by hospitals for the two most recent 12-month reporting periods of the Annual Hospital Questionnaire and/or its Perinatal Addendum by the number of projected resident live births divided by the actual number of resident live births (RB) available from the Department of Public Health or other official source for the most recent calendar year:

$$PN2Days = N2Daysx\frac{PRB}{RB}$$

(iv) Project neonatal intermediate care bed need (N2Beds) into the horizon year by dividing the projected patient days for neonatal intermediate care services by 292 (the result of 365 days multiplied by the occupancy rate of eighty percent (80%)) with any fraction rounded up to a whole bed:

$$N2Beds = PN2\frac{Days}{292}$$

(v) To determine unmet numerical bed need (UN), subtract the official inventory (OI) from the projected neonatal intermediate care bed need:

$$UN = N2Beds - OI$$

3. The numerical need for a new or expanded Level III Neonatal Intensive Care Service in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps below, and all data elements relate to each planning area:

(i) Calculate the average resident live-birth rate (ABR) using the sum of the resident live births (RB) for the three most recent calendar years available from the Department of Public Health or other official source divided by the corresponding years' female population ages 15 to 44 (FP):

$$ABR = \frac{RB_1 + RB_2 + RB_3}{FP_{YR}1 + FP_{YR}2 + FP_{YR}3}$$

(ii) Determine the number of projected resident live births (PRB) for the horizon year by multiplying the average resident live-birth rate by the estimated female population ages 15 to 44 (PFP) for the horizon year:

$$PRB = ABRxPFP$$

(iii) Calculate the projected number of neonatal intensive care patient days (PN2Days) in the horizon year by multiplying the average number of patient days (N2Days) in neonatal intensive care beds reported by hospitals for the two most recent 12-month reporting periods of the Annual Hospital Questionnaire and/or its Perinatal Addendum by the number of projected resident live births divided by the actual number of resident live births (RB) available from the Department of Public Health or other official source for the most recent calendar year:

$$PN2Days = N2Daysx\frac{PRB}{RB}$$

(iv) Project neonatal intensive care bed need (N2Beds) into the horizon year by dividing the projected patient days for neonatal intensive care services by 292 (the result of 365 days multiplied by the occupancy rate of eighty percent (80)) with any fraction rounded up to a whole bed:

$$N2Beds = PN2\frac{Days}{292}$$

(v) To determine unmet numerical bed need (UN), subtract the official inventory (OI) from the projected neonatal intensive care bed need:

$$UN = N2Beds - OI$$

4. Prior to approval of a new or expanded Obstetric Service, Neonatal Intermediate Care Service or Neonatal Intensive Care Service in a planning area, the aggregate occupancy rate for all similar services in that planning area shall equal or exceed seventy-five percent (75%) for an Obstetric Service and eighty percent (80%) for a Neonatal Intermediate Care Service or Neonatal Intensive Care Service for each of the two (2) most recent years.

(b) Exceptions to need may be considered by the Department as follows:

1. To provide that an applicant for new basic perinatal services shall not be subject to the need standard of section (3)(a)1. or the aggregate occupancy standard of section (3)(a)4. of this Rule if:

(i) The proposed new service would be located in a county where only one civilian health care facility or health system is currently providing basic perinatal services; and

(ii) There are not at least three (3) different health care facilities in a contiguous county providing basic perinatal services.

2. To allow expansion of an existing Level I or Level II or Level III service, if the actual utilization of that service has exceeded 80 percent occupancy over the most recent two years; or

3. To remedy an atypical barrier to perinatal services based on cost, quality, financial access, or geographic accessibility. An applicant seeking such an exception shall have the burden of proving to the Department that the cost, quality, financial access, or geographic accessibility of current services, or some combination thereof, result in a barrier to services that should typically be available to citizens in the planning area and/or the communities under review. In approving an applicant through the exception process, the Department shall document the bases for granting the exception and the barrier or barriers that the successful applicant would be expected to remedy.

(c) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care or Neonatal Intensive Care Service shall document the impact on existing and approved services in the planning area with the goal of minimizing adverse impact on the delivery system and as follows:

1. An existing perinatal physician training program shall not be adversely impacted by the establishment of a new or expanded perinatal service to the extent that the existing service could not sustain a sufficient number and variety of patients to maintain an appropriate number of providers and provider competencies and the training program's accreditation and funding status;

2. An existing nurse midwifery training program shall not be adversely impacted by the establishment of a new or expanded perinatal service to the extent that the existing service could not sustain an appropriate number of providers and provider competencies to sustain a sufficient number and variety of patients to maintain the training program's accreditation; and

3. An existing regional perinatal center shall not be adversely impacted by the establishment of a new or expanded perinatal service to the extent that the existing service could not sustain a sufficient volume and case mix of patients including both low risk and high risk deliveries to maintain its regional center status.

(d) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall foster an environment that assures access to services to individuals unable to pay and regardless of payment source or circumstances by the following:

1. providing evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis;

2. providing a written commitment that unreimbursed services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the entire facility after Medicare and Medicaid contractual adjustments and bad debt have been deducted;

3. providing a written commitment to participate in the Medicaid program;

4. providing a written commitment to participate in any other public reimbursement programs available for perinatal services for which the hospital is eligible; and

5. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to individuals unable to pay based on the past record of service to Medicare, Medicaid, and indigent and charity patients, including the level of unreimbursed indigent and charity care.

(e) The desired minimum bed size for a Basic Perinatal Service, Neonatal Intermediate Care Service or Neonatal Intensive Care Service is as follows:

1. At least four beds for a new Basic Perinatal, Neonatal Intermediate Care, or Neonatal Intensive Care Service.

2. The Department may grant an exception to these standards when the Department determines that unusual circumstances exist that justify such action.

(f) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall provide evidence of ability to meet the following continuity of care standards:

1. Document a plan whereby the hospital and its medical staff agree to provide a full array of perinatal services to the community, including but not limited to community education and outreach, prenatal, intrapartum, postpartum, newborn, and postnatal services; and

2. As appropriate, provide a formal transfer agreement with at least one hospital within reasonable proximity that provides services to high-risk mothers and babies.

(g) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall provide evidence of the ability to meet the following quality of care standards:

1. evidence that qualified personnel will be available to ensure a quality service to meet licensure, certification and/or accreditation requirements;

2. written policies and procedures for utilization review consistent with state, federal and other accreditation standards. This review shall include assessment of medical necessity for the service, quality of patient care, and rates of utilization;

3. written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division; and

4. evidence that there are no uncorrected operational standards in any existing Georgia hospitals owned and/or operated by the applicant or the applicant's parent organization. Plans of correction in the applying facility must be included in the application.

(h) An applicant for a new or expanded Basic Perinatal Service or Neonatal Intermediate Care Service or Neonatal Intensive Care Service shall document an agreement to provide Department requested information and statistical data related to the operation and provision of services and to report that data to the Department in the time frame and format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.24

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq.***

HISTORY: Original Rule entitled "Specific Review Considerations for Perinatal Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

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Note: Rule 111-2-2-.24, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.25 Specific Review Considerations for Freestanding Birthing Centers

(1) A Certificate of Need for a proposed new freestanding birthing center will be issued only if the services to be provided are consistent with the philosophy of family-centered care as defined in the State Health Plan and if there is evidence of safe and quality service at a charge lower than charges for deliveries provided on an inpatient basis.

(2) The applicant must agree to meet the rules and regulations for the development and operation of birthing centers required by the Healthcare Facility Regulation Division.

(3) The applicant must provide evidence that the birthing center will function as part of the established regionalized system of perinatal care. This includes arrangements for referral of those clients who develop complications that make them ineligible for delivery at the birthing center.

(4) A birthing center must have a written agreement for transfer and emergency services with a backup hospital(s) that provides at least Level II perinatal services. Each physician practicing at the center must have admitting privileges at the backup hospital.

(5) It must be demonstrated that agreements for ambulance service are available. In emergency situations, the center must have the capability of transporting the adult and/or newborn patients to the backup hospital within 30 minutes from initiation of transfer to the arrival at the hospital.

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13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.26 Specific Review Considerations for Psychiatric and Substance Abuse Inpatient Programs

(1) **Applicability.**

(a) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing acute care adult psychiatric and/or substance abuse inpatient program. An application for Certificate of Need for a new or expanded acute care adult psychiatric and/or substance abuse inpatient program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule. For purposes of these Rules, a service, facility, or program approved as an acute care adult psychiatric and/or substance abuse inpatient program may offer both acute care psychiatric and acute care substance abuse inpatient care, acute care substance abuse inpatient care alone, or acute care psychiatric inpatient care alone. A facility approved to offer acute care adult psychiatric and/or substance abuse inpatient services may not offer an acute care pediatric psychiatric and/or substance abuse inpatient program, nor any type of extended care psychiatric and/or substance abuse program without first obtaining a Certificate of Need.

(b) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing acute care pediatric psychiatric and/or substance abuse inpatient program. An application for Certificate of Need for a new or expanded acute care pediatric psychiatric and/or substance abuse inpatient program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule. For purposes of these Rules, a service, facility, or program approved as an acute care pediatric psychiatric and/or substance abuse inpatient program may offer both acute care psychiatric and acute care substance abuse inpatient care, acute care substance abuse inpatient care alone, or acute care psychiatric inpatient care alone. A facility approved to offer acute care pediatric psychiatric and/or substance abuse inpatient services may not offer an acute care adult psychiatric and/or substance abuse inpatient program, nor any type of extended care psychiatric and/or substance abuse program without first obtaining a Certificate of Need.

(c) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing extended care adult psychiatric and/or substance abuse inpatient program. An application for Certificate of Need for a new or expanded extended care adult psychiatric and/or substance abuse inpatient program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule. For purposes of these Rules, a service, facility, or program approved as an extended care adult psychiatric and/or substance abuse inpatient program may offer both extended care psychiatric and extended care substance abuse inpatient care, extended care substance abuse inpatient care alone, or extended care psychiatric inpatient care alone. A facility approved to offer extended care adult psychiatric and/or substance abuse inpatient services may not offer an extended care pediatric psychiatric and/or substance abuse inpatient program, nor any type of acute care psychiatric and/or substance abuse program without first obtaining a Certificate of Need.

(d) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing extended care pediatric psychiatric and/or substance abuse inpatient program. An application for Certificate of Need for a new or expanded extended care pediatric psychiatric and/or substance abuse inpatient program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule. For purposes of these Rules, a service, facility, or program approved as an extended care pediatric psychiatric and/or substance abuse inpatient program may offer both extended care psychiatric and extended care substance abuse inpatient care, extended care substance abuse inpatient care alone, or extended care psychiatric inpatient care alone. A facility approved to offer extended care pediatric psychiatric and/or substance abuse inpatient services may not offer an extended care adult psychiatric and/or substance abuse inpatient program, nor any type of acute care psychiatric and/or substance abuse program without first obtaining a Certificate of Need.

(2) **Definitions**.

(a) "Acute care psychiatric and/or substance abuse inpatient program", for purposes of these Rules, means a psychiatric or substance abuse program, as defined in Ga. Comp. R. & Regs. r. 111-2-2-.26(1)(a), that provides acute and/or emergency stabilization and other treatment for acute episodes. An acute care program provides medically oriented evaluation, diagnosis, stabilization, and short-term treatment using individual and/or group therapies as well as other treatment activities. Two acute care programs are defined: adult psychiatric and/or substance abuse and pediatric psychiatric and/or substance abuse.

(b) "Adult", for purposes of these Rules, means a person 18 years of age and over or an emancipated person.

(c) "Expansion" or "Expanded" means exceeding a health care facility's total approved inpatient bed capacity through the addition of beds to an existing CON-authorized or grandfathered psychiatric and/or substance abuse inpatient program. A CON-authorized or grandfathered freestanding psychiatric and/or substance abuse hospital may request a letter of determination to increase its bed capacity by the lesser of ten percent (10%) of existing capacity or ten (10) beds if it has maintained an average occupancy of eighty-five percent (85%) for the previous twelve (12) calendar months provided that there has been no such increase in the prior two (2) years and provided that the capital expenditures associated with the increase do not exceed the Capital Expenditure Threshold. If such an increase exceeds the Capital Expenditure Threshold, a Certificate of Need shall be required under these Rules.

(d) "Extended care psychiatric and/or substance abuse inpatient program", for purposes of these Rules, means a psychiatric or substance abuse program, as defined in Ga. Comp. R. & Regs. r. 111-2-2-.26(1)(a), that focuses on self-help and basic living skills to enhance the patient's abilities to perform successfully in society upon discharge by emphasizing psycho-social, vocational and/or prevocational, and educational components in its treatment plan. The program is designed to treat people who do not require acute care and who usually have already had at least one acute care admission. Due to this design, the staffing of extended care programs is different from that of acute care programs by having proportionately more therapeutic activities, educational, and social work staff and proportionately fewer nurses and physicians. Two extended care programs are defined: adult psychiatric and/or substance abuse and pediatric psychiatric and/or substance abuse.

(e) "Freestanding psychiatric and/or substance abuse hospital", for purposes of these Rules, means a self-contained hospital which provides only psychiatric and/or substance abuse treatment and is licensed as a separate hospital, either as a specialized hospital or specialized hospital/intensive residential treatment facility.

(f) "Inpatient" means services that are provided to patients admitted to a short-stay general hospital, specialized hospital, or specialized hospital/intensive residential treatment facility.

(g) "New" means a psychiatric and/or substance abuse inpatient program that has not offered a similar program in the prior twelve (12) months. Adult programs and pediatric programs and acute care programs and extended care programs shall each be considered independent programs such that a provider seeking to add a program not offered by that provider in the previous twelve (12) months shall be considered to be offering a new program for which a Certificate of Need must be obtained. For purposes of these Rules, an existing program which proposes to be relocated to a location more than three miles from its present location shall be considered "new".

(h) "Pediatric", for purposes of these Rules, means a person seventeen (17) years of age and under or persons age twenty-one (21) or under as clinically indicated.

(i) "Planning Region" means one of the twelve state service delivery regions established by O.C.G.A. § 50-4-7.

(j) "Psychiatric and/or substance abuse inpatient program", for purposes of these Rules, means an organized entity with a specific plan and intent to serve a special population via designated staff in designated beds in a licensed hospital. Such a program provides services on a 24-hour, seven days per week basis. The characteristics of a program shall include:

1. a clear, distinct plan which includes admission policies and criteria, treatment protocol, etc.; and

2. appropriately trained personnel for the age and disability group to be served by the program; and

3. all of the beds in a program are designated for patients in that specific program.

(k) "Psychiatric and/or substance abuse service", for purposes of these Rules, means any combination of organized psychiatric and substance abuse programs in a hospital.

(l) "Public sector bed", for purposes of these Rules, means a bed located in state owned and operated psychiatric and substance abuse regional hospitals which are maintained by the Department of Behavioral Health & Developmental Disability.

(m) "Similar existing and approved program", for purposes of these Rules, means an approved or existing organized program as defined in Ga. Comp. R. & Regs. r. 111-2-2-.26(1)(a) that provides services to the same age group (adults or pediatric), and for the same treatment model (acute or extended).

(3) **Standards.**

(a) An application for a new or expanded psychiatric and/or substance abuse inpatient program(s) shall provide sufficient documentation of the need for such program(s) in the planning area. In the case of an application for an expanded psychiatric and/or substance abuse inpatient program, the applicant shall justify the need for the expansion by, at a minimum, documenting that the expansion program has achieved an occupancy rate of eighty percent (80%) for an adult program or an occupancy rate of seventy percent (70%) for a pediatric program for the most recent twelve (12) months prior to submitting an application, except that a pediatric program which has obtained an occupancy rate of sixty-five percent (65%) may be permitted to expand if such program demonstrates clinical reasons why seventy percent (70%) occupancy is not attainable.

(b) An application for a new or expanded psychiatric and/or substance abuse inpatient program(s) in an existing hospital shall not be approved unless the applicant provides sufficient documentation that it is not appropriate to convert existing hospital beds to beds designated for the proposed program(s) or to close existing hospital beds.

(c) An applicant for a new or expanded psychiatric and/or substance abuse inpatient program(s) shall document that the establishment or expansion of its program(s) will not have an adverse impact on similar existing and approved programs in its planning area. State-owned and -operated psychiatric and substance abuse regional hospitals shall not be required to document this standard.

1. Accounting for market share and future population growth, an applicant for a new or expanded adult psychiatric and/or substance abuse inpatient program(s) shall have an adverse impact on similar existing and approved programs if it will:

(i) decrease annual utilization of a similar existing program, whose current utilization is at or above eighty-five percent (85%), to a projected annual utilization of less than seventy-five percent (75%) within the first twenty-four (24) months following the acceptance of the applicant's first patient; or

(ii) decrease annual utilization of a similar existing program, whose current utilization is below eighty-five percent (85%), by ten percent (10%) over the twenty-four (24) months following the acceptance of the applicant's first patient.

2. Accounting for market share and future population growth, an applicant for a new or expanded pediatric psychiatric and/or substance abuse inpatient program(s) shall have an adverse impact on similar existing and approved programs if it will:

(i) decrease annual utilization of a similar existing program, whose current utilization is at or above eighty-five percent (85%), to a projected annual utilization of less than eighty percent (80%) within the first twenty-four (24) months following the acceptance of the applicant's first patient; or

(ii) decrease annual utilization of a similar existing program, whose current utilization is below eighty-five percent (85%), by five percent (5%) over the twenty-four (24) months following the acceptance of the applicant's first patient.

(d) A new psychiatric and/or substance abuse inpatient program(s) shall have the following minimum bed sizes based on type of program offered:

1. The minimum bed size of a new acute psychiatric and/or substance abuse program is eight beds.

2. The minimum bed size of a new extended care psychiatric and substance abuse inpatient program is eight beds.

3. The minimum bed size of a new freestanding psychiatric and/or substance abuse hospital primarily providing acute care and licensed as a specialized hospital is 50 beds.

4. The minimum bed size of a new freestanding psychiatric and/or substance abuse hospital primarily providing extended care and licensed as a specialized hospital or a specialized hospital/intensive residential treatment facility is 50 beds.

5. The minimum number of designated beds in the aggregate of any and all acute psychiatric and/or substance abuse programs in a general hospital is ten beds.

6. The minimum number of designated beds in the aggregate of any and all extended care psychiatric and substance abuse inpatient programs in a general hospital is ten beds.

(e) An applicant for a new psychiatric and/or substance abuse inpatient program(s) shall demonstrate the intent to meet the standards of the Joint Commission or another nationally recognized health care accreditation body applicable to the type of program to be offered within twelve (12) months of offering the new program. Extended care programs may demonstrate their intent to meet the standards of the Council on the Accreditation of Rehabilitation Facilities (CARF) or the Council on Accreditation (COA) in lieu of the Joint Commission or another nationally recognized health care accreditation body.

(f) An applicant for an expanded psychiatric and/or substance abuse inpatient program(s) shall be accredited by the Joint Commission for the type of program which the applicant seeks to expand prior to application. The applicant must provide proof of such accreditation. Extended care programs may be accredited by the Council on the Accreditation of Rehabilitation Facilities (CARF) or the Council on Accreditation (COA) in lieu of the Joint Commission or another nationally recognized health care accreditation body.

(g) An applicant for a new freestanding psychiatric hospital or intensive residential treatment facility shall demonstrate the intent to meet the licensure Rules of the Healthcare Facility Regulation Division for such facilities.

(h) An applicant for an expanded freestanding psychiatric hospital or intensive residential treatment facility shall demonstrate a lack of uncorrected deficiencies as documented by letter from the Healthcare Facility Regulation Division.

(i) An applicant for a new or expanded psychiatric and/or substance abuse inpatient program(s) shall provide documentation that the applicant has no uncorrected history of conditional level Medicare and Medicaid certification deficiencies in the past three years.

(j) An applicant for a new or expanded psychiatric and/or substance abuse inpatient program(s) shall provide sufficient documentation that the proposal is consistent with the following quality standards:

1. The program(s) shall maintain standards for the review and improvement of quality. To document such standards, the program(s) must submit quality improvement policies.

2. The program(s) shall maintain standards to ensure the continuity of patient care. To document such standards, the program(s) must submit policies governing admissions and availability of adequate discharge planning.

(k) An applicant for a new or expanded freestanding psychiatric and/or substance abuse inpatient program(s) shall document the existence of referral arrangements, including transfer agreements, with an acute-care hospital(s) within

the planning region to provide emergency medical treatment to any patient who requires such care. If the nearest acute-care hospital is in an adjacent planning region, the applicant may document the existence of transfer agreements with that hospital in lieu of such agreements with a hospital located within the planning region.

(l) An applicant for a new or expanded acute or extended care psychiatric and/or substance abuse program(s) shall document that the program(s) will be financially accessible by:

1. providing sufficient documentation that unreimbursed services for indigent and charity patients in a new or expanded program(s) will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the program after provisions have been made for bad debt, and Medicaid and Medicare contractual adjustments have been deducted. If an applicant, or any facility in Georgia owned or operated by the applicant's parent organization, received a Certificate of Need for a hospital program(s) or service(s) or a total facility and the CON included an expectation that a certain level of unreimbursed indigent and/or charity care would be provided in the program(s), service(s), or hospital(s), the applicant shall provide sufficient documentation of the facility's(ies') provision of such care. An applicant's history, or the history of any facility in Georgia owned or operated by the applicant's parent organization, of not following through with a specific CON expectation of providing indigent and/or charity care at or above the expected level will constitute sufficient justification to deny an application; and

2. agreeing to participate in the Medicare and Medicaid programs, whenever these programs are available to the facility.

(m) Reserved.

(n) An applicant for a new or expanded psychiatric and/or substance abuse inpatient program(s) shall agree to provide the Department with requested information and statistical data related to the operation of such a program(s) on a yearly basis, or as needed, and in a format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.26

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq.***

HISTORY: Original Rule entitled "Specific Review Considerations for Psychiatric and Substance Abuse Inpatient Programs" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Nov. 22, 2006; eff. Dec. 12, 2006.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.26, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.30 Specific Review Considerations for Skilled Nursing and Intermediate Care Facilities

(1) **Applicability**. A Certificate of Need will be required prior to the establishment of a new or expanded skilled nursing facility, intermediate care facility, or an intermingled facility.

(2) **Definitions.**

(a) "Horizon year" means the last year of the three-year projection period for need determinations for a nursing facility.

(b) "Hospital-based nursing facility" means a nursing facility which meets the current definition of "Hospital-Based Nursing Facilities" as defined in the current Policies and Procedures for Nursing Facility Services by the Georgia Department of Community Health, Division of Medical Assistance. A new hospital-based nursing facility can only result from conversion of existing inpatient space on the hospital's campus.

(c) "Intermediate care facility" ("ICF") means an institution which provides, on a regular basis, health related care and services to individuals who do not require the degree of care and treatment which a hospital or skilled nursing facility is designed to provide but who, because of their mental or physical condition, require health related care and services beyond the provision of room and board.

(d) "Intermingled facility" means a nursing facility that provides both skilled intermediate levels of care.

(e) "Medicare distinct part skilled nursing unit" means a unit which meets the current definition of "Distinct Part of an Institution as SNF" as defined in the current Medicare Part A Intermediary Manual by the Centers for Medicare and Medicaid Services ("CMS") of the U.S. Department of Health and Human Services.

(f) "Nursing facility" means a facility classified as either a skilled nursing facility, an intermediate care facility or an intermingled facility which admits patients by medical referral and provides for continuous medical supervision via 24-hour-a-day nursing care and related services in addition to food, shelter, and personal care.

(g) "Official State Health Component Plan" means the document related to the above-named services developed by the Department, established by the Georgia State Health Strategies Council, and adopted by the Board of Community Health.

(h) "Planning area" for all nursing facilities, with the exception of state nursing facilities, means the geographic regions in Georgia defined in the "Official State Health Component Plan". "Planning area for a state nursing facility" means the State of Georgia.

(i) "Retirement community-based nursing facility" means a nursing facility which operates as a lesser part of a retirement community which is a planned, age-restricted, congregate living development which offers housing, recreation, security, dietary services, and shared living areas accessible to all residents.

(j) "Skilled nursing facility" ("SNF") means a public or private institution or a distinct part of an institution which is primarily engaged in providing inpatient skilled nursing care and related services for patients who require medical or nursing care or rehabilitation services for the rehabilitation of the injured, disabled or sick persons.

(k) "State nursing facility" is a facility that meets the definition of a Nursing Facility as defined above and is owned and operated by a branch or branches of government of the State of Georgia.

(l) "Urban county" means a county with a projected population for the horizon year of 100,000 or more and population density for that year of 200 or more people per square mile. All other counties are "rural".

(3) **Standards**.

(a) The need for a new or expanded nursing facility in a planning area in the horizon year shall be determined through application of a numerical, supply-oriented need method and an assessment of current planning area utilization designed to measure demand for services.

1. The numerical need for a new or expanded nursing facility in any planning area in the horizon year shall be determined by a population-based formula which is a sum of the following:

(i) a ratio of 0.43 beds per 1,000 projected horizon year Resident population age 64 and younger;

(ii) a ratio of 9.77 beds per 1,000 projected horizon year Resident population age 65 through 74;

(iii) a ratio of 32.5 beds per 1,000 projected horizon year Resident population age 75 through 84; and

(iv) a ratio of 120.00 beds per 1,000 projected horizon year Resident population age 85 and older.

2. The demand for services in each planning area will be measured by the cumulative facility bed utilization rate during the most recent survey year period. The utilization rate shall be determined by dividing the actual bed days of resident care by the bed days available for resident care.

3. In order to establish need for a new or expanded nursing facility in any planning area, the utilization rate in that planning area shall have equaled or exceeded ninety-five percent (95%) during the most recent survey year.

(b) The required bed size for a new nursing facility in a rural or urban county is as follows: (Rural/urban designation shall be based on the county within which the proposed facility is to be located.)

1. A freestanding nursing facility in a rural county: a minimum of 60 beds;

2. A freestanding nursing facility in an urban county: a minimum of 100 beds;

3. A hospital-based nursing facility in a rural county: a minimum of 10 beds and a maximum of 20 beds;

4. A hospital-based nursing facility in an urban county: a minimum of 20 beds and a maximum of 40 beds;

5. A retirement community-based nursing facility: 1 nursing home bed for each 4 residential units, with a minimum of 20 beds and a maximum of 30 beds.

(c) In competing applications, favorable consideration may be given for the inclusion of services for special needs populations, such as but not limited to, persons with Alzheimer's Disease and related disorders, medically fragile children, or persons with HIV/AIDS. An applicant must document a need for the service and that it is cost effective.

(d) The Department may allow an exception to Ga. Comp. R. & Regs. r. 111-2-2-.30(3)(a) under the following circumstances:

1. the establishment of a new Medicare distinct part skilled nursing unit if the proposed unit is to be in a county that does not have an existing Medicare unit; and if the applicant can document that there is limited access in the proposed planning area for skilled nursing services for Medicare patients. Limited access means that existing nursing facilities have not provided the proposed services in response to a demonstrated demand for the services over the three (3) most recent years. The implementation of an approved Certificate of Need will be valid only if the proposed beds will be limited to Medicare recipients. This exception is available to existing nursing facilities and hospitals; or

2. the applicant for a new or expanded nursing facility can show that there is limited access in the proposed geographic service area for special groups such as, but not limited to medically fragile children and HIV/AIDS patients. Limited access means that existing nursing facilities have not provided the proposed services in response to a demonstrated demand for the services over the three (3) most recent years.

(e) An applicant for a new or expanded facility must document provision of continuity of care by meeting each of the following:

1. An applicant shall provide a community linkage plan which demonstrates factors such as, but not limited to, referral arrangements with appropriate services of the healthcare system and working agreements with other related community services assuring continuity of care; and

2. An applicant shall document the existence of proposed and/or existing referral agreements with a nearby hospital to provide emergency services and acute-care services to residents of the proposed or existing facility; and

3. An applicant shall provide existing or proposed rehabilitation plans for services to facility residents; and

4. An applicant shall provide existing or proposed discharge planning policies.

(f) An applicant for a new or expanded nursing facility must provide evidence of the intent to meet all appropriate requirements regarding quality of care as follows:

1. An applicant shall provide a written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division;

2. An applicant shall provide evidence that there are no uncorrected operational standards in any existing Georgia nursing homes owned and/or operated by the applicant or by the applicant's parent organization. Plans to correct physical plant deficiencies in the applying facility must be included in the application;

3. An applicant and any facility owned and/or operated by the applicant or its parent organization shall have no previous conviction or Medicaid or Medicare fraud;

4. An applicant shall demonstrate the intent and ability to recruit, hire and retain qualified personnel to meet the current Medicaid certification requirements of the Department's Division of Medical Assistance for the services proposed to be provided and that such personnel are available in the proposed geographic service area;

5. An applicant shall provide a plan for a comprehensive quality improvement program that includes, but is not limited to, procedures and plans for staff training and a program to monitor specific quality indicators and measure the facility's performance; accordingly, and

6. In competing applications, favorable consideration will be given to an applicant that provides evidence of the ability to meet accreditation requirements of appropriate accreditation agencies within two years after the facility becomes operational.

(g) An applicant or a new or expanded facility must provide evidence of meeting the following standards pertaining to financial accessibility:

1. An applicant shall provide a written commitment of intent to participate in the Medicaid and Medicare programs if appropriate;

2. An applicant shall demonstrate a case-mix of Medicaid, Medicare and private pay patients; and

3. Document policies and practices of nondiscrimination by past performance of the applicant or its parent organization.

(h) A new or expanded state nursing facility may be exempted from the provisions of Ga. Comp. R. & Regs. r. 111-2-2-.30(3)(a), (b), (c), (d), and (g) when the facility meets all of the following criteria:

1. documentation that the proposed facility will meet the definition of a state nursing facility as defined in Ga. Comp. R. & Regs. r. 111-2-2-.30(1)(k);

2. documentation that the applicant will admit patients from any of Georgia's counties with a primary focus on a pre-designated, multi-county service area or region;

3. the facility intends to become accessible to patients whose care, because of income and other limitations, would normally come under the jurisdiction of the state; and

4. such other considerations as may be considered necessary by the Department at the time of the application.

(i) An applicant for a new or expanded nursing facility shall document an agreement to provide Department requested information and statistical data related to the operation and provision of nursing facility services and to report that data to the Department in the time frame and format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.30

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq*****.**

HISTORY: Original Rule entitled "Specific Review Considerations for Skilled Nursing and Intermediate Care Facilities" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.30, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.31 Specific Review Considerations for Personal Care Homes

(1) **Applicability.** A Certificate of Need for a personal care home will be required prior to the establishment of a new personal care home, of twenty-five beds or more, and the expansion of any personal care home which is or will be twenty-five beds or more.

(2) **Definitions.**

(a) "Health planning area" for all personal care homes, means the geographic regions in Georgia defined in the State Health Plan or Component Plan.

(b) "Horizon Year" means the last year of a three-year projection period for need determinations for a personal care home.

(c) "Official State Health Component Plan" means the document related to personal care homes developed by the Department adopted by the State Health Strategies Council and approved by the Board of Community Health.

(d) "Personal care home" means a residential facility that is certified as a provider of medical assistance for Medicaid purposes pursuant to Article 7 of Chapter 4 of Title 49 having at least twenty-five (25) beds and providing, for compensation, protective care and oversight of ambulatory, non-related persons who need a monitored environment but who do not have injuries or disabilities which require chronic or convalescent care, including medical, nursing, or intermediate care. Personal care homes include those facilities which monitor daily residents' functioning and location, have the capability for crisis intervention, and provide supervision in areas of nutrition, medication, and provision of transient medical care. Such term does not include:

1. old age residences which are devoted to independent living units with kitchen facilities in which residents have the option of preparing and serving some or all of their own meals; or

2. boarding facilities that do not provide personal care.

(3) **Standards.**

(a) 1. The numerical need for a new or expanded personal care home in a health planning area shall be determined by a population-based formula which is used to project the number of personal care home beds needed in the horizon year and which is a sum of the following:

(i) a ratio of 18.00 beds per 1,000 projected horizon year Resident population age 65 through 74;

(ii) a ratio of 40.00 beds per 1,000 projected horizon year Resident population age 75 through 84; and

(iii) a ratio of 60.00 beds per 1,000 projected horizon year Resident population age 85 and older.

2. The net numerical unmet need for personal care home beds in each health planning area shall be determined by subtracting the number of existing and approved personal care home beds in the health planning area from the projected number of personal care home beds needed in the horizon year; provided, however, that if the net numerical unmet need exceeds fifty percent (50%) of the current existing and approved beds in the planning area, the net numerical unmet need shall be limited to fifty percent (50%) of the existing and approved beds at the time the calculation is made.

(b) The Department may allow an exception to Ga. Comp. R. & Regs. r. 111-2-2-.31(3)(a) as follows:

1. to allow expansion of an existing personal care home if actual utilization has exceeded ninety percent (90%) average annual occupancy based on number of licensed beds for the two-year period immediately preceding application;

2. to allow expansion of an existing personal care home if the applicant has substantial occupancy by out-of-state residents. "Substantial occupancy by out-of-state residents" shall be defined as having at least thirty-three percent (33%) of the available licensed beds in the personal care home utilized by individuals who resided outside of the State of Georgia immediately prior to moving into the personal care home; or

3. to remedy an atypical barrier to personal care home services based on cost, quality, financial access, or geographic accessibility.

(c) In competing applications, favorable consideration may be given to any applicant for a new or expanded personal care home which historically has provided and/or provides sufficient documentation of plans to provide a higher percentage of un-reimbursed services to indigent and charity residents than requirement by the indigent and charity standard of Ga. Comp. R. & Regs. r. 111-2-2-.31(3)(j). Favorable consideration also may be given to any applicant for a new or expanded personal care home which historically has provided and/or provides sufficient documentation of plans to provide personal care home residential services at monthly and/or annual rates that are affordable to the greatest number of individuals based on analysis of the national rate for services and the income ranges of individuals at or above age 65 and in the applicant's market area(s).

(d) A new or expanded personal care home shall be approved in a health planning area only if the applicant complies with the following physical standards:

1. the physical plant design and the program design shall support the concept of a non-institutional, home-like setting;

2. the proposed physical plant design is in compliance with the Rules and licensure standards of the Healthcare Facility Regulation Division and the applicant stipulates that the services required by such Rules and licensure standards will be provided and any services prohibited by such Rules and licensure standards will not be provided and will not be implied to be provided either through advertising or other means;

3. there shall be a designated area for staff on duty in each personal care home and on each floor in the case of a multistory facility;

4. the facility has the option of building kitchens or kitchenettes in the living units as long as the facility intends to provide three meals per day to residents. The kitchens or kitchenettes must comply with the Fire Marshal's and the Healthcare Facility Regulation Division's minimum licensure standards; and

5. the facility provides assurance that it will not lease or contract space within the personal care home to an outside entity to provide services that the personal care home would otherwise not be allowed to provide.

(e) An applicant for a new or expanded personal care home must document provision of continuity of care by providing a community linkage plan which demonstrates factors such as, but not limited to, referral arrangements with appropriate services of the healthcare system and working agreements with other related community services assuring continuity of care.

(f) An applicant for a new or expanded personal care home shall provide evidence of intent to comply with all appropriate licensure requirements, resident life safety standards and operational procedures required by the Healthcare Facility Regulation Division.

(g) An applicant for a new or expanded personal care home shall provide evidence of the intent and ability to recruit, hire, and retain qualified personnel and that such personnel are available in the proposed geographic service area.

(h) An applicant for a new or expanded personal care home shall provide evidence that no existing Georgia personal care home of any size owned and/or operated by the applicant, a related entity or by the applicant's parent organization has had a permit or license revoked, denied or otherwise sanctioned through formal licensure enforcement action by the Healthcare Facility Regulation Division within the two years immediately preceding application.

(i) An applicant for a new or expanded personal care home shall provide a plan for assuring quality of care which includes, but is not limited to, procedures and plans for staff training and a program to monitor specific quality indicators.

(j) An applicant for a new or expanded personal care home shall foster an environment which assures access to services to individuals by providing a written commitment that un-reimbursed services to residents who are indigent or meet the guidelines of a charity policy of the personal care home will be offered at a standard which meets or exceeds one percent (1%) of annual gross revenues for the personal care home after bad debt has been deducted.

(k) An applicant for a new or expanded personal care home shall agree to provide the Department with requested information and statistical data related to the operation and provision of personal care homes and to report that data to the Department in the time frame and format requested.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.31

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq.***

HISTORY: Original Rule entitled "Specific Review Considerations for Personal Care Homes" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

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Note: Rule 111-2-2-.31, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.32 Specific Review Considerations for Home Health Services

(1) **Applicability.** A Certificate of Need for a home health agency will be required prior to the establishment of a new home health agency or the expansion of the geographic service area of an existing home health agency unless such expansion is a result of a non-reviewable acquisition of another existing home health agency.

(2) **Definitions.**

(a) "Home health agency" means a public agency or private organization, or a subdivision of such an agency or organization, which is primarily engaged in providing to individuals who are under a written plan of care of a physician, on a visiting basis in the place of residence used as such individual's home, part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse, and one or more of the

following services: physical therapy, occupational therapy, speech therapy, medical-social services under the direction of a physician, or part-time or intermittent services of a home health aide.

(b) "Horizon year" means the last year of the three-year projection period for need determinations for a new or expanded home health agency.

(c) "Geographic service area" means a grouping of specific counties within a planning area for which the home health agency is authorized to provide services to individuals residing in the specific counties pursuant to an existing or future Certificate of Need. For purposes of establishing a service area for a new home health agency, the geographic service area shall consist of any individual county or combination of contiguous counties which have an unmet need as determined through the numerical need formula or the exception. For purposes of an expansion of an existing agency, the geographic service area shall consist of an individual county or any combination of counties which have an unmet need, and which are within any planning area in which the home health agency already provides service; however, in no case may an existing home health agency apply to provide services outside the health planning areas in which its current geographic service area is located.

(d) "Nursing care" means such services provided by or under the supervision of a licensed registered professional nurse in accordance with a written plan of medical care by a physician. Such services shall be provided in accordance with the scope of nursing practice laws and associated rules.

(e) "Planning area" for all home agencies means the geographic regions in Georgia defined in the State Health Plan or Component Plan.

(3) **Standards.**

(a) The need for a new or expanded home health agency shall be determined through application of a numerical need method and an assessment of the projected number of patients to be served by existing agencies.

1. The numerical need for a new or expanded home health agency in any planning area in the horizon year shall be based on the estimated number of annual home health patients within each health planning area as determined by a population-based formula which is a sum of the following for each county within the health planning area:

(i) a ratio of 4 patients per 1,000 projected horizon year Resident population age 17 and younger;

(ii) a ratio of 5 patients per 1,000 projected horizon year Resident population age 18 through 64;

(iii) a ratio of 45 patients per 1,000 projected horizon year Resident population age 65 through 79; and

(iv) a ratio of 185 patients per 1,000 projected horizon year Resident population age 80 and older.

2. The net numerical unmet need for home health services shall be determined by subtracting the projected number of patients for the current calendar year from the projected need for services as calculated in (3)(a)1. The projected number of patients for the current calendar year is determined by multiplying the number of patients having received services in each county, as reported in the most recent survey year, by the county population change factor. The county population change factor is the percent change in total population between the most recent survey year and the current calendar year.

(b) 1. The Department shall accept applications for review as enumerated below:

(i) If the net numerical unmet need in a given planning area is 250 patients or more, the Department shall authorize the submission of applications for an expanded home health agency; or

(ii) If the net numerical unmet need in a given planning area is 500 patients or more, the Department shall authorize the submission of applications for a new home health agency as well as an expanded home health agency.

2. An applicant must propose to provide service only within a county or group of counties, each of which reflects a numerical unmet need, and contained within the given planning area for which the Department has authorized the submission of applications.

3. The Department shall only approve applications in which the applicant has applied to serve all of the unmet numerical need in any one county in which need is projected. The need within counties shall not be divided or shared between any two or more applicants.

(c) The Department may authorize an exception to Ga. Comp. R. & Regs. r. 111-2-2-.32(3)(a) if:

1. the applicant for a new or expanded home health agency can show that there is limited access in the proposed geographic service area for special groups such as, but not limited to, medically fragile children, newborns and their mothers, and HIV/AIDS patients. For purposes of this exception, an applicant shall be required to document, using population, service, special needs and/or disease incidence rates, a projected need for services in the planning area of at least 200 patients within a defined geographic service area. A successful applicant applying under this section will be restricted to serving the special group or groups identified in the application within the county or counties stipulated in the application; or

2. a particular county is served by no more than two (2) home health agencies and either of the following conditions exists:

(1) less than one percent (1%) of the county's population has received home health services, or

(2) one of the two home health agencies has demonstrated a failure to adequately serve Medicaid patients as evidenced by a level of service to such individuals that is less than the statewide average within each of the past two years as reported on the Annual Home Health Services survey. For purposes of this exception, an applicant must already be approved to provide service in a contiguous county or be approved to provide service in a county that is no further than 15 miles from the county authorized through the exception. In all other aspects of the application process, the applicant shall be required to comply with provisions applicable to expanded home health agencies. For purposes of this exception, "served by" shall mean the agency(ies) are licensed to serve the county by the Healthcare Facility Regulation Division of the Georgia Department of Community Health.

(d) An applicant for a new or expanded home health agency shall provide a community linkage plan which demonstrates factors such as, but not limited to, referral arrangements with appropriate services of the healthcare system and working agreements with other related community services assuring continuity of care focusing on coordinated, integrated systems which promote continuity rather than acute, episodic care. Working agreements with other related community services may include the ability to streamline referrals to other appropriate services and to participate in the development of cross-continuum care plans with other providers.

(e) An applicant for a new or expanded home health agency shall provide a written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division of the Georgia Department of Community Health.

(f) An applicant for a new or expanded home health agency or agency(ies) owned and/or operated by the applicant or its parent organization shall have no history of uncorrected or repeated conditional level violations or uncorrected standard deficiencies as identified by licensure inspections or equivalent deficiencies as noted from Medicare or Medicaid audits.

(g) An applicant for a new or expanded home health agency or agency(ies) owned and/or operated by the applicant or its parent organization shall have no previous conviction of Medicaid or Medicare fraud.

(h) An applicant for a new or expanded home health agency shall provide a written plan which demonstrates the intent and ability to recruit, hire and retain the appropriate numbers of qualified personnel to meet the requirements of the services proposed to be provided and that such personnel are available in the proposed geographic service area.

(i) An applicant for a new home health agency shall provide evidence of the intent to meet the appropriate accreditation requirements of The Joint Commission (TJC), the Community Health Accreditation Program, Inc. (CHAP), and/or other appropriate accrediting agencies.

(j) An applicant for an expanded home health agency shall provide documentation that they are fully accredited by The Joint Commission (TJC), the Community Health Accreditation Program, Inc. (CHAP), and/or other appropriate accrediting agency.

(k) An applicant for a new or expanded home health agency shall provide its existing or proposed plan for a comprehensive quality improvement program.

(l) An applicant for a new or expanded home health agency shall assure access to services to individuals unable to pay and to all individuals regardless of payment source or circumstances by:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, disability, gender, race, or ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds one percent (1%) of annual, adjusted gross revenues for the home health agency or, in the case of an applicant providing other health services, the applicant may request that the Department allow the commitment for services to indigent and charity patients to be applied to the entire facility;

3. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients;

4. providing a written commitment to participate in the Medicare, Medicaid and PeachCare for Kids® programs; and

5. providing a written commitment to participate in any other state health benefits insurance programs for which the home health service is eligible.

(m) An applicant for a new or expanded home health agency shall demonstrate that their proposed charges compare favorably with the charges of existing home health agencies in the same geographic service area.

(n) An applicant for a new or expanded home health agency shall document an agreement to provide Department requested information and statistical data related to the operation and provision of home health services and to report that data to the Department in the time frame and format requested by the Department.

(o) The Department may authorize an existing home health agency to transfer one county or several counties to another existing home health agency without either agency being required to apply for a new or expanded Certificate of Need, provided the following conditions are met:

1. the two agencies agree to the transfer and submit such agreement and a joint request to transfer in writing to the Department at least thirty (30) days prior to the proposed effective date of the transfer;

2. the two agencies document within the written request that the transfer would result in increased and improved services for the residents of the county or counties including Medicare and Medicaid patients;

3. the agency to which the county or counties are being transferred currently offers services in at least one contiguous county or within the health planning area(s) in which county or counties are located; and

4. the two agencies are in compliance with all other requirements of these Rules; such compliance to be evaluated with the written transfer request.

No such transfer shall become effective without written approval from the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.32

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq*., 31-6** ***et seq*.**

HISTORY: Original Rule entitled "Specific Review Considerations for Home Health Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: New Rule entitled "Specific Rule Considerations for Home Health Services" adopted. F. Feb. 16, 2010; eff. Mar. 8, 2010.

Amended: New title, "Specific Review Considerations for Home Health Services." F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.32, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.33 Specific Review Considerations for Life Plan Community (LPC) Sheltered Nursing Facilities

(1) **Applicability.** A Certificate of Need will be required prior to the establishment of a new or expanded LPC Sheltered Nursing Facility, if not exempt as provided by O.C.G.A. § 31-6-47(a)(17) and Ga. Comp. R. & Regs. r. 111-2-2-.03(20). These Rules apply to sheltered nursing facilities located in LPC facilities defined herein as Type A and Type B Life Plan Communities. A LPC that has obtained nursing facility beds approved under the standards contained in Ga. Comp. R. & Regs. r. 111-2-2-.30 does not qualify for sheltered nursing facility beds, and to convert existing nursing facility beds to sheltered nursing facility beds, such a LPC must apply for a new Certificate of Need. Conversely, a LPC that obtains sheltered nursing facility beds under these Rules may not qualify for beds under Ga. Comp. R. & Regs. r. 111-2-2-.30, and is therefore only required to complete these specific review considerations for the sheltered nursing facility beds.

(2) **Duration.** Notwithstanding Ga. Comp. R. & Regs. r. 111-2-2-.02(6), the initial implementation period of a Certificate of Need granted for a new or expanded LPC Sheltered Nursing Facility pursuant to these Rules shall be twenty-four (24) months from the effective date.

(3) **Definitions.**

(a) "A Life Plan Community" (LPC) is an organization which offers a contract to provide an individual of retirement status, other than an individual related by consanguinity or affinity to the provider furnishing the care, with board and lodging, licensed nursing facility care and medical or other health related services, or both. These services are provided for a minimum period of more than one (1) year and may be for as long as the lifetime of the resident.

(b) "Type A Life Plan Community" (Type A LPC) provides LPC services at the same location for the life of an individual, including mutually terminable contracts, and in consideration of the payment of an entrance fee with or without other periodic charges. A Type A LPC offers nursing facility care for a little or no substantial increase in monthly payments, except normal operating costs and inflation adjustments.

(c) "Type B Life Plan Community" (Type B LPC) provides LPC services at the same location for a period in excess of one year, including mutually terminable contracts, and in consideration of the payment of an entrance fee with other periodic charges. A Type B LPC offers a specified amount of nursing facility care for little or no substantial increase in monthly payments except normal operating costs and inflation adjustments. After the specified amount of nursing care is received, residents pay either a discounted rate or the full per diem rate for nursing care required.

(d) "A Continuing Care Contract" means furnishing pursuant to an agreement shelter, food, and either nursing care or personal services, whether such nursing care or personal services are provided in the facility or in another setting designated by the agreement for continuing care, to an individual not related by consanguinity or affinity to the provider furnishing such care upon payment of an entrance fee. Other personal services provided shall be designated in the continuing care agreement. Agreements to provide continuing care include agreements to provide care for any duration, including agreements that are terminable by either party.

(e) "LPC Sheltered Nursing Facility", for purposes of these Rules, is a nursing facility that meets the definition of a nursing facility as defined by Ga. Comp. R. & Regs. r. 111-2-2-.30 of the Rules of the Department. A LPC Sheltered Nursing Facility shall be for the exclusive use of residents of a Type A or Type B LPC.

(f) "Official State Health Component Plan" means the document related to the above-named services developed by the Department, established by the Georgia Health Strategies Council, and signed by the Governor of Georgia.

(g) "Resident" is an individual entitled to receive continuing care in a Type A or Type B Life Plan Community.

(4) **Standards.**

(a) The numerical need for a new LPC sheltered nursing facility shall be based on a ratio of one nursing facility bed for each five independent living units. The applicant for a LPC Sheltered Nursing Facility shall demonstrate to the Department that the potential market for LPC Independent Living Units in the proposed service area is based on a valid feasibility study which takes into account factors such as, but not limited to, the age and annual household income of the target population and the geographic area to be served.

(b) The numerical need for an expanded LPC sheltered nursing facility shall be based on a ratio of one nursing facility bed for each four independent living units provided that the LPC's existing nursing facility has experienced an occupancy rate of at least eighty percent (80%) during the most recent year.

(c) Sheltered nursing facility beds approved under these Rules shall be used exclusively for persons who are residents of the LPC, and who are a party to a continuing care contract with the facility or the parent organization and who have lived in a non-nursing unit of the LPC for a period of at least ninety (90) days. Exceptions shall be allowed when one spouse or sibling is admitted to the nursing unit at the time the other spouse or sibling moves into a non-nursing unit, or when the medical condition requiring nursing care was not known to exist or be imminent when the individual became a party to the continuing care contract.

(d) The applicant shall provide evidence of intent that at no time will the nursing facility be certified for participation in the Medicaid Program.

(e) A LPC which is the applicant for a new or expanded LPC sheltered nursing facility shall provide evidence of the intent and ability to meet all appropriate authorization and disclosure requirements of the Georgia State Department of Insurance and of any appropriate accrediting agency(ies). The LPC shall furnish reports in such form and at such times as may be specified, which accurately and fully disclose it has met specified requirements.

(f) A new or expanded LPC sheltered nursing facility shall provide evidence of the intent and ability to meet all appropriate requirements regarding licensure and accreditation of the nursing facility as follows:

1. Compliance with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division;

2. No uncorrected operational standards in any existing Georgia general or LPC sheltered nursing facilities owned and/or operated by the entity, its affiliates, or its principals. Plans to correct physical plant deficiencies must be provided;

3. No previous conviction of Medicaid and/or Medicare fraud by the entity, its affiliates, or its principals;

4. Provision of a plan for a comprehensive quality improvement program which includes, but is not limited to, procedures and plans for staff training and a program to monitor specific quality indicators and measure the facility's performance and patient outcomes accordingly; and

5. Intent to meet accreditation requirements of the appropriate accrediting agency(ies).

(g) A LPC which is the applicant for a new or expanded LPC sheltered nursing facility shall demonstrate the existence of a Health Care Fund whose liability is documented by a relevant Actuarial Study and certified by a qualified actuary; or the existence of a Long Term Care Insurance Policy issued to individual residents; or a Group Long Term Care Insurance Policy issued to the LPC for the coverage of all residents. An Individual or Group Insurance Policy must conform to all the requirements of Chapter 120-20-16 of the Rules and Regulations of the State of Georgia Insurance Department entitled "Long Term Care Insurance Regulation". The period and scope of coverage must be identical to the period and scope of coverage in the continuing care contract.

(h) A LPC in which a new or expanded sheltered nursing facility is to be located shall provide the Department with requested information and statistical data related to the operation and programmatic elements of the LPC and the Sheltered Nursing Facility. Analyses are predicated upon accurate, consistent, and systematically obtained information.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.33

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq.***

HISTORY: Original Rule entitled "Specific Review Considerations for Continuing Care Retirement Community ("CCRC") Sheltered Nursing Facilities" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Nov. 13, 2007; eff. Dec. 3, 2007.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: New title, "Specific Review Considerations for Life Plan Community (LPC) Sheltered Nursing Facilities." F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.33, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.34 Specific Review Considerations for Traumatic Brain Injury Facilities

(1) **Applicability.** The following Rules apply to Traumatic Brain Injury Facilities defined herein as providing transitional living programs and/or lifelong living programs.

(a) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing Transitional Living Program, if not exempt as provided by O.C.G.A. § 31-6-47(a)(25) and Ga. Comp. R. & Regs. r. 111-2-2-.03(28). An application for Certificate of Need for a new or expanded Transitional Living Program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(b) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing Life Long Living Program, if not exempt as provided by O.C.G.A. § 31-6-47(a)(25) and Ga. Comp. R. & Regs. r. 111-2-2-.03(28). An application for Certificate of Need for a new or expanded Life Long Living Program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(2) **Definitions.**

(a) "Expansion" or "Expanded Service" means increasing the number of beds in an existing Traumatic Brain Injury Facility or program; or an existing Traumatic Brain Injury Facility or program which makes expenditures which exceed the capital expenditure threshold; or an existing Traumatic Brain Injury Facility or program which seeks to add a program which it currently does not offer.

(b) "Life Long Living Program" means such treatment and rehabilitative care as shall be delivered to traumatic brain injury clients who have been discharged from a more intense level of rehabilitation, but who cannot live at home independently, and who require on-going lifetime support. Such clients are medically stable, may have special needs, but need less than 24 hour per day medical support.

(c) "New" means a facility that has not operated as a Traumatic Brain Injury Facility in the previous twelve (12) months. For purposes of these Rules, an existing Traumatic Brain Injury Facility or program which proposes to be relocated to a location more than three miles from its present location shall be considered "new".

(d) "Official State Health Component Plan" means the document related to Traumatic Brain Injury Facilities developed by the Department, established by the Georgia State Health Strategies Council and signed by the Governor of Georgia.

(e) "Planning Region" means one of the twelve state service delivery regions established by O.C.G.A. § 50-4-7.

(f) "Transitional Living Program" means such treatment and rehabilitative care as shall be delivered to traumatic brain injury clients who require education and training for independent living with a focus on compensation for skills which cannot be restored. Such care prepares clients for maximum independence, teaches necessary skills for community interaction, works with clients on pre-vocational and vocational training and stresses cognitive, speech, and behavioral therapies structured to the individual needs of clients. Such clients are medically stable, may have special needs, but need less than twenty-four (24) hour per day medical support.

(g) "Traumatic Brain Injury" means a traumatic insult to the brain and its related parts resulting in organic damage thereto that may cause physical, intellectual, emotional, social, or vocational changes in a person. It shall also be recognized that a person having a traumatic brain injury may have organic damage or physical or social disorders but shall not be considered mentally ill.

(h) "Traumatic Brain Injury Facility" means a building or place which is devoted to the provision of residential treatment and rehabilitative care in a transitional living program or a life long living program for periods continuing for twenty-four (24) hours or longer for persons who have traumatic brain injury. Such a facility is not classified by the Healthcare Facility Regulation Division as a hospital, nursing home, intermediate care facility or personal care home.

(3) **Standards.**

(a) An application for a new or expanded Traumatic Brain Injury Facility or program shall provide sufficient documentation of the need for such a program in the Planning Region. In the case of an application for an expanded program, the applicant shall justify the need for the expansion by, at a minimum, documenting that the expansion program has achieved an occupancy rate of eighty percent (80%) or more for the most recent twelve (12) months prior to submitting application.

(b) An applicant for a new or expanded Traumatic Brain Injury Facility or program shall document that the establishment or expansion of its Facility or program will not have an adverse impact on existing and approved programs of the same type in its Planning Region. An applicant for a new or expanded Traumatic Brain Injury Facility or program shall have an adverse impact on existing and approved facilities or programs of the same type if it will:

1. decrease annual utilization of an existing facility or program, whose current utilization is at or above eighty-five percent (85%), to a projected annual utilization of less than seventy-five percent (75%) within the first twelve (12) months following the acceptance of the applicant's first patient; or

2. decrease annual utilization of an existing facility or program, whose current utilization is below eighty-five percent (85%), by ten percent (10%) over the twelve (12) months following the acceptance of the applicant's first patient.

The applicant shall provide evidence of projected impact by taking into account existing planning region market share of facilities or programs of the same type and future population growth or by providing sufficient evidence that the current population is underserved by the existing Traumatic Brain Injury facility or program of the same type within the planning region.

(c) The Department may grant an exception to the need methodologies of Ga. Comp. R. & Regs. r. 111-2-2-.34(3)(a) and (3)(b) to remedy an atypical barrier to the services of a Traumatic Brain Injury Facility or program based on cost, quality, financial access, or geographic accessibility.

(d) Minimum bed size for a Traumatic Brain Injury Facility or program is six beds; A Life Long Living Program may not exceed thirty beds, except that an applicant for a new or expanded Life Long Living Program may be approved for total beds to exceed thirty (30) beds only if the applicant provides documentation satisfactory to the Department that the program design, including staffing patterns and the physical plant, are such as to promote services which are of high quality, are cost-effective and are consistent with client needs.

(e) An applicant for a new or expanded Traumatic Brain Injury Facility shall demonstrate the intent to meet the standards of the Commission on Accreditation of Rehabilitation Facilities (CARF) which apply to post acute brain injury programs and residential services within twenty-four (24) months of accepting its first patient. An applicant for an expanded Traumatic Brain Injury Facility or program shall be CARF-certified as of the date of its application and shall furnish proof of the certification as a part of the Certificate of Need application process.

(f) An applicant for a new or expanded Traumatic Brain Injury Facility shall demonstrate the intent to meet the licensure Rules of the Healthcare Facility Regulation Division for such facilities. An applicant for an expanded Traumatic Brain Injury Facility or program shall demonstrate a lack of uncorrected deficiencies as documented by letter from the Healthcare Facility Regulation Division.

(g) An applicant for a new or expanded Traumatic Brain Injury Facility shall have written policies and procedures for utilization review. Such review shall consider the rehabilitation necessity for the service, quality of client care, rates of utilization and other considerations generally accepted as appropriate for review.

(h) An applicant for a new or expanded Traumatic Brain Injury Facility shall document the existence of referral arrangements, including transfer agreements, with an acute care hospital within the planning region to provide emergency medical treatment to any patient who requires such care. If the nearest acute-care hospital is in an adjacent planning region, the applicant may document the existence of transfer agreements with that hospital in lieu of such agreements with a hospital located within the planning region.

(i) An applicant for a new or expanded Traumatic Brain Injury Facility shall document that the Facility will be financially accessible by:

1. providing sufficient documentation that un-reimbursed services for indigent and charity patients in a new or expanded Facility shall be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the Facility after provisions have been made for bad debt and Medicaid/Medicare contractual adjustments have been deducted. If an applicant, or any facility owned or operated by the applicant's parent organization, received a Certificate of Need for a Traumatic Brain Injury Facility and the Certificate of Need included an expectation that a certain level of un-reimbursed indigent and/or charity care would be provided in the Facility(ies), the applicant shall provide sufficient documentation of the Facility's provision of such care. An applicant's history, or the history of any facility owned or operated by the applicant's parent organization, of not following through with a Certificate of Need

expectation of providing indigent and/or charity care at or above the level agreed to will constitute sufficient justification to deny an application; and

2. agreeing to participate in the Medicare and Medicaid programs, whenever these programs are available to the Facility.

(j) Reserved.

(k) An applicant for a new or expanded Traumatic Brain Injury Facility shall document an agreement to provide the Department requested information and statistical data related to the operation of such a Facility and to report that information and statistical data to the Department on a yearly basis, and as needed, in a format requested by the Department and in a timely manner.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.34

AUTHORITY: O.C.G.A. §§ 31-2 **et seq., 31-6 et seq.**

HISTORY: Original Rule entitled "Specific Review Considerations for Traumatic Brain Injury Facilities" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Nov. 22, 2006; eff. Dec. 12, 2006.

Amended: F. Nov. 13, 2007; eff. Dec. 3, 2007.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.34, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.35 Specific Review Considerations for Comprehensive Inpatient Physical Rehabilitation Services

(1) **Applicability.**

(a) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing Comprehensive Inpatient Physical Rehabilitation Adult Program. An application for Certificate of Need for a new or expanded Comprehensive Inpatient Physical Rehabilitation Adult Program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(b) A Certificate of Need shall be required prior to the establishment of a new or the expansion of an existing Comprehensive Inpatient Physical Rehabilitation Pediatric Program. An application for Certificate of Need for a new or expanded Comprehensive Inpatient Physical Rehabilitation Pediatric Program shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(2) **Definitions.**

(a) 'Adults' means persons eighteen (18) years of age and over. However, a Certificate of Need authorized or grandfathered Comprehensive Inpatient Physical Rehabilitation Adult Program will not be in violation of the

Certificate of Need laws and regulations if it provides service to a patient older than fifteen years if the provider has determined that such service is medically necessary, provided that the treatment days and patient census associated with patients sixteen and seventeen years of age do not exceed ten percent (10%) of annual treatment days and annual census, respectively. Rehabilitation programs specifically focused towards treatment of spinal cord injuries and disorders and which existed prior to the effective date of this version of Ga. Comp. R. & Regs. r. 111-2-2-.35 shall not be subject to the adult age limitations; such programs may treat any patient aged twelve (12) and over.

(b) 'Comprehensive Inpatient Physical Rehabilitation Programs' means rehabilitation services, which have been classified by Medicare as an inpatient rehabilitation facility pursuant to 42 C.F.R. §412.23(b)(2), provided to a patient who requires hospitalization, which provides coordinated and integrated services that include evaluation and treatment, and emphasizes education and training of those served. The program is applicable to those individuals who require an intensity of services which includes, as a minimum, physician coverage twenty-four (24) hours per day, seven (7) days per week, with daily (at least five (5) days per week) medical supervision, complete medical support services including consultation, 24-hour-per-day nursing, and daily (at least five (5) days per week) multidisciplinary rehabilitation programming for a minimum of three hours per day. For regulatory purposes, the definition includes a program which asserts its intent to be Medicare-classified as an inpatient rehabilitation facility no later than twenty-four (24) months after accepting its first patient. If a program, which has been awarded a CON pursuant to this Rule, has not been so classified by Medicare within the timeframe outlined above, the CON issued to that entity shall be revoked.

(c) 'Expansion' and 'Expanded' mean the addition of beds to an existing CON-authorized or grandfathered Comprehensive Inpatient Physical Rehabilitation Program. However, a CON-authorized or grandfathered provider of Comprehensive Inpatient Physical Rehabilitation in a freestanding rehabilitation hospital may increase the bed capacity of an existing program by the lesser of ten percent (10%) of existing capacity or ten (10) beds if it has maintained an average occupancy of eighty-five percent (85%) for the previous twelve (12) calendar months provided that there has been no such increase in the prior two years and provided that the capital expenditures associated with the increase do not exceed the capital expenditure threshold. If such an increase exceeds the capital expenditure threshold, the increase will be considered an expansion for which a Certificate of Need shall be required under these Rules.

(d) 'Freestanding Rehabilitation Hospital' means a specialized hospital organized and operated as a self-contained health care facility that provides one or more rehabilitation programs and which has been classified as an inpatient rehabilitation facility by the Medicare program pursuant to 42 C.F.R. §412.23(b)(2). For regulatory purposes, the definition includes a hospital which asserts its intent to be Medicare-classified as an inpatient rehabilitation facility no later than twenty-four (24) months after accepting its first patient. If an entity, which has been awarded a CON pursuant to this Rule, has not been so classified by Medicare within the timeframe outlined above, the CON issued to that entity shall be revoked. An entity, which has had its CON revoked pursuant to this Rule, shall not have the authority to operate as a general acute care hospital.

(e) 'New' means a Program that has not been classified by the Medicare program as a rehabilitation hospital or program in the previous twelve (12) months. Adult programs described in Ga. Comp. R. & Regs. r. 111-2-2-.35(1)(a) and pediatric programs described in Ga. Comp. R. & Regs. r. 111-2-2-.35(1)(b) shall be considered independent programs such that a provider seeking to add a program not offered by that provider in the previous twelve (12) months shall be considered to be offering a new program for which a Certificate of Need must be obtained. For purposes of these Rules, an existing program which proposes to be relocated to a location more than three (3) miles from its present location shall be considered "new".

(f) 'Official State Health Component Plan' means the document related to Physical Rehabilitation Programs and Services developed by the Department, established by the Georgia Health Strategies Council and signed by the Governor of Georgia.

(g) 'Pediatric' means persons seventeen (17) years of age and under. However, a CON-authorized or grandfathered Comprehensive Inpatient Rehabilitation Pediatric Program will not be in violation of the CON laws and regulations if it provides service to a patient younger than twenty-two (22) years if the provider has determined that such service is medically necessary, provided that the treatment days and patient census associated with patients eighteen, nineteen, twenty, and twenty-one years of age do not exceed ten percent (10%) of annual treatment days and annual

census, respectively. Rehabilitation programs specifically focused towards treatment of spinal cord injuries and disorders and which existed prior to the effective date of this version of Ga. Comp. R. & Regs. r. 111-2-2-.35 shall not be subject to the pediatric age limitations; such programs may treat any patient aged twelve (12) and over.

(h) 'Planning Region' means one of the four sub-state regions for Physical Rehabilitation Programs and Services as follows:

1. Rehabilitation Region 1, including the following counties: Dade, Walker, Catoosa, Whitfield, Murray, Gilmer, Fannin, Union, Towns, Rabun, Stephens, Habersham, White, Lumpkin, Dawson, Pickens, Gordon, Chattooga, Floyd, Bartow, Cherokee, Forsyth, Hall, Banks, Franklin, Hart, Elbert, Madison, Jackson, Barrow, Gwinnett, Fulton, Cobb, Paulding, Polk, Haralson, Carroll, Douglas, DeKalb, Rockdale, Walton, Oconee, Clarke, Oglethorpe, Greene, Morgan, Newton, Butts, Henry, Clayton, Fayette, Coweta, Heard, Troup, Meriwether, Pike, Spalding, Lamar, and Upson

2. Rehabilitation Region 2, including the following counties: Wilkes, Lincoln, Columbia, McDuffie, Warren, Taliaferro, Hancock, Glascock, Putnam, Jasper, Monroe, Jones, Baldwin, Washington, Jefferson, Richmond, Burke, Screven, Jenkins, Emmanuel, Johnson, Treutlen, Montgomery, Wheeler, Telfair, Wilcox, Dodge, Laurens, Pulaski, Bleckley, Houston, Peach, Twiggs, Wilkinson, Bibb, and Crawford

3. Rehabilitation Region 3, including the following counties: Harris, Talbot, Taylor, Muscogee, Chattahoochee, Marion, Schley, Macon, Dooly, Sumter, Webster, Stewart, Quitman, Randolph, Terrell, Lee, Crisp, Ben Hill, Irwin, Turner, Worth, Dougherty, Calhoun, Clay, Early, Baker, Mitchell, Colquitt, Miller, Cook, Tift, Berrien, Lanier, Echols, Lowndes, Brooks, Thomas, Grady, Decatur, and Seminole

4. Rehabilitation Region 4, including the following counties: Effingham, Bulloch, Candler, Toombs, Tattnall, Evans, Bryan, Chatham, Liberty, Long, Wayne, Appling, Jeff Davis, Coffee, Bacon, Pierce, Brantley, McIntosh, Glynn, Camden, Charlton, Ware, Atkinson, and Clinch

(3) **Service-Specific Review Standards.**

(a) The need for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program ("CIPR") shall be determined and applied as follows:

1. The need for new or expanded Comprehensive Inpatient Physical Rehabilitation Adult Program in a planning region shall be determined using the following demand-based need projection:

(i) Determine the comprehensive inpatient physical rehabilitation utilization rate per 1,000 for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharges from licensed providers of inpatient rehabilitation in the planning region for patients aged eighteen (18) and over by current year projected resident population (aged 18 and over) for the planning region and multiplying by 1,000. The source of current year discharge data for purposes of this Rule include data collected pursuant to O.C.G.A. § 31-7-280(c)(14), or in the Department's discretion, discharge data collected on the most recent Annual Hospital Questionnaire. The source for current and horizon year resident population shall be resident population projections from the Governor's Office of Planning and Budget. For the first Horizon Year projection using this Rule, and for the first horizon year projection only, the utilization rate per 1,000 for each planning region shall be reduced by sixteen percent (16%) to account for anticipated utilization reduction after full implementation of the Center for Medicare and Medicaid Services' ("CMS") seventy-five percent (75%) rule.

(ii) Calculate the projected horizon year discharges for each planning region by multiplying the planning region utilization rate obtained in Step (i) by the horizon year resident population projection (aged 18 and over) for that planning region.

(iii) Determine the comprehensive inpatient physical rehabilitation average length of stay for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharge days of care from licensed providers of inpatient rehabilitation in the planning region for patients aged eighteen (18) and over by the current year inpatient rehabilitation discharges determined in Step (i).

(iv) Multiply the projected discharges obtained in Step (ii) by the current year's average length of stay (aged 18 and over) determined in Step (iii) to determine the horizon year projected patient days for each planning region.

(v) Divide the product obtained in Step (iv) by the number of calendar days in the horizon year to obtain the average projected daily census in each planning region.

(vi) Divide the result obtained in Step (v) by .85 to determine the number of projected beds utilizing an eighty-five percent (85%) capacity standard for each planning region.

(vii) Determine the current inventory of comprehensive inpatient physical rehabilitation beds for adults in the planning region from Departmental data. For all CIPR providers, which have been licensed as a Rehabilitation Hospital by the Healthcare Facility Regulation Division, the current inventory of CIPR beds shall reflect the number of beds reported as CON-authorized in the Facility Inventory prior to the date of adoption of these Rules augmented from that time forward only by increases in bed capacity approved through the CON process (or by exemptions thereto) and by decreases due to a provider ceasing to provide such services for a period in excess of twelve (12) months. For purposes of this Rule, the initial inventory shall not include the beds of licensed Long Term Care Hospitals; the beds of such facilities shall be included in the applicable Long Term Care Hospital inventory.

(viii) If the projected bed need in Step (vi) is greater than the current inventory of adult CIPR beds in the planning region, the application for the Certificate of Need should reflect a number of beds equal to or lesser than the resulting unmet bed need.

2. The need for new or expanded Comprehensive Inpatient Physical Rehabilitation Pediatric Program in a planning region shall be determined using the following demand-based need projection:

(i) Determine the comprehensive inpatient physical rehabilitation utilization rate per 1,000 for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharges from licensed providers of inpatient rehabilitation in the planning region for patients aged seventeen (17) and under by current year resident population (aged 17 and under) for the planning region. The source of current year discharge data for purposes of this Rule include data collected pursuant to O.C.G.A. § 31-7-280(c)(14), or in the Department's discretion, discharge data collected on the most recent Annual Hospital Questionnaire.

(ii) Calculate the projected horizon year discharges for each planning region by multiplying the planning region utilization rate obtained in Step (i) by the horizon year resident population projection (aged 17 and under) for that planning region.

(iii) Determine the comprehensive inpatient physical rehabilitation average length of stay for the current year for each planning region by dividing the total number of inpatient physical rehabilitation discharge days of care from licensed providers of inpatient rehabilitation in the planning region for patients aged seventeen (17) and under by the current year inpatient rehabilitation discharges determined in Step (i).

(iv) Multiply the projected discharges obtained in Step (ii) by the current year's average length of stay (aged 17 and under) determined in Step (iii) to determine the horizon year projected patient days for each planning region.

(v) Divide the product obtained in Step (iv) by the number of calendar days in the horizon year to obtain the average projected daily census in each planning region.

(vi) Divide the result obtained in Step (v) by .85 to determine the number of projected beds utilizing an eighty-five percent (85%) capacity standard for each planning region.

(vii) Determine the current inventory of comprehensive inpatient physical rehabilitation beds for pediatric patients in the planning region from Departmental data. For all CIPR providers, which have been licensed as a Rehabilitation Hospital by the Healthcare Facility Regulation Division, the current inventory of CIPR beds shall reflect the number of beds reported as CON-authorized in the Facility Inventory prior to the date of adoption of these Rules augmented from that time forward only by increases in bed capacity approved through the CON process (or by exemptions

thereto) and by decreases due to a provider ceasing to provide such services for a period in excess of twelve (12) months. For purposes of this Rule, the initial inventory shall not include the beds of licensed Long Term Care Hospitals; the beds of such facilities shall be included in the applicable Long Term Care Hospital inventory.

(viii) If the projected bed need in Step (vi) is greater than the current inventory of pediatric CIPR beds in the planning region, the application for the Certificate of Need should reflect a number of beds equal to or lesser than the resulting unmet bed need.

(b) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall document that the establishment or expansion of its program will not have an adverse impact on existing and approved programs of the same type in its planning region. An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall have an adverse impact on existing and approved programs of the same type if it will:

1. decrease annual decrease annual utilization of an existing program, whose current utilization is at or above eighty-five percent (85%), to a projected annual utilization of less than seventy-five percent (75%) within the first twelve (12) months following the acceptance of the applicant's first patient; or

2. decrease annual utilization of an existing program, whose current utilization is below eighty-five percent (85%), by ten percent over the twelve (12) months following the acceptance of the applicant's first patient.

(c) The Department may grant the following exceptions:

1. The Department may grant an exception to the need methodology of Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a)1. and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(b) for an applicant proposing a program to be located in a county with a population of less than 75,000 and to be located a minimum of fifty (50) miles away from any existing program in the state.

2. The Department may grant an exception to the need methodologies of either Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a)1. or 111-2-2-.35(3)(a)2. and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(b) to remedy an atypical barrier to Comprehensive Inpatient Physical Rehabilitation Programs based on cost, quality, financial access or geographic accessibility or if the applicant's annual census demonstrates thirty percent (30%) out of state utilization for the previous two years.

3. The Department may grant an exception to the need methodologies of Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a)1. or Ga. Comp. R. & Regs. r. 111-2-2-.35(3)(a)2. in a planning area which has no existing provider provided that the applicant demonstrates a need for the service based on patient origin data.

