GEORGIA DEPARTMENT
OF COMMUNITY HEALTH

Nathan Deal, Governor

Frank W. Berry, Commissioner

2 Peachtree Street, NW | Atlanta, GA 30303-3159 | 404-656-4507 | www.dch.georgia.gov

PUBLIC NOTICE OF PROPOSED RULE CHANGES

Pursuant to the Georgia Administrative Procedures Act, Official Code of Georgia (O.C.G.A.) 50-13-1 et seq., the Georgia Department of Community Health is required to provide public notice of its intent to adopt, amend or repeal certain rules other than interpretive rules or general statements of policy. Accordingly, the Department hereby provides notice of its intent to amend the **Rules and Regulations for Narcotic Treatment Programs, Chapter 111-8-53**. These changes are being proposed pursuant to the authority granted to the Department in O.C.G.A. §§ 31-2-5 and 31-2-7.

NOTICE OF BOARD CONSIDERATION FOR FINAL ADOPTION

An opportunity for public comment was previously held on November 8, 2017 at the Department of Community Health (2 Peachtree Street, N.W., Atlanta, Georgia 30303) in the 5th Floor Board Room.

Written comments on the proposed rule changes were accepted by the Department on or before November 10, 2017.

Comments from written and public testimony will be provided to the Board of Community Health prior to the February 8, 2018 Board meeting. The Board will vote on the Final Adoption of proposed changes at the Board meeting to be held at 10:30 a.m. on February 8, 2018 at the Georgia Department of Community Health (2 Peachtree Street, N.W., Atlanta, Georgia 30303 in the Fifth Floor Board Room).

NOTICE IS HEREBY GIVEN THIS 11th DAY OF January, 2018.

Frank W. Berry, Commissioner

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NOTICE OF PUBLIC HEARING

An opportunity for public comment will be held on **November 8, 2017 at 11:00 a.m.**, at the Department of Community Health (2 Peachtree Street, N.W., Atlanta, Georgia 30303) in the 5th Floor Board Room. Oral comments may be limited to 10 minutes per person. Individuals who are disabled and need assistance to participate during this meeting should contact the Office of General Counsel at (404) 657-7195 at least three (3) business days prior to the meeting.

Citizens wishing to comment in writing on any of the proposed changes should do so on or before November 10, 2017. Comments may be faxed to (404) 656-0663, emailed to renee.robinson@dch.ga.gov or mailed to the following address:

Attention: Office of General Counsel
Georgia Department of Community Health
Post Office Box 1966
Atlanta, Georgia 30301

Comments from written and public testimony will be provided to the Board of Community Health prior to the December 14, 2017 Board meeting. The Board will vote on the proposed changes at the Board meeting to be held at 10:30 a.m. on December 14, 2017 at the Georgia Department of Community Health (2 Peachtree Street, N.W., Atlanta, Georgia 30303 in the 5th Floor Board Room).

NOTICE IS HEREBY GIVEN THIS 12th DAY OF OCTOBER, 2017.

Frank W. Berry w/p @

Frank W. Berry, Commissioner

Attachments

RULES OF
GEORGIA DEPARTMENT OF COMMUNITY HEALTH
HEALTHCARE FACILITY REGULATION DIVISION
REVISE CHAPTER 111-8-53
RULES AND REGULATIONS FOR NARCOTIC TREATMENT PROGRAMS

SYNOPSIS OF PROPOSED RULE CHANGES

STATEMENT OF PURPOSE: The Georgia Department of Community Health proposes to revise the Rules and Regulations for Narcotic Treatment Programs, Chapter 111-8-53. These changes are being proposed pursuant to the authority granted the Department of Community Health in O.C.G.A. § 31-6-21 and O.C.G.A. § 31-6-21.1.

MAIN FEATURE OF THE PROPOSED RULE: Comprehensive revision of the rules to comply with Senate Bill 88 and House Bill 249, and to make other changes for purposes of program improvement in the areas of administration; staffing; patient screening, assessment and admission; individual treatment plan; narcotic drugs; drug-screen tests; central registry; reporting; and variance and waiver.

RULES
OF
DEPARTMENT OF COMMUNITY HELTH

CHAPTER 111-8
HEALTHCARE FACILITY REGULATION

111-8-53
NARCOTIC TREATMENT PROGRAMS

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Chapter 111-8-53
RULES AND REGULATIONS FOR NARCOTIC TREATMENT PROGRAMS

Rule 111-8-53-.01 Legal Authority

These rules are adopted and published pursuant to the Official Code of Georgia Annotated § 26-5-2 *et seq.*

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.02 Title and Purpose

These rules shall be known as the Rules and Regulations for Narcotic Treatment Programs. The purpose of these rules is to provide for the licensing and inspection of narcotic treatment programs.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.03 Definitions

Unless the context otherwise requires, as used in these rules the term:

(a) "Administrator" means the individual designated by the program's governing body who is responsible for the on-going and day-to- day operations of the program, for overall compliance with federal, state, and local laws and regulations regarding the operation of narcotic treatment programs, and for all program employees including practitioners, agents, or other persons providing services at the program;

(b) "Applicant" means any individual affiliated with a partnership, corporation, association or individuals or groups of individuals submitting an application to operate a narcotic treatment program under this article.