(d) A new Comprehensive Inpatient Physical Rehabilitation Program shall have the following minimum bed sizes based on type of program offered:

1. A new Comprehensive Inpatient Physical Rehabilitation Adult Program shall have a minimum bed size of twenty (20) beds in a freestanding rehabilitation hospital already offering another Comprehensive Inpatient Physical Rehabilitation Program, twenty (20) beds or in an acute-care hospital, and forty (40) beds for a new freestanding rehabilitation hospital not already offering another Comprehensive Inpatient Physical Rehabilitation Program.

2. A new Comprehensive Inpatient Physical Rehabilitation Pediatric Program shall have a minimum of 10 beds in a freestanding rehabilitation hospital already offering another Comprehensive Inpatient Physical Rehabilitation Program, 10 beds in an acute-care hospital, and forty (40) beds for a new freestanding rehabilitation hospital not already offering another Comprehensive Inpatient Physical Rehabilitation Program.

(e) An applicant for a new Comprehensive Inpatient Physical Rehabilitation Program shall demonstrate the intent to meet the standards of the Commission on Accreditation of Rehabilitation Facilities ("CARF") applicable to the type of Program to be offered within eighteen (18) months of offering the new service.

(f) An applicant for an expanded Comprehensive Inpatient Physical Rehabilitation Program shall be accredited by the CARF for the type of Program which the applicant seeks to expand prior to application. The applicant must provide proof of such accreditation.

(g) An applicant for a new freestanding rehabilitation hospital shall demonstrate the intent to meet the licensure Rules of the Healthcare Facility Regulation Division for such hospitals.

(h) An applicant for an expanded freestanding rehabilitation hospital shall demonstrate a lack of uncorrected deficiencies as documented by letter from the Healthcare Facility Regulation Division.

(i) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall have written policies and procedures for utilization review. Such review shall consider, but is not limited to, factors such as medical necessity, appropriateness and efficiency of services, quality of patient care, and rates of utilization.

(j) An applicant for a new or expanded freestanding rehabilitation hospital shall document the existence of referral arrangements, including transfer agreements with an acute-care hospital(s) within the planning region to provide emergency medical treatment to any patient who requires such care. If the nearest acute-care hospital is in an adjacent planning region, the applicant may document the existence of transfer agreements with that hospital in lieu of such agreements with a hospital located within the planning region.

(k) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall foster an environment that assures access to services to individuals unable to pay and regardless of payment source or circumstances by the following:

1. providing evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis;

2. providing a written commitment that un-reimbursed services for indigent and charity patients in the service will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the service after Medicare and Medicaid contractual adjustments and bad debt have been deducted; and

3. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to individuals unable to pay based on the past record of service to Medicare, Medicaid, and indigent and charity patients, including the level of un-reimbursed indigent and charity care.

(l) Reserved.

(m) An applicant for a new or expanded Comprehensive Inpatient Physical Rehabilitation Program shall agree to provide the State Health Department with requested information and statistical data related to the operation of such a Program on a yearly basis, or as needed, and in a format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.35

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq*****.**

HISTORY: Original Rule entitled "Specific Review Considerations for Comprehensive Inpatient Physical Rehabilitation Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Nov. 22, 2006; eff. Dec. 12, 2006.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.35, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March

13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.36 Specific Review Considerations for Long Term Care Hospitals

(1) **Applicability.** A Certificate of Need ("CON") shall be required prior to the establishment of a new or the expansion of an existing Long Term Care Hospital. An application for Certificate of Need for a new or expanded Long Term Care Hospital shall be reviewed under the General Review Considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09 and the service-specific review considerations of this Rule.

(2) **Definitions.**

(a) 'Expansion' or 'Expanded' means the addition of beds to an existing CON-authorized or grandfathered Long Term Care Hospital. A CON-authorized or grandfathered Long Term Care Hospital may increase the bed capacity of an existing hospital by the lesser of ten percent (10%) of existing capacity or 10 beds if it has maintained an average occupancy of eighty-five percent (85%) for the previous twelve (12) calendar months provided that there has been no such increase in the prior two years and provided that the capital expenditures associated with the increase do not exceed the Capital Expenditure Threshold. If such an increase exceeds the Capital Expenditure Threshold, the increase will be considered an expansion for which a Certificate of Need shall be required under these Rules.

(b) 'Free-standing LTCH' or 'Free-standing LTACH' means a Long Term Care Hospital organized and operated as a self-contained health care facility.

(c) 'Hospital-within-a-Hospital LTCH' or 'Hospital-within-a-Hospital LTACH' means a Long Term Care Hospital co-located within the same building or the same campus as another CON-Authorized hospital.

(d) 'Long Term Care Hospital' or 'LTCH' or 'Long Term Acute Care Hospital' or 'LTACH' means a hospital that is classified as a long term hospital by the Medicare program pursuant to 42 CFR 412.23(e). These hospitals typically provide extended medical and rehabilitative care for patients who are clinically complex and may suffer from multiple acute or chronic conditions. Services typically include comprehensive rehabilitation, respiratory therapy, head trauma treatment, and pain management. For regulatory purposes, the definition includes a hospital which asserts its intent to be Medicare-classified as a long term hospital within twenty-four (24) months of accepting its first patient. If an entity, which has been awarded a CON pursuant to this Rule, has not been so classified by Medicare within this timeframe, the CON issued to that entity shall be revoked. An entity, which has had its CON revoked pursuant to this Rule, shall not have the authority to operate as a general acute care hospital. However, an acute care hospital, which has been awarded a CON to convert acute care beds for use as a long term care hospital, may again use such beds for acute care if such beds have not been Medicare-classified as a long term care hospital within twenty-four (24) months of accepting its first patient. Furthermore, a hospital that has been approved through the Certificate Of Need process to use all of its short-stay beds for a Freestanding LTCH shall have such beds removed from the official inventory of available short-stay beds when the LTCH is certified by Medicare; provided, however, that the hospital's beds will revert to the official inventory of available short-stay beds at any point that the facility ceases to be certified by Medicare as an LTCH.

(e) 'New' means a hospital that has not been classified by the Medicare program as a long term hospital in the previous twelve (12) months. For purposes of these Rules, an existing hospital which proposes to be relocated to a location more than three miles from its present location shall be considered "new".

(f) 'Occupancy Rate' means the ratio of beds occupied by inpatients as reported on the most recent Annual Hospital Questionnaire divided by the total licensed beds.

(g) 'Official State Health Component Plan' means the document related to Long Term Care Hospitals developed by the Department, established by the Georgia Health Strategies Council and signed by the Governor of Georgia.

(h) 'Planning Region' means one of the four sub-state regions for Long Term Care Hospitals, as follows:

1. LTCH Region 1, including the following counties: Dade, Walker, Catoosa, Whitfield, Murray, Gilmer, Fannin, Union, Towns, Rabun, Stephens, Habersham, White, Lumpkin, Dawson, Pickens, Gordon, Chattooga, Floyd, Bartow, Cherokee, Forsyth, Hall, Banks, Franklin, Hart, Elbert, Madison, Jackson, Barrow, Gwinnett, Fulton, Cobb, Paulding, Polk, Haralson, Carroll, Douglas, DeKalb, Rockdale, Walton, Oconee, Clarke, Oglethorpe, Greene, Morgan, Newton, Butts, Henry, Clayton, Fayette, Coweta, Heard, Troup, Meriwether, Pike, Spalding, Lamar, and Upson

2. LTCH Region 2, including the following counties: Wilkes, Lincoln, Columbia, McDuffie, Warren, Taliaferro, Hancock, Glascock, Putnam, Jasper, Monroe, Jones, Baldwin, Washington, Jefferson, Richmond, Burke, Screven, Jenkins, Emmanuel, Johnson, Treutlen, Montgomery, Wheeler, Telfair, Wilcox, Dodge, Laurens, Pulaski, Bleckley, Houston, Peach, Twiggs, Wilkinson, Bibb, and Crawford

3. LTCH Region 3, including the following counties: Harris, Talbot, Taylor, Muscogee, Chattahoochee, Marion, Schley, Macon, Dooly, Sumter, Webster, Stewart, Quitman, Randolph, Terrell, Lee, Crisp, Ben Hill, Irwin, Turner, Worth, Dougherty, Calhoun, Clay, Early, Baker, Mitchell, Colquitt, Miller, Cook, Tift, Berrien, Lanier, Echols, Lowndes, Brooks, Thomas, Grady, Decatur, and Seminole

4. LTCH Region 4, including the following counties: Effingham, Bulloch, Candler, Toombs, Tattnall, Evans, Bryan, Chatham, Liberty, Long, Wayne, Appling, Jeff Davis, Coffee, Bacon, Pierce, Brantley, McIntosh, Glynn, Camden, Charlton, Ware, Atkinson, and Clinch

(3) **Service-Specific Review Standards.**

(a) The need for new or expanded Long Term Care Hospital in a LTCH planning region shall be determined using the following need projection:

1. Determine the total discharges from general acute care hospitals less LTCH discharges, and less perinatal and neonatal discharges, and less psychiatric and substance abuse discharges, and less comprehensive inpatient physical rehabilitation discharges for the planning region in which the Long Term Care Hospital is or will be located. The source of discharge data for purposes of this Rule include data collected pursuant to O.C.G.A. § 31-7-280(c)(14), or in the Department's discretion, discharge data collected on the most recent Annual Hospital Questionnaire.

2. Calculate the discharge rate for each planning region by dividing the number of current acute care discharges obtained in Step 1 in each planning region by the corresponding year's resident population projection from the Governor's Office of Planning and Budget in each planning region.

3. Calculate the projected discharges for each planning region by multiplying the discharge rate obtained in Step 2 by the horizon year resident population projection for that planning region and then reduce that figure by six percent (6%) to account for overlap with rehabilitation facilities.

4. Calculate gross beds needed in the horizon year as follows:

(i) Multiply the projected discharges obtained in Step 3 by a utilization factor of 1.3% to determine the projected number of acute care discharge who may benefit from services at a LTCH.

(ii) Multiply the product obtained in Step 4(i) by the average LTCH length of stay for the most recent previous three-year period. Beginning with the first need calculation and continuing until the third complete year of survey data collected pursuant to this Rule, the Department shall use 28.1 as a proxy for the average LTCH length of stay for the previous three years.

(iii) Divide the product obtained in Step 4(ii) by 365 to determine the projected daily LTCH census.

(iv) Divide the result obtained in Step 4(iii) by .85 to determine the number of projected LTCH beds utilizing an eighty-five percent (85%) capacity standard.

5. Determine the current inventory of LTCH beds in the planning region from Departmental data. For all long term care hospital providers, which have been licensed as a Long Term Care Hospital by the Healthcare Facility Regulation Division, the current inventory of LTCH beds shall reflect the number of beds reported as CON-authorized in the Facility Inventory prior to the date of adoption of these Rules augmented from that time forward only by increases in bed capacity approved through the CON process (or by exemptions thereto) and by decreases due to a provider ceasing to provide such services for a period in excess of twelve (12) months. For purposes of this Rule, the initial inventory shall not include the beds of licensed rehabilitation hospitals even if such hospitals have a reported average length of stay of greater than twenty-five (25) days for Medicare patients; the beds of such facilities shall continue to be included in the applicable Comprehensive Inpatient Physical Rehabilitation inventory.

6. If the projected LTCH bed need in Step 4(iv) is greater than the current inventory of LTCH beds in the planning region, the application for the Certificate of Need should reflect a number of beds equal to or lesser than the resulting unmet bed need.

(b) An applicant for a new or expanded Long Term Care Hospital shall document that the establishment or expansion of its hospital will not have an adverse impact on an existing and approved long term care hospital in its planning region. An applicant for a new or expanded Long Term Care Hospital shall have an adverse impact on existing and approved hospitals of the same type if it will:

1. decrease annual utilization of an existing hospital, whose current utilization is at or above eighty-five percent (85%), to a projected annual utilization of less than seventy-five percent (75%) within the first twelve (12) months following the acceptance of the applicant's first patient; or

2. decrease annual utilization of an existing hospital, whose current utilization is below eighty-five percent (85%), by ten percent (10%) over the twelve (12) months following the acceptance of the applicant's first patient.

The applicant shall provide evidence of projected impact by taking into account existing planning region market share of hospitals of the same type and future population growth or by providing sufficient evidence that the current population is underserved by the existing Long Term Care Hospitals within the planning region.

(c) The Department may grant an exception to the need methodology of Ga. Comp. R. & Regs. r. 111-2-2-.36(3)(a) and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-2-2-.36(3)(b) for an applicant proposing a program to be located in a county with a population of less than 75,000 and to be located a minimum of fifty (50) miles away from any existing program in the state; or to remedy an atypical barrier to the services of a Long Term Care Hospital based on cost, quality, financial access or geographic accessibility. The Department may grant an exception to the need methodologies of either Ga. Comp. R. & Regs. r. 111-2-2-.36(3)(a) and to the adverse impact standard of Ga. Comp. R. & Regs. r. 111-2-2-.36(3)(b) if the applicant's annual census demonstrates thirty percent (30%) out of state utilization for the previous two years.

(d) A new or expanded Long Term Care Hospital shall have the following minimum bed sizes:

1. A new freestanding LTCH shall have a minimum bed size of forty (40) beds.

2. A new Hospital-within-a-Hospital LTCH shall have a minimum bed size of twenty (20) beds.

3. The minimum number of beds for the expansion of an existing Long Term Care Hospital, including satellite locations, shall be ten (10) beds or ten percent (10%) of the total current licensed bed total of current Long Term Care Hospital, whichever is less.

(e) An applicant for a new Long Term Care Hospital shall demonstrate the intent to meet the standards of the Joint Commission or another nationally recognized health care accreditation body within twenty-four (24) months of accepting its first patient. An applicant for an expanded Long Term Care Hospital shall be Joint Commission-certified or certified by another nationally recognized health care accreditation body as of the date of its application and shall furnish proof of the certification as a part of the Certificate of Need application process.

(f) An applicant for a new Long Term Care Hospital shall demonstrate the intent to meet the Licensure Rules of the Healthcare Facility Regulation Division for such hospitals. An applicant for an expanded Long Term Care Hospital shall demonstrate a lack of uncorrected deficiencies as documented by letter from the Healthcare Facility Regulation Division.

(g) An applicant for a new or expanded Long Term Care Hospital shall have written policies and procedures for utilization review. Such review shall consider, but is not limited to, factors such as medical necessity, appropriateness and efficiency of services, quality of patient care, and rates of utilization.

(h) An applicant for a new or expanded Long Term Care Hospital shall document the existence of referral arrangements, including transfer agreements, with an acute-care hospital(s) within the planning region to provide emergency medical treatment to any patient who requires such care. If the nearest acute-care hospital is in an adjacent planning region, the applicant may document the existence of transfer agreements with that hospital in lieu of such agreements with a hospital located within the planning region.

(i) An applicant for a new or expanded Long Term Care Hospital shall foster an environment that assures access to services to individuals unable to pay and regardless of payment source or circumstances by the following:

1. providing evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis;

2. providing a written commitment that un-reimbursed services for indigent and charity patients in the service will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the service after Medicare and Medicaid contractual adjustments and bad debt have been deducted;

3. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to individuals unable to pay based on the past record of service to Medicare, Medicaid, and indigent and charity patients, including the level of un-reimbursed indigent and charity care;

4. providing documentation of current or proposed charges and policies, if any, regarding the amount or percentage of charges that charity patients, self pay patients, and the uninsured will be expected to pay; and

5. agreeing to participate in the Medicare and Medicaid programs if such programs reimburse for such services.

(j) Reserved.

(k) An applicant for a new or expanded Long Term Care Hospital shall agree to provide the Department with requested information and statistical data related to the operation of such a Program on a yearly basis, or as needed, and in a format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.36

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq*.., 31-6** ***et seq*.**

HISTORY: Original Rule entitled "Specific Review Considerations for Long Term Care Hospitals" adopted. F. Nov. 17, 2005; eff. Dec. 7, 2005.

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Note: Rule 111-2-2-.36, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March

13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.40 Specific Review Considerations for Ambulatory Surgery Services

(1) **Applicability**. For Certificate of Need purposes, an Ambulatory Surgery Service is considered a new institutional health service if it is to be offered in an ambulatory surgery facility ("ASF") or in a diagnostic, treatment, or rehabilitation center ("DTRC").

(a) If the ambulatory surgery service is or will be provided as "part of a hospital", the hospital's provision of such service is not subject to Certificate of Need review under this Rule. For purposes of this Rule, the following are always considered to be "part of a hospital":

a) if the service is located within a hospital; or

b) if the service is located in a building on the hospital's primary campus and that building, or relevant portion thereof, is included within the hospital's permit issued by the State's licensing agency, subject to determination by the Department. The Department also will make a determination of reviewability on a case-by-case basis in other situations involving hospitals.

(b) The entity that develops any ambulatory surgery service shall be the applicant.

(c) A single specialty ambulatory surgery service will be issued a single specialty CON. A new CON will be required to become a multi-specialty service.

(d) These Rules do not apply to adult open-heart surgery, adult cardiac catheterization, pediatric cardiac catheterization, pediatric open-heart surgery, and obstetrical services because these services are covered under other CON Rules. If an ambulatory surgery service, which is part of a hospital, expands the number of ambulatory surgery operating rooms and the capital expenditure exceeds the CON threshold, the project will be reviewed under Ga. Comp. R. & Regs. r. 111-2-2-.40. If an ambulatory surgery service, which is part of a hospital, involves a capital expenditure, which exceeds the CON threshold and does not increase the number of ambulatory surgery operating rooms, the project will be reviewed under the General Review Considerations (Ga. Comp. R. & Regs. r. 111-2-2-.09).

(2) **Definitions.**

(a) "Ambulatory surgery" means surgical procedures that include but are not limited to those recognized by the Centers for Medicare and Medicaid Services ("CMS"), the Department's Division of Medical Assistance ("DMA"), the State Health Benefit Plans, or by any successor entities, as reimbursable ambulatory surgery procedures. Ambulatory surgery is provided only to patients who are admitted to a facility which offers ambulatory surgery and which does not admit patients for treatment that normally requires stays that are overnight or exceed twenty-four (24) hours and which does not provide accommodations for treatment of patients for periods of twenty-four hours or longer.

(b) "Ambulatory surgery facility" means a public or private facility, not part of a hospital, which provides surgical treatment performed under general or regional anesthesia in an operating room environment to patients not requiring hospitalization. In addition to operating rooms, an ambulatory surgery facility includes all components of pre and post-operative ambulatory surgery care.

(c) "Ambulatory surgery operating room" means an operating room located either in a hospital, in an ambulatory surgery facility, or in a DTRC facility that is equipped to perform surgery and is constructed to meet the specifications and standards of the Healthcare Facility Regulation Division.

(d) "Ambulatory surgery service" means the provision of ambulatory surgery including pre and post-operative care to patients not requiring hospitalization. An ambulatory surgery service may be provided within any of the following types of healthcare facilities: hospitals, ambulatory surgery facilities, or DTRCs.

(e) "Ambulatory surgery services patient" means a person who makes a single visit to an operating room during which one or more surgical procedures are performed.

(f) "Authorized ambulatory surgery service" means a Department sanctioned ambulatory surgery service, which is either existing or approved prior to the date on which the Department renders a decision on a proposed project. An existing ambulatory surgery service is an authorized service, which has become operational, and an approved ambulatory surgery service is an authorized service, which has not yet become operational, including any approvals under appeal.

(g) "Diagnostic, treatment, or rehabilitation center ("DTRC") facility" means, for purposes of this Rule, any professional or business undertaking, whether for profit or not-for-profit, which offers or proposes to offer an ambulatory surgery service in a setting that is not part of a hospital.

(h) "Most recent year" means the most current twelve-month period within a month of the date of completion of an application or within a month of the date of completion of the first application when applications are joined. If the Department has received an annual or ad hoc survey within six (6) months of the date of completion of the application (or first application when applications are joined), the Department may consider the report period covered in such a survey as the most recent year.

(i) "Multi-specialty ambulatory surgery service" means an ambulatory surgery service offering surgery in more than one of, but not limited to, the following specialties; dentistry/oral surgery, gastroenterology, general surgery, obstetrics/gynecology, ophthalmology, orthopedics, otolaryngology, pain management/anesthesiology, plastic surgery, podiatry, pulmonary medicine, or urology.

(j) "Not requiring hospitalization" means patients who do not require an inpatient admission to an acute care general hospital prior to receiving ambulatory surgery services, who normally would not require a stay that is overnight or exceeds twenty-four (24) hours, and who are not expected to require an inpatient admission after receiving such services.

(k) "Official inventory" means the inventory of all facilities authorized to perform ambulatory surgery services maintained by the Department based on responses to the most recent Annual Hospital Questionnaire ("AHQ") Surgical Services Addendum and Freestanding Ambulatory Surgery Center Survey and/or the most recent appropriate surveys and questionnaires.

(l) "Official state component plan" means the document related to ambulatory surgery services adopted by the State Health Strategies Council, approved by the Board of Community Health, and implemented by the State of Georgia for the purpose of providing adequate health care services and facilities throughout the state.

(m) "Operating room environment" means an environment, which meets the minimum physical plant and operation standards specified by Chapter 111-8-4 of the Rules of the Healthcare Facility Regulation Division or such substantially equivalent standards as determined by the Department. Such acceptable standards shall be maintained on the Department's website.

(n) "Planning Area" means fixed sub-state regions for reviewable services as defined in the State Health Component Plan for Ambulatory Surgery Services.

(o) "Single specialty ambulatory surgery service" means an ambulatory surgery service providing surgery in only one of the specialty areas as defined in Ga. Comp. R. & Regs. r. 111-2-2-.40(2)(i).

(3) **Standards.**

(a) The need for an ambulatory surgery service shall be determined through application of a numerical need method and an assessment of the aggregate utilization rate of existing services.

1. The numerical need for an ambulatory surgery service shall be determined by a demographic formula which includes the number of ambulatory surgery services cases in a planning area. The following need calculation applies to each planning area:

(i) determine the projected ambulatory surgery services patients for the horizon year by multiplying the planning area ambulatory surgery patients' rate by the total Resident population for the planning area for the horizon year;

(ii) determine the number of operating rooms needed by dividing the number of projected ambulatory surgery services patients (step i) by the capacity per operating room. Capacity per operating room per year is 1000 patients. (This is based on 250 operating room days per year (50 weeks x 5 days/weeks) x 5 patients per room per day x 80% utilization.);

(iii) determine the existing and approved inventory of ambulatory surgery operating rooms by adding:

(I) The pro-rata portion of hospital shared inpatient/ambulatory surgery operating rooms devoted to ambulatory surgery services. This portion is determined as follows: (# ambulatory surgery patients x 90 min.) {(ambulatory surgery patients x 90 min)+(inpatient patients x 145 min.)} x # shared rooms

(II) # of hospital dedicated ambulatory surgery operating rooms; and

(III) # of freestanding ambulatory surgery operating rooms.

(iv) determine the projected net surplus or deficit for ambulatory surgery services by subtracting the total ambulatory surgery operating rooms needed (step iii) from the inventory of existing and approved ambulatory surgery services operating rooms in the planning area.

2. Prior to approval of a new or expanded ambulatory surgery service in any planning area, the aggregate utilization rate of all existing and approved ambulatory surgery service in that planning area shall equal or exceed eighty percent (80%) during the most recent year; and

3. A proposed multi-specialty ambulatory surgery service shall have a minimum of three operating rooms and a single specialty ambulatory surgery service shall have a minimum of two operating rooms.

(b) The Department may allow an exception to the need standard referenced in (3)(a), in order to remedy an atypical barrier to ambulatory surgery services based on cost, quality, financial access, or geographic accessibility. An applicant seeking such an exception shall have the burden of proving to the Department that the cost, quality, financial access, or geographic accessibility of current services, or some combination thereof, result in a barrier to services that should typically be available to citizens in the planning area and/or the communities under review. In approving an applicant through the exception process, the Department shall document the bases for granting the exception and the barrier or barriers that the successful applicant would be expected to remedy.

(c) Each applicant shall have a hospital affiliation agreement and/or the medical director must have admitting privileges and other acceptable documented arrangements to insure the necessary backup for medical complications. The applicant must document the capability to transfer a patient immediately to a hospital with adequate emergency room services.

(d) An applicant shall submit written policies and procedures regarding discharge planning. These policies should include, where appropriate, designation of responsible personnel, participation by the patient, family, guardian or significant other, documentation of any follow-up services provided and evaluation of their effectiveness.

(e) An applicant shall provide evidence of a credentialing process that provides that surgical procedures will be performed only by licensed physicians who have been granted privileges to perform these procedures by the organization's governing body.

(f) An applicant shall assure that an anesthesiologist, a physician qualified to administer anesthesia, an oral surgeon, or a nurse anesthetist trained and currently certified in emergency resuscitation procedures is present on the premises at all times a surgical patient is present.

(g) An applicant shall submit evidence that qualified personnel will be available to insure a quality service to meet licensure, certification and/or accreditation requirements.

(h) An applicant shall submit a policy and plan for reviewing patient care, including a stated set of criteria for identifying those patients to be reviewed and a mechanism for evaluating the patient review process.

(i) An applicant shall submit written policies and procedures for utilization review consistent with state federal and accreditation standards. This review shall include review of the medical necessity for the service, quality of patient care, and rates of utilization.

(j) An applicant shall provide a written statement of its intent to comply with all appropriate licensure requirements and operational procedures required by the Healthcare Facility Regulation Division.

(k) An applicant for a new ambulatory surgery service shall provide a statement for the intent to meet, within twelve (12) months of obtaining state licensure, the appropriate accreditation requirements of the Joint Commission or another nationally recognized health care accreditation body, the Accreditation Association for Ambulatory Health Care (AAAHC), the American Association for Accreditation of Ambulatory surgery Facilities, Inc. (ASF) and/or other appropriate accrediting agency.

(l) An applicant for an expanded ambulatory surgery service shall provide documentation that they fully meet the appropriate accreditation requirements of the Joint Commission or another nationally recognized health care accreditation body, the Accreditation Association for Ambulatory Health Care ("AAAHC"), the American Association for Accreditation of Ambulatory Surgery Facilities, Inc. ("ASF") and/or other appropriate accrediting agency.

(m) An applicant shall provide documentation that charges are reasonable compared to other similar surgery services serving the same planning area.

(n) An applicant shall foster an environment that assures access to services to individual's unable to pay and regardless of payment source or circumstances by the following:

1. providing evidence of written administrative policies and directives related to the provision of services on a nondiscriminatory basis;

2. providing a written commitment that unreimbursed services for indigent and charity patients in the service will be offered at a standard which meets or exceeds three percent (3%) of annual gross revenues for the service after Medicare and Medicaid contractual adjustments and bad debt have been deducted; and

3. providing documentation of the demonstrated performance of the applicant, and any facility in Georgia owned or operated by the applicant or the applicant's parent organization, of providing services to individuals unable to pay based on the past record of service to Medicare, Medicaid, and indigent and charity patients, including the level of unreimbursed indigent and charity care.

(o) An applicant for an ambulatory surgery service shall document an agreement to provide Department requested information and statistical data related to the operation and provision of ambulatory surgery and to report that data to the Department in the time frame and format requested by the Department. This information shall include, but not be limited to, any changes in number of ambulatory surgery operating rooms that may occur as a result of service expansion.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.40

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq*****.**

HISTORY: Original Rule entitled "Specific Review Considerations for Ambulatory Surgery Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Amended: F. Dec. 14, 2007; eff. Jan. 3, 2008.

Amended: F. Sept. 11, 2008; eff. Oct. 1, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.40, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.41 Specific Review Considerations for Positron Emission Tomography Units

(1) **Applicability.**

(a) A Certificate of Need shall be required for a new or expanded positron emission tomography ("PET") unit.

(b) On or after January 1, 2008, the Department shall only consider and approve applications for dual modality PET units; stand-alone PET units shall not be approved.

(c) On or after January 1, 2008, an applicant for a mobile unit site shall be the hospital or DTRC which has entered into an agreement to receive mobile services. The actual mobile service provider shall not be the applicant. The hospital or DTRC that is serviced by the mobile provider shall be responsible for the provision of annual surveys and the provision of information to the Department.

(d) On or after January 1, 2008, a mobile provider shall be required to obtain a CON only if the fair market value or purchase price of the unit and any and all functionally related equipment exceeds the equipment threshold. If the fair market value or purchase price exceeds the equipment threshold, the mobile provider shall apply for a Certificate of Need under the general review considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09(1).

(e) A Certificate of Need obtained by a hospital or DTRC to offer mobile PET services shall be valid for the provision of mobile PET services only. A hospital or DTRC approved to offer mobile PET services must obtain a separate CON prior to offering fixed PET services.

(2) **Definitions.**

(a) "Health Planning Area" or "planning area" means the thirteen (13) geographic regions in Georgia as defined in the official State Health Component Plan for use in planning for PET Scan services.

(b) "Horizon Year" means the last year of a five-year projection period for need determinations.

(c) "Expansion" or "expanded service" means the addition of a fixed or mobile unit at a hospital or DTRC. The addition of a component or components, such as computer tomography (CT) imaging, to an existing fixed or mobile unit or the upgrade of an existing fixed or mobile unit shall not be considered an expansion and shall not be subject to the need standards; provided, however, that if any such addition or upgrade is subject to review due to the equipment threshold at that time, the applicant shall demonstrate compliance with or document a plan and agreement to comply with Ga. Comp. R. & Regs. r. 111-2-2-.41(3)(d),(e),(f), and (g).

(d) "Fixed Unit" means a unit that is stationary within one approved facility.

(e) "Mobile Unit" means a unit that is operated by one or shared by two or more health care facilities and which has a data acquisition system and a computer. In order to meet the definition of mobile unit, the applicant must provide proof of the following:

1. The unit must not be on site at any Facility more than three (3) consecutive operating days per week or sixteen (16) total days per month.

2. The facilities involved with the mobile unit are fully informed and participating in the service as evidenced by written agreements or correspondence provided in the application.

3. For applications approved prior to January 1, 2008, a mobile provider is limited to providing service only to those facilities approved in the mobile provider's application for CON. On or after January 1, 2008, a mobile provider may serve any hospital or DTRC that receives a Certificate of Need for mobile PET services, provided that no hospital or DTRC may be serviced by more than one mobile provider at a time.

4. The applicant shall project scans per facility on a pro-rated basis for the first year of operation, and such projections shall be used in any need determinations during that first year of operation. Thereafter, in annual surveys, the applicant, if successful, must document scans by each service facility for use in need determinations.

(f) "Optimal Utilization" refers to scans per year and shall be defined as 2,750 PET scans per year. A PET Scan or Study means the gathering of data during a single patient visit from which one or more images may be constructed.

(g) "PET Scan Service" or "Service" means a facility that owns one or more units and provides diagnostic imaging through positron emission tomography exclusively or as a dedicated PET/CT or dual modality unit.

(h) "Positron Emission Tomography" or "PET" means a noninvasive diagnostic technology, which enables the body's physiological and biological processes to be observed through the use of positron emitting radiopharmaceuticals.

(i) "Unit" means a single piece of equipment that performs PET scans.

(3) **Standards.**

(a) The need for a new or expanded service shall be determined through the application of a Numerical Need method and an assessment of the aggregate utilization rate of existing and approved units.

1. The numerical need for a new unit in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:

(i) Calculate the projected incidence of cancer for each county by multiplying the most recent Cancer Incidence Rate, as published by the State Cancer Registry, for each county by the horizon year population for the county;

(ii) Multiply the projected incidence of cancer by fifty percent (50%) to determine the projected number of patients diagnosed with cancer who might benefit from a scan.

(iii) Add the number of cancer cases that might benefit from a scan for each county within a Health Planning Area to determine the estimated need for services within a Health Planning Area for persons diagnosed with cancer.

(iv) Multiply the number of cancer cases for each Health Planning Area from subsection (iii) by 1.4 to accommodate for non-oncology patients and for follow-up scans for oncology patients in the projected need for services. On or after January 1, 2010, in lieu of multiplying by 1.4 each year, the Department shall use actual data from the previous 2 survey years to determine the multiplication factor by adding 1 to the ratio of cardiology, neurology and follow up oncology scans to the number of initial oncology scans.

(v) Calculate the number of needed units by dividing the number of individuals who might receive scanning services as determined from subsection (iv) by 2,750, which represents the optimal utilization of a unit.

(vi) Determine the net numerical unmet need for PET scan unit(s) by subtracting the total number of PET/CT or dual modality units currently existing or approved for use from the number of needed units. Mobile units shall be subtracted based on the number of days providing service to sites within a planning area in the most recent survey year divided by 365. Stand-alone PET units shall not be included in the inventory and shall not be subtracted to determine the net numerical unmet need.

(vii) If the net numerical unmet need in any Health Planning Area is at or above seventy-five percent (75%) of a unit (approximately 2,062 individuals needing scans), the needed units shall be rounded up by one unit. If the balance net numerical need in any Health Planning Area is at or above 3.2875% of a unit (approximately (90) individuals needing scans), a mobile unit may be approved to serve the planning area. The maximum number of days a mobile unit may be approved to provide services in the planning area shall be determined using the following formula:

APPROVED DAYS PER YEAR

< NET NUMERICAL UNMET NEED

365

2. Prior to the approval of a new or expanded unit in a planning area, the aggregate utilization rate for all units in that planning area that existed during the most recent survey year and that provided data to the Department for the most recent survey year shall equal or exceed eighty percent (80%) of optimal utilization for the most recent survey year.

(b) Exceptions to the need standards and requirements in (3)(a) may be granted by the Department:

1. to an applicant seeking to remedy an atypical barrier to services based on cost, quality, financial access, or geographic accessibility when the applicant has documented such a barrier;

2. to an applicant seeking the addition of a fixed unit who has been served solely by a mobile PET when the applicant demonstrates that 850 studies have been performed on the mobile unit at the applicant's facility in the most recent survey year; and

3. to an applicant hospital that treats as inpatients persons who have been diagnosed with cancer and are undergoing treatment for the disease and who will offer the PET service to its patients through a contract with a mobile PET provider.

(c) In considering applications joined for review, the Department may give favorable consideration to an applicant that has historically provided a higher annual percentage of un-reimbursed services to indigent and charity patients.

(d) An applicant for a new or expanded service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing a written policy regarding the provision of any services provided by or on behalf of the applicant that stipulates that any such services shall be provided regardless of race, age, sex, creed, religion, disability, or patient's ability to pay, and documentation or evidence that the applicant has a service history reflecting the principles of such a policy; and

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds five percent (5%) of annual, adjusted gross revenues of the PET scan service; or

3. providing a written commitment to participate in Medicaid, Peach Care and Medicare programs, to the extent such programs reimburse for PET scan services, and to accept any Medicaid-, Peach Care- and/or Medicare-eligible patient for services;

4. providing a written commitment that the applicant, subject to good faith negotiations, will participate in any state health benefits insurance programs for which the service is deemed eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients. The applicant's or its parent organization's failure to provide services at an acceptable level to Medicare, Medicaid and indigent and charity patients, and/or the failure to fulfill any previously made commitment to indigent and charity care may constitute sufficient justification to deny the application.

(e) An applicant for a new or expanded service shall provide evidence of the ability to meet the following quality of care standards:

1. Document certification or a plan for securing certification for operation of a unit from the Georgia Department of Natural Resources.

2. Document that the unit proposed for purchase is approved for use by the U.S. Food and Drug Administration and for reimbursement by the Center for Medicare and Medicaid Services.

3. Document that the service will function as a component of a comprehensive diagnostic service and that appropriate referral to treatment and follow-up will be provided. The applicant must have accessible the following modalities and capabilities on site or through agreements, as evidenced by documentation provided at the time of application: computed tomography, magnetic resonance imaging, nuclear medicine, and conventional radiography.

4. Document that the PET service shall be under the direction of a physician who is board certified in nuclear medicine or diagnostic radiology; and is licensed as an authorized user of radioactive materials in accordance with the Rules of the Georgia Department of Natural Resources.

5. Document that the PET services has arrangements with board-certified interpreting physician(s) that are licensed in the State of Georgia.

6. Document the training and experience in PET scan services of the physician, nuclear medicine technologist, and radiology technologist. Such personnel shall be certified by appropriate national accreditation bodies.

7. Document fully the safe and timely access to radiopharmaceuticals.

(f) An applicant for a new or expanded service shall provide evidence of the ability to meet the following continuity of care standards:

1. Document that the applicant provides or has signed emergency transfer agreements and arrangements with one or more acute care hospital(s) located within the applicant's health planning area or in the case where the nearest acute care hospital is located in an adjacent health planning area, the nearest acute care hospital.

2. Document a referral system that includes a feedback mechanism for communicating scan results and any other pertinent patient information to the referring physician.

3. Document that the applicant will maintain current listings of appropriate clinical indications for PET procedures and will provide such listings to referring physicians and patients.

4. Document how medical emergencies will be managed in conformity with accepted medical practice.

(g) An applicant for a new or expanded service shall agree to provide the Department with all requested information and statistical data related to the operation and provision of services and to report that data to the Department in the time and format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.41

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq*****.**

HISTORY: Original Rule entitled "Specific Review Considerations for Positron Emission Tomography Units" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: New Rule of same title adopted. F. May 13, 2008; eff. June 2, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.41, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

111-2-2-.42 Specific Review Considerations for MegaVoltage Radiation Therapy Services/Units

(1) **Applicability.**

(a) A Certificate of Need will be required for the establishment of any new or expanded MegaVoltage Radiation Therapy Service.

(b) MegaVoltage Radiation Therapy, including Stereotactic Radiosurgery (SRS) and Stereotactic Body Radiation Therapy (SBRT) may be conducted on non-special units or on special purpose units.

(c) A Certificate of Need will be required for the addition of a non-special MRT unit. An application for the addition of a non-special MRT unit shall address the standards contained in Ga. Comp. R. & Regs. r. 111-2-2-.42(3) in addition to the general review considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09(1). A certificate holder who has been authorized to provide MRT service solely on a non-special unit may not provide service on a special purpose unit without obtaining a special purpose MRT Certificate of Need.

(d) A Certificate of Need will be required for the addition of a special purpose MRT unit. An application for the addition of a special purpose MRT unit shall address the standards contained in Ga. Comp. R. & Regs. r. 111-2-2-.42(4) in addition to the general review considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09(1). A certificate holder who has been authorized to provide MRT service solely on a special purpose unit may not provide service on a non-special unit without obtaining a non-special MRT Certificate of Need.

(e) An application for the establishment of a new or expanded MegaVoltage Radiation Therapy Service with the addition of both non-special and special purpose MRT units shall address the standards of Ga. Comp. R. & Regs. r. 111-2-2-.42(3), 111-2-2-.42(4) and the general review considerations of Ga. Comp. R. & Regs. r. 111-2-2-.09(1).

(2) **Definitions.**

(a) "Brachytherapy" means the administration of radiation therapy by applying a radioactive material inside or in close proximity to the patient. The material may be contained in various types of apparatus; may be on the surface of plaques; or may be enclosed in tubes, needles, wire, seeds, or other small containers. Common materials that are or have been used for the administration of brachytherapy include but are not limited to radium, Cobalt-60, Cesium-137, Iodine-125, Palladium-103 and Iridium-192.

(b) "Complex treatment visit" means a treatment visit involving three or more treatment sites, tangential fields with wedges, rotational or arc techniques or other special arrangements, or custom blocking.

(c) "Course of treatment" means the planned series of visits that compose a plan for treatment of one or more cancer sites for a single patient.

(d) "Gamma knife" means a special stereotactic radiosurgery unit consisting of multiple cobalt sources all simultaneously focused to irradiate cancer or other neoplasms in the brain or cerebrovascular system abnormalities.

(e) "Health Planning Area" or "Planning Area" means the geographic regions in Georgia for use in planning for MRT services.

1. The Health Planning Areas or Planning Areas for non-special MRT services are the twelve state service delivery regions established by O.C.G.A. § 50-4-7.

2. The Health Planning Areas or Planning Areas for special purpose MRT services are five sub-state regions comprised as follows:

(i) Special Purpose MRT Region 1, including the following counties: Dade, Walker, Catoosa, Whitfield, Murray, Gilmer, Fannin, Union, Towns, Rabun, Stephens, Habersham, White, Lumpkin, Dawson, Pickens, Gordon, Chattooga, Floyd, Bartow, Cherokee, Forsyth, Hall, Banks, Franklin, Hart, Gwinnett, Fulton, Cobb, Paulding, Polk, Haralson, Douglas, DeKalb, Rockdale, Newton, Henry, Clayton, and Fayette;

(ii) Special Purpose MRT Region 2, including the following counties: Elbert, Madison, Jackson, Barrow, Oconee, Clarke, Oglethorpe, Greene, Morgan, Walton, Wilkes, Lincoln, Columbia, McDuffie, Warren, Taliaferro, Glascock, Jefferson, Richmond, Burke, Screven, Jenkins, and Emmanuel;

(iii) Special Purpose MRT Region 3, including the following counties: Carroll, Coweta, Heard, Troup, Meriwether, Pike, Spalding, Lamar, Upson, Harris, Talbot, Taylor, Muscogee, Chattahoochee, Marion, Schley, Macon, Sumter, Webster, Stewart, Quitman, Randolph, Terrell, Lee, Worth, Dougherty, Calhoun, Clay, Early, Baker, Mitchell, Colquitt, Miller, Brooks, Thomas, Grady, Decatur, and Seminole;

(iv) Special Purpose MRT Region 4, including the following counties: Hancock, Putnam, Jasper, Butts, Monroe, Jones, Baldwin, Washington, Johnson, Treutlen, Montgomery, Wheeler, Telfair, Wilcox, Dodge, Laurens, Pulaski, Bleckley, Houston, Peach, Twiggs, Wilkinson, Bibb, Crawford, Dooly, Crisp, Ben Hill, Irwin, Turner, Cook, Tift, Berrien, Lanier, Echols, and Lowndes; and

(v) Special Purpose MRT Region 5, including the following counties: Effingham, Bulloch, Candler, Toombs, Tattnall, Evans, Bryan, Chatham, Liberty, Long, McIntosh, Wayne, Appling, Jeff Davis, Coffee, Bacon, Pierce, Brantley, Glynn, Camden, Charlton, Ware, Atkinson, and Clinch.

(f) "Heavy particle accelerator" means a machine such as a cyclotron, which produces beams of high-energy particles such as protons, neutrons, pions, or heavy ions with rest masses greater than that of an electron (mc2 = 0.511 MeV).

(g) "Horizon Year" means the last year of a five-year projection period for need determinations for MRT services.

(h) "Intensity modulated radiation therapy" or "IMRT" means a treatment delivery utilizing a radiotherapy treatment plan optimized using an inverse or forward planning technique to modulate the particle or energy fluence to create a highly conformal dose distribution. This beam modulated treatment delivery can be accomplished either by the use of the computer controlled multi-leaf collimator or high resolution milled or cast compensators.

(i) "Intermediate treatment visit" means a treatment visit involving two separate treatment sites, three or more fields to a single treatment site, or the use of special blocking.

(j) "Megavoltage radiation therapy" or "MRT" means a clinical modality in which patients with cancer, other neoplasms, or cerebrovascular system abnormalities are treated with radiation which is delivered by an MRT unit.

(k) "MRT service" means the CON approved MRT utilization of a MRT unit(s) at one geographic location.

(l) "MRT unit" or "unit" means a CON approved linear accelerator; cobalt unit; or other piece of medical equipment operating at an energy level equal to or greater than 1.0 million electron volts (megavolts or MeV) for the purpose of delivering doses of radiation to patients with cancer, other neoplasms, or cerebrovascular system abnormalities.

(m) "Non-special MRT unit" or "non-special unit" means an MRT unit other than an MRT unit meeting the definition of a special purpose MRT unit.

(n) "Operating room based intraoperative MRT unit" or "OR-based IORT unit" means an MRT unit that is designed to emit only electrons, is located in an operating room in the surgical department of a licensed hospital and is available for the treatment of a patient undergoing a surgical procedure with megavoltage radiation.

(o) "Simple treatment visit" means a treatment visit involving a single treatment site, single treatment field, or parallel opposed fields with the use of no more than simple blocks.

(p) "Simulation" is the process of defining relevant normal and abnormal anatomy, acquiring the images and data necessary to develop the patient's approved radiation treatment plan. Simulation always occurs prior to treatment and may be repeated multiple times during the course of treatment depending on the type of cancer, the radiation therapy technique utilized and the patient's clinical response to treatment. Simulation is used to direct the treatment beams to the specific volume.

(q) "Special purpose MRT unit" or "special purpose unit" or "special unit" means any of the following types of MRT units:

(i) heavy particle accelerator;

(ii) gamma knife;

(iii) dedicated linear accelerator stereotactic radiosurgery unit (SRS LINAC), including CyberKnife; or

(iv) an OR-based IORT unit.

(r) "Stereotactic body radiation therapy (SBRT)" is a term used to describe extracranial stereotactic radiosurgery (SRS) or radiotherapy (SRT). SBRT is a radiotherapy treatment method to deliver a high dose of radiation to the target, utilizing either a single dose or a small number of fractions with a high degree of precision within the body.

(s) "Stereotactic treatment visit" or "SRS treatment visit" means a visit involving SRS or SBRT treatment techniques.

(t) "Stereotactic Radiosurgery (SRS)" is performed in a limited number of treatment visits (up to a maximum of five), using a rigidly attached stereotactic guiding device, other immobilization technology and/or a stereotactic image-guidance system to treat lesions in the body (extracranial) or brain (intracranial). Technologies that are used to perform SRS include linear accelerators, particle beam accelerators and multi source Cobalt-60 units.

(u) "SRS LINAC" is a dedicated linear accelerator stereotactic radiosurgery unit that consists of three key components:

(i) an advanced linear accelerator (linac) (this device is used to produce a high energy megavoltage of radiation),

(ii) a device which can point the linear accelerator from a wide variety of angles, and

(iii) image-guidance patient positioning system using kilovoltage x-rays for either in-room diagnostic x-rays or tomographic images. The devices obtain pictures of the patient (planar x-ray or computed tomography) before or during treatment and use this information to target the radiation beam emitted by the linear accelerator, SRS LINAC includes units such as CyberKnives.

(v) "Treatment site" means the anatomical location of the MRT treatment.

(w) "Treatment visit" means one patient encounter during which MRT is administered. One treatment visit may involve one or more treatment ports or fields. Each separate encounter by the same patient at different times of the same day shall be counted as a separate treatment visit.

(x) "Unit" means a single machine used for MRT services.

(y) "Urban County" means a county with a projected population for the horizon year of 100,000 or more and a population density for that year of 200 or more people per square mile. All other counties are "rural."

(3) **Standards for Non-Special MRT.**

(a) The need for the addition of a non-special MRT unit shall be determined through the application of a Numerical Need method and an assessment of the aggregate utilization rate of existing services not including units added through the exception in section (3)(b)(2) of this Rule.

1. The numerical need for the addition of a non-special MRT unit in a planning area shall be determined through the application of a demand-based forecasting model. The model is outlined in the steps listed below, and all data elements relate to each planning area:

(i) Calculate the projected incidence of cancer excluding basal, epithelial, papillary, and squamous cell carcinomas of the skin from other than a genital area for each county by multiplying the most recent Cancer Incidence Rate, as published by the State Cancer Registry, for each county by the horizon year population for the county;

(ii) Multiply the projected incidence of cancer by fifty percent (50%) to determine the number of projected cancer cases in each county that could be treated with a non-special MRT unit;

(iii) Add the number of treatable cases for each county within a Health Planning Area to determine the projected number of patients needing treatment with a non-special MRT unit within the Health Planning Area in the horizon year;

(iv) Multiply the number obtained in step (iii) above by the most recent two year average of treatment visits per patient for the respective planning area of each county to project the number of projected patient visits in the horizon year;

(v) Determine the percentage of total visits in each planning area attributable to (1) Simple treatment visits, (2) Intermediate treatment visits, (3) Complex treatment visits, (4) IMRT, and (5) SRS treatment visits performed on non-special equipment as based on a running average of the most recent two annual surveys for facilities located in each respective planning area. Prior to the 2008 survey year, the percentage of total visits in each planning area shall be based on the most recent annual survey for facilities located in each respective planning area;

(vi) Determine the number of projected equivalent visits in the horizon year for each planning area as follows:

A. Project the number of equivalent simple visits by multiplying the percentage obtained in step (v) for simple visits by the projected patient visits in the horizon year obtained in step (iv);

B. Project the number of equivalent intermediate visits by multiplying the percentage obtained in step (v) for intermediate visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for intermediate visits, 1.1;

C. Project the number of equivalent complex visits by multiplying the percentage obtained in step (v) for complex visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for complex visits, 1.3;

D. Project the number of equivalent IMRT visits by multiplying the percentage obtained in step (v) for IMRT visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for IMRT visits, 1.8;

E. Project the number of equivalent SRS visits by multiplying the percentage obtained in step (v) for SRS visits by the projected patient visits in the horizon year obtained in step (iv) and multiply the product by the weighted equivalent for SRS visits, 7.0; and

F. Sum the products obtained in step (vi)A. through step (vi)E.;

(vii) Calculate the number of needed non-special MRT units by dividing the number of projected equivalent visits obtained in step (iv)F. by 9,000, which represents the weighted equivalent capacity of a non-special MRT unit within a given year; and

(viii) Determine the net numerical unmet need for non-special MRT units by subtracting the total number of non-special MRT units currently existing or approved for use, not including units approved pursuant to the exception in section (3)(b)2. of this Rule, from the number of needed non-special MRT units obtained in step (vii).

2. Prior to approval of an additional non-special MRT unit in a planning area, the aggregate utilization rate for all existing non-special MRT units, not including units approved pursuant to the exception in section (3)(b)2. of this Rule, in that planning area shall equal or exceed eighty percent (80%) of capacity based on 9,000 weighted equivalent visits. For those existing non-special MRT units that have not reported data in the most recent survey year, the Department shall include the non-reporting unit at the statewide average utilization rate.

(b) Exceptions to the need standard referenced in (3)(a) may be granted for applicants proposing any of the following:

1. To assure geographic access to non-special MRT services in rural areas when the proposed service is:

(i) to be located in a rural county;

(ii) to be located a minimum of 45 miles away from any existing or approved non-special MRT service; and

(iii) projected to serve a minimum of 150 patients per year. For purposes of this requirement, service projections must be submitted by the applicant using, at a minimum, state cancer registry data and documented cancer treatments within the service area.

2. To allow expansion of an existing service if the actual utilization of each radiation therapy unit within that service has exceeded ninety percent (90%) of optimal utilization over the most recent two years. Any such units approved pursuant to this exception shall not be included in the calculation of need and aggregate utilization for the applicable service delivery region but will be included in the Department non-special MRT unit inventory.

3. To allow the addition of a non-special MRT unit at the same defined location if the applicant has a substantial out-of-state patient base. 'Substantial out of state patient base' shall be defined as using at least thirty-three percent (33%) of capacity or 2,970 weighted equivalent visits at the applicant's own percentage of treatment visits weighted by treatment type using the statewide weighted equivalent factor for each non-special MRT unit over the most recent two years to treat patients who reside outside of the State of Georgia.

4. To remedy an atypical barrier to non-special MRT services based on cost, quality, financial access and geographic accessibility.

(c) An applicant for a new or expanded non-special MRT service shall document the impact on existing and approved services which already provide non-special MRT to the residents of the planning area with the goal of minimizing adverse impact on existing and approved services of the same type in its planning area. An applicant for a new or expanded non-special MRT service shall have an adverse impact on existing and approved programs if it will:

1. decrease annual utilization of an existing service, whose current utilization is at or above eighty percent (80%), to a projected utilization of less than seventy percent (70%) within the first twenty-four (24) months of the initial operation of the service or additional non-special MRT unit; or

2. decrease annual utilization of an existing service, whose current utilization is below eighty percent (80%), by ten percent (10%) or more within the first twenty-four (24) months of the initial operation of the service or additional non-special MRT unit.

An applicant shall provide evidence of projected impact by taking into account existing planning area market share of existing non-special MRT services and future population growth or by providing sufficient evidence that the current population is underserved by the existing non-special MRT services, if any, within the planning area. An applicant proposing an additional non-special MRT unit pursuant to the exceptions to need standards referenced in (3)(b)2. shall not be required to document impact on existing and approved services as required by this paragraph.

(d) An applicant for a new or expanded non-special MRT service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, or ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the non-special MRT service;

3. providing a written commitment to participate in the Medicaid and Peach Care programs;

4. providing a written commitment to participate in any other state health benefits insurance programs for which the radiation therapy service is eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients.

(e) An applicant for a new or expanded non-special MRT service shall provide evidence of a cancer treatment program, which shall include the provision of the following, either on-site or through written agreements with other providers:

1. Access to simulation capabilities, which may include a dedicated simulator, a radiation therapy treatment unit, a virtual-reality based three-dimensional simulation system, or other diagnostic X-ray, magnetic resonance, ultrasound, or nuclear medicine equipment that has been modified to localize volumes to define the area requiring treatment; and which must be at the defined location of the non-special MRT service;

2. Access to a computer-based treatment planning system, which shall be a computer system capable of interfacing with diagnostic patient data acquisition systems such as CT, MRI, PET-CT to obtain the patient specific anatomical data. The planning system must be able to display radiation doses and 3-D dose distributions within a patient's anatomical contour and utilize measured or modeled radiation output data from the specific unit used to treat the patient. The minimum software requirements for the treatment planning system are an external beam program, an irregular field routine, and a Brachytherapy package;

3. Non-Special MRT capability including electron beam capability;

4. Capability to fabricate treatment aids; and

5. Access to brachytherapy;

(f) The applicant must provide a written commitment that physicians providing professional radiation oncology services at the MRT facility shall at all times have privileges or be eligible for and have an active pending application for privileges and be members in good standing of the medical staff, or are eligible for and have an active pending application for privileges, of a hospital with a comprehensive cancer treatment program located within the applicant's service area which will provide those physicians with access to participate in all of the following:

1. Consultative services from all major disciplines needed to develop a comprehensive treatment plan.

2. A multi-disciplinary cancer committee, which shall be a standing committee that:

(i) includes representatives from the medical specialties or sub-specialties which refer patients to the MRT service; representatives from the specialties of diagnostic radiology, radiation oncology, and pathology; representatives from those who oversee the tumor registry; and representatives from administration, nursing, social services, pharmacy, and rehabilitation;

(ii) meets at least on a quarterly basis; and

(iii) is responsible for the following:

A. establishing educational and problem oriented multi-disciplinary, facility-wide cancer conferences that include the major anatomic locations of cancer seen at the facility;

B. monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and

C. oversight of the applicant's tumor registry for quality control, staging, and abstracting;

3. Patient care evaluation studies, which shall be a system of patient care evaluation, conducted annually, that documents the methods used to identify problems and the opportunities to improve patient care. Examples of patient care evaluation studies include nationwide patient evaluation studies; facility quality assurance activities; and ongoing monitoring, evaluating, and action planning; and

4. Cancer prevention and education programs.

(g) The applicant must participate and report to the Georgia Comprehensive Cancer Registry of the Georgia Department of Public Health.

(h) An applicant shall demonstrate that the following staff, at a minimum, will be identified and available:

1. One (1) FTE board-certified or board-qualified physician trained in radiation oncology, which shall be available by continuous means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

2. One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with a special competence in radiation oncology physics; and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

3. One (1) medical dosimetrist, who shall be a member of the radiation oncology team who has the knowledge of the overall characteristics and clinical relevance of radiation oncology treatment machines and equipment, is cognizant of procedures commonly used in brachytherapy and has the education and expertise necessary to generate radiation dose distributions and dose calculations in collaboration with the medical physicist and radiation oncologists; and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

4. Two (2) radiation therapy technologists, who shall be registered or eligible by the American Registry of Radiological Technologists (ARRT) or the American Registry of Clinical Radiography Technologists (ARCRT); and who shall be on-site at all times of operation of the facility; and

5. One (1) program director, who shall be a board-certified physician trained in radiation oncology who may also be the physician required under (h)1.; and who shall be available by means of direct communication with the non-special MRT unit in person or by radio, telephone, or telecommunication;

(i) An applicant for a new or expanded non-special MRT service shall agree to provide the Department with all requested information and statistical data related to the operation and provision of services and to report that data to the Department in the time frame and format requested by the Department.

(4) **Standards for Special Purpose MRT.**

(a) The need for the addition of a special purpose MRT unit shall be determined through analysis of the capacity and utilization of the existing units of the same type in the planning area and an applicant's reasonable and documented projection of a minimum volume as follows:

Special MRT Equipment	**Capacity**	**Minimum Aggregate Utilization**	**Minimum Projected Volume**
Gamma Knife	500	80%	300 by 3rd Year of Operation
Heavy Particle Accelerator	4,000 per Gantry	80%	2,400 per Gantry by 3rd Year of Operation
Dedicated SRS LINAC (including CyberKnife)	850	80%	510 by 3rd Year of Operation
OR-based IORT	350	80%	150 by 3rd Year of Operation

Where capacity is measured in annual procedures; where minimum aggregate utilization is the aggregate utilization rate for all existing special purpose MRT units of the same type (Gamma Knife utilization for Gamma Knife, etc.) in the planning area, except that for those existing special purpose MRT units that have not reported data in the most recent survey year, the Department shall include the non-reporting unit at the statewide average utilization rate for special purpose equipment of the same type; and where the minimum projected volume is measured in procedures per year.

(b) Exceptions to the need standards referenced in (3)(a) may be granted for applicants proposing to remedy an atypical barrier to special purpose MRT services based on cost, quality, financial access and geographic accessibility.

(c) An applicant for a new or expanded special purpose MRT service shall document the impact on existing and approved services of the same type (Gamma Knife for Gamma Knife application, etc.) which already provide special purpose MRT to the residents of the planning area with the goal of minimizing adverse impact on existing and approved services of the same type in its planning area. An applicant for a new or expanded special purpose MRT service shall have an adverse impact on existing and approved programs if it will:

1. decrease annual utilization of an existing service of the same type, whose current utilization is at or above seventy percent (70%), to a projected utilization of less than sixty percent (60%) within the first twenty-four (24) months of the initial operation of the service or additional special purpose MRT unit; or

2. decrease annual utilization of an existing service of the same type, whose current utilization is below seventy percent (70%), by ten percent 10% or more within the first twenty-four (24) months of the initial operation of the service or additional special purpose MRT unit.

An applicant shall provide evidence of projected impact by taking into account existing planning area market share of existing special purpose MRT services and future population growth or by providing sufficient evidence that the current population is underserved by the existing special purpose MRT services, if any, within the planning area.

(d) An applicant for a new or expanded special purpose MRT service shall foster an environment that assures access to individuals unable to pay, regardless of payment source or circumstances, by the following:

1. providing evidence of written administrative policies that prohibit the exclusion of services to any patient on the basis of age, race, or ability to pay;

2. providing a written commitment that services for indigent and charity patients will be offered at a standard which meets or exceeds three percent (3%) of annual, adjusted gross revenues for the special purpose MRT service;

3. providing a written commitment to participate in the Medicaid and PeachCare for Kids® programs;

4. providing a written commitment to participate in any other state health benefits insurance programs for which the radiation therapy service is eligible; and

5. providing documentation of the past record of performance of the applicant, and any facility in Georgia owned or operated by the applicant's parent organization, of providing services to Medicare, Medicaid, and indigent and charity patients.

(e) An applicant for a new or expanded special purpose MRT service shall provide evidence of a cancer treatment program, which shall include the provision of the following, either on-site or through written agreements with other providers:

1. Access to simulation capabilities, which may include a dedicated simulator, a radiation therapy treatment unit, a virtual-reality based three-dimensional simulation system, or other diagnostic X-ray, magnetic resonance, ultrasound, or nuclear medicine equipment that has been modified to localize volumes to define the area requiring treatment; and which must be at the defined location of the special purpose MRT service;

2. Access to a computer-based treatment planning system, which shall be a computer system capable of interfacing with diagnostic patient data acquisition systems such as CT, MRI, PET-CT to obtain the patient specific anatomical data. The planning system must be able to display radiation doses and 3-D dose distributions within a patient's anatomical contour and utilize measured or modeled radiation output data from the specific unit used to treat the patient; and

3. Capability to fabricate treatment aids as applicable.

(f) The applicant must provide written commitment that physicians providing professional radiation oncology services at the special purpose MRT facility shall at all times have privileges or be eligible for and have an active pending application for privileges and be members in good standing of the medical staff of a hospital with a comprehensive cancer treatment program located within the applicant's service area which will provide those physicians with access to participate in all of the following:

1. Consultative services from all major disciplines needed to develop a comprehensive treatment plan.

2. A multi-disciplinary cancer committee, which shall be a standing committee that:

(i) includes representatives from the medical specialties or sub-specialties which refer patients to the MRT service; representatives from the specialties of diagnostic radiology, radiation oncology, and pathology; representatives from those who oversee the tumor registry; and representatives from administration, nursing, social services, pharmacy, and rehabilitation;

(ii) meets at least on a quarterly basis; and

(iii) is responsible for the following:

A. establishing educational and problem oriented multi-disciplinary, facility-wide cancer conferences that include the major anatomic locations of cancer seen at the facility;

B. monitoring, evaluating, and reporting to the medical staff and governing body on the quality of care provided to patients with cancer; and

C. oversight of the applicant's tumor registry for quality control, staging, and abstracting;

3. Patient care evaluation studies, which shall be a system of patient care evaluation, conducted annually, that documents the methods used to identify problems and the opportunities to improve patient care. Examples of patient care evaluation studies include nationwide patient care evaluation studies; facility quality assurance activities; and ongoing monitoring, evaluating, and action planning; and

4. Cancer prevention and education programs.

(g) The applicant must participate and report to the Georgia Comprehensive Cancer Registry of the Georgia Department of Public Health.

(h) An applicant shall demonstrate that the following staff, at a minimum, will be identified and available;

1. For applicants seeking the addition of a Gamma Knife:

(i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology, who shall have received special training in operating a Gamma Knife and who shall be available on-site; and

(ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating a Gamma Knife; and who shall be available on-site;

2. For applicants seeking the addition of a Heavy Particle Accelerator, Two (2) radiation therapy technologists, who shall be registered or eligible by the American Registry of Radiological Technologists ("ARRT") or the American Registry of Clinical Radiography Technologists ("ARCRT"); who shall have received special training in operating a Heavy Particle Accelerator and who shall be on-site at all times of operation of the facility;

3. For applicants seeking the addition of a dedicated SRS LINAC:

(i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology, who shall have received special training in operating an SRS LINAC and who shall be available on-site; and

(ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating an SRS LINAC; and who shall be available on-site;

(iii) One (1) radiation therapy technologist, who shall be registered or eligible by the American Registry of Radiological Technologists or the American Registry of Clinical Radiography Technologists; who shall have received special training in operating an SRS LINAC; and who shall be on-site at all times of operation of the facility; and

4. For applicants seeking the addition of an OR-Based IORT unit:

(i) One (1) FTE board-certified or board-qualified physician trained in radiation oncology; who shall have received special training in operating an OR-Based IORT unit; and who shall be available on-site; and

(ii) One (1) medical radiation physicist, who shall be an individual who is board-certified or board-qualified by the American Board of Radiology in therapeutic radiological physics; or board-certified by the American Board of Medical Physics in medical physics with special competence in radiation oncology physics; who shall have received special training in operating an OR-Based IORT unit; and who shall be available on-site.

(i) An applicant for a new or expanded special purpose MRT service shall agree to provide the Department with all requested information and statistical data related to the operation and provision of services and to report that data to the Department in the time frame and format requested by the Department.

Cite as Ga. Comp. R. & Regs. R. 111-2-2-.42

AUTHORITY: O.C.G.A. §§ 31-2 ***et seq.*****, 31-6** ***et seq*****.**

HISTORY: Original Rule entitled "Specific Review Considerations for Radiation Therapy Services" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: New Rule entitled "Specific Review Considerations for MegaVoltage Radiation Therapy Services/Units" adopted. F. May 13, 2008; eff. June 2, 2008.

Amended: F. Mar. 11, 2022; eff. Mar. 31, 2022.

Note: Rule 111-2-2-.42, the incorrect version of the Rule was inadvertently filed (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) and appeared on the Rules and Regulations website April 28, 2022 through March 12, 2023. The correct version, as promulgated and adopted on March 10, 2022, was updated on the Rules and Regulations website March 13, 2023, the original filed and effective dates (i.e., F. Mar. 11, 2022; eff. Mar. 31, 2022.) were retained, as requested by the Agency. Effective March 10, 2023.

Department 111. RULES OF DEPARTMENT OF COMMUNITY HEALTH

Chapter 111-2. HEALTH PLANNING

Subject 111-2-3. [Repealed]

111-2-3-.01 [Repealed]

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.01

AUTHORITY: O.C.G.A. § 31-6 ***et seq.***

HISTORY: Original Rule entitled "Applicability" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: F. Mar. 10, 2023; eff. Mar. 30, 2023.

111-2-3-.02 [Repealed]

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.02

AUTHORITY: O.C.G.A. § 31-6 ***et seq.***

HISTORY: Original Rule entitled "Definitions" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: F. Mar. 10, 2023; eff. Mar. 30, 2023.

111-2-3-.03 [Repealed]

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.03

AUTHORITY: O.C.G.A. § 31-6 ***et seq.***

HISTORY: Original Rule entitled "Standards" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: F. Mar. 10, 2023; eff. Mar. 30, 2023.

111-2-3-.04 [Repealed]

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.04

AUTHORITY: O.C.G.A. § 31-6 ***et seq.***

HISTORY: Original Rule entitled "Request for Independent Review" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: F. Mar. 10, 2023; eff. Mar. 30, 2023.

111-2-3-.05 [Repealed]

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.05

AUTHORITY: O.C.G.A. § 31-6 ***et seq.***

HISTORY: Original Rule entitled "Procedure for Request for Independent Review" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: F. Mar. 10, 2023; eff. Mar. 30, 2023.

111-2-3-.06 [Repealed]

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.06

AUTHORITY: O.C.G.A. § 31-6 ***et seq.***

HISTORY: Original Rule entitled "The Conduct of the Review by the Independent Review Organization" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: F. Mar. 10, 2023; eff. Mar. 30, 2023.

111-2-3-.07 [Repealed]

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.07

AUTHORITY: O.C.G.A. § 31-6 ***et seq.***

HISTORY: Original Rule entitled "Independent Review Organization Decision" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: F. Mar. 10, 2023; eff. Mar. 30, 2023.

111-2-3-.08 [Repealed]

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.08

AUTHORITY: O.C.G.A. § 31-6 ***et seq.***

HISTORY: Original Rule entitled "Independent Review Organization Telephone Access" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: F. Mar. 10, 2023; eff. Mar. 30, 2023.

111-2-3-.09 [Repealed]

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.09

AUTHORITY: O.C.G.A. § 31-6 ***et seq.***

HISTORY: Original Rule entitled "Independent Review Organization Confidentiality Provisions" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: F. Mar. 10, 2023; eff. Mar. 30, 2023.

111-2-3-.10 [Repealed]

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.10

AUTHORITY: O.C.G.A. § 31-6 ***et seq.***

HISTORY: Original Rule entitled "Complaints and Inquiries Regarding Conduct of Independent Review Organizations" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: F. Mar. 10, 2023; eff. Mar. 30, 2023.

111-2-3-.11 [Repealed]

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.11

AUTHORITY: O.C.G.A. § 31-6 ***et seq.***

HISTORY: Original Rule entitled "On-Site Inspections by the Department" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: F. Mar. 10, 2023; eff. Mar. 30, 2023.

111-2-3-.12 [Repealed]

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.12

AUTHORITY: O.C.G.A. § 31-6 ***et seq.***

HISTORY: Original Rule entitled "Violations by Independent Review Organizations" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: F. Mar. 10, 2023; eff. Mar. 30, 2023.

111-2-3-.13 [Repealed]

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.13

AUTHORITY: O.C.G.A. § 31-6 ***et seq.***

HISTORY: Original Rule entitled "Fees for Independent Review" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: F. Mar. 10, 2023; eff. Mar. 30, 2023.

111-2-3-.14 [Repealed]

Cite as Ga. Comp. R. & Regs. R. 111-2-3-.14

AUTHORITY: O.C.G.A. § 31-6 ***et seq.***

HISTORY: Original Rule entitled "Assignment of Requests for Independent Review" adopted. F. Dec. 16, 2004; eff. Jan. 5, 2005.

Repealed: F. Mar. 10, 2023; eff. Mar. 30, 2023.

Department 111. RULES OF DEPARTMENT OF COMMUNITY HEALTH

Chapter 111-8. HEALTHCARE FACILITY REGULATION

Subject 111-8-22. END STAGE RENAL DISEASE FACILITIES

111-8-22-.06 Facility Organization and Administration

(1) **Governing Body**. The facility shall function under the control of an identifiable governing body, which has full legal authority for the governance and operation of the facility.

(a) The governing body shall specify in writing the operational objectives of the facility, including which services are to be offered.

(b) The governing body shall be responsible for the establishment, adoption, and annual review of administrative rules and regulations and facility policies and procedures, and for ensuring that they are in accordance with accepted standards of practice and safeguard the health and safety of patients.

(c) The governing body shall be responsible for ensuring that the facility's design and operation are in compliance with all relevant federal, state, and local legal requirements.

(d) The governing body shall adopt for the facility admission criteria that ensure equitable access to services for individuals needing care for end stage renal disease.

(e) The governing body shall designate sufficient staff and allocate sufficient staff time to implement the facility's quality management program and shall provide for leadership support of the program.

(f) The governing body shall establish and implement written policies regarding the determination, selection, or privileging of medical staff for the facility.

(g) The governing body shall appoint a facility administrator to be responsible for the administrative management of the facility and the enforcement of adopted rules and regulations.

1. The governing body shall delineate the responsibilities of the facility administrator in writing and shall ensure that the administrator is sufficiently free of other duties to provide effective management of the facility.

2. The governing body of the facility shall notify the Department of a change in the administrator of the facility and shall at that time provide the name and contact numbers of the new administrator.

(2) **Facility Administrator.**

(a) The facility administrator may serve on a full-time or part-time basis, but shall serve sufficient time to plan, organize, and direct the overall function of the facility, and to carry out those responsibilities as assigned by the governing body. The facility administrator shall meet one of the following qualifications:

1. Holds at least a baccalaureate degree and has at least one (1) year experience in an end stage renal disease facility; or

2. Meets the qualifications for a physician director or a nurse responsible for nursing services for an end stage renal disease facility as described in these rules; or

3. As of the first effective date of these rules, has been acting for at least two years as a facility administrator for an end stage renal disease facility which has been certified for a federal Medicare program.

(b) The facility administrator shall be responsible for:

1. Management of the facility's fiscal affairs, including maintenance of financial records and generating regular reports of expenses and revenues for review by the governing body;

2. Implementing the policies and procedures of the facility as approved by the governing body, and ensuring that all personnel at the facility are familiar with applicable policies as well as applicable state and federal regulations;

3. Coordinating the provision of services at the facility, including establishing clear lines of authority and accountability for those involved in patient care;

4. Ensuring that the facility employs sufficient qualified staff to provide patient care services, and adequately orients staff to their work responsibilities while meeting the following minimum staffing ratios:

(i) There must be one (1) licensed and qualified nurse for every twelve (12) patients receiving dialysis care and one qualified dialysis care giver for each four (4) patients present in the immediate clinical care area. At least one licensed and qualified registered nurse shall be available in the immediate clinical care area to provide nursing care whenever patients are being dialyzed.

(ii) Trainees may not be counted in the staff:patient ratios.

5. Maintaining facility records, including a chronological record of patient care services provided, and submitting reports on facility functions and operations as required by the governing body or the Department.

(c) The facility administrator shall serve as the liaison between the governing body and the medical staff and other healthcare workers at the facility.

(d) The facility administrator shall designate in writing a qualified individual to act on his/her behalf in the event of his/her absence.

(e) The facility administrator shall be responsible for ensuring that the care of dialysis patients of the facility is coordinated appropriately when a patient is being transferred to a hospital or another dialysis provider or being received back by the facility.

Cite as Ga. Comp. R. & Regs. R. 111-8-22-.06

AUTHORITY: O.C.G.A. §§ 31-2-5**,** 31-2-7**,** 31-44-3**.**

HISTORY: Original Rule entitled "Facility Organization and Administration" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Amended: F. Mar. 15, 2023; eff. Apr. 4, 2023.

Department 111. RULES OF DEPARTMENT OF COMMUNITY HEALTH

Chapter 111-8. HEALTHCARE FACILITY REGULATION

Subject 111-8-56. NURSING HOMES

111-8-56-.20 Nursing Home Permit Requirements

(1) To be eligible for a permit the nursing home must be in satisfactory compliance with these rules and regulations and the provisions at law which apply to the locations, construction and maintenance of homes and the safety of the patients therein.

(2) Prior to the issuance of a permit and at the request of the Commissioner, the governing body or operator shall furnish to the Department evidence of satisfactory compliance with any laws or regulations thereunder applicable to homes but the enforcement of which is the responsibility of a department or agency of government other than the Department.

(3) The permit shall be framed and publicly displayed at all times.

(4) Permits are not transferable from one governing body or operator to another, nor valid when the home is moved from one location to another.

(5) Nursing homes shall provide the Department at least ninety (90) days prior written notice of the following events via electronic mail at HFRD.NH@dch.ga.gov (or such other updated address posted on the Department's website), and, for applicable events, shall take the following required actions:

(a) Date of a proposed transfer of ownership and/or change of the operator of the nursing home. The transferring nursing home owner and/or the owner of the real estate upon which the nursing home is located shall provide to the Department a copy of the acquisition agreement, operator or management agreement, lease agreement, and any other documents regarding the transfer as requested by the Department.

(b) Date of closure of the nursing home or anticipated interruption of nursing home operations. Prior to ceasing operations, a nursing home shall timely notify the Department of the planned storage location for residents' medical records, medical staff information, and other critical information. The nursing home shall publish on its webpage in a prominent location and in a widely circulated newspaper(s) in the nursing home service area a notice indicating where medical records and other critical information can be retrieved. The nursing home shall also provide this information to its residents or their designated representatives in writing. Following its closure, the nursing home shall promptly notify the Department in writing of any change in location of the residents' medical records, medical staff information, and other critical information;

(c) The effective date of a transaction involving a nursing home's acquisition, sale, divestment, transfer of operations, or merger with another nursing home or other business entity; or

(d) Effective date of material changes affecting nursing home operations, including but not limited to the addition of any services, reduction or elimination of bed capacity, or other material change(s) regarding the nursing home's delivery of services. Such notification shall include a detailed description of the material changes.

A nursing home may be fined by the Department in an amount of $1000.00 per day that any notification required by Ga. Comp. R. & Regs. r. 111-8-56-.20 is late, subject to waiver or reduction of such notice requirement by the Department for good cause, as it determines in its sole discretion. A nursing home may also be fined $1000.00 per day that it fails to take any other action required by Ga. Comp. R. & Regs. r. 111-8-56-.20, after receipt of written

notice by the Department. The Department shall review all proposed events and actions in accordance with its regulatory authority. A nursing home must also promptly respond to information requests issued by the Department.

(6) The permit shall be surrendered to the Department upon occurrence of any of the following events:

(a) The final onsite inspection by the Department on the last day of operation for the nursing home;

(b) The nursing home's cessation of operations;

(c) A nursing home's relocation of its facility to a new premises;

(d) A change of more than fifty percent (50%) of the nursing home's ownership or governing body, or any change of operator of the nursing home; or

(e) The Department's suspension or revocation of the nursing home's permit.

(7) A permit shall be required for each nursing home located on different premises where more than one home is operated under the same governing body. When a nursing home operates as distinct parts, then a permit shall be required for each distinct part.

(8) Each nursing home shall be in compliance with O.C.G.A. § 26-2-370 et seq., entitled "Food Service Establishments" and the Rules and Regulations as adopted and promulgated thereunder entitled "Rules and Regulations for Food Service" and with any amendment to the law or rules promulgated thereunder.

Cite as Ga. Comp. R. & Regs. R. 111-8-56-.20

AUTHORITY: O.C.G.A. §§ 26-2-370 ***et seq.*****, 31-2-1,** ***et seq.*****, 31-7-1** ***et seq.***

HISTORY: Original Rule entitled "Permits" adopted. F. Feb. 20, 2013; eff. Mar. 12, 2013.

Amended: New title, "Nursing Home Permit Requirements." F. Mar. 10, 2023; eff. Mar. 30, 2023.

Department 160. RULES OF GEORGIA DEPARTMENT OF EDUCATION

Chapter 160-1.

Subject 160-1-4. GRANT PROGRAMS

160-1-4-.310 Computer Science Opportunity Grant

1. **Purpose of the Grant**. The purpose of the Computer Science Opportunity Grant is to (1) build a community for computer science teachers that will provide professional support for instruction, practice, and pedagogy and (2) promote the use of physical computing as a means to engage students in computer science education.

2. **Term and Conditions**. Grants are awarded through a competitive process to local educational agencies (LEA). Grant recipients must use the funding to obtain memberships for identified teachers, who have not previously benefitted from this grant, to join a local and national computer science teacher consortium and to pay for registration costs to attend a national computer science teacher conference. Additionally, grant recipients must purchase a class set of physical computing devices and receive the necessary professional training for implementation and use. Grant recipients must submit a completion report and all other reports required by the Georgia Department of Education (GaDOE). Only one grant will be awarded per LEA per fiscal year.

3. **Eligible Recipient(s)**. All LEAs are eligible to apply on behalf of eligible educators. An eligible educator is an individual teaching at least one computer science course, which includes both discrete computer science courses and courses that integrate computer science, such as gifted or STEM courses, in a K-12 Georgia public school during the current school year.

4. **Criteria for Award.** Applications are reviewed by GaDOE for adherence to the terms and conditions described in the application.

5. **Directions and Deadlines for Applying.** Application materials, including information regarding the deadline, are available on GaDOE's Computer Science webpage. For additional information, please contact Bryan Cox, Lead Computer Science Program Specialist, Curriculum and Instruction, Georgia Department of Education, at bcox@doe.k12.ga.us.

Cite as Ga. Comp. R. & Regs. R. 160-1-4-.310

AUTHORITY: O.C.G.A. § 20-2-240**.**

HISTORY: Original grant description entitled "Computer Science Opportunity Grant." Submitted March 22, 2023.

160-1-4-.311 Individuals with Disabilities Education Act (IDEA) Rural Grant

1. **Purpose of Grant**. The purpose of the Individuals with Disabilities Education Act (IDEA) Rural Grant is to provide rural local educational agencies (LEA) in Georgia with federal funding to support the needs of their students with disabilities.

2. **Term and Conditions**. Eligible grant recipients must submit a completed application. Awarded grant funds must be expended to provide one or more of the following: (1) adaptive equipment, (2) professional learning, or (3) instructional materials for students with disabilities. Grant recipients must submit a completion report and all other reports required by the GaDOE. The grant awards are one-time funds for use during the fiscal year of the award.

3. **Eligible Recipient(s**). Eligible grant recipients are LEAs that are eligible to receive federal grant funds through the Federal Rural and Low-Income School Program or the Small Rural Achievement Program.

4. **Criteria for Award**. Applications are reviewed by the GaDOE for adherence to the terms and conditions described in the application. All recipients will receive 100% of their proposed budget until funds are exhausted. No partial grants will be awarded.

5. **Directions and Deadlines for Applying**. The Division of Rural Education Initiatives will provide information about the grant to all eligible districts. Additionally, information about the grant, including eligibility requirements and the deadline, may be obtained by contacting the Georgia Department of Education Division of Special Education Services and Supports at specialeducation@doe.k12.ga.us.

Cite as Ga. Comp. R. & Regs. R. 160-1-4-.311

AUTHORITY: O.C.G.A. § 20-2-240**.**

HISTORY: Original grant description entitled "Individuals with Disabilities Education Act (IDEA) Rural Grant." Submitted March 22, 2023.

160-1-4-.312 Cultivating Teachers Grant

1. **Purpose of Grant**. The purpose of the Cultivating Teachers Grant is to provide professional learning and educator recruitment support to increase interest in the field of education in local educational agencies (LEA) that offer courses in the Teaching as a Profession pathway.

2. **Term and Conditions**. Grants are awarded through a competitive process to eligible LEAs to (1) provide training on the best practice to reach middle and high students to build connection and awareness of the education profession, (2) provide professional learning opportunities and resources on engaging learning activities that increase the students understanding of the profession of teaching, and (3) create or provide recruitment resources that supports the teacher's ability to invite identified students to participate using best practices. Grant recipients must submit all required completion documentation. Completion data shall include the summary of the activities plan, a detailed expenditure report, including supporting documentation for goods and services provided or received, and artifacts of what was accomplished. The grant awards are one-time funds for use during the fiscal year of the award. There is no allowability for carryover.

3. **Eligible Recipient(s).** LEAs that offer courses related to the Teaching as a Profession pathway during the grant period are eligible to apply.

4. **Criteria for Award.** All applications are reviewed and scored by the Georgia Department of Education. Funding will be awarded based on rank (the highest score first) and available funding.

5. **Directions and Deadlines for Applying.** Application materials, including information regarding the deadline, are available on GaDOE's Educator Support and Development webpage. For additional information, please contact Shauntice Wheeler, Title II & Educator Pipeline Support Program Manager, Georgia Department of Education, at swheeler@doe.k12.ga.us.

Cite as Ga. Comp. R. & Regs. R. 160-1-4-.312

AUTHORITY: O.C.G.A. § 20-2-240**.**

HISTORY: Original grant description entitled "Cultivating Teachers Grant." Submitted March 22, 2023.

160-1-4-.313 Title I, Section 1003 School Improvement Leadership Development (SILD) Grant

1. **Purpose of Grant**. The purpose of the Title I, Section 1003 SILD Grant is to provide federally-identified Comprehensive Support and Intervention (CSI) schools funding for leaders to effectively lead, maintain, and support continuous improvement.

2. **Term and Conditions**. An eligible grant recipient must submit a completed application that (1) responds to a leadership need identified in its comprehensive needs assessment and (2) identifies professional development supports and learning opportunities focused on developing leaders and creating leadership pipelines. Grant funds must be utilized on strong, moderate, or promising evidence-based leadership training. Grant recipients must submit a completion report and all other reports required by the Georgia Department of Education (GaDOE). The grant awards are one-time funds for use during the fiscal year of the award.

3. **Eligible Recipient(s**). Eligible applicants must be local educational agencies (LEA) serving Title I schools identified as CSI as defined by the Every Student Succeeds Act. LEAs with more than one federally-identified CSI school may submit one application for all eligible schools.

4. **Criteria for Award**. GaDOE will review grant applications for completeness and compliance with application and eligibility guidelines. All required materials, including forms and appendices, must be submitted for the application to be considered complete and eligible for funding consideration. Funding will be awarded based on rank (the highest score first) Applicants scoring sixty or below will not be awarded funds.

5. **Directions and Deadlines for Applying**. Information about the grant, including the application and deadline, can be found on the Office of School Improvement, Division of School and District Effectiveness's webpage. Interested LEAs may also contact the Office of School Improvement at schoolimprovement@doe.k12.ga.us for additional information.

Cite as Ga. Comp. R. & Regs. R. 160-1-4-.313

AUTHORITY: O.C.G.A. § 20-2-240.

HISTORY: Original grant description entitled "Title I, Section 1003 School Improvement Leadership Development (SILD) Grant." Submitted March 22, 2023.

160-1-4-.314 Georgia Outdoor Learning Demonstration (GOLD) Grant

1. **Purpose of Grant.** The purpose of the GOLD grant is to allow interested local educational agencies (LEAs) and non-formal environmental education providers to launch, revitalize, or expand outdoor learning opportunities of their choice.

2. **Term and Conditions.** Grants are awarded through a competitive process for recipients to provide professional learning, to improve to outdoor learning spaces, to purchase outdoor learning teaching supplies, or to provide field trips to nature centers or field investigations. Grant recipients must submit a completion report and all other reports required by the Georgia Department of Education (GaDOE). The grant awards are one-time funds for use during the fiscal year of the award.

3. **Eligible Recipient(s).** Eligible applicants are LEAs and non-formal environmental education providers.

4. **Criteria for Award.** Grant applications will be reviewed and scored by a team of individuals consisting of GaDOE staff members and external stakeholders who are interested in science and outdoor learning. Funding will be awarded based on rank (highest score first), geographic location, and availability of grant funds.

5. **Directions and Deadlines for Applying.** Information about the grant, including the application and deadline, will be shared directly with all LEAs. Additional requests for information should be made to Matt Cardoza, Director of External Affairs & K-12 Public Health Liaison, at mcardoza@doe.k12.ga.us.

Cite as Ga. Comp. R. & Regs. R. 160-1-4-.314

AUTHORITY: O.C.G.A. § 20-2-240**.**

HISTORY: Original grant description entitled "Georgia Outdoor Learning Demonstration (GOLD) Grant." Submitted March 23, 2023.

Department 160. RULES OF GEORGIA DEPARTMENT OF EDUCATION

Chapter 160-4.

Subject 160-4-7. SPECIAL EDUCATION

160-4-7-.03 Child Find Procedures

(1) **DEFINITIONS.**

(a) Definitions related to all special education rules can be found in State Board of Education Rule 160-4-7-.21 DEFINITIONS.

(2) **GENERAL.**

(a) Each LEA must have in effect policies and procedures to ensure that all suspected children with disabilities, including those who are homeless, are wards of the State or are attending private schools, regardless of the severity of their disability, and who are in need of special education and related services, are identified, located and evaluated. [34 C.F.R. §300.111]

(b) Each LEA shall ensure that before conducting any significant activity that is designed to identify, locate or evaluate children, annual notice must be published or announced in newspapers or other media, or both, to notify parents of this activity. [34 C.F.R. §300.612(b)]

(c) These policies and procedures shall provide for the screening and evaluation of all children with suspected disabilities birth through age 21 to include:

1. Children birth through age three. An LEA may fulfill its child find responsibility through referral to the Babies Can't Wait early intervention program operated by the Department of Public Health.

2. Preschool children, ages 3-5, not yet eligible for state-funded kindergarten.

3. Children enrolled in the LEA schools including public charter schools.

4. Children who are suspected of being children with disabilities and in need of special education, even though they are progressing from grade to grade. [34 C.F.R. §300.111(c)(1)]

5. Highly mobile children, including migrant children. [34 C.F.R. §300.111(c)(2)]

6. Children who are detained or incarcerated in city/county operated jails or correctional facilities.

7. Children who reside in the LEA and are enrolled in home school/study programs.

8. Parentally-placed private school children. [34 C.F.R. §300.131(a)]

(i) Children enrolled by their parents in private, including religious, elementary and secondary schools located in the LEA's jurisdiction. [34 C.F.R. §300.130]

(d) Each LEA must have in effect policies and procedures to ensure a practical method is developed and implemented to determine which children are currently receiving needed special education and related services. [34 C.F.R. §300.111(a)(ii)]

1. Each LEA shall submit to the Georgia Department of Education (GaDOE), in an electronic format specified by GaDOE, data requested by the GaDOE on all children ages 3 through 21 who have been found eligible for special education and related services.

2. All data shall be accurate and timely. [34 C.F.R. §300.645]

Cite as Ga. Comp. R. & Regs. R. 160-4-7-.03

AUTHORITY: O.C.G.A. §§ 20-2-152**,** 20-2-240**.**

HISTORY: Original Rule entitled "Procedural Safeguards" adopted. F. Apr. 20, 1990; eff. May 10, 1990.

Amended: F. Dec. 14, 1990; eff. Jan. 3, 1991.

Amended: F. Jan. 25, 1994, eff. Feb. 14, 1994.

Repealed: New Rule entitled "Child Find Procedures" adopted. F. Aug. 14, 2000; eff. Sept. 3, 2000.

Repealed: New Rule of same title adopted. F. June 14, 2007; eff. July 4, 2007.

Repealed: New Rule of same title adopted. F. Mar. 11, 2010; eff. Mar. 31, 2010.

Amended: F. Mar. 23, 2023; eff. Apr. 12, 2023.

160-4-7-.16 Georgia Learning Resources System (GLRS)

(1) **DEFINITIONS.**

(a) Definitions related to all special education rules can be found in State Board of Education Rule 160-4-7-.21 DEFINITIONS.

(2) **EACH GEORGIA LEARNING RESOURCES SYSTEM (GLRS) PROGRAM SHALL:**

(a) Engage in the following statewide activities.

1. Develop and provide training, coaching and support for the implementation of evidence-based practices to support children with disabilities through on-going professional learning with assistance from the Georgia Department of Education, Division for Special Education Services and Supports (GaDOE/DSESS).

2. Provide, with training and supervision by the GaDOE/DSESS, assistance to Local Education Agencies (LEA) in preparation of their Consolidated LEA Improvement Plan (CLIP), including the Individuals with Disabilities Education Act (IDEA) and Support LEAs with IDEA monitoring.

3. Assist LEAs with the development and implementation of any corrective action plans; and assist in the revision of the CLIP following any monitoring on-site reviews, if requested.

4. Collaborate with the GaDOE special education division, and state, regional, and local partners to develop, revise and deliver training and support to parents, school and district leaders, teachers, support staff, related service providers, advocacy groups and other agencies regarding appropriate educational services for children with disabilities.

(b) Engage in other activities relating to GLRS responsibilities as determined by regional and state priorities and GLRS regional needs assessments, comprehensive data analysis of each regions' LEAs, in conformity with the GLRS Scope of Work requirements.

(c) Operate within established parameters of the reviewed GLRS scope of work and budget to satisfy the terms of the contract.

(d) Designate a fiscal agent to oversee the established parameters of the contract. The fiscal agent may be a RESA or LEA in that GLRS region.

1. If most of the LEAs served by the GLRS program desire to change the fiscal agent, a vote shall be taken no later than January 30 of each fiscal year to allow GaDOE ample time for contract forecasting for the next year. Each fiscal agent services at the discretion of the GaDOE. Written notification must be sent to GaDOE to request the change by January 30.

2. If available, funding shall be awarded annually by the State Board of Education to an approved fiscal agent for the operation of the GLRS program upon review of a scope of work and budget submitted annually to the GaDOE.

(e) Submit quarterly program reports as directed by GaDOE.

(f) Be evaluated through a continuous improvement accountability process or as determined necessary by the GaDOE/DSESS.

(3) **THE FISCAL AGENTS FOR GLRS PROGRAMS SHALL:**

(a) Submit a scope of work and detailed budget to the GaDOE by April 1 of each fiscal year, for receipt of funds to operate the GLRS program. The scope of work must include program activities and evaluation plans. The budget must be itemized and align to the scope of work. Both the GLRS scope of work and budget shall be submitted annually and approved by the State board.

(b) Recruit, select, employ, and terminate program personnel.

(c) At a minimum, employ or contract with one fulltime individual, or two parttime individuals that equal a fulltime position, on a twelve-month basis to serve as the primary GLRS program contact(s). The primary GLRS program contact(s) will be required to possess, at a minimum, a level five professional renewable certificate in special education or school psychology. Leadership certification, in addition to the required certification, is a preferred qualification. As appropriate the GaDOE may participate in the selection process for the key staff responsible for implementing the GLRS program.

(d) Provide and maintain adequate and accessible physical facilities and operating equipment, at no cost to the GLRS program.

(e) Submit reports of fund expenditures and assure accurate accounting and reporting of program budgets.

(f) Establish administrative policies and procedures for staff and program operation consistent with state and federal internal control regulations for fiscal management, location, operations, and personnel.

(g) Develop a job description for the GLRS program contact and any other personnel consistent with GLRS program objectives.

(h) Establish and implement procedures for objective evaluation of the GLRS program services, staff performance and program effectiveness.

(i) Report, periodically, fiscal, and other matters pertaining to program operation to the GLRS Advisory Board, GaDOE/ DSESS participating systems and to other agencies as necessary and appropriate.

(4) **THE GLRS ADVISORY BOARD SHALL:**

(a) Assist the fiscal agent in developing written program policies regarding location, operation, personnel, funding priorities and other matters relating to the program.

(b) Advise the GLRS program contact of regional priorities for expenditure of available GLRS funds.

(c) Advise the GLRS program contact of other identified needs in professional learning.

(d) Provide input to the fiscal agent during the development and review of administrative policies for the GLRS program that will provide optimal services to all LEAs served.

(e) Provide ongoing constructive feedback for improved operations regarding GLRS program activities.

(f) Assist the fiscal agent in devising procedures for performance evaluation of GLRS personnel.

(g) Assure compliance with state and federal regulations in planning and implementing GLRS programs and services.

Cite as Ga. Comp. R. & Regs. R. 160-4-7-.16

AUTHORITY: O.C.G.A. §§ 20-2-152**,** 20-2-240**,** 20-2-270**,** 20-2-270.1**,** 20-2-273**,** 20-2-274**.**

HISTORY: Original Rule entitled "Mediation" adopted. F. Aug. 14, 2000; eff. Sept. 3, 2000.

Amended: F. Apr. 16, 2002; eff. May 6, 2002.

Repealed: New Rule entitled "Georgia Learning Resources System (GLRS)" adopted. F. June 14, 2007; eff. July 4, 2007.

Amended: F. Mar. 23, 2023; eff. Apr. 12, 2023.

160-4-7-.18 Grants For Services

(1) **DEFINITIONS.**

(a) Definitions related to all special education rules can be found in State Board of Education Rule 160-4-7-.21 DEFINITIONS.

(2) **AUTHORIZATION.**

(a) The State Board shall have authority to provide grant funds for the implementation of other educational programs or additional personnel for the unique needs of children with disabilities.

(b) The Local Educational Agency (LEA) in receipt of these grant funds shall ensure a free appropriate public education (FAPE) for children with disabilities and follow state and federal regulations and Georgia Department of Education (GaDOE) state board rules for implementation of these programs.

(3) **GRANT FOR RESIDENTIAL AND REINTEGRATION SERVICES.**

(a) The Residential and Reintegration Services Grant is available to an LEA making a referral to a GaDOE-approved residential private school or facility when the LEA is unable to provide appropriate special education and related services to a child with disabilities within the boundaries of the LEA, within a regional program operated by the LEA, or within an educational setting operated by the State of Georgia.

1. Private schools to which children are recommended for placement shall be accredited.

(b) LEAs with children with disabilities meeting the criteria in Paragraph (2)(a) may be eligible to receive partial or total funding for educational costs, related services, and room and board. LEAs must assume all costs for transportation expenses.

(c) Educational costs funded through the Residential and Reintegration Services Grant program shall be shared between the LEA and the GaDOE. The LEA shall assume the cost prior to grant application submission and approval. GaDOE, as state funding permits, will reimburse the approved costs assumed prior to the grant application and included in the proposed approved budget submitted with the grant application.

1. If there is insufficient state funding to cover approved costs or budgets, the LEA shall assume a percentage of the total cost equal to the percent of local funds utilized for the educational costs, related services, and room and board. The GaDOE shall maintain a record of the percent requirement for LEAs and state participation in this program.

2. It is the LEA's responsibility to initiate and submit an application for the Residential and Reintegration Services Grant. The LEA may use other funds from public or private agencies to assist in the cost of educating a child in a residential private school or facility, provided the services are arranged by the LEA.

(d) LEAs that apply for assistance shall assume full responsibility for the cost of educating a child in a residential private school or facility at the time of submitting an application. Grants are not automatically funded. Approval for grant applications shall be based on the availability of funds. If there are more applicants than funding, the applications will be approved based on the severity of the disabling condition. The priorities are:

1. Children with profound and severe disabilities requiring residential services who are wards of the State.

2. Children with profound and severe disabilities requiring reintegration from a residential program.

3. Children with profound disabilities needing residential services.

4. Children with severe disabilities needing residential services.

(e) This grant is also available to the Department of Human Services (DHS) and Department of Behavioral Health and Developmental Disabilities (DBHDD) for children with disabilities who are wards of the State and in their custody.

(f) All children placed in a residential private school or facility must have a reintegration plan developed by the LEA's Individualized Education Program (IEP) Team. The reintegration plan, which shall include a specific timeline, must detail the process for moving the child toward a less restrictive environment. Parents shall be invited to participate in the development of the reintegration plan and with the transition.

1. LEAs may submit a grant application for reimbursement of educational costs, correlated services, and other costs directly related to the reintegration plan. GaDOE will reimburse the approved costs assumed prior to the grant application and the proposed approved budget submitted with the grant application as state funding permits.

(g) All children placed in a residential private school or facility or placed in a reintegration program following full-time placement in a residential private school or facility shall be observed at least once a year by an LEA representative. This observation may coincide with the IEP annual review. The progress reports and other related information for each child shall be reviewed at the IEP annual review. Observations and reviews may take place more frequently as determined by the IEP team.

(h) If a child who is currently funded through the Grant for Residential and Reintegration Services program becomes the subject of a due process hearing, fiscal maintenance of the placement shall be continued, funds permitting; however, the LEA is still responsible for payment.

(4) **GRANT TO ACCESS STATE INTERAGENCY SERVICES.**

(a) This grant is designed to provide access for the education of children with disabilities who are placed in one of the state-operated facilities for an appropriate educational program designed to meet their unique needs.

(b) This grant may be used to reimburse teacher costs, intake costs, and placement costs incurred by state agencies that provide special education and related services to children with disabilities.

(c) State agencies may submit a grant application for reimbursement of teacher costs, intake costs, and placement costs of these children incurred by the state agencies. GaDOE will reimburse the approved costs assumed prior to the grant application and the proposed approved budget submitted with the grant application as state funding permits.

(d) The LEA's IEP Team has the full and final responsibility for determining appropriate special education services and the least restrictive environment for education placement.

(e) The LEA's IEP Team shall consult with the treatment team as to the appropriate location of services and shall review the following: safety, level of behavioral control, treatment factors, health, and any other medical considerations.

Cite as Ga. Comp. R. & Regs. R. 160-4-7-.18

AUTHORITY: O.C.G.A. §§ 20-2-152**,** 20-2-240**.**

HISTORY: Original Rule entitled "Hearing Processes" adopted. F. Aug 14, 2000; eff. September 3, 2000.

Amended: F. Apr. 16, 2002; eff. May 6, 2002.

Amended: F. Apr. 13, 2006; eff. May 3, 2006.

Repealed: New Rule of same title adopted. F. June 14, 2007; eff. July 4, 2007.

Repealed: New Rule entitled "Grants for Services" adopted. F. Feb. 9, 2009; eff. Mar. 1, 2009.

Repealed: New Rule of same title adopted. F. Mar. 11, 2010; eff. Mar. 31, 2010.

Amended: F. Mar. 23, 2023; eff. Apr. 12, 2023.

Department 240. GEORGIA STATE BOARD OF COSMETOLOGY AND BARBERS

Chapter 240-13. SCHOOL REQUIREMENTS

240-13-.05 Online and Distance Learning Requirements

(1) Board licensed or approved schools and supervising licensees may teach the theoretical portion of the curriculum to their students or apprentices through online or distance learning classes. All practical training must be hands-on and taught on the clinic floor inside the school by a Board licensed or approved instructor. Practical training for apprentices must be monitored by the designated licensed supervisor inside the Board approved salon or shop. Schools shall maintain test results and records of the monitoring process in accordance to Rule 240-13-.04(b), and apprentice test results and records shall be maintained in accordance with Rule 240-5-.03(c).

(a) Barbering

1. Master Barber

(i.) A student enrolled in a Board licensed or approved Master Barber program, or an apprentice apprenticing under a designated licensed supervisor, may accrue up to two hundred fifty (250) hours of Level I credit, and/or two hundred (200) hours of Level II credit through an online delivery system only for the theory portion of the curriculum. Schools are responsible for monitoring the student's online hours, course progress, and all testing.

2. Barber II

(i) A student enrolled in a Board licensed or approved Barber II program, or an apprentice apprenticing under a designated licensed supervisor, may accrue up to one hundred ninety (190) hours of Level I credit, and/or two hundred (200) hours of Level II credit through an online delivery system only for the theory portion of the curriculum. Schools are responsible for monitoring the student's online hours, course progress, and all testing.

(b) Cosmetology

1. Master Cosmetology

(i.) A student enrolled in a Board licensed or approved Master Cosmetology program, or an apprentice apprenticing under a designated licensed supervisor, may accrue up to two hundred fifty (250) hours of Level I credit, and/or one hundred (100) hours of Level II credit through an online delivery system only for the theory portion of the curriculum. Schools are responsible for monitoring the student's online hours, course progress, and all testing.

2. Hair Design

(i.) A student enrolled in a Board licensed or approved Hair Design program, or an apprentice apprenticing under a designated licensed supervisor, may accrue up to two hundred fifty (250) hours of Level I credit, and/or one hundred (100) hours of Level II credit through an online delivery system only for the theory portion of the curriculum. Schools are responsible for monitoring the student's online hours, course progress, and all testing.

3. Esthetician

(i.) A student enrolled in a Board licensed or approved Esthetician program, or an apprentice apprenticing under a designated licensed supervisor, may accrue up to two hundred fifty (250) hours of Level I credit, and/or one hundred (100) hours of Level II credit through an online delivery system only for the theory portion of the curriculum. Schools are responsible for monitoring the student's online hours, course progress, and all testing.

4. Nail Technician

(i.) A student enrolled in a Board licensed or approved Nail Technician program, or an apprentice apprenticing under a designated licensed supervisor, may accrue up to one hundred and forty (140) hours of Level I credit through an online delivery system only for the theory portion of the curriculum. Schools are responsible for monitoring the student's online hours, course progress, and all testing.

5. Cosmetology and Barber Instructors

(i.) A student enrolled in a Board licensed or approved Master Cosmetology, Esthetician, Nail Technician, Hair Designer, Master Barber, or Barber II Instructor training program may accrue up to two hundred and twenty-five (225) hours of credit through an online delivery system only for the theory portion of the curriculum. Schools are responsible for monitoring the student's online hours, course progress, and all testing.

Cite as Ga. Comp. R. & Regs. R. 240-13-.05

AUTHORITY: O.C.G.A. §§ 43-1-25**,** 43-10-2(d)**,** 43-10-12**,** 43-10-13(a)**.**

HISTORY: Original Rule entitled "Online and Distance Learning Requirements" adopted. F. Mar. 6, 2023; eff. Mar. 26, 2023.

Department 290. RULES OF DEPARTMENT OF HUMAN SERVICES

Chapter 290-9. OFFICE OF REGULATORY SERVICES

Subject 290-9-2. RULES AND REGULATIONS FOR CHILD-PLACING AGENCIES

290-9-2-.04 Criminal History Background Checks, Agency Personnel

(1) Criminal History Background Checks for Owners Required. Prior to approving any license for a new child placing agency and periodically as established by the department by rule and regulation, the department shall require an owner to submit a records check application so as to permit the department to obtain criminal history background information on the owner.

(a) An owner may not be required to submit a records check application if it is determined that the owner does not do at least one of the following:

1. Maintains an office at the location where services are provided to children;

2. Resides at a location where services are provided to children;

3. Has direct access to residents receiving care; or

4. Provides direct personal supervision of personnel by being immediately available to provide assistance and direction during the time services are being provided to children.

(b) In lieu of a records check application, an owner may submit evidence, satisfactory to the department, that within the immediately preceding 12 months the owner has received a satisfactory criminal history background check determination.

(2) A child placing agency license shall not be issued, and any license issued shall be revoked where it has been determined that the owner has a criminal record involving any of the following covered crimes, as outlined in O.C.G.A. Sec. 49-2-14.1 *et seq.*:

(a) A violation of Code Section 16-5-1, relating to murder and felony murder;

(b) A violation of Code Section 16-5-21, relating to aggravated assault;

(c) A violation of Code Section 16-5-24, relating to aggravated battery;

(d) A violation of Code Section 16-5-70, relating to cruelty to children;

(e) A violation of Code Section 16-5-100, relating to cruelty to a person 65 years of age or older;

(f) A violation of Code Section 16-6-1, relating to rape;

(g) A violation of Code Section 16-6-2, relating to aggravated sodomy;

(h) A violation of Code Section 16-6-4, relating to child molestation;

(i) A violation of Code Section 16-6-5, relating to enticing a child for indecent purposes;

(j) A violation of Code Section 16-6-5.1, relating to sexual assault against persons in custody, detained persons, or patients in hospitals or other institutions;

(k) A violation of Code Section 16-6-22.2, relating to aggravated sexual battery;

(l) A violation of Code Section 16-8-41, relating to armed robbery;

(m) A violation of Code Section 30-5-8, relating to abuse, neglect, or exploitation of a disabled adult or elder person; or

(n) Any other offense committed in another jurisdiction that, if committed in this state, would be deemed to be a crime listed in this paragraph without regard to its designation elsewhere.

(3) An owner with a valid child placing agency license issued on or before June 30, 2007 shall be required to obtain a criminal records check determination no later than December 31, 2008.

(a) An owner with a valid child placing agency license issued on or before June 30, 2007 who is determined to have a criminal record for any of the crimes listed in Rule .04(2)(a)-(n) above, shall not have the license revoked prior to a hearing being held before a hearing officer pursuant to Chapter 13 of Title 50, the "Georgia Administrative Procedure Act."

(b) An owner with a valid license who acquires a criminal record as defined in Rule .04(2)(a)-(n) above subsequent to the effective date of these rules shall disclose the criminal record to the department.

(c) If at any time the department has reason to believe an owner holding a valid license has a criminal record for any of the crimes listed in Rule .04(2)(a)-(n) above, the department shall require the owner to submit a records check application immediately for determination of whether a revocation action is necessary. Prior to the revocation of the license becoming final, the owner is entitled to an administrative hearing unless the owner has not begun providing services under the license. Where services are not currently being provided under the license, the decision of the administrative hearing officer must precede the initiation of services.

(4) Criminal History Background Checks for Director and Employees Required. Prior to serving as a director of a licensed agency, a person shall submit a records check application and receive a satisfactory determination or be determined to be eligible to serve as a director as a result of an administrative hearing.

(a) A person with an unsatisfactory criminal history background check determination may not serve as a director of a licensed child placing agency if it is determined that such person has a criminal record involving any of the following covered crimes:

1. Any felony under Georgia law;

2. A violation of Code Section O.C.G.A. Sec. 16-4-1, relating to criminal attempt when the crime attempted is any of the crimes specified by this paragraph;

3. A violation of Code Section O.C.G.A. Sec. 16-5-23, relating to simple battery; where the victim is a minor;

4. A violation of Code Section O.C.G.A. Sec. 16-6-1 *et seq.*, relating to sexual offenses, excluding the offenses of bigamy or marrying a bigamist;

5. A violation of Code Section O.C.G.A. Sec. 16-21-1, relating to contributing to the delinquency of a minor;

6. Any other offense committed in another jurisdiction that, if committed in this state, would be deemed to be a crime listed in this paragraph without regard to its designation elsewhere.

(b) Prior to serving as an employee other than a director of a licensed agency, a person must submit a preliminary record check application and receive a satisfactory determination. Provided however, should there be an

unsatisfactory determination, the person must submit to a fingerprint record check and get a satisfactory determination or be determined eligible to be employed as a result of an administrative hearing.

(c) A person with an unsatisfactory background check determination may not serve as an employee of a licensed child placing agency if it is determined that such person has a criminal record involving any of the covered crimes outlined in O.C.G.A. Secs. 16-4-1, 16-5-23, 16-6-1 and 16-21-1 and in Rule .04(2)(a)1. - 6. above.

(d) In lieu of a records check application, a director or employee may submit evidence, satisfactory to the department, that within the immediately preceding 12 months the above personnel have received a satisfactory records check determination or a satisfactory preliminary records check determination, whichever is applicable.

(5) Criminal History Background Checks for Foster Parents Required. No facility that provides care in foster homes shall place a child in a foster home unless the foster parent or parents of the home and other adult persons that reside in the home or provide care to children placed in the home have obtained a criminal records check as required by law.

(6) No child shall continue to be placed in such foster home care unless the foster parent or parents also subsequently receive a satisfactory fingerprint records check determination or be determined eligible to serve as foster parents as a result of an administrative hearing.

(7) Personnel. In accordance with these rules and regulations, the agency shall have the administrative and professional service staff necessary to provide the services it is authorized to provide.

(a) Agencies operating multi-state programs under the supervision of an Executive Director who resides outside of Georgia shall employ an assistant director to whom the responsibility for administration of the Georgia program shall be delegated;

(b) Executive Director. The Executive Director or assistant director with responsibility for the administration of the Georgia program shall have as a minimum a Bachelor's degree and two years administrative experience in the field of human services. If the Executive Director or assistant director is responsible for supervision of casework services or provides direct placement services he/she shall also meet the educational and experience requirements for a casework supervisor.

(8) The Executive Director or the assistant director with responsibility for the administration of the Georgia program shall be:

(a) A full-time resident of the State of Georgia;

(b) Responsible for administration of policies and procedures established by the Board for operation of the Agency;

(c) Responsible for preparation, or assisting in the preparation of the annual budget, and control of expenditures according to budget allowance;

(d) Responsible for personnel matters including hiring, assigning duties, in-service training, supervision, evaluation of staff and terminations; and

(e) Responsible for professional leadership and technical consultation to the Board, determination of policy, and for periodic evaluations of the Agency's performance in terms of the conditions of licensure.

(9) Casework Supervisor. There shall be at least one casework supervisor employed by the Agency.

(a) The casework supervisor shall have the minimum qualifications of a master's degree from an accredited college or university in the area of social work, psychology, childhood education, special education, guidance counseling, behavioral or social science, or related field, with a minimum of one year experience in a human services delivery field as it relates to child welfare or a bachelor's degree from an accredited college or university in one of the

aforementioned areas of study with two years of paid work experience in a human services delivery field as it relates to child welfare.

(b) The Executive Director or assistant director may perform this function if qualified.

(c) The casework supervisor shall be responsible for the supervision of the placement services provided by the agency, and for the designation of approval for prospective adoptive and foster families and for assessing the appropriateness of the placement's room, board and watchful oversight capacity.

(10) Caseworker(s). There shall be at least one caseworker employed by the Agency.

(a) The caseworker shall have the minimum qualification of a bachelor's degree from an accredited college or university.

(b) The caseworker shall provide direct placement services and supervision following placements.

(c) A casework supervisor may perform this function.

(11) Annual Training. All supervisory and social service staff members, whether employees or contracted staff, must complete job-related training annually.

(a) Each supervisory and social service staff member employed or contracted by the agency to work more than twenty (20) hours per week shall be required to complete 15 hours of job-related training annually, as calculated from the employment date.

(b) Each supervisory or social service staff member employed or contracted for twenty (20) hours or less per week shall be required to complete 7 hours of job-related training annually, as calculated from the employment date.

(12) Clerical Staff. There shall be clerical staff employed by the Agency as necessary to keep correspondence, records, bookkeeping and files current and organized.

(13) Personnel Policies. The Agency shall have written personnel policies which shall include:

(a) Hiring and termination procedures;

(b) Job descriptions;

(c) Provisions for work performance evaluations conducted at least annually;

(d) Provisions for staff training, including the use of behavior management techniques and emergency safety interventions; and

(e) Provisions for addressing concerns, disagreements and grievances of staff relating to the care of children.

(14) Personnel Files. There shall be a personnel file on each employee which shall include:

(a) Application for employment;

(b) A satisfactory criminal history background check completed in accordance with O.C.G.A. Secs. 49-5-60, *et seq.*, and a ten-year employment history;

(c) Documentation of at least two professional, educational, or personal reference contacts that attest to the person's capabilities of performing the duties for which they are employed and to the person's suitability of working with or around children, with at least one of the reference contacts being a previous employer;

(d) Satisfactory documentation of education and other qualifications prior to employment;

(e) Date of employment or contract with the Agency;

(f) Current job description;

(g) Annual performance evaluation reports and any records of discipline involving the inappropriate use of behavior management techniques or emergency safety interventions signed and dated by both the employee or contracted individual and the supervisor;

(h) Documentation of participation in job-related training, including the dates of all such training, as required annually;

(i) Letter of resignation or reason for termination;

(15) Contracted Social Service Staff. All contracted social service staff must meet the same qualifications as employees and have a contract file with all of the same items required for the personnel files of other Agency staff.

(16) Personnel practices shall conform to the written policies and to these rules and regulations.

Cite as Ga. Comp. R. & Regs. R. 290-9-2-.04

AUTHORITY: O.C.G.A. § 49-5-12**.**

HISTORY: Original Rule entitled "Agency Personnel" adopted. F. Mar. 16, 2000; eff. Apr. 5, 2000.

Repealed: New Rule of same title adopted. F. Aug. 21, 2006; eff. Sept. 10, 2006.

Repealed: New Rule of same title adopted. F. Nov. 20, 2006; eff. Dec. 10, 2006.

Repealed: New Rule of same title adopted. F. June 5, 2007; eff. June 25, 2007.

Repealed: New Rule entitled "Criminal History Background Checks, Agency Personnel" adopted. F. Jan. 24, 2008; eff. Feb. 13, 2008.

Note: Correction of typographical error in Rule History only, in accordance with title change cited in January 24, 2008 filing, "***Repealed:*** *New Rule of same title adopted. F. Jan. 24, 2008; eff. Feb. 13, 2008.*" corrected to "***Repealed:*** *New Rule entitled "Criminal History Background Checks, Agency Personnel" adopted. F. Jan. 24, 2008; eff. Feb. 13, 2008.*" Effective Mar. 12, 2023.

Amended: F. Feb. 20, 2023; eff. Mar. 12, 2023.

Department 351. GEORGIA ACCESS TO MEDICAL CANNABIS COMMISSION

Chapter 351-1. ORGANIZATION

351-1-.01 Organization of the Commission

(1) The Georgia's Hope Act provides that the Georgia Access to Medical Cannabis Commission ("GMCC" or the "Commission"), a State of Georgia executive branch agency, is created to protect public health, safety, and welfare, and to provide for the regulated production, growing, manufacturing, and dispensing of products in Georgia for the lawful access to medical cannabis by patients on the Georgia Low-THC Oil Patient Registry.

(2) The Georgia's Hope Act further dictates the Commission's composition, methods of appointment, and terms of office. The Act specifies Commission functions and duties thus providing for the implementation of the Georgia's Hope Act through the adoption of rules and regulations.

(3) The Commission receives, reviews, and adjudicates complaints with regard to its licensees, licensee conduct, cannabis, and products regulated by the Commission.

(4) The public may obtain information from and submit requests to the Executive Director. The contact information for the GMCC Executive Director may be obtained from the Commission's website at www.gmcc.ga.gov.

Cite as Ga. Comp. R. & Regs. R. 351-1-.01

AUTHORITY: O.C.G.A. §§ 16-12-202**,** 16-12-203**,** 16-12-210**,** 50-13-3**.**

HISTORY: Original Rule entitled "Organization of the Commission" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-1-.02 Meetings, Officers, Duties

(1) The Commission shall meet as set forth in Code Section 16-12-202.

(2) A majority of the seven (7) Commission Members shall constitute a quorum.

(3) Annually, the Commission shall elect from its Members a Vice Chair, and may elect additional officers from among its Members as it deems appropriate.

(4) The Chair shall preside at meetings, perform all duties of that office, and appoint Commission Members to serve on committees as created. The Vice Chair shall preside in the absence of the Chair and shall assume the duties of the Chair when necessary.

(5) Meetings of the Commission shall be conducted, to the extent practicable and permissible, in accordance with Robert's Rules of Order, Newly Revised. The Chair of the Commission, or the Member of the Commission acting in such capacity, shall have authority to make rulings regarding procedural matters and issues coming before the Commission.

Cite as Ga. Comp. R. & Regs. R. 351-1-.02

AUTHORITY: O.C.G.A. §§ 16-12-202**,** 16-12-203**,** 16-12-210**,** 16-12-224**.**

HISTORY: Original Rule entitled "Meetings, Officers, Duties" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-1-.03 Declaratory Rulings

(1) A person whose legal rights are affected by the application of any statutory provision or any rule or order of the Commission may petition the Commission to request a declaratory ruling thereon.

(a) The petition shall be sent by certified mail, return receipt requested, addressed to the Executive Director at the Georgia Access to Medical Cannabis Commission with the attention line referencing a petition for declaratory ruling. The contact information for the Executive Director may be obtained from the Commission's website at www.gmcc.ga.gov.

(b) Declaratory rulings shall not be made upon untrue, moot, contingent, or hypothetical facts or situations, but only upon actual facts set forth in the petition requesting a declaratory ruling.

(2) The petition shall be made in writing and include the following:

(a) Name and contact information of the petitioner;

(b) The notarized signature of the petitioner;

(c) The full text of the statute, rule, or order of the Commission upon which a ruling is requested;

(d) All pertinent facts and evidence necessary to make a ruling;

(e) The petitioner's contention, if any, as to the applicability of the aforesaid statute, rule, or order with citations of legal authorities, if any, that authorize, support, or require a ruling in accordance therewith;

(f) A statement, setting forth in detail, the petitioner's interest in the requested ruling, including how and why the petitioner is uncertain with respect to his or her rights in the matter; and

(g) Any legal authorities relevant to the requested ruling not provided pursuant to any of the other paragraphs of this subsection.

(3) Within thirty (30) days of the date of filing such petition, the Commission shall issue such declaratory ruling, provided, however, that:

(a) The Chair of the Commission may issue an order to extend such thirty (30) day period stating the reason for such extension.

(b) If it is determined that the requisites for a declaratory ruling are not present, then the Commission shall issue a written explanation for such determination.

(4) The date of filing shall be the date received by the Commission office.

(5) The Commission shall not be required to render a declaratory ruling if it relates to an investigation pending before the Commission.

(6) If the petition requests a declaration as to the applicability of an order of the Commission, then the petitioner shall serve a copy of the petition on all parties to the case.

Cite as Ga. Comp. R. & Regs. R. 351-1-.03

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 50-13-11**.**

HISTORY: Original Rule entitled "Declaratory Rulings" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-1-.04 Petition for Promulgation, Amendment, or Repeal of Rules

(1) Each petition for promulgation, amendment, or repeal of rules shall be submitted in writing to the Commission. The petition shall be verified under oath by the petitioner and shall include:

(a) The name, address, and contact information of the petitioner;

(b) The full text of the rule requested to be amended with the petitioner's proposed changes or desired language, the citation and full text of the rule desired to be repealed, or the full text of the rule desired to be promulgated;

(c) A statement of the reason such rule should be amended, repealed, or promulgated, including a statement of all pertinent existing facts which relate to petitioner's interest in the matter; and

(d) Citations of legal authority, if any, which authorize, support, or require the action requested by the petition.

(2) Within thirty (30) days after receipt of the petition, the Commission shall either deny the petition in writing or initiate rule-making proceedings in accordance with Code Section 50-13-4.

Cite as Ga. Comp. R. & Regs. R. 351-1-.04

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 50-13-9**.**

HISTORY: Original Rule entitled "Petition for Promulgation, Amendment, or Repeal of Rules" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-1-.05 Fees

(1) All fee payments submitted to the Commission are non-refundable.

(2) Fees shall be paid in U.S. funds; the Commission may require certified funds at its discretion.

(3) The fee schedule shall be made available at the Commission office and on the Commission's website.

(4) Checks returned for insufficient funds will be addressed, as set forth in Code Section 16-9-20, and the Commission shall assess a processing fee, as outlined on the fee schedule, for any returned check, money order, or payment.

(5) Notices for fees due are sent only as a courtesy.

Cite as Ga. Comp. R. & Regs. R. 351-1-.05

AUTHORITY: O.C.G.A. §§ 16-9-20**,** 16-12-203**,** 16-12-206**,** 16-12-211**,** 16-12-212**,** 16-12-222**.**

HISTORY: Original Rule entitled "Fees" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Department 351. GEORGIA ACCESS TO MEDICAL CANNABIS COMMISSION

Chapter 351-2. DEFINITIONS

351-2-.01 Definitions

The following words and terms as used in these rules shall have the meaning hereinafter ascribed to them:

(a) "Accreditation" means the procedure by which an authoritative body gives formal recognition that an organization is competent to carry out specific tasks and verifies that the appropriate quality management system is in place.

(b) "Act" means O.C.G.A. Sections 16-12-190 through 16-12-236, as amended, and referred to as "Georgia's Hope Act."

(c) "Adverse event" means an undesirable experience associated with the lawful use of product in final packaged form where the outcome was death, life-threatening complications, hospitalization, disability or permanent damage, congenital anomaly or birth defect, required intervention to prevent permanent impairment or damage, or any other important medical event.

(d) "Advertise" means, but is not limited to, the act of publicizing, disseminating, soliciting, or circulating visual, oral, or written communication to induce or persuade any person to purchase or consume any specific regulated cannabis. This definition does not include education and consultation provided directly to patients and caregivers regarding product safety information.

(e) "Agent" means the company contact or authorized agent as listed on the license application, who shall be the individual responsible for all daily and regulatory operations of the licensee.

(f) "Analyte" means a chemical, compound, element, bacteria, yeast, fungus, microbial, or toxin for which a product sample is tested by an independent laboratory.

(g) "Applicant" means an entity applying for a license as set forth in Code Section 16-12-200(1).

(h) "Batch" means a quantity of regulated cannabis harvested or produced together at the same time by the same production licensee, the meaning of which shall include the following:

1. "Harvest batch" means a specific quantity of regulated cannabis grown under the same conditions, and harvested during a specified period of time from specified cultivation space(s), using the same standards.

2. "Manufactured batch" means a quantity of regulated cannabis produced and manufactured together at the same time, using the same standards.

(i) "Batch number" means the number assigned to each batch of regulated cannabis by a production licensee.

(j) "Cannabinoid profile" means a list of the chemical compounds that are the active constituents of cannabis, which are present in the product.

(k) "Cannabis" means marijuana, hashish, and other substances which are identified as including any parts of the plant family Cannabaceae and including any and all genera, strains, and subspecies, such as cannabis sativa, indica, ruderalis, and any and all derivatives thereof, whether growing or not, the seeds thereof, the resin extracted from any part of such plant, and any compound, salt, derivative, mixture, or preparation of such plant, its seeds, or resin,

including tetrahydrocannabinol (THC), cannabidiol, and all other cannabinol derivatives, including its naturally occurring ingredients, whether produced directly or indirectly by extraction.

(l) "Canopy" means the designated area(s) of a production licensee's cultivation space that contains mature, flowering plants at any point in time.

(m) "Caregiver" shall have the same meaning as set forth in Code Section 31-2A-18.

(n) "Certificate of analysis" means the report of analytical testing of product in final packaged form performed and the results obtained by an independent laboratory.

(o) "Child-resistant package" means the special packaging of a product in final package form in compliance with the United States Poison Prevention Packaging Act of 1970, 15 U.S.C. Section 1471 *et seq.*, as amended, and with the rules of the Commission.

(p) "Clone" means regulated cannabis that is produced by asexual reproduction and is a genetic match to the mother plant.

(q) "Commission" or "GMCC" means the Georgia Access to Medical Cannabis Commission created as set forth in Code Section 16-12-202.

(r) "Complainant" means the person who submitted a complaint to the Commission alleging violations of state laws, rules, and/or regulations by an entity or person.

(s) "Concentrate" means a condensed accumulation of cannabis, having a greater proportion of cannabinoids and terpenes than those that are naturally occurring in cannabis or flowers.

(t) "Contaminant" means any pollutant, physical, chemical, biological, or radiological substance or matter found in the production of regulated cannabis.

(u) "Contractor" means a third-party individual or company performing work for a licensee under contractual agreement associated with the production or dispensing of regulated cannabis and any subcontractor.

(v) "Corrective action plan" means the plan created by a licensee or registrant detailing how they will correct any deficiencies or violations found during an inspection.

(w) "Cultivation space" means the measured canopy for the indoor production of regulated cannabis and equipped with locks or other security devices that allow access only by an authorized person, but which does not include propagation or vegetative spaces, ancillary spaces, and aisles between grow spaces, as set forth in Code Sections 16-12-211 and 16-12-212.

(x) "Day" means a calendar day.

(y) "Dispensary" means the retail outlet of a dispensing licensee. As used throughout the rules of the Commission, the related terms "dispensing licensee" and "dispensing license" refer to such terms as set forth in Code Section 16-12-206(a)(2).

(z) "Duress alarm" means a silent security alarm signal generated by the entry of a designated code into an Arming Station that signals duress.

(aa) "Employee" means, but is not limited to, any person, corporation, entity, contractor, or consultant whose duties involve any aspect of the production, research, testing, transportation, or dispensing of regulated cannabis, whether or not compensated for the performance of such duties.

(bb) "Enclosed" means a structure or object with a base or floor that is covered securely, or able to be covered securely, on all vertical sides and an ultimate horizontal covering affixed on top of said vertical sides.

(cc) "Entity" means, but is not limited to, a corporation and foreign corporation, nonprofit corporation and foreign nonprofit corporation, professional corporation and foreign professional corporation, limited partnership and foreign limited partnership, limited liability partnership and foreign limited liability partnership, and limited liability company and foreign limited liability company as set forth in Code Section 14-2-203.

(dd) "Extract" means a preparation that contains the active ingredient(s) of a substance in concentrated form.

(ee) "Fence" means a locking barrier, railing, or other upright structure fully enclosing an area of ground to mark a boundary, and to effectively prevent or control access.

(ff) "Final packaged form" means product in properly labeled, tamper-evident, child-resistant packaging, including the unique batch number for the purposes of identifying and tracking, ready for dispensing. This definition does not include exit packaging or a shipping container or an outer wrapping used solely for the transport of products in bulk quantity to or from the premises of a licensee or registrant.

(gg) "Floor" means the lower inside surface of a structure that serves as a barrier between the native soil and regulated cannabis that is nonporous, impermeable, impervious, waterproof, or otherwise sealed from, covered over, and permanently restrictive to the earth's terranean shell.

(hh) "Formulation" means the ingredients, recipe, method of processing in order to be shelf stable, certificates of analysis for any ingredient used, and description of the process in which all ingredients are combined to produce a final form.

(ii) "Fully operational" means:

1. A Class 1 or Class 2 production licensee is active and operational such that its production facility is capable of producing adequate amounts of product in final packaged form to ensure uninterrupted availability at its dispensaries, for a period of thirty (30) days for patients; or

2. A dispensing licensee is active and operational such that it maintains an adequate on-site inventory of product in final package form to ensure uninterrupted availability of inventory for a period of thirty (30) days for patients.

(jj) "Holdup alarm" means a silent alarm signal generated by the manual activation of a device for the purpose of signaling that a robbery is in progress.

(kk) "Immature plant" means a non-flowering cannabis plant that is no taller than 8 inches (203.2 mm) from the growing or cultivating medium and no wider than 8 inches (203.2 mm), produced from a cutting, clipping, tissue culture, or seedling that is in a growing or cultivating medium or in a growing or cultivating container.

(ll) "Independent laboratory" means a laboratory approved and authorized by the Commission, pursuant to the rules of the Commission, to test product for purposes specified in the Act and the rules of the Commission.

(mm) "Indoor" means of or relating to the interior of a building or enclosed structure.

(nn) "Ingredient" means a component of regulated cannabis that is:

1. An inactive ingredient approved by the U.S. Food and Drug Administration ("FDA") cataloged in its current database; the published FDA database is accessible at https://www.accessdata.fda.gov/scripts/cder/iig/index.cfm; or

2. A substance or group of substances, which includes, but is not limited to, purified compounds, oils, therapeutic chemicals, oleoresins, essences or extracts, protein hydrolysates, distillates, or isolates.

(oo) "Inspection" means an evaluation of facilities, laboratory, testing, records, employees, equipment, operations, methodology, and quality assurance practices conducted by the Commission or its employees for the purpose of ensuring compliance with the requirements of the Act and these rules.

(pp) "Labeling" means any display of written, printed, or graphic matter printed on or affixed to any container, wrapper, liner, or insert accompanying the product. This shall include any material or image printed on or attached to the final retail package and bulk package unit.

(qq) "Licensee" means any entity with an active license issued by the Commission.

(rr) "Low-THC oil" shall have the same meaning as set forth in Code Section 16-12-190.

(ss) "Low-THC Oil Patient Registry" means the registration of individuals who have been issued registration cards by the Georgia Department of Public Health.

(tt) "Manufacture" shall have the same meaning as set forth in Code Section 16-12-200(13).

(uu) "Manufacturing space" means the indoor area utilized to manufacture and package products, including extraction and other related practices applied to harvested plant material.

(vv) "Market" or "marketing" means any act or process of promoting or selling products, including, but not limited to, sponsorship of sporting events, point-of-sale advertising, and development of products specifically designed to appeal to certain demographics.

(ww) "Minor" shall have the same meaning as set forth in Code Section 39-1-1.

(xx) "Minority Business Enterprise" shall have the same meaning as set forth in Code Section 50-5-131.

(yy) "Mother plant" means a plant grown for the purpose of being a source of propagative material.

(zz) "Package" or "packaging" means any container or wrapper that may be used for enclosing or containing any product. This definition does not include a shipping container or an outer wrapping used solely for the transport of products in bulk quantity to the premises of a licensee or registrant.

(aaa) "Panic alarm" means an audible system signal to indicate an emergency situation.

(bbb) "Patient" means the same as set forth in Code Section 16-12-200(16).

(ccc) "Perimeter alarm" means a security alarm signal generated by a breach or crossing of, or entry to, the outermost parts or boundary of a premises.

(ddd) "Pest" means an undesired insect, rodent, nematode, fungus, bird, vector, vertebrate, invertebrate, undesired herbaceous plant, virus, bacteria, or other microorganism (except for microorganisms on or in living humans or other living animals) that is, or is likely to become, injurious, dangerous, or detrimental to health, the environment, or the agricultural environment of the state; provided however, nothing in this definition shall apply to industry recognized beneficial biological control agents.

(eee) "Pesticide" means any substance or mixture of substances intended for preventing, destroying, eradicating, repelling, or mitigating any pest.

(fff) "Physician" means a person licensed to practice medicine by, and in good standing with, the Georgia Composite Medical Board as set forth in Code Section 43-34-2.

(ggg) "Plant waste" means all plant parts including roots, stalks, leaves, stems, flower, trim, or solid plant material and any plant material rendered from the extraction process not used directly for production that have been pruned, trimmed, shucked, or otherwise removed during cultivation, harvest, or manufacturing.

(hhh) "Premises" means a licensee's or registrant's building(s), together with its real property.

(iii) "Produce" means to grow and harvest regulated cannabis to manufacture and create low-THC oil and products in accordance with the Act and these rules.

(jjj) "Product" shall have the same meaning as set forth in Code Section 16-12-200(15).

(kkk) "Proficiency testing" means the evaluation, relative to a given set of criteria, of the performance, under controlled conditions, of an independent laboratory in analyzing unknown samples provided by an external source.

(lll) "Program participant" means the same as set forth in Code Section 16-12-191(b)(1)(A)(i).

(mmm) "Propagation space" means an indoor area or facility used for the growing of immature or nonflowering plants including but not limited to: seeds, seedlings, clones or cuttings, tissue culture, and any other propagative means. This definition does not include space used for mother plants which will be used for harvest.

(nnn) "Quality control" means the set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control for which errors have been reduced to acceptable levels.

(ooo) "Recall" means the return of product in final packaged form, whether Commission-ordered or licensee-initiated, due to the potential for, or actual occurrence of, adverse events from the use of such product by patients.

(ppp) "Registrant" means an entity that is approved by the Commission, pursuant to the rules of the Commission, as an independent laboratory for purposes of testing low-THC oil and products and is on the Commission's approved and current list of such approved independent laboratories.

(qqq) "Regulated cannabis" means all cannabis regulated by the Commission, including, but not limited to, plants and plant material, plant waste, extracts, concentrates, and products.

(rrr) "Regulated cannabis waste" means the waste related to or directly produced by regulated cannabis.

(sss) "Remediation" means the neutralization or removal of dangerous substances or other contaminants from products including, but not limited to, manipulating the THC level.

(ttt) "Restricted access area" means a building, room, or other area in a licensee's or registrant's premises where regulated cannabis is grown, cultivated, harvested, weighed, packaged, tested, researched, processed, or stored.

(uuu) "Sample" means a single or representative part of a batch which is composed of several sample increments.

1. "Controlled sample" means the official sample of product in final packaged form collected by a sample collector from an independent laboratory, which is used to determine, among other things, official compliance with THC limits.

2. "Reserve sample" means an internal sample of regulated cannabis taken for purposes of ensuring product quality and making determinations about whether to dispense the product.

(vvv) "Standard operating procedures" means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, process, task, or action.

(www) "Tag" means an approved unique identifier for the purpose of tracking regulated cannabis in the tracking system provided or operated by a Commission-approved vendor.

1. "Plant tag" means an approved tag attached to each individual plant.

2. "Product tag" means an approved tag printed on, or attached to, the individual product in final packaged form.

3. "Bulk package tag" means an approved tag printed on, or attached to, the product batch package for the purpose of storage and transport.

(xxx) "Tamper-evident" means having one (1) or more indicators of modification which, if breached, missing, or altered, can reasonably be expected to provide visible evidence that tampering has occurred.

(yyy) "Total THC" means the sum of the percentage by weight of delta-9-tetrahydrocannabinolic acid (D9-THCA) multiplied by 0.877, plus the percentage by weight of delta-8-tetrahydrocannabinol (D8-THC), plus the percentage by weight of delta-9-tetrahydrocannabinol (D9-THC), plus the percentage by weight of exo-tetrahydrocannabinol (Exo-THC), plus the percentage by weight of delta-10-tetrahydrocannabinol (D10-THC), i.e., Total THC = (% D9-THCA * 0.877) + % D8-THC + % D9-THC + % Exo-THC + % D10-THC.

(zzz) "Tracking system" or "Commission-approved tracking system" means a seed-to-sale tracking system provided or operated by a vendor approved by the Commission to track regulated cannabis that is grown, processed, manufactured, transferred, transported, stored, dispensed, recalled, or disposed of.

(aaaa) "Transport" and "transportation" means to move or transfer product from one location to another.

(bbbb) "Universal symbol" means the universal cannabis product symbol authorized by the Commission for use on product containers, packaging, and labeling.

(cccc) "Visitor" means a non-employee or contractor, present on a licensee's premises for a specific purpose or task not directly related to the production of regulated cannabis or the dispensing of product in final packaged form.

(dddd) "Visitor identification badge" means a physical badge issued to a visitor used to easily verify the status of a person while on a licensee's premises.

Cite as Ga. Comp. R. & Regs. R. 351-2-.01

AUTHORITY: O.C.G.A. §§ 16-12-200**,** 16-12-203**,** 16-12-206**,** 16-12-210**.**

HISTORY: Original Rule entitled "Definitions" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Department 351. GEORGIA ACCESS TO MEDICAL CANNABIS COMMISSION

Chapter 351-3. APPLICATIONS

351-3-.01 Class 1 and Class 2 Production License Applications

(1) An application for a Class 1 or Class 2 production license shall only be accepted during an open application period announced by the Commission.

(2) An applicant for a Class 1 or Class 2 production license shall submit the following to the Commission:

(a) A complete application as required by the Commission; and

(b) The required non-refundable application fee, as listed on the fee schedule, payable in certified funds.

(3) Applications for a Class 1 or Class 2 production license shall meet the requirements outlined in the Commission's Competitive Application Request for Proposals and all requirements in the Commission's application instructions, mandatory requirements, addenda, and exhibits.

(4) The applicant for a Class 1 or Class 2 production license shall submit with their application sufficient documentation to prove that the applicant possesses one (1) of the following:

(a) A $1.5 million bond;

(b) An irrevocable letter of credit; or

(c) Other comparable surety approved by the Commission.

(5) An application for a Class 1 or Class 2 production license will not be accepted from any owner or entity holding a Class 1 or Class 2 production license who is seeking to gain ownership interest in a second production license.

(6) If an initial application contains information that the applicant claims to be confidential, then the applicant shall submit a redacted and an unredacted version of the application, along with an affidavit explaining or justifying such redactions.

Cite as Ga. Comp. R. & Regs. R. 351-3-.01

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-211**,** 16-12-212**,** 16-12-219**,** 16-12-221**.**

HISTORY: Original Rule entitled "Class 1 and Class 2 Production License Applications" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-3-.02 Dispensing License Applications

(1) Only Class 1 or Class 2 production licensees are eligible to apply for a dispensing license as set forth in Code Section 16-12-206.

(2) An application for a dispensing license shall only be submitted during an open application period announced by the Commission.

(3) An applicant may submit applications for up to the maximum number of dispensing licenses as set forth in Code Section 16-12-206. If such applicant wishes to apply for more than one dispensing license, as provided for in the Act, then such applicant shall submit a separate application for each dispensing license.

(4) An applicant for a dispensing license shall submit the following for approval by the Commission:

(a) A complete dispensing license application as required by the Commission;

(b) The required non-refundable application fee, as listed on the fee schedule;

(c) The Class 1 or Class 2 production license name and number associated with the application and attestation that the information provided to the Commission on the associated Class 1 or Class 2 production license application is true and current;

(d) The legal name of the dispensing license applicant, as reflected in the articles of incorporation or organizational documents filed with the Georgia Secretary of State, including:

1. The type of corporation or entity of the dispensing license applicant;

2. A copy of the dispensing license applicant's articles of incorporation, articles of organization, or partnership document; and

3. The trade name of the dispensing license applicant, if applicable and if different from the legal name.

(e) The physical address, county, and global positioning satellite coordinates where the proposed dispensary will be located;

(f) The U.S. Postal Service mailing address of the dispensing license applicant;

(g) The name of the agent at the proposed dispensary;

(h) The telephone number(s) of the dispensing license applicant and agent;

(i) The electronic mail address of the dispensing license applicant and agent;

(j) A copy of the secure and verifiable document as set forth in Code Section 50-36-2 for each owner, officer, and the agent;

(k) Attestation that all persons, including all owners, officers, agents, and employees have been fingerprinted, demonstrating a lack of drug related felony convictions, except for drug felony convictions that are greater than ten years old or that have been expunged or pardoned;

(l) A description of any investigation or adverse action resulting in the revocation, suspension, citation, fine, or order against any cannabis-related license held by the applicant by any commission, licensing board, government, law enforcement agency, or court in Georgia or any other state;

(m) A description of any denied application or refused renewal of any cannabis-related license held by the applicant by any commission, licensing board, government, law enforcement agency, or court in Georgia or any other state;

(n) A copy of floor- and site-specific plans and renderings showing the interior and exterior of the proposed dispensary, drawn to scale with square footage clearly illustrated. The site-specific plans shall include and identify all of the following:

1. The area of the retail point of dispensing;

2. Restricted access areas;

3. Patient consultation room(s);

4. Other areas;

5. An enclosed receiving bay or other equally secured delivery area where product in final packaged form will be received pursuant to a standard operating procedure approved by the Commission; and

6. Parking.

(o) Attestation that, upon issuance of the dispensing license, the dispensing license applicant will maintain compliance with all local ordinances, rules, or regulations adopted by the locality where the proposed dispensary is located, which are in effect at the time of the application, including copies of any required local registration, license, or permit of the locality where the proposed dispensary is located;

(p) Documentation relating to the location of the proposed dispensary, including the following:

1. Attestation that the proposed dispensary is at least one thousand (1,000) feet from a covered entity as set forth in Code Section 16-12-215(a), measured from property boundary to property boundary;

2. The location of the proposed dispensary as it relates to being within a reasonable distance to service patients;

3. The proximity of the proposed dispensary to all existing dispensaries of the applicant and to all proposed dispensaries identified in other pending applications submitted by such applicant; and

4. Whether the patient population in the geographic area proposed by the dispensing license applicant justifies the need for a dispensing license.

(q) A demonstration of significant involvement in the business by one or more minority business enterprises as defined in Code Section 50-5-131, either as co-owners of the business or as significant suppliers of goods and services for the business;

(r) The description of the proposed organizational structure of the dispensing license applicant, including both of the following:

1. An organizational chart showing all owners and officers of the entity applying for a dispensing license, irrespective of ownership interest; and

2. A list of all owners and officers of the entity applying for a dispensing license that contains the following information for each person:

(i) Current title;

(ii) Role, if different from the person's current title;

(iii) Whether the person has served or is currently serving as an owner, officer, or agent for another business licensed by the Commission;

(iv) Whether another like business with which the owner or officer is associated has had a license revoked, disciplined, or the equivalent thereof, in this state or any other jurisdiction;

(v) The ownership interest that person has in the dispensing license applicant, if any; and

(vi) The ownership interest or financial interest in any other entity licensed by the Commission, if any.

(s) Documentation of the applicant's ability to maintain the following:

1. Adequate prevention of diversion, theft, and loss of product; and

2. Knowledge, understanding, procedures, security controls, and ethics to ensure optimal safety and accuracy in the dispensing of product in final packaged form.

(t) Attestation that the application for a dispensing license is true and current at the time of signing; and

(u) Any other documentation requested by the Commission or its employees to determine the dispensing license applicant's suitability for licensure or to protect public health and safety.

(5) A dispensing license applicant shall, as part of its application, provide to the Commission a true, correct, and current copy of its standard operating procedures, and shall maintain such procedures in accordance with the Act and these rules. Such procedures, at a minimum, shall include:

(a) Procedures for the oversight of the dispensing licensee including, but not limited to, documentation of the reporting and management structure of the dispensing licensee;

(b) Procedures for safely dispensing product in final packaged form to patients or their caregivers;

(c) Procedures to ensure adequate inventory of product in final packaged form and to maintain an inventory management plan;

(d) Procedures to ensure accurate record keeping;

(e) A recall procedure plan for conducting licensee-initiated or Commission-ordered recalls of products that are determined to be misbranded, adulterated, or otherwise deemed a threat to patient health or public safety, including:

1. Factors that necessitate a recall;

2. Employees responsible for implementing the recall procedures;

3. Notification protocols, including;

(i) To the Commission;

(ii) To the affected patients or caregivers; and

(iii) To the public.

4. Procedures for the collection of any recalled product; and

5. Procedures for the transport of any recalled product in final packaged form from a dispensing licensee to the originating production licensee.

(f) Employee security policies;

(g) Safety and security procedures, including a disaster plan with procedures to be followed in case of fire or other emergencies;

(h) Personal safety and crime prevention techniques;

(i) A job description or employment contract developed for all employees and a volunteer agreement for all volunteers which includes duties, responsibilities, authority, qualifications, and supervision; and

(j) The dispensing license applicant's alcohol and drug-free workplace policy, which shall include routine and random drug and alcohol screening.

(6) An application for a dispensing license shall not be approved for any location that sells any items other than Commission-approved products and accessories, as allowed by the Act, for the safe use and application of such products as directed by the originating production licensee.

(7) If an application for a dispensing license contains information that the applicant claims to be confidential, then the applicant shall submit a redacted and an unredacted version of the application, along with an affidavit explaining or justifying such redactions.

(8) An application may be denied for failure to meet requirements set forth in the Act and these rules.

Cite as Ga. Comp. R. & Regs. R. 351-3-.02

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-215**,** 16-12-219**.**

HISTORY: Original Rule entitled "Dispensing License Applications" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-3-.03 Renewals

(1) The responsibility to renew a license on or before the expiration date remains with the respective licensee.

(2) A license expires upon the expiration date if a licensee has not filed a renewal application and remitted all of the required application, where applicable, and payment of the license fees prior to the expiration date.

(3) To apply for renewal, a licensee shall submit a complete application and the required non-refundable annual renewal fee, as listed on the fee schedule.

(a) A licensee shall apply for the renewal prior to the expiration date.

(b) The licensee may submit a renewal application, once the renewal period opens, prior to the expiration of its respective license.

(c) When applying for a renewal, licensees shall update, as needed, all information submitted in the initial application or the last renewal application, whichever was last approved by the Commission. Licensees shall include all approved changes and modifications to such application, if applicable to the respective licensee.

(d) Once the licensee submits a complete and timely application for renewal, the license remains in active or valid status pending renewal until the Commission renews the license. The Commission hereby delegates the authority and responsibility to determine whether applications for renewal are approved, or denied, to the GMCC Executive Director.

(4) If a renewal application contains information that the applicant claims to be confidential, then the applicant shall submit a redacted and an unredacted version of the application, along with an affidavit explaining or justifying such redactions.

(5) A licensee who does not submit a complete and timely renewal application shall:

(a) Cease all licensed operations at all premises upon expiration of the respective license; and

(b) Dispose of any regulated cannabis by the date specified by the Commission.

(6) The licensee is responsible for payment of all unpaid and undisputed fines by the time of renewal. A license shall not be renewed if the licensee has any unpaid and undisputed fines.

(7) Class 1 and Class 2 production licensees are required to renew annually during the renewal period established by the Commission and follow any additional terms of renewal as stated in their license contracts. In addition to such contract terms, Class 1 and Class 2 production licensees shall also submit the following with their renewal applications:

(a) Proof that one (1) of the following has been maintained as an operational requirement for the year:

1. A $1.5 million bond;

2. An irrevocable letter of credit; or

3. Other comparable surety approved by the Commission.

(b) Detailed records documenting the involvement of minorities and women in:

1. Ownership;

2. Leadership or management positions;

3. Employment; and

4. Contracts:

(i) With contractors; and

(ii) With suppliers.

(8) A dispensing license may renew on the condition that the requisite Class 1 or Class 2 production license has an active status with no unpaid and undisputed fines with the Commission. Unless otherwise provided by law, the expiration of a Class 1 or Class 2 production license shall automatically result in the expiration of all dependent dispensing licenses.

Cite as Ga. Comp. R. & Regs. R. 351-3-.03

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-210**,** 16-12-211**,** 16-12-212**,** 16-12-221**.**

HISTORY: Original Rule entitled "Renewals" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Department 351. GEORGIA ACCESS TO MEDICAL CANNABIS COMMISSION

Chapter 351-4. CLASS 1 AND CLASS 2 PRODUCTIONS LICENSEES

351-4-.01 Production Pre-operational Inspections

(1) A production licensee shall submit to pre-operational progress inspections conducted by the Commission or its employees to ensure and confirm that the production licensee is fully operational as required by Code Section 16-12-223(a)(5).

(2) Prior to the inspection to be deemed fully operational, a production licensee shall submit the following to the Commission:

(a) A satisfactory report of full compliance with, and completion of, all applicable public safety inspections required by local, state, and federal jurisdictions, including, without limitation, fire, building, health, and air quality inspections; and

(b) A list of all plant strains and cultivars which will be propagated and/or cultivated at the premises, which shall be maintained at the premises during the term of the production license contract and provided to the Commission or its employees upon request.

(3) Failure of a production licensee to be fully operational within twelve (12) months of the date the license is awarded will result in the revocation of the license and any associated dispensing licenses.