(c~~b~~) "Clinical director" means the individual designated by the program's governing body who is responsible for the on-going and day-to- day clinical aspects of treatment for those patients admitted to the program;

(d~~c~~) "Clinical staff " means registered nurses, licensed practical nurses, and registered pharmacists, all operating within their respective scope of practice as authorized by law and regulation, as well as those members of the medical staff as such term is defined by these rules;

(e) "Counselor" means an individual who is qualified by education, training, and experience to provide substance abuse counseling and who is licensed or certified if required by state practice acts or these rules;

(f) "Crime means the commission of any of the following offenses:

1. A violation of Code Section 30-5-8, relating to abuse, neglect, or exploitation of a disabled adult or elder person;
2. A violation of Code Section 16-5-1, relating to murder;
3. A violation of Code Section 16-5-2, relating to voluntary manslaughter;
4. A violation of Code Section 16-5-21, relating to aggravated assault;
5. A violation of Code Section 16-8-41, relating to armed robbery with a firearm;
6. A violation of Code Section 16-6-21, relating to aggravated sexual battery;
7. A violation of Code Section 16-6-5, relating to enticing a child for indecent purposes;
8. A violation of Code Section 16-5-70, relating to cruelty to children;
9. A violation of Code Section 16-5-101, relating to cruelty to a person 65 years of age or older or a disabled adult;
10. A violation of Code Section 16-6-1, relating to rape;
11. A violation of Code Section 16-6-4, relating to child molestation;
12. A felony violation of Code Section 16-8-2, relating to theft by taking;
13. A felony violation of Code Section 16-8-3, relating to theft by deception;
14. A felony violation of Code Section 16-8-4, relating to theft by conversion;
15. A felony violation of Code Section 16-9-1; relating to forgery;
16. A violation of Code Section 16-8-40, relating to robbery;
17. A felony violation of Chapter 13 of Title 16, relating to controlled substances;
18. A felony violation of Code Section 16-5-23.1, relating to battery; or
19. Any other offense committed in another jurisdiction which, if committed in this state, would be deemed to be such a crime without regard to its designation elsewhere.

Any other criminal offense as determined by the Department and established by rule adopted pursuant to Chapter 13 of Title 50, the "Georgia Administrative Procedure Act," that would indicate the unfitness of an individual to be involved in the operations or activities of a narcotic treatment program.

(g) "Criminal history background check" means a search as required by law of the criminal records maintained by law enforcement authorities to determine whether the individual has a criminal record as defined in these rules.

(h) "Criminal record" means:

1. Conviction of a crime; or
2. Arrest, charge, and sentencing for a crime where:
   (i) A plea of nolo contendere was entered to the charge; or
   (ii) First offender treatment without adjudication of guilt pursuant to the charge was granted; or
   (iii) Adjudication or sentence was otherwise withheld or not entered on the charge; or
3. Arrest and being charged for a crime if the charge is pending, unless the time for prosecuting such crime has expired pursuant to Chapter 3 of Title 17 O.C.G.A.

(ie) "Department" means the Department of Community Health, operating through the Division of Healthcare Facility Regulation, or its successor;

(j) "Director of Pharmacy Services" means a pharmacist licensed by the Georgia Board of Pharmacy who has been designated by the governing body of the narcotic treatment program to direct, oversee, establish protocols and be responsible for all pharmacy related transactions of the narcotic treatment program;

(k~~f~~) "Final administrative decision" means the issuance of a ruling by the Commissioner of the Department of Community Health or his or her designee or any appeal from a decision of an administrative law judge pursuant to a contested case involving the imposition of a sanction; a decision of an administrative law judge finalized by operation of law where no appeal is made to the Commissioner of the Department of Community Health; the disposition of a contested case through settlement by the parties; or a sanction imposed by the Department that is uncontested by a facility within the allotted time period;

(l~~g~~) "Governing body" means the county board of health, the partnership, the corporation, the association, or the person or group of persons who maintains and controls a narcotic treatment program, who is legally responsible for its operation, and who holds the license to operate that program;

(m~~h~~) "Individual treatment plan" means a comprehensive plan that outlines for each patient attainable short-term and long-term treatment goals that are mutually acceptable to the patient and the narcotic treatment program and that specify the services to be provided and the frequency and schedule for such provision;

(n~~i~~) "Inspection" means any examination by the Department or its representatives of a provider, including, but not limited to, the premises, staff, persons in care, and documents pertinent to initial and continued licensing so that the Department may determine whether a provider is operating in compliance with licensing requirements or has violated any licensing requirements. The term inspection includes any survey, monitoring visit, complaint investigation, or other inquiry conducted for the purposes of making a compliance determination with respect to licensing requirements;

(o~~j~~) "License" means the official permit issued by the Department that authorizes the holder to operate a narcotic treatment program for the term provided therein;

(p~~k~~) "Medical director" means a physician licensed by the Georgia Composite Medical Board who has been designated by the governing body of the narcotic treatment program to be responsible for the administration of all medical services performed by the narcotic treatment program, including compliance with all federal, state, and local laws and rules regarding medical treatment of narcotic addiction;

(q~~l~~) "Medical staff" means the physicians licensed in the State of Georgia who are responsible for the medical treatment being provided to patients through a licensed narcotic treatment program. In limited circumstances, as defined in these rules, medical staff may also include a nurse practitioner, operating under an approved written protocol, and a physician's assistant, operating under an approved job description, supervised by either the program physician or medical director;

(r~~m~~) "Methadone" means an opioid agonist treatment medication as approved by the Food and Drug Administration under Section 505 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355, for use in the treatment of opiate addiction;

(s~~n~~) "Narcotic treatment program" means any system of treatment provided for chronic heroin or opiate-like drug-dependent individuals that administers narcotic drugs under physicians' orders either for detoxification purposes or for maintenance treatment in a

rehabilitative context offered by any county board of health, partnership, corporation, association, or person or groups of persons engaged in such administration;

(t) "Owner" means any individual or any person affiliated with the corporation, partnership, or association with 10 percent or greater ownership interest in a business or agency licensed as a narcotic treatment program and who:

1. Purports to or exercises authority of an owner in the business or agency;
2. Applies to operate or operates the business or agency; or
3. Enters into a contract to acquire ownership of such a business or agency.