Cite as Ga. Comp. R. & Regs. R. 351-4-.01

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-210**,** 16-12-211**,** 16-12-212**,** 16-12-217**,** 16-12-223**.**

HISTORY: Original Rule entitled "Production Pre-operational Inspections" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-4-.02 General Production License Rules

(1) A production licensee shall conduct activities and operations as represented in the respective license contract awarded by the Commission. Such license contract includes compliance with the following:

(a) The initial application submission;

(b) License contract amendments agreed to in writing between the licensee and the Commission;

(c) The Act, as amended;

(d) The Commission's rules and regulations, as promulgated and amended; and

(e) The Commission's policies and procedures, as approved.

(2) A production licensee shall be fully operational within twelve (12) months from the date of which the respective Notice of Award is issued.

(3) A production licensee shall operate only at the physical location as listed on the respective license contract. The licensee shall prominently display the following to be viewed by individuals entering the premises:

(a) The license;

(b) Any signage required by the Act and these rules; and

(c) The laws and these rules; provided, however, that signage approved by the Commission may be displayed in lieu of a complete copy of the laws and rules.

(4) Failure to remain fully operational during licensure shall result in citations and fines up to and including revocation.

(5) A production licensee shall not:

(a) Dispense product in final packaged form at the premises;

(b) Give away or receive free or complimentary regulated cannabis under any circumstances;

(c) Use the Commission's name or logo on any sign at the premises, on the business' website, or in any advertising or social media, except to the extent that information is contained on the proof of licensure or is contained in part of warnings, signage, or other documents required by these rules;

(d) Sublet any portion of a premises; or

(e) Produce, prepare, package, warehouse, store, or label any product at the premises other than the products approved by the Commission as set forth in these rules.

(6) Each room door on the premises shall be clearly labeled on the exterior of the door to identify the purpose of the room.

(7) A production licensee shall continue to provide the Commission and its employees with current contact information and notify the Commission and its employees, in writing, of any changes to the mailing addresses, phone numbers, or electronic mail addresses.

(8) A production licensee shall notify the Commission and its employees within ten (10) days of the initiation and/or conclusion of any new citations, fines, judgments, lawsuits, legal proceedings, charges, or government investigations, whether initiated, pending, or concluded, that involve the licensee and its affiliates in Georgia and in any other state.

(9) A production licensee shall create and maintain employee policies and procedures, including, at a minimum, the following:

(a) Code of ethics;

(b) Whistle-blower policy;

(c) A policy which notifies persons with disabilities of their rights, which includes provisions prohibiting discrimination and providing reasonable accommodations; and

(d) All applicable state and federal Department of Labor procedures and posting of appropriate placards.

(10) A production licensee shall have a continuing responsibility to comply with the following fingerprinting and criminal background check requirements:

(a) Ensure that all owners and officers have been fingerprinted and attest that all employees have no history of drug related felony convictions, except for drug felony convictions that are greater than ten (10) years old or that have been expunged or pardoned.

(b) Ensure that the Commission and its employees are notified in writing of a criminal conviction of any owner, agent, or employee, either by mail or electronic mail, within forty-eight (48) hours of the licensee becoming aware of such conviction. The written notification to the Commission and its employees shall include the name and position of the person, the date of conviction, the court docket number, the name of the court in which the person was convicted, and the specific offense(s) for which the person was convicted.

(11) A production licensee shall take reasonable measures and precautions to ensure all employees working with direct access to regulated cannabis use hygienic practices while on duty for the prevention of contamination, including:

(a) Ensuring handwashing facilities are located within all production spaces, equipped with effective hand-cleaning and sanitizing preparations and sanitary towel service or electronic drying devices;

(b) Requiring employees wash hands thoroughly with soap before starting work and at any other time when hands have become soiled or contaminated; and

(c) Responding reasonably and promptly to reports or concerns of any employee who has been diagnosed with, or has displayed, or experienced symptoms of, a contagious illness or a communicable disease.

(12) If a production licensee has common areas, including but not limited to, a designated area for the consumption of food and beverages for employees, toilet and lavatory facilities, office or meeting space, or a lobby, then it shall conform to the following requirements:

(a) The common areas shall be separated from all areas with regulated cannabis by tight, floor-to-ceiling-high walls to prevent the spread of hair, skin, dirt, dust, and debris and to reduce the spread of moisture, mold, bacteria, and other contaminants;

(b) The door separating the common areas from areas with regulated cannabis shall have secure electronic controls to restrict access; and

(c) Toilet and lavatory facilities shall be equipped with toilet tissue, soap dispenser with soap or other hand cleaning material, sanitary towels, or other device such as a wall-mounted electric hand-dryer, and at least one (1) waste receptacle.

Cite as Ga. Comp. R. & Regs. R. 351-4-.02

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-211**,** 16-12-212**,** 16-12-217**,** 16-12-219**,** 16-12-223**.**

HISTORY: Original Rule entitled "General Production License Rules" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-4-.03 Security

(1) A production licensee is responsible for the security of all regulated cannabis on the premises, including providing adequate safeguards against theft or diversion of regulated cannabis.

(2) A production licensee shall have a comprehensive security system to prevent and detect diversion, theft, or loss of regulated cannabis utilizing commercial grade equipment, which shall, at a minimum, include:

(a) An alarm system which provides:

1. A perimeter alarm;

2. A duress alarm;

3. A panic alarm;

4. A holdup alarm; and

5. Sensors at all possible points of entry into the facility to include all doors, windows, roof hatches, and skylights.

(b) A surveillance system that includes:

1. Motion detectors;

2. Video cameras in all areas that contain regulated cannabis and at all points of entry and exit, which shall be appropriate for the normal lighting conditions of the area under surveillance.

(i) A production licensee shall direct video cameras at:

(I) All safes and vaults;

(II) All areas where regulated cannabis is being propagated, cultivated, harvested, manufactured, stored, or handled;

(III) Regulated cannabis waste processing and storage areas;

(IV) All restricted access areas;

(V) The entrance to the video surveillance room;

(VI) Shipping and receiving area;

(VII) All parking lots; and

(VIII) Entry and exit points to ensure that cameras are angled to capture a clear and certain identification of all persons entering or exiting the facility and at all perimeter controlled access points.

(ii) Video cameras shall operate twenty-four (24) hours a day, seven (7) days a week, recording interior and exterior, which the production licensee shall make available for viewing upon request by the Commission or its employees and shall retain all recordings for at least forty-five (45) days.

(I) Editing or altering the recordings at any point is strictly prohibited.

(II) The physical media or storage device on which surveillance recordings are stored shall be secured in a manner to protect the recording from decay, tampering, or theft.

(III) Any failed component of the video surveillance recording system shall be repaired within twenty-four (24) hours unless notice is provided to the Commission and its employees. The GMCC Executive Director may issue an extension to allow additional time for repair(s).

(iii) All video cameras shall:

(I) Have the ability to produce a clear, color, still photo either live or from a recording;

(II) Have a minimum digital resolution of 2560 x 1440 pixels or pixel equivalent for analog;

(III) Record continuously twenty-four (24) hours per day, at a minimum of thirty (30) frames per second;

(IV) Utilize a failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the production licensee within five (5) minutes of the failure, either by telephone, electronic mail address, or text message;

(V) Have a date and time stamp embedded on all recordings. The date and time shall be synchronized and set correctly and shall not significantly obscure the picture; and

(VI) Remain operational during a power outage.

3. Surveillance recording and monitoring equipment shall be housed in a designated, locked, and secured room or other enclosure with restricted access.

(c) Sufficiently lit outside perimeter to facilitate surveillance by employees, security, or law enforcement.

1. External lighting shall be equipped to automatically activate and remain operational in the event of a power outage.

2. External lighting shall be equipped with protective devices to prevent breakage.

(d) The use of non-residential door locks and secure electronic access by each person at all restricted access points and all entry and exit points.

(3) A production licensee shall utilize perimeter fencing in order to establish a boundary and provide security of the premises. The fencing shall, at a minimum, meet the following requirements:

(a) Have a height of at least seven (7) feet;

(b) Utilize wood or metal posts securely anchored in the ground;

(c) The bottom of the fence shall be no more than three (3) inches from the ground;

(d) There may be a maximum of three (3) inches between any location at which fencing abuts, or is adjacent to, a permanent structure;

(e) Only utilize gated, locking, and controlled entry and exit points;

(f) Incorporate secure access measures as a part of the production facility's security system;

(g) All gates through which vehicles and/or personnel enter or exit shall be monitored at all times by cameras that meet the requirements as set forth in this rule; and

(h) Fencing systems shall be regularly inspected for integrity, functionality, and signs of damage, and repaired within twenty-four (24) hours.

(4) Fences shall be constructed of high quality, durable materials. Acceptable materials include:

(a) Chain-link;

(b) Wood;

(c) Brick;

(d) Masonry block;

(e) Stone;

(f) Tubular steel;

(g) Wrought iron;

(h) Vinyl, composite, or recycled materials;

(i) Other manufactured material or combination of materials commonly used for fencing; and

(j) Other materials of similar quality and durability, but not listed herein, may be used upon approval by the Commission and as set forth in these Rules.

(5) A production licensee shall utilize security personnel who are licensed under the Georgia Private Detective and Security Agencies Act, O.C.G.A. Sections 43-38-1 through 43-38-16, as amended, for the licensee's premises.

(6) A production licensee shall establish an adequate facility maintenance system to ensure both the interior and exterior of the licensee's building structures are maintained to ensure security, safety, and sanitation.

(7) A production licensee shall ensure the surrounding premises are adequately maintained and manicured in order to prevent the introduction and spread of pests and contaminants into the facility and to deter possible criminal activity.

(8) A production licensee shall keep all security system components and equipment in good-working order and shall test such system quarterly.

(a) A production licensee shall keep a log of all security systems tests completed, which shall include:

1. Date(s) the security systems tests were completed;

2. Name(s) of the individual(s) who completed the testing;

3. Details regarding tests completed; and

4. Any issues found during the testing.

(b) The security system testing log shall be maintained on the premises for a period of at least three (3) years.

(c) The security system testing log shall be provided upon request to the Commission or its employees.

(9) A production licensee shall notify the Commission and its employees, within twenty-four (24) hours, of any security system failure.

(a) The production licensee shall keep a log of any security system failure.

(b) The security system failure log shall be maintained on the premises for a period of at least three (3) years.

(c) The security system failure log shall be provided upon request to the Commission or its employees.

(10) While on the premises, all production licensee employees shall wear a form of identification that clearly identifies them, including their position on the premises. An employee identification shall contain:

(a) The name of the employee;

(b) Job title;

(c) The date of issuance;

(d) The expiration date, which shall not exceed the quinquennial expiration date of the production license;

(e) The name of the production licensee;

(f) The license number of the production license;

(g) An alphanumeric identification number that is unique to the employee;

(h) A photographic image of the employee; and

(i) Security measures to prevent unauthorized duplication of the identification.

(11) Upon termination of an employee, a production licensee shall:

(a) Obtain and destroy the terminated employee's identification within twenty-four (24) hours of termination of employment;

(b) Immediately disable the employee's electronic access; and

(c) Immediately disable the employee's access to the Commission-approved tracking system and all other security access systems.

(12) A production licensee employee shall escort and monitor visitors at all times.

(a) A visitor shall visibly display the visitor identification badge at all times the visitor is on the premises.

(b) A visitor shall return the visitor identification badge to a production licensee employee upon exiting the premises.

(c) A production licensee shall maintain a current and accurate inventory of all visitor identification badges.

(d) Any loss of a visitor identification badge shall be documented separately and maintained with the visitor log.

(e) A production licensee shall log all visitors, contractors, and local, state, and federal government officials, and shall maintain a log that includes the date, time in and out, and purpose of the visit. The log shall:

1. Retain a photocopy of the government-issued photo identification for each individual in a secure location with controlled access;

2. Include the name and identification number of the employee escorting the individual;

3. Be maintained for at least three (3) years; and

4. Be made available to the Commission or its employees upon request.

(f) A visitor shall not handle any regulated cannabis.

(13) A production licensee shall ensure that only authorized individuals access the restricted access areas of the premises.

(a) Prior to entering a restricted access area, all authorized individuals shall obtain and wear an identification badge from management employees of the licensee which shall remain visible while in the restricted access area.

(b) A production licensee shall maintain a record of all authorized individuals, who are not employees of the licensee, who enter the restricted access areas. The record shall include:

1. The name of the individual;

2. The individual's employer;

3. The reason the individual entered the restricted access area; and

4. The date and times the individual entered and exited the restricted access area.

5. The restricted access areas log shall be maintained for at least three (3) years.

6. These records shall be made available to the Commission or its employees upon request.

(c) A production licensee shall not prohibit the Commission or its employees, or local, state, or federal law enforcement from entering a restricted access area upon presentation of official credentials identifying them as such.

(d) All restricted access areas shall have a sign posted on or near the door indicating that access to the area is restricted to authorized individuals or employees only.

(14) A production licensee shall keep a surveillance equipment maintenance activity log on the premises to record all service activity and equipment updates.

(a) The log shall include, at a minimum, the following:

1. The date of the service and maintenance activity;

2. A summary of the service and maintenance activity performed; and

3. The name, signature, and title of the individual(s) who performed the service and maintenance activity.

(b) The surveillance equipment maintenance activity log shall be maintained for a period of at least three (3) years.

(c) The surveillance equipment maintenance activity log shall be provided upon request by the Commission or its employees.

(15) A production licensee shall maintain documentation in an auditable form for a period of at least three (3) years:

(a) Any alarm activation or other event which requires a response by public safety employees; and

(b) Any unauthorized breach of security.

(16) A production licensee shall notify the Commission and its employees as well as local law enforcement within twenty-four (24) hours any time there is a suspected loss of regulated cannabis and shall cooperate fully with any investigation into any of the following:

(a) Diversion, theft, loss, or any other criminal activity by an agent or employee of the licensee pertaining to the operations of the licensee;

(b) Suspected diversion, theft, loss, or any other criminal activity by an individual not employed by the licensee; or

(c) Loss or unauthorized alteration of records related to regulated cannabis.

(17) A production licensee shall establish, maintain, and follow standard operating procedures, for the security of all regulated cannabis on the premises and during all transport, including providing adequate safeguards against theft or diversion of regulated cannabis.

Cite as Ga. Comp. R. & Regs. R. 351-4-.03

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-211**,** 16-12-212**,** 16-12-217**.**

HISTORY: Original Rule entitled "Security" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-4-.04 Propagation and Cultivation Operations

(1) Propagation space shall be used for growing immature and non-flowering plants only.

(a) Mother plants in this space shall not be utilized for harvest but for propagation only.

(b) Immature or nonflowering plants in this space shall not be calculated in cultivation space.

(c) Plant material located in the propagation space intended for harvest and production shall be entered in the Commission-approved tracking system.

(2) All cultivation space shall be contained within the canopy as set forth in Code Sections 16-12-211(a)(1) and 16-12-212(a)(1).

(a) Square footage of canopy shall be measured using clearly identifiable boundaries of all space(s) that will contain mature flowering plants at any point in time, including all space(s) within the boundaries;

(b) The canopy may be noncontiguous, including vertical space, but each unique space included in the total canopy calculation shall be separated by an identifiable boundary that includes, but is not limited to, tables, benches, shelves, or interior walls;

(c) If mature flowering plants are being cultivated using a shelving system, the surface area of each level shall be included in the total calculation of the canopy;

(d) Canopy is measured starting from the outermost point of a plant on the perimeter of a dedicated growing space and continuing around the outside of all plants located within the dedicated growing space; and

(e) This space shall be separate from the manufacturing space.

(3) A production licensee shall submit to the Commission and its employees a list of any new plant strains and cultivars which will be propagated and/or cultivated at the premises at least ten (10) days prior to entry into the Commission-approved tracking system. The list shall be maintained at the premises during the term of the license contract and shall be provided upon request to the Commission or its employees.

(4) All pesticides applied to plants shall be:

(a) Certified organic as set forth in Code Sections 16-12-211(b)(6) and 16-12-212(b)(6);

(b) Documented in a pesticide application log, which shall be maintained for a minimum of twelve (12) months, with the following information:

1. Date;

2. Time;

3. Location, bench, or growing chamber;

4. Batch number;

5. Chemical name and active ingredient(s); and

6. Name and employee identification number of pesticide applicator(s).

(c) Stored separately from regulated cannabis, in a designated storage area, which shall have a door separating the secured area with locked access to provide authorized access only; and

(d) Used in a manner consistent with the manufacturer's label.

(5) All pesticides and other chemicals present on the premises not directly related to cultivation or propagation shall be securely stored in a designated area, separate from all regulated cannabis and all pesticides used for production.

(6) A production licensee shall establish, maintain, and follow standard operating procedures for cultivation and propagation operations, which shall include:

(a) Adherence to all recommended personal protective equipment guidelines utilized on the premises.

(b) Sanitation procedures for:

1. The handling of infested or infected plant material prior to disposal;

2. Growing space(s) between harvests; and

3. Tools involved in the growth of plant material in all dedicated and/or separate cultivation or propagation spaces.

(c) Storage procedures for:

1. Growing media;

2. Growing containers;

3. Growing media inputs; and

4. Harvested regulated cannabis prior to being manufactured into products, which shall be:

(i) Separated according to batch and appropriately labeled;

(ii) Stored in a secure enclosed container;

(iii) Located in designated, secure areas of the facility with secure electronic access required; and

(iv) Maintained with adequate ventilation, climate, and humidity control.

(d) A water management plan that includes:

1. Disposal of wastewater generated during the cultivation of regulated cannabis in a manner that complies with applicable local, state, and federal laws and regulations;

2. Water storage;

3. Water recycling and re-treatment;

4. Stormwater collection and greywater reclamation; and

5. Runoff and discharge.

(e) An odor and air pollution reduction plan that may include the use and regular maintenance of:

1. Air filtration systems, both internal and exhaust, such as a high efficiency particulate air or carbon;

2. Air scrubbers;

3. Air purification systems;

4. Ozone generators;

5. Internal air quality practices such as plastic door curtains or negative pressure;

6. Odor neutralizers; and

7. High intensity ultraviolet light.

(f) A sensor system which detects when any gas, utilized in or emitted as a result of the production process, reaches an unsafe level and can signal an alert, if applicable.

(g) The preventative measures designed to reduce the risk of transmission of:

1. Infectious diseases;

2. Quarantined pests;

3. Invasive alien species;

4. Harmful biological agents; and

5. Living modified organisms.

(h) A plan for cultivation and propagation spaces to be routinely inspected by employees for pests and documented in a scouting log with the following information:

1. Date;

2. Location, bench, or growing chamber;

3. Findings; and

4. Name and employee identification number of the scout(s).

(7) The cultivation and propagation standard operating procedures shall be:

(a) Maintained on the premises;

(b) Provided to every owner and employee who performs a task, or set of tasks, that are referenced in the standard operating procedures and documentation of training;

(c) Provided to the Commission or its employees upon request; and

(d) Made available during an inspection by the Commission or its employees.

Cite as Ga. Comp. R. & Regs. R. 351-4-.04

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-211**,** 16-12-212**,** 16-12-213**.**

HISTORY: Original Rule entitled "Propagation and Cultivation Operations" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-4-.05 Production Operations

(1) A production licensee shall ensure all phases of production take place in designated, restricted access areas only.

(2) A production licensee shall document the formulation and size for each batch produced.

(3) All ingredients, other than those naturally occurring in or otherwise derived from cannabis, shall be approved by the U.S. Food and Drug Administration.

(4) Each batch shall meet the following requirements:

(a) Plant tags and plant strains shall be easily identifiable and legible.

(b) Each immature plant batch shall consist of no more than one hundred (100) immature plants.

(c) After a tagged plant is harvested, it is part of a harvest batch.

(d) A harvest batch shall be easily distinguishable from other harvest batches until the batch is manufactured into products.

(e) Once the harvest batch is manufactured into products, it is part of a manufactured batch.

(5) A production licensee shall submit a list of all products and their formulations, which will be manufactured on the premises, to the Commission and its employees within thirty (30) days of licensure. The list shall be maintained on the premises during the term of the license contract and provided to the Commission or its employees upon request.

(6) A production licensee shall ensure that all regulated cannabis is stored in a designated, locked, and secured room or enclosure with restricted access.

(7) A production licensee shall ensure that all recalled products for remediation are stored in a designated, locked, and secured room or enclosure with restricted access and are segregated from other products.

(8) A production licensee shall ensure that regulated cannabis waste is:

(a) Stored in a securely locked and enclosed container that is securely fastened to a permanent structure so that the receptacles cannot be moved;

(b) Located in a restricted access area designated for regulated cannabis waste; and

(c) Disposed, documented, and managed in accordance with all local, state, and federal regulations.

(9) Regulated cannabis waste shall be disposed of by:

(a) Rendering all regulated cannabis waste unusable and unrecognizable or irretrievable prior to the waste leaving the premises;

(b) Transferring the regulated cannabis waste securely to a processor for recycling, reuse, or composting; or

(c) A Commission approved plan for onsite composting, burial or other means of disposing of regulated cannabis waste.

(10) A production licensee shall establish, maintain, and follow standard operating procedures for production operations, which shall include processes for the following:

(a) Monitoring, recording, and regulating:

1. Temperature;

2. Humidity;

3. Ventilation; and

4. Lighting.

(b) Storage and handling requirements of all fuel, chemicals, pesticides, solvents, and any other hazardous materials utilized on the premises.

(c) Extraction including, but not limited to, one (1) or more of the following extraction methods:

1. Using hydrocarbons N-butane, isobutane, propane, heptane, or other solvents or gasses exhibiting low to minimal potential human health related toxicity approved by the Commission. These solvents shall be of at least ninety-nine percent (99%) purity and a production licensee shall:

(i) Use the solvents in a professional grade, closed-loop extraction system designed to recover the solvents;

(ii) Work in a spark-free environment with proper ventilation;

(iii) The hydrocarbon extraction system or room shall have sensors which detect when hydrocarbon levels reach unsafe levels and signal an alert; and

(iv) Follow all applicable state and local fire, safety, and building codes in the processing, storage, and disposal of the solvents.

2. A professional grade, closed-loop CO2 gas extraction system where every cylinder is rated to a minimum of nine hundred (900) pounds per square inch and it follows all applicable state and local fire, safety, and building codes in the processing and the storage of the solvents.

(i) The CO2 shall be of at least ninety-nine percent (99%) purity.

(ii) The CO2 gas extraction system shall have sensors which detect when CO2 levels reach unsafe levels and signal an alert.

3. Ethanol extraction, provided a system to recover the ethanol to be properly disposed of exists.

4. Mechanical extraction using potable water, ice, dry screening or sieving, cryonic extraction, pressure, or temperature provided a detailed description of the processes shall be on the premises.

(d) Verification of compliance of any vessel, cylinder, or tank that is used in the extraction process containing pressures greater than fifteen (15) pounds per square inch with the American Society of Mechanical Engineers (ASME);

(e) Refinement practices and procedures; and

(f) Proper disposal of any:

1. Wastewater;

2. Spent solvents;

3. Any other by-product resulting from the manufacturing of regulated cannabis; and

4. Outdated, damaged, deteriorated, misbranded, or adulterated regulated cannabis.

(11) A production licensee shall establish and implement a product waste management plan that describes, at a minimum:

(a) Procedures for retrieving or receiving product waste from the dispensing licensees; and

(b) Record maintenance and retention procedures for product waste records.

(12) The production standard operating procedures shall be:

(a) Maintained on the premises;

(b) Provided to every owner and employee who performs a task, or set of tasks, that are referenced in the standard operating procedures; and

(c) Made available upon request by the Commission or its employees.

(13) If a production licensee makes a change to their standard operating procedures, then the licensee shall:

(a) Document the change and revise the standard operating procedures accordingly;

(b) Maintain records detailing the change on the premises and submit them to the Commission or its employees upon request; and

(c) Record any change from the standard operating procedure:

1. The change log shall be maintained on the premises for a period of at least three (3) years.

2. The change log shall be made available to the Commission or its employees upon request.

Cite as Ga. Comp. R. & Regs. R. 351-4-.05

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-211**,** 16-12-212**.**

HISTORY: Original Rule entitled "Production Operations" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-4-.06 Quality Control Procedures

(1) A production licensee shall contract directly with an independent laboratory listed on the Commission's list of approved independent laboratories as set forth in Code Section 16-12-217(b).

(2) A production licensee shall not transfer any regulated cannabis to any entity, other than an independent laboratory, until the manufactured batch has passed all required testing.

(3) A production licensee shall ensure that all products undergo quality control testing for purity, safety, and integrity.

(4) A production licensee shall ensure that controlled samples of product in final packaged form are collected according to the following requirements:

(a) A controlled sample shall be collected from the premises:

1. In full view of security cameras;

2. By an employee of a registered independent laboratory; and

3. In the presence of an employee of the production licensee.

(b) The sample collector from the independent laboratory shall have access to the entire manufactured batch.

(c) Collection of sample increments shall be performed independently utilizing a randomized system that provides each potential sample increment the same probability of being selected.

(d) The sample shall be collected in a manner that allows for the collection of a sample and reserve sample from incremental locations in the manufactured batch.

(e) All sample increments from the same manufactured batch shall be combined into one (1) sample container to create one (1) laboratory test sample for one (1) complete quality assurance compliance test and one (1) reserve sample.

(f) After collection, the sample collector from the independent laboratory shall apply a custody seal to each laboratory test sample container or bulk package containing a single facility's laboratory test samples in a manner which prevents tampering between the sampling event, prior to and during transport, and receipt at the independent laboratory.

(5) A production licensee shall ensure proper sample collection and sanitation throughout the sample collection process, including:

(a) Preventing cross-contamination of samples and ensuring samples collected are representative of the manufactured batch, sampling tools shall be cleaned with the appropriate solvent or cleaning agent as follows:

1. Prior to collection;

2. Between batches; and

3. Any time contamination is observed or suspected.

(b) Ensuring the sample collector from the independent laboratory changes gloves if they become contaminated, are suspected to be contaminated, or if they come into direct contact with the sample; and

(c) Ensuring the sample collector from the independent laboratory cleans any shared surface that sample increments come into direct contact with, including but not limited to balance plates, weigh boats, weigh paper, and sampling tools.

(6) A production licensee shall conduct and maintain quality assurance of product in final package form by:

(a) Submitting samples for controlled sample testing:

1. A sample from each manufactured batch of product in final packaged form shall be taken and undergo required testing after it has been packaged in final packaged form.

2. Only one (1) test of each manufactured batch may be conducted to determine compliance. The independent laboratory may retest the sample or analyze a different sample from the same batch by following its standard operating procedure to confirm or refute the original result, upon request by the production licensee or upon request by the Commission at the production licensee's expense, provided that no more than two re-analyses may be performed for the same batch.

3. Sample results shall be valid for one hundred eighty (180) days from the date on the sample certificate of analysis. Product in final packaged form shall be retested upon expiration of the certificate of analysis prior to transport.

4. All samples of product in final packaged form shall pass all testing required in Rule 351-7-.07 prior to being transported to a dispensary.

(b) Retaining a reserve sample which:

1. Consists of the quantity necessary to perform all the required testing as set forth in Rule 351-7-.05(7);

2. Shall be stored for a minimum of one hundred eighty (180) days after analyses, after which time the reserve sample shall be immediately disposed of as set forth in Rule 351-4-.05(11);

3. Is securely stored in a manner that prohibits sample degradation, contamination, and tampering and is consistent with product labeling; and

4. Shall be made available to the Commission or its employees upon request.

(7) A batch which has failed required testing, has been contaminated, or otherwise presents a risk of cross-contamination to other regulated cannabis may be remediated, retested, or shall be disposed of, according to the following requirements:

(a) The batch shall be packaged so that it is physically quarantined and contained in a sealed package that prevents cross-contamination and labeled in a manner that indicates that the batch has failed required testing;

(b) If remediated, then a batch shall undergo two (2) separate and consecutive tests with new samples at each test to be eligible for dispensing;

1. If both samples fail required testing, then the entire batch shall be remediated before being transported to a dispensary; and

2. Each test shall be completed within twenty-four (24) hours of the previous test.

(c) If the failed batch is not remediated, then the batch shall be disposed of as set forth in Rule 351-4-.05(11).

(d) The production licensee shall maintain a log for batch remediation.

1. A batch remediation log shall include the date of remediation, the batch numbers included in the remediation, process of remediation, and the persons who completed the remediation.

2. A batch remediation log shall be maintained for a period of at least three (3) years and be made available to the Commission or its employees upon request.

(8) A production licensee shall ensure all samples submitted for testing are entered into the Commission-approved tracking system and properly reflected in inventory totals.

(9) A production licensee shall establish, maintain, and follow standard operating procedures for quality control and assurance, which shall include:

(a) Documenting preventive measures, monitoring results, and compliance with corrective actions; and

(b) Assessment of the chemical and microbiological composition of all products to determine appropriate storage conditions and expiration dates. The assessment shall include:

1. A profile of the active ingredients;

2. The presence of inactive ingredients and contaminants; and

3. Recommended shelf life.

(10) The quality control standard operating procedures shall be:

(a) Maintained on the premises;

(b) Provided to every owner and employee who performs a task or set of tasks that are referenced in the standard operating procedures and documentation of training; and

(c) Provided to the Commission or its employees upon request.

(11) If a production licensee makes a change to their standard operating procedures, then they shall:

(a) Document the change and revise the standard operating procedures accordingly;

(b) Maintain records detailing the change on the premises and submit them to the Commission or its employees upon request; and

(c) Record any change from the standard operating procedure:

1. The change log shall be maintained on the premises for a period of at least three (3) years.

2. The change log shall be made available to the Commission or its employees upon request.

Cite as Ga. Comp. R. & Regs. R. 351-4-.06

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-211**,** 16-12-212**,** 16-12-213**,** 16-12-217**.**

HISTORY: Original Rule entitled "Quality Control Procedures" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-4-.07 Packaging and Labeling

(1) A production licensee shall submit drafts of the packaging and labeling designs to the Commission for approval prior to using such designs for the product. The Commission hereby delegates the authority and responsibility to review packaging and labeling designs as set forth in Code Section 16-12-203(6), to the GMCC Executive Director to determine whether such designs shall be approved. The licensee shall not use such designs unless they have been approved by the GMCC Executive Director.

(2) Each batch shall be packaged in bulk together, tagged, and labeled as set forth in Rule 351-5-.03.

(3) Prior to transport to a dispensary, product in final packaged form shall be labeled and placed in a tamper-evident, child-resistant package and shall include the unique batch number for the purposes of identifying and tracking product in final packaged form.

(4) A label shall be unobstructed and conspicuous so that it can be read by the consumer.

(5) A label shall be made of weather-resistant and tamper-evident materials.

(6) A package used to contain product shall comply with the following requirements:

(a) The package shall protect the product from contamination and shall not expose the product to any toxic or harmful substance;

(b) The package shall be tamper-evident;

(c) The package shall be opaque;

(d) If the product has more than one (1) dose, then the package shall be resealable;

(e) The package shall not imitate any package used for products typically marketed to minors or attractive to minors such as, but not limited to, the following:

1. Any cartoon, comic drawing, a series of drawings, or animation;

2. Words such as "candy" or "candies" or any alternative spelling of such words; and

3. Depictions of people or animals.

(f) The package and label shall use only Commission-approved trademarks, logos, or imagery;

(g) The package shall be a child-resistant package; and

(h) The package shall not impart any toxic or deleterious substance to the product in final packaged form.

(7) A production licensee shall label each product, in accordance with the American Society for Testing and Materials standards, prior to transfer to a dispensary and shall securely affix to the package a label that states in legible English:

(a) The name, address, and license number of the production licensee;

(b) The brand or strain name of the product;

(c) The unique identifying number of the product, including:

1. The manufactured batch number; and

2. The product's tracking identification.

(d) The registration number of the independent laboratory who completed the required testing;

(e) The expiration date;

(f) The quantity contained therein;

(g) The weight of the product in grams;

(h) A profile and list of all active ingredients, including:

1. Tetrahydrocannabinol (THC);

2. Tetrahydrocannabinol acid (THCA);

3. Cannabidiol (CBD);

4. Cannabidiolic acid (CBDA); and

5. Any other active ingredient that constitutes at least one percent (1%) of the cannabis used in the product.

(i) The American Society for Testing and Materials International Intoxicating Cannabinoid Product Symbol standard (D8441/D8441M) universal symbol, or other symbol requirements for labeling, if designated by the Commission, indicating that products contain intoxicating cannabinoids; and

(j) A statement that the product, in final packaged form, has been tested by an independent laboratory.

(8) A production licensee shall package the product in final packaged form on the premises.

(9) The final package seal shall not be broken by the production licensee except for internal quality control testing or disposal.

Cite as Ga. Comp. R. & Regs. R. 351-4-.07

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-211**,** 16-12-212**,** 16-12-213**.**

HISTORY: Original Rule entitled "Packaging and Labeling" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-4-.08 Inventory

(1) A production licensee shall conduct an initial comprehensive inventory of all cannabis plants, which shall be maintained throughout the entirety of licensure and made available to the Commission or its employees upon request.

(2) A production licensee shall establish and implement an inventory control plan capable of tracking the location and disposition of all regulated cannabis on the premises.

(a) A production licensee shall reconcile the on-hand inventory of regulated cannabis on premises with the records in the Commission-approved tracking system at least once every thirty (30) days.

(b) If a production licensee finds a discrepancy between the on-hand inventory and the Commission-approved tracking system, then the licensee shall conduct an audit.

(c) The production licensee shall notify the Commission and its employees of a discrepancy in an inventory or audit, within twenty-four (24) hours, for any of the following:

1. Any plant designated for cultivation;

2. Any plant designated for propagation;

3. More than three percent (3%) of any harvest batch;

4. More than three percent (3%) of any manufactured batch; or

5. Any remediated or quarantined product.

(3) Upon beginning production operations, a production licensee shall conduct a monthly inventory of regulated cannabis, which shall include, at a minimum:

(a) The date of the inventory;

(b) The amount of regulated cannabis on hand, which shall include the following:

1. The total count of plants, whether in the mother, clone, vegetative, or flowering phase of growth and organized by room in which the plants are being grown;

2. The total amount of plant material and the identifier of every unique plant that has been harvested, but are not yet associated with a harvest batch;

3. The batch number, weight, and strain name associated with each batch at the production licensee that is ready for transfer to a dispensary or has been quarantined for testing;

4. An inventory of any and all warehoused or stored finished product, concentrate, or recalled product in final packaged form for remediation; and

5. The total amount of plant waste.

(c) The name, signature, and title of the individuals who conducted the inventory.

(d) The monthly inventory shall be maintained for a period of at least three (3) years and made available to the Commission or its employees upon request.

Cite as Ga. Comp. R. & Regs. R. 351-4-.08

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-211**,** 16-12-212**,** 16-12-213**.**

HISTORY: Original Rule entitled "Inventory" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-4-.09 Transportation

(1) A production licensee shall ensure security and oversight throughout any transfer of product, and compliance with Commission rules and all applicable local, state, and federal transportation and vehicle safety laws.

(a) Transfer of product from or to the production license premises shall be:

1. Transported only by an authorized employee of a production licensee or by an employee of an independent laboratory;

2. Entered into the Commission-approved tracking system and properly reflected in inventory totals;

3. Contained in a sealed package that prevents cross-contamination and labeled as such.

(b) Samples transported to an independent laboratory for testing shall be sealed and labeled as such.

(c) Production licensees are prohibited from transporting product outside the state of Georgia.

(d) Vehicles and trailers transporting product are subject to inspection by the Commission or its employees at any time.

(e) A production licensee shall notify the Commission and its employees immediately when:

1. A vehicle transporting products is involved in any accident or other situation involving product loss;

2. There is a stop at a location that exceeds one (1) hour in duration and is not already listed in the shipping manifest; or

3. A mechanical issue involving the transport vehicle necessitates the transfer of product to an alternate vehicle to complete the transport. The production licensee shall enter the information into the Commission-approved tracking system immediately to reflect the change.

(f) Production licensee employee's personal vehicles shall not be utilized to transport product under any circumstances.

(g) Production licensees are prohibited from utilizing third parties for the transport of product, except for the transport of product samples by a dispensing licensee or an independent laboratory.

(2) A production licensee shall provide the Commission and its employees with current information about such licensee's drivers who transport product.

(a) Each employee authorized by the production licensee to transport product shall:

1. Possess a valid, state-issued driver's license; and

2. Be at least twenty-one (21) years of age.

(b) The licensee shall maintain a current list, updated at least monthly, of such licensee's drivers, including the following information of each employee:

1. First, middle, and last name;

2. Date of birth;

3. Photograph; and

4. Contact information including telephone number.

(3) Any vehicle used for the transportation of product by a production licensee shall comply with the following:

(a) A production licensee shall register each vehicle or vehicle-trailer combination used for the transportation of product by submitting the following to the Commission:

1. A copy of the vehicle registration or lease which shall include the VIN assigned by the vehicle manufacturer;

2. A copy of the vehicle's annual safety inspection;

3. A copy of the vehicle's unique vehicle number assigned by the production licensee; and

4. Photos of the vehicle:

(i) Left front corner;

(ii) Right front corner;

(iii) Right rear corner;

(iv) Rear, including the affixed, government-issued license plate;

(v) Left rear corner; and

(vi) Vehicle Identification Number ("VIN") plate.

(b) All vehicles utilized for transporting product shall contain a global positioning system ("GPS") device for identifying the geographic location of the transport vehicle.

1. The device shall be permanently affixed to the transport vehicle.

2. The device shall remain active at all times during transportation of products.

3. At all times, the production licensee shall be able to identify the geographic location of all vehicles and employees transporting product.

4. The production licensee shall provide the GPS information to the Commission or its employees upon request.

5. The use of cellular telephones as a device for GPS tracking does not meet the requirements of this rule.

(c) All vehicles shall be equipped with:

1. Climate control capabilities to ensure the integrity of the product being transported;

2. A vehicle alarm system designed to discourage theft and unauthorized entry or access to the vehicle; and

3. Permanently installed video cameras that shall:

(i) Constantly record during the transport of product;

(ii) Provide constant coverage of the driver and product being transported; and

(iii) Maintain recorded material available for no less than forty-five (45) days and be made available for review by the Commission or its employees upon request.

(d) All transport vehicles shall be insured as set forth in Code Section 40-2-137.

(4) A production licensee shall ensure that the following transportation security requirements are followed:

(a) All transport vehicles shall be staffed with a minimum of two (2) employees. At least one (1) transport team member shall remain with the vehicle at all times that the vehicle contains product;

(b) Employees shall carry their employee identification and valid state-issued driver license at all times when transporting or delivering product;

(c) Employees shall produce their identification to the Commission or its employees or to a law enforcement officer acting in the course of official duties upon request;

(d) Product shall only be transported inside of a registered vehicle or trailer and shall not be visible or identifiable from outside of the vehicle or trailer;

(e) Product shall be locked in a fully enclosed box, container, or cage that is secured to the inside of the vehicle or trailer, shielded from view from the exterior of the vehicle. No portion of the enclosed box, container, or cage shall be comprised of any part of the body of the vehicle or trailer. For the purposes of this section, the inside of the vehicle also includes, but is not limited to, the trunk and cargo areas;

(f) The vehicle transporting the product shall not contain any marks, logos, brands, or other illustrations on the exterior of the vehicle, other than those affixed to the vehicle by the vehicle manufacturer or dealership, or required placards and signage; and

(g) All transport times and routes are randomized and within the borders of the state of Georgia.

(5) All shipments initiated by a production licensee shall comply with the following requirements:

(a) Prior to transporting product off of the premises, the licensee originating the shipment shall prepare a shipping manifest that contains the following information:

1. The name, license number, and premises address of the originating licensee;

2. The name, license number, and premises address of the licensee receiving the product into inventory or storage;

3. The batch number(s) for all product being transferred;

4. The item name, description, count, and weight of product associated with each batch;

5. The estimated date and time of departure from the premises;

6. The estimated date and time of arrival at each premises;

7. The valid driver's license number of each employee transporting product, and the make, model, and license plate number of the vehicle used for transport; and

8. Name and signature of the employees accompanying the transport.

(b) A production licensee shall not alter the information of the receiving licensee after the information has been entered on the shipping manifest.

(c) During transportation, the production licensee transporting the product shall maintain a physical or digital copy of the shipping manifest and make it available upon request to the Commission or its employees.

1. A production licensee may elect to use a paper copy or digital copy of the shipping manifest.

2. Production licensees are required to ensure all information is preserved with valid and verified signatures on any digital copy of a shipping manifest.

3. If product on the shipping manifest is undeliverable to the final destination for any reason, the product that is undeliverable shall be transported back to the originating licensee.

(6) When a shipment is complete, the production licensee shall:

(a) Enter a record verifying the receiving licensee's receipt of the shipment in the Commission-approved tracking system with the details of the shipment;

(b) Ensure that the shipment has been received by the receiving licensee or independent laboratory registrant is as described on the shipping manifest; and

(c) Immediately adjust its inventory records to reflect such receipt.

(7) If any product on the shipping manifest is damaged or otherwise undeliverable, then the production licensee shall:

(a) Off-load damaged product only when it can be properly quarantined in the receiving licensee's or receiving independent laboratory's inventory and storage;

(b) Document the receipt of any damaged product and the quantities received in the Commission-approved tracking system;

(c) Update the shipping manifest accordingly; and

(d) Maintain a log of any damaged and any returned product as set forth in Rule 351-4-.11.

(8) The standard operating procedures for transportation shall be:

(a) Maintained at the licensed premises;

(b) Provided to every owner, agent, and employee who performs a task or set of tasks related to transportation that are referenced in the standard operating procedures; and

(c) Made available during an inspection or upon a request by the Commission or its employees.

(9) If a production licensee makes a change to their standard operating procedures, then the licensee shall:

(a) Document the change and revise the standard operating procedures accordingly;

(b) Maintain records detailing the change on the premises and submit them to the Commission or its employees upon request; and

(c) Record any change from the standard operating procedure:

1. The change log shall be maintained on the premises for a period of at least three (3) years.

2. The change log shall be made available to the Commission or its employees upon request.

Cite as Ga. Comp. R. & Regs. R. 351-4-.09

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-211**,** 16-12-212**,** 16-12-213**,** 16-12-217**.**

HISTORY: Original Rule entitled "Transportation" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-4-.10 Advertising and Marketing

(1) A production licensee shall ensure that information regarding its products shall be accurate, truthful, and appropriately substantiated and as permissible by the Act and these rules.

(2) A production licensee may provide information regarding its products directly to physicians as set forth in Code Section 16-12-215, via:

(a) Electronic communication;

(b) Printed mail pieces; or

(c) In-person communication.

(3) No production licensee shall advertise or market products to patients, caregivers, or the public as set forth in Code Section 16-12-215.

Cite as Ga. Comp. R. & Regs. R. 351-4-.10

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-215**.**

HISTORY: Original Rule entitled "Advertising and Marketing" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-4-.11 Records

(1) A production licensee shall keep records identified by these rules on the premises.

(2) All records shall be provided to the Commission or its employees upon request.

(3) A production licensee shall keep and maintain records in connection with the production license for at least five (5) years from the date the record was created, unless a shorter time is specified in these rules or otherwise specific by law.

(4) Records shall be kept in a manner that allows the records to be made available upon request to the Commission or its employees.

(5) Records shall be legible and accurate.

(6) No person may intentionally misrepresent or falsify records, including the use of software or other methods, to manipulate or alter the accuracy of growing or production data.

(7) Records, whether physical or virtual, shall be stored in a secured area where the records are protected from debris, moisture, contamination, hazardous waste, fire, and theft.

(8) Records shall be kept of all regulated cannabis produced, manufactured, transferred, recalled, and disposed of by the production licensee.

(9) A production licensee shall maintain all inventory, sales, and financial records in accordance with generally accepted accounting principles.

(10) A production licensee shall retain a copy of all shipping manifests for at least three (3) years.

(11) A production licensee shall retain records of all testing, certificate(s) of analysis, and samples of each batch for at least twelve (12) months.

(12) A production licensee shall maintain records identifying the source of each ingredient used in the production and manufacturing of regulated cannabis, including:

(a) The originating source of each ingredient;

(b) The date of receipt of the ingredient;

(c) The contractor's name and address;

(d) The grade and quantity of said ingredient; and

(e) The name of the ingredient and the contractor's control number or other identifying number or symbol, if any, used by the contractor to identify the ingredient.

Cite as Ga. Comp. R. & Regs. R. 351-4-.11

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-213**.**

HISTORY: Original Rule entitled "Records" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-4-.12 Product Recall Procedures

(1) A recall shall be initiated when there is circumstantial or actual evidence of a risk to public health and safety due to the production of a specific product.

(a) A licensee shall initiate a recall based on evidence that the product in final packaged form is contaminated, incorrectly labeled, improperly formulated or dosed, causing adverse patient responses, or otherwise unfit for safe use, consumption, or application. Written notification of a licensee-initiated recall shall be made to the Commission and its employees within twenty-four (24) hours of initiation.

(b) The Commission may order a recall of product in final packaged form, in addition to or apart from a licensee-initiated recall, if it deems such action is necessary to protect patients or to protect public health and safety from any of the following:

1. Defective or potentially defective product;

2. Product that has failed laboratory testing in accordance with these rules;

3. Mislabeled product(s); and

4. Any other compelling information as determined by the Commission that would warrant a recall.

(c) If the Commission determines that an ordered recall has been successfully completed, and the risk to patients or public health and safety is no longer present, then the Commission shall notify the affected licensee and terminate the recall.

(2) The licensee shall begin notifying all affected patients or caregivers and other required parties within twenty-four (24) hours of a licensee-initiated or Commission-ordered recall.

(3) For any recall, the licensee shall generate a report to the Commission and its employees which includes the following:

(a) Any reports by affected patients or caregivers, including:

1. Patient conditions;

2. Date and location of occurrence;

3. Symptoms; and

4. Adverse reactions.

(b) Details of the recalled product, including:

1. Product name(s);

2. Batch number(s);

3. ID label information; and

4. Expiration date(s).

(c) A remediation or destruction plan for recalled products, if any.

1. The remediated batches shall be tested twice by an independent laboratory to confirm that the issue requiring the recall has been identified and resolved.

2. Only after the independent laboratory has issued two (2) passing certificates of analysis can the affected batches continue to be produced and transferred to dispensing licensees to be dispensed to patients or caregivers.

3. Remediated batches shall have the remediation status included in the batch number and updated in the Commission-approved tracking system.

(d) A corrective action plan which details how the licensee plans to prevent similar recalls in the future.

(e) The licensee shall report weekly to the Commission and its employees on the progress of the recall efforts for the duration of the recall, including:

1. Notification to patients and caregivers;

2. Collection and return efforts with dispensing licensees;

3. Total amount of recalled product;

4. The amount of affected product in final packaged form that has been returned; and

5. The amount of affected product in final packaged form outstanding.

(4) A licensee shall perform an internal investigation to determine the cause(s) and issue(s) leading to the recall and provide the findings to the Commission and its employees upon completion.

(5) The licensee shall provide a public notice of recall, including readily accessible information, which may be written, provided by a link to an internet website, or with a scannable barcode or QR code, regarding patient health, safety, treatment, disposal, poison control, or overdose.

(a) The notice of recall shall be posted at the premises and in a prominent location on the licensee's website and/or social media, if applicable.

(b) The notice of recall shall include:

1. Details which identify the affected product to the public:

(i) Product name(s);

(ii) Batch number(s);

(iii) ID label information; and

(iv) Expiration date(s).

2. Contact Information, including:

(i) A designated phone number for recall communication;

(ii) A designated electronic mail address for recall communication; and

(iii) A designated website for descriptions and details relating to the recalled product and process.

(c) The notice of recall shall remain posted for a period of ninety (90) days.

(6) A licensee shall make available to the public a notice of recall completion for a period of thirty (30) days once the Commission has notified the licensee of the recall termination.

Cite as Ga. Comp. R. & Regs. R. 351-4-.12

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-211**,** 16-12-212**,** 16-12-213**.**

HISTORY: Original Rule entitled "Product Recall Procedures" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Department 351. GEORGIA ACCESS TO MEDICAL CANNABIS COMMISSION

Chapter 351-5. SEED-TO-SALE TRACKING

351-5-.01 Tracking System Operations

(1) Class 1 production licensees, Class 2 production licensees, and dispensing licensees shall select a vendor approved by the Commission for their respective seed-to-sale tracking systems capable of utilizing an Application Programming Interface ("API") designed to integrate with the Commission's state tracking system.

(2) Class 1 production licensees, Class 2 production licensees, and dispensing licensees shall provide the Commission and its employees with access to their respective seed-to-sale tracking systems.

(3) Class 1 production licensees, Class 2 production licensees, and dispensing licensees shall be responsible for their respective selected vendor. Violations of the Act and these rules shall result in citations and fines up to and including revocation.

(4) Class 1 production licensees, Class 2 production licensees, and dispensing licensees shall:

(a) Establish a Commission-approved tracking system prior to engaging in any regulated cannabis production, transfer, testing, or dispensing;

(b) Use a Commission-approved tracking system as the primary inventory tracking system of record;

(c) Use the tracking system to ensure regulated cannabis is identified and tracked from the point the regulated cannabis is propagated from seed or cutting to the point the product in final packaged form is dispensed or is otherwise disposed of;

(d) Maintain accurate and comprehensive records regarding regulated cannabis waste that accounts for, reconciles, and evidences all waste activity related to the disposal of regulated cannabis; and

(e) Reconcile all on-premises and in-transit regulated cannabis inventories each day in the tracking system by the close of business.

(5) All inventory tracking activities at the premises shall be tracked through the use of a Commission-approved tracking system and on any forms as may be required by the Commission.

(6) Class 1 production licensees, Class 2 production licensees, and dispensing licensees are responsible for the accuracy and completeness of all data and information entered into a Commission-approved tracking system.

(7) Class 1 production licensees, Class 2 production licensees, and dispensing licensees are accountable for all actions their respective employees take while logged into the tracking system or while otherwise conducting cannabis inventory tracking activities.

Cite as Ga. Comp. R. & Regs. R. 351-5-.01

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-210**,** 16-12-211**,** 16-12-212**,** 16-12-213**.**

HISTORY: Original Rule entitled "Tracking System Operations" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-5-.02 Approved Tracking System Requirements

(1) Any seed-to-sale tracking vendor shall not have a direct or indirect financial interest in any licensee or registrant of the Commission.

(2) A Commission-approved tracking system vendor shall:

(a) Provide the Commission and its employees access to real-time tracking data;

(b) Utilize an Application Programming Interface designed to integrate with the Commission's state tracking system to include:

1. Inventory management and tracking systems to shipping manifests;

2. Test results; and

3. Dispensing point-of-sale data.

(c) Establish, document, and maintain procedures to prevent fraud, abuse, and other unlawful or prohibited activities associated with the production and dispensing of regulated cannabis in this state, and the ability to provide additional tools for the administration and enforcement of the Act and these rules; and

(d) Institute procedures to ensure that the information in the system shall not be disclosed or used for any purpose other than to ensure public health and safety, product quality and efficacy, and compliance with the Act and these rules.

(3) The tracking system shall be capable of:

(a) Tracking all plants, products, packages, amounts dispensed to patients, waste disposals, transfers, conversions, and returns that, if practicable, are linked to unique identification numbers;

(b) Tracking batch information throughout the entire chain of custody;

(c) Tracking all regulated cannabis throughout the entire chain of custody;

(d) Tracking regulated cannabis destruction;

(e) Performing complete batch recall tracking that clearly identifies all of the following details relating to the specific batch subject to the recall:

1. Amount of product in final packaged form dispensed;

2. Amount of product in final packaged form that has been used for the potential therapeutic treatment of program participants;

3. Amount of product in final packaged form inventory that is finished and available for dispensing;

4. Amount of regulated cannabis being processed into another form; and

5. Amount of post-harvest regulated cannabis, such as regulated cannabis that is in the drying, trimming, or curing process.

(f) Reporting and tracking loss, theft, or diversion of regulated cannabis;

(g) Reporting and tracking all inventory discrepancies;

(h) Reporting and tracking adverse patient responses or dose related efficacy issues;

(i) Reporting and tracking all transfers and returns;

(j) Receiving electronically submitted information required to be reported under the Act;

(k) Receiving testing results electronically within twenty-four (24) hours of completion from an independent laboratory via a secured API into the tracking system and directly linking the testing results to each applicable source batch and sample;

(l) Flagging test results that have characteristics indicating that they may have been altered;

(m) Providing information to ensure that the product in final packaged form has been dispensed to a patient or caregiver, and that the product in final packaged form received and passed the required testing;

(n) Providing the Commission and its employees with real-time access to information in the tracking system; and

(o) Providing real-time information to the Commission and its employees regarding key performance indicators, including:

1. Total regulated cannabis in production;

2. Total daily transfers of product in final packaged form;

3. Total product in final packaged form dispensed;

4. Total regulated cannabis destroyed; and

5. Total inventory adjustments.

Cite as Ga. Comp. R. & Regs. R. 351-5-.02

AUTHORITY: O.C.G.A. §§ 16-12-203, 16-12-206, 16-12-210, 16-12-213.

HISTORY: Original Rule entitled "Approved Tracking System Requirements" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-5-.03 Plant and Product Tags

(1) Class 1 and Class 2 production licensees shall only use plant and product tags that comply with the Act and the rules of the Commission.

(2) Class 1 and Class 2 production licensees shall only use plant and product tags assigned by the tracking system to that licensee and shall not transfer unused tags to any other licensee.

(3) Class 1 and Class 2 production licensees shall maintain a sufficient supply of plant and product tags to support tagging in accordance with this chapter.

(4) Plant and product tags shall be indelible and tamper-evident.

(5) Plant and product tags shall not be reused.

(6) All plants, samples, harvest batches, and manufactured batches shall be issued a unique batch number in the inventory tracking system.

(a) Batch numbers cannot be reused.

(b) Each plant, sample, harvest batch, and manufactured batch shall have a tag, with the correct unique batch number listed, placed on or otherwise affixed to it.

(c) The plant tag shall be legible, placed in a position that can be clearly read, and shall be kept free from dirt and debris.

(d) Each batch packaged in bulk together shall be easily identifiable with a bulk package tag attached.

(7) Class 1 and Class 2 production licensees shall not transfer any product in final packaged form that does not have a product tag or bulk package tag attached and entered in the tracking system.

(8) Dispensing licensees shall not dispense any product in final packaged form that does not have a product tag attached and entered in the tracking system.

Cite as Ga. Comp. R. & Regs. R. 351-5-.03

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-210**,** 16-12-211**,** 16-12-212**,** 16-12-213**.**

HISTORY: Original Rule entitled "Plant and Product Tags" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-5-.04 Loss of Access

(1) If a Class 1 production licensee, Class 2 production licensee, or dispensing licensee loses access to the tracking system for any reason, then the respective licensee shall:

(a) Notify the Commission and its employees if the loss of access exceeds twelve (12) hours; and

(b) Prepare and maintain comprehensive tracking records detailing all licensed business that was conducted during the loss of access.

(2) Once access has been restored, the Class 1 production licensee, Class 2 production licensee, or dispensing licensee shall:

(a) Notify the Commission and its employees when access has been restored;

(b) Enter all regulated cannabis production, transfer, testing, or dispensing that occurred during the loss of access into the tracking system, within three (3) days; and

(c) Document the cause for loss of access, and the dates and times of the duration of loss of access.

Cite as Ga. Comp. R. & Regs. R. 351-5-.04

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-210**,** 16-12-213**.**

HISTORY: Original Rule entitled "Loss of Access" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-5-.05 Review and Auditing

(1) The Class 1 production licensee, Class 2 production licensee, or dispensing licensee shall review the inventory recorded in the Commission-approved tracking system at least once every thirty (30) days to ensure its accuracy, including, at a minimum:

(a) Reconciling recorded inventory with physical inventory of regulated cannabis in the tracking system; and

(b) Reviewing the Class 1 production licensee's, Class 2 production licensee's, or dispensing licensee's authorized users to document and remove access for any users who are no longer authorized to enter information into the tracking system.

(2) The Class 1 production licensee, Class 2 production licensee, or dispensing licensee shall document its inventory reviews which shall include:

(a) The name of the person(s) completing the review; and

(b) The results of the inventory reconciliation.

(3) If a Class 1 production licensee, Class 2 production licensee, or dispensing licensee finds a discrepancy in the inventory review between the physical inventory and the inventory data in the tracking system, then the Class 1 production licensee, Class 2 production licensee, or dispensing licensee shall conduct an audit.

(a) The Class 1 production licensee, Class 2 production licensee, or dispensing licensee shall notify the Commission and its employees of the initiation of an audit within twenty-four (24) hours.

(b) Audit findings shall be reported to the Commission and its employees within three (3) days of the completion of the audit.

(c) All review and audit records shall be maintained for at least three (3) years and shall be provided to the Commission or its employees upon request.

Cite as Ga. Comp. R. & Regs. R. 351-5-.05

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-210**,** 16-12-213**.**

HISTORY: Original Rule entitled "Review and Auditing" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Department 351. GEORGIA ACCESS TO MEDICAL CANNABIS COMMISSION

Chapter 351-6. DISPENSING LICENSEES

351-6-.01 Dispensing Preliminary Inspection

(1) A dispensing licensee shall not begin operations until after a successful and passing preliminary inspection is completed by the Commission or its employees.

(2) Scheduling the preliminary inspection shall be the responsibility of the dispensing licensee.

(3) The Commission or its employees will not perform a preliminary inspection for a dispensing licensee until the Commission or its employees have received a satisfactory report of full compliance with, and completion of, all applicable public safety inspections required by local and state jurisdictions, including, but not limited to, fire, building, health, and air quality inspections.

Cite as Ga. Comp. R. & Regs. R. 351-6-.01

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-217**.**

HISTORY: Original Rule entitled "Dispensing Preliminary Inspection" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-6-.02 General Dispensing License Rules

(1) Dispensing of product in final packaged form shall:

(a) Only occur at a dispensary; and

(b) Be dispensed in the approved and original packaging and labeling of the production licensee as set forth in Rule 351-4-.07.

(2) A dispensing licensee shall:

(a) Prominently display the following signage to be viewed by individuals entering the premises:

1. The dispensing license;

2. The laws and these rules; provided, however, that signage approved by the Commission may be displayed in lieu of a complete copy of the laws and rules;

3. Hours of operation, during which product in final packaged form will be dispensed to patients and caregivers;

4. A sign stating "No products can be administered, applied, ingested, or consumed on the premises"; and

5. Any other signage required by the Act and these rules.

(b) Ensure that the dispensary is operating and available to dispense product in final packaged form to patients and caregivers during, and only during, hours of operation as authorized by the locality in which the dispensary is located;

(c) Notify the Commission and its employees of any patient reports of adverse events within twenty-four (24) hours;

(d) Only receive and dispense product in final packaged form that:

1. Have been produced by a production licensee licensed by the Commission;

2. Are approved by the Commission as set forth in the rules of the Commission;

3. Are entered into the Commission-approved tracking system required by Rule Chapter 351-5;

4. Have passed the requirements for quality control, security, purity, and dosage required by Rule 351-4-.06;

5. Are labeled to meet the packaging and labeling requirements of Rule 351-4-.07; and

6. Have been transported to the dispensary as set forth in Rule 351-4-.09.

(e) Notify the Commission and its employees of the closing or change of location of a dispensary no less than thirty (30) days prior to the date of final closure or change of location to schedule a closing inspection.

(3) A dispensing licensee shall not do any of the following:

(a) Produce regulated cannabis;

(b) Accept, store, or dispense any product not in final packaged form;

(c) Dispense any product in final packaged form that has expired or does not have a valid certificate of analysis;

(d) Dispense any product in final packaged form that has been damaged or shows signs of tampering;

(e) Use the Commission's name or logo on any sign at the premises, on the business' website, or in any advertising or social media, except to the extent that the Commission's name or logo is contained on the proof of licensure or is incorporated into the warnings, signage, or other documents required by these rules;

(f) Sublet any portion of the dispensary;

(g) Purchase or store products from any entity that does not have an active production license that is in good standing from the Commission, or any source outside of the state of Georgia;

(h) Provide samples of, or free products to, any person;

(i) Allow products to be administered, applied, ingested, or otherwise consumed inside of, or on the premises of, the dispensary;

(j) Offer any tours of restricted access areas to the general public; or

(k) Display product in final packaged form in windows or in public view.

(4) A dispensing licensee shall be fully operational within one hundred and twenty (120) days of the date its dispensing license is issued.

(5) Failure to remain fully operational during licensure shall constitute a break in supply of product, and shall result in citations and fines up to and including revocation.

(6) Each room of the dispensary shall be clearly labeled on the entry door to identify the purpose of the room.

(7) Dispensing licensees shall continue to provide the Commission and its employees with current contact information and notify the Commission and its employees, in writing, of any changes to the mailing addresses, phone numbers, or electronic mail addresses.

(8) A dispensing licensee shall notify the Commission and its employees within ten (10) days of the initiation and/or conclusion of any new citations, fines, judgments, lawsuits, legal proceedings, charges, or government investigations, whether initiated, pending, or concluded, that involve the licensee and its affiliates in Georgia or in any other state.

(9) A dispensing licensee shall create and maintain employee policies and procedures, including, at a minimum, the following:

(a) Code of ethics;

(b) Whistle-blower policy;

(c) A policy which notifies persons with disabilities of their rights, which includes provisions prohibiting discrimination and providing reasonable accommodations; and

(d) All applicable state and federal Department of Labor procedures and posting of appropriate placards.

(10) Dispensing licensees shall require and ensure its owners, officers, agents, and employees comply with the fingerprinting and criminal background check requirements as set forth in Rule 351-3-.02.

(a) A dispensing licensee shall ensure that the Commission and its employees are notified in writing of a criminal conviction of any owner, agent, or employee, either by mail or electronic mail, within forty-eight (48) hours of the licensee becoming aware of the conviction; and

(b) The written notification to the Commission and its employees shall include the name and position of the person, the date of conviction, the court docket number, the name of the court in which the person was convicted, and the specific offense(s) for which the person was convicted.

(11) A dispensing licensee shall take reasonable measures and precautions to ensure all employees working with direct access to product in final packaged form shall use hygienic practices while on duty for the prevention of contamination, including:

(a) Ensuring handwashing facilities are located within the dispensary and are equipped with effective hand-cleaning and sanitizing preparations and sanitary towel service or electronic drying devices;

(b) Requiring employees wash hands thoroughly with soap before starting work and at any other time when hands have become soiled or contaminated; and

(c) Responding reasonably and promptly to reports or concerns of any employee who has been diagnosed with, or has displayed or experienced symptoms of, a contagious illness or a communicable disease.

(12) If the dispensary has common areas, including but not limited to, toilet and lavatory facilities, office or meeting space, or a lobby, then it shall conform to the following requirements:

(a) The common areas shall be separated from all areas with product in final packaged form by tight, floor-to-ceiling-high walls;

(b) The door separating the common areas from areas with product in final packaged form shall have secure electronic controls to restrict access; and

(c) Toilet and lavatory facilities shall be equipped with toilet tissue, soap dispenser with soap or other hand cleaning material, sanitary towels or other device such as a wall-mounted electric hand-dryer, and at least one (1) waste receptacle.

Cite as Ga. Comp. R. & Regs. R. 351-6-.02

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-210**,** 16-12-219**,** 16-12-223**.**

HISTORY: Original Rule entitled "General Dispensing License Rules" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-6-.03 Security

(1) The dispensing licensee is responsible for the security of all products on the premises, including providing adequate safeguards against theft or diversion of product in final packaged form.

(2) The dispensing licensee shall have a comprehensive security system to prevent and detect diversion, theft, or loss of product in final packaged form utilizing commercial grade equipment, which shall, at a minimum, include:

(a) An alarm system that provides:

1. A perimeter alarm;

2. A duress alarm;

3. A panic alarm;

4. A holdup alarm; and

5. Sensors at all possible points of entry into the dispensary, to include all doors, windows, roof hatches, and skylights.

(b) A surveillance system that includes:

1. Motion detectors;

2. Video cameras in all areas that may contain product in final packaged form and at all points of entry and exit, appropriate for the conditions of the area under surveillance;

(i) The dispensing licensee shall direct video cameras at:

(I) All safes and vaults;

(II) The retail point of dispensing;

(III) All other areas where product in final packaged form is being stored or handled;

(IV) All restricted access areas;

(V) The entrance to the video surveillance room;

(VI) The loading dock or area, if applicable;

(VII) All parking lots or parking areas; and

(VIII) All entry and exit points, which shall be angled so as to allow for the capture of clear and certain identification of all persons entering or exiting the dispensary.

(ii) Video cameras shall operate twenty-four (24) hours a day, seven (7) days a week, recording interior and exterior;

(I) The dispensing licensee shall make all recordings available to the Commission or its employees upon request.

(II) The dispensing licensee shall retain all recordings for a minimum of forty-five (45) days.

(III) Editing or altering the recordings at any point is strictly prohibited and doing so shall result in penalties, up to and including revocation.

(IV) The physical media or storage device on which surveillance recordings are stored shall be secured in a manner to protect the recording from decay, tampering, or theft.

(iii) All video cameras shall:

(I) Have a minimum digital resolution of 2560 x 1440 pixels or pixel equivalent for analog;

(II) Record continuously twenty-four (24) hours per day, or on a motion-sensor system, at a minimum of fifteen (15) frames per second;

(III) Have the ability to produce a still photo that is clear, unobstructed, and in color from either live or from a recording;

(IV) Have an embedded date-and-time stamp on all recordings that shall be synchronized and not obscure the picture; and

(V) Continue to operate during a power outage.

3. Surveillance recording and monitoring equipment shall be housed in a designated, locked, and secured room or other enclosure with restricted access.

(c) Exterior lighting sufficient to deter nuisance activity and facilitate surveillance; and

(d) A failure notification system that provides an audible, text, or visual notification of any failure in the surveillance system. The failure notification system shall provide an alert to the dispensing licensee within five (5) minutes of the failure, either by telephone, electronic mail, or text message.

(3) The dispensing licensee shall notify the Commission and its employees, within twenty-four (24) hours, of any security system failure.

(a) The dispensing licensee shall keep a log of any security system failure.

(b) The security system failure log shall be maintained on the premises for a period of at least three (3) years.

(c) The security system failure log shall be provided to the Commission or its employees upon request.

(4) A dispensing licensee shall keep all security equipment in good-working order and shall test the function of all such equipment at least quarterly.

(a) The dispensing licensee shall keep a log of all security systems tests completed, which shall include:

1. Date security systems test was completed;

2. Name(s) of the individual(s) who completed the testing;

3. Details regarding tests completed; and

4. Any issues found during the testing.

(b) The security system testing log shall be maintained on the premises for a period of at least three (3) years.

(c) The security system testing log shall be provided to the Commission or its employees upon request.

(5) A dispensing licensee shall ensure that product in final packaged form is stored in a restricted access area separated by tight, floor-to-ceiling-high walls.

(6) At any time the dispensary is not open for dispensing, a dispensing licensee shall ensure that:

(a) The dispensary is securely locked with commercial-grade, non-residential door locks;

(b) All product in final packaged form is locked in a secure storage area;

(c) The dispensary is equipped with an active alarm system, which shall be activated when the dispensing licensee employees are not at the dispensary; and

(d) Only employees of the dispensing licensee and other authorized individuals are allowed access into restricted access areas of the dispensary. For the purposes of this section, authorized individuals include individuals employed by the dispensing licensee as well as any outside contractors or other individuals conducting business that requires access to the restricted access areas.

(7) A dispensing licensee shall ensure the use of secure electronic access and non-residential door locks with the ability to remain operational during a power outage at all restricted access entry and exit points.

(8) While inside the dispensary, all dispensing licensee employees shall wear a form of identification that clearly identifies them as such to the public.

(9) Employee identification shall contain:

(a) The name of the employee;

(b) Job title;

(c) The date of issuance;

(d) The expiration date, which shall not exceed the expiration date of the dispensing license;

(e) The name of the dispensing licensee;

(f) The license number of the dispensing license;

(g) An alphanumeric identification number that is unique to the employee;

(h) A photographic image of the employee; and

(i) Security measures to prevent unauthorized duplication of the identification.

(10) Upon termination of an employee, a dispensing licensee shall:

(a) Immediately disable the employee's access to any restricted access areas of the dispensing license facility;

(b) Immediately disable the employee's access to the Commission-approved tracking system and all other security access systems; and

(c) Obtain and destroy the terminated employee's identification within twenty-four (24) hours of termination of employment.

(11) A dispensing licensee shall have at least two (2) employees physically present at the dispensary during all hours that the dispensary is open to patients and caregivers.

(12) A dispensing licensee shall maintain a daily log of employees for at least three (3) years.

(13) Any non-employee, prior to entering a restricted access area, shall obtain a visitor identification badge from management employees of the dispensing licensee.

(a) Visitors shall visibly display the badge while in the restricted access area.

(b) A dispensing licensee employee shall escort and monitor visitors at all times.

(c) A visitor shall return the visitor identification badge to a dispensing licensee's employee upon exiting the dispensary.

1. The dispensary shall maintain a current and accurate inventory of all visitor identification badges.

2. Any loss of a visitor identification badge shall be documented separately and maintained with the visitor log.

(d) The dispensing licensee shall log all visitors in and out, and shall maintain a log that includes the date, time, and purpose of the visit.

1. The log shall retain a photocopy of the government-issued photo identification for each visitor.

2. The log shall include the name and identification number of the employee escorting the visitor.

3. The visitor log shall be maintained for at least three (3) years.

4. The log shall be made available to the Commission or its employees upon request.

(e) Nothing shall prohibit the Commission or its employees, or local, state, or federal law enforcement from entering restricted access areas.

(f) All restricted access areas shall have a sign posted on or near the door indicating that access to the area is restricted to employees only.

(14) A dispensing licensee shall keep a surveillance equipment maintenance activity log at the dispensary to record all service activity including the identity of any individual performing the service, the service date and time, and the reason for service to the surveillance system.

(a) The security equipment maintenance activity log shall be made available to the Commission or its employees upon request.

(b) The security equipment maintenance activity log shall be maintained for at least three (3) years.

(15) A dispensing licensee shall maintain documentation in an auditable form for a period of at least three (3) years for:

(a) Any alarm activation or other event which requires response by public safety employees; and

(b) Any unauthorized breach of security.

(16) A dispensing licensee shall notify the Commission and its employees as well as the appropriate law enforcement authorities within twenty-four (24) hours after discovering any of the following:

(a) Discrepancies identified during inventory reconciliation;

(b) Diversion, theft, loss, or any criminal activity pertaining to the operation of the dispensing licensee;

(c) Diversion, theft, loss, or any criminal activity by any agent or employee of the dispensing licensee pertaining to the operation of the dispensing licensee;

(d) The loss or unauthorized alteration of records related to products, patients, caregivers, or employees or agent of the dispensing licensee; and

(e) Any other breach of security.

Cite as Ga. Comp. R. & Regs. R. 351-6-.03

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**.**

HISTORY: Original Rule entitled "Security" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-6-.04 Inventory

(1) A dispensing licensee shall conduct an initial comprehensive inventory of all products at each dispensary on the date the dispensing licensee first dispenses product in final packaged form.

(2) A dispensing licensee shall maintain an accurate record of its inventory. A dispensing licensee shall provide the Commission and its employees with the record of inventory upon request.

(a) In conducting an inventory reconciliation, a dispensing licensee shall verify that the dispensing licensee's physical inventory is consistent with the dispensing licensee's records in the Commission-approved tracking system.

(b) The result of inventory reconciliation shall be retained in the dispensing licensee's records for twelve (12) months and shall be made available to the Commission or its employees upon request.

(3) All inventory stored at the dispensary shall be secured in a restricted access area, unless in the process of being dispensed to a patient or caregiver.

(4) A dispensing licensee shall track its inventory in the Commission-approved tracking system, including data on the products in the final packaged form it receives, returns, transfers, and dispenses in accordance with the Act and these rules.

(5) Upon commencing business, a dispensing licensee shall conduct a monthly inventory of product in final packed form. The inventory documentation shall include, at a minimum, the following:

(a) Date of the inventory;

(b) A summary of the inventory findings;

(c) The name, signature, and title of the individual(s) who conducted the inventory;

(d) The date of receipt of product in final packaged form;

(e) The name, license number, and address of the production licensee from whom the product in final packaged form was received; and

(f) The kind and quantity of product in final packaged form received.

(6) Monthly inventories shall be maintained for at least three (3) years and shall be provided to the Commission or its employees upon request.

Cite as Ga. Comp. R. & Regs. R. 351-6-.04

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-210**.**

HISTORY: Original Rule entitled "Inventory" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-6-.05 Dispensing License Operations

(1) Upon receipt of transported product in final packaged form from a production or dispensing licensee, the receiving dispensing licensee shall:

(a) Submit to the Commission-approved tracking system a record verifying its receipt of the shipment and the details of the shipment;

(b) Ensure that the product in final packaged form received is as described in the shipping manifest and shall immediately adjust its records to reflect the receipt of inventory;

(c) Separately document the receipt of any damaged product in final packaged form on the shipping manifest and the quantities received in the Commission-approved tracking system; and

(d) Only accept damaged product in final packaged form if the damaged product in final packaged form can be properly quarantined in its inventory and storage.

(2) No individual other than a dispensing licensee agent or employee may handle the inventory until dispensed to a registered patient or their designated caregiver.

(3) All areas where product in final packaged form is stored shall be:

(a) Dry;

(b) Well-lit;

(c) Well-ventilated;

(d) Maintained in a clean and orderly fashion; and

(e) Maintained at temperatures and lighting conditions which will ensure the integrity of product in final packaged form prior to dispensing.

(4) A dispensing licensee agent or employee shall physically view and inspect the patient or caregiver's registry card and proof of identification to confirm accuracy and validity of the information contained on the documents before authorizing the dispensing of product in final packaged form.

(5) Before dispensing product in final packaged form to a patient or caregiver, a dispensing licensee, agent, or employee shall ensure the patient or caregiver has an active and valid Low-THC Oil Patient Registry Card.

(6) A dispensing licensee shall establish, maintain, and follow standard operating procedures that describe quality assurance policies and procedures to detect, identify, and prevent dispensing errors.

(a) A dispensing licensee shall provide to the Commission or its employees, upon request, a written copy of the quality assurance procedures, shall distribute it to all dispensing licensee employees, and shall make it readily available at the dispensary.

(b) A dispensing licensee shall create a record of every quality assurance review. This record shall contain, but is not limited to, the following:

1. The date or dates of the quality assurance review;

2. The name(s) of the agent and/or employees performing the quality assurance review;

3. The pertinent data and other information relating to the dispensing error reviewed;

4. Documentation of contact with the patient, caregiver where applicable, and the recommending physician;

5. The findings and determinations generated by the quality assurance review; and

6. Recommended changes to the dispensing licensee's policies, standard operating procedures, systems, or processes.

(7) A dispensing licensee shall establish, maintain, and follow standard operating procedures for the handling of product in final packaged form that cannot be dispensed, which shall address, at a minimum, the following:

(a) Identification and storage of any product in final packaged form that:

1. Are outdated, damaged, deteriorated, misbranded, or adulterated;

2. Are part of a Commission-ordered or licensee-initiated recall; or

3. Have been improperly or accidentally opened.

(b) Security and storage protocols to ensure that, prior to returning such product in final packaged form to the originating production licensee, product in final packaged form will be:

1. Stored in a securely locked, enclosed container;

2. Securely fastened to a permanent structure so that it cannot be removed;

3. Located in a secured area of the facility with secure electronic access required; and

4. Stored, secured, and managed in accordance with all applicable local, state, and federal regulations.

(c) The transfer of an entire stock of product in final packaged form to the originating production licensee within seven (7) days of the dispensing license becoming inactive if revoked, expired, or voluntarily surrendered.

(8) A dispensing licensee shall ensure that adequate training is provided to every owner, agent, and employee who performs a task or set of tasks that are referenced in the standard operating procedures.

(a) Documentation of training for each employee shall be maintained on the premise to include:

1. Employee names(s);

2. Date of training; and

3. Brief description of training completed.

(b) Documentation shall be maintained for a minimum of twelve (12) months and provided to the Commission or its employees upon request.

(9) The standard operating procedures shall be:

(a) Maintained at the dispensary;

(b) Provided to every owner, agent, and employee who performs a task or set of tasks that are referenced in the standard operating procedures; and

(c) Made available during an inspection or upon a request by the Commission or its employees.

(10) If a dispensing licensee makes a change to their standard operating procedures, then they shall:

(a) Document the change and revise the standard operating procedures accordingly;

(b) Maintain records detailing the change on the premises and submit them to the Commission or its employees upon request; and

(c) Record any change from the standard operating procedure:

1. The change log shall be maintained on the premises for a period of at least three (3) years.

2. The change log shall be made available to the Commission or its employees upon request.

Cite as Ga. Comp. R. & Regs. R. 351-6-.05

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-210**.**

HISTORY: Original Rule entitled "Dispensing License Operations" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-6-.06 Labeling and Exit Packaging

(1) Dispensing licensees are prohibited from removing, altering, covering, or otherwise tampering with the originating production licensee's product label affixed to product in final packaged form as set forth in Rule 351-4-.07.

(2) A dispensing licensee shall use weather-resistant and tamper-resistant labels for all product in final packaged form and shall include the following information on such labels:

(a) The date the product in final packaged form is dispensed to the patient;

(b) Patient identification information, including:

1. Name, address, and license number of the dispensing licensee;

2. The unique patient registry serial number of the patient, assigned by the Georgia Department of Public Health;

3. Patient's first and last name;

4. Patient's date of birth; and

5. Where applicable, the caregiver's first and last name and unique patient registry serial number, assigned by the Georgia Department of Public Health.

(c) Directions for use of the product; and

(d) Any cautionary statements or symbols as may be required by the Commission.

(3) A dispensing licensee shall use approved exit packaging for all product in final packaged form prior to dispensing such product in final packaged form to a patient or caregiver. Prior to use, all exit packaging shall meet the following:

(a) Reviewed and approved by the GMCC Executive Director;

(b) Only use trademarks, licensed logos, or imagery previously approved by the Commission or the GMCC Executive Director; and

(c) Be plain-colored, light-resistant, and opaque.

Cite as Ga. Comp. R. & Regs. R. 351-6-.06

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-210**.**

HISTORY: Original Rule entitled "Labeling and Exit Packaging" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-6-.07 Advertising and Marketing

(1) A dispensing licensee shall ensure that information regarding all product in final packaged form that is dispensed to patients shall be accurate, truthful, and appropriately substantiated as permissible by Commission rules.

(2) No dispensing licensee shall advertise or market product in final packaged form to patients, caregivers, or the public as set forth in Code Section 16-12-215(b).

(3) A dispensing licensee may provide information regarding product in final packaged form directly to physicians as set forth in Code Section 16-12-215, via:

(a) Electronic communication;

(b) Printed mail pieces; or

(c) In-person communication.

Cite as Ga. Comp. R. & Regs. R. 351-6-.07

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-210**,** 16-12-215**.**

HISTORY: Original Rule entitled "Advertising and Marketing" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-6-.08 Records

(1) Dispensing licensees shall keep all documents required by the Commission at the dispensary.

(2) All required records shall be provided upon request to the Commission or its employees.

(3) Records shall be kept for at least five (5) years from the date of creation unless a shorter time is specified.

(4) Records shall be legible and accurate.

(5) Records, whether physical or electronic, shall be stored in a secure or restricted access area where the records are protected from debris, moisture, contamination, hazardous waste, and theft.

(6) A dispensing licensee is prohibited from utilizing software or other methods to manipulate or alter dispensing data or other required records.

(7) Dispensing licensees shall maintain the following records at the dispensary:

(a) Each day's beginning and ending inventory, monthly inventory, and comprehensive annual inventory;

(b) Detailed records of sales to registered patients, including:

1. Registry ID number;

2. Product name;

3. Batch number; and

4. Quantity.

(c) Detailed financial reports of proceeds and expenses;

(d) Detailed receiving, shipping, inventory, and dispensing records;

(e) All financial records in accordance with generally accepted accounting principles;

(f) All maintenance inspections, tests, servicing, modifications, and upgrades performed on the security alarm system, including, at a minimum:

1. Date of the action;

2. Summary of the actions performed; and

3. Name, signature, and title of the individual(s) who performed the actions.

(g) Any alarm activation or other event which requires response by public safety employees;

(h) Any unauthorized breach of security; and

(i) Any refusal of services to patients and caregivers.

Cite as Ga. Comp. R. & Regs. R. 351-6-.08

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**.**

HISTORY: Original Rule entitled "Records" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-6-.09 Recall Procedures

(1) A dispensary shall serve as the point of return for all licensee-initiated or Commission-ordered recalls for product in final packaged form.

(2) A dispensing licensee shall ensure that all recalled product in final packaged form is:

(a) Removed from availability for retail purchase or transfer;

(b) Entered into the Commission-approved tracking system indicating such product in final packaged form has been returned and removed;

(c) Immediately separated and quarantined from all other product in final packaged form that is not part of the recall;

(d) Stored and secured as set forth in Rule 351-6-.03; and

(e) Returned to the originating production licensee for remediation or destruction.

(3) A dispensing licensee shall submit a daily log of all patient reports regarding adverse events from use of product in final packaged form to the originating production licensee.

(4) The dispensing licensee shall make available to the public any notice of licensee-initiated or Commission-ordered recall, which shall:

(a) Provide readily accessible information regarding patient health, safety, treatment, disposal, poison control, or overdose, which may be made available:

1. In writing;

2. On an internet website; or

3. By providing a barcode or QR code linked to the information which may be scanned by an electronic device.

(b) Designate a phone number, electronic mail address, and website for the public regarding recalled product in final packaged form.

(c) Clearly identify the product in final packaged form affected by the recall including:

1. Product name(s);

2. Batch number(s);

3. ID label information; and

4. Expiration date(s).

(d) Be displayed within fifteen (15) feet of the dispensary entrance at all times in an open area of the dispensary, unobstructed, and easily viewable for patients and caregivers to read.

Cite as Ga. Comp. R. & Regs. R. 351-6-.09

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-210**.**

HISTORY: Original Rule entitled "Recall Procedures" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-6-.10 Changes

(1) Changes to a dispensing licensee's name, owner(s), or agent require:

(a) A complete change application;

(b) A secure and verifiable document as set forth in Code Section 50-36-2;

(c) The required fee, as set forth in the fee schedule;

(d) Other documents and information as may be required by this rule;

(e) Other documents upon request by the Commission or its employees; and

(f) Commission approval. The Commission hereby delegates the authority and responsibility to determine whether changes to a dispensing licensee's name, owner, or agent are approved, or denied, to the GMCC Executive Director.

(2) If a dispensing licensee submits a change application to add an owner or remove an owner listed on the dispensing license, then such application shall include the following, to the extent applicable:

(a) To add an owner, provide the following information for the new owner:

1. Name;

2. Title;

3. Role, if different from the owner's current title;

4. Whether the person has served or is currently serving as an owner, officer, or agent for another entity licensed by the Commission;

5. Whether another like entity with which the owner or officer is associated has had a license revoked, disciplined, or the equivalent thereof, in this state or any other jurisdiction;

6. The ownership interest or financial interest in any other entity licensed by the Commission, if any; and

7. A copy of the new owner's secure and verifiable document as set forth in Code Section 50-36-2.

(b) To remove an owner, due to an owner being deceased, or due to an owner being ineligible due to a drug related felony conviction, provide the following about such owner:

1. A copy of the obituary or death certificate of the owner to be removed; or

2. A certified copy of the final disposition from the court in which the drug related felony conviction occurred.

(c) To remove an owner for any other reason, provide the following:

1. A signed and notarized affidavit from the respective owner attesting that they no longer hold any ownership interest in the dispensary; or

2. A signed and notarized affidavit from the applicant or agent, as listed on the application, attesting that an owner no longer holds any ownership interest in the dispensary.

(3) A request to change the location of a dispensing license shall be made by submitting a new dispensing license application as set forth in Rule 351-3-.02. Such application shall include the dispensing license number.

(a) If such application is approved, then the dispensing license number shall remain the same. However, the dispensing licensee shall not begin licensed operations at the new and approved location until after a successful and passing preliminary inspection as set forth in Rule 351-6-.01.

(b) A dispensing licensee receiving approval from the Commission for a change of location shall have a transition period of thirty (30) days from the date of approval unless a written extension for a longer period is issued by the Commission. The Commission hereby delegates the authority and responsibility to determine whether an extension is made and its duration, if any, to the GMCC Executive Director.

(c) In order to transfer inventory of product in final packaged form and begin operations at the new location, the following restrictions apply:

1. No product in final packaged form may be transferred to the new location prior to the beginning date of the approved transition period;

2. All product in final packaged form transferred to the new location shall be documented in the tracking system;

3. The licensee shall notify the Commission and its employees in writing or by electronic transmission once the transfer of inventory is complete; and

4. Any product in final packaged form remaining at the original location past the thirty (30) day transition period shall be destroyed and documented in the tracking system.

(4) If a change application contains information that the applicant claims to be confidential, then the applicant shall submit a redacted and an unredacted version of the application, along with an affidavit explaining or justifying such redactions.

Cite as Ga. Comp. R. & Regs. R. 351-6-.10

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-210**,** 16-12-217**,** 16-12-219**.**

HISTORY: Original Rule entitled "Changes" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Department 351. GEORGIA ACCESS TO MEDICAL CANNABIS COMMISSION

Chapter 351-7. INDEPENDENT LABORATORIES

351-7-.01 Independent Laboratory Registration and Renewal

(1) An independent laboratory shall be approved by the Commission prior to testing product in final packaged form from production licensees. The Commission hereby delegates the authority and responsibility to approve or deny registration forms submitted by independent laboratories to the GMCC Executive Director.

(2) To request approval by the Commission, the requesting independent laboratory shall submit the following to the Commission:

(a) A complete independent laboratory registration form as required by the Commission;

(b) The required non-refundable registration fee as listed on the fee schedule;

(c) The legal name of the independent laboratory as reflected in the articles of incorporation or organizational documents filed with the Georgia Secretary of State, including:

1. The type of corporation or entity of the independent laboratory;

2. A copy of the independent laboratory's articles of incorporation, articles of organization, or partnership document; and

3. The trade name of the independent laboratory, if applicable and if different from the legal name.

(d) The physical address, county, and global positioning satellite coordinates where the independent laboratory is located;

(e) The U.S. Postal Service mailing address of the independent laboratory;

(f) The name(s) of the independent laboratory owner(s) and the director or agent;

(g) The telephone number(s) of the independent laboratory director or agent;

(h) The electronic mail address of the independent laboratory director or agent;

(i) A copy of the secure and verifiable document as set forth in Code Section 50-36-2 for the independent laboratory owner;

(j) Attestation that, upon registration with the Commission, the independent laboratory will maintain compliance with all local ordinances, rules, or regulations adopted by the locality where the independent laboratory is located, which are in effect at the time of submitting the registration form, including copies of any required local registration, license, or permit of the locality where the independent laboratory is located;

(k) Documentation related to a certificate of accreditation for International Organization for Standardization ("ISO")/International Electrotechnical Commission ("IEC") 17025:2017 or higher:

1. A copy of such certificate for each required testing field as set forth in Rule 351-7-.08; or

2. Records demonstrating that such certificate for each required testing field as set forth in Rule 351-7-.08 has been applied for, including all of the following:

(i) A copy of the application to the accrediting body for ISO/IEC 17025:2017 (or higher) accreditation;

(ii) Documentation of the payment receipt(s) for accreditation with the accrediting body;

(iii) Documentation acknowledging receipt of the application and payment(s) by the accrediting body;

(iv) Tentative schedule of any remaining steps in obtaining such certificate, including supporting documentation; and

(v) Documentation from the accrediting body for all accreditation audit(s), including dates and status, that have been scheduled and completed.

(l) A copy of the United States Department of Justice, Drug Enforcement Administration Controlled Substances Act Certificate of the independent laboratory.

(m) A current copy of its standard operating procedures which shall address, at a minimum, the following:

1. Oversight of the independent laboratory, including, but not limited to, documentation of the reporting and management structure of the independent laboratory;

2. Accurate record keeping;

3. Employee safety and security;

4. Safety and security plans, including a disaster plan with procedures to be followed in case of fire or other emergencies;

5. Secure transportation plan and techniques for crime prevention;

6. A job description or employment contract developed for all employees which includes duties, responsibilities, authority, qualification, and supervision;

7. Alcohol and drug-free workplace policies;

8. Storage of product in final packaged form prior to testing which ensure product quality and efficacy are maintained;

9. Testing of product in final packaged form, including:

(i) Each batch of product in final packaged form produced by a production licensee; and

(ii) Product in final packaged form from a dispensing licensee, when necessary.

10. A detailed description of how the product in final packaged form will be tested, including:

(i) The process detailing how samples are collected by the independent laboratory;

(ii) The number of samples tested;

(iii) The size of sample tested;

(iv) The tests conducted;

(v) Creation and reporting of the certificate of analysis to the production licensee;

(vi) Reporting results to the Commission; and

(vii) Disposal of samples.

11. An inventory of equipment and the methods used for the testing of product in final packaged form to detect the following for a certificate of analysis as set forth in Rule 351-7-.08:

(i) Potency;

(ii) Cannabinoid profile;

(iii) Heavy metals;

(iv) Pesticides;

(v) Residual solvents;

(vi) Visible foreign material;

(vii) Microbiological contaminants and mycotoxins; and

(viii) Terpenes.

(n) Attestation that the registration form and its required documentation are true and current at the time of submission to the Commission and its employees.

(o) Other information upon request by the Commission or its employees.

(3) The Commission or the GMCC Executive Director may require a satisfactory compliance inspection prior to the approval of a registration.

(4) An independent laboratory shall submit a complete registration form, fee, and required documentation as set forth in this rule, for each location of such laboratory.

(5) If an independent laboratory applied for registration as set forth in Rule 351-7-.01(2)(k)(2), then documentation of ISO accreditation for each required testing field as set forth in Rule 351-7-.08 shall be received by the Commission and the GMCC Executive Director within (180) days of the date of which the registration form is approved.

(6) The Commission may remove or not add an independent laboratory to the Commission's list of approved independent laboratories for noncompliance with the rules of the Commission.

(7) An independent laboratory shall renew its registration annually, during an open renewal period announced by the Commission, by submitting to the Commission:

(a) A complete independent laboratory registration renewal form;

(b) Payment of the required non-refundable annual renewal fee;

(c) Results of any internal or external audits conducted in the preceding twelve months; and

(d) Results of the most recent third-party proficiency testing obtained by the independent laboratory as set forth in Rule 351-7-.02(6).

(8) A registrant who does not submit a complete and timely renewal registration form shall be removed from the Commission's list of approved independent laboratories.

Cite as Ga. Comp. R. & Regs. R. 351-7-.01

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-217**.**

HISTORY: Original Rule entitled "Independent Laboratory Registration and Renewal" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-7-.02 General Rules

(1) A valid registration from the Commission authorizes an independent laboratory to test regulated cannabis from a production licensee.

(2) A current list of approved and registered independent laboratories shall be maintained by the Commission and made available to the public on the Commission's website.

(3) All costs and expenses incurred to test product in final packaged form shall be paid by the production licensee and not by the Commission.

(4) An independent laboratory is prohibited from any other activities regulated by the Commission including production, selling, or dispensing of products.

(5) A person with a financial interest in an independent laboratory is prohibited from holding a financial interest in any other type of license or registration issued by the Commission under the Act.

(6) All independent laboratories on the Commission's current list shall participate in a third-party proficiency-testing program provided by an ISO/IEC 17043:2010 or higher-accredited proficiency test provider, at least semi-annually.

(7) The independent laboratory shall ensure that copies of all ISO/IEC audits and inspection reports are submitted to the Commission and its employees within twenty-four (24) hours of completion.

(8) An independent laboratory shall continue to provide the Commission and its employees with current contact information and notify the Commission and its employees, in writing, of any changes to the mailing addresses, phone numbers, or electronic mail addresses.

(9) An independent laboratory shall not use the Commission's name or logo on any sign on its premises, website, or any advertising or social media, except to the extent that information is contained on the proof of registration or is contained in part of warnings, signage, or other documents required by these rules.

(10) An independent laboratory shall create and maintain employee policies and procedures, including, at a minimum, the following:

(a) Code of ethics;

(b) Whistle-blower policy;

(c) A policy which notifies persons with disabilities of their rights, which includes provisions prohibiting discrimination and providing reasonable accommodations; and

(d) All applicable state and federal Department of Labor regulations for posting required notices in the workplace.

(11) An independent laboratory shall take reasonable measures and precautions to ensure all employees working with direct access to product in final packaged form shall use hygienic practices while on duty for the prevention of contamination, including:

(a) Ensuring handwashing facilities are located within all testing areas, equipped with effective hand-cleaning and sanitizing preparations, and sanitary towel service or electronic drying devices;

(b) Requiring employees wash hands thoroughly with soap before starting work and at any other time when hands have become soiled or contaminated; and

(c) Responding reasonably and promptly to reports or concerns of any employee who has been diagnosed with, or has displayed or experienced symptoms of, a contagious illness or a communicable disease.

(12) The independent laboratory shall notify the Commission and its employees of the following:

(a) The initiation or conclusion of any new judicial decisions, lawsuits, legal proceedings, charges, or government investigation and enforcement actions, whether initiated, pending, or concluded, that involve the registrant within ten (10) days of such initiation or conclusion.

(b) The loss or suspension of its required accreditation, within twenty-four (24) hours of such loss or suspension.

1. If the accreditation is not restored within thirty (30) days of such loss or suspension, then the independent laboratory shall be removed from the Commission's list of approved independent laboratories.

2. An independent laboratory shall be required to submit a new registration form to the Commission if such laboratory has been removed from the Commission's list of approved independent laboratories.

Cite as Ga. Comp. R. & Regs. R. 351-7-.02

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-217**.**

HISTORY: Original Rule entitled "General Rules" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-7-.03 Security

(1) An independent laboratory is responsible for the security of regulated cannabis on its premises, including providing adequate safeguards against theft or diversion of product in final packaged form and records for chain of custody that are required to be kept.

(2) An independent laboratory shall implement appropriate security and safety measures to deter and prevent unauthorized entrance into areas containing product in final packaged form and the theft of such product. Such measures shall include the following:

(a) Access from outside the premises shall be kept to a minimum and be well controlled;

(b) The outside perimeter of the premises shall be well lit;

(c) Entry into any area where product in final packaged form is held shall be limited to authorized employees;

(d) An independent laboratory shall have a security alarm system that will provide suitable protection against theft and diversion;

(e) Video surveillance shall record access areas and anywhere the product in final packaged form is handled; and

(f) An independent laboratory shall ensure that product in final packaged form is stored in a locked area with adequate security.

(3) The independent laboratory shall log all local, state, and federal government officials, contractors, and visitors in and out, and shall maintain a log that includes the date, time, and purpose of the visit.

(a) An independent laboratory shall maintain a copy of the daily log required by this rule for a period of at least three (3) years; and

(b) The daily log shall be made available upon request to the Commission or its employees.

Cite as Ga. Comp. R. & Regs. R. 351-7-.03

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-217**.**

HISTORY: Original Rule entitled "Security" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-7-.04 Independent Laboratory Operations

(1) An independent laboratory shall establish, maintain, and follow standard operating procedures, meeting the minimum standards set forth in these rules, detailing the performance of all methods employed by the facility used to test the analytes it reports, and made available for testing analysts to follow at all times.

(2) The standard operating procedures shall include, at a minimum, procedures for:

(a) Sample collecting;

(b) Sample increments;

(c) Sample receiving;

(d) Sample accessioning;

(e) Sample storage;

(f) Identifying and rejecting unacceptable samples;

(g) Recording and reporting discrepancies;

(h) Security of samples, aliquots, extracts, and records;

(i) Validating a new or revised method prior to testing samples to include:

1. Accuracy;

2. Precision;

3. Analytical sensitivity;

4. Analytical specificity (interferences);

5. Limit of Detection ("LOD");

6. Limit of Quantitation ("LOQ"); and

7. Verification of the reportable range.

(j) Aliquoting samples to avoid contamination and carry-over;

(k) Sample retention to assure stability, as follows:

1. For samples that comprise test batches submitted for testing other than pesticide contaminant testing, sample retention for fourteen (14) days; and

2. For samples that comprise test batches submitted for pesticide contaminant testing, sample retention for ninety (90) days.

(l) Disposal of samples and hazardous waste;

(m) The theory and principles behind each assay;

(n) Preparation and identification of reagents, standards, calibrators, and controls and ensure all standards are traceable to National Institute of Standards of Technology ("NIST");

(o) Special requirements and safety precautions involved in performing assays;

(p) Frequency and number of control and calibration materials;

(q) Recording and reporting assay results;

(r) Protocol and criteria for accepting or rejecting analytical procedure to verify the accuracy of the final report;

(s) Pertinent literature references for each method;

(t) Current step-by-step instructions, with sufficient detail to perform the assay, to include equipment operation and any abbreviated versions used by a testing analyst;

(u) Acceptability criteria for the results of calibration standards and controls as well as between two (2) aliquots or columns;

(v) A documented system for reviewing the results of testing calibrators, controls, standards, and subject tests results, as well as reviewing for clerical errors, analytical errors, and any unusual analytical results; and

(w) Laboratory and sample contamination prevention.

(3) The independent laboratory director or agent shall approve, sign, and date each procedure. If any modifications are made to those procedures, then the independent laboratory director or agent shall approve, sign, and date the revised version prior to use.

(4) The independent laboratory's standard operating procedures shall be kept on the independent laboratory premises, be accessible to all employees during all hours of operation, and be made available upon request to the Commission or its employees.

(5) An independent laboratory shall establish, monitor, and document on an ongoing basis the quality control measures taken by the independent laboratory to ensure the proper functioning of equipment, validity of standard operating procedures, and accuracy of results reported. Such quality control measures shall include the following, at a minimum:

(a) Documentation of instrument preventive maintenance, repair, troubleshooting, and corrective actions taken when performance does not meet established levels of quality;

(b) Review and documentation of the accuracy of automatic and adjustable pipettes and other measuring devices when placed into service and annually thereafter;

(c) Cleaning, maintaining, and calibrating as needed the analytical balances, and in addition, verifying the performance of the balance annually using certified weights to include three (3) or more weights bracketing the ranges of measurement used by the independent laboratory;

(d) Annually verifying and documenting the accuracy of thermometers using a NIST traceable reference thermometer;

(e) Recording temperatures on all equipment when in use where temperature control is specified in the standard operating procedures, such as water baths, heating blocks, incubators, ovens, refrigerators, and freezers;

(f) Properly labeling reagents as to the identity, concentration, date of preparation, storage conditions, lot number tracking, expiration date, and identity of the preparer(s);

(g) Avoiding mixing different lots of reagents in the same analytical run;

(h) Performing and documenting a calibration curve with each analysis using, at minimum, five (5) calibrators throughout the reporting range;

(i) For qualitative analyses, analyzing, at minimum, a negative and a positive control with each batch of samples analyzed;

(j) For quantitative analyses, analyzing, at minimum, a negative and two (2) levels of controls that challenge the linearity of the entire curve;

(k) Using a control material or materials that differ in either source, lot number, or concentration from the calibration material used with each analytical run;

(l) For multi-analyte assays, performing and documenting calibration curves and controls specific to each analyte, or at minimum, one with similar chemical properties as reported in the analytical run;

(m) Analyzing an appropriate matrix blank and control with each analytical run, when available;

(n) Analyzing calibrators and controls in the same manner as unknowns;

(o) Documenting the performance of calibration standards and controls for each analytical run to ensure the acceptability criteria as defined in the standard operating procedure is met;

(p) Documenting all corrective actions taken when unacceptable calibration, control, and standard or instrument performance does not meet acceptability criteria as defined in the standard operating procedure;

(q) Maintaining records of validation data for any new or modified methods to include; accuracy, precision, analytical specificity (interferences), LOD, LOQ, and verification of the linear range; and

(r) Performing validation testing to ensure that current standard operating procedures are followed for the test or tests to be performed.

(6) The independent laboratory shall conduct an internal audit at least once per year or in accordance with the accrediting body's requirements for such laboratory's ISO/IEC 17025:2017 (or higher) accreditation, whichever interval occurs more frequently, and submit the results of the internal audit to the Commission and its employees within three (3) days of completing the internal audit.

(7) An independent laboratory shall ensure adequate training will be provided to every employee who performs a task, or set of tasks, referenced in the standard operating procedures.

(8) An independent laboratory is prohibited from testing product in final packaged form or providing results to a production licensee during the time that its accreditation is lost or suspended.

(a) An independent laboratory shall reestablish accreditation within one hundred eighty (180) days of the effective date of the loss or suspension of accreditation. If an independent laboratory fails to reestablish its accreditation

within one hundred eighty (180) days of the loss or suspension, then the independent laboratory's registration shall become invalid and the respective laboratory shall be removed from the Commission's list of approved independent laboratories for the purpose of testing regulated cannabis.

(b) An independent laboratory shall notify the Commission and its employees of the reestablishment of its accreditation within twenty-four (24) hours of the effective date of reaccreditation.

Cite as Ga. Comp. R. & Regs. R. 351-7-.04

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-217**.**

HISTORY: Original Rule entitled "Independent Laboratory Operations" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-7-.05 Sample Collection Requirements

(1) An independent laboratory shall maintain and practice sampling methods that are ISO/IEC 17025:2017 or higher accredited.

(2) The sample method chosen shall achieve a ninety-five percent (95%) or greater confidence level of the batch for the testing of the following:

(a) Total THC content;

(b) Cannabinoids;

(c) Heavy metals;

(d) Residual pesticides;

(e) Residual solvents;

(f) Visible foreign material;

(g) Microbial impurities and mycotoxins; and

(h) If tested, terpenes.

(3) An independent laboratory shall develop and document which scientifically defensible incremental sampling method is utilized for testing.

(4) The independent laboratory shall:

(a) Maintain a document of the sample method selection at the premises during the term of the registration;

(b) Document any changes to the sample method chosen and submit the changes to the Commission and its employees within twenty-four (24) hours; and

(c) Provide the document of sample method selection to the Commission and its employees.

(5) The sample increments shall be combined into a controlled sample, completing the same procedure with a second set of equivalent sample increments to form the reserve sample.

(6) The amount of controlled sample supplied to the independent laboratory shall be large enough to complete all required testing, to complete a replicate test, and to create a homogenized sample that is representative of the manufactured batch.

(7) The sample collector shall collect samples of product in final packaged form that are representative relative to the size of the batch size. The sample collector may collect a greater number of units if necessary to perform the required testing or to ensure that the samples collected are representative. The controlled sample and reserve sample of product in final packaged form shall consist of the following minimum number of sample unit increments taken:

(a) Eight (8) units for a sample product batch with 5-500 products;

(b) Twelve (12) units for a sample product batch with 501-1,000 products;

(c) Sixteen (16) units for a sample product batch with 1,001-5,000 products; and

(d) Twenty (20) units for a sample product batch with 5,001-10,000 products.

(8) A sample collection form shall be utilized for each batch sample, establishing the chain of custody, and shall contain the following information:

(a) Date and time sample was collected;

(b) Name and license number of the originating production licensee;

(c) Batch number of the batch from which the representative sample was obtained and assigned unique sample identifier;

(d) Total batch size, by weight, or unit count;

(e) Total weight or unit count of the representative sample;

(f) Sampling conditions or problems encountered during the sampling process, if any;

(g) Printed name and signature of the authorized agent of the production licensee;

(h) Printed name and signature of the sample collector from the independent laboratory; and

(i) The date, time, and the names and signatures of persons involved, each time a sample changes custody, is transported, or is destroyed.

(9) Once the independent laboratory removes the sample from the production licensee's premises, the sample collection form may not be altered.

(10) After a sample is collected, but prior to testing, an independent laboratory shall label the batch with the following information:

(a) The independent laboratory's name and registration number;

(b) The date the samples were taken; and

(c) In bold, all capitalized letters: "PRODUCT NOT TESTED."

Cite as Ga. Comp. R. & Regs. R. 351-7-.05

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-217**.**

HISTORY: Original Rule entitled "Sample Collection Requirements" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-7-.06 Transportation of Samples

(1) An independent laboratory registrant shall have an ongoing duty to ensure security and oversight throughout any transfer of product in final packaged form, and to comply with Commission rules, and applicable local, state, and federal transportation, traffic, and vehicle safety laws.

(a) The transfer of product in final packaged form from the production licensee's premises to an independent laboratory shall be completed via secure transportation:

1. By an authorized employee of the independent laboratory or a production licensee; and

2. Sealed and labeled as a sample.

(b) Registrants are prohibited from transporting product in final packaged form outside the state of Georgia.

(c) Vehicles and trailers transporting product in final packaged form are subject to inspection by the Commission or its employees at any time.

(d) A registrant shall notify the Commission and its employees immediately:

1. If a vehicle transporting product in final packaged form is involved in a motor vehicle crash or other incident involving product damage or loss;

2. If there is a stop at a location that is not licensed or registered with the Commission that exceeds one (1) hour in duration and is not already listed in the shipping manifest; or

3. If a mechanical issue involving the transport vehicle necessitates the transfer of product in final packaged form to an alternate vehicle to complete the transport.

(e) Registrant employees' personal vehicles may not be utilized to transport product in final packaged form under any circumstances.

(f) Registrants are prohibited from utilizing third-party transportation.

(2) The registrant shall provide current information about such registrant's drivers who transport product in final packaged form, upon request by the Commission or its employees.

(a) Each employee authorized by the registrant to transport product in final packaged form shall:

1. Possess a valid state-issued driver's license; and

2. Be at least twenty-one (21) years of age.

(b) The registrant shall maintain a list of such registrant's drivers, including the following information of each employee:

1. First, middle, and last name;

2. Date of birth;

3. Valid state-issued driver license number, state, and expiration date;

4. Photograph; and

5. Contact information including telephone number.

(c) The registrant shall notify the Commission and its employees within twenty-four (24) hours of any addition to or removal from the list of the registrant's drivers who transport product in final packaged form.

(d) Registrants shall have a continuing duty to provide the Commission and its employees with current contact information for drivers and shall notify the Commission and its employees in writing of any changes to the contact information they provide the Commission.

(3) Any vehicle used for the transportation of product in final packaged form by a registrant shall comply with the following:

(a) A registrant shall register each vehicle or vehicle-trailer combination used for the transportation of product in final packaged form by submitting the following to Commission and its employees:

1. A copy of the vehicle registration or lease which shall include the VIN assigned by the vehicle manufacturer;

2. A copy of the vehicle's annual safety inspection;

3. A copy of the vehicle's unique vehicle number assigned by the registrant; and

4. Photos of the vehicle:

(i) Left front corner;

(ii) Right front corner;

(iii) Right rear corner;

(iv) Rear, including the affixed, government-issued license plate;

(v) Left rear corner; and

(vi) Vehicle Identification Number ("VIN") plate.

(b) All vehicles utilized for transporting product in final packaged form shall contain a global positioning system ("GPS") device for identifying the geographic location of the transport vehicle.

1. The device shall be permanently affixed to the transport vehicle.

2. The device shall remain active at all times during transportation of product in final packaged form.

3. At all times, the registrant shall be able to identify the geographic location of all transportation vehicles and employees who are transporting product in final packaged form.

4. The registrant shall provide the GPS information upon request by the Commission or its employees.

5. The use of cellular telephones as a device for GPS tracking does not meet the requirements of this rule.

(c) All vehicles shall be equipped with:

1. Climate control capabilities to ensure the integrity of the product in final packaged form being transported;

2. An alarm system; and

3. Permanently installed video cameras which shall:

(i) Constantly record during the transport of product in final packaged form;

(ii) Provide constant coverage of the driver and product being transported;

(iii) Be capable of maintaining video recordings for no less than forty-five (45) days; and

(iv) Be accessible or capable of producing video recordings upon request to the Commission or its employees.

(d) All transport vehicles shall be insured as set forth in Code Section 40-2-137.

(4) Independent laboratories are prohibited from transporting any product in final packaged form without a valid sampling form.

(a) The independent laboratory shall prepare a sampling form prior to transferring product in final packaged form off of the production premises.

(b) During transportation, the independent laboratory shall maintain a physical copy of the sampling form and make it available upon request to the Commission or its employees.

1. An independent laboratory may elect to use a paper copy or digital copy of the sampling form.

2. Independent laboratories are required to ensure all information is preserved with valid and verified signatures on any digital copy of a sampling form.

(5) Upon arrival at the independent laboratory's premises, the independent laboratory shall:

(a) Submit to the Commission-approved tracking system a record verifying receipt of the samples and the details of the samples; and

(b) Ensure that the product in final packaged form received are as described in the sampling form and shall immediately adjust its records to reflect the receipt of the samples.

(6) An independent laboratory shall create security standards for transportation, including ensuring that:

(a) Product in final packaged form shall only be transported inside of a vehicle or trailer that meets the requirements of the rules of the Commission and shall not be visible or identifiable from outside of the vehicle or trailer;

(b) Product in final packaged form shall be locked in a fully enclosed box, container, or cage that is secured to the inside of the vehicle or trailer, and shielded from view from the exterior of the vehicle. No portion of the enclosed box, container, or cage shall be comprised of any part of the body of the vehicle or trailer. For the purposes of this section, the inside of the vehicle also includes, but is not limited to, the trunk and cargo areas;

(c) The vehicle transporting the product in final packaged form shall not contain any marks, logos, brands, or other illustrations on the exterior of the vehicle, other than those affixed to the vehicle by the vehicle manufacturer or dealership, or required placards and signage;

(d) All transport times and routes are randomized and within the borders of the state of Georgia; and

(e) An independent laboratory shall staff all transport vehicles with a minimum of two (2) employees. At least one (1) transport team member shall remain with the vehicle at all times that the vehicle contains product in final packaged form.

1. An employee shall carry the employee's identification at all times when transporting or delivering product in final packaged form.

2. The employee shall produce the identification to the Commission or its employees or to a law enforcement officer acting in the course of official duties.

Cite as Ga. Comp. R. & Regs. R. 351-7-.06

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-217**.**

HISTORY: Original Rule entitled "Transportation of Samples" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-7-.07 Testing Requirements

(1) All products intended for dispensing shall be tested in final packaged form.

(2) The independent laboratory shall test any part of the product in final packaged form that will be consumed or used internally or externally by a patient.

(3) The independent laboratory shall follow the methodologies, ranges, and parameters which are contained in the scope of the accreditation for testing product in final packaged form.

(4) An independent laboratory shall develop, implement, and validate test methods for the analyses of samples. If an Association of Official Analytical Collaboration (AOAC) International Standard Method Performance Requirement (SMPR) exists, then the selected testing method shall meet the SMPR.

(5) The independent laboratory shall analyze the representative sample of product in final packaged form to determine whether foreign material is present.

(6) The independent laboratory shall report the results of each analysis performed by the independent laboratory on the certificate of analysis.

(7) If a sample of product in final packaged form passes the required testing, then an independent laboratory shall certify the batch for manufacturing or dispensing.

(8) If a sample of product in final packaged form failed required testing, then the independent laboratory shall:

(a) Notify the originating production licensee who submitted the controlled sample for testing; and

(b) Report the failure in accordance with the Commission-approved tracking system reporting requirements.

(9) If a sample of product in final packaged form is from a remediated batch, then the independent laboratory shall conduct two (2) separate and consecutive tests of new samples from the remediated batch:

(a) The two (2) separate and consecutive remediated batch tests shall be completed, at a minimum, twenty-four (24) hours apart; and

(b) The results of the two (2) separate and consecutive remediated batch tests shall be passing.

(10) An independent laboratory shall destroy the remains of the samples of product in final packaged form upon completion of the analysis.

Cite as Ga. Comp. R. & Regs. R. 351-7-.07

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-217**.**

HISTORY: Original Rule entitled "Testing Requirements" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-7-.08 Certificate of Analysis

(1) An independent laboratory shall only test and certify product in final packaged form.

(2) An independent laboratory shall issue to the production licensee a certificate of analysis for each batch of product in final packaged form tested for that production licensee.

(3) The certificate of analysis shall, at a minimum, include the results with supporting data for the following:

(a) The chemical profile of the batch for the following compounds:

1. Total tetrahydrocannabinol ("THC") sum percentage by weight of:

(i) Delta-9-tetrahydrocannabinol (D9-THC); and

(ii) Delta-9-tetrahydrocannabinolic acid (D9-THCA)

2. Cannabidiol (CBD);

3. Cannabidiolic Acid (CBDA);

4. Cannabigerol (CBG);

5. Cannabinol (CBN);

6. If an abnormality is found during the required testing listed above, then test for the presence of following isomers and esters:

(i) THC isomers, which have published peer-reviewed proficiency standards and measurements that have been validated for cannabis testing by an independent third party:

(I) Delta-6a(7)-tetrahydrocannabinol (D6a(7)-THC);

(II) Delta-6a(10a)-tetrahydrocannabinol (D6a(10a)-THC);

(III) Delta-7-tetrahydrocannabinol (D7-THC);

(IV) Delta-8-tetrahydrocannabinol (D8-THC);

(V) Delta-9(11) exo-tetrahydrocannabinol (Exo-THC); and

(VI) Delta-10-tetrahydrocannabinol (D10-THC).

(ii) THC esters, which have published peer-reviewed proficiency standards and measurements that have been validated for cannabis testing by an independent third party:

(I) THC-O Acetate (THCOA);

(II) THC-O-phosphate;

(III) THC hemisuccinate; and

(IV) THC morpholinylbutyrate (SP-111).

(b) The presence of the following contaminants, which shall not exceed the following parts per million levels:

1. Heavy metals:

(i) Arsenic: 0.2;

(ii) Cadmium: 0.2;

(iii) Chromium: 0.3;

(iv) Lead: 0.5; and

(v) Mercury: 0.2.

2. Pesticides regulated by the United States Environmental Protection Agency, which shall not exceed 0.01 parts per million level for the following pesticides:

(i) Abamectin;

(ii) Acephate;

(iii) Acequinocyl;

(iv) Acetamiprid;

(v) Aldicarb;

(vi) Azoxystrobin;

(vii) Bifenazate;

(viii) Bifenthrin;

(ix) Chlormequat Chloride;

(x) Chlordane;

(xi) Chlorpyrifos;

(xii) Cyfluthrin;

(xiii) Daminozide;

(xiv) Diazinon;

(xv) Dichlorvos;

(xvi) Dimethoate;

(xvii) Etoxazole;

(xviii) Fenoxycarb;

(xix) Fenhexamid;

(xx) Fluoxastrobin;

(xxi) Fipronil;

(xxii) Imazalil;

(xxiii) Imidacloprid;

(xxiv) Malathion;

(xxv) Myclobutanil;

(xxvi) Paclobutrazol;

(xxvii) Permethrin;

(xxviii) Spirotetramat;

(xxix) Thiacloprid; and

(xxx) Trifloxystrobin.

3. Contaminants in solvents which shall not exceed the following parts per million levels:

(i) Acetones: 800.0;

(ii) Butanes: 800.0;

(iii) Benzene: 1.0;

(iv) Methanol: 800.0;

(v) Ethanol: 1,000.0;

(vi) Heptanes: 500.0;

(vii) Hexane: 10.0;

(viii) Toluene: 1.0; and

(ix) Total Xylenes (m,o,p-xylene): 1.0.

(c) Any visible foreign material, that is not intended to be part of the product being produced, including but not limited to mold, hair, insects, metal, or plastic;

(d) Microbiological impurities, which shall not exceed the following levels:

1. Total Viable Aerobic Bacteria: 10^5 CFU/g (colony-forming unit per gram);

2. Total Yeast and Mold: 10,000 CFU/g (colony-forming unit per gram);

3. Total Coliforms: 10^3 CFU/g (colony-forming unit per gram);

4. Bile-tolerant Gram Negative Bacteria: 10^3 CFU/g (colony-forming unit per gram);

5. Shiga-toxin producing Escherichia coli (STEC) and *Salmonella spp.:* Not detected in 1 gram;

6. Aspergillus fumigatus, Aspergillus flavus, Aspergillus niger, and Aspergillus terreus: Not detected in 1 gram; and

7. Mycotoxins:

(i) Aflatoxin B1: <20 µg (micrograms) of any mycotoxin per kg of material;

(ii) Aflatoxin B2: <20 µg (micrograms) of any mycotoxin per kg of material;

(iii) Aflatoxin G1: <20 µg (micrograms) of any mycotoxin per kg of material;

(iv) Aflatoxin G2: <20 µg (micrograms) of any mycotoxin per kg of material; and

(v) Ochratoxin A: <20 µg (micrograms) of any mycotoxin per kg of material.

(e) If tested, terpenes.

(4) The independent laboratory shall submit the certificate of analysis to the Commission and its employees at the same time the certificate of analysis is submitted to the originating production licensee.

(5) The independent laboratory shall upload the certificate of analysis into a Commission-approved tracking system within twenty-four (24) hours of the completion of tests.

(6) In addition to the requirements of this rule, the Commission may make available, via its website or other public means, additional bulletins outlining any contaminants and their actionable levels.

Cite as Ga. Comp. R. & Regs. R. 351-7-.08

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-217**.**

HISTORY: Original Rule entitled "Certificate of Analysis" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-7-.09 Records

(1) An independent laboratory shall establish a system to create, retain, and maintain all required records.

(2) In addition, the independent laboratory shall maintain the test results for at least twelve (12) months from the date of the completion of the test and make them available upon request to the Commission or its employees.

(3) An independent laboratory shall establish an account with a Commission-approved tracking system to document the complete chain of custody for samples, from receipt through disposal or return to the originating production licensee, before receiving or testing any product in final packaged form.

(4) An independent laboratory shall track and submit into the Commission-approved tracking system any information the Commission determines necessary for tracking product in final packaged form, including, but not limited to, transportation of samples, sample inventory, and certificates of analysis.

Cite as Ga. Comp. R. & Regs. R. 351-7-.09

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-217**.**

HISTORY: Original Rule entitled "Records" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-7-.10 Changes

(1) Changes to a registrant's name, location, or agent require:

(a) A written notice to the Commission of any proposed change at least sixty (60) days prior to the proposed effective date of the change;

(b) A complete registration change form;

(c) A secure and verifiable document as set forth in Code Section 50-36-2;

(d) The required fee, as set forth in the fee schedule, within thirty (30) days of any written notice of change; and

(e) Commission approval. The Commission hereby delegates the authority and responsibility to determine whether changes to a registration are approved, or denied, to the GMCC Executive Director.

(2) A change of location for an independent laboratory shall require a new form.

(a) An independent laboratory cannot begin registered operations at the new location until a preliminary inspection of the proposed independent laboratory has been completed.

(b) An independent laboratory receiving approval from the Commission, as set forth in these rules, for a change of location shall have a transition period of thirty (30) days from the date of approval, unless an extension is granted at the discretion of the GMCC Executive Director, to begin operations at the new independent laboratory.

(c) In order to transfer inventory and begin operations at the new location, the following restrictions apply:

1. No product in final packaged form may be transferred to the new location prior to the beginning date of the approved transition period;

2. Any product in final packaged form remaining at the original location past the thirty (30) day transition period shall be destroyed; and

3. The independent laboratory shall notify the Commission and its employees, in writing or by electronic transmission, once the transfer of inventory is complete.

(3) If a registration change form and supporting documentation contains information that the independent laboratory claims to be confidential, then the independent laboratory shall submit a redacted and an unredacted version of the form, along with an affidavit explaining or justifying such redactions.

Cite as Ga. Comp. R. & Regs. R. 351-7-.10

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-215**,** 16-12-217**.**

HISTORY: Original Rule entitled "Changes" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Department 351. GEORGIA ACCESS TO MEDICAL CANNABIS COMMISSION

Chapter 351-8. ENFORCEMENT

351-8-.01 Authority to Investigate, Inspect, and Levy Fines

(1) The Commission and its employees shall have the authority to:

(a) Investigate violations, or suspected violations, of the Act and any rules promulgated pursuant to it;

(b) Refer complaints to the Georgia Bureau of Investigation, the Georgia Drugs and Narcotics Agency, local law enforcement, and other appropriate government authorities, and to cooperate with such entities in their respective investigations and processes;

(c) Serve all orders, summonses, administrative citations, notices, or other processes relating to the enforcement of the Act and the rules of the Commission;

(d) Conduct on-demand and scheduled inspections and investigations of the premises of licensees and registrants; and

(e) Exercise any other power or duty authorized by law.

(2) Prior notice of an inspection, investigation, review, or audit is not required.

(3) During an inspection or investigation, the Commission and its employees shall have the authority to:

(a) Have full and immediate access to enter and inspect the entire premises of the licensee or registrant, and all locations, vehicles, and equipment associated with the operations, storage, and records of a licensee or registrant;

(b) Question any individual on the premises;

(c) Obtain and test any regulated cannabis possessed by, in the control of, or used by a licensee or registrant and its employees;

(d) Access, review, request, and receive copies of any physical or electronic data, materials, books, or records of any licensee or registrant and its employees; and

(e) Provide a written notice of specific violations found during the inspection or investigation.

(4) Nothing in this rule prohibits the Commission or its employees from investigating or inspecting the premises of a licensee or registrant at any time, or from referring potential criminal activity to law enforcement.

(5) Pursuant to, and consistent with, Code Section 16-12-203(17), the Commission hereby delegates the authority and responsibility to determine and levy fines to the GMCC Executive Director.

(a) Fines levied may be progressively structured up to the maximum amount as set forth in Code Section 16-12-203(17) and as may be identified on the inspection report or a Commission order.

(b) A fine schedule may be established and published on the Commission's website.

Cite as Ga. Comp. R. & Regs. R. 351-8-.01

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-213**,** 16-12-216**,** 16-12-217**.**

HISTORY: Original Rule entitled "Authority to Investigate, Inspect, and Levy Fines" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-8-.02 Production License Inspections

(1) A production licensee shall provide and deliver records upon request by the Commission or its employees.

(2) A production licensee shall ensure that the Commission and its employees have immediate access to their premises. If the Commission or its employees are denied access to the premises for any reason, then the licensee shall be subject to citations and fines up to and including revocation.

(3) No licensee shall interfere with, obstruct, or impede the Commission or its employees from exercising their duties as set forth in the Act and these rules. This includes, but is not limited to, the following:

(a) Denying or delaying the Commission or its employees access to the premises, during business hours or times of operation, where the licensee's regulated cannabis is grown, stored, cultivated, manufactured, tested, or transferred;

(b) Providing false or misleading statements, documents, data, or records;

(c) Failing to timely produce documents, data, or records that are required to be maintained by the licensee;

(d) Failing to timely respond to any other request for information made by the Commission or its employees in connection with an investigation of the qualifications, conduct, or compliance of a licensee; or

(e) Threatening force or violence against the Commission or its employees, or otherwise endeavoring to intimidate, obstruct, or impede the Commission or its employees from exercising their duties. The term "threatening force" includes the threat of bodily harm to such individual or to a member of his or her family.

(4) If an inspection report has findings of any non-compliance of the laws, rules, or regulations of the Commission, then the production licensee shall develop and submit a corrective action plan in writing to the Commission within seven (7) days after the licensee's receipt of the inspection report, unless a written extension is issued by the Commission. The Commission hereby delegates the authority and responsibility to determine whether an extension is made, and the duration to develop and submit such corrective action plan(s), if any, to the GMCC Executive Director.

(a) The corrective action plan shall respond to the deficiencies and/or violations found in the inspection report and include specific steps the licensee has taken, or will take, to address such findings.

(b) The production licensee shall perform and complete such steps identified in its corrective action plan within fourteen (14) days of the date of inspection. A production licensee is subject to additional inspections by the Commission or its employees to confirm the corrective action plan has been completed and that all deficiencies and violations have been resolved.

(5) Nothing in this subsection shall be construed to prohibit an appropriate local, state, or federal administrative authority from conducting an inspection of the facilities or operations of a production licensee as provided by law, rule, or regulation of a local, state, or federal government.

Cite as Ga. Comp. R. & Regs. R. 351-8-.02

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-213**,** 16-12-217**.**

HISTORY: Original Rule entitled "Production License Inspections" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-8-.03 Dispensing License Inspections

(1) Prior notice of an inspection, investigation, review, or audit is not required.

(2) Dispensing licensees shall provide and deliver records to the Commission or its employees upon request.

(3) Dispensing licensees shall ensure that the Commission and its employees have immediate access to their dispensary. If the Commission or its employees are denied access to a dispensary for any reason, then the dispensing licensee shall be subject to citations and fines up to and including revocation.

(4) No dispensing licensee shall interfere with, obstruct, or impede the Commission or its employees from exercising their duties as set forth in the Act and these rules. This includes, but is not limited to:

(a) Denying or delaying the Commission or its employees access to the dispensary, where the licensee's product in final packaged form are stored, during business hours or times of apparent operation;

(b) Providing false or misleading statements;

(c) Providing false or misleading documents and records;

(d) Failing to timely produce requested books and records required to be maintained by the licensee;

(e) Failing to timely respond to any other request for information made by the Commission or its employees in connection with an investigation of the qualifications, conduct, or compliance of the licensee; or

(f) Threatening force or violence against the Commission or its employees, or otherwise endeavoring to intimidate, obstruct, or impede the Commission or its employees from exercising their duties. The term "threatening force" includes the threat of bodily harm to such individual or to a member of his or her family.

(5) Upon receipt of an inspection report with deficiencies, violations, or fines, the dispensing licensee shall develop a corrective action plan for each deficiency and/or violation and submit the plan in writing to the Commission within seven (7) days after receipt of the statement of deficiencies and/or violations, unless a written extension is issued by the Commission. The Commission hereby delegates the authority and responsibility to determine whether an extension is made and its duration to develop and submit such corrective action plan(s), if any, to the GMCC Executive Director.

(a) The corrective action plan shall include specific requirements for corrective action that will be performed within fourteen (14) days of the date of the inspection.

(b) A dispensing licensee is subject to additional inspections by the Commission or its employees to confirm that the corrective action plan has been implemented and the deficiencies or violations have been resolved.

(6) Nothing in this rule shall be construed to prohibit an appropriate local, state, or federal administrative authority from conducting an inspection of the dispensary or operations of a dispensing licensee as provided by law, rule, or regulation of a local, state, or federal government.

Cite as Ga. Comp. R. & Regs. R. 351-8-.03

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-210**,** 16-12-215**,** 16-12-217**,** 16-12-223**.**

HISTORY: Original Rule entitled "Dispensing License Inspections" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-8-.04 Complaints

Complaints submitted to the Commission shall include the following information:

(a) The name and contact information of the complainant;

(b) The name and license number, if applicable, of the person or entity that is the subject of the complaint;

(c) A detailed description of the alleged violation of law(s) or rule(s);

(d) The date of the alleged violation or, if such date is unknown, the date that the alleged violation was identified or became known by the complainant;

(e) The address or description of the location where the alleged violation occurred; and

(f) Information, documentation, or evidence to support the complaint.

Cite as Ga. Comp. R. & Regs. R. 351-8-.04

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**.**

HISTORY: Original Rule entitled "Complaints" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-8-.05 Violations of the Act and Rules

(1) At the conclusion of an inspection or investigation, the completed inspection form shall serve as the initial written notice of specific violations of the Act and these rules.

(a) If the licensee fails to remedy the specified violations within fourteen (14) days of the issuance date of such written notice, then the GMCC Executive Director shall provide a final written notice of such unresolved violations and fine(s) levied.

(b) The licensee shall pay the levied fine, in full, within thirty (30) days of the date of the final written notice.

(c) Failure to pay such levied fine(s) in full within thirty (30) days shall constitute a separate violation and shall be subject to additional action by the Commission pursuant to the Act and these rules.

(2) Upon receipt of the final written notice, and within thirty (30) days of such notice, the licensee may submit a written request for a hearing before the Commission to be heard on the specific violations and the levied fine(s) stated in such notice. The Commission may designate a hearing officer to serve in the hearing(s).

(a) If a written request for a hearing has been received and such hearing has been scheduled, then the payment of the levied fine(s) shall remain pending until the Commission issues a decision from the hearing, and such decision may, as applicable, provide the due date for the payment of the remaining fine(s).

(b) If the licensee does not submit a written request for a hearing before the Commission, then the final written notice and fine(s) levied shall stand and such levied fines shall remain due.

(3) The Commission or its employees may forward information regarding violations of the Act or these rules to any other local, state, or federal law enforcement agency, district attorney or attorney general, and the prosecutor for the local jurisdiction in which the alleged violation occurred.

Cite as Ga. Comp. R. & Regs. R. 351-8-.05

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-210**,** 16-12-216**.**

HISTORY: Original Rule entitled "Violations of the Act and Rules" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

351-8-.06 Suspensions

(1) For the purpose of this Rule 351-8-.06, the term "licensee" shall mean a Class 1 production licensee, a Class 2 production licensee, or a dispensing licensee.

(2) Consistent with Code Section 16-12-203(17), the Commission shall provide a licensee with notice and an opportunity to be heard on the violations of the Act and these rules prior to entering an order to suspend a license for a period of up to thirty (30) days.

(3) A licensee whose license has been suspended shall conspicuously and continuously display two (2) notices at the licensee's premises during the term of the suspension, with one (1) on the exterior and one (1) on the interior.

(a) The notices shall read: NOTICE OF SUSPENSION The Georgia Access to Medical Cannabis Commission license(s) issued to [name of licensee] [license number] has been suspended for violation of state law and/or rules.

(b) The Commission may require the licensee to prominently display the notice on the homepage of the licensee's website and social media.

Cite as Ga. Comp. R. & Regs. R. 351-8-.06

AUTHORITY: O.C.G.A. §§ 16-12-203**,** 16-12-206**,** 16-12-210**.**

HISTORY: Original Rule entitled "Suspensions" adopted. F. Mar. 16, 2023; eff. Apr. 5, 2023.

Department 375. RULES OF DEPARTMENT OF DRIVER SERVICES

Chapter 375-3. DRIVER LICENSE SERVICES

Subject 375-3-1. GENERAL PROVISIONS

375-3-1-.02 Applications and Supporting Documentation

(1) Customers applying for issuance or renewal of any driver's license, permit, or identification card issued by the Department shall complete a written application in a form to be determined by the Department. Such application shall require the applicant to indicate the following:

(a) Whether he or she has ever been issued a driver's license by the State of Georgia or any other state or agency, and if so, the date and place of issuance with the license number, if known;

(b) Whether any previously issued license, whether issued by the State of Georgia or any other state or licensing agency, has ever been revoked, suspended or canceled, or whether any application for a motor vehicle driver's license has ever been denied. The application shall state the cause for revocation, suspension, cancellation or denial, the circumstances surrounding the action taken, the number of times such action has been taken and whether the license has been re-issued or application granted; and

(2) Applications executed pursuant to paragraph (1) shall include a declaration under penalty of perjury that the information contained in the application is true and correct.

(3) Each application must be supported by documentation of the customer's identity, specifically his or her name and date of birth. Documents that are acceptable include the following:

(a) Valid, unexpired U.S. passport;

(b) Certified copy of a birth certificate filed with the State Office of Vital Statistics or equivalent agency in the customer's state of birth;

(c) Consular Report of Birth Abroad issued by the U.S. Department of State, Form FS-240, DS-1350 or FS-545;

(d) Valid, unexpired Permanent Resident Card (Form I-551) issued by the U.S. Department of Homeland Security (DHS) or Immigration and Naturalization Service (INS);

(e) Unexpired Employment Authorization Document (Form I-766/EAD) issued by the DHS;

(f) Unexpired foreign passport with a valid unexpired U.S. visa affixed accompanied by the approved I-94 form documenting the applicant's most recent admittance into the United States;

(g) Certificate of Naturalization issued by the DHS, Form N-550 or N-570;

(h) Certificate of Citizenship, Form N-560 or N-561, issued by the DHS; or

(i) An uncertified copy of a state-issued birth certificate or a hospital or other commemorative birth certificate for a birth in the State of Georgia if such can be verified electronically with the records of the Georgia Department of Public Health. The driver's license, permit or identification card issued by the Department shall reflect the full legal name reflected on such documentation. If a customer's name has changed from the name listed in the document presented in satisfaction of this paragraph, such change must be supported by documentation in the form of a marriage license, marriage license application, divorce decree, adoption decree, or other court order. Original or certified copies of documents are required.

(4) Each customer may be required to provide documentation of his or her Social Security number in one of the following forms:

(a) Social Security card;

(b) DDS approved application pursuant to paragraph (1); or

(c) other approved documentation which contains the customer's Social Security number.

(5) Social security numbers provided pursuant to paragraph (4) shall be verified as required by 6 C.F.R. §37.11(e)(2) and 6 C.F.R. §37.13(b)(2). This paragraph shall not apply to non-U.S. citizen customers who are not eligible for issuance of a Social Security number due to their ineligibility to work pursuant to their immigration status. Customers claiming this exemption must provide documentation thereof from the Social Security Administration.

(6) Each customer must provide two (2) documents to substantiate residence in the State of Georgia. Such documents must contain the customer's name and residence address, and they must be dated by the sender or postmarked within six (6) months prior to the date on which they are presented. Renewal customers who are providing such documentation to satisfy the requirements of 6 C.F.R. §37.11 may utilize any previously issued driver's license, permit, or identification card, and they may submit such documents electronically so long as the address reflected therein matches the address already reflected on such person's most recently issued driver's license, permit, or identification card.

The following forms of documentation are examples of what can be used to satisfy the proof of residence requirement.

This is not an exhaustive list as acceptable document types are subject to change.

*** Mortgage Documents**

*** Lease**

*** Military Housing Agreement Letter**

*** Utility Bills** - Dated within previous six (6) months. Utility bill for services installed at your residential address (water, sewer, gas, electricity, cable/satellite TV, Internet, telephone/cell phone, or garbage collection). **Please redact account numbers.**

*** Motor Vehicle Information** - Vehicle Registration or Title, Insurance policy or Insurance Card with address displayed.

*** Documents Issued by Federal, State or Local Governments - From current or preceding calendar year**

(7) Each customer must provide documentation of his or her citizenship or lawful status in the United States. Pursuant to 6 C.F.R. §37.3 a person has lawful status if he or she presents proof that he or she is a citizen or national of the United States; or an alien: lawfully admitted for permanent or temporary residence in the United States; with conditional permanent resident status in the United States; who has an approved application for asylum in the United States or has entered into the United States in refugee status; who has a valid nonimmigrant status in the United States; who has a pending application for asylum in the United States; who has a pending or approved application for temporary protected status (TPS) in the United States; who has approved deferred action status; or who has a pending application for lawful permanent residence (LPR) or conditional permanent resident status.

(a) The following documents shall suffice as proof of citizenship:

(i) Valid, unexpired U.S. passport;

(ii) Certified copy of a birth certificate filed with the State Office of Vital Statistics or equivalent agency in the customer's state of birth;

(iii) Consular Report of Birth Abroad issued by the U.S. Department of State, Form FS-240, DS-1350 or FS-545;

(iv) Certificate of Naturalization issued by the DHS, Form N-550 or N-570; or

(v) Certificate of Citizenship, Form N-560 or N-561, issued by the DHS.

(b) A valid, unexpired Permanent Resident Card (Form I-551) issued by the DHS or USCIS shall suffice as proof of lawful status in the United States. Non-U.S. citizen customers whose identities are proven using an unexpired Employment Authorization Document (Form I-766/EAD) issued by DHS; or an unexpired foreign passport with a valid, unexpired U.S. visa affixed accompanied by the approved I-94 form documenting the applicant's most recent admittance into the United States; or a REAL ID driver's license or identification card issued in compliance with the standards established by 6 C.F.R. §37.11 must also present a second verifiable document issued by the DHS or other Federal agencies demonstrating lawful status as determined by USCIS. All documentation of lawful status is required to be verified with the DHS' Systematic Alien Verification for Entitlements Program (SAVE) in the manner prescribed in 6 C.F.R. §37.13.

(8) (a) The Department shall not accept documents issued outside the United States except foreign passports. Notwithstanding the foregoing, if a customer cannot, for reasons beyond his or her control, present any other document as proof of his or her name, including changes thereto, such documentation shall be accepted pursuant to the foregoing exception process. Such documentation must be printed in English or translated into English by a professional translating service, non-profit corporation, consular official of the country of issuance, or other entity approved by the Department. The original certified document and the original English translation document must be presented to the Department.

(b) Customers who have been designated as asylees by the United States Department of Homeland Security may satisfy the requirements for proof of identity, lawful status in the United States, and residence by providing the following:

(i) Original I-94 indicating asylee status; and

(ii) Proof of residence as set forth in paragraph (6).

(c) Customers who have been designated as refugees by the United States Department of Homeland Security may satisfy the requirements for proof of identity, lawful status in the United States, and residence by providing the following:

(i) If the applicant is a refugee initially placed in the State of Georgia upon arrival in the United States:

1) Original I-94 indicating refugee status;

2) Reception and placement form identifying agency responsible for settling applicant in the State of Georgia; and

3) Refugee Affidavit form bearing notarized signature of representative of the placement agency identified in the reception and placement form submitted to satisfy paragraph (8)(c)(i)(2) and containing applicant's residence address. The Department will notarize said forms at the Customer Service Center at which the applicant applies for said initial issuance if the placement agency does not have a notary on staff.

(ii) If the applicant is a refugee age eighteen (18) or over who was initially placed in a state other than Georgia upon arrival in the United States, but who has since moved to the State of Georgia:

1) Original I-94 indicating refugee status;

2) Driver's license or identification card issued by previous state of residence; and

3) Proof of residence as set forth in paragraph (6).

(iii) If the applicant is a refugee under age eighteen (18) who was initially placed in a state other than Georgia upon arrival in the United States, but who has since moved to the State of Georgia:

1) Original I-94 indicating refugee status; and

2) Proof of residence as set forth in paragraph (6).

(d) If the applicant is a probationer, parolee or person who has been released from the custody of the Georgia Department of Corrections within the last sixty (60) days, and he or she is unable to provide one or both documents needed to prove his or her residence, he or she may prove his or her residence address by submitting confirmation thereof from an employee of the Department of Corrections or the State Board of Pardons and Paroles on the form designated by the Department.

(e) If the applicant is a resident of a nursing home or other medical care facility, and he or she is unable to provide both documents needed to prove his or her residence, he or she may prove his or her residence address as the address of such nursing home or medical care facility based upon confirmation thereof from the nursing home or medical care facility on its letterhead. Such confirmation must include the customer's name and date of birth, the address of the nursing home, the name and phone number of a representative thereof, and the signature of such representative.

(f) If the applicant is a homeless individual, he or she may utilize the address of a homeless shelter or other service provider upon confirmation thereof from the homeless shelter or care provider. Such confirmation must include the customer's name and date of birth, the address of the homeless shelter or care provider, the name and phone number of a representative thereof, and the signature of such representative.

(g) If the applicant is in the care of the Department of Human Services or the Department of Juvenile Justice, he or she may prove his or her residence address by submitting confirmation thereof from an employee of thereof.

(h) If the applicant is age seventy (70) or more, he or she may prove his or her name and date of birth utilizing an original discharge document from the military or a statement from the Social Security Administration containing the customer's name and date of birth.

(i) If the applicant became a United States citizen pursuant to the Child Citizenship Act of 2000 upon his or her adoption by a Georgia resident, then he or she may satisfy the requirements for proving his or her identity and citizenship by presenting a State of Georgia Certificate of Foreign Birth.

(j) If the applicant is age sixty (60) or more and has held a Georgia driver's license, permit, or identification card for at least twenty (20) years prior to making application for renewal thereof, he or she may prove his or her name and date of birth utilizing an original discharge document from the military or a statement from the Social Security Administration containing the customer's name and date of birth.

(k) As provided in 6 C.F.R. Part 37, if for reasons beyond the control of an applicant who has satisfied citizenship and is renewing their Georgia drivers' license, permit, or identification card cannot provide an identity document, the Department may accept a Georgia Driver's license, permit or identification card that is valid or has been expired less than two (2) years provided it bears the name that has previously been and continues to verify through the Social Security Administration and the applicants' photographs continue to match without incident, and use of such card is approved by an authorized managing supervisor of the Department.

(l) In the event a customer is unable to satisfy the documentary requirements set forth herein, he or she may propose the use of alternative documents. Such requests shall contain a specific explanation of why the customer is unable to provide the documents, a showing that the alternative documents are equivalent to the documents required in the regulation and include copies of the documents proposed. The Department shall not accept alternative documentation as proof of lawful status in the United States.

(9) Customers applying for the renewal of a driver's license, permit or identification card by means other than personal appearance, shall be authorized to do so pursuant to Ga. Comp. R. & Regs. R. 375-3-2-.04.

Cite as Ga. Comp. R. & Regs. R. 375-3-1-.02

AUTHORITY: O.C.G.A. §§ 40-5-4**,** 40-5-101**,** 40-16-2**,** 40-16-3**.**

HISTORY: Original Rule entitled "Documentation Required for Initial Issuance" adopted. F. Sept. 1, 2004; eff. Sept. 21, 2004.

Amended: F. Dec. 14, 2005; eff. Jan. 3, 2006.

Amended: F. Sept. 11, 2006; eff. Oct. 1, 2006.

Repealed: New Rule of same title adopted. F. Mar. 22, 2007; eff. Apr. 11, 2007.

Amended: F. Oct. 10, 2007; eff. Oct. 30, 2007.

Repealed: New Rule entitled "Documentation Required for Issuance" adopted. F. Nov. 23, 2009; eff. Dec. 13, 2009.

Repealed: New Rule entitled "Applications and Supporting Documentation" adopted. F. Mar. 30, 2012; eff. Apr. 19, 2012.

Amended: F. Jan. 22, 2013; eff. Feb. 11, 2013.

Amended: F. Jan. 21, 2014; eff. Feb. 10, 2014.

Amended: F. Apr. 24, 2014; eff. May 14, 2014.

Amended: F. Aug. 20, 2014; eff. Sept. 9, 2014.

Amended: F. Nov. 18, 2014; eff. Dec. 8, 2014.

Amended: F. Sep. 15, 2015; eff. Oct. 5, 2015.

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Department 391. RULES OF GEORGIA DEPARTMENT OF NATURAL RESOURCES

Chapter 391-3. ENVIRONMENTAL PROTECTION

Subject 391-3-20. ENHANCED INSPECTION AND MAINTENANCE

391-3-20-.01 Definitions

The following terms as used in these rules shall have the meaning hereinafter respectively ascribed, except that to the extent terms are not defined in these rules, the Act's definitions control; and provided that definitions within any subsequent rule or subdivision thereof, which are expressly made applicable to the rule or subdivision within which they appear, shall apply for purposes of such specific rule or subdivision thereof.

(a) "Act" means O.C.G.A. § 12-9-40 et seq., as amended, "The Georgia Motor Vehicle Emission Inspection and Maintenance Act."

(b) "Biometrics" means the automated recognition of individuals by means of unique physical characteristics, typically for the purposes of security. For Georgia's Clean Air Force inspectors, biometric finger vein readers are used for biometric logins.

(c) "Calibration" means, in the case of the Georgia Analyzer System (GAS), the process of establishing or verifying that the test values of the GAS emissions bench are accurate by using the applicable calibration gases. In the case of a fuel cap tester, "calibration" means the process of verifying that the measured pressure drop over time is between the upper and lower control limits.

(d) "Certificate" means the license issued by the Director to a person authorizing him or her to perform emission inspections in accordance with the requirements of the Act and this Chapter.

(e) "Certificate of Authorization" means a certificate issued by the Director to each establishment or location designated as an official emission inspection station.

(f) "Certificate of Emissions Inspection" means an official certificate that exhaust emissions, evaporative emissions, emission control equipment, and on-board diagnostic equipment have been inspected and approved in accordance with the Act and this Chapter. Such certificates will be furnished to official emission inspection stations by EPD to be completed and issued by such stations to the owner or operator of a responsible motor vehicle upon inspection and approval certifying that such responsible motor vehicle has been inspected and complies with the inspection and maintenance required by the Act and this Chapter.

(g) "DLC" means the data or diagnostic link connector for a vehicle's on-board diagnostic system.

(h) "Dedicated data transmission line" means a unique communication line identifiable by a transmitted digital identification number which allows the Vehicle Information Database or (VID) to identify the Georgia Analyzer System (GAS) unit communicating with the VID.

(i) "Department" means the Department of Natural Resources.

(j) "Diagnostic Trouble Codes (DTC)" means that for vehicles equipped with on-board diagnostic (OBD) computer systems, a five digit code that is associated with a specific test of the OBD system.

(k) "Director" means the Director of the Environmental Protection Division of the Department of Natural Resources.

(l) "E-Certs" means blank Electronic Certificates of Emission Inspection that are pre-purchased by official emissions inspection stations for the purpose of performing emission inspections.

(m) "Emission Inspection" means all tests and inspections required by the Act and this Chapter, including an on-board diagnostic system check, a fuel cap test, a tampering inspection, and an exhaust emissions test where applicable.

(n) "Emissions Inspector Certification Training Program Manual", means the manual supplied to inspectors during their initial and re-certification classes; the most current version of this manual is available on the Georgia Clean Air Force website at www.cleanairforce.com.

(o) "Emission Recall Compliance Check" means determining whether a recall campaign has been issued by the original equipment manufacturer of a vehicle.

(p) "E-VIN" means the Electronic Vehicle Identification Number embedded in the OBD computer system on 1996 and later model year vehicles.

(q) "EPD" means the Environmental Protection Division of the Georgia Department of Natural Resources.

(r) "Exhaust Emission Test" means the determination of the amount of specified gases in a vehicle's exhaust by use of the 2-speed idle (TSI) test.

(s) "Fleet Vehicle" means a motor vehicle owned or leased by a person engaged in a commercial activity, utility service, or government service; or a motor vehicle offered for sale, rent, or lease at a business which is licensed to sell, rent, or lease motor vehicles.

(t) "Fuel Cap Test" means the determination of the ability of the fuel cap(s) to retain pressure.

(u) "Gas Calibration" means the calibration of the Georgia Analyzer System (GAS) by the use of a manufactured calibration gas.

(v) "Georgia Analyzer System" (GAS) means the test systems approved by EPD for use in performing emission inspections in Georgia in accordance with the Act and this Chapter.

(w) "Georgia Analyzer System Hardware and Software Specifications" (GAS Specs) means the Georgia Analyzer System Hardware and Software Specifications, Phase V, August 31, 2016, which contains the hardware and software requirements for a GAS.

(x) "Georgia's Clean Air Force" (GCAF) means the partnership between EPD and the Management Contractor to implement Georgia's Enhanced Motor Vehicle Emission Inspection and Maintenance Program (I/M Program).

(y) "GVWR" means the gross vehicle weight rating, i.e., the weight of the vehicle and contents when loaded to its maximum capacity, as established by the vehicle manufacturer.