(u~~o~~) "Patient" means any individual who undergoes treatment in a narcotic treatment program;

(v~~p~~) "Program physician" means any physician licensed in the State of Georgia, including the medical director, who is employed by a narcotic treatment program to provide medical services to patients; ~~and~~

(w) "Registered Nurse" means a person who holds a current and valid license as a registered nurse issued by the State of Georgia;

(x) "Records check application" means two sets of classifiable fingerprints, a records search fee to be established by the Department by rule and regulation, payable in such form as the Department may direct to cover the cost of a fingerprint records check, and an affidavit by the applicant disclosing the nature and date of any arrest, charge, or conviction of the applicant for the violation of any law, except for motor vehicle parking violations, whether or not the violation occurred in this state, and such additional information as the Department may require;

(y) "Region" means one of the 49 geographical areas specified in O.C.G.A. § 26-5-48(h);

(z) "Satisfactory criminal history background check determination" means a written determination that a person for whom a records check was performed was found to have no criminal record which includes one of the covered crimes outlined in paragraph (f) of this section, if applicable;

(aa~~q~~) ~~"~~"State Board of Pharmacy~~"~~" means the board created to regulate the practice of pharmacy pursuant to Article 2 of Chapter 4 of Title 26 of the Official Code of Georgia Annotated and the Rules and Regulations of the Georgia State Board of Pharmacy, Chapter 480-18; and~~.~~

(bb) "Unsatisfactory criminal history background check determination" means a written determination that a person for whom a records check was performed has a criminal record which includes one of the covered crimes outlined in paragraph (f) of this section, if applicable.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.04 Governing Body

Eaceh licensed program shall have a clearly identified governing body that accepts responsibility for operating the narcotic treatment program in accordance with applicable laws, rules, and regulations.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.05 Licenses

No governing body may operate a narcotic treatment program in the state without first obtaining a license from the Department.

(a) License. A license will be issued, upon presentation of evidence satisfactory to the Department, that the program is in compliance with these rules and all applicable federal and state laws for the handling and dispensing of drugs and all state and local health, safety, sanitation, building, and zoning requirements. Unless suspended or revoked by the Department, a license shall remain in force and effect for a period determined by the Department based upon outcomes and a program's compliance history with these rules. Effective July 1, 2017, the Department shall limit licenses to four (4) per Region unless a waiver is approved pursuant to Rule 111-8-53-.07(12).

(b) Compliance with Requirements of Other State and Federal Agencies. To obtain a license, a program must submit evidence satisfactory to the Department that it will operate in compliance with the requirements of the Substance Abuse and Mental Health Services Administration (SAMHSA), the Drug Enforcement Administration (DEA), the Georgia State Board of Pharmacy, and any other applicable federal or state agency.

(c) License is Nontransferable. A license to operate a narcotic treatment program is nontransferable for a change of location or governing body. Each license shall be returned to the Department in cases of changes in location or governing body or if suspended or revoked. When a licensee intends to relocate or there is change in governing body, it must notify the Department and submit an application in accordance with these rules. The program may be subjected to an on-site visit by the Department prior to the issuance of a license at the discretion of the Department.

(d) Exceptions for programs licensed prior to May 4, 2017. Programs licensed prior to May 4, 2017 must submit an application only in the event of a change of governing body or location. If such program is in good standing with the Department and the change of location is within the program's Region, the requirements of Rule 111-8-53-.07 shall not apply except for 111-8-53-.07(4)(b) and (4)(n). Upon application for an additional program by a current licensee, each location operated by such licensee shall be inspected, except that any such location inspected within the preceding 36 months shall be exempt from the requirement of an on-site inspection.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.06 Provisional Licenses

(1) Provisional licenses may be issued for a period not to exceed 90 days to the governing body of a new narcotic treatment program that is in substantial compliance with these rules or of an existing program that is in substantial compliance with these rules as a result of having submitted an acceptable plan of correction to the Department.

(2) A provisional license shall not be issued to a narcotic treatment program in which there are conditions that present an immediate hazard to the life, health, or safety of patients or staff.

(3) Provisional licenses shall be renewed at the discretion of the Department only in cases of extreme hardship and in no case for longer than 90 days.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.07 Applications

(1) Mandatory Information Forum. Potential applicants must send at least one representative to attend the Information Forum which shall be held at least fourteen (14) days prior to the start of the Open Enrollment Period. Failure to attend the Information Forum shall disqualify any applicant from consideration during open enrollment.

(2) Letter of Intent. Applicants for licensure must submit a letter of intent to stating such applicant's intention to apply for a narcotic treatment program license. Such letter of intent shall include the intended address and Region location. The letter shall be delivered to the Department at least seven (7) days prior to the beginning of the Open Enrollment Period.

(3) The first Open Enrollment Period shall be held December 1, 2017 through December 31, 2017. Thereafter, the Open Enrollment Period shall be held in the month of December of each following year unless the Department issues a Public Notice prior to December 1 specifying an alternate time frame for enrollment.

(4) No later than the last day of the Open Enrollment Period, an application for a license to operate a narcotic treatment program must be submitted by the governing body to the Department on forms provided by the Department and must contain all information and documents designated by the Department, including, at a minimum:

(a) Data and details regarding treatment and counseling plans;
(b) Written operating standards that demonstrate an organizational capability to meet these rules;
(c) Biographical and qualifications of owners, medical directors, counselors, and other required staff;
(d) A listing of all currently licensed narcotic treatment programs within the Region of the proposed location and within a 75 mile radius, whether or not such other programs are outside of the Region.