(z) "Hot Rod" means a vehicle in which the original engine has been replaced with an engine from another manufacturer, or with a different type of engine from the same manufacturer which was never installed in that model vehicle. For the purposes of this definition, a different type of engine will include engines with a different number of cylinders from any engine which was originally installed in that make of vehicle. It will not include engines of the same family, e.g., Chevrolet V8s of 283, 305, 327, 350 and 400 cubic inch displacement, nor will it include engines different from the original, but which were also installed in that make of vehicle, e.g., gasoline for diesel engine swaps in General Motors or Volkswagen vehicles, or V8 for V6 swaps where both engines were installed in that model vehicle by the manufacturer for retail sale.

(aa) "Idle RPM" means for vehicles equipped with a manual transmission, the manufacturer's recommended engine speed with the transmission in neutral or with the clutch disengaged. For vehicles equipped with an automatic

transmission, idle revolutions per minute (RPM) means the manufacturer's recommended engine speed with the transmission in neutral or park.

(bb) "Inspection Term" means the period of time a certificate of emission inspection shall be considered valid. The specific period of an inspection term is established in this Chapter.

(cc) "Inspector" means a person certified by the Director to perform emission inspections in accordance with the requirements of the Act and this Chapter.

(dd) "Kit Car" means a motor vehicle which does not utilize a chassis from a vehicle certified by the manufacturer to meet emission control standards or for which the original manufacturer's identification has been eliminated due to the replacement of the vehicle's body with one of a different make and/or style.

(ee) "Light Duty Truck" means any motor vehicle with a GVWR of 8,500 pounds or less which has a vehicle curb weight of 6,000 pounds or less and which has a basic vehicle frontal area of 45 square feet or less, which is:

1. Designed primarily for purposes of transportation of property or is a derivation of such a vehicle, or

2. Designed primarily for transportation of persons and has a capacity of more than 12 persons, or

3. Available with special features enabling off-street or off-highway operation and use.

(ff) "Light Duty Vehicle" means a passenger car or passenger car derivative, capable of seating 12 passengers or less with a GVWR of 8,500 pounds or less.

(gg) "Management Contractor" means the person, corporation or entity under contract to design and operate the data management system and to perform other functions for the I/M Program.

(hh) "Malfunction Indicator Light (MIL)" means a light on the dashboard of OBD equipped vehicles that notifies the driver that an emission related fault has been detected and the vehicle should be repaired as soon as possible.

(ii) "Non-conforming Vehicle" means a covered vehicle that has not obtained an EPA certification or has an emissions control component that is obsolete according to the manufacturer; such a vehicle would be subject to an alternative tail pipe emissions standard based upon its model year to obtain a vehicle registration in the Georgia covered counties.

(jj) "On-Board Diagnostic (OBD) System" means a computer system installed on 1996 or later model year vehicles as required by Section 202(m) of the Clean Air Act (42 U.S.C. 7521) which is designed to identify engine or primary emission control component problems which cause excess emissions.

(kk) "On-Board Diagnostic (OBD) System Check" means the determination of readiness codes and diagnostic trouble codes stored within the memory of the on-board diagnostic system.

(ll) "Primary Emission Control Component" means the catalytic converter, air injection system, exhaust gas recirculation system or other major component, as determined by the Director, which is installed on a vehicle primarily for the purpose of emission control.

(mm) "Public Vehicle" means a motor vehicle that is not a fleet vehicle.

(nn) "Recognized Repair Technician" means any person professionally engaged in vehicle repair, employed by an ongoing business whose purpose is vehicle repair or possessing a nationally recognized certification for vehicle emission related diagnosis and repair.

(oo) "Responsible Motor Vehicle" means any motor vehicle defined as a light duty vehicle or a light duty truck, excluding any motor vehicle exempted from the Act and this Chapter such as vehicles not in a Covered County as defined in 391-3-20-.02.

(pp) "Revolutions per Minute" (RPM) means the number of times the crankshaft of an engine makes a complete 360 degree turn in one minute (60 seconds).

(qq) "State-Certified Emissions Inspection Station" means a facility that has met all the qualifications of this Act and this Chapter and is certified by the Director.

(rr) "Station Owner" means the individual, partnership, firm, corporation, association, municipality, governmental agency, lessee, or other entity having ownership of or control of the daily operation of an inspection station.

(ss) "Tampering Inspection" means the determination of whether the catalytic converter(s) as installed by the original manufacturer has been removed from the vehicle or modified.

(tt) "Time Extension" means any time extension as defined in section "Extensions and Reciprocal Inspections" of these rules and issued by EPD, the Management Contractor or an authorized agent of EPD to the owner of a responsible motor vehicle certifying that such owner and vehicle have met the requirements in the Act and this Chapter for extending the time to comply with the emission inspection requirement.

(uu) "Vehicle" means a motor vehicle.

(vv) "Vehicle Information Database" (VID) means the data collection and management system for Georgia's Enhanced Motor Vehicle Emission Inspection and Maintenance Program (I/M Program) that contains current and historical program data. The VID is comprised of data collection tables, including the table of inspection records. The term "VID" is used to refer to the VID as a whole or to any part, e.g., Enforcement database, Audit database, Emission Inspections database, and Waiver database.

(ww) "Waiver" means the official form issued by EPD, the Management Contractor or an authorized agent of EPD to the owner of a responsible motor vehicle certifying that such owner and vehicle have met the requirements in the Act and this Chapter for obtaining a waiver of the emission inspection requirement.

(xx) "2-speed idle (TSI) test" means an exhaust emission test where the vehicle under test is run at an idle revolutions per minute (RPM) speed and a higher RPM speed as defined in the GAS Specs.

Cite as Ga. Comp. R. & Regs. R. 391-3-20-.01

AUTHORITY: O.C.G.A. §§ 12-9-40***, et seq.*****, as amended.**

HISTORY: Original Rule entitled "Definitions" adopted. F. Nov. 1, 1993; eff. Nov. 21, 1993.

Amended: F. May 24, 1994; eff. June 13, 1994.

Amended: F. Aug. 31, 1994; eff. Sept. 20, 1994.

Repealed: New Rule of same title adopted. F. Aug. 28, 1995; eff. Sept. 17, 1995.

Amended: ER. 391-3-20-0.33-.01 adopted. F. June 4, 1996; eff. May 29, 1996, the date of adoption.

Amended: Permanent Rule adopted. F. Aug. 26, 1996; eff. Sept. 15, 1996.

Amended: F. June 3, 1997; eff. June 23, 1997.

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Amended: F. Mar. 27, 1998; eff. Apr. 16, 1998.

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Amended: F. June 18, 1999; eff. July 8, 1999.

Amended: F. Sept. 17, 1999; eff. Oct. 7, 1999.

Amended: F. Dec. 8, 2000; eff. Dec. 28, 2000.

Amended: F. June 28, 2001; eff. July 18, 2001.

Amended: F. Dec. 6, 2001; eff. Dec. 26, 2001.

Amended: F. Dec. 5, 2003; eff. Dec. 25, 2003.

Amended: F. Dec. 20, 2004; eff. Jan. 9, 2005.

Amended: F. Dec. 21, 2006; eff. Jan. 10, 2007.

Amended: F. May 30, 2014; eff. June 19, 2014.

Amended: F. Nov. 2, 2016; eff. Nov. 22, 2016.

Amended: F. Mar. 8, 2018; eff. Mar. 28, 2018.

Amended: F. Jan. 28, 2019; eff. Feb. 17, 2019.

Amended: F. Mar. 24, 2021; eff. Apr. 13, 2021.

Amended: F. Mar. 30, 2022; eff. Apr. 19, 2022.

Amended: F. Mar. 1, 2023; eff. Mar. 21, 2023.

391-3-20-.03 Covered Vehicles; Exemptions

(1) The requirements of this Chapter apply to the following classes of gasoline-powered responsible motor vehicles, as defined by the Act, registered or required to be registered in Covered Counties:

(a) All light duty vehicles 24 model years old and newer.

(b) All light duty trucks 24 model years old and newer with a gross vehicle weight rating of 8,500 pounds or less.

(2) The requirements of this Chapter also apply to the following vehicles in the classes listed above which are operated in Covered County:

(a) Vehicles which are owned and operated by a federal or state agency, municipality or other political subdivision in a Covered County.

(b) Vehicles which are operated for 60 days or more per year on federal installations located in whole or in part in a Covered County.

(3) Vehicles which are capable of being operated on both gasoline and any alternate fuel are covered by the inspection requirements and shall be tested on gasoline.

(4) New vehicles are exempt from the emission inspection requirement until the inspection term three years following the model year of the vehicle.

(5) EPD may require that any vehicle registered or operated in the Covered Counties but which is claimed to be not subject to the requirements of the State Inspection Program, be presented for verification that the vehicle is not subject.

(6) For vehicles which do not have the original engine, the model year of the chassis will be considered the model year of the vehicle.

(7) For kit cars, the model of the vehicle shall be deemed to be the model year of the vehicle as established in the vehicle registration database maintained by the Georgia Department of Revenue, Motor Vehicle Division or its successor agency.

(8) Owners of vehicles which qualify as non-conforming vehicles may request special inspection standards as described in Rule 391-3-20-.05(2). Such vehicles will be subject to the special inspection standards at subsequent inspections.

(9) A vehicle which is otherwise subject to the provisions of this Chapter is exempt from inspection if it is driven less than 5,000 miles per year, is 10 model years old or older and the current primary registered owner is a person 65 years old or older.

(10) No responsible motor vehicle shall be registered in a Covered County unless it has received a valid passing Certificate of Emission Inspection, a time extension or a waiver meeting all requirements of the Act and this Chapter.

Cite as Ga. Comp. R. & Regs. R. 391-3-20-.03

AUTHORITY: O.C.G.A. §§ 12-9-40***, et seq.,*** **as amended.**

HISTORY: Original Rule entitled "Covered Vehicles; Exemptions" adopted. F. Nov. 1, 1993; eff. Nov. 21, 1993.

Amended: F. Aug. 31, 1994; eff. Sept. 20, 1994.

Repealed: New Rule of same title adopted. F. Aug. 28, 1995; eff. Sept. 17, 1995.

Amended: ER. 391-3-20-0.33-.03 adopted. F. June 4, 1996; eff. May 29, 1996, the date of adoption.

Amended: Permanent Rule adopted. F. Aug. 26, 1996; eff. Sept. 15, 1996.

Amended: F. June 3, 1997; eff. June 23, 1997.

Amended: F. Mar. 27, 1998; eff. Apr. 16, 1998.

Amended: F. Sept. 17, 1999, eff. Oct. 7, 1999.

Amended: F. Dec. 8, 2000; eff. Dec. 28, 2000.

Amended: F. June 28, 2001; eff. July 18, 2001.

Amended: F. June 27, 2002; eff. July 17, 2002.

Amended: F. Dec. 20, 2004; eff. Jan. 9, 2005.

Amended: F. May 30, 2014; eff. June 19, 2014.

Amended: F. Mar. 8, 2018; eff. Mar. 28, 2018.

Amended: F. Jan. 28, 2019; eff. Feb. 17, 2019.

Amended: F. Mar. 1, 2023; eff. Mar. 21, 2023.

391-3-20-.04 Emission Inspection Procedures

(1) Prior to performing an emission inspection, the inspector shall determine whether the vehicle has leaking fluids, is overheating, or is otherwise unsafe to inspect. The inspector shall not perform an emission inspection on any vehicle which is unsafe to inspect.

(2) Inspectors shall perform a complete emission inspection on any responsible motor vehicle presented for an initial inspection, in accordance with the requirements of the Act and this Chapter and the procedures as prompted by the GAS, including the following:

(a) For OBD equipped vehicles.

1. A tampering inspection.

2. An OBD system check. On occasion, when activated by EPD, the GAS will prompt the inspector at the conclusion of the OBD system check to perform the 2-speed idle test to collect exhaust emission data. The exhaust emission data will not be used to determine Pass/Fail results of the vehicle.

3. A fuel cap test.

(b) For non-OBD equipped vehicles.

1. A tampering inspection.

2. An exhaust emission test. The inspector may perform a 2-speed idle test on vehicles as prompted by the GAS.

3. A fuel cap test.

(c) For non-conforming vehicles.

1. A tampering inspection. The inspector shall perform a tampering inspection only for those vehicles given non-conforming status by EPD that were originally equipped with a catalytic converter by the vehicle manufacturer or that have been subsequently equipped with a catalytic converter.

2. An exhaust emission test. The inspector shall perform a 2-speed idle test on all vehicles that have been given non-conforming status by EPD.

3. A fuel cap test.

(3) The station owner and inspector shall take all reasonable precautions to avoid damage to vehicles during the emission inspection.

(4) EPD may require alternate procedures for certain types or classes of vehicles when it determines that such alternate procedures are necessary to safely and effectively inspect such vehicles.

(5) Emission inspections may be performed on any vehicle when done "at motorist's request," for reasons such as performing a reciprocal inspection for a motorist to meet the emission inspection requirements in his or her state of residence, as allowed by the Georgia Analyzer System software. The inspection procedure to be performed by certified inspectors shall be as prompted by the GAS.

(6) Inspectors shall perform a reinspection of the portions previously failed during an emission inspection on any vehicle presented for an after repairs inspection, in accordance with the requirements of the Act and this Chapter and the procedures as prompted by the GAS.

Cite as Ga. Comp. R. & Regs. R. 391-3-20-.04

AUTHORITY: O.C.G.A. §§ 12-9-40**,** ***et seq.,*** **as amended.**

HISTORY: Original Rule entitled "Emission Inspection Procedures" adopted. F. Nov. 1, 1993; eff. Nov. 21, 1993.

Amended: F. May 24, 1994; eff. June 13, 1994.

Amended: F. Aug. 31, 1994; eff. Sept. 20, 1994.

Repealed: New Rule of same title adopted. F. Aug. 28, 1995; eff. Sept. 17, 1995.

Amended: ER. 391-3-20-0.33-.04 adopted. F. June 4, 1996; eff. May 29, 1996, the date of adoption.

Amended: Permanent Rule adopted. F. Aug. 26, 1996; eff. Sept. 15, 1996.

Amended: F. June 3, 1997; eff. June 23, 1997.

Amended: ER. 391-3-20-0.36-.04 adopted. F. Oct. 17, 1997; eff. Oct. 15, 1997, the date of adoption.

Amended: ER. 391-3-20-0.38-.04 adopted. F. Dec. 5, 1997; eff. Dec. 3, 1997, the date of adoption.

Amended: F. Mar. 27, 1998; eff. Apr. 16, 1998.

Amended: F. Aug. 27, 1998; eff. Sept. 16, 1998.

Amended: F. Sept. 17, 1999; eff. Oct. 7, 1999.

Amended: F. Dec. 8, 2000; eff. Dec. 28, 2000.

Amended: F. June 28, 2001; eff. July 18, 2001.

Amended: F. Dec. 6, 2001; eff. Dec. 26, 2001.

Amended: F. Dec. 10, 2002; eff. Dec. 30, 2002.

Amended: F. Dec. 20, 2004; eff. Jan. 9, 2005.

Amended: F. May 30, 2014; eff. June 19, 2014.

Amended: F. Nov. 2, 2016; eff. Nov. 22, 2016.

Amended: F. Mar. 8, 2018; eff. Mar. 28, 2018.

Amended: F. Mar. 24, 2021; eff. Apr. 13, 2021.

Amended: F. Mar. 30, 2022; eff. Apr. 19, 2022.

Amended: F. Mar. 1, 2023; eff. Mar. 21, 2023.

391-3-20-.05 Emission Standards

(1) An inspector shall not perform a tampering inspection, an exhaust emission test, a fuel cap test, or an OBD system check on a vehicle which:

(a) has a missing exhaust system, or

(b) is unsafe to inspect.

(2) The inspector shall not issue a Certificate of Emission Inspection indicating an overall passing result for the emission inspection unless the inspector has inspected the vehicle in accordance with the requirements of the Act and this Chapter and the vehicle has passed the tampering inspection, the OBD system check, the fuel cap test, and the exhaust emissions test where applicable.

(a) The vehicle shall pass the tampering inspection if:

1. the catalytic converter(s) has not been removed or disconnected;

2. no catalytic converter was installed by the original equipment manufacturer as determined from the vehicle emission control label;

3. in the case of a vehicle which has been converted from a single exhaust system to a dual exhaust system and a catalytic converter(s) was part of the original single exhaust system configuration, a catalytic converter has been installed in each pipe of the dual exhaust system;

4. in the case of a non-conforming vehicle for which either the original vehicle or the replacement engine was equipped with a catalytic converter(s), a catalytic converter(s) has been installed; or

5. a catalytic converter(s) installed by the original equipment manufacturer has been removed and replaced with another catalytic converter(s).

(b) The vehicles shall pass the OBD system check if:

1. the Georgia Analyzer System (GAS) is able to communicate with the vehicle's OBD system;

2. the MIL illuminates with the ignition key in the "on" position and the engine not running, which is known as Key On Engine Off (KOEO);

3. the OBD system does not command the MIL to illuminate with the ignition key in the on position with the engine running;

4. all nonexempt OBD system monitors, as specified in the GAS, are set to "ready";

5. the OBD system does not contain any fault codes which command the MIL to illuminate, as specified by the vehicle manufacturer, indicating problems with the emissions control parameters monitored by the OBD system; and

6. the MIL does not illuminate with the ignition key in the "on" position and the engine running, which is known as Key On Engine Running (KOER).

(c) The vehicle shall pass the fuel cap test if:

1. the vehicle's primary fuel cap and, when equipped, one secondary fuel cap, holds pressure in accordance with the standard established by the GAS; and

2. where a vehicle has two or more fuel caps, each fuel cap is present.

(d) The vehicle shall pass the exhaust emission test if:

1. in the case of a vehicle subject to a 2-speed idle test any simultaneous pair of values for hydrocarbons and carbon monoxide, in each mode, do not exceed the exhaust levels established in the GAS, and the combined value for carbon monoxide and carbon dioxide is equal to or more than the minimum combined value established in the GAS; or

2. in the case of a kit car, hot rod, or non-conforming vehicle that has been given non-conforming status by EPD under this Chapter, any simultaneous pair of values for hydrocarbon and carbon monoxide, in each mode of the 2-speed idle test, do not exceed the exhaust levels established in the GAS for 1975 model year vehicles, or for the model year of the vehicle, and the combined value for carbon monoxide and carbon dioxide is equal to or more than the minimum combined value established in the GAS.

Cite as Ga. Comp. R. & Regs. R. 391-3-20-.05

AUTHORITY: O.C.G.A. §§ 12-9-40***, et seq.,* as amended.**

HISTORY: Original Rule entitled "Emission Standards" adopted. F. Nov. 1, 1993; eff. Nov. 21, 1993.

Amended: F. Aug. 31, 1994; eff. Sept. 20, 1994.

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Amended: ER. 391-3-20-0.33-.05 adopted. F. June 4, 1996; eff. May 29, 1996, the date of adoption.

Amended: Permanent Rule adopted. F. Aug. 26, 1996; eff. Sept. 15, 1996.

Amended: F. June 3, 1997; eff. June 23, 1997.

Amended: ER. 391-3-20-0.38-.05 adopted. F. Dec. 5, 1997; eff. Dec. 3, 1997, the date of adoption.

Amended: F. Mar. 27, 1998; eff. Apr. 16, 1998.

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Amended: F. Sept. 17, 1999; eff. Oct. 7, 1999.

Amended: F. Dec. 8, 2000; eff. Dec. 28, 2000.

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Amended: F. Dec. 6, 2001; eff. Dec. 26, 2001.

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Amended: F. May 30, 2014; eff. June 19, 2014.

Amended: F. Nov. 2, 2016; eff. Nov. 22, 2016.

Amended: F. Mar. 8, 2018; eff. Mar. 28, 2018.

Amended: F. Mar. 24, 2021; eff. Apr. 13, 2021.

Amended: F. Mar. 30, 2022; eff. Apr. 19, 2022.

Amended: F. Mar. 1, 2023; eff. Mar. 21, 2023.

391-3-20-.11 Inspector Qualifications and Certification

(1) No person shall perform an emission inspection, or any part of an emission inspection, or issue a Certificate of Emission Inspection, unless he or she:

(a) has submitted an Inspector Certification Application to EPD in a format established by EPD. The application shall include all information required by the Director to determine that the applicant meets the requirements of the Act and this Chapter. An update shall be filed with the Management Contractor, in a format approved by EPD, no later than the next business day for any change in the information in or submitted with the application.

(b) has obtained the age of 18 prior to attending the inspector training class;

(c) has completed the appropriate EPD-approved training program for the type of inspection he or she will be performing;

(d) has obtained training on the proper operation of inspection equipment from the manufacturer of the GAS that will be used to perform the emission inspections;

(e) has passed a written and practical test of proficiency, and,

(f) holds a valid Certificate as a certified emission inspector issued by the Director.

(2) The EPD-approved training program will include information on:

(a) air pollution, its causes and effects;

(b) the purpose and functions of the I/M Program;

(c) inspection regulations and procedures, including technical details and the rationale for their design;

(d) emission control devices, their functions, configuration, identification and inspection;

(e) Georgia Analyzer System (GAS) operation, calibration and maintenance;

(f) quality control procedures and their purpose;

(g) public relations; and

(h) safety and health issues related to inspections.

(3) Inspectors must demonstrate knowledge and proficiency in proper inspection procedures. Inspectors must pass (with 80% correct answers) a written test on all aspects of the training.

Inspectors must also pass a practical test by demonstrating that they have knowledge about conducting all parts of the inspection correctly.

(4) The Director shall issue a Certificate and one Inspector picture ID badge to inspectors who satisfactorily complete the EPD-approved training program and pass the written and hands-on tests. Certificates may be suspended or revoked at any time, after notice and offer of a hearing, for failure to conduct inspections properly or to otherwise comply with the Act or this Chapter.

(5) Unless suspended, revoked or voluntarily surrendered, a Certificate issued by the Director is valid for two years from the date of issuance.

(a) For inspectors intending to renew their Certificate, a complete application for renewal of an inspector's Certificate must be submitted at least 30 calendar days prior to the expiration of the existing Certificate.

(b) The Director shall renew the Certificate upon timely receipt of a renewal application, determination that there is no cause to deny the renewal in accordance with the Act or Chapter 391-3-20 of the Rules, the inspector successfully completing an EPD approved retraining program, and the inspector passing the written test.

(6) No inspector shall perform an emissions inspection unless he or she is wearing his or her EPD-issued Inspector picture ID badge so the picture is clearly visible on his or her front upper body area. Replacement of a lost, missing, damaged or illegible ID badge is the responsibility of the inspector at a cost of twenty-five dollars ($25.00) paid to the Management Contractor.

(7) No inspector shall hold or attempt to fraudulently obtain two (2) or more valid Certificates.

(8) Whenever an inspector, after applying for and receiving a Certificate, moves from the address listed in his or her application or changes the telephone or e-mail address contact information, the inspector shall notify the Management Contractor of his or her change of address or contact information no later than the next business day. The address in the application or as updated by the inspector shall serve as the address for any and all notice required by law.

(9) No unauthorized person shall use a certified emission inspector's personal access code or biometric login to perform any part of an emission inspection. No certified emission inspector shall use the personal access code or biometric login of another certified emission inspector to perform any part of an emission inspection.

(10) An inspector shall not divulge or authorize the use of his or her personal access code or biometric login by any other person(s). An inspector shall be held responsible for all inspections performed by any person using his or her personal access code or biometric login.

(11) Before an inspector may perform emissions inspections at a station, the Management Contractor must allow the inspector access to the test system(s) at the station. Inspectors must notify the Management Contractor at least three (3) business days before they begin employment at a given station, and no later than the next business day when they cease employment at a station.

(12) The Director may deny issuance or renewal of a Certificate for cause, including, but not limited to, the inspector's compliance history.

Cite as Ga. Comp. R. & Regs. R. 391-3-20-.11

AUTHORITY: O.C.G.A. §§ 12-9-40***, et seq.*****, as amended.**

HISTORY: Original Rule entitled "Schedules for Emission Tests" adopted. F. Nov. 1, 1993; eff. Nov. 21, 1993.

Amended: Rule retitled "Inspector Qualifications and Certification." F. Aug. 31, 1994; eff. Sept. 20, 1994.

Repealed: New Rule of same title adopted. F. Aug. 28, 1995; eff. Sept. 17, 1995.

Amended: ER. 391-3-20-0.33-.11 adopted. F. June 4, 1996; eff. May 29, 1996.

Amended: Permanent Rule adopted. F. Aug. 26, 1996; eff. Sept. 15, 1996.

Amended: F. June 3, 1997; eff. June 23, 1997.

Amended: F. Mar. 27, 1998; eff. Apr. 16, 1998.

Amended: F. Sept. 17, 1999; eff. Oct. 7, 1999.

Amended: F. Dec. 2, 1999; eff. Dec. 22, 1999.

Amended: F. Dec. 8, 2000; eff. Dec. 28, 2000.

Amended: F. Dec. 6, 2001; eff. Dec. 26, 2001.

Amended: F. Dec. 20, 2004; eff. Jan. 9, 2005.

Amended: F. May 30, 2014; eff. June 19, 2014.

Amended: F. Mar. 8, 2018; eff. Mar. 28, 2018.

Amended: F. Jan. 28, 2019; eff. Feb. 17, 2019.

Amended: F. Mar. 24, 2021; eff. Apr. 13, 2021.

Amended: F. Mar. 30, 2022; eff. Apr. 19, 2022.

Amended: F. Mar. 1, 2023; eff. Mar. 21, 2023.

Department 391. RULES OF GEORGIA DEPARTMENT OF NATURAL RESOURCES

Chapter 391-5. HISTORIC PRESERVATION

Subject 391-5-1. STATE PARKS AND HISTORIC SITES SYSTEM

391-5-1-.05 Safety and General Conditions of Use

(1) **Vehicles.**

(a) Traffic Control. Site managers and associates are authorized to direct traffic in sites. All persons shall comply with lawful orders, signals, and direction of such site managers and associates. All persons shall observe and comply with posted traffic control devices and signs.

(b) Motor Vehicles. Motor vehicles are restricted to site roads, through roads, and parking areas. The operation of motor vehicles within a site after normal operating hours is limited to division associates and registered overnight guests, except in an emergency.

(c) Bicycles.

1. Bicycles shall be ridden on designated bicycle trails or roads only. They may be pushed by hand over open spaces, such as lawns or beaches, or paved areas reserved for pedestrian use. Bicycles shall be neither ridden or pushed along designated nature trails or footpaths.

2. Where provided, bicycle racks must be used for parking bicycles. Bicycles shall not be chained and locked to trees or site structures or placed so as to obstruct pedestrian or vehicular movement.

(d) Obstructing Traffic. No person shall cause or permit any vehicle to obstruct traffic by unnecessary stopping. In the event of mechanical difficulties, the driver shall report the occurrence at once to site associates and make arrangements for the expeditious removal of the vehicle. No vehicle shall be left standing or parked on any site road at night without lights visible for at least two hundred feet (200') from both front and rear of the vehicle.

(e) Trucks. No trucks or other vehicles commonly used for carrying freight, merchandise or goods for sale, unless traversing the site on a through highway, shall operate on site roads without obtaining written permission from the site manager, except when such vehicles are used in connection with delivery of supplies, site work, activities, or concessions, or are used for transporting persons to a site for recreational purposes and not for compensation.

(f) Towing Other Vehicles. No person shall operate or park within any site, a vehicle in tow of another vehicle, except boat, camping or travel trailers or recreational vehicles towing auxiliary automobiles.

(g) Parking.

1. Parking vehicles at any place with in a site, including upon the right of way of any county, state, or federal highway which traverses the site, is prohibited except in designated parking areas in accordance with markings and signs and any instructions given by site associates. Double parking or obstructing traffic is prohibited.

2. No person shall park a motor vehicle in any site without a parking pass except as set forth in Rule 391-5-1-.03(3).

(h) Exemptions. This subparagraph shall not be applicable to vehicles engaged in official business of the department or law enforcement agencies or used in emergency rescue in accordance with the directions of the site manager.

(2) **Aircraft.**

(a) No person operating or responsible for any aircraft shall cause such aircraft to land in or take off from any site or deliver by air any person, material or equipment by parachute or other means, except in emergencies threatening human life or when authorized in writing by the director.

(b) This paragraph shall not be applicable to aircraft engaged in official business of federal, state or local governments or law enforcement agencies, aircraft used in emergency rescue in accordance with the directions of the site manager, or aircraft forced to land due to circumstances beyond the control of the operator.

(3) **Skating, Skateboards, and Similar Devices.** Using roller skates, roller blades, skateboards, roller skis, coasting vehicles, or similar devices is prohibited, except in designated areas.

(4) **Weapons.** The use and possession of weapons are prohibited in all sites except:

(a) When used, or possessed by authorized federal, state and local law enforcement officers in the performance of their official duties;

(b) When unloaded and packed, cased or stored in a manner that will prevent their ready use;

(c) When such use or possession has been authorized in restricted areas and under terms and conditions specified in writing by the director; or

(d) When a person is a lawful weapons carrier as defined in O.C.G.A. § 16-11-125.1, that person may carry a handgun or a long gun (as defined in O.C.G.A. § 16-11-125.1), in all parks, historic sites and recreational areas, except in places where prohibited by federal law.

(5) **Noise.** It is prohibited to operate televisions, radios, tape or compact disk players, public address systems, musical instruments, vehicles, or other noise-making devices or machines at volume levels which are unreasonable, considering the nature and purpose of the actor's conduct, location, time of day or night, purpose for which the area is operated, impact on site users, and other factors that would govern the conduct of a reasonably prudent person under the circumstances.

(6) **Interfering with Agency Functions.** The following are prohibited:

(a) Threatening, resisting, intimidating, or intentionally interfering with a government employee or agent engaged in an official duty or on account of the performance of an official duty.

(b) Disobeying any lawful order of a law enforcement official, site manager, or authorized associates.

(c) Knowingly giving a false or fictitious report or other false information:

1. To a government employee or agent in the conduct of official duties; or

2. On an application, registration form, or other document required by law or regulation.

(7) **First Amendment Activities.**

(a) Public assemblies, meetings, gatherings, demonstrations, religious activities and other public expressions of views under the First Amendment of the U.S. Constitution, including the distribution of non-commercial printed matter, are allowed within sites, provided a permit therefore has been issued by the director or site manager.

(b) An application for such a permit shall set forth the name of the applicant; the name of the organization (if any); the date, time, duration, nature and place of the proposed event or activity; the estimated number of persons expected to participate; the equipment and facilities to be used; and any other information required by the permit application form.

(c) Where the number of persons expected to attend, or participate is ten or fewer, a permit may be issued by the site manager. If more than ten persons are expected to attend or participate, approval of the director is required. Permit applications requiring the director's approval will be approved or denied within five business days. Permit applications submitted to the site manager will be approved or denied within 48 hours.

(d) The site manager or director shall, within the prescribed time, issue a permit on proper application unless:

1. A prior application for a permit for the same time and place has been made that has been or will be granted and the activities authorized by that permit do not reasonably allow multiple occupancy of that particular area; or

2. It reasonably appears that the event or activity will threaten the health, safety, and welfare of persons using the site; or

3. The event or activity is of such nature or duration that it cannot reasonably be accommodated in the particular location applied for, considering such things as damaged to site resources or facilities, impairment of the atmosphere of peace and tranquility in natural or historic areas, interference with interpretive, visitor service, program, or administrative activities, or impairment of public use facilities or services of concessionaires or contractors; or

4. The event or activity would constitute a violation of an applicable law or regulation.

(e) The permit may contain such conditions as are reasonably consistent with protection and use of the site for the purposes for which it is operated including limitations on the time, location, number of participants, use and facilities, and number and types of equipment used, but not on the content or the message. Locations which are not appropriate for first amendment activities include but are not limited to: museums; archaeological and interpretive areas, historic structures; ruins; trails; sensitive or fragile natural areas; and the habitats of threatened or endangered species.

(f) No permit shall be issued for a period in excess of 14 consecutive days, provided that permits may be extended for like periods, upon a new application, unless another applicant has requested use of that same location and multiple occupancy of that location is not reasonably possible.

(g) If a permit is denied, the applicant shall be so informed in writing, with the reason(s) for the denial set forth.

(h) It is prohibited for persons engaged in activities covered under this section to obstruct or impede pedestrians or vehicles, or harass site visitors with physical contact or persistent demands.

(i) Participants in events and activities covered under this section are subject to usual fees for site parking, admission, or use.

(j) Violation of the terms and conditions of a permit issued in accordance with this section may result in the suspension or revocation of the permit.

(8) **Special Events.**

(a) Special events, attractions, and entertainments are allowed, provided there is a meaningful association between the site and the events, or the observance contributes to visitor understanding of the significance of the site, and a permit therefore has been issued by the director. A permit shall be denied if such activities would:

1. have an undesirable impact on site resources; or

2. threaten the health, safety, and welfare of persons using the site; or

3. be contrary to the purposes for which the site is operated or compromise the atmosphere of peace and tranquility maintained in natural or historic areas; or

4. interfere with normal site usage or operations.

(b) An application for such a permit shall set forth the name of the applicant, the name of the organization (if any) the date, time, duration, nature and place of the proposed event, an estimate of the number of persons expected to attend, a statement of equipment and facilities to be used, and any other information required by the permit application form. The application shall be submitted so as to reach the director at least thirty days in advance of the proposed event.

(c) As a condition of permit issuance, the director may require:

1. The filing of a bond payable to the department in an amount adequate to cover costs such as restoration, rehabilitation, and cleanup of the area used, and other costs resulting from the special event. In lieu of a bond, a permittee may elect to deposit cash equal to the amount of the required bond. No interest shall be paid by the department on cash deposits.

2. Compliance with other statutory requirements, including but not limited to bonds for fireworks displays.

3. The acquisition of liability insurance in which the State of Georgia is name as co-insured in an amount sufficient to protect the State of Georgia.

(d) Permits may contain such conditions as are reasonably consistent with protection and use of the site for the purposes for which it is operated. It may also contain reasonable limitations on the equipment used and the time and area within which the event is allowed.

(e) Concession agreements.

1. Persons sponsoring or conducting special events at which money will be collected must be covered under a concession agreement signed by the director.

2. The director may waive the required fees when he deems such waiver to be in the best interest of the division.

(f) Violation of the terms and conditions of a permit or concession agreement issued in accordance with this section is prohibited and may result in the suspension or revocation of the permit or concession agreement.

(9) **Solicitation.** No person shall solicit contributions in any site in the form of money, goods, services, or otherwise for any purpose. This paragraph shall not apply to contributions made by members of the public to the department for the benefit of state parks and historic sites.

(10) **Vending, Advertising, Signs, and Broadcasts.**

(a) Vending. No person, other than a licensed concessionaire, citizen support group, or authorized site associates, shall offer for sale, lease, rent or hire any goods, perishable or non-perishable, services, property, or merchandise, or engage in any business or erect any building, booth, tent, stall or any other structure whether temporary or permanent in nature for purposes of offering for sale, lease, rent, or hire any goods, services, property or merchandise.

(b) Advertising.

1. No person shall display, distribute, post or fix any handbill, pamphlet, literature, circular, poster or other printed matter containing advertising within any site; provided, however, authorization may be obtained from the site manager to post, at specified locations, announcements of site sponsored or authorized events and gatherings.

2. This section shall not apply to signs placed or authorized by the site manager advertising goods or services available at the site or to informational brochures published by governmental or non-profit organizations describing natural or historic attractions in Georgia to which admission may be charged.

3. No person shall operate, park, moor or station in a site any vehicle or vessel displaying a sign advertising goods or services for sale or exchange. This paragraph shall not apply to commercial vehicles making deliveries or providing services to the site.

(c) Signs. No signs or notices of any kind shall be posted in any site without permission of the site manager.

(d) Broadcasts. No musical instrument, radio, tape recording, television or sound tract shall be operated or any noise made which demonstrates, advertises or calls attention to any article or service for sale, rent or hire, except as provided for in a written concession agreement approved by the director.

(e) Still and Motion Pictures. No person shall take still or motion pictures, either commercial or private, involving the use of special settings or structures or the performance of a cast of persons, either amateur or professional, without first obtaining written permission from the director.

(11) **Authorization of Special Uses.** Authorization of special uses of government-owned property administered by the division shall be in writing on forms prescribed by the division and must be approved by the director.

(12) **Property.**

(a) Unattended and Abandoned Property. No personal property of any kind shall be abandoned or left unattended on site lands or waters. Unattended personal property shall be presumed to be abandoned after a period of 24 hours, or at any time after a posted closure hour, except in locations where longer time periods have been designated or in accordance with conditions established by the site manager.

(13) **Reporting Accidents.** Accidents involving bodily injury, death, or damage to property shall be reported to site associates as expeditiously as possible.

Cite as Ga. Comp. R. & Regs. R. 391-5-1-.05

AUTHORITY: O.C.G.A. §§ 12-2-24**,** 16-11-125.1**.**

HISTORY: Original Rule entitled "Safety and General Conditions of Use" adopted. F. Jun. 30, 1994; eff. July 20, 1994.

Amended: F. Aug. 9, 2005; eff. Aug. 29, 2005.

Amended: F. June 1, 2017; eff. June 21, 2017.

Amended: F. June 8, 2021; eff. June 28, 2021.

Amended: F. Mar. 29, 2023; eff. Apr. 18, 2023.

Department 430. RULES OF GEORGIA STATE BOARD OF EXAMINERS IN OPTOMETRY

Chapter 430-3. CODE OF ETHICS

430-3-.01 Code of Ethics

The following Code of Ethics is hereby adopted by the Board to govern and as a guide for the conduct of licensed Doctor of Optometry in the practice of optometry in this state. Each licensed Doctor of Optometry shall:

(a) keep the visual or optometric welfare of the patient uppermost at all times;

(b) promote in every possible way the better care of the health needs of the citizens of this state;

(c) enhance continuously their educational and technical proficiency to the end that their patients shall receive the benefits of all acknowledged improvements in visual care;

(d) see that no worthy person shall lack for optometric care regardless of the financial status of the person;

(e) advise each patient whenever consultation with an optometric colleague or referral for other professional care seems advisable;

(f) hold in professional confidence all information concerning a patient and use such data only for the benefit of the patient;

(g) conduct themselves as exemplary citizens;

(h) maintain their office and practice in harmony with true professional standards:

(i) maintain and promote cordial and useful mutual relationships with members of their profession and other professions for the interchange of information for the advantage of mankind;

(j) refrain from any exaggeration of a patient's condition.

Cite as Ga. Comp. R. & Regs. R. 430-3-.01

AUTHORITY: O.C.G.A. §§ 43-1-25**,** 43-30-5**.**

HISTORY: Original Rule entitled "Code of Ethics" was filed and effective on June 30, 1965.

Amended: Rule repealed and a new Rule of the same title adopted. Filed June 13, 1984; effective July 3, 1984.

Amended: F. Mar. 6, 2023; eff. Mar. 26, 2023.

Department 478. RULES OF THE STATE PERSONNEL BOARD

Chapter 478-1. RULES OF THE STATE PERSONNEL BOARD

478-1-.16 Absence from Work

(1) **Introduction**:

The State recognizes value in providing a reasonable amount of time off to assist employees with balancing work and personal needs. To be a responsible steward of public funds, however, the State must account for any pay provided to employees for time not worked. Paid time off must be charged to appropriate paid leave, accumulated compensatory time, paid holiday time, or suspension with pay.

This Rule defines the available types of paid and unpaid leave and the eligibility for each. It further provides a framework for leave, compensatory time, and holiday administration. Information about paid suspension is available in Rule 478-1-.15, Changes to Employment Status, and more detailed information about compensatory time can be found in statewide policy #7 - Rules, Regulations, and Procedures Governing Working Hours, the Payment of Overtime, and the Granting of Compensatory Time, jointly issued by the Governor's Office of Planning and Budget and the Department of Administrative Services.

(2) **Applicability**:

(a) The policies and procedures described in this Rule apply to all agencies of the Executive branch, excluding the Board of Regents of the University System of Georgia.

(b) In accordance with State law (O.C.G.A. § 45-20-32), Section (18) of this Rule, Education Support Leave, is applicable to all branches and entities of State government.

(3) **Definitions**:

For the purposes of this Rule, the following terms and definitions apply in addition to those in Rule 478-1-.02, Terms and Definitions:

(a) "Administrative Leave" means paid time off for specified reasons defined in State law. This paid time off is not charged to accrued leave, and the duration is defined in applicable statute.

(b) "Immediate family" means the employee's spouse, child, parent, grandparent, grandchild, brother, and sister, including active step and in-law relationships. Immediate family also includes any other person who resides in the employee's household and is recognized by law as a dependent of the employee.

(c) "Seasonal activity" means work during periods of significantly increased demand, which are of a regular and recurring nature.

(d) "Workday" means a day an employee is regularly scheduled to work.

(4) **General Leave Administration Provisions**:

(a) Each agency should establish procedures for employees to request and receive approval for absence from work.

(b) Employees are expected to properly request and receive approval for absence from work. Failure to follow the employer's procedures may result in denial of the request and/or other employment action deemed appropriate by the agency, up to and including termination of employment.

(c) If a request for absence is denied, the employee is expected to work, as scheduled. Failure to do so might result in leave without pay and/or other employment action deemed appropriate by the agency, up to and including termination of employment.

(d) The agency may require an employee on leave with an uncertain end date to provide periodic reports during the leave regarding the employee's status and intent to return to work.

(e) An employee absent on official agency business is not considered to be on leave.

(f) An employee is expected to return to work as scheduled at the expiration of approved absence. If an extension is desired, the employee must request it in writing from her/his supervisor prior to the leave expiration or adhere to other agency procedures for timely requesting an extension.

(g) Failure to obtain approval for additional time off beyond the expiration of an approved absence may result in separation from employment or other employment action deemed appropriate by the agency.

(h) Each agency may, as a condition of return, require an employee who is absent from work because of illness or injury to supply an appropriate medical release or certification that the employee is able to return to work. The release or certification must explain the extent to which the employee is able to perform the essential functions of her/his position, with or without reasonable accommodation.

1. Each agency must comply with the requirements of the Americans with Disabilities Act, as amended, including providing reasonable accommodation to its qualified employees with disabilities.

2. A limitation exists for employees returning to work from using intermittent or reduced schedule Family and Medical Leave. An agency may require fitness-for-duty certification only if the agency reasonably believes the return could pose significant risk of harm to the employee or others. Such certification may be required no more often than every 30 calendar days.

3. If the medical certification does not release the employee to perform essential functions, and there is no available reasonable accommodation, as defined in the Americans with Disabilities Act, as amended, or if the employee fails to provide the required release, the agency may take the employment action it deems appropriate, up to and including termination of employment.

(i) Prior to engaging in other employment, including self-employment, while on leave employees must comply with the notice and other requirements set forth in Rule 478-1-.07, Outside Employment.

(j) Misrepresenting reasons for requesting or continuing an absence may result in disciplinary action, up to and including termination of employment.

(k) Exceptions to this Rule will occur if necessary to comply with applicable laws.

(5) **Types of Paid Leave**:

(a) The State's paid leave program offers a combination of accrued, personal, and administrative leave for eligible employees.

(b) The following employees are not eligible for any paid leave benefits:

1. All temporary employees except for those eligible to receive Paid Parental Leave under Section (26) of this Rule,

2. All hourly employees except for those eligible to receive Paid Parental Leave under Section (26) of this Rule, and

3. Active, salaried, non-temporary employees who are rehired retirees of the Employees' Retirement System of Georgia (ERS) while receiving retirement annuity payments during the first 1,040 hours of work performed in the calendar year.

Eligibility for other employees is defined in the applicable leave section within this Rule.

(c) Accrued Leave:

1. Accrued leave includes annual leave and sick leave. Both annual and sick leave are earned based on time in pay status and automatically accrue to eligible employees. (See Section (6) Annual Leave and Section (7) Sick Leave of this Rule).

2. Each agency, by written policy, may set a minimum period of annual and/or sick leave to be charged for any use which is only a fraction of that period. The minimum leave period cannot be greater than 15 minutes.

3. Dual Eligibility Relating to Leave Accrual:

(i) An employee who is simultaneously employed in two different agencies and is entitled to earn leave under each position s/he holds will independently accrue leave in accordance with each agency's policies.

(ii) If employment is terminated with one agency but not the other, all leave accruals will be combined and available in the remaining position, provided both agencies use the same leave accrual program. An exception applies when one of the agencies is a Community Service Board, County Board of Health, or Board of Health Community Operated Program. Leave accrued in these organizations cannot be transferred to an Executive Branch agency.

(iii) If the leave programs differ or if leave cannot otherwise transfer, the terminating agency will payout/divest the employee's leave as provided in the Annual, Sick, and Personal Leave sections of this Rule.

(d) Administrative Leave:

State law provides paid administrative leave to eligible employees for certain activities. Such leave is in addition to, and not charged against, an employee's accrued leave. Administrative leave is available for/during the following:

1. Absence Due to Emergency Office Closures (See Section (12) of this Rule.),

2. Blood Donation Leave (See Section (13) of this Rule.),

3. Bone Marrow Donation Leave (See Section (14) of this Rule.),

4. Organ Donation Leave (See Section (15) of this Rule.),

5. Court Leave (See Section (16) of this Rule.),

6. Employee Voting Leave (See Section (17) of this Rule.),

7. Education Support Leave (See Section (18) of this Rule.),

8. Disaster Volunteer Leave (See Section (19) of this Rule.),

9. Line-of-Duty Injury Leave, also known as Special Injury Leave (See Section (20) of this Rule.),

10. Leave for Contracting TB or infectious Hepatitis on the job (See Section (21) of this Rule.),

11. Military Leave (See Rule 478-1-.19, Military Leave.), and

12. Paid Parental Leave (See Section (26) of this Rule).

(e) Limitation on Concurrent Use of Paid Leave and Wage Substitutes:

An employee is not allowed to use any type of paid leave, except in special situations discussed in Section (20) of this Rule, for any time that the employee receives any form of State of Georgia-funded wage substitute, including but not limited to Workers' Compensation.

(6) **Annual Leave**:

(a) Eligibility:

1. Each agency provides paid annual leave for non-temporary salaried employees who are regularly scheduled to work 20 or more hours a week.

2. The Georgia Industries for the Blind provides paid annual leave for non-temporary manufacturing employees who are regularly scheduled to work 20 hours or more a week.

3. The following employees are not eligible to accrue annual leave:

(i) All temporary employees,

(ii) All hourly employees, and

(iii) Active, salaried, non-temporary employees who are rehired retirees of the Employees' Retirement System of Georgia while receiving retirement annuity payments during the first 1,040 hours of work performed in the calendar year.

(b) Accrual:

1. The accrual process begins on the first date of employment. Annual leave is credited to eligible employees at the end of each pay period.

2. Annual leave accrues on a graduated scale based on an employee's length of continuous, unbroken State service in a position entitled to accrue leave under this Rule.

3. Full-time employees scheduled for at least 40 hours per workweek accrue annual leave at the following rates:

Complete Months of Continuous Service	Paid Semi-Monthly	Paid Monthly
0 through 60	5 hours per pay period	10 hours per pay period
60+ through 120	6 hours per pay period	12 hours per pay period
120+	7 hours per pay period	14 hours per pay period

(i) Employees paid semi-monthly must be in pay status for at least 40 hours during the pay period to accrue annual leave at the end of that pay period.

(ii) Employees paid on a monthly basis must be in pay status for at least 80 hours during the pay period to accrue annual leave at the end of that pay period. An agency that compensates employees on a monthly basis may choose to administer annual leave as if those employees were compensated on a semi-monthly basis.

4. Part-time employees scheduled to work at least 20 (but fewer than 40) hours per workweek accrue annual leave as outlined for full-time employees, but at a prorated rate.

(i) The prorated rate is determined by dividing the employee's standard weekly work hours by 40. For example, a part-time employee scheduled for 20 hours per workweek would accrue annual leave at 50% of the rate a full-time employee accrues annual leave (20 hours ÷ 40 = .5 or 50%). A new 20-hour employee would earn 2.5 hours of annual leave semi-monthly or 5 hours monthly.

(ii) The minimum periods of time in pay status required for annual leave accrual noted in Section (6)(b)3(i)-(ii), above, are similarly prorated for part-time employees. A 20-hour employee would need to be in pay status at least 20 hours during a semi-monthly pay period, or 40 hours during a monthly pay period, in order to accrue leave at the end of that pay period.

(c) Use and Limitations of Annual Leave:

1. Annual leave may be used for vacation or other personal reasons.

2. Employees may not take annual leave before it is actually earned.

3. An agency may by written policy require its employees to use compensatory time and/or deferred holiday time before using annual leave.

4. An agency may by written policy require its employees to use available sick leave before using annual leave when the absence involves medical reasons that would qualify for sick leave.

5. In scheduling annual leave, agencies should try to accommodate employee preferences. However, employees who request annual leave during busy periods or at times when coworkers have already requested leave might need to make alternate plans. Supervisors must weigh the agency's business needs and the timeliness of the requests in approving annual leave.

(d) Carryover and Forfeiture of Annual Leave:

1. An employee may accrue up to 360 hours of annual leave. Any leave balance in excess of 360 is forfeited at the end of each month.

2. Annual leave that is forfeited may be restored as sick leave by the agency if an employee exhausts all paid leave and compensatory time and must be absent because of a personal or immediate family medical condition. The restoration of leave is limited to:

(i) The amount required by the circumstances of the medical condition; and

(ii) The leave forfeited during the current period of employment. Forfeited leave accrued prior to a break in service cannot be restored except as outlined in Section (7)(h) of this Rule.

(e) Annual Leave Payout:

1. Annual leave payout can occur in four circumstances:

(i) Payout Upon Separation. Employees are paid for their accrued and unused annual leave, which has not been forfeited, upon separation from State employment for at least one full workday for any reason.

A. Annual leave payout is limited to a maximum of 360 hours.

B. Annual leave is not paid out when an employee transfers between State agencies with no break in service or when annual leave will otherwise transfer to the new employer. (See Section (10) of this Rule.)

C. Once a separation date has been determined, the pay status of an employee cannot be extended for the purpose of granting a holiday or unanticipated non-workday occurring after the last day in pay status. Once an employee notifies the agency of the intent to terminate employment, the employee cannot be continued on the payroll on leave with pay status for the purpose of increasing the current salary, the rate of leave accrual, or the rate at which accrued leave would be paid.

(ii) Extended Leave of Absence Payout: An employee who is taking an approved leave of absence without pay of 30 calendar days or more may request and receive an annual leave payout for all accrued annual leave excluding

forfeited leave, up to a maximum of 360 hours. The lump sum payment will be calculated as outlined in (6)(e)2, below.

(iii) Payout Upon Transfer to Position Ineligible to Earn Leave: Upon transfer into a position that is not entitled to earn annual leave (i.e., temporary position, hourly position for which the employee is paid only for the time worked, or part-time position scheduled for fewer than 20 hours per week) an employee will be paid for accrued and unused annual leave, up to a maximum of 360 hours.

(iv) Annual Leave Conversion Payout: Employees may convert annual leave into a cash payout once per fiscal year upon notice of the availability of this payout option.

A. The availability of the annual leave conversion program shall be determined on an annual basis by the Governor's Office of Planning and Budget. The Governor's Office of Planning and Budget shall determine both the availability of funding and timing of the annual leave conversion payout.

B. Agencies shall annually certify to the Governor's Office of Planning and Budget the intention to participate in the program and the availability of sufficient funding within individual agency budgets to do so.

C. Upon notice of the availability of the annual leave conversion payout, an employee may elect to irrevocably convert an increment of 40 hours of annual leave to a cash payout if the employee has an accrued annual leave balance of at least 160 hours and a sick leave balance of 80 hours at the time of request.

D. Agencies should ensure that employees who are absent in a protected leave status (e.g., FMLA, military leave) during the election period are advised of any eligibility to convert annual leave to a cash payout and provided reasonable opportunity to make the conversion.

E. Each agency is required to track employee transfers between state agencies to ensure that the payout limitation of 40 hours per fiscal year per employee is not exceeded.

2. To calculate annual leave payout for a full-time employee, the annual base pay last received by the employee is divided by 2,080 hours to determine the value of each hour of leave. (Annual base pay for a part-time employee must first be converted to the equivalent full-time salary for purposes of this calculation.) The hourly rate is then multiplied by the number of hours to be paid. Decimal fractions of an hour will be rounded to the next highest hundredth of an hour.

3. Each agency has discretion to determine whether it will pay out accrued annual leave for its active, salaried, non-temporary employees who are rehired retirees of the Employees' Retirement System of Georgia when they become ineligible for paid leave benefits upon reinstatement of retirement annuity payments at the beginning of each calendar year. If any agency chooses not to pay out the accrued annual leave, the leave balance will remain credited to the rehired retiree who can then use the leave upon regaining eligibility for paid leave benefits.

(7) **Sick Leave**:

(a) Eligibility:

1. Each agency provides paid sick leave for non-temporary salaried employees who are regularly scheduled to work 20 or more hours a week.

2. The Georgia Industries for the Blind provides paid sick leave for non-temporary manufacturing employees who are regularly scheduled to work 20 or more hours a week.

3. The following employees are not eligible to accrue sick leave:

(i) All temporary employees,

(ii) All hourly employees, and

(iii) Active, salaried, non-temporary employees who are rehired retirees of the Employees' Retirement System of Georgia while receiving retirement annuity payments during the first 1,040 hours of work performed in the calendar year.

(b) Accrual:

1. The accrual process begins on the first date of employment. Sick leave is credited to eligible employees at the end of each pay period.

2. Full-time employees paid on a semi-monthly basis will accrue five (5) hours of sick leave at the end of each pay period, provided the employee is in pay status for at least 40 hours during the pay period.

3. Full-time employees paid on a monthly basis will accrue 10 hours of sick leave at the end of each pay period, provided the employee is in pay status for at least 80 hours during the pay period. An agency that compensates employees on a monthly basis may choose to administer sick leave as if those employees were compensated on a semi-monthly basis.

4. Part-time employees scheduled to work at least 20 (but fewer than 40) hours per workweek accrue sick leave as outlined for full-time employees, but at a prorated rate.

(i) The prorated rate is determined by dividing the employee's standard weekly work hours by 40. For example, a part-time employee scheduled for 20 hours per workweek would accrue sick leave at 50% of the rate a full-time employee accrues sick leave (20 hours ÷ 40 = .5 or 50%). A 20-hour employee would earn 2.5 hours of sick leave semi-monthly or five (5) hours monthly.

(ii) The minimum periods of time in pay status required for sick leave accrual noted in Section (7)(b)2-3, above, are similarly prorated for part-time employees. A 20-hour employee would need to be in pay status at least 20 hours during a semi-monthly pay period or 40 hours during a monthly pay period in order to accrue leave at the end of that pay period.

(c) Use and Limitations of Sick Leave:

1. Provided the employee adheres to the procedures for approval of leave, an employee may use accrued sick leave for any absence due to:

(i) Personal illness, injury, or disability;

(ii) Adoption of a child by the employee when the employee's presence is required for health-related reasons;

(iii) Dental or medical care;

(iv) Illness, injury, or disability in the employee's immediate family which requires the employee's presence; or,

(v) Death in the employee's immediate family which requires the employee's presence; however, sick leave used for this purpose shall be limited to five (5) workdays or the equivalent of a workweek.

2. Sick leave may also be used to allow an employee paid time off from work because s/he has been exposed to a contagious disease and may reasonably expose others and endanger their health by being present at work.

3. Employees may not use sick leave before it is actually earned.

4. An agency may by written policy require its employees to use compensatory time and/or deferred holiday time before using sick leave.

5. An employee may be required to furnish evidence to support the use of sick leave if the employee uses 17 or more hours of sick leave in a 30 calendar day period or has demonstrated excessive or abusive use of sick leave.

6. Employees using sick leave during a period of Family and Medical Leave (FMLA) are also subject to the medical certification provisions associated with FMLA. (See Rule 478-1-.23, Family and Medical Leave.)

(d) Excessive or Abusive Use of Sick Leave:

Excessive or abusive use of sick leave is defined as a pattern of intermittent, short-term usage that includes, but is not limited to, the following:

1. Frequent use of sick leave in conjunction with holidays, scheduled off days, weekends, or paydays;

2. Frequent use of sick leave when scheduled for undesirable temporary shifts or assignments, or during periods of peak workload;

3. A request for sick leave for an absence for which other paid leave has previously been denied;

4. Frequent occurrences of illness during the workday;

5. Peculiar and increasingly improbable excuses;

6. Repetitive use of fewer than 17 hours of sick leave in 30-day periods; or,

7. Prior written notification of failure to adhere to procedures for approval of leave, inappropriate attendance, or inappropriate use of leave (e.g., written warning, active attendance plan, etc.).

(e) Illness during Annual Leave:

If an employee is ill for three (3) workdays or more during a period of annual leave, the period of illness may be charged to sick leave if the employee provides satisfactory written evidence supporting the illness during annual leave. A request for substitution of sick leave for annual leave must be made to the agency within two (2) weeks after the employee has returned to duty. No substitution will be allowed for illness that does not last for three (3) or more workdays.

(f) Exhaustion of Sick Leave:

If an absence because of illness, injury, or disability extends beyond available sick leave, the absence may be charged to available annual leave, personal leave, compensatory time, or deferred holiday time, unless the employee applies for, and the agency approves, a leave of absence without pay. Leave donations may be available to an employee who must be absent for an extended period of time after exhausting all paid leave and compensatory time. (See Rule 478-1-.17, Leave Donation, for program details.)

(g) Carryover and Forfeiture of Sick Leave:

1. An employee may accrue up to 720 hours of sick leave. Any leave balance in excess of 720 is forfeited at the end of each month.

2. Sick leave that is forfeited may be restored by the agency if an employee exhausts all paid leave and compensatory time and must be absent because of a personal or immediate family medical condition. The restoration of leave is limited to:

(i) The amount required by the circumstances of the medical condition; and,

(ii) The leave forfeited during the current period of employment. Forfeited leave accrued prior to a break in service cannot be restored except as outlined in Section (7)(h) of this Rule.

(h) Divestment and Restoration of Sick Leave:

1. Upon a break in State service (i.e., separation from State employment for at least one full workday), an employee's accrued sick leave is divested and not paid out. (See Section (10)(e) of this Rule for an exception in such case as when a Community Service Board, County Board of Health, or Board of Health Community Operated Program agrees to accept an employee's leave upon transfer without a break in service.)

2. An employee's accrued sick leave is divested and not paid when an employee transfers into a position that is not entitled to earn sick leave (i.e., temporary position, hourly position for which the employee is paid only for the time worked, or part-time position scheduled for fewer than 20 hours per week).

3. Each agency has discretion to determine whether it will divest accrued sick leave for its active, salaried, non-temporary employees who are rehired retirees of the Employees' Retirement System of Georgia when they become ineligible for paid leave benefits upon reinstatement of retirement annuity payments at the beginning of each calendar year. If an agency chooses not to divest the accrued sick leave, the leave balance will remain credited to the rehired retiree who can then use the leave upon regaining eligibility for paid leave benefits.

4. Employees who return to State employment on or after July 1, 2003, and remain employed for a period of two (2) consecutive years in a position entitled to accrue leave in accordance with this Rule, are eligible to regain sick leave divested when their most recent previous period of State service ended.

5. Divested sick leave includes any sick leave that was available for use at the time of the employee's last separation from State service. It does not include any sick leave forfeited prior to the employee's last separation.

6. The maximum amount of divested sick leave the employee may regain is 720 hours. Divested leave will only be restored to the extent that the restored leave and current unused sick leave total 720 hours. Any remaining balance of divested sick leave will be credited to the employee's current forfeited leave balance.

7. If a Community Service Board, County Board of Health, or Board of Health Community Operated Program accepts leave upon transfer from the State, then sick leave is not considered divested at the time the employee leaves State service. Should the employee later return to State employment, sick leave divested at the time the employee returns to the Executive Branch would not be eligible for reinstatement.

8. To obtain restoration of divested sick leave, an employee must apply in writing to the employing agency and include supporting documentation. The agency will determine the appropriate amount of divested sick leave to be restored.

9. Employees returning to State employment within one year of being laid off by a State agency in accordance with a reduction-in-force plan will immediately receive restoration of the sick and forfeited leave that was lost at the time of layoff, provided they return to a position entitled to accrue leave in accordance with this Rule. (See Section (11) of this Rule.)

(8) **Personal Leave**:

Each year, an employee who has an accrued sick leave balance of more than 120 hours as of November 30 may convert up to 24 hours of the excess sick leave to personal leave.

(a) The employee must have a remaining sick leave balance of at least 120 hours after conversion.

(b) The employee must notify the agency of such a conversion no later than December 31 of that year. Agencies should ensure that employees who are absent in a protected leave status (e.g., FMLA, military leave) during the election period are advised of any eligibility to convert sick leave to personal leave and provided a reasonable opportunity to make the conversion.

(c) Sick leave that is converted during December becomes personal leave on January 1 and cannot be reversed after it is converted. Personal leave is available for use only during the calendar year following conversion.

(d) Each agency, by written policy, may set a minimum period of personal leave to be charged for any use which is only a fraction of that period. The minimum leave period cannot be greater than fifteen (15) minutes.

(e) Personal leave may be used for any reason, upon receiving supervisory approval, with the following exceptions:

1. Employees cannot use personal leave while they are receiving Georgia State-funded wage substitutes, such as Workers' Compensation wage loss benefits.

2. An agency may by written policy require its employees to use available sick leave before using personal leave when the absence involves medical reasons that would qualify for sick leave.

(f) Agencies should make every reasonable effort to accommodate requests to utilize personal leave. An employee is, however, expected to give as much advance notice as possible to minimize disruptions.

(g) Personal leave not used by December 31 of the year the leave was available will be divested and cannot be restored.

(h) Any unused personal leave at the time of an employee's break in State service of at least one full workday is divested and not paid to the employee.

(i) When an employee transfers into a position that is not entitled to earn leave (i.e., temporary position, hourly position for which the employee is paid only for the time worked, or part-time position scheduled for fewer than 20 hours per week) any unused personal leave is divested and not paid.

(j) Personal leave carries no cash value if unused. There will be no payout for unused personal leave upon termination.

(9) **Election to Use Accrued Leave or Personal Leave for Workers' Compensation Absence**:

(a) An employee may not use annual, sick, or personal leave for an accidental injury or occupational disease which is compensable under the Georgia Workers' Compensation Act, unless the employee elects in writing to use paid leave in lieu of receiving Workers' Compensation wage loss benefits.

(b) The leave granted for such purpose will be credited on a day-for-day basis as compensation against any indemnity award by the State Board of Workers' Compensation.

(c) An employee may prospectively submit to the agency a written election to use annual, sick, and/or personal leave in lieu of receiving Workers' Compensation wage loss benefits.

(10) **Transfer of Accrued Leave and Personal Leave**:

The following provisions define the transfer of accrued leave and personal leave when employees transfer to a different State government agency or entity without a break in service from a position entitled to accrue leave into another position entitled to accrue leave. Note that accumulated compensatory time does not transfer between State entities. Upon transfer, the losing organization must payout unused FLSA compensatory time, and unused State compensatory time balances are divested and not paid. (See Sections (23) FLSA Compensatory Time and (24) State Compensatory Time of this Rule.)

(a) Transfer between Executive Branch Agencies:

Unused sick, annual, and personal leave and the record of forfeited leave will transfer between Executive branch agencies.

(b) Transfer between Branches of State Government:

1. Unused sick, annual, and personal leave and the record of forfeited leave will transfer from an Executive branch agency into the Legislative or Judicial branch to the extent the receiving organization agrees to accept the transfer. The employee will be paid for unused annual leave that cannot be transferred, up to a maximum of 360 hours, once the agency has received confirmation that the employee cannot receive credit. Accrued personal leave and sick leave balances that cannot be transferred are not paid and are divested.

2. The unused leave and record of forfeited leave will transfer into an Executive branch agency from the Legislative or Judicial branch only when the losing and receiving organizations have the same leave accrual program. If the Legislative or Judicial branch entity's leave program deviates from this Rule, leave balances and the record of forfeited leave will not transfer into the Executive branch agency, and the employee will be considered a new hire for purposes of graduated annual leave accrual.

(c) Transfer between Board of Regents and Executive Branch:

1. Unused sick, annual, and personal leave and the record of forfeited leave will transfer from an Executive branch agency into a unit of the Board of Regents/University System of Georgia to the extent the receiving organization agrees to accept the transfer. The employee will be paid for unused annual leave that cannot be transferred, up to a maximum of 360 hours, once the agency has received confirmation that the employee cannot receive credit. Accrued personal leave and sick leave balances that cannot be transferred are not paid and are divested.

2. Unused leave and the record of forfeited leave will not transfer into an Executive branch agency from the Board of Regents/University System of Georgia. Transferring employees are considered new hires for purposes of graduated annual leave accrual.

(d) Transfer between Authorities and Executive Branch:

1. Unused sick, annual, and personal leave and the record of forfeited leave will transfer from an Executive branch agency into an authority to the extent the receiving organization agrees to accept the transfer. The employee will be paid for unused annual leave that cannot be transferred, up to a maximum of 360 hours, once the agency has received confirmation that the employee cannot receive credit. Accrued personal leave and sick leave balances that cannot be transferred are not paid and are divested.

2. The unused leave and record of forfeited leave will transfer into an Executive branch agency from an authority only when the losing and receiving organizations have the same leave accrual program. If the authority's leave program deviates from this Rule, leave balances and the record of forfeited leave will not transfer into the Executive branch agency, and the employee will be considered a new hire for purposes of graduated annual leave accrual.

(e) Transfers between Community Service Boards (CSB), County Boards of Health, and Board of Health Community Operated Programs (BOHCOP) and Executive Branch:

1. Unused sick, annual, and personal leave and the record of forfeited leave will transfer from an Executive branch agency into a unit of a CSB, County Board of Health, and BOHCOP to the extent the receiving organization agrees to accept the transfer. The employee will be paid for unused annual leave that cannot be transferred, up to a maximum of 360 hours, once the agency has received confirmation that the employee cannot receive credit. Accrued personal leave and sick leave balances that cannot be transferred are not paid and are divested.

2. Unused leave and the record of forfeited leave will not transfer into an Executive branch agency from any CSB, County Board of Health, or BOHCOP. Transferring employees are considered new hires for purposes of graduated annual leave accrual. An exception applies to classified employees whose unused sick, annual, and personal leave and record of forfeited leave will transfer into the Executive branch.

(11) **Credit for Leave on Return from Layoff**:

The provisions in this section apply to employees rehired into State service in a position entitled to accrue leave in accordance with this Rule within one (1) year of being laid off as a result of agency downsizing or reorganization.

(a) Upon rehire, the employee's sick leave balance existing at the time of layoff will be reinstated.

(b) Any record of forfeited leave existing at the time of layoff will be reinstated, but the leave will not be available for the employee's use, except as provided for in Section (7), Sick Leave, of this Rule.

(c) The period of absence for the layoff will not constitute a break in service for purposes of graduated annual leave accrual.

(d) Upon rehire, the employee's personal leave balance will be reinstated, unless the employee returns in the calendar year after the personal leave would have expired.

(12) **Absence Due to Emergency Office Closures**:

When the Governor, or an agency upon delegated authority by the Governor, closes an office or facility because of weather conditions or other emergency circumstances, affected employees are excused from duty without loss of pay as provided in this Rule section. Employees who are not directly affected by an emergency office closure will not be excused from work.

(a) Employees considered directly affected by a closure:

1. Employees who were scheduled to work in an affected area during an emergency office closure are considered affected by the closure.

2. Non-temporary salaried employees affected by the closure are paid for the scheduled work time they do not work because of the closure. This paid time off is not charged against their accrued leave.

3. The following employees are not eligible for compensation for absences due to emergency closure:

(i) Unaffected employees,

(ii) All temporary employees,

(iii) All hourly employees, and

(iv) Active, salaried, non-temporary employees who are rehired retirees of the Employees' Retirement System of Georgia while receiving retirement annuity payments during the first 1,040 hours of work performed in the calendar year.

(b) Employees considered unaffected by the closure:

Employees who were not scheduled to work in an affected area during an emergency office closure are considered unaffected by the closure. Employees scheduled to use leave or compensatory time during an emergency office closure will be charged for that pre-approved leave or compensatory time because they are considered unaffected by the closure.

(c) Essential Staff:

An agency may determine that it is essential to continue certain functions during an emergency office closure. Employees whose functions are deemed essential may be required to work, rather than excused from duty.

1. Such employees will be compensated as usual for the time worked during their normal work schedule and do not have any right to additional absence or compensation for this time as a result of paid absence authorized for non-essential staff.

2. Essential employees who are required to work additional time because of an office or facility closing will be compensated in accordance with the provisions of statewide policy #7 - Rules, Regulations and Procedures Governing Working Hours, the Payment of Overtime and the Granting of Compensatory Time.

(d) If an employee is absent from duty because of severe weather conditions or other emergencies that do not cause her/his office or facility to close, the agency may permit the employee to:

1. Make up time lost from work. In order to comply with the Fair Labor Standards Act, a non-exempt employee must make up time during the same workweek as the time lost;

2. Charge the period of absence to accrued compensatory time;

3. Charge the period of absence to accrued annual leave;

4. Charge the period of absence to personal leave;

5. Charge the period of absence to deferred holiday time;

6. Telework (if determined appropriate by the agency); or,

If none of the above options are available, place the employee on leave without pay for the period of absence.

(13) **Blood Donation Leave**:

(a) Non-temporary salaried employees are permitted to take up to two (2) hours of paid time off to donate blood, up to four (4) times each calendar year. Employees who donate blood platelets or granulocytes through the plasmapheresis process may take up to four (4) hours of paid time off, up to four (4) times a calendar year.

(b) An eligibility exception applies to active, salaried, non-temporary employees who are rehired retirees of the Employees' Retirement System of Georgia. Such employees are not eligible for blood donation leave while receiving retirement annuity payments during the first 1,040 hours of work performed in the calendar year.

(c) The agency may specify the hours during which an employee may be absent in order to donate blood. An employee who does not use the entire time allowed at the time of each donation does not accrue any right to any subsequent paid or unpaid leave.

(14) **Bone Marrow Donation Leave**:

(a) Non-temporary salaried employees are granted seven (7) workdays of paid leave to donate bone marrow for transplantation. The amount of leave will not be deducted from any accrued leave balance and will be included as service time for purposes of computing any retirement or pension benefits.

(b) An eligibility exception applies to active, salaried, non-temporary employees who are rehired retirees of the Employees' Retirement System of Georgia. Such employees are not eligible for bone marrow donation leave while receiving retirement annuity payments during the first 1,040 hours of work performed in the calendar year.

(c) To receive paid bone marrow donation leave, the employee must have approval from the agency for absence and provide the agency with a written statement from a medical practitioner performing the procedure. If the donation does not occur, bone marrow donation leave is not applicable.

(15) **Organ Donation Leave**:

(a) Non-temporary salaried employees are granted 30 workdays of paid leave to donate an organ for transplantation. The term "organ" means any human organ, including an eye, which is capable of being transferred from the body of

one person to another. The amount of leave will not be deducted from any accrued leave balance and must be included as service time for purposes of computing any retirement or pension benefits.

(b) An eligibility exception applies to active, salaried, non-temporary employees who are rehired retirees of the Employees' Retirement System of Georgia. Such employees are not eligible for organ donation leave while receiving retirement annuity payments during the first 1,040 hours of work performed in the calendar year.

(c) To receive paid organ donation leave, the employee must have approval from the agency for absence and provide the agency with a written statement from a medical practitioner performing the transplant procedure or a hospital administrator indicating that the employee is making an organ donation. If the donation does not occur, organ donation leave is not applicable.

(16) **Court Leave**:

(a) The State recognizes employees' obligation to perform civic duties when summoned as a potential juror or witness and grants time off to employees for such purposes. An employee may not be discharged, disciplined, or otherwise penalized because the employee is absent from employment for the purpose of attending a judicial proceeding in response to a subpoena, summons for jury duty, or other court order or process which requires the attendance of the employee.

(b) Leave Request and Supporting Documentation:

1. An employee who is summoned to perform jury duty or to serve as a witness during scheduled work time and needs to be absent from work is expected to provide a copy of the summons, subpoena, or other court order when requesting leave.

2. Because employees will typically not know in advance how much time will be required to fulfill their court obligation, employees may be required to update the agency at reasonable intervals concerning the time needed for absence from duty.

(c) Paid Court Leave:

1. Paid court leave is granted to non-temporary salaried employees, as outlined in this Rule Section, for the purpose of attending a judicial proceeding in response to a subpoena, summons for jury duty, or other court order or process which requires the attendance of the employee during scheduled work hours. Such paid time off is not charged to an employee's accrued leave.

2. The following employees are not eligible for paid court leave:

(i) All temporary employees,

(ii) All hourly employees, and

(iii) Active, salaried, non-temporary employees who are rehired retirees of the Employees' Retirement System of Georgia while receiving retirement annuity payments during the first 1,040 hours of work performed in the calendar year.

(d) Jury Duty:

1. Eligible employees will receive paid court leave while on jury duty for the time they are otherwise scheduled to work. Employees will be paid only for the time they are required to appear by the court, plus any additional time that is reasonably necessary, in the opinion of the agency, for the employee to prepare for or return from jury duty.

2. Employees will not receive any compensation for time spent serving as a juror that exceeds the employee's regular work schedule.

3. Employees may keep any juror fees and travel allowances they receive from the court.

(e) Court Attendance and Witness Duty Leave:

1. An employee summoned to appear as a witness or required by a court to attend a proceeding will typically be paid in the same manner as an employee serving on a jury. However, an employee will not receive paid court leave to attend a trial, arbitration hearing, or other judicial proceeding in which s/he:

(i) Is charged with a crime;

(ii) Is a plaintiff or defendant;

(iii) Voluntarily appears as a witness;

(iv) Is a witness in a case arising from or related to her/his outside employment or outside business activity;

(v) Is testifying for a fee as an expert witness; or,

(vi) Has any other personal or familial interest in the proceeding.

2. When paid court leave is not applicable, the employee must use annual leave, personal leave, compensatory time, deferred holiday time, or take leave without pay.

(f) Return from Court Leave:

Employees are required to report back to work as soon as they are released from jury duty or other court ordered appearance if the release occurs before the end of the scheduled workday. Management may require verification from the court showing the time served. Failure to return timely from court leave is treated as an unexcused absence.

(17) **Voting Leave**:

The State encourages employees to exercise their right to vote in all federal, state, and local elections. Non-temporary salaried employees may be granted paid time off to vote, up to a maximum of two (2) hours per Election Day, as provided in this section. Paid voting leave is not charged to an employee's accrued leave.

(a) Eligibility for Voting Leave:

1. Paid voting leave is available to employees when their work schedule does not allow them at least two (2) hours (including travel) to vote either before or after work. Employees who are scheduled to begin work at least two (2) hours after the polls open or end work at least two (2) hours before the polls close are not eligible for voting leave.

2. Paid voting leave is not available for voting midday. It must be used either at the beginning or end of the employee's regular workday.

3. Active, salaried, non-temporary employees who are rehired retirees of the Employees' Retirement System of Georgia are not eligible for voting leave while receiving retirement annuity payments during the first 1,040 hours of work performed in the calendar year.

(b) Voting leave covers only the time necessary to give an employee two (2) hours either before or after work to vote. For example, an employee whose work schedule allows only 1½ hours to vote either before or after work would be eligible for 30 minutes of voting leave.

(c) For those employees not eligible for voting leave, agencies have the discretion to arrange flexible work schedules for voting purposes. Agencies may also allow employees to use other available paid leave, other than sick leave, if they are not eligible for voting leave or need more than two (2) hours to vote.

(d) Early Voting:

An agency may allow employees paid voting leave on early voting days if it determines that doing so minimally disrupts normal operations.

(e) Notification Requirement:

Employees are responsible for requesting and obtaining approval from their supervisor in advance of taking time off to vote and should schedule the time off in a manner that minimally disrupts normal agency operations.

(18) **Education Support Leave**:

To supplement work-life balance options for State employees, the State provides up to eight (8) paid hours of leave per calendar year to eligible employees for the purpose of promoting education in Georgia. Such leave is in addition to, and not charged against, an employee's accrued leave.

(a) Education support leave may be taken in increments of fewer than eight (8) hours utilizing the same minimum period an agency has established for other forms of paid leave.

(b) Eligibility:

All eligibility criteria defined below must be met before an employee can use education support leave.

1. Any non-temporary, full-time employee of the State of Georgia, or of any branch, department, board, bureau, or commission thereof, may request to use and be considered for education support leave. An exception applies to active, salaried, non-temporary employees in the Executive branch who are rehired retirees of the Employees' Retirement System. Such employees are not eligible for education support leave while receiving retirement annuity payments during the first 1,040 hours of work performed in the calendar year.

2. Only activities directly related to student achievement and academic support will qualify for education support leave. Such activities may range from early care and learning through higher education. Each State employer maintains the authority to determine, in accordance with the provisions outlined in this Rule, whether an activity would qualify for education support leave.

3. To use education support leave, an employee may be, but is not required to be, the parent of a student.

4. Employees must not receive pay for services they perform while using education support leave.

5. Employees must receive prior approval from their supervisor before providing the services for which they are requesting education support leave. The State employer has discretion to require written verification from a school administrator, teacher, or other official prior to approval.

6. The State employer maintains discretion to approve or deny requests for education support leave based on operational needs or other reasons, such as conduct, attendance, or unsatisfactory work performance. The State employer should ensure that denials are applied consistently for all similarly situated employees.

7. Use of education support leave for any political purpose or agenda is prohibited.

(c) Education support leave does not accumulate, and unused leave does not roll over into subsequent calendar years. Rather, eligible employees may use education support leave for qualifying absences that occur during their regular scheduled work hours, up to a total of eight (8) hours in any calendar year.

(d) Employees can use no more than eight (8) paid hours of education support leave in a calendar year regardless of transfer from one State employer to another. Each State employer is responsible for conducting due diligence to ensure an employee has not exhausted education support leave prior to approving the paid leave.

(e) Education support leave carries no cash value if unused. There will be no payout for unused education support leave upon termination.

(f) Education support leave is not available to support education outside of the State of Georgia.

(19) **Disaster Volunteer Leave**:

The State recognizes that cooperation among government agencies and volunteer service agencies is vital in coping with natural disasters and other emergencies. To help prevent the loss and destruction of life and property, the State believes that employees who are trained and experienced in disaster relief should be able to provide assistance for brief periods without loss of pay and benefits.

(a) Eligibility:

1. To be eligible for paid disaster volunteer leave, an employee must be a certified disaster service volunteer of the American Red Cross whose services have been requested by the American Red Cross or by the Civil Air Patrol Auxiliary of the United States Air Force. The request for leave is subject to approval by the employee's agency and must be coordinated through the Director of Emergency Management.

2. The following employees are not eligible for disaster volunteer leave:

(i) All temporary employees,

(ii) All hourly employees, and

(iii) Active, salaried, non-temporary employees who are rehired retirees of the Employee's Retirement System of Georgia while receiving retirement annuity payments during the first 1,040 hours of work performed in the calendar year.

(b) Paid Disaster Volunteer Leave:

An eligible employee may be granted leave with pay to participate in specialized disaster relief services for the American Red Cross or for the Civil Air Patrol Auxiliary of the United States Air Force. Paid leave to participate in specialized disaster relief services for the Civil Air Patrol Auxiliary of the United States Air Force is available only for service on a numbered mission in support of a county emergency management agency, the Georgia Emergency Management and Homeland Security Agency, or a comparable federal agency.

1. Paid leave under this section cannot exceed 15 workdays in any 12-month period and can be granted only for services related to a disaster occurring within the State of Georgia or in a bordering state which has a reciprocal statutory provision.

2. Paid disaster volunteer leave is not charged against an employee's accrued leave.

3. The employee will be compensated at the rate of pay for the regularly scheduled hours during which the employee is absent from work as a result of disaster volunteer leave.

(20) **Line-of-Duty Injury Leave (Special Injury Leave)**:

A non-temporary salaried employee scheduled to work 30 or more hours per week who becomes physically disabled as a result of an injury incurred in the line-of-duty and caused by a willful act of violence committed by a non-agency employee is entitled to a leave of absence for the period the employee is physically unable to perform her/his duties. Such a leave of absence will be provided in lieu of using accrued leave, and the employee will continue to receive regular compensation, subject to the limitations below.

(a) Leave granted under this provision cannot exceed 180 workdays for any single incident.

(b) An employee seeking leave under this section must submit documentation of disability to the agency.

(c) The following employees are not eligible for line-of-duty injury leave:

1. All temporary employees,

2. All hourly employees, and

3. Active, salaried, non-temporary employees who are rehired retirees of the Employees' Retirement System of Georgia while receiving retirement annuity payments during the first 1,040 hours of work performed in the calendar year.

(d) Benefits received under this provision of the Rule will be subordinate to any Workers' Compensation wage loss benefits that the employee is awarded and will be limited to the difference between the amount of Workers' Compensation benefits actually paid and the amount of the employee's regular compensation.

(e) Injury to Employees of the Department of Transportation:

When an employee of the Department of Transportation is disabled while working in the proximity of traffic movements or equipment movements doing maintenance, construction, or other activities which may be construed as hazardous, the reasons that qualify for line-of-duty injury leave are expanded. Qualifying reasons include: an act of violence, accident, or injury that is caused by a person other than an employee of the agency or an employee of a contractor or subcontractor performing duties under a contract with the agency.

(f) Permanent Disability to Law Enforcement Personnel:

Law enforcement personnel who are permanently disabled by an act of external violence or injury on the job and who qualify for a disability retirement benefit under O.C.G.A. § 47-2-221 are not eligible to receive line-of-duty injury leave under this provision.

(21) **Leave for Contracting TB or Hepatitis on the Job**:

(a) A non-temporary salaried employee who contracts tuberculosis or infectious hepatitis while charged with the care, treatment, or diagnosis of a person infected with tuberculosis or infectious hepatitis, and who has exhausted all available sick and annual leave will be granted a paid leave of absence of one-half her/his total compensation or $150 per month, whichever is less, for the duration of the disability due to the tuberculosis or infectious hepatitis, not to exceed 350 weeks.

(b) The following employees are not eligible for paid leave for contracting TB or hepatitis on the job:

1. All temporary employees,

2. All hourly employees, and

3. Active, salaried, non-temporary employees who are rehired retirees of the Employees' Retirement System of Georgia while receiving retirement annuity payments during the first 1,040 hours of work performed in the calendar year.

(c) An employee receiving leave under this special situation will be given credit for all salary adjustments and advancements, which would have been received had the employee remained in the same position with the same capacity and status held at the time the leave was granted.

(22) **Leave Without Pay**:

(a) Leave without pay may be used in the following situations:

1. When an employee is authorized for absence but does not have available paid leave to cover the absence;

2. When an employee is authorized for absence but foregoes the use of available paid leave for a Workers' Compensation-related absence or for other absence with the concurrence of the agency;

3. When an employee does not have approval for an absence (See Section (22)(g), below);

4. When there is insufficient funding for salaries (See Section (22)(h), below); and

5. When there is insufficient work available (See Section (22)(i), below).

(b) Leave without pay is not included as service time for purposes of computing retirement or pension benefits, unless otherwise specified.

(c) Short-Term Authorized Leave without Pay:

Agencies may grant an employee who is absent, but does not have accrued leave to cover the period of absence, leave without pay for a period of not more than 10 consecutive workdays in any one continuous absence. At the expiration of the approved leave, the employee shall be returned to the same position without any loss of rights provided the employee returns within the terms of the leave granted.

(d) Regular Leave of Absence without Pay:

1. A regular leave of absence without pay allows an employee to take unpaid time off for up to 12 continuous months and be granted return to work if the employee returns within the terms of the leave approval.

2. The employee must submit a written request to the agency. If approved, a written notice specifying the terms and conditions of the approval must be provided to the employee, including a statement indicating that the employee will be reinstated to the former position or to a position of equal grade and pay without loss of any rights provided the employee returns within the terms of the leave granted.

3. Although a regular leave of absence without pay does not constitute a break in service and does not result in divestment of leave, an employee who is taking an approved leave of absence without pay of 30 calendar days or more may request and receive an annual leave payout for all accrued annual leave excluding forfeited leave, up to a maximum of 360 hours. (See Section (6)(e)4 of this Rule.)

(e) Contingent Leave of Absence without Pay:

1. A contingent leave of absence without pay is similar to a regular leave of absence, but does not guarantee a position will be available for the employee's return.

2. The employee may submit a written request to the agency to take a continuous leave without pay for a period not exceeding 12 months. The notice of approval must include the terms and conditions of the approval including a statement that the employee's right to return at the expiration of leave is not guaranteed and will be contingent upon a suitable vacancy being available.

3. Because a contingent leave of absence without pay does not guarantee an employee the right to return to work at the expiration, it may not be considered a reasonable accommodation under the Americans with Disabilities Act, as amended.

4. Although a contingent leave of absence without pay does not constitute a break in service and does not result in divestment of leave, an employee who is taking an approved leave of absence without pay of 30 calendar days or more may request and receive an annual leave payout for all accrued annual leave excluding forfeited leave, up to a maximum of 360 hours. (See Section (6)(e)4 of this Rule.)

(f) Extending a Leave of Absence without Pay:

1. The agency may extend an approved leave of absence without pay when such extension is properly requested. The employee must submit a written request for extension before the expiration of approved leave or follow other agency procedures. If approved, a written notice specifying the terms and conditions of the extension, including any rights to reinstatement, must be provided.

2. A continuous unpaid leave of absence may not exceed 24 months, unless otherwise required as a reasonable accommodation.

(g) Unauthorized Leave without Pay:

1. An employee who is absent without approval may be placed in non-pay status and may be subject to disciplinary action, up to and including termination of employment.

2. An unclassified employee who is absent from duty for three (3) consecutive workdays or equivalent without proper authorization may be considered to have voluntarily resigned. (See Rule 478-1-.15, Changes to Employment Status.)

3. A classified employee who is absent from duty for five (5) consecutive workdays or the equivalent of a scheduled workweek without proper authorization may be considered to have voluntarily resigned. (See Rule 478-1-.28, Voluntary Separations for Classified Employees.)

(h) Furlough - Insufficient Funding:

1. Due to a curtailment of funds, an agency may place employees in a non-pay status as a temporary reduction-in-force pursuant to a plan filed with the Department of Administrative Services.

2. On furlough days, an employee does not perform work and does not receive pay.

3. Employees may not be placed in non-pay furlough status for more than a total of 30 workdays in any 12-month period.

4. Absences under these circumstances will not be charged against accrued leave or compensatory time, will not be considered a break in service, and will not affect eligibility for salary increases.

(i) Temporary Layoff - Insufficient Work:

1. If sufficient work is temporarily unavailable or not feasible, the supervisor may, pursuant to a prior written employment agreement with an employee, place the employee in a non-pay status during the period.

2. The agreement should clearly specify the terms and conditions of the leave without pay and any rights to reinstatement.

3. An employee affected by a temporary layoff because of insufficient work may request the use of accrued annual leave, personal leave, deferred holiday time, or compensatory time to remain in pay status.

4. This provision may not be used in lieu of an adverse action against an employee.

(23) **FLSA Compensatory Time**:

Overtime for non-exempt employees will be governed by the provisions of the Fair Labor Standards Act (FLSA). Overtime worked by non-exempt employees will normally be credited as FLSA compensatory time at a rate of one and one-half hours of compensatory time for each hour of overtime worked. (See statewide policy #7 - Rules, Regulations and Procedures Governing Working Hours, the Payment of Overtime and the Granting of Compensatory Time.)

(a) Overtime:

1. Each agency is responsible for the control of all overtime worked in the agency and for accurately approving and recording such overtime worked in the agency time and leave system.

2. For most non-exempt employees, overtime is credited when the employee actually works more than 40 hours in a defined workweek. The overtime threshold is defined differently for law enforcement, fire protection, hospital, and nursing home employees if they use extended FLSA work period options as provided in statewide policy #7 - Rules, Regulations and Procedures Governing Working Hours, the Payment of Overtime and the Granting of Compensatory Time.

3. Time worked does not include paid time off, such as leave, holidays, or suspension.

4. Unscheduled and unauthorized overtime worked by non-exempt employees will be compensated. However, disciplinary action determined appropriate by the agency, up to and including separation from employment, may be taken against a non-exempt employee who works unscheduled or unauthorized hours.

(b) Use and Limitations of FLSA Compensatory Time:

1. An employee must be granted FLSA compensatory time off within a reasonable time after making the request if the use of such time off does not unduly disrupt operations.

2. An agency may by written policy require its employees to use accumulated FLSA compensatory time before using annual and/or sick leave.

3. For most employees, the maximum FLSA compensatory time accrual is 240 hours at any given time. The maximum accrual is 480 hours for employees in a public safety activity, emergency response activity, or seasonal activity. Compensatory time in excess of 240 hours (480 hours for employees in a public safety activity, emergency response activity, or seasonal activity) must be paid out.

(c) Payment for Overtime:

1. Employees receive pay for overtime only in the following situations:

(i) When the agency approves payment in lieu of FLSA compensatory time as provided in statewide policy #7 - Rules, Regulations and Procedures Governing Working Hours, the Payment of Overtime and the Granting of Compensatory Time.

(ii) Upon exceeding the accumulation limits of FLSA compensatory time. (See Section (23)(b)2.)

(iii) Upon separation from employment with the agency, including transfer from the agency to another State employer.

2. Payment for overtime is typically made the pay period following the pay period in which the overtime is earned. Payment for law enforcement, fire protection, hospital, and nursing home staff with unique FLSA work periods is made the pay period following the FLSA work period during which the overtime is earned.

(24) **State Compensatory Time**:

State compensatory time is hour-for-hour paid time off for employees who work longer than the normally assigned hours in a work period but do not qualify for FLSA compensatory time. Each agency by written policy defines which of its employees, if any, are eligible for state compensatory time as provided in statewide policy #7 - Rules, Regulations and Procedures Governing Working Hours, the Payment of Overtime and the Granting of Compensatory Time.

(a) The maximum state compensatory time accrual allowed is 240 hours at any given time. Any state compensatory time earned in excess of 240 hours is lost and not paid out.

(b) Generally, state compensatory time not used within one (1) year of the date that it is earned is lost and not paid out.

1. An agency may, by written policy, allow state compensatory time earned during the Public Health State of Emergency declared on March 14, 2020, and ended on July 1, 2021, to be used within two (2) years of the date it is earned.

2. Such written policy may be applied to an entire agency or may identify eligible employees or job classes of employees that were so impacted by the increased workload during the Public Health State of Emergency that the state compensatory time was unable to be used prior the regular one (1) year expiration.

(c) Unused state compensatory time is lost upon separation from employment. The employee will not be compensated for such time in any manner, and it will not transfer with the employee to another State entity.

(d) An agency may by written policy require its employees to use accumulated state compensatory time before using annual and/or sick leave.

(25) **Holidays**:

(a) Observing State Holidays:

The State observes 13 public holidays each calendar year on dates declared by the Governor. State offices are closed and employees do not report for work on declared holidays, except as noted below.

1. 24-7 operations, such as hospitals and correctional facilities, will remain open on holidays, and designated staff will report for work.

2. State operations with seasonal fluctuations that result in insufficient availability of work during certain times of the year may establish a policy for its employees to observe holidays during the work down cycle, rather than on the dates declared by the Governor. The policy must be in writing and communicated to all affected employees, and the alternate holidays must be observed within the same calendar year as the dates declared by the Governor.

3. In emergency situations or to meet essential business needs, an agency may require one or more employees to work on a holiday.

(b) Eligibility for Paid Holiday:

1. Salaried employees and other employees designated by the Georgia Industries for the Blind are eligible to receive paid time off for State holidays they observe, as provided in this Rule section.

2. To be eligible for pay on a State holiday, an employee must be in pay status for the full scheduled work shift on either the workday immediately before or immediately after the holiday. "Pay status" means either working or taking approved paid time off.

3. Employees are not paid for a holiday that occurs the day before they enter or reenter State service.

4. Employees are not paid for a holiday that occurs the day after they leave State employment.

5. Employees are not paid for a holiday that occurs on their last day of State employment, unless the holiday is at the end of their normal workweek. (See item 6, below, for an exception.)

6. The compensation for employees retiring from State employment will not be reduced when their last day of employment before retirement falls on a holiday.

7. The following employees are not eligible for paid State holidays:

(i) All temporary employees,

(ii) All hourly employees, and

(iii) Active, salaried, non-temporary employees who are rehired retirees with the Employees' Retirement System of Georgia while receiving retirement annuity payments during the first 1,040 hours of work performed in the calendar year.

8. Part-time salaried employees and part-time employees of the Georgia Industries for the Blind are not paid for a holiday that falls on a day they would not have otherwise been scheduled to work. For example, a part-time employee who is scheduled to work Mondays, Wednesdays, and Fridays, would not be paid for a holiday that falls on a Thursday.

(c) Pay for Holidays and Provisions for Employees on Alternative Work Schedules:

1. Employees eligible for a paid holiday receive pay for the time they would otherwise have worked that day, up to a maximum of eight (8) hours.

2. An agency with full-time salaried employees on alternative work schedules will define the options available to its employees who would have been scheduled for shifts longer than eight (8) hours on the holiday. Such options include allowing employees to:

(i) Revert to an 8x5 work schedule during the week of the holiday (or for a 2-week cycle for employees on a 9-hour workday schedule);

(ii) Use paid leave to supplement the holiday pay and receive full pay for the day; or,

(iii) Work additional time during the week of the holiday to remain in pay status the full workweek.

3. An agency with full-time salaried employees on alternative work schedules whose scheduled day off falls on a holiday may allow such employees to revert to an 8x5 schedule, as indicated in Section 25(c)2, above, or allow them to remain on their alternative schedule and receive equivalent time off for the holiday, as defined in Section (25)(d), below.

(d) Equivalent Time Off or Deferred Holiday Payout:

1. Equivalent time off (i.e., deferred holiday time) will be made available to employees who would otherwise have been eligible for a paid holiday but were either required to work on part or all of a holiday or whose scheduled day off occurred on a holiday. See exceptions in (i) and (ii), below.

(i) Neither equivalent time off, nor additional compensation, will be given to those employed on an academic school year basis whose annual compensation is based on a specified number of workdays, and the holiday is a workday on which their salary is based.

(ii) Part-time employees whose scheduled day off occurred on a holiday are not given equivalent time off or additional compensation for the holiday.

2. Equivalent time off to observe the holiday will not exceed the time actually worked on the holiday or eight (8) hours, whichever is less.

3. An agency may by written policy require its employees to use deferred holiday time before using annual leave, sick leave, personal leave, or compensatory time.

4. Deferred holiday time must be used within 365 days after the day proclaimed as a holiday; otherwise, it must be paid out by the agency.

5. An employee who separates from an agency will be paid for any deferred holiday time not used or paid out prior to separation.

6. An employee will not be paid for a holiday in advance of the observance of the holiday.

7. An employee scheduled to work on a holiday who, without prior approval, fails to report for any portion of the scheduled duty will not be granted deferred holiday time for the time (if any) that was worked on the holiday. Such employee may be subject to leave without pay for the scheduled time not worked and/or other appropriate.

(e) Request to Observe Other Religious Holiday:

1. An employee may request priority consideration for time off from work to observe a religious holiday that is not observed as a State holiday. To receive priority consideration, the request should be made at least seven (7) calendar days in advance.

2. An employee may request priority consideration for up to three (3) workdays in each calendar year.

3. A request by an employee for time off for religious observance cannot be denied unless:

(i) The duties performed by the employee are urgently required, and the employee, in the agency's judgment, is the only person available who can perform the duties; or,

(ii) The agency can otherwise show that accommodating the request would be an undue hardship.

4. Any paid time off granted to observe a religious holiday will be deducted from the employee's accrued annual leave, personal leave, compensatory time, or deferred holiday time available at the time of the observance. If the employee does not have sufficient annual leave, personal leave, compensatory time, or deferred holiday time to cover the period of absence, the agency must allow leave without pay for the absence, unless doing so would be an undue hardship.

(26) **Paid Parental Leave**:

To enhance work-life balance for employees, the State provides full-time employees, as well as hourly employees who meet the criteria noted in subsection (a) 2 (ii) below, with up to 120 hours of paid parental leave in a 12-month period. Paid parental leave is not charged against an employee's accrued leave.

(a) Eligibility:

1. Eligibility for paid parental leave is based on one of the following qualifying life events:

(i) birth of the employee's child;

(ii) placement of a minor child for adoption with the employee; or

(iii) placement of a minor child for foster care with the employee.

2. To be eligible to use paid parental leave for a qualifying life event, an employee must meet one of the two following criteria:

(i) if salaried, the employee must have six continuous months of employment with an employing entity (as defined in O.C.G.A. 45-20-17(a)(2)(A)); or,

(ii) if hourly, the employee must have worked 700 hours for an employing entity (as defined in O.C.G.A. 45-20-17(a)(2)(A)) in the six months immediately preceding the first requested paid parental leave date.

Rehired retirees of the Employees' Retirement System of Georgia, whether salaried or hourly, are not eligible for paid parental leave while receiving retirement annuity payments during the first 1,040 hours of work performed in the calendar year.

(b) Usage of Paid Parental Leave

1. An eligible employee may take a maximum of 120 hours of paid parental leave in a rolling 12-month period. The rolling period will be measured backward from the first date of leave taken. The amount of leave in a rolling 12-month period cannot exceed 120 hours, regardless of the number of qualifying events that occur during that period and regardless of transfers between employing entities (as defined in O.C.G.A. § 45-20-17(a)(2)(A)). Each state employer is responsible for conducting due diligence to ensure an employee has not exhausted the 120- hour allotment prior to approval of paid parental leave.

2. Leave may be taken as needed and in increments of less than eight hours, using the same minimum period an agency has established for other forms of paid leave.

(c) If an employee eligible for paid parental leave is also eligible for leave under the federal Family and Medical Leave Act (FMLA) (see Rule 478-1-.23, Family and Medical Leave), an agency may, by written policy, require paid parental leave to run concurrently with FMLA leave.

(d) Agencies may require employees to submit appropriate supporting documentation for the use of paid parental leave. Any required supporting documentation shall be the same as that required for the use of federal family and medical leave under Section (7) of Rule 478-1-.23, Family and Medical Leave, for the same qualifying event.

(e) Any paid parental leave remaining 12 months after the initial qualifying event shall not carry over for future use.

(f) Unused paid parental leave shall have no cash value and shall not be paid out at the time of the employee's separation from employment.

Cite as Ga. Comp. R. & Regs. R. 478-1-.16

AUTHORITY: O.C.G.A. §§ 45-20-3**,** 45-20-3.1**,** 45-20-4**.**

HISTORY: Original Rule entitled "Veteran's Preference" adopted. F. July 31, 1985, eff. July 1, 1985, as specified by the Board.

Amended: F. Jan. 22, 1988; eff. Nov. 12, 1987, as specified by the Board.

Amended: R. 478-1-.0C repealed and renumbered R. 478-1-.16 of same title adopted. F. Aug. 11, 1992; eff. July 2, 1992, as specified by the Board.

Amended: F. Oct. 17, 1994; eff. Oct. 6, 1994, as specified by the Board.

Amended: F. Apr. 22, 1997; eff. Apr. 9, 1997, as specified by the Board.

Amended: F. Oct. 8, 1997; eff. Sept. 25, 1997, as specified by the Board.

Amended: F. Jan. 13, 2003; eff. Dec. 4, 2002, as specified by the Board.

Amended: F. Jan. 5, 2006; eff. Dec. 22, 2005, as specified by the Board.

Repealed: New Rule entitled "Absence from Work" adopted. F. Dec. 23, 2008; eff. Dec. 17, 2008, as specified by the Board.

Amended: F. Oct. 28, 2009; eff. Aug. 27, 2009, as specified by the Board.

Amended: F. July 30, 2010; eff. July 16, 2010, as specified by the Board.

Amended: F. Dec. 30, 2013; eff. Sept. 25, 2013, as specified by the Board.

Amended: F. July 1, 2015; eff. June 25, 2015, as specified by the Board.

Amended: F. Jan. 17, 2017; eff. Jan. 9, 2017, as specified by the Board.

Amended: F. July 15, 2021; eff. June 22, 2021, as specified by the Board.

Amended: F. Nov. 23, 2021; eff. Nov. 3, 2021, as specified by the Board.

Amended: F. Mar. 29, 2023; eff. Mar. 16, 2023, as specified by the Board.

Department 500. STATE BOARD OF PODIATRY EXAMINERS

Chapter 500-5. CONTINUING PODIATRIC MEDICAL EDUCATION

500-5-.01 Continuing Education Hours. Amended

(1) The purpose of continuing education hours for podiatrists is to maintain and enhance the professional competence of podiatrists licensed to practice in Georgia for the protection of the health and welfare of the people of the State of Georgia.

(2) As a requirement for the biennial renewal of his/her license, a podiatrist must certify to the Georgia State Board of Podiatry Examiners the completion of not less than fifty (50) hours of approved continuing education in the preceding two (2) years prior to the license expiration date.

(a) No more than twenty-five (25) hours shall be obtained from online courses/correspondence courses/webinar, and such courses must be approved by the Council of Podiatric Medical Education (CPME).

(b) Up to ten (10) hours may be obtained live (in person) from any healthcare related source.

(c) At least thirty (30) continuing medical education hours must be approved by the Council of Podiatric Medical Education (CPME) and/or the Georgia Podiatric Medical Association (GPMA).

(d) Every Podiatrist who maintains an active DEA certificate and prescribes controlled substances, except those holding a residency training permit, shall complete, at least one time, three (3) hours of CME that is specifically designed to address controlled substance prescribing practices. The controlled substance prescribing CME shall include instruction on controlled substance prescribing guidelines, recognizing signs of the abuse or misuse of controlled substances, and controlled substance prescribing for acute pain management.

(i) Beginning the biennium ending August 31, 2023, Podiatrists must certify on their renewal application that the controlled substance prescribing CME requirement has been met. Once completed, this specific CME requirement shall not be required for subsequent renewals.

(ii) Any controlled substance prescribing guidelines coursework that meets the requirements of this rule will count toward completion of this requirement provided that the podiatrist can submit documentation of such to the satisfaction of the Board.

(iii) Completion of this requirement may count toward the CME requirement for license renewal if submitted during the biennium in which the coursework was taken.

(3) A podiatrist who has obtained a Georgia license by reciprocity, reinstatement or by examination, and who must renew his or her Georgia license for the first time, shall obtain the following number of continuing education hours prior to renewal of the license:

(a) If the license was issued or reinstated during the first six (6) months of the biennial renewal period, from September of the odd numbered year to the end of the following February, the full fifty (50) hours of continuing education shall be required for renewal in accordance with (2)(a-d) of this rule;

(b) If the license was issued or reinstated during the following twelve (12) months of the biennial renewal period, from March of the even numbered year to February of the odd numbered year of the licensure period, thirty (30) hours of continuing education shall be required for the license renewal;

(i) No more than five (5) hours shall be obtained from online courses/correspondence courses/webinar, and such courses must be approved by the Council of Podiatric Medical Education (CPME).

(ii) Up to five (5) hours may be obtained live (in person) from any healthcare related source.

(iii) At least twenty (20) continuing medical education hours must be approved by the Council of Podiatric Medical Education (CPME) and/or the Georgia Podiatric Medical Association (GPMA) and must be obtained live (in person).

(iv) Podiatrist who maintain an active DEA certificate and prescribes controlled substances, except those holding a residency training permit, shall complete, at least one time, three (3) hours of CME that is specifically designed to address controlled substance prescribing practices. The controlled substance prescribing CME shall include instruction on controlled substance prescribing guidelines, recognizing signs of the abuse or misuse of controlled substances, and controlled substance prescribing for pain management. Completion of this requirement may count toward the CME requirement for license renewal if submitted during the biennium in which the coursework was taken.

(c) If the license was issued or reinstated during the last six (6) months of the biennial renewal period, from March of the odd numbered year to August of the odd numbered year, the licensee shall be exempt from the continuing education requirements for that biennial licensing cycle and no continuing education hours shall be required to renew the license.

Cite as Ga. Comp. R. & Regs. R. 500-5-.01

AUTHORITY: O.C.G.A. §§ 43-1-4**,** 43-1-25**,** 43-35-9**,** 43-35-15**.**

HISTORY: Original Rule entitled "General Requirements" adopted. F. Sept. 7, 1989; eff. Sept. 27, 1989.

Repealed: New Rule of same title adopted. F. May 15, 1995; eff. June 4, 1995.

Repealed: New Rule entitled "Continuing Education Hours" adopted. F. May 7, 2012; eff. May 27, 2012.

Amended: F. Sep. 4, 2015; eff. Sept. 24, 2015.

Amended: F. Mar. 1, 2017; eff. Mar. 21, 2017.

Amended: F. Nov. 22, 2022; eff. Dec. 12, 2022.

Note: Rule 500-5-.01, correction of a recently discovered typographical error as requested by the Board, in subparagraph (2)(c), "*At least thirty (30) continuing medical education hours must be approved by the Council of Podiatric Medical Education (CPME) and/or the Georgia Podiatric Medical Association (GPMA) and must be obtained live (in person).*" corrected to "*At least thirty (30) continuing medical education hours must be approved by the Council of Podiatric Medical Education (CPME) and/or the Georgia Podiatric Medical Association (GPMA)." The text "... and must be obtained live (in person)*" was deleted to reflect the Rule as originally promulgated and adopted. Effective March 15, 2023.

Department 505. PROFESSIONAL STANDARDS COMMISSION

Chapter 505-2. CERTIFICATION

505-2-.39 Certification Appeal

(1) **Summary.** This rule creates a formalized system of tiered reviews that allows individuals to appeal certification decisions resulting in a denial based on a staff analysis of application documentation. The decision at each tier is based solely on review of an individual's written appeal. There are two (2) tiers of appeal, which include:

(a) Tier 1. A review by the Certification Appeals Committee with a written decision by the Chair of the Certification Appeals Committee of the Georgia Professional Standards Commission (GaPSC).

(b) Tier 2. A review and written decision by the Executive Secretary of the Georgia Professional Standards Commission (GaPSC).

(2) Appeal Procedures.

(a) The individual must begin the appeal process at Tier 1 and a decision must be rendered before requesting a Tier 2 appeal.

(b) The appeal must be in writing, sent by U.S. Mail, FedEx, UPS or another mail carrier.

1. Appeals will not be received by phone, email, or delivered in person.

(c) The written appeal must be sent to the Georgia Professional Standards Commission,

ATTN: Executive Secretary, and must contain the following information:

1. Name (as listed in the individual's MyPSC account), certification identification number, mailing address, email address, and telephone number.

2. The tier being requested (Tier 1 or Tier 2).

3. A concise statement describing the nature of the appeal and why it should be granted.

4. Supporting documentation that might constitute evidence that supports the appeal including transcripts, physician statements, etc.

(d) The failure of an individual to request an appeal within sixty (60) calendar days from the date the certification request is denied is considered as a waiver of the right to appeal. Individuals are responsible for tracking the delivery of their appeal to the GaPSC.

1. Tier 1 appeals must be received by the Executive Secretary of the GaPSC within sixty (60) calendar days of the date of certificate issuance or the -GaPSC notification letter of denial.

2. Tier 2 appeals must be received by the Executive Secretary of the GaPSC within sixty (60) calendar days of the date of the GaPSC notification letter of denial of the Tier 1 appeal.

3. Appeals must be received before the first day of the month in order to be reviewed during that month's meeting. If after initial review it is determined that additional information or documentation is needed, a subsequent review of the appeal will be completed during the next scheduled appeal meeting after the requested documentation is received.

4. Appeals may only be requested upon initial denial of a certification request as outlined above. Appeals submitted prior to initial denial will not be considered.

i. Educators may not resubmit a request for a transaction that was previously denied in order to meet the 60-day Tier 1 or Tier 2 appeal submission timeline.

ii. Tier 2 decisions are final. Individuals may not appeal the same issue after a final written Tier 2 decision is determined.

(e) When a Tier 1 or Tier 2 appeal is received, staff will send the appellant written verification of receipt by email and the scheduled date for review.

(f) After a decision to grant or deny an appeal has been made, the appellant will receive correspondence posted to MyPSC detailing the decision.

(g) The effective date of the certificate update based on an approved appeal will be the date the Certification Appeals Committee met and determined to honor the appeal request or the date the Executive Secretary reviewed and made a determination for the Tier 2 appeal.

Cite as Ga. Comp. R. & Regs. R. 505-2-.39

AUTHORITY: O.C.G.A. § 20-2-200**.**

HISTORY: Original Rule entitled "Reinstatement of Certificates" adopted. F. Dec. 18, 1991; eff. Jan. 7, 1992.

Repealed: New Rule entitled "Certificate Extension for Active Military Duty" adopted. F. Dec. 16, 1992; eff. July 1, 1993, as specified by the Agency.

Repealed: New Rule entitled "Technology/Career Education" adopted. F. Feb. 20, 2004; eff. Mar. 15, 2004, as specified by the Agency.

Amended: F. Aug. 20, 2004; eff. Sept. 15, 2004, as specified by the Agency.

Repealed: New Rule of same title adopted. F. June 7, 2010; eff. July 15, 2010, as specified by the Agency.

Amended: F. Sep. 25, 2013; eff. Oct. 15, 2013, as specified by the Agency.

Repealed: New Rule entitled "Certification Appeal" adopted. F. Jun. 11, 2014; eff. July 1, 2014, as specified by the Agency.

Amended: F. Dec. 18, 2018; eff. Jan. 15, 2019, as specified by the Agency.

Repealed: New Rule of same title adopted. F. June 11, 2020; eff. July 1, 2020, as specified by the Agency.

Amended: F. Mar. 24, 2023; eff. Apr. 15, 2023, as specified by the Agency.

Department 511. RULES OF GEORGIA DEPARTMENT OF PUBLIC HEALTH

Chapter 511-3. ENVIRONMENTAL HEALTH HAZARDS

Subject 511-3-8. BODY ART

511-3-8-.01 Authority

The legal authority for this Chapter is Chapter 31-40 of the Official Code of Georgia Annotated.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.01

AUTHORITY: O.C.G.A. § 31-40-1 *et seq.*

HISTORY: Original Rule entitled "Applicability" adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013.

Repealed: F. Jun. 20, 2014; eff. July 10, 2014.

Adopted: New Rule entitled "Authority." F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.02 Purpose

The purpose of this Chapter is to establish reasonable standards for individuals performing body art procedures and for the facilities in which those procedures are provided. If followed, such standards should ensure the health and safety of all individuals performing and receiving these services. They also provide for the permitting and regular inspection of studios wherein Body Art activities are to be performed and contain enforcement provisions including revocation of the certification of any person or permit of any studio deemed in violation of this Chapter.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.02

AUTHORITY: O.C.G.A. § 31-40-1 *et seq.*

HISTORY: Original Rule entitled "Definitions" adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013.

Repealed: F. Jun. 20, 2014; eff. July 10, 2014.

Adopted: New Rule entitled "Purpose." F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.03 Applicability

(1) These regulations do not apply to a physician or osteopath licensed under O.C.G.A. Chapter 34 of Title 43, or to a technician acting under the direct supervision of such licensed physician or osteopath.

(2) Individuals who pierce only the lobe of the ear (and not the ear cartilage, nose or eyebrows, etc.) with a pre-sterilized single-use stud-and clasp ear piercing system are exempt from these regulations, provided that such ear-piercing systems conform to the manufacturer's directions on use and applicable FDA requirements.

(3) The Department and the applicable Health Authority retain the authority to investigate consumer complaints and outbreaks relating to the alleged misuse or improper disinfection of ear-piercing systems.

(4) These rules shall take effect six months after official posting by the Secretary of State.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.03

AUTHORITY: O.C.G.A. §§ 31-40-1**,** 31-40-6**.**

HISTORY: Original Rule entitled "Provisions" adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013.

Repealed: F. Jun. 20, 2014; eff. July 10, 2014.

Adopted: New Rule entitled "Applicability." F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.04 Definitions

(1) "Antimicrobial solution" means any solution capable of killing or used to retard the growth of microorganisms approved for application to human skin, and includes all products labeled accordingly, as approved by the FDA; when referring to antimicrobial mouthwash, only those approved for use may be allowed in the studio, such as hydrogen peroxide, alcohol-based solution and others commonly found in hospital or dental settings.

(2) "Antiseptic" means an agent or substance that will destroy or inhibit the growth and development of infectious microorganisms on human skin or mucous membranes.

(3) "Aseptic technique" means to render or maintain free from infectious material so as to prevent transfer or transmission of infectious agents.

(4) "ASTM" means the American Society for Testing Materials International.

(5) "Autoclave" means an apparatus (chamber or cassette) for sterilization of equipment utilizing steam pressure at a specific temperature over a period of time per manufacturer's specifications. For the purposes of this Chapter, all chamber and cassette autoclaves shall be Class B, Class S, or other medical grade autoclave as specified by manufacturer for sterilization of body art equipment and jewelry.

(6) "Biomedical waste" means the following:

(a) Pathological waste, which means all recognizable human tissues which are removed during procedures;

(b) Biological waste, which means blood and blood products, exudates, secretions, suctioning, and other body fluids which contains free liquids and cannot be or are not directly discarded into a municipal sewer system. The term does not include materials, such as wipes or paper towels, containing small amounts of blood or body fluids that would not drip if the material were compressed;

(c) Sharps, which means any discarded article that may cause punctures or cuts, such as needles and razor blades; and

(d) Discarded equipment and parts, excluding expendable supplies and materials included in paragraphs (a) through (c) of this subsection, which have not been decontaminated, and which were in contact with infectious agents.

(7) "Blood" means human blood, human blood components, and products made from human blood.

(8) "Bloodborne pathogens" means pathogenic microorganisms present in human blood that can cause disease in humans. These pathogens include but are not limited to Hepatitis B virus (HBV), Hepatitis C virus (HCV), and Human Immunodeficiency virus (HIV).

(9) "Board of Health" means the local County Board of Health or Health Authority.

(10) "Body art" means a tattoo or piercing placed on the body of a person for aesthetic or cosmetic purposes. This definition does not include practices considered medical procedures by the Georgia Medical Composite Board, such

as implants under the skin, which are prohibited unless such medical procedures are performed by a person licensed by the Georgia Medical Composite Board.

(11) "Body artist" means any person who performs body art. Such term shall not include a physician or osteopath licensed under Chapter 34 of Title 43, or a technician acting under the direct supervision of such licensed physician or osteopath.

(12) "Body artist certification" means a certification issued by the Department to a specifically identified person who is qualified to engage in the practice of body art in accordance with these regulations and in conjunction with a permitted studio.

(13) "Body Art Advisory Committee" means a committee that may be established by the Department to provide technical guidance on the practice of body art. If established, the committee shall be composed of one individual from the state environmental health program, one District Environmental Health Director, one County Environmental Health Specialist, one person with infection control training, and two members of the body art profession with current certification.

(14) "Body Art Studio" means any facility or building on a fixed foundation wherein a body artist performs body art, whether or not for profit.

(15) "Body Art Studio permit" means Health Authority approval in writing authorizing the permit holder to operate a Body Art Studio for the purpose of engaging in the practice or business of body art procedures. Health Authority approval shall be granted solely for the practice of body art pursuant to these regulations, and the following types of Body Art Studio permits shall be issued: tattoo, body piercing, and microblading.

(16) "Body piercing" means puncturing or penetrating the skin or mucosa of a client for the purpose of inserting jewelry or other adornment into the body for non-medical purposes; body piercing includes ear piercing, except when ear piercing procedure is performed with a pre-sterilized single-use stud and clasp ear-piercing system (Piercing Gun) conforming to the manufacturer's directions on use and applicable FDA requirements.

(17) "Cleaning/clean room" means the area in a Body Art Studio used in the sterilization, sanitation or other cleaning of instruments or other equipment used for the practice of body art and shall be separated from any other area in the studio by means of doors, nonabsorbent curtains, or similar approved partition extending from floor to ceiling or a height of eight feet.

(18) "Client" means an individual upon whom one or more body art procedures are to be performed.

(19) "Contaminated" means the presence or the reasonably anticipated presence of blood, other potentially infectious materials, or potentially harmful chemicals on an item or surface.

(20) "Contaminated waste" means any liquid or semi-liquid blood or other potentially infectious material; contaminated items that would release blood or other potentially infectious material in a liquid or semi-liquid state if compressed; items on which there is dried blood or other potentially infectious material, and which are capable of releasing these materials during handling; sharps and any wastes containing blood or other potentially infectious materials.

(21) "Convention" means a large meeting of people who gather to talk about their shared work or other interests or to make decisions as a group or to perform body art procedures, such as an industry trade show.

(22) "Cosmetic tattoo" means a tattoo, by someone other than a licensed physician, which includes but is not limited to microblading of the eyebrow, lips, and other parts of the body for beauty marks, hair imitation, or areola repigmentation. This term includes any procedures whether referred to as but not limited to, microdermapigmentation, micropigment implantation, micro-needling with the use of pigment or any other similar procedure and for the purpose of this Chapter has the same meaning as "tattoo."

(23) "Critical violation" means a violation of this Chapter which poses a serious hazard to health and safety. Critical violations shall include but not limited to the following:

(a) Autoclave does not meet minimum time, pressure, or temperature requirements, or written standard operation procedures are not established or approved by the Health Authority;

(b) Lack of a negative spore test on a minimum frequency of every 40 hours of operation of the autoclave but not less than on a monthly basis;

(c) Non-disposable tubes and needles are not sterilized, packaging has been compromised or contaminated, or expiration date has been exceeded;

(d) Work area is not equipped as required or is not stocked;

(e) Reuse of single use articles;

(f) Sterile instruments are not properly handled to prevent contamination;

(g) Body artists with exposed infectious lesions on hands and arms not restricted from body art procedures;

(h) Body artists and employees not practicing proper cleanliness and good hygienic practices;

(i) Water supply not approved, hot and cold running water under pressure not available, or written emergency procedure for water not established before or approved for a studio operating during an interruption of water;

(j) Cross connection allowing back-siphonage present in plumbing system;

(k) Hand washing facilities not available or accessible for body artists and employees;

(l) Toxic items not properly stored, labeled, or used;

(m) Prohibited procedures performed within the studio; and

(n) Non-certified artist performing procedures.

(24) "Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

(25) "Department" means the Georgia Department of Public Health or its agents.

(26) "Disinfectant" means a solution registered as a disinfectant by the U.S. Environmental Protection Agency (EPA) and intended to destroy or inactivate specific viruses, bacteria, or fungi on clean, inanimate surfaces. Labeling should specifically state that the product is bactericidal, virucidal, fungicidal, and tuberculocidal.

(27) "Disinfection" means the destruction of disease-causing microorganisms on inanimate objects or surfaces, thereby rendering these objects safe for use or handling.

(28) "Easily cleanable" means that surfaces are readily accessible and made of such materials and finish and so fabricated to be smooth and non-absorbent such that residue may be effectively removed by normal cleaning methods.

(29) "Ear piercing" means the puncturing of the lobe of the ear with a pre-sterilized single-use stud-and clasp ear piercing system following manufacturer's instructions. Under no circumstance shall ear piercing studs and clasp be used anywhere on the body other than the lobe of the ear unless otherwise specified by the manufacturer.

(30) "EPA" means the United States Environmental Protection Agency.

(31) "EPD" means the Georgia Department of Natural Resources, Environmental Protection Division.

(32) "Equipment" means all machinery, including fixtures, containers, vessels, tools, devices, implements, furniture, display and storage areas, sinks, and all other items used in connection with the operation of a Body Art Studio.

(33) "FDA" means the United States Food and Drug Administration.

(34) "Germicidal solution" means any solution which destroys microorganisms and is so labeled.

(35) "Gloves" means medical grade disposable single use gloves labeled for surgical or examination purposes. Vinyl gloves are not allowed to be used to perform body art procedures.

(36) "Guest body artist" means a visiting body artist, tattooist, body piercer, or microblader, not certified by the Department possessing a guest body artist permit issued by the Health Authority to perform body art in a permitted Body Art Studio.

(37) "Guest body artist permit" means a seven-day permit by the Health Authority which allows a person to practice body art as a tattoo artist, body piercer, or microblader, in accordance with this Chapter while under the direct supervision of a body artist holding a valid Body Artist Certification in the same category.

(38) "Handwash facilities" means an installed sink/lavatory providing an adequate supply of potable hot and cold running water under pressure, through a mixing valve or combination faucet, used solely for washing hands, arms, or other portions of the body. The facility shall include a soap dispenser, soap, and single use disposable towels in a covered dispenser.

(39) "Handwashing sink" means a lavatory or plumbing fixture especially placed for use in personal hygiene and designed for the washing of the hands in the facility, including an automatic handwashing facility.

(40) "Health Authority" means the local County Board of Health

(41) "Hot water" means water that attains and maintains a minimum temperature of 100°F.

(42) "Imminent health hazard" means any condition, deficiency, or practice which, if not corrected, is very likely to result in disease transmission, serious injury, or loss of life to any person. If an imminent health hazard exists because of an emergency such as a fire, flood, interruption of electrical or water service for two or more hours, sewage malfunction, misuse of poisonous or toxic materials, onset of an apparent bloodborne illness outbreak, serious injury, gross unsanitary occurrence or condition, or other circumstances that may endanger public health, then operations must be immediately discontinued, and the Health Authority must be notified.

(43) "Instruments" means hand pieces, needles, needle bars, and other instruments that may come in contact with a client's body or may be exposed to bodily fluids during any body art procedure.

(44) "ISO" means the International Standards Organization.

(45) "Jewelry" means any ornament used in any body art procedure which is inserted into a newly pierced area and meets the following minimum requirements:

(a) Steel that is ASTM F138 compliant or ISO 5832-1 compliant.

[Note: The EEC Nickel Directive is a regulation that requires a low rate of nickel release for all materials used for costume or fine jewelry, belt buckles, watches, or other metallic accessories with direct skin contact. It does not specify nor prove that a material is safe to wear in the body; therefore, compliance with this directive alone is not sufficient for meeting the APP initial jewelry standards.]

(b) Steel that is ISO 10993-6, 10993-10 and/or 10993-11 compliant.

(c) Unalloyed titanium that is ASTM F67 or ISO 5832-2 compliant.

(d) Alloyed Titanium (Ti6Al4V ELI) that is ASTM F136 compliant or ISO 5832-3 compliant.

(e) Alloyed Titanium (Ti6Al7Nb ELI) that is ASTM F1295 compliant or ISO 5832-11 compliant.

(f) Polytetrafluoroethylene (PTFE) that is ASTM F754 compliant.

(g) Any polymer or plastic material that is ISO 10993-6, 10993-10 or 10993-11 compliant and/or meets the United States Pharmacopeia (USP) Class VI material classification.

(h) Solid 14 karat or higher yellow, white, or rose gold that is nickel and cadmium free.

(i) Gold jewelry used for initial piercing may not be:

1. Plated, unless using materials approved by this standard over solid 14 karat or higher yellow, white, or rose gold that is 14k or higher, or white rhodium.

2. Gold-filled

3. Gold overlay/vermeil

(j) Solid unalloyed or alloyed platinum that is cadmium, nickel, and lead free.

(k) Unalloyed Niobium (Nb) that is ASTM B392 compliant. This includes but is not limited to:

1. Commercial grade 2 Niobium

2. Commercial grade 4 Niobium that contains 1% Zirconium

(l) Glass that is lead free. This includes but is not limited to:

1. Fused quartz

2. Borosilicate

3. Soda-lime

(m) All threaded or press-fit jewelry used for initial piercing must have internal tapping (no threads on exterior of posts and barbells).

(n) For body jewelry purposes, surfaces and ends must be smooth and free of nicks, scratches, burrs, stamps, hallmarks, polishing compounds, and other potentially harmful residues.

(o) Metals must have a consistent mirror finish on surfaces that frequently come in contact with tissue.

(p) All jewelry used for initial piercing on people above the age of twelve must be ASTM F2999 compliant.

(q) All jewelry used for initial piercing on people age twelve and under must be ASTM F2923 compliant.

(r) Copies of the jewelry manufacturer's documentation, which verify compliance with standards, must be available for inspection on request.

(46) "Major structural modifications" means modifications in which the resulting structure differs significantly from what was originally approved by the Health Authority at the time of the Health Authority's issuance of the permit, including, but not limited to changes involving the addition, removal, or relocation of structurally existing walls, openings, floor or counters; or modifications to plumbing, mechanical, or electrical components other than decorative fixtures. It does not include minor cosmetic changes such as painting, moving equipment for detailed cleaning, detailed cleaning of physical facilities, replacing carpeting in the lobby area, or repairing damage to walls, floors, and ceilings.

(47) "Microblading of the eyebrow" means a form of cosmetic tattoo artistry where ink is deposited superficially in the upper three layers of the epidermis using a handheld or machine powered tool made up of needles known as a microblade to improve or create eyebrow definition, to cover gaps of lost or missing hair, to extend the natural eyebrow pattern, or to create a full construction if the eyebrows have little to no hair.

(48) "Minor" means an individual under the age of eighteen.

(49) "NSF" means the National Sanitation Foundation.

(50) "Occupational exposure" means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of a body artist's or employee's duties.

(51) "OSHA" means the Occupational Safety and Health Administration.

(52) "Other potentially infectious material" means the following human body fluids: semen, vaginal secretions, saliva, and any other body fluid visibly contaminated with blood.

(53) "Permit" means Health Authority approval in writing authorizing the permit holder to operate a Body Art Studio for the purpose of engaging in the practice or business of body art procedures.

(54) "Permit holder" means the partnership, corporation, association, or the person or group of persons who maintain and control the Body Art Studio and personnel, and who are legally responsible for the operation of the studio.

(55) "Person" means an individual, any form of business or social organization or any other non-governmental legal entity, including but not limited to corporations, partnerships, limited-liability companies, associations, trusts, or unincorporated organizations.

(56) "Personal protective equipment" means specialized clothing or equipment, such as gloves or lap cloth, worn by a body artist or employee for protection against a hazard. General work clothes not intended to function as protection against a hazard are not considered to be personal protective equipment.

(57) "Physician" or "osteopath" means an individual licensed to practice medicine in Georgia pursuant to OCGA Chapter 34 Title 43.

(58) "Pierce" or "piercing" means body piercing.

(59) "Potable water" means water that is from an approved water system meeting Georgia Safe Drinking Water Standards

(60) "Proof of age" means any government issued State Driver's License, Military ID, Passport or US Passport Card, or State-Issued ID Card that describes the individual as eighteen years of age or older as applicable, contains a photograph and appears to be valid.

(61) "Safe materials" means articles manufactured for the specific purpose of body art procedures which are unlikely to cause injury or disease under proper use and care.

(62) "Sanitary" means clean and free of agents of infection or disease.

(63) "Sanitized" means the application of an EPA registered sanitizer on a cleaned surface by a process that provides sufficient concentration of chemicals for enough time to reduce the microorganism level, including pathogens, to a safe level on instruments and equipment in accordance with the label instructions.

(64) "Sewage" means human excreta, all water-carried waste, and liquid wastes from residences, buildings, commercial or industrial establishments.

(65) "Sharps" means any object, sterile or contaminated, that may intentionally or accidentally cut or penetrate the skin or mucosa.

(66) "Sharps container" means a puncture-resistant, leak-proof container that can be closed for handling, storage, transportation, and disposal that is labeled with the International Biohazard Symbol and specifically made for the disposal of sharps.

(67) "Single-use" or "single-service" means disposable products or items that are intended for one-time, one-person use and are properly disposed of by appropriate measures after use on each client. Single-use items include but are not limited to cotton swabs or balls, single-use instruments, tissues or paper products, paper or plastic cups, gauze and sanitary coverings, razors, piercing needles, stencils, ink cups, and protective gloves.

(68) "Solid waste" means refuse, garbage, trash, rubbish, and any other item which could cause an unsanitary condition or undesirable health and safety conditions.

(69) "Spore" means a dormant, non-reproductive body able to survive adverse environmental conditions including high temperatures, dryness, and lack of nourishment for long periods of time. Under the proper conditions, the spore may revert to an actively multiplying form of the bacteria, fungi, or protozoa.

(70) "Spore test" means a biological monitoring process in which resistant spore growth on test media is processed in a studio's autoclave to verify that it is functioning properly. A third-party culturing service must be engaged for this process to provide documentation serving as a tangible record and legal document verifying the autoclave's ability to achieve proper sterilization.

(71) "Sterilization" or "sterilize" means the use of a physical or chemical procedure by which all forms of microbial life, including bacteria, viruses, spores, and fungi are destroyed including highly resistant bacterial endospores. This is achieved by holding in a commercial, Class B, Class S, or other medical grade autoclave according to manufacturer's instructions as approved by the Health Authority.

(72) "Sterilization indicator" means a tape, strip, bag, or other device designed to change color to indicate that sterilization temperature has been achieved during the sterilization procedure.

(73) "Sterilizer" means an autoclave certified to meet generally accepted medical standards. See Autoclave.

(74) "Tattoo" means to mark or color the skin of any person by pricking in, inserting, or implanting indelible pigments or dyes under the skin, including without limitation cosmetic tattooing and microblading of the eyebrow.

(75) "Temporary Body Art Studio" means any location, place, facility, or business for which a permit has been granted to practice body art by the Health Authority for no more than a period of seven consecutive days in connection with conventions or industry trade shows.

(76) "Temporary Body Artist" means any person not certified by the Department, who performs body art in a temporary Body Art Studio who is responsible for complying with applicable provisions of these regulations. The permit to practice body art by the Health Authority is granted for no more than a period of seven consecutive days only for the purpose of product demonstration in connection with conventions or industry trade shows.

(77) "Temporary Body Artist Permit" means the issuance of a seven-day permit by the Health Authority which allows a person to practice body art as a tattoo artist, body piercer, or microblader, in accordance with this Chapter for the purpose of product demonstration in connection with conventions or industry trade shows.

(78) "Ultrasonic cleaning unit" means a device approved by the Health Authority with a lid, physically large enough to fully submerge instruments in liquid, which removes foreign matter from the instruments by means of high energy and high frequency oscillations transmitted through the contained liquid.

(79) "Universal precautions", also known as "standard precautions", means treating all blood and body fluids as if they contain bloodborne pathogens and taking proper precautions to prevent the spread of any bloodborne pathogens.

(80) "Waste" means solid waste, sewage, blood and body fluids or other waste resulting from the operation of a Body Art Studio.

(81) "Work area" or "workstation" means an area where clients receive body art from an individual body artist.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.04

AUTHORITY: O.C.G.A. § 31-40-5**.**

HISTORY: Original Rule entitled "Locations of Land Disposal Sites" adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013.

Repealed: F. Jun. 20, 2014; eff. July 10, 2014.

Adopted: New Rule entitled "Definitions." F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.05 Permits

(1) Body Art Studio permits.

(a) No person shall operate a Body Art Studio without first obtaining a Body Art Studio permit in accordance with the timeframes specified in these rules. Upon the effective date of this Chapter, as stated in Section 511-3-8-.03(4), existing Body Art Studios shall have one year to obtain and display a valid Department of Public Health Body Art Studio permit issued by the Health Authority. This deadline may be extended for all applicants upon public notice by the Department on its website.

(b) Permits shall be issued by the Health Authority on forms prescribed by the Department and shall designate one or more specialties which may be practiced in the studio: tattooing, piercing, or microblading. The Health Authority may authorize an electronic signature method for signing prescribed forms.

(c) Permits shall only be issued to a single permit holder operating at a single location. A permit shall not be transferable from one place to another, or from one person to another.

(d) An applicant for a Body Art Studio permit shall provide written evidence of satisfactory compliance with the provisions of this Chapter and any other applicable laws and regulations. The permit holder shall be responsible for maintaining compliance with the requirements of this Chapter and any other applicable laws and regulations.

(e) The permit shall be displayed near the front entrance of the studio within fifteen feet of the front or primary public door and between five feet and seven feet from the floor, and in an area where it can be read at a distance of one foot away or, if for some reason this is impractical, in an area approved by the Health Authority.

(f) The permit shall expire when the Body Art Studio ceases to operate, relocates, or has a change of ownership. For purposes of this subsection, a "change of ownership" means the transfer of a 50% or greater interest in the studio to a person or entity not currently holding an interest.

(g) An operating permit is not transferable from one studio to another.

(h) An application for a Body Art Studio must be submitted to the Health Authority no less than fourteen days prior to the start of construction or major structural modifications.

(i) The applicant shall certify in its application the names and exact duties of the employees and body artists who will be responsible for carrying out the rules and policies adopted by the permit holder. The following information shall be included for each such person:

1. Valid driver's license or Government issued ID;

2. Date of birth (DOB);

3. Home address;

4. Telephone numbers; and

5. Department-issued Body Artist Certification of all artists who will practice in the studio.

(j) Each application for a permit shall be accompanied by an 8 ½" x 11" or larger page containing a detailed, to-scale floor plan of the Body Art Studio. Such plan shall show the accurate placement of each of the following: windows, doors, chairs, tables, sinks, restrooms, waiting area, and all equipment placement whether affixed or not for clients or staff, and shall include room measurements.

(k) Specification sheets for all equipment to be in the studio shall be provided as determined by the Health Authority. Studios using all commercially purchased, individually packaged, sterile, single-use, disposable jewelry and instruments shall provide adequate manufacturer documentation to avoid requirements for an ultrasonic cleaner and autoclave.

(l) The ownership of the studio shall be fully disclosed in its application for a permit. The individual owners shall be listed, if a sole proprietorship or partnership; the members, if a limited liability company; and the shareholders, if a corporation. No permit shall be issued if any person with an ownership interest in the proposed studio is under eighteen years old, has previously had a body art permit or certification revoked, or is currently the subject of disciplinary proceedings related to body art chapter enforcement.

(m) The applicant shall show that it has demonstrated compliance with zoning and other local requirements regarding proper location and establishment of Body Art Studios, including any applicable building, fire safety, plumbing, mechanical and electrical codes.

(n) The Health Authority shall issue a Body Art Studio permit after:

1. Receipt of a completed application;

2. Payment of applicable fees;

3. Plan review approval; and

4. An inspection of the proposed studio which reveals that it is in compliance with requirements of this Chapter.

(o) Before being granted a permit, each Body Art Studio shall develop a written statement of policies and standard operating procedures that address:

1. Sterilization of instruments and equipment and Emergency Sterilization Procedures;

2. Body Artist and Employee Health;

3. Body Artist and Employee Drug and Alcohol Use;

4. Sanitizing areas and equipment between use;

5. Disposal of waste;

6. Record keeping;

7. Client screening;

8. Aftercare;

9. Exposure control plan;

10. Emergency plan for accidents that addresses first aid procedures; and

11. Water Interruption Plan.

(2) Body Art Studio Permit Holder Responsibilities. Upon acceptance of the permit issued by the Health Authority, in order to retain the permit, the permit holder shall:

(a) Ensure compliance with the provisions of this Chapter, including the conditions of any variance granted by the Department, and allow inspections by representatives of the Health Authority during hours of operation;

(b) Immediately discontinue operations and notify the Health Authority if an imminent health hazard may exist; and

(c) Replace existing facilities and equipment that do not comply with this Chapter if:

1. The Health Authority directs the replacement because the facilities and equipment constitute a public health hazard or no longer comply with the criteria upon which the facilities and equipment were accepted; or

2. The facilities and equipment require replacement due to wear and tear in the normal course of operation.

(3) A copy of the most current version of this Chapter must be in the studio at all times.

(4) Temporary Body Art Studio Permits.

(a) A temporary Body Art Studio permit may be issued for body art services provided outside of a permitted location for the purpose of product demonstration in connection with body art conventions or industry trade shows.

(b) A temporary Body Art Studio permit may be obtained after submitting an application that contains the name of the body artists, location, the operating days, hours of operation of the temporary studio, and the plans or description of the temporary studio. The applicant will provide information related to solid waste, biomedical waste, and sharps disposal.

(c) A temporary Body Art Studio permits will not be issued unless the applicant demonstrates to the Health Authority successful compliance with all the requirements of this Chapter. This includes education, disclosure, consent, minimum design standards, and furnishing and fixtures requirements.

(d) The application for a permit must be submitted for review by the Health Authority at least thirty days prior to the event and all applicable fees must be paid before a permit will be issued.

(e) The following criteria pertain to permits for temporary Body Art Studios:

1. No permit may be valid for more than seven consecutive days.

2. An applicant shall not receive more than two seven-day permits during a thirty-day period.

3. A permit shall not be transferable from one place to another, or from one person to another.

4. A permit shall be posted in a prominent and conspicuous place as determined by the Health Authority so clients can readily observe it.

5. The temporary Body Art Studios shall meet the requirements of this Chapter. In addition, the following will be required:

(i) A convenient handwashing facility must be located within 30 feet of each work or demonstration area for body artist handwashing. In the absence of a hand wash station meeting the requirements of this Chapter, this facility shall consist of, at least, a catch bucket, a pressurized or gravity fed, hands-free container filled with potable water, liquid antimicrobial hand soap, and individual paper towels at the service site.

(ii) Only single-use, disposable, pre-sterilized supplies may be used.

(5) Prohibited Facilities.

(a) Neither Body Art Studios nor body art procedures shall be allowed in a private residence or other structure used for human habitation, food services, retail sales not directly related to body art, grocery stores, convenience stores, or similar purposes; however, body art operations may take place in completely separate areas of certain businesses deemed safe and appropriate by the Health Authority.

(b) Body Art Studios shall not be allowed in automobiles, mobile trailers, tents, recreational vehicles, or other non-fixed facilities.

(6) Prohibited Procedures and Restrictions.

(a) Implants, 3-D procedures, or other procedures involving insertion of foreign objects completely under the skin.

(b) Any body art procedure that results in the permanent removal of tissue or that requires medical equipment such as scalpels or dermal punches.

(c) The use of manipulating needles, sharps, or any other item to serve the purpose of a scalpel is prohibited.

(d) Scarification (branding, cutting, or skin peeling), suspension piercing, neck rings, foot binding, corseting, play piercing, and tooth gems/dental bonding are prohibited.

(e) In accordance with O.C.G.A. Section 16-5-71, no person under the age of eighteen shall be tattooed.

(f) It shall be unlawful for any person to pierce the body, with the exception of the ear lobes, of any person under the age of eighteen for the purposes of allowing the insertion of earrings, jewelry, or similar objects into the body, unless the body piercing is performed in the presence of the person's parent or legal guardian. The parent or legal guardian must have proper identification and sign a written consent form provided by the Body Art Studio. The consent form must indicate the methods and parts of the minor's body upon which the body piercing procedure is performed. Nipple and genital piercing are prohibited on minors regardless of parental or legal guardian consent.

(g) With the exception of microblading of the eyebrow, and in accordance with O.C.G.A. Section 16-12-5, it shall be unlawful for any person to perform tattooing or cosmetic micropigmentation procedures within any area within one inch of the nearest part of the eye socket. Such prohibited procedures include but are not limited to tattooing eyeliner.

(h) No person except a duly licensed physician or a Georgia licensed cosmetic laser practitioner as defined under Chapter 34 Title 43 shall remove or attempt to remove any tattoo.

(7) Body artists shall not be under the influence of alcohol or drugs that cause drowsiness or other impairment while performing body art procedures.

(8) Body Art Studios and body artists shall refuse services to any person who appears to be under the influence of alcohol or drugs.

(9) Live animals shall be excluded from within the studio and adjacent areas under the control of the permit holder. However, this exclusion does not apply to fish in clean, maintained aquariums which are maintained outside of an artist work area. Service animals accompanying disabled persons shall be permitted in the studio.

(10) The body artist must be free of any open wound that cannot be covered, any infection, or other visible or communicable diseases that can be transmitted as a result of carrying out the body art procedures

(11) A body artist shall not conduct any form of body art activity upon any area of a client that evidences the presence of any rash, lesion, or other visible signs of infection.

(12) Body art procedures not covered within these rules which have the potential for transmitting infectious disease must receive written departmental approval prior to being offered to clients.

(13) Body art shall only be performed by individuals holding a current Body Artist Certification issued by the Department, a Temporary Body Artist Permit or Guest Body Artist Permit issued by the Health Authority, and only at a location named in a Body Art Studio Permit or a Temporary Body Art Studio Permit.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.05

AUTHORITY: O.C.G.A. § 31-40-2**.**

HISTORY: Original Rule entitled "Management of Land Disposal Sites" adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013.

Repealed: F. Jun. 20, 2014; eff. July 10, 2014.

Adopted: New Rule entitled "Permits." F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.06 Employee Files

(1) The permit owner of a Body Art Studio must maintain a file on all body artists who practice within the studio. Employee and body artist files must be kept on location for the duration of the person's employment and for a minimum of two years after the person is no longer employed. The employee and body artist files must be available for inspection and include the Department issued Body Artist Certification and a copy of the body artist's government issued ID.

(2) Any Body Artist working in an existing Body Art Studio on the effective date of this Chapter, as stated in Section 511-3-8-.03(4), shall have one year to obtain the Department certifications and education required in this Chapter. This timeframe may be extended for all applicants upon public notice by the Department on its website.

(3) The permit holder of the Body Art Studio shall make available, at no cost to the employee or body artist, the Hepatitis B vaccination series to body artists and any other employees who may have occupational exposure to blood or other potentially infectious material. For new employees and body artists, the vaccination must be offered after the worker is trained and within ten days of initial assignment to a job where there is potential occupational exposure, unless the employee has previously received the vaccine series, antibody testing has revealed that the worker is immune, the vaccine is contraindicated for medical reasons, or if the individual has declined the Hepatitis B vaccination series in writing. The employer must obtain a written opinion from the licensed healthcare professional within fifteen days of the completion of the evaluation for vaccination. This written opinion is limited to whether hepatitis B vaccination is indicated for the worker and if the worker has received the vaccination.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.06

AUTHORITY: O.C.G.A. § 31-40-5.

HISTORY: Original Rule entitled "Vector Reduction Management" adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013.

Repealed: F. Jun. 20, 2014; eff. July 10, 2014.

Adopted: New Rule entitled "Employee Files." F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.07 Body Artist Certification and Decertification

(1) No person shall practice body art procedures without first obtaining a Body Artist Certification from the Department in accordance with the timeframes specified in these rules. Upon the effective date of this Chapter, as stated in Section 511-3-8-.03(4), existing Body Artists shall have one year to obtain and display a valid certificate issued by the Department. This deadline may be extended for all applicants upon public notice by the Department on its website.

(2) An applicant for a Body Artist Certification must be at least eighteen years of age and shall demonstrate to the Department successful compliance with all education, disclosure, consent, and fee requirements of this Chapter. An applicant shall request certification in one or more of the following areas:

(a) Tattooing;

(b) Piercing; and/or

(c) Microblading.

(3) Applicants shall submit a completed Department application provided by the Health Authority. The Department may authorize an electronic signature method for signing prescribed forms. As part of the application process, the applicant shall:

(a) Pay an exam fee not to exceed $50.00 to the Health Authority;

(b) Pay Department Certification fees; and

(c) Complete and pass a Department-approved exam on this Chapter.

(4) Initial application for the Body Artist Certification shall include:

(a) Name;

(b) Date of Birth;

(c) Residence address;

(d) Mailing address;

(e) Phone number;

(f) Photocopy of a government issued ID;

(g) Proof of United States Citizenship or lawful residence in the United States.

(h) Proof of successful completion of an OSHA-compliant Bloodborne Pathogen/Universal Precautions training program and Basic First Aid/CPR classes given or approved by the Department; and

(i) Valid documentation of a Hepatitis B Virus (HBV) vaccination status including:

1. Documentation of HBV vaccination; or

2. Laboratory evidence of immunity or documentation of no response following two full HBV vaccine series; or

3. Documentation stating the vaccine is contraindicated for medical reasons. Contraindications require a dated and signed licensed health care professional's statement specifying the name of the Body Artist applicant or employee and that the vaccine cannot be given; or a

4. Signed certificate of vaccination declination of HBV as required by OSHA.

(5) No Body Artist Certification will be issued without successfully completing an approved course in Bloodborne Pathogens/Universal Precautions and a Basic First Aid/CPR course approved by the Department.

(6) The Body Artist Certification shall be valid for one year and may be renewed on a standard date to be determined by the Department. Issuance and renewal shall be conditioned on compliance with this Chapter, successful completion of required courses, and paying required certification fees to the Department. Certifications shall be issued on forms provided by the Department.

(7) A body artist shall only perform that form of body art which is indicated in the Body Artist Certification.

(8) A copy of the Body Artist Certification shall be posted where it may be readily observed by clients.

(9) For annual Body Artist Certification Renewal, each artist:

(a) Must submit a completed Body Artist Certification Renewal Application;

(b) Must pay all applicable fees to the Department;

(c) Must submit proof of current immunizations and education requirements as referenced in the initial certification section; and

(d) Must not have any unresolved disciplinary actions or have committed any illegal activities related to the industry during the previous certification period.

(10) Temporary Body Artist Permit.

(a) No body artist shall practice body art at a Temporary Studio without a Temporary Body Artist Permit issued by the Health Authority or Body Artist Certification issued by the Department.

(b) The Health Authority may issue a seven-day permit to engage in the practice of body art if the body artist is not currently certified by the Department. Such temporary body artist permit will allow a person to practice body art only in a permitted Temporary Studio under the supervision of the permit holder. Temporary Body Artist Permits will not be issued unless the applicant demonstrates to the Health Authority successful compliance with all education, disclosure, consent, and requirements of this Chapter. The issuance of a Temporary Body Artist Permit is conditioned upon the following:

1. A completed application submitted no less than ten days in advance of the start date of providing services; the Health Authority may authorize an electronic signature method for signing prescribed forms.

2. Documentation that the applicant has received education requirements set by this Chapter;

3. Must be listed on the temporary Body Art Studio permit application where the applicant will perform body art;

4. Payment of all applicable fees as determined by the Health Authority; and

5. Documentation of a Hepatitis B Virus (HBV) vaccination completion status including:

(i) Documentation of HBV vaccination;

(ii) Laboratory evidence of immunity or documentation of no response following two full HBV vaccine series;

(iii) Documentation stating the vaccine is contraindicated for medical reasons, including a dated and signed licensed health care professional's statement specifying the name of the Body Artist applicant or employee and that the vaccine cannot be given; or

(iv) Signed certificate of vaccination declination of HBV as required by OSHA.

(11) Guest Body Artist Permit.

(a) No visiting out-of-state body artist shall practice body art without a Guest Body Artist Permit issued by the Health Authority.