(e) Patient levels of currently licensed programs in the proposed Region of care and within 75 miles, including
   1. The number of patients admitted to current narcotic treatment programs in the most recent month; and
   2. The number of patients served by current narcotic treatment programs in the most recent month.
(f) Data on demographic, social, health, economic, alcohol and drug related crimes, alcohol and drug overdoses, and hospital and emergency department admission of individuals addicted to opioids for the program location;
(g) Applicant experience operating a narcotic treatment program or working at such program, including complete history of such experience both within this state and in any other state;
(h) Program ownership in other locations, if any, including a complete and accurate description of narcotic treatment program experience, including whether the applicant currently holds, has held, or had revoked any licenses, registrations, enrollments, accreditations, contracts, and network memberships. The applicant shall disclose any adverse actions against the applicant while employed by or as a result of ownership of a narcotic treatment program;
(i) Evidence the applicant sought community input for the proposed location from substance abuse advocacy organizations, civic organizations, neighborhood associations, locally elected officials, and other groups;
(j) Proof of notification of intent to file an application with all law enforcement offices within a 25 mile radius of the proposed program location;
(k) Proof of notification of intent to file an application with all drug courts within a 75 mile radius of the proposed program location;
(l) A narrative description of and information about adjoining businesses and occupancies within 200 feet of the facility, including a description of transportation access, traffic patterns, security features, local area police and crime reports, and neighborhood safety;
(m) A complete description of the facility's parking arrangements for staff and patients; and
(n) Assurances satisfactory to the Department that the program is in compliance with all applicable federal and state laws for the handling and dispensing of drugs and all state and local health, safety, sanitation, building, and zoning requirements.

~~Information. An application for a license to operate a narcotic treatment program must be submitted by the governing body to the Department on forms provided by the Department, must contain all information and documents designated by the Department, and must include assurances satisfactory to the Department that the program is in compliance with all applicable federal and state laws for the handling and dispensing of drugs and all state and local health, safety, sanitation, building, and zoning requirements. The application must also include a comprehensive outline of the program to be operated by the applicant, including written operating standards that demonstrate an organizational capability to meet these rules.~~

(~~2~~5) Approval by SAMHSA, the DEA, and the Georgia State Board of Pharmacy. An application must include assurances satisfactory to the Department that the program will meet the requirements for approval by SAMHSA or other applicable federal agency, the DEA, and the Georgia State Board of Pharmacy.

(~~3~~6) False or Misleading Information. An application for a license must be truthfully and fully completed. In the event that the Department has reason to believe that an application has not been completed truthfully, the Department may require additional verification of the facts alleged. The Department may revoke a license or refuse to issue a license where material false statements have been made on or in connection with an application.

(~~7~~4) History of Compliance. When an existing licensee applies to operate another program, the Department will consider the licensee's history of compliance in Georgia and may consider the licensee's compliance in any other state when determining the applicant's eligibility for another license. When an applicant that has previously operated a program applies to operate a new program, the Department will consider the compliance history of the applicant in Georgia and may consider the compliance history of the applicant in any other state.

(~~8~~5) No license shall be issued to any governing body that has been denied a license by the Department during the previous 12 months. No license shall be issued to any governing body that has had a license revoked by the Department during the previous 12 months.

(9) Criminal Background Checks for Applicant/Owner. Prior to the issuance of any new license, the applicant of the business or agency applying for the license shall be required to submit a records check application so as to permit the Department to obtain a criminal history background check. After initial licensure, the owner shall be required to submit evidence of a satisfactory background check to the Department every three (3) years.

(a) At the time of initial licensure, in lieu of a records check application, the applicant may submit evidence, satisfactory to the Department, that within the immediately preceding 12 months the owner has received a satisfactory narcotic treatment program criminal records check determination.
(b) A narcotic treatment program license shall not be issued, and any issued license shall be revoked, where it has been determined that the applicant/owner has received an unsatisfactory criminal records check determination involving any of the covered crimes, as defined in paragraph (f) of Rule 111-8-53-.03.
(c) An owner with a valid narcotic treatment program license who acquires a criminal record for any of the crimes listed in paragraph (f) of Rule 111-8-53-.03 subsequent to the effective date of the license shall disclose the criminal record to the Department.
(d) If at any time the Department has reason to believe an owner holding a valid license has been arrested, charged, or convicted of any of the covered crimes listed in paragraph (f) of Rule 111-8-53-.03, the Department shall require the owner to submit a records check application immediately for determination of whether a revocation action is necessary.
(e) An owner holding a valid narcotic treatment program license issued prior to May 4, 2017 shall not be subject to any of the background check requirements stated in this Rule 111-8-53-.07(9). However, if there is a change in the governing body of a program licensed prior to May 4, 2017, any new individuals with an ownership interest in the program shall be subject to the requirements of this Rule 111-8-53-.07(9).

(10) Application Review Committee. Where more applications are received for a particular Region during the Open Enrollment Period than are permissible under these rules, the Department shall first review the applications to determine that all information required under subsections (1)-(9) above has been submitted. All complete applications will then be sent to the Application Review Committee to be scored based on the following criteria:

(a) Compliance with all state and federal laws and regulations;
(b) Compliance with all applicable standards of practice;
(c) Program structure for successful service delivery; and
(d) Impact on the delivery of opioid treatment services of the applicant in the applicable population.

(11) Notice of Intent to Issue License/Notice of Appeal Rights. Programs selected for licensure by the Application Review Committee shall receive a notice of the Department's intent to issue a license. Programs not selected shall receive notice of the right to an administrative hearing. Upon waiver of or exhaustion of administrative appeal rights, the Department shall issue license(s) to the selected program(s).

(12) Waiver Applications Under O.C.G.A. § 26-5-48(f). The Department, in its discretion, may grant a waiver to an applicant to allow an application to be submitted for review in a Region that has four or more licensed narcotic treatment programs. The Application Review Committee shall consider such waiver applications based on criteria developed jointly by the Department and the Department of Behavioral Health and Developmental Disabilities with emphasis on the needs assessment and/or justification for the establishment of a new program (including identification of treatment gaps), as well as community stakeholder support.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.08 Inspections and Plans of Correction

(1) The Department is authorized to conduct on-site inspections of any program to verify compliance with these rules and all relevant laws or regulations at any time. A program shall permit any authorized representative of the Department to enter upon and inspect any and all program premises which, for the purpose of these rules, shall include access to all parts of the facility, staff, persons in care, and all records pertinent to initial and continued licensure. For the purpose of conducting any investigation, inspection, or survey, the Department shall have the authority to require the production of any books, records, papers, including all patient records or other information related to the initial or continued licensing of any program. The Department may require at reasonable intervals that each licensee shall furnish copies of complete records of each person treated or advised by the program, provided, however, that patient identifying information shall be redacted from such records prior to submission to the Department. Failure to permit entry and inspection is a violation of these rules and may result in the denial of any license applied for or in the suspension or revocation of a license.

(2) If, as a result of an inspection, violations of these rules requiring corrective action are identified, the Department shall issue a written inspection report that identifies the rules violated and requires the program to submit a written plan of correction that

states what the program will do to correct each of the violations identified. The program may offer an explanation or dispute the findings of violations in the written plan of correction so long as an acceptable plan of correction is submitted within 10 days of the receipt of the inspection report. Failure to submit an acceptable plan of correction may constitute cause for the Department to deny a license or suspend or revoke a license. Upon the discovery of any violation of these rules, the Department may proceed to suspend or revoke a program's license in accordance with these rules. In determining whether to suspend or revoke a license, the Department may consider whether the violations can be corrected, the program's history of compliance, the nature and seriousness of the violations, the impact of the violations on the safety and welfare or the program's patients and the surrounding community and any other relevant circumstances.

(3) Programs shall also cooperate with interested parties seeking to apply for licensure by providing the information detailed in Rule 111-8-53-.07(4)(e) within a reasonable period of time.

(4) After initial licensure, the Department shall conduct on-site inspections of each program on an annual basis. The Department may authorize third party audits or inspections of programs for the purpose of determining whether or not a program is in compliance with these rules.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.09 Administration

(1) Program Purpose. A licensed program shall operate, in accordance with these rules, under written policies and procedures that define its philosophy, purpose, program orientation, and procedures. Such policies and procedures must identify the types of drug-dependent individuals and the ages of the patients that the program serves, including referral sources.

(2) Program Description. A licensed program shall develop and fully implement written policies and procedures that describe the range of treatment and services provided by the program. These policies and procedures must describe how identified treatment and services will be provided and how such treatment and services will be assessed and evaluated. A program description must show what services are provided directly by the program and what treatment and services are provided in cooperation with available community or contract resources.

(3) Finances. The governing body shall provide for the preparation of an annual budget and approve such budget. Copies of the current year's budget and expenditure records must be made available to the Department for examination and review by the Department upon request.

(4) Fees. The program shall develop and implement a written schedule of patient fees. The schedule must identify all fees that are chargeable to patients and a copy of the current schedule shall be posted in a conspicuous place so as to inform patients and their parents, guardians, or responsible parties of such schedule of fees.

(5) Patient Records. The patient record must accurately reflect the course of appropriate treatment provided to the patients. Programs must organize and coordinate patient records in a manner that demonstrates that all pertinent patient information is accessible to all appropriate staff and to the Department. The patient's Central Registry I.D. number must be maintained in each patient record and some form of a patient identification must appear on each page of the record. Each patient record must contain, at a minimum, the following:

(a) Basic identifying information including name, current address, current telephone number, date of birth, sex, and race;

(b) If applicable, the names, addresses, and telephone number of parents, or guardians, or responsible parties;

(c) Persons to notify in case of an emergency if different from above;

(d) Appropriate evidence of a history of opiate addiction prior to entry into the program;

(e) Records of screening and assessment, including information about expected charges for services;

(f) If applicable, documentation of why the patient was not admitted for treatment and suggested referrals given to patient;

(g) Written consents, signed by the patient and dated and witnessed, as required in Rule 111-8-53-.12(1)(c)1.;

(h) Documentation of Central Registry clearance as required in Rule 111-8-53-.19;

(i) Documentation of orientation as required in Rule 111-8-53- .12(1)(c) 3.;

(j) The individual treatment plan and documentation of patient involvement in the development of the individual treatment plan;

(k) Medical reports, nursing notes, laboratory results including reports of drug screens, progress notes, and documentation of current dose and other dosage data, with all entries signed and dated by the appropriate professional staff;

(l) Dated and signed case entries of all significant contacts with or concerning patients, including a record of each counseling session in chronological order, as well as dated and signed forms and assessments;

(m) Correspondence with the patient, his or her family members, and other individuals and record of each referral for service and the results thereof;

(n) Documentation by appropriate professional staff that supports the course of treatment being provided; and

(o) Discharge summary, including reasons for discharge and any referral.

(6) Confidentiality of Patient Records. Written policies and procedures shall be established and implemented for the maintenance and security of patient records specifying who shall supervise the maintenance of such records, who shall have custody of such records, and to whom records may be released. Confidentiality of patient records and release of such records must comply with 42 CFR, Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records and any applicable state laws, including but not limited to O.C.G.A. § 26-5-56.~~.~~ Patients shall be informed that all clinical records are subject to inspection by the Department in connection with the initial and on-going licensure of the program.

(7) Drug Records. Medication orders and dosage changes must be written or printed on a physician's order sheet or a form that clearly displays the physician's signature and tracks orders over time. Dosage dispensed, prepared, or received must be recorded and accounted for by written or printed notation in a manner that reflects an accurate inventory at all times. Every dose shall be recorded in the patient's individual medication record at the time the dose is dispensed or administered and shall be properly authenticated by the licensed person administering such dose. Where computerized systems are used, authentication procedures will be strictly enforced. If initials are used, the full signature and credentials of the qualified person administering or dispensing must appear at the end of each page of the medication sheet. The perpetual inventory must be totaled and recorded in milligrams daily. Methadone and related drugs shall be counted and reconciled with the written inventory at the beginning and end of each dosing day with all discrepancies satisfactorily resolved.