(b) The Health Authority may issue a seven-day permit to engage in the practice of body art. Such guest body artist permit will allow a person to practice body art under the direct supervision of a body artist holding a valid Department issued certification in the same category. The issuance of a Guest Body Artist Permit is conditioned upon the following:

1. A completed application submitted no less than ten days in advance of the start date of providing services; the Health Authority may authorize an electronic signature method for signing prescribed forms.

2. Documentation that the applicant has received education specified in by this Chapter;

3. A letter of consent signed by a body artist certified by the Department, a copy of the Body Artist Certification of the sponsoring artist, and a copy of the Body Art Studio permit where the applicant will perform body art;

4. Payment of all applicable fees as determined by the Health Authority; and

5. Documentation of a Hepatitis B Virus (HBV) vaccination completion status including:

(i) Documentation of HBV vaccination;

(ii) Laboratory evidence of immunity or documentation of no response following two full HBV vaccine series;

(iii) Documentation stating the vaccine is contraindicated for medical reasons, including a dated and signed licensed health care professional's statement specifying the name of the Body Artist applicant or employee and that the vaccine cannot be given; or

(iv) Signed certificate of vaccination declination of HBV as required by OSHA.

(c) An applicant shall not receive more than two seven-day Guest Body Artist Permits during a thirty-day period.

(12) Decertification and Denial.

(a) The Department may deny or revoke the certification of any person for one or more of the following reasons:

1. Failure to comply with this Chapter;

2. A material misrepresentation or omission on any application for certification or renewal;

3. Failure to pay certification or renewal fees;

4. A civil judgement based on conduct related to the Body Art industry; or

5. Such other conduct, as in the opinion of the Department, would render certification of the person a threat to the health or safety of the public.

(b) The Department may, in its discretion, impose a lesser sanction where the circumstances of the violation do not merit revocation of the certification, including suspension or probation on specific terms.

(c) Disciplinary Procedure.

1. The Department may, but is not required to, refer information concerning a certified person to the Body Art Advisory Committee, if established. The Committee shall review the evidence and make a recommendation to the Department.

2. The Department shall give written notice of any disciplinary action taken pursuant to this regulation by certified mail or statutory overnight delivery to the last known address of the person or entity. The notice shall set forth the facts which support disciplinary action.

3. Upon request made in writing and received by the DPH Office of General Counsel no later than twenty days after the written notice of disciplinary action is mailed, the Department shall refer the matter to the Georgia Office of Administrative Hearings for hearing in accordance with its rules. The burden of proof shall be on the person or entity seeking the hearing.

4. Effective date of disciplinary action.

(i) All disciplinary actions by the Department are effective twenty days after the certified person's receipt of the notice, unless otherwise specified in the notice, or unless the certified person makes a timely request for a hearing.

(ii) Upon a written finding set forth in the notice of disciplinary action that the public safety, health, and welfare imperatively require emergency action, the suspension of the certification shall be effective immediately upon issuance of the notice.

5. Upon request for exculpatory, favorable, or arguably favorable information relative to pending allegations involving disciplinary action, the Department shall either furnish such information, indicate that no such information exists, or provide such information to the hearing officer for *in camera* inspection pursuant to O.C.G.A. § 50-13-18(d)(2).

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.07

AUTHORITY: O.C.G.A. §§ 31-40-2**,** 31-40-3**,** 31-40-4**,** 50-13-13**,** 50-13-18**.**

HISTORY: Original Rule entitled "Pathogen Control Management" adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013.

Repealed: F. Jun. 20, 2014; eff. July 10, 2014.

Adopted: New Rule entitled "Body Artist Certification and Decertification." F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.08 Client Files

(1) Every Body Art Studio shall require that each client complete an application, client evaluation and informed consent form approved by the Health Authority prior to having any body art activity performed upon or to their body. All records required by this Rule may be kept in digital or print form.

(2) The application shall contain a minimum of the following:

(a) Name;

(b) Date of birth;

(c) Copy of government issued identification (ID);

(d) In the case of piercings for a minor client, the parent or legal guardian's government issued ID, proof of parentage or legal guardianship through a certified copy of a birth certificate or court order of guardianship respectively, state-issued photo ID or other Health Authority approved ID for the minor client, and the written consent to conduct the contemplated Body Art activity to be performed upon the minor client;

(e) A brief description and location of the Body Art procedure to be performed;

(f) The phone number of the Health Authority and instructions for the client, or in the case of a minor client, the minor client and parent or legal guardian, to contact the Health Authority with any complaint, question or concern regarding safety, sanitization, or sterilization procedures;

(g) The name and certification number of the Body Artist who is to conduct the Body Art on the client or minor client;

(h) Signature of the client or, in the case of a minor client, the signature of the client's parent or legal guardian signed in the presence of the Body Artist;

(i) A statement by the client attesting that he or she is not under the influence of alcohol or drugs;

(j) The signature of the Body Artist; and

(k) The dates of all signatures.

(3) The Body Art Studio shall complete a client evaluation to ensure that the client inform the Body Artist of any known chronic medical or communicable conditions, including, but not limited to the following:

(a) History of diabetes or any disorder or medication that affects the neurological or immune system in fighting infection;

(b) Bloodborne conditions such as Hepatitis B, Hepatitis C, HIV;

(c) History of hemophilia or any other blood clotting abnormalities;

(d) History of skin disease, skin lesions, or skin sensitivities to soap, disinfectants, etc.;

(e) History of allergies or adverse reactions to pigments, dyes, or other skin sensitivities;

(f) History of epilepsy, seizures, fainting or narcolepsy;

(g) The taking of medications such as aspirin or other anticoagulants (such as warfarin, XareltoT, Plavix, EliquisT, etc.) which thin the blood and or interfere with blood clotting;

(h) History of or suspicion of adverse reaction to latex or products containing latex; and

(i) History of keloid formation.

(j) If the client is pregnant or has been pregnant in the last three (3) months; and,

(k) If the client has eaten in the last four (4) hours.

(4) The body artist must tell the client to consult a physician prior to the procedure if they have any concerns related to the evaluation questions outlined in (3).

(5) The Body Artist shall inform the client, verbally and in writing that the health conditions outlined in (3) may increase health risks associated with receiving a body art procedure.

(6) If the client refuses to disclose the information in (3) of this subsection, then the Body Artist shall require the client to sign a form stating that the client was asked to provide the information and refused.

(7) The client must sign an informed consent form that includes but not limited to the following:

(a) Client is voluntarily obtaining services of their own free will and volition;

(b) Client has had the opportunity to read and understand the documents presented to them;

(c) Client has the ability to ask questions about the procedure; and

(d) Client has received and understands written and verbal aftercare.

(8) For each client, proper records of identification, an application, client evaluation, and informed consent form shall be kept, in digital or print form, and retained for a minimum of three years. Records must be kept on premises for a minimum of one year. All three years of records must be available to the Department or Health Authority upon request. The files must be stored in a manner that prohibits access from unauthorized personnel.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.08

AUTHORITY: O.C.G.A. § 31-40-5**.**

HISTORY: Original Rule entitled "Application Rate" adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013.

Repealed: F. Jun. 20, 2014; eff. July 10, 2014.

Adopted: New Rule entitled "Client Files." F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.09 Minimum Design Standards

(1) A studio shall provide work areas separate from observers or visitors. An individual body artist shall not perform body art procedures simultaneously on different clients.

(2) There shall be adequate floor space for each work area in the studio. At a minimum, an adequate area includes space for all items required by this Chapter, such as a handwashing sink, a waste receptacle, and a sharps container, as well as space for the Body Artist to safely perform body art procedures.

(a) Work areas must be separated from lobby and waiting areas by nonabsorbent curtains, knee walls, or other partitions approved by the Health Authority.

(b) Floors shall be nonabsorbent and easily cleanable.

(c) Work areas shall provide privacy, if desired by the client, by means of nonabsorbent curtains or similar approved partitions.

(d) If body art procedures are conducted in an environment where airborne particulates are of concern (including but not limited to hair and nail salons), the body art procedures shall take place behind a floor-to-ceiling partition or in a separate room.

(3) A Body Art Studio shall have a cleaning room to be used exclusively for the cleaning, disinfection, and sterilization of instruments.

(a) The cleaning room shall have a separate stainless-steel instrument sink reserved only for instrument disinfection activities and shall be equipped with hot and cold running water. Sink shall have smooth welds and joints, be free of breaks and open seams, and be easily cleanable.

(b) The cleaning room shall be separated from any other area in the studio by means of doors, nonabsorbent curtains, or similar approved partition extending from floor to ceiling or a height of at least eight feet and must be labeled to prevent clients from entering the room.

(c) The cleaning room shall be equipped with an ultrasonic cleaning unit and a Class B or S medical grade autoclave or another approved autoclave. The autoclave shall be used to sterilize all non-disposable and reusable body art equipment.

(d) The instrument sink, ultrasonic cleaning unit, and autoclave shall each be separated by a minimum distance of forty-eight inches unless using a splashguard approved by the Health Authority.

(e) The cleaning room walls, floors, doors, windows, skylight, and other components shall be constructed of smooth, nonabsorbent, durable material and be maintained in good repair.

(f) The requirement for a cleaning room with an ultrasonic cleaning unit and autoclave may be waived by the Health Authority if the studio only stores and uses commercially purchased sterile single-use disposable body art tattoo instruments.

(4) Hand washing facilities shall be provided within 30 feet of each workstation and must be fully accessible in an unobstructed pathway. Additional hand sinks may be placed at the discretion of the Health Authority if warranted. Hand washing facilities will also be made available in the cleaning rooms. These are in addition to the required sinks in toilet rooms. Studios that are open and operating on the effective date of this Chapter will be required to have one hand wash sink that is available by an unobstructed pathway within thirty feet of each work area not to include any hand wash sinks in toilet rooms.

(5) Hand washing sinks and instrument sinks shall be used for those intended purposes only.

(6) At least one service sink or one curbed cleaning facility equipped with a floor drain shall be provided and conveniently located for the cleaning of mops or similar wet floor cleaning tools and trash cans and for the disposal of service water and similar liquid waste. After the effective date of this Chapter, mop sinks will be required upon renovation to any existing studio or any major plumbing renovation.

(7) The use of common towels and cloths for any purpose is prohibited.

(8) Sanitary Facilities and Controls.

(a) Enough potable water for the needs of the Body Art Studio shall be provided from a public water system, or from an approved nonpublic water system that is constructed, maintained, and operated according to applicable state or local codes as amended.

(b) Non-Public Water Supply - Approved Wells.

1. Water from a non-public water system shall follow guidelines established in the Georgia Department of Natural Resources, Environmental Protection Division (EPD) Memorandum of Understanding for Non-Public Water Supplies.

2. Sampling Report. The most recent sample report for the non-public water system shall be retained on file in the Body Art Studio and results must be forwarded to the Health Authority.

(c) Sewage. All sewage, including liquid water, shall be disposed of by a public sewage system or by an approved on-site sewage disposal system.

(d) Plumbing. Plumbing shall be sized, installed, and maintained according to law, state and local code. There shall be no cross-connection between the potable water supply and any other water supply or other possible source of contamination.

(9) Toilet Facilities.

(a) There shall be a minimum of one restroom containing a toilet and a handwash facility readily accessible to any Body Artist or client that does not require passage through a cleaning room and work area with the exception that access through such areas may be allowed if the risk of contamination is determined to be minimal.

(b) Toilet rooms. Toilet rooms opening directly into work or client waiting areas shall be completely enclosed and shall have tight-fitting, solid self-closing doors, which shall be closed except during cleaning or maintenance.

(c) All toilet rooms shall have sufficient mechanical ventilation to keep them free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes.

(d) Toilet fixtures. Toilet fixtures shall be kept clean and in good repair. A supply of toilet tissue shall always be provided at each toilet. Easily cleanable receptacles with trash liners shall be provided for waste materials. Toilet rooms shall have at least one covered waste receptacle.

(10) Handwash Facilities.

(a) Handwash facilities shall be designed, installed, and maintained according to law, state and local code.

(b) Each handwashing sink shall be equipped to provide hot water at a temperature of at least 100ºF (38 ºC). Hot and cold water shall be tempered by means of a mixing valve or combination faucet. Any self-closing, slow-closing, or metering faucet used shall be designed to provide a flow of water for at least twenty seconds without the need to reactivate the faucet.

(c) A soap dispenser and a supply of antiseptic, hand-cleaning soap or detergent shall be available at each handwash facility. A fully covered or enclosed towel dispenser with a supply of single use sanitary towels shall be conveniently located near each handwash facility. Easily cleanable waste receptacles with self-closing lids with hands-free controls shall be conveniently located near the hand washing facilities.

(d) Sinks, soap dispensers, paper towel dispensers, and all related fixtures shall be kept clean, in good repair, and supplied at all times.

(11) Solid Waste.

(a) Non-Biomedical Waste Containers.

1. Garbage and refuse shall be kept in durable, easily cleaned containers that do not leak and do not absorb liquids.

2. All outside refuse containers shall be covered and maintained.

3. Containers used in work areas shall be kept covered when not in use. At least one waste receptacle shall be provided in each artist area. Receptacles in the body artist area shall be emptied daily or more if necessary. Solid waste shall be removed from the premises at least weekly or more if necessary.

4. There shall be a sufficient number of containers to hold all the garbage and refuse that may accumulate.

(b) Garbage and refuse shall be disposed of at such frequency to prevent the development of odor and the attraction of insects, rodents, or vermin.

(c) Biomedical Waste Containment.

1. Disposal of infectious waste such as blood, fluids, used inks, or other liquid waste may be deposited directly into a drain connected to an approved sewer system or on-site sewage system via a sink dedicated to that purpose.

2. Containment of biomedical waste shall be in a manner and location which affords protection from animals, rain, and wind, does not provide a breeding place or a food source for insects and rodents, and minimizes exposure to the public.

3. Biomedical waste shall be segregated by separate containment from other waste at the point of origin.

4. Biomedical waste, except for sharps, shall be placed in containers which are impervious to moisture and have strength sufficient to preclude ripping, tearing, or bursting under normal conditions of use. The containers shall be securely closed so as to prevent leakage or expulsion of solid or liquid wastes during storage, handling, or transport.

5. Sharps shall be contained for storage, transportation, treatment, and subsequent disposal in leak-proof, rigid, puncture-resistant containers which are taped closed or tightly lidded to preclude loss of contents.

(i) Rigid containers of discarded sharps and all other disposable containers used for containment of biomedical waste shall be red or orange in color and clearly identified with the universal biohazard symbol or clearly marked with the word "Biohazard."

(ii) Biomedical waste contained in disposable containers as prescribed above shall be placed for storage, handling, or transport in disposable or reusable pails, cartons, boxes, drums, or portable bins. The containment system shall have a tight-fitting cover and be kept clean and in good repair. The containers may be of any color and shall be conspicuously labeled with the universal biohazard symbol and the word "Biohazard" on the sides so as to be readily visible from any lateral direction when the container is upright.

(iii) Reusable containers used for shipment of biomedical waste shall be thoroughly washed and decontaminated each time they are emptied. Reusable pails, drums, dumpsters, or bins used for containment of biomedical waste shall not be used for other purposes.

(iv) Sharps container must be placed within arm's reach and below eye level at their point of use.

(12) Physical Facilities, Floors, Walls, Ceilings, and Attached Equipment: Floors, walls, ceilings, and attached equipment and decorative materials shall be kept clean and maintained in good repair.

(a) Floors.

1. Floors and floor coverings of all work areas, dressing rooms, locker rooms, toilet rooms and vestibules shall be constructed of smooth, nonabsorbent, hard durable material and maintained in good repair.

2. The floor and cove base/joint shall be properly sealed.

3. Carpeting is allowed in the lobby area only and shall be of closely woven construction, properly installed, easily cleanable, and maintained in good repair.

(b) Walls and Ceilings.

1. Maintenance. Walls and ceilings, including doors, windows, skylight, and similar closures shall be constructed of durable, easily cleanable material and be maintained clean and in good repair.

2. Attachments. Light fixtures, vent covers, wall-mounted fans, and similar equipment attached to walls and ceilings shall be easily cleanable and maintained in good repair.

(13) Lighting.

(a) Permanently fixed artificial light sources shall be installed to provide at least fifty-foot candles of light on all work area surfaces and at equipment washing work levels.

(b) Permanently fixed artificial light sources shall be installed to provide at a distance of thirty inches from the floor at least ten-foot candles of light in all other areas.

(14) Ventilation. All rooms shall have sufficient ventilation to keep them free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes.

(15) Poisonous or Toxic Materials.

(a) Materials permitted. There shall be present in the Body Art Studio only those poisonous or toxic materials necessary for maintaining the studio and cleaning or sanitizing equipment, as well as controlling insects and rodents.

(b) Labeling of materials. Containers of poisonous or toxic materials shall be prominently and distinctly labeled according to law for easy identification of contents and approved for intended use.

(c) Toxic items shall be separated from other materials used in body art procedures by way of a closed cabinet or separate room.

(d) Spray bottles labeled with contents may be used for the purpose of cleaning but not for body art procedure preparation.

(16) Premises.

(a) Body Art Studios shall be kept neat, clean, and free of litter and rubbish.

(b) Only articles necessary for the operation and maintenance of the Body Art Studio shall be stored on or within the studio. Lockers or other designated area will be provided for such personal items as purses, jackets, medications, etc.

(c) Aisles and working spaces. Aisles and working spaces between units of equipment and walls shall be unobstructed and of sufficient width to permit body artists and employees to perform their duties readily without contamination of equipment or operational surfaces by clothing or personal contact.

(d) The premises shall be kept in such condition as to prevent the entrance, harborage, or feeding of insects, rodents, or vermin.

(17) Equipment and Instruments.

(a) Materials.

1. Multi-use equipment and instruments shall be constructed and repaired with safe materials, including finishing materials; they shall be corrosion-resistant and nonabsorbent; and they shall be smooth, easily cleanable, and durable under conditions of normal use. Single-service articles shall be made from clean, sanitary, and safe materials.

2. Re-use of single-service articles is prohibited.

(b) Design and Fabrication.

1. General. All equipment and instruments, including plastic ware, shall be designed, and fabricated for durability under conditions of normal use and shall be resistant to denting, buckling, pitting, and chipping.

(i) Body art operational surfaces shall be easily cleanable, smooth, and free of breaks, open seams, cracks, chips, pits, and similar imperfections, as well as free of difficult to clean internal corners and crevices.

(ii) Sinks and drain boards shall be self-draining.

2. Operational surfaces. Surfaces of equipment not intended as operational surfaces, but which are exposed to splash or debris or which otherwise require frequent cleaning, shall be designed, and fabricated to be smooth, washable, free of unnecessary ledges, projections, or crevices and readily accessible for cleaning. Such surfaces shall be of material and in such repair as to be easily maintained in a clean and sanitary condition.

3. Needles, needle assembly with bar, dyes, or pigments shall be designed and manufactured for the sole purpose of body art.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.09

AUTHORITY: O.C.G.A. § 31-40-5.

HISTORY: Original Rule entitled "Septage Holding Facilities" adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013.

Repealed: F. Jun. 20, 2014; eff. July 10, 2014

Adopted: New Rule entitled "Minimum Design Standards." F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.10 Furnishings and Fixtures

(1) Furnishings of the Body Art Studio shall be maintained in good condition, intact, and functional. Furnishings should be made of or covered in a material that is easily cleanable and non-absorbent.

(2) All surfaces in the work area that could potentially be contaminated during a procedure must be non-porous to allow for proper cleaning. This includes but is not limited to worktables, chair mats and bases, shelving, and counters.

(3) Worktables and chairs shall be provided for each body artist workstation.

(a) All exposed surfaces of all worktables and chairs shall be constructed of material which is smooth, nonabsorbent, corrosive resistant, and easily sanitized.

(b) All exposed surfaces of worktables and chairs shall be sanitized with an EPA registered disinfectant approved by the Health Authority after each use and between clients.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.10

AUTHORITY: O.C.G.A. § 31-40-5.

HISTORY: Original Rule entitled "Record Keeping" adopted. F. Sep. 20, 2013; eff. Oct. 10, 2013.

Repealed: F. Jun. 20, 2014; eff. July 10, 2014.

Adopted: New Rule entitled "Furnishings and Fixtures." F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.11 Supplies

(1) Bulk single-use articles shall be commercially packaged and handled to protect them from contamination. These articles shall be stored in an area separate from the work area and toilet facilities.

(2) All materials intended for single-use application to the human skin shall be from single-use containers and shall be disposed of after each use.

(3) Cabinets and closed, sealable containers for the storage of instruments, pigments, single use articles such as gloves, ink caps, carbon, or stencils, shall be provided for each body artist and shall be maintained in a sanitary manner which protects them from contamination.

(4) Minimum supplies of a studio. Each workstation is to be equipped or stocked with enough of the following items:

(a) Body Tattooing Studios shall have packaged, single use, pre-sterilized needle assembly with bar and sterilized needle tubes;

(b) Body Piercing Studios shall have packaged, single-use, pre-sterilized needles, sterilized needle tubes, sterilized forceps, and sterilized hemostats; single-use pens or equivalent instruments. Piercing Studios may sterilize equipment at point of use if they have a cassette autoclave.

(c) Extra packages of disposable towels other than the package that is being used;

(d) Extra boxes of medical grade disposable gloves other than the box being used; and

(e) An extra supply of bandages, ointment or gel, and antimicrobial soap.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.11

AUTHORITY: O.C.G.A. § 31-40-5.

HISTORY: Original Rule entitled "Supplies" adopted. F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.12 Health and Hygiene

(1) With the exception of a plain ring such as a wedding band, jewelry on the hands and wrists of a body artist, such as watches, rings, or bracelets, shall be removed prior to the start of the body art procedure.

(2) Prior to the procedure, the artist shall inspect their hands for hangnails, small cuts, sores, and abrasions. If a cut, sore, or abrasion is detected, a bandage shall be applied for added protection before gloving. The artist shall trim fingernails to ensure gloves are not punctured. Recent tattoos or piercings in the healing process shall also be properly covered to prevent any bodily fluid transfer.

(3) Use aseptic technique. Thorough hand washing is essential after client contact, after handling blood and body fluids, after wearing gloves, and prior to exiting the work area.

(4) The artist must thoroughly wash their hands in hot, running water with soap, then rinse hands and dry with disposable paper towels before and after performing body art procedures; anytime there is an interruption in body art procedure that requires the artist to remove and replace gloves; after using the restroom; and after touching their face, hair or other areas.

(5) Medical grade, single-use, disposable gloves labeled for surgical, or examination purposes shall be worn when coming in contact with the client and during the body art procedure. Gloves shall be changed and properly disposed of each time there is an interruption in the body art procedure, the gloves become torn or punctured, or whenever their ability to function is compromised. Under no circumstances shall a single pair of gloves be used on more than one individual. Vinyl gloves are not allowed.

(6) A body artist shall maintain the highest degree of personal cleanliness, conform to standard hygienic practices, and wear clean clothes when performing body art procedures. Single-use aprons, smocks, or sleeve covers are acceptable. Open-toed shoes or shoes with holes shall not be permissible.

(7) The skin of the artist shall be free of rash, open lesions, or infection. No artist affected with boils, infected or open wounds or sores, abrasions, weeping dermatological lesions, fever, vomiting, diarrhea, or acute or chronic cough or respiratory infection shall work in any area of a Body Art Studio in any capacity in which there is a likelihood that the individual could contaminate body art equipment, supplies, working surfaces with body substances or pathogenic organisms or expose other staff or clients to infections.

(8) Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. All body artists and employees shall be trained in universal precautions and present documentation of yearly training upon request.

(a) The body artist should assume that all human blood, plasma, serum, body fluids and tissues are contaminated with Human Immunodeficiency Virus (HIV) and/or Hepatitis viruses (e.g., HBV, HCV).

(b) The most susceptible route of occupational infection for HIV, HBV, and HCV is by accidental needle sticks, but may include contamination of the mucous membranes, or through broken, abraded, or irritated skin. Use appropriate caution and maximum protection to prevent such contact.

(c) Proper decontamination procedures, emergency biohazard spill management, and proper use of biosafety equipment shall be utilized.

(d) Use aseptic technique. Thorough hand washing is essential after client contact, after handling blood and body fluids, after wearing gloves, and prior to exiting the work area.

(e) Infectious material spills shall be cleaned using an EPA registered disinfectant and following universal precautions.

(f) Clean all work areas and equipment used in handling human biohazardous materials with an EPA-registered disinfectant when concluding work to protect personnel from accidental infection.

(g) Eating, drinking, use of tobacco products, and applying cosmetics or lip balm are not permitted in the area where body art preparations or procedures are performed and any location where instruments or supplies are stored or cleaned. Exceptions may be made for the purpose of rendering first-aid.

(h) All procedures shall be performed carefully to minimize the creation of aerosols.

(i) Employees and body artists shall report all work-related accidents, incidents, and unexplained illness to their supervisor immediately.

(j) Soiled gloves shall be removed in a manner to minimize the risk of self-contamination or cross-contamination after each operation and prior to contacting work surfaces, doorknobs, wall switches, or telephones. Dispose of used gloves in a bagged trash container.

(k) Food storage cabinets or refrigerators shall be located outside the work area.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.12

AUTHORITY: O.C.G.A. § 31-40-5**.**

HISTORY: Original Rule entitled "Health and Hygiene" adopted. F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.13 Instrument Cleaning and Sterilization

(1) An ultrasonic cleaning unit and operational Class B or S medical grade or other approved medical-grade autoclave is required and shall be provided in each Body Art Studio unless the use of pre-sterilized items and equipment or single-use items has been approved by the Health Authority.

(2) Ultrasonic cleaning units used for cleaning instruments shall be clearly labeled "biohazardous" and shall be operated in accordance with the manufacturer's recommendation.

(3) The ultrasonic cleaning unit and medical-grade autoclave shall be used and maintained according to manufacturer's specifications. Each ultrasonic cleaning unit and medical-grade autoclave shall be emptied and thoroughly cleaned and disinfected as per manufacturer's recommendations. Ultrasonic cleaning unit and medical-grade autoclave maintenance records must be maintained for two years and be made available upon request.

(4) Used non-disposable instruments shall be kept in a separate puncture-resistant container and soaked in a protein-dissolving detergent-enzyme cleaner until cleaned. The solution shall be changed as recommended by the solution manufacturer. The cleaning method shall include the following:

(a) Employees and body artists shall use personal protective equipment, protecting their eyes, nose, mouth, and hands while cleaning instruments and follow manufacturer's safety precautions for any chemicals used. Instruments shall be completely disassembled and pre-scrubbed prior to being placed into an ultrasonic cleaning unit. The ultrasonic unit must be sealed and covered when in use to protect from aerosolization.

(b) After removal from the ultrasonic cleaning unit, rinsed in clean water and air dried.

(c) Prior to being placed in the autoclave, all equipment shall be bagged, labeled as to its contents, initialed, dated and sealed. If multiple autoclaves are in use, the autoclave used must be designated on the packaging.

(d) Instruments shall be packed individually in sterilization packs and sterilized in a medical-grade autoclave. All sterilized packs shall contain either a sterilization indicator or internal temperature indicator and marked with the date of sterilization. Sterilized instruments may be stored for use up to one year, as long as the integrity of the packaging has not been compromised.

(e) Each autoclave bag must be used in accordance with the manufacturer's recommendations and may hold no more than one individual item. A piercing set may be bagged together.

(5) After sterilization, the packaged instruments shall be stored in a clean dry cabinet or other tightly covered container reserved and labeled for storage of sterile instruments.

(6) If a sterilized package has been breached or allowed to get wet, the instruments must be re-packaged and sterilized again before use.

(7) A log of sterilization procedures shall be maintained near the sterilizing equipment. Included in the log, shall be type of load, quantity of load, temperature, pressure, and length of sterilizing time.

(8) Spore tests shall be used at a minimum frequency of every 40 hours of operation of the autoclave but not less than on a monthly basis unless the manufacturer specifies more frequent monitoring. Records of the results must be kept for a minimum of three years. An independent commercial testing laboratory contracted by the permit owner or body artist, or both shall perform biological spore testing of the autoclave. A provision shall be included in the contract with the commercial testing laboratory requiring the body art studio to notify the Health Authority of any failure of the autoclave to eradicate all living organisms, including spores.

(9) Upon notification of a positive microbiological monitoring report, the autoclave shall be immediately checked for proper use and function and the permit owner shall cease use of the autoclave immediately upon receipt of the positive report. Any items remaining bagged after sterilization must be reprocessed and sterilized by a medical-grade autoclave approved for use prior to return to service. A negative biological test and passing a Class 5

integrating indicator must be achieved before the autoclave can be used again and the studio is reopened. The studio shall have the option to obtain a properly functioning sterilizer with a negative biological report in order to remain open or if the studio has more than one autoclave in operation, they may be given approval to remain open. The Body Art Studio's standard operation procedure should include an emergency plan should an autoclave failure or malfunction occur.

(10) Any item or instrument used for body art that is contaminated during the procedure shall be discarded and replaced immediately with a new disposable item or a new sterilized instrument or item before the procedure resumes.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.13

AUTHORITY: O.C.G.A. § 31-40-5**.**

HISTORY: Original Rule entitled "Instrument Cleaning and Sterilization" adopted. F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.14 Dyes and Pigments

(1) All dyes or pigments used in tattooing shall be from commercial professional suppliers specifically manufactured as dyes or pigments only for the tattooing of human skin, and shall be used according to the manufacturer's instructions. Products banned or restricted by the Food and Drug Administration are prohibited.

(2) All ink shall be handled using the following protocol:

(a) Bulk containers of ink shall not be used for longer than the manufacturer's expiration date.

(b) Inks and pigments can be stored in workstations or in an approved location and must be properly stored to prevent contamination.

(c) Containers of ink may only be handled while wearing clean medical grade gloves.

(d) The tops of containers of ink must be disinfected prior to dispensing. After dispensing, the containers must be disinfected and immediately returned to their approved storage location before any tattoo procedures begin.

(e) All ink must be dispensed into approved single use containers.

(3) In preparing or mixing of dyes or pigments, only nontoxic materials shall be used. Dyes or pigments shall be mixed and placed in individual single-use containers.

(4) After tattooing, the remaining unused dye or pigment in the single-use container shall be properly discarded along with the container.

(5) The Safety Data Sheets of all inks must be available for client review to assess any possible allergic reaction to ingredients.

(6) Dyes and pigments shall be mixed only with distilled or sterile water.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.14

AUTHORITY: O.C.G.A. § 31-40-5**.**

HISTORY: Original Rule entitled "Dyes and Pigments" adopted. F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.15 Tattoo Procedures

(1) Medical grade disposable gloves shall be worn during the preparation of equipment for a tattoo procedure and during the procedure. Vinyl gloves are not permissible.

(2) Before the procedure begins, all instruments to be used during the tattooing must be placed on a medical grade absorbent liner which must be placed on a disinfected surface.

(3) Only a commercially packaged, single-use, pre-sterilized needle assembly with bar shall be used and disposed of immediately after use into a puncture-resistant, or disposable biohazard container. Expired, breached needle packages or needle packages that have become wet may not be re-sterilized and must be discarded.

(4) Sterilized instruments shall remain in sterile packages until opened in front of the client.

(5) Any part of a tattooing machine that may be touched by the artist during the procedure shall be covered with a disposable plastic sheath that is discarded after each procedure and the machine shall be disinfected.

(6) A clip cord sleeve and barrier film shall be used over exposed electrical cords or other approved cleaning and disinfection methods demonstrated to prevent contamination.

(7) All devices used to apply pigments must be designed and used to prevent backflow of pigments into the machine. Needle cartridges must have a membrane.

(8) Single-use towels or gauze shall be used in preparing the site to be tattooed and shall be disposed of after use on each client.

(9) If shaving is necessary, single-use disposable razors shall be used and discarded into a puncture-resistant container between clients and as otherwise needed.

(10) After shaving the area to be tattooed, or if the area does not need to be shaved, the site of the tattoo shall be thoroughly cleaned with an antimicrobial solution used in accordance with the manufacturer's label instructions.

(11) When a workstation rinse cup is used alone, the cup and solution shall be disposable and discarded after each client.

(12) If squirt bottles are used to dispense liquids, the liquid shall be applied onto a single use wipe rather than directly onto the client.

(13) Single-use ointment tubes, applicators, and supplies shall be discarded after each tattoo application.

(14) When a paper stencil is used by a tattoo artist for transferring the design to the skin, it shall be single-use and disposable. The use of roll-on or stick deodorants for tattoo site preparation is prohibited.

(15) The stencil shall be applied with antimicrobial soap, or a Health Authority approved product dispensed from a container in a manner that does not contaminate the unused portion.

(16) When the design is drawn directly onto the skin, autoclavable, pre-sterilized pens shall be used, or single-use, non-toxic pens or markers shall be used and discarded after each use.

(17) The completed tattoo shall be washed with a single-use towel saturated with an antimicrobial solution.

(18) A sterile bandage or dressing shall then be applied to the finished tattoo. For procedures such as "permanent makeup", "microdermapigmentation", "micropigment implantation", "microblading", "microshading", "micro-needling with the use of pigment", cosmetic tattooing or any other similar procedures, the use of a sealed or non-sticking wrap or dressing is not required.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.15

AUTHORITY: O.C.G.A. § 31-40-5**.**

HISTORY: Original Rule entitled "Tattoo Procedures" adopted. F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.16 Piercing Jewelry

(1) Client and the body piercer should have appropriate size and quality jewelry chosen before the procedure begins.

(2) Jewelry used in piercing shall meet the requirements of DPH Rule 511-3-8-.04(45)(a) - (k) and consist of a material rated by the ASTM or the ISO as being suitable for permanent surgical implant, such as stainless steel, titanium, niobium, solid platinum, or a dense low porosity plastic such as Tygon or PTFE. Copies of the jewelry manufacturer's documentation which verify compliance with standards must be available for inspection on request. Solid 14 karat or higher, white, or yellow nickel-free gold may also be used. Purity verification must be available for inspection on request.

(3) The jewelry must be free of nicks, scratches, or irregular surfaces.

(4) All jewelry must be properly sterilized prior to use in a medical grade chamber or cassette autoclave. Any two-piece or multi-piece jewelry that is screwed or pieced together must be separated prior to sterilization. Pre-sterilized jewelry is allowed if documentation is provided from the manufacturer stating all parts of the jewelry is pre-sterilized.

(5) Should jewelry become contaminated during the piercing process, a sterile piece of jewelry must be used, or re-sterilization must occur prior to use.

(6) Ear studs or other jewelry designed for ear lobe piercing are not appropriate jewelry for other body parts and shall not be used for any other purpose.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.16

AUTHORITY: O.C.G.A. § 31-40-5**.**

HISTORY: Original Rule entitled "Piercing Jewelry" adopted. F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.17 Body Piercing Procedures

(1) Medical grade disposable gloves shall be worn during the preparation of equipment for a piercing procedure and during the procedure. Vinyl gloves are not permissible.

(2) Before the procedure begins, all sterilized instruments to be used in the body piercing must be placed on a medical grade liner that is placed on a disinfected surface. Any nonsterilized equipment may be sterilized in a medical grade cassette autoclave before the procedure begins and kept in the cassette.

(3) Single use, sterilized piercing needles shall be used and disposed of immediately after use into a puncture-resistant or disposable biohazard container.

(4) No approved tool may be modified and used for anything other than its intended use as per the manufacturer's recommendations.

(5) Pre-sterilize all reusable equipment such as forceps, hemostats, calipers, and tubes in sealed, properly labeled, sterile indicator bags. These items are to be used only on one person in one sitting. After one such use, they must be

cleaned in an ultrasonic cleaner, placed in sealed indicator bags, properly labeled, autoclaved, and stored in sterile indicator bags.

(6) Sterilized instruments shall remain in sterile packages until opened in front of the client.

(7) Single-use towels or gauze shall be used in preparing the piercing site and shall be disposed of after use on each client.

(8) If shaving is necessary, single-use disposable razors shall be used and discarded into a puncture-resistant container between clients and as otherwise needed.

(9) After shaving the area to be pierced, or if the area does not need to be shaved, the piercing site shall be thoroughly cleaned with an antimicrobial solution used in accordance with manufacturer's label instructions.

(10) In the case of oral piercings, the operator shall provide the individual with antimicrobial mouthwash in a single-use cup and shall ensure that the individual utilizes the mouthwash provided and rinses based on the manufacturer's label instructions prior to the procedure. In the case of a lip, labret, or cheek piercing, procedures described in this section for both skin and oral piercings shall be followed.

(11) If piercing a minor, the legal parent or guardian that signed the application must be in the procedure area while the minor is receiving the piercing.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.17

AUTHORITY: O.C.G.A. § 31-40-5**.**

HISTORY: Original Rule entitled "Body Piercing Procedures" adopted. F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.18 Body Art After Care

(1) Verbal and written instructions reviewed and approved by the Health Authority for the care of the body art procedure site shall be provided to each client by the artist upon completion of the procedure.

(a) The written instruction shall include, at a minimum: what to do, what to avoid, suggested care solutions/over-the-counter balms or treatments, cleaning instructions, and what to look for during the healing process.

(b) The written instructions shall advise the client to consult a healthcare provider at the first sign of infection and will contain the name, address, and phone number of the studio.

(c) The instructions will also list the name, address, and phone number of the Health Authority.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.18

AUTHORITY: O.C.G.A. § 31-40-5**.**

HISTORY: Original Rule entitled "Body Art After Care" adopted. F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.19 Disinfection of Workplace

(1) Each Body Art Studio must be kept clean and sanitary. The owner must develop and implement a written cleaning schedule that includes appropriate methods of decontamination and tasks or procedures to be performed.

(2) This written schedule must be based on the location within the studio, the type of surfaces to be cleaned, type of possible contamination present, the tasks, or procedures to be performed, and their location within the studio.

(3) The following procedures should be adhered to:

(a) A Body Artist shall only conduct body art activities under sanitary conditions.

(b) Clean and sanitize all equipment and work surfaces with an appropriate EPA-registered disinfectant after completion of the body art procedures and at the end of the work shift or when surfaces have become contaminated since the last cleaning.

(c) Remove and replace protective coverings after each body art procedure.

(d) Inspect and sanitize, on a daily basis, reusable receptacles such as bins, pails, and cans that have the likelihood of becoming contaminated. When contamination is visible, clean and sanitize receptacles immediately.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.19

AUTHORITY: O.C.G.A. § 31-40-5**.**

HISTORY: Original Rule entitled "Disinfection of Workplace" adopted. F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.20 Disposal of Biomedical Waste

(1) Needles, razors, or other sharp instruments used during body art procedures, shall be placed in puncture-resistant, closed containers immediately after use, handled and disposed of according to the provisions of this Chapter.

(2) Used needles shall not be purposely bent or broken, or otherwise manipulated by hand to prevent needle sticks or injury and exposure to blood or body fluids.

(3) Containers of sharp waste shall be sent to a facility where they are either incinerated, rendered non-hazardous, or deposited in a landfill approved to accept biomedical waste in compliance with the Solid Waste Management regulations of the Georgia Department of Natural Resources, Environmental Protection Division.

(4) Contaminated waste, which may release liquid blood or body fluids when compressed or may release dried blood or body fluids when handled, must be placed in a sealed bag. It must then be disposed of in compliance with Georgia Department of Natural Resources - Environmental Protection Division - Solid Waste Management - Chapter 391-3-4.15.

(5) Waste containers shall be kept closed when not in use.

(6) Disposable waste shall be handled, stored, and disposed of to minimize direct exposure of personnel to waste materials.

(7) At least one covered waste receptacle shall be provided in each artist area. Receptacles in the artist area shall be emptied daily, and solid waste shall be removed from the premises at least weekly or more often if necessary. All waste receptacles shall be covered and maintained.

(8) Solid waste shall not be stored outdoors unless in a secured and lidded dumpster that complies with applicable county or municipal solid waste ordinances.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.20

AUTHORITY: O.C.G.A. § 31-40-5**.**

HISTORY: Original Rule entitled "Disposal of Biomedical Waste" adopted. F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.21 Signage

Each Body Art Studio shall conspicuously display in a prominent place, easily seen by clients, a printed sign that warns that any body art on the face, neck, forearm, hand, or lower leg of an individual may automatically disqualify such individual from military service in the armed forces of the United States. Such notice shall be at least 11 inches by 14 inches in size, with letters at least one inch in height.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.21

AUTHORITY: O.C.G.A. § 31-40-8.

HISTORY: Original Rule entitled "Signage" adopted. F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.22 Inspections

(1) The studio and all its records shall be available for review and examination by properly identified representatives of the Health Authority. A Body Art Studio shall be inspected no less than twice annually.

(2) A copy of the most recent inspection report shall be displayed in a conspicuous location within fifteen feet of the front or primary public door and between five feet and seven feet from the floor and in an area where it can be read at a distance of one foot away, or if this is impractical, in an area designated by the Health Authority.

(3) Representatives of the Health Authority, after proper identification, shall be permitted to enter any Body Art Studio or operation at any time during business hours for the purpose of making inspections and reviewing of pertinent records to determine compliance with this Chapter. The permit holder is responsible for ensuring that at least one person on site is authorized and able to provide access to all rooms, facilities, and records of the Body Art Studio, and who can demonstrate that there is sufficient daily oversight of employees, body artists and perform routine monitoring of operations.

(4) Representatives of the Health Authority who conduct inspections of Body Art Studios must complete an OSHA compliant Bloodborne Pathogens/ Universal Precautions training, pass a written exam developed by the Department, and comply with other training requirements established by the Department.

(5) Inspection results - Reporting and Scoring.

(a) Inspection results for Body Art Studios shall be recorded on standard forms provided by the Department.

(b) The scoring system shall include a weighted point value for each requirement in which critical items are assigned values of five points, with non-critical violations having assigned values of either one or two points.

(6) The rating score shall be the total of the weighted point values for all violations subtracted from one hundred.

(a) Correction of imminent health hazards shall be corrected immediately. Critical violations shall be corrected within seventy-two hours, and non-critical violations within ten calendar days.

(b) Upon declaration of an imminent health hazard which cannot be immediately corrected, the local Health Authority shall issue an order requiring the studio to immediately cease operations until authorized to reopen.

(c) Considering the nature of the potential hazard involved and the complexity of the corrective action needed, the Health Authority may agree to or specify a longer time frame, not to exceed ten calendar days after the inspection, for the permit holder to correct violations.

(d) Failure to correct these violations to the satisfaction of the Health Authority or the Department may result in such emergency action including enforcement actions pursuant to O.C.G.A. § 31-5-2 and 31-5-9(a).

(e) In the case of temporary Body Art Studios, all critical violations shall be corrected immediately, or provisions must be made to satisfy the violation until a complete correction can be made within twenty-four hours. If critical violations are not corrected within twenty-four hours, the studio shall immediately cease operations until authorized to resume by the Health Authority. Upon declaration of an imminent health hazard which cannot be immediately corrected, the Health Authority shall issue an order requiring the studio to immediately cease operations until authorized to reopen by the Health Authority.

(f) Follow up inspections when required will be performed within the time or as determined by the Health Authority.

(7) Inspection Frequency.

(a) The Health Authority shall conduct one or more construction inspections for newly constructed or major structurally modified studios to verify that the Body Art Studio is constructed and equipped in accordance with the approved plans and specifications and is in compliance with law and this Chapter. In addition, the Health Authority may conduct one or more preoperational inspections to verify compliance with the construction and equipment requirements of this Chapter at the time of a change in the permit holder of an existing Body Art Studio.

(b) An initial inspection will be conducted in a studio prior to the body art permit being issued.

(c) To allow the permit holder of the Body Art Studio sufficient time to fully train body artists, employees and to ensure the studio has implemented all written procedures, the first routine inspection will be conducted within sixty days after the opening of the studio; and it will mark the beginning of the studio's compliance history with this Chapter.

(c) After the first routine inspection, studios maintaining an "A" or "B" score shall be inspected based on the minimum inspection frequency established by this Rule.

(e) Studios that receive a "C" or "U" score will have at least one additional routine inspection added in a twelve-month period and may have more inspections at the discretion of the Health Authority.

(f) Follow-up inspections may be conducted at any time at the discretion of the Health Authority but shall be conducted within ten days after a studio receives a grade "U".

(8) Grading Inspections. Inspections will receive a letter grade based on the numerical score as follows:

(a) The letter grade "A" means that the majority of the requirements of this Chapter have been met and is applied to a score of 90 to 100.

(b) The letter grade "B" means satisfactory compliance and is applied to a score of 80 to 89.

(c) The letter grade "C" means marginal compliance and is applied to a score of 70 to 79.

(d) The letter grade "U" means unsatisfactory compliance and is applied to a score of 69 or less.

(9) Informal Follow-up Inspection. If a follow-up inspection cannot be conducted by the Health Authority, then an informal follow-up may be performed to confirm correction of the violations that were cited on the routine inspection that were not corrected at the time of the inspection. On an informal follow-up inspection, an inspection report addendum will be completed, documenting the violations that have been corrected. It will be noted on the addendum that this was an informal follow-up inspection, and the studio will keep the same grade that was earned

on the previous routine inspection. The addendum will be made available by the Body Art Studio to the public upon request.

(10) Upon the completion of an inspection, the person in charge of the studio shall sign the inspection report form. The Health Authority shall inform the person in charge that:

(a) The person in charge's signature shall not necessarily indicate agreement with the findings noted on the inspection.

(b) Refusal to sign an acknowledgment of receipt will not affect the permit holder's obligation to correct the violations noted in the inspection report within the time frames specified, and the refusal to sign an acknowledgment of receipt will be noted in the inspection report and conveyed to the Health Authority's historical record for the Body Art Studio.

(11) Failure to make timely corrections to the satisfaction of the Health Authority or the Department may subject the Body Art Studio to suspension or revocation of its permit.

(12) The Health Authority may approve a compliance schedule that extends beyond the time limits specified in this Rule if a schedule of compliance is submitted by the permit holder and no imminent health hazard exists or will result from allowing an extended schedule for compliance.

(13) Voluntary Closure. A Body Art Studio that is graded with two critical violations or is graded as a "U" on two consecutive inspections or is graded as a "U" and does not earn at least a grade of "C" within ten days of receiving the "U" or does not correct requires violations within seventy-two hours (if allowed) of receiving an inspection report may be requested to voluntarily close until all violations are corrected.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.22

AUTHORITY: O.C.G.A. §§ 31-40-3**;** 31-40-6**.**

HISTORY: Original Rule entitled "Inspections" adopted. F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.23 Compliance and Enforcement

(1) The administration and enforcement of this Chapter shall be as prescribed in O.C.G.A. Section 31-5-1 et seq. The Health Authority shall have the power and authority to suspend, or revoke body art studio permits for failure to comply with the provisions of this Chapter.

(2) The Health Authority shall have primary responsibility for the enforcement of this Chapter within its jurisdiction.

(3) No person or entity shall operate a Body Art Studio or conduct body art activities without a valid permit or certification issued pursuant to this Chapter.

(4) Suspension or Revocation of Permits. The Health Authority shall have the power and authority to suspend or revoke a permit if the permit owner or its body artists or employees are unwilling or unable to comply with these regulations, the regulations of the local Health Authority, or the provisions of O.C.G.A. Section 31-28-1 et seq.

(a) A permit holder shall be presumed unwilling or unable to comply if it refuses to allow the Health Authority to enter upon and inspect the premises of the Body Art Studio at any reasonable time, or if any critical violation is found to be uncorrected upon two consecutive inspections, or upon continuous violation of this Chapter.

(b) The revocation of a permit may be appealed to the Department of Public Health in accordance with O.C.G.A. Section 31-5-3 by sending written notice, by certified mail or statutory overnight delivery, addressed to the Department of Public Health, Office of General Counsel, with a copy to the Health Authority official that revoked the permit. Within ten days of receiving the notice, the Health Authority shall provide the Department with a copy of

its entire file on the inspections and actions that led to the revocation of the permit. The Department shall schedule a hearing within twenty days of receiving the notice and shall decide the matter upon the arguments of the parties and the administrative record.

(5) Conditions Warranting Action. The Health Authority may summarily suspend a permit to operate a Body Art Studio if it determines through inspection, or examination of body artists, employees, records, or other means as specified in this Chapter, that an imminent health hazard exists.

(6) Resumption of Operations. If operations of a Body Art Studio are discontinued due to the existence of an imminent health hazard, voluntary closure, or otherwise according to law, the permit holder shall obtain approval from the Health Authority before resuming operations.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.23

AUTHORITY: O.C.G.A. §§ 31-5-1 ***et seq.*****; 31-40-3; 31-40-4.**

HISTORY: Original Rule entitled "Compliance and Enforcement" adopted. F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

511-3-8-.24 Fees

The Department will adopt a fee schedule for Body Artist Certification.

Cite as Ga. Comp. R. & Regs. R. 511-3-8-.24

AUTHORITY: O.C.G.A. § 31-40-5**.**

HISTORY: Original Rule entitled "Fees" adopted. F. Mar. 8, 2023; eff. Apr. 6, 2023, as specified by the Agency.

Department 560. RULES OF DEPARTMENT OF REVENUE

Chapter 560-11. LOCAL GOVERNMENT SERVICES DIVISION

Subject 560-11-6. CONSERVATION USE PROPERTY

560-11-6-.09 Table of Conservation Use Land Values

(1) For the purpose of prescribing the 2023 current use values for conservation use land, the state shall be divided into the following nine Conservation Use Valuation Areas (CUVA 1 through CUVA 9) and the following accompanying table of per acre land values shall be applied to each acre of qualified land within the CUVA for each soil productivity classification for timber land (W1 through W9) and agricultural land (A1 through A9):

(a) CUVA #1 counties: Bartow, Catoosa, Chattooga, Dade, Floyd, Gordon, Murray, Paulding, Polk, Walker, and Whitfield. Table of per acre values: W1 985, W2 884, W3 803, W4 736, W5 675, W6 625, W7 586, W8 537, W9 490, A1 1,791, A2 1,693, A3 1,569, A4 1,438, A5 1,296, A6 1,159, A7 1,031, A8 904, A9 773;

(b) CUVA #2 counties: Barrow, Cherokee, Clarke, Cobb, Dawson, DeKalb, Fannin, Forsyth, Fulton, Gilmer, Gwinnett, Hall, Jackson, Lumpkin, Oconee, Pickens, Towns, Union, Walton, and White. Table of per acre values: W1 1,334, W2 1,209, W3 1,089, W4 986, W5 908, W6 853, W7 804, W8 738, W9 669, A1 1,962, A2 1,749, A3 1,556, A4 1,374, A5 1,230, A6 1,100, A7 985, A8 894, A9 804;

(c) CUVA #3 counties: Banks, Elbert, Franklin, Habersham, Hart, Lincoln, Madison, Oglethorpe, Rabun, Stephens, and Wilkes. Table of per acre values: W1 1,309, W2 1,139, W3 1,027, W4 986, W5 908, W6 831, W7 699, W8 568, W9 475, A1 1,493, A2 1,358, A3 1,215, A4 1,076, A5 938, A6 846, A7 695, A8 580, A9 490;

(d) CUVA #4 counties: Carroll, Chattahoochee, Clayton, Coweta, Douglas, Fayette, Haralson, Harris, Heard, Henry, Lamar, Macon, Marion, Meriwether, Muscogee, Pike, Schley, Spalding, Talbot, Taylor, Troup, and Upson. Table of per acre values: W1 963, W2 862, W3 781, W4 716, W5 623, W6 580, W7 504, W8 436, W9 354, A1 1,223, A2 1,096, A3 1,004, A4 897, A5 787, A6 653, A7 566, A8 438, A9 314;

(e) CUVA #5 counties: Baldwin, Bibb, Bleckley, Butts, Crawford, Dodge, Greene, Hancock, Houston, Jasper, Johnson, Jones, Laurens, Monroe, Montgomery, Morgan, Newton, Peach, Pulaski, Putnam, Rockdale, Taliaferro, Treutlen, Twiggs, Washington, Wheeler, and Wilkinson. Table of per acre values: W1 819, W2 759, W3 697, W4 638, W5 575, W6 518, W7 453, W8 392, W9 325, A1 906, A2 788, A3 733, A4 669, A5 597, A6 507, A7 416, A8 328, A9 238;

(f) CUVA #6 counties: Bulloch, Burke, Candler, Columbia, Effingham, Emanuel, Glascock, Jefferson, Jenkins, McDuffie, Richmond, Screven, and Warren. Table of per acre values: W1 810, W2 744, W3 679, W4 619, W5 552, W6 489, W7 424, W8 357, W9 291, A1 1,028, A2 902, A3 827, A4 759, A5 669, A6 557, A7 453, A8 347, A9 243;

(g) CUVA #7 counties: Baker, Calhoun, Clay, Decatur, Dougherty, Early, Grady, Lee, Miller, Mitchell, Quitman, Randolph, Seminole, Stewart, Sumter, Terrell, Thomas, and Webster. Table of per acre values: W1 868, W2 790, W3 719, W4 645, W5 569, W6 497, W7 424, W8 347, W9 273, A1 1,195, A2 1,083, A3 963, A4 837, A5 717, A6 601, A7 464, A8 351, A9 236;

(h) CUVA #8 counties: Atkinson, Ben Hill, Berrien, Brooks, Clinch, Coffee, Colquitt, Cook, Crisp, Dooly, Echols, Irwin, Jeff Davis, Lanier, Lowndes, Telfair, Tift, Turner, Wilcox, and Worth. Table of per acre values: W1 944, W2 855, W3 766, W4 679, W5 590, W6 504, W7 415, W8 328, W9 266, A1 1,209, A2 1,142, A3 1,031, A4 919, A5 807, A6 697, A7 537, A8 436, A9 321;

(i) CUVA #9 counties: Appling, Bacon, Brantley, Bryan, Camden, Charlton, Chatham, Evans, Glynn, Liberty, Long, McIntosh, Pierce, Tattnall, Toombs, Ware, and Wayne. Table of per acre values: W1 956, W2 862, W3 781, W4

695, W5 603, W6 520, W7 431, W8 344, W9 266, A1 1,119, A2 1,078, A3 968, A4 862, A5 754, A6 645, A7 537, A8 428, A9 321.

Cite as Ga. Comp. R. & Regs. R. 560-11-6-.09

AUTHORITY: O.C.G.A. §§ 48-2-12**,** 48-5-7**,** 48-5-7.4**,** 48-5-269**.**

HISTORY: Original Rule entitled "Table of Conservation Use Land Values" adopted. F. May 28, 1993; eff. June 17, 1993.

Repealed: New Rule of same title adopted. F. May 13, 1994; eff. June 2, 1994.

Repealed: New Rule of same title adopted. F. Mar. 1, 1995; Mar. 21, 1995.

Repealed: New Rule of same title adopted. F. Jan. 28, 1996; eff. Feb. 18, 1996.

Repealed: New Rule of same title adopted. F. Feb. 24, 1997; eff. Mar. 16, 1997.

Repealed: New Rule of same title adopted. F. Jan. 27, 1998; eff. Feb. 16, 1998.

Repealed: New Rule of same title adopted. F. Mar. 10, 1999; eff. Mar. 30, 1999.

Amended: F. Feb. 2, 2000; eff. Feb. 22, 2000.

Amended: F. Apr. 20, 2001; eff. May 10, 2001.

Repealed: New Rule of same title adopted. F. Apr. 17, 2002; eff. May 7, 2002.

Repealed: New Rule of same title adopted. F. May 19, 2003; eff. June 8, 2003.

Repealed: New Rule of same title adopted. F. Mar. 4, 2004; eff. Mar. 24, 2004.

Amended: F. Mar. 29, 2005; eff. Apr. 18, 2005.

Repealed: New Rule of same title adopted. F. Mar. 1, 2006; eff. Mar. 21, 2006.

Amended: F. Feb. 21, 2007; eff. Mar. 13, 2007.

Amended: F. Apr. 21, 2008; eff. May 11, 2008.

Repealed: New Rule of same title adopted. F. Apr. 15, 2009; eff. May 5, 2009.

Repealed: New Rule of same title adopted. F. Mar. 15, 2010; eff. Apr. 4, 2010.

Repealed: New Rule of same title adopted. F. Mar. 3, 2011; eff. Mar. 23, 2011.

Amended: F. Apr. 24, 2012; eff. May 14, 2012.

Amended: F. Jun. 10, 2013; eff. Jun. 30, 2013.

Amended: F. Apr. 22, 2014; eff. May 12, 2014.

Amended: F. May 18, 2015; eff. June 7, 2015.

Amended: F. Feb. 23, 2016; eff. Mar. 14, 2016.

Amended: F. Mar. 24, 2017; eff. Apr. 13, 2017.

Amended: F. Mar. 6, 2018; eff. Mar. 26, 2018.

Amended: F. Feb. 1, 2019; eff. Feb. 21, 2019.

Amended: F. Mar. 6, 2020; eff. Mar. 26, 2020.

Amended: F. Mar. 4, 2021; eff. Mar. 24, 2021.

Amended: F. May 4, 2022; eff. May 24, 2022.

Amended: F. Mar. 13, 2023; eff. Apr. 2, 2023.

Department 560. RULES OF DEPARTMENT OF REVENUE

Chapter 560-11. LOCAL GOVERNMENT SERVICES DIVISION

Subject 560-11-11. FOREST LAND PROTECTION

560-11-11-.12 Table of Forest Land Protection Act Land Use Values

(1) For the purpose of prescribing the 2023 current use values for conservation use land, the state shall be divided into the following nine Forest Land Protection Act Valuation Areas (FLPAVA 1 through FLPAVA 9) and the following accompanying table of per acre land values shall be applied to each acre of qualified land within the FLPAVA for each soil productivity classification for timber land (W1 through W9):

(a) FLPAVA #1 counties: Bartow, Catoosa, Chattooga, Dade, Floyd, Gordon, Murray, Paulding, Polk, Walker, and Whitfield. Table of per acre values: W1 985, W2 884, W3 803, W4 736, W5 675, W6 625, W7 586, W8 537, W9 490;

(b) FLPAVA #2 counties: Barrow, Cherokee, Clarke, Cobb, Dawson, DeKalb, Fannin, Forsyth, Fulton, Gilmer, Gwinnett, Hall, Jackson, Lumpkin, Oconee, Pickens, Towns, Union, Walton, and White. Table of per acre values: W1 1,334, W2 1,209, W3 1,089, W4 986, W5 908, W6 853, W7 804, W8 738, W9 669;

(c) FLPAVA #3 counties: Banks, Elbert, Franklin, Habersham, Hart, Lincoln, Madison, Oglethorpe, Rabun, Stephens, and Wilkes. Table of per acre values: W1 1,309, W2 1,139, W3 1,027, W4 986, W5 908, W6 831, W7 699, W8 568, W9 475;

(d) FLPAVA #4 counties: Carroll, Chattahoochee, Clayton, Coweta, Douglas, Fayette, Haralson, Harris, Heard, Henry, Lamar, Macon, Marion, Meriwether, Muscogee, Pike, Schley, Spalding, Talbot, Taylor, Troup, and Upson. Table of per acre values: W1 963, W2 862, W3 781, W4 716, W5 623, W6 580, W7 504, W8 436, W9 354;

(e) FLPAVA #5 counties: Baldwin, Bibb, Bleckley, Butts, Crawford, Dodge, Greene, Hancock, Houston, Jasper, Johnson, Jones, Laurens, Monroe, Montgomery, Morgan, Newton, Peach, Pulaski, Putnam, Rockdale, Taliaferro, Treutlen, Twiggs, Washington, Wheeler, and Wilkinson. Table of per acre values: W1 819, W2 759, W3 697, W4 638, W5 575, W6 518, W7 453, W8 392, W9 325;

(f) FLPAVA #6 counties: Bulloch, Burke, Candler, Columbia, Effingham, Emanuel, Glascock, Jefferson, Jenkins, McDuffie, Richmond, Screven, and Warren. Table of per acre values: W1 810, W2 744, W3 679, W4 619, W5 552, W6 489, W7 424, W8 357, W9 291;

(g) FLPAVA #7 counties: Baker, Calhoun, Clay, Decatur, Dougherty, Early, Grady, Lee, Miller, Mitchell, Quitman, Randolph, Seminole, Stewart, Sumter, Terrell, Thomas, and Webster. Table of per acre values: W1 868, W2 790, W3 719, W4 645, W5 569, W6 497, W7 424, W8 347, W9 273;

(h) FLPAVA #8 counties: Atkinson, Ben Hill, Berrien, Brooks, Clinch, Coffee, Colquitt, Cook, Crisp, Dooly, Echols, Irwin, Jeff Davis, Lanier, Lowndes, Telfair, Tift, Turner, Wilcox, and Worth. Table of per acre values: W1 944, W2 855, W3 766, W4 679, W5 590, W6 504, W7 415, W8 328, W9 266;

(i) FLPAVA #9 counties: Appling, Bacon, Brantley, Bryan, Camden, Charlton, Chatham, Evans, Glynn, Liberty, Long, McIntosh, Pierce, Tattnall, Toombs, Ware, and Wayne. Table of per acre values: W1 956, W2 862, W3 781, W4 695, W5 603, W6 520, W7 431, W8 344, W9 266.

Cite as Ga. Comp. R. & Regs. R. 560-11-11-.12

AUTHORITY: O.C.G.A. §§ 48-2-12**,** 48-5-7**,** 48-5-7.7**,** 48-5-269**.**

HISTORY: Original Rule entitled "Table of Forest Land Protection Act Land Use Values" adopted as ER. 560-11-11-0.40-.12. F. and eff. May 22, 2009, the date of adoption.

Amended: Permanent Rule of same title adopted. F. June 26, 2009; eff. July 16, 2009.

Repealed: New Rule of same title adopted. F. Mar. 15, 2010; eff. Apr. 4, 2010.

Repealed: New Rule of same title adopted. F. Mar. 3, 2011; eff. Mar. 23, 2011.

Amended: F. Apr. 24, 2012; eff. May 14, 2012.

Amended: F. June 25, 2013; eff. July 15, 2013.

Amended: F. Apr. 22, 2014; eff. May 12, 2014.

Amended: F. May 18, 2015; eff. June 7, 2015.

Amended: F. Feb. 23, 2016; eff. Mar. 14, 2016.

Amended: F. Mar. 24, 2017; eff. Apr. 13, 2017.

Amended: F. Mar. 6, 2018; eff. Mar. 26, 2018.

Amended: F. Feb. 1, 2019; eff. Feb. 21, 2019.

Amended: F. Mar. 6, 2020; eff. Mar. 26, 2020.

Note: Correction of non-substantive typographical error in paragraph (d), "316 W1 882" corrected to "W1 882", as requested by the Agency. Effective March 26, 2020.

Amended: F. Mar. 4, 2021 ; eff. Mar. 24, 2021.

Amended: F. May 4, 2022; eff. May 24, 2022.

Amended: F. Mar. 13, 2023; eff. Apr. 2, 2023.

Department 691. RULES OF STATE CHARTER SCHOOLS COMMISSION OF GEORGIA

Chapter 691-2. PRACTICE AND PROCEDURE

691-2-.06 State Charter School Sites and Facilities

(1) Sites and Facilities in General. All state charter schools must ensure a safe and healthy school environment that creates a conducive learning environment and protects the well-being of students and employees. Each state charter school must comply with all applicable laws, rules, regulations, and provisions of its charter contract relating to the school's site and facilities or any material modifications thereto.

(2) Site and Facility Approval. All state charter schools must obtain a site code, facility code, and school code from the Georgia Department of Education (GaDOE) prior to utilizing any site or facility for serving students. Each state charter school is responsible for adhering to the process or procedures outlined by GaDOE for the issuance of site codes, facility codes, and school codes.

(3) Required Documents.

(a) Any state charter school that utilizes a facility it does not own shall execute a written lease or rental agreement with the appropriate party to use the facility as a charter school. State charter schools must submit the final draft lease or rental agreement to the SCSC Executive Director prior to executing any lease or rental agreement. State charter schools must submit any amendment to a lease or rental agreement to the SCSC Executive Director prior to executing the amendment.

(b) Any state charter school that purchases a facility using proceeds from a loan, bond, or other form of debt shall submit the loan, bond, or other financing agreement to the SCSC Executive Director thirty (30) days before closing on the facility's purchase.

(c) Any state charter school that intends to use, lease, occupy, purchase, remodel, or renovate a site, building, or facility through an arrangement with an Education Service Provider (ESP) shall enter a written agreement for such use, lease, occupancy, purchase, remodel, or renovation. State charter schools shall submit a final draft of the written agreement required by this subsection to the SCSC Executive Director and receive prior written approval before executing the agreement.

(d) Each state charter school shall obtain and display a Certificate of Occupancy for its facility prior to occupancy. Each state charter school shall maintain a valid Certificate of Occupancy throughout its entire charter term.

(e) Each state charter school shall prepare a safety plan in accordance with O.C.G.A. § 20-2-1185 and must submit such plan to the local emergency management agency that oversees the area in which the school is located no later than July 1 each year of its charter term.

(f) Each state charter school shall secure adequate insurance coverage prior to occupancy and maintain adequate coverage throughout the charter term.

(4) Changing Facilities. A state charter school shall not change facilities without prior written approval from the SCSC Executive Director.

(a) To change facilities means to change the physical location of a charter school building, facility, or site.

(b) A majority vote of the state charter school governing board is required to authorize negotiations to purchase, dispose of, or lease property.

(c) A state charter school shall notify the SCSC no later than twenty-four (24) hours after a vote pursuant to (4)(b) occurs.

(d) A charter school shall not begin negotiations to change facilities less than ten (10) months prior to the beginning of a new school year, except as expressly authorized in writing by the SCSC Executive Director.

(e) A state charter school changing facilities shall adhere to all applicable provisions of this Rule and all SCSC facility requirements.

(5) Adding or Expanding Facilities. A state charter school shall not add or expand facilities during the term of its charter contract without prior written approval from the SCSC Executive Director. The addition or expansion of facilities must be consistent with the SCSC's rules, guidance, and policies regarding school expansion and replication. A state charter school adding or expanding facilities during the charter term shall adhere to all applicable provisions of this Rule and SCSC facility requirements. State charter schools utilizing multiple sites or facilities must comply with all open enrollment requirements described in O.C.G.A. § 20-2-2066 and SCSC Rule 691-2-.05.

(6) Safety and Security. Each state charter school must take reasonable steps to ensure the safety and security of students, employees, and visitors, including but not limited to, ensuring the facility is clean and in good repair; remediating any visible safety concerns in a timely manner; and taking steps to protect the campus from potential intrusion.

(7) Asbestos Remediation. All state charter schools must comply with the Asbestos Hazard Emergency Response Act (AHERA) and the terms of any applicable asbestos remediation plan.

(8) Onsite Inspection. Each state charter school shall allow the SCSC and its staff to conduct onsite inspections of any and all facilities or property either owned or utilized by the charter school. The SCSC or its staff may conduct such onsite inspections without prior notification to the charter school.

(9) **Compliance.** Failure to comply with the requirements of this Rule may result in one or more of the following:

(a) additional oversight by the SCSC;

(b) point deductions on the SCSC Comprehensive Performance Framework (CPF);

(c) probation;

(d) suspension; or,

(e) recommendation for termination.

Cite as Ga. Comp. R. & Regs. R. 691-2-.06

AUTHORITY: O.C.G.A. §§ 20-2-2083**; 2091.**

HISTORY: Original Rule entitled "State Charter School Sites and Facilities" adopted. F. June 30, 2016; eff. July 20, 2016.

Amended: F. Mar. 29, 2023; eff. Apr. 18, 2023.

691-2-.10 State Charter School Suspension and Probation

(1) Pre-Opening Suspension

(a) The governing board of any non-profit organization approved to operate a start-up, replication, or transfer state charter school must demonstrate that the state charter school is adequately prepared to begin operations by meeting the State Charter Schools Commission's (SCSC) pre-opening requirements and demonstrating the state charter school's ability to meet the obligations of the charter contract.

(b) To demonstrate that the state charter school is adequately prepared to begin operations, the state charter school must meet all SCSC pre-opening requirements in the form and manner prescribed by the SCSC and must demonstrate its compliance with applicable laws; rules of the State Board of Education; rules, and policies of the SCSC; and the charter contract. The SCSC Executive Director shall have the sole discretion to determine whether a state charter school has demonstrated adequate preparation for operations.

(c) If the SCSC Executive Director determines that a state charter school has failed to demonstrate adequate preparation to begin operations, the Executive Director may suspend the state charter school's opening until the SCSC Executive Director determines that the state charter school has demonstrated adequate preparation to begin operations.

(d) Any pre-opening suspension imposed pursuant to this rule shall not result in the automatic extension of the charter term.

(2) Suspension

(a) In cases where the physical and/or mental health, safety, or welfare of students or staff of a state charter school is in danger or the SCSC has reasonable suspicion of fraud, waste, or abuse of state charter school funds, the SCSC may, through a regular or called meeting, suspend the operations of the state charter school.

1. If the SCSC suspends the operations of a state charter school, the state charter school shall not enroll new students or continue to implement its education program, or otherwise provide instruction to enrolled students. The state charter school shall not receive state funding allocations for the period of suspension. The state charter school shall not enter any new contractual agreements without prior written consent from the SCSC Executive Director. The state charter school shall be prohibited from continuing all but essential functions for the period of suspension.

2. Essential functions include oversight of pre-existing contractual obligations, ensuring the protection of school records, funds, property and equipment, transfer of records to other schools, school districts, or educational providers, and other activities deemed essential by SCSC staff.

(b) If operations are suspended, the state charter school shall be required to provide documents and information to the SCSC in the form and at the time required by the SCSC relevant to school operations, finance, and academics through the period of suspension and until the end of the suspension period or until such time that the charter contract is terminated pursuant to procedures in 691-2-.04(3).

(c) Nothing in this subsection shall prohibit a state charter school placed on suspension from requesting that the SCSC terminate its charter pursuant to SCSC rule 691-2-.04(4). Such request shall be made in writing to the SCSC. The SCSC shall act upon the request for termination without conducting a hearing.

(3) Placing a Charter on Probationary Status

(a) The SCSC Executive Director may place a state charter school on probationary status if there is reason to believe that any of the following has occurred or is imminent:

1. failure to timely remedy noncompliance with any material term of the charter after written notice from the SCSC, including but not limited to, the performance goals set forth in the charter;

2. repeated failure to adhere to the rules, policies, and guidelines adopted or established by the SCSC;

3. repeated failure to meet generally accepted government accounting (GAAP) standards;

4. repeated violations of applicable federal, state, or local laws or court orders;

5. the existence of substantial evidence that the continued operation of the state charter school could be contrary to the best interest of the students or the community;

6. the governing board has demonstrated an inability to provide effective leadership or otherwise oversee the state charter school's operation;

7. failure to disclose material information regarding violations or potential violations of any material term of the charter or applicable federal, state, or local laws or court orders;

8. failure to disclose to the SCSC the conditions that place the physical health, safety, or welfare of students or staff of the state charter school at risk;

9. repeated failure to disclose to the SCSC circumstances that may impair or prevent the state charter school from implementing the education program required by the charter;

10. failure to meet the academic, financial, or operational standards in the SCSC's Comprehensive Performance Framework (CPF) for two consecutive years;

11. for schools serving students in grades 9 through 12, failure to maintain accreditation and meet the requirements to be an eligible high school as defined in O.C.G.A. § 20-3-519(6)(A) prior to any student's high school graduation from the state charter school; and,

12. any other reason that would lead to the eventual termination or non-renewal of the charter if not resolved.

(b) If a state charter school is placed on probation, the following shall apply:

1. the SCSC shall provide written notice to the state charter school of the reasons for such placement and the duration of probation, not later than five (5) days after the placement;

2. no later than thirty (30) days after the date of such placement, the state charter school shall file with the SCSC a corrective action plan that addresses the reasons outlined for the probation and a timeline for remedying those issues;

3. the SCSC may approve the corrective action plan as submitted, require specific corrective action, or impose additional terms of probation on the state charter school that it deems necessary;

4. the state charter school shall implement the corrective action plan and complete any required corrective or other actions that the SCSC requires;

5. during the term of probation, the SCSC may require the state charter school to file interim reports concerning any matter deemed relevant to the probationary status of the state charter school, non-renewal of the charter, or termination of the charter, including inventory and financial reports or statements; and,

6. the SCSC may amend the probation length based on its review of the interim reports or corrective actions.

(c) The state charter school may be removed from probation upon fulfilling the terms of its corrective action plan and upon the SCSC's determination that the conditions which precipitated the probation no longer exist and that no new conditions necessitate probationary status.

(d) Failure to implement the corrective action plan within the required time, to produce interim reports in the form and at the time required by the SCSC, or to remediate the conditions that precipitated the probation may result in a recommendation that the SCSC initiate charter termination proceedings consistent with the provisions of SCSC Rule 691-2-.04(3) or a notice to the state charter school of the SCSC's intent not to renew the charter.

(e) If the SCSC notifies the state charter school that it will not renew the charter during the probationary period, the state charter school shall be required to provide documents and information to the SCSC in the form and at the time required by the SCSC relevant to the school's operations, finance, and academics. The SCSC may require the state charter school to communicate specific information to its stakeholders. If the SCSC requires the state charter school to communicate specific information to its stakeholders, the state charter school must do so in the form and at the time required by the SCSC.

(f) The SCSC may consider a state charter school's probationary status at any time, including but not limited to charter renewal or termination, when reviewing a request to expand, add grades, or replicate, or when returning surplus funds from the SCSC's authorized administrative withhold to state charter schools.

Cite as Ga. Comp. R. & Regs. R. 691-2-.10

AUTHORITY: O.C.G.A. §§ 20-2-2083**; 2091.**

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