(8) Personnel Records. A program shall maintain written and verified records for each employee. Each employee file shall include:

(a) Identifying information including name, current address, current telephone number, and emergency contact persons;

(b) A five-year employment history or a complete employment history if the person has not worked five years;

(c) Evidence of a criminal record check obtained from a state or local law enforcement agency ~~authorities~~ that reflects the individual does not have any convictions of a crime, as defined in paragraph (f) of Rule 111-8-53-.03, ~~recent criminal history~~ within the previous five~~two~~ years ~~and that does not disqualify the individual from providing care to patient~~; for employees working in an administrative capacity who are not providing care to patients and for employees working as peer counselors, the program may accept a criminal record check which includes conviction of a nonviolent crime such as those listed in 111-8-53-.03(f)(12)-(17);~~s;~~

(d) Records of educational qualifications if applicable;

(e) Date of employment;

(f) The person's job description or statements of the person's duties and responsibilities;

(g) Documentation of training and orientation required by these rules;

(h) Any records relevant to the employee's performance, including an appropriate health status of the employee; and

(i) Evidence that any professional license required as a condition of employment is current and in good standing.

(9) Referral to Other Programs. Each program shall have arrangements for referral of patients to other programs that offer different treatment modalities.

(10) Closing of a Program. A program that intends to close the program voluntarily shall notify the Department no later than sixty (60)~~thirty~~ days prior to closure. Any program that closes, either voluntarily or involuntarily,~~s~~ shall submit satisfactory evidence to the Department that the program has developed a transition plan for the continuity of care for its patients. Such transition plan shall include, at a minimum:

(a) Written notice to all current patients of record that the program is closing. Such notice shall be provided to patients at least thirty (30) days prior to closure and shall include information on other programs in close proximity which have availability to treat new patients;

(b) Coordination with other programs to ensure continuity of care for patients that need assistance in locating a new treatment program;

(c) Use of the Central Registry to transfer patients to the receiving program;

(d) A plan for the transfer of appropriate clinical/treatment records to the receiving program in a manner that complies with state and federal privacy laws;

(e) A timeline for management of closure-related activities; and

(f) A protocol for securing all medications to ensure that there is no diversion and to transfer any excess medications to the U.S. Drug Enforcement Administration.

(11) Hours of Operation. Program hours of operation shall accommodate persons involved in activities such as school, homemaking, childcare, and variable-shift work. Programs shall offer comprehensive services, including, but not limited to, individual and group counseling, medical services, and referral services, at least five days per week. A program may close on Sundays and state and federal holidays provided appropriate treatment arrangements are made for patients. In order to accommodate patients for whom take-home medication has not been authorized, the program shall dispense medication at least seven days per week when necessary. Programs shall further develop a plan for contingencies, emergencies, etc., including 24 hour emergency services during non-operating hours to assist patients in crisis situations.

(12) Community Liaison and Concerns. A program shall schedule and provide services to its patients in such a manner as to minimize the impact on local community services.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.10 Staffing

(1) Staff Ratios and Responsibilities. The program shall have sufficient and appropriate types and numbers of staff to provide the treatment and services as required by applicable state law and regulation and as outlined in its program description. When the program is open to provide treatment, there shall be a minimum of one clinical staff member and at least one additional staff member on site at all times. Patient-staff ratios shall be adjusted to ensure reasonable and prompt access to medical staff and counselors by patients and to provide the frequency and intensity of medical and counseling services required by the patients.

(a) Administrator. The governing body of each program shall designate in writing an administrator. The administrator shall be responsible for the on-going and day-to-day operations of the program, for overall compliance with federal, state, and local laws and regulations regarding the operation of narcotic treatment programs, and for all program employees including practitioners, agents, or other persons providing services at the program. The administrator must be at least 21 years of age, must have at least one year of supervisory and administrative experience in the field of substance abuse treatment, and must have at least one year of experience working in a narcotic treatment program. Programs must notify the Department in writing within 10 calendar days whenever there is a change in administrator.

(i) Criminal History Background Check – Administrators. The program must obtain a satisfactory criminal history background check for the person being considered for employment as an administrator and must obtain a new background check for the employed administrator every three (3) years thereafter. The records check must be performed as prescribed in these rules. Programs licensed prior to May 4, 2017 shall only be subject to the requirements of Rule 111-8-53-.10(a)(i)-(iv) if there is a change in the administrator.

(ii) At the time of initial employment, in lieu of a records check application, the program may submit evidence, satisfactory to the Department, that within the immediately preceding 12 months the administrator has received a satisfactory narcotic treatment program criminal records check determination.

(iii) A person with an unsatisfactory criminal history background check determination must not serve as an administrator of a licensed narcotic treatment program. Failure to satisfy this requirement may result in enforcement action against the facility as prescribed in Chapter 111-8-25.

(iv) The administrator must immediately submit to an additional criminal history background check when the Department provides the administrator with written notice of any one of the following:

1. There is reason to believe that the administrator has acquired a criminal record as defined by these rules; or
2. The criminal history background check is required in connection with a complaint investigation being conducted by the Department.

(b) Clinical Director. The governing body of each program shall designate in writing a clinical director. The clinical director shall be responsible for the day-to-day and on-going clinical aspects of the program and of the treatment for those patients admitted to the program. Programs must notify the Department in writing within 10 calendar days whenever there is a change in clinical director.

(c) Medical Director. The governing body of each program shall designate in writing a medical director to be responsible for the administration of all medical services, including compliance with all federal, state, and local laws and regulations regarding the medical treatment of narcotic addiction. A~~No~~ physician may serve as medical director of no more than two~~one~~ narcotic treatment programs provided that~~unless~~ all such programs are in substantial compliance with these rules and are within 50 miles of the physician's primary residence or primary office location~~.~~ Programs must notify the Department in writing within 10 calendar days whenever there is a change in medical director.

(d) Program Physician. Programs are required to provide sufficient physician coverage to provide the medical treatment and oversight necessary to serve patient needs. A program physician's responsibilities for each patient include, but are not limited to, performing medical history and physical exams, determination of diagnosis under current DSM criteria, determination of narcotic dependence, reviewing treatment plans determining dosage and all changes in doses, ordering take-home privileges, discussing cases with the treatment team, and issuing any emergency or verbal orders relating to patient care. At all times a program is open and a physician is not present on site, a program physician must be available on call for consultation and emergency orders. Programs must be able to document a referral agreement with a local hospital or health care facility. Any program physician who is not a medical director must work under the supervision of the program's medical director.

(e) Physician's Assistants and Nurse Practitioners. Licensed physician's assistants and certified nurse practitioners may be employed by programs and perform any functions permitted under Georgia law.

(f) Nurses. Programs shall ensure that appropriate nursing care is provided at all times the program is in operation and that an appropriately licensed and qualified health care professional is present at all times medication is administered at the program.

~~Programs that do not employ a registered nurse to supervise the nursing staff must ensure that licensed practical nurses adhere to written protocols and are supervised by the medical director to ensure that nursing services are being appropriately delivered.~~

(g) Counselors. There must be at least one full-time counselor for every 50 patients. To be considered "full-time," a counselor must work a minimum of 35 hours per week. The program shall assign no more than 40 patients to counselors in training who are not yet certified.~~.~~

(2) Staff Qualifications.

(a) Medical Director. All medical directors shall be licensed to practice medicine in Georgia, shall maintain their licenses in good standing and shall have had, at a minimum, 12 hours of training in narcotic-addiction treatment within the 12 months preceding the date of hire when hired after the effective date of these rules.

(b) Program Physician. All program physicians must be licensed to practice medicine in the State of Georgia, must maintain their licenses in good standing, and must have had, at a minimum, 12 hours of training in narcotic-addiction treatment within the 12 months preceding the date of hire when hired after the effective date of these rules. If the program physician has not had such training, he or she must be working under the direction of a qualified medical director with an acceptable training plan, completed within 12 months of the date of hire, that consists of a combination of continuing education in addiction medicine and in-service training by the program's medical director.

(c) Medical staff. All medical staff must be licensed and in good standing to practice their respective professions in the State of Georgia, have 12 hours of training in narcotic-addiction treatment within the 12 months preceding the date of hire when hired after the effective date of these rules, and practicing within the scope authorized by law. If any member of the medical staff has not had such training, he or she must be working under the direction of a qualified medical director with an acceptable training plan, completed within 12 months of the date of hire, that consists of a combination of continuing education in addiction medicine and in-service training by the program's medical director.

(d) Nurses. All registered nurses and licensed practical nurses must be licensed to practice in Georgia in compliance with Chapter 26 of Title 43 of the Official Code of Georgia Annotated, the "Georgia Registered Professional Nurse Practice Act," and must maintain their licenses in good standing.

(e) Counselors. All counselors must be certified in addiction counseling pursuant to Section 7(b)(15) ~~qualified by training, education, and experience to provide addiction counseling services to persons who are addicted to narcotics and must be in compliance with~~ of Chapter 10A of Title 43 of the Official Code of Georgia Annotated within three (3) years of employment by the program. Programs licensed prior to May 4, 2017 shall have three (3) years to comply with this requirement.~~.~~

(f) Clinical Directors. All clinical directors must be licensed to practice medicine in the State of Georgia, licensed as a practitioner to provide treatment, therapeutic advice, or counseling for the rehabilitation of drug-dependent persons in compliance with state practice acts, or certified as an addiction counselor, must be at least 21 years of age, and must have at least one year of supervisory and administrative experience in the field of substance abuse treatment.

(g) Professional Practice. All professional staff members, including, but not limited to, physicians, pharmacists, physicians' assistants, nurse practitioners, registered nurses, licensed practical nurses, and counselors, may perform only those duties that are within the scope of their applicable professional practice acts and Georgia licenses.

(3) Medical Staff Supervision. Programs that do not employ a registered nurse to supervise the nursing staff must ensure that licensed practical nurses adhere to written protocols and are supervised by the Medical Director to ensure that nursing services are being appropriately delivered.

(a) Supervision by Medical Director must occur at least one time per month, be documented in writing, reviewed with the Administrator and Clinical Director, and include the following areas:

1. the written policies and procedures required in Rule 111-8-53-.15;
2. changes made to policies and procedures required in Rule 111-8-53-.15; and
3. areas identified by Administrator, Clinical Director, Director of Pharmacy Services, Medical Director or Program Physician as requiring training for all licensed practical nurses;

(4~~3~~) Staff Training and Orientation. Prior to working with patients, all staff members who provide treatment and services must be oriented in accordance with these rules and must thereafter receive additional training in accordance with these rules.

(a) Orientation must include instruction in:

1. The program's written policies and procedures that are relevant to the employee's range of duties and responsibilities;

2. The employee's assigned duties and responsibilities;

3. Reporting patient progress and problems to supervisory personnel and procedures for handling medical emergencies or other incidents that affect the delivery of treatment or services; and

4. Customer service.

(b) Additional training consisting of a minimum of 16 hours of training or instruction must be provided annually for each staff member who provides treatment services to patients. Such training must be in subjects that relate to the employee's assigned duties and responsibilities and in subjects about current clinical practice guidelines for narcotic treatment, such as dosage based on a physician's clinical decision making and an individual patient's needs; drug screens; take-home medication practices; phases of treatment; treating abusers of multiple substances; narcotic treatment during pregnancy; HIV and other infectious diseases; co-morbid psychiatric conditions; and referring patients for primary care or other specialized services. Programs shall maintain records documenting that each staff member has received the required annual training.

(5~~4~~) Employee Drug Testing. Programs shall establish and implement written policies and procedures for pre-employment and ongoing random drug testing of all program employees. Each sample must be collected and handled in accordance with accepted standards of clinical laboratory practice and tested for opiates, methadone and related drugs, amphetamines, cocaine, benzodiazepines, THC, and other drugs with satisfactory documentation of the results retained by the program.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.11 Physical Plant and Safety

(1) A program shall be in compliance with all applicable local health, safety, sanitation, building, and zoning requirements.

(2) A program shall be in compliance with all applicable laws and rules issued by the state fire marshal and the proper local fire marshal or state inspector and shall have a certificate of occupancy, if required.

(3) All buildings and grounds must be accessible by the disabled and constructed and maintained in a safe manner in accordance with these rules.

(4) A program shall have appropriate and sufficient space to meet the programmatic needs of its patients, and carry out the program's array of services. Such space must include areas conducive to privacy for dosing, counseling and group activities, reception/waiting areas, and bathrooms that ensure privacy for collection of urine specimens.

(5) Medications shall be separately and appropriately stored. Medical specimens and food will be stored separately and appropriately to prevent cross-contamination.

(6) Facilities shall have NARCAN, or other medically appropriate emergency narcotic antagonists, available on site when care is being provided to patients; and.

(7) Any laboratory functions performed by the program shall conform to the Rules and Regulations for Licensure of Clinical Laboratories, Chapter 111-8-10.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.12 Patient Screening, Assessment, and Admission

(1) A program may only admit and retain patients whose known needs can be met by the program in accordance with its program purpose and description and applicable federal and state laws and regulations. Written policies and procedures for patient referral, intake, screening, assessment, and admission must be established and implemented and must include the following provisions or requirements.

(a) Screening. All applicants for admission must be initially screened by program staff to determine eligibility for admission. No applicant may be admitted until it has been verified that he or she meets all applicable criteria and that the sources and methods of verification have been recorded in the applicant's case folder. The screening process must include:

1. Verification, to the extent possible, of an applicant's identity, including name, address, date of birth, and other identifying data;

2. Drug history and current status, including determination and substantiation, to the extent possible, of the duration of substance dependence;

3. If an applicant has been previously discharged from treatment at another narcotic treatment program, the admitting program must initiate an investigation into the applicant's prior treatment history, inquiring of the last program attended the reasons for discharge from treatment;

4. If an applicant is 18 years of age or older, verification of dependence on opium, morphine, heroin or any derivative or synthetic drug of that group for a period of one year; and

5. If an applicant is under 18 years of age, verification that the applicant has had two documented unsuccessful attempts at short-term detoxification or drug-free treatment within a 12 month period to be eligible for maintenance treatment. No person under 18 years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible party consents in writing to such treatment.

(b) Assessment. Each patient admitted to the program must be assessed by the medical director, the program physician, or an appropriately licensed and qualified member of the medical staff who has been determined to be qualified by law, education, training, and experience to perform or coordinate the provision of such assessments. A program shall not admit a patient for a maintenance program unless it is the most appropriate treatment modality. Before any medication is prescribed or administered, a patient who is admitted to a program shall be assessed by the medical director, the program physician, or an appropriately licensed and qualified member of the medical staff who has been determined to be qualified by law, education, training, and experience to perform or coordinate the provision of such assessments. The assessment must include:

1. Medical history, including HIV status, pregnancy, current medications (prescription and non-prescription), and active medical complications;

2. Psychiatric history and current medical status examination;

3. Determination if the applicant needs special services, such as treatment for alcoholism, or psychiatric services, and determination that the program is capable of addressing these needs either directly or through referral;

4. Explanation of treatment options, detoxification rights, and program charges, including fee agreement, signed by the applicant; and

5. An in-person physical examination in accordance with current and accepted standards of medical practice, complete with laboratory tests, including drug screens, HIV status (if the applicant consents to be tested), CBC and chemistry profile, and pregnancy, STD, and Mantoux TB tests, to determine dependence on opium, morphine, heroin, or any derivative or synthetic drug of that group and to determine current DSM diagnosis. The purpose of such assessments shall be to determine whether narcotic substitution, short-term detoxification, long-term

detoxification, or drug-free treatment will be the most appropriate treatment modality for the patient and to establish additional educational, vocational, and treatment needs of the patient. In lieu of a complete physical examination being performed by the program physician, the individual may present a complete physical examination, dated within 90 days of admission, performed by a physician licensed in good standing in the State of Georgia. Such examination shall be updated as necessary to reflect the individual's current condition at the time of admission, including updated laboratory tests.

(c) Admission.

1. Consent. Except as otherwise authorized by law, no person may be admitted for treatment without written authorization from the patient and parent, guardian, or responsible party, if applicable. The following information must be explained by a trained staff person to the patient and other consenters, signed by the patient and such other consenters, and documented in the patient file:

   (i) The program's services and treatment;

   (ii) The specific condition that will be treated;

   (iii) The expected charges for service including any charges that might be billed separately to the patient or other parties; and

   (iv) The program's rules regarding patient conduct and responsibilities.

2. Admission Clearance. No person may receive medications unless the program first conducts an inquiry with the Central Registry in accordance with Rule 111-8-53-.19 and receives clearance from the Central Registry that the person is not simultaneously enrolled in another program.

3. Orientation. The program shall provide orientation to patients who are admitted for treatment within 24 hours of admission. Orientation must be done by a staff person who has been determined to be qualified by education, training, and experience to perform the task. Patients must be reoriented as needed to ensure an understanding of the program. Programs shall ensure that each patient signs a statement confirming that the following has been explained to the patient:

   (i) The expected benefits of the treatment that the patient is expected to receive;

   (ii) The patient's responsibilities for adhering to the treatment regimen and the consequences of non-adherence;

   (iii) An explanation of individual treatment planning;

(iv) The identification of the staff person who is expected to provide treatment or coordinate the treatment;

(v) Program rules including requirements for conduct and the consequences of infractions, including involuntary discharge;

(vi) Patient's rights and responsibilities;

(vii) Procedures for complaining to the program and to the Department of Community Health;

(viii) Drug screening policies and procedures;

(ix) HIV education; and

(x) Community awareness.

4. Programs shall ensure that patients receive a written copy of the orientation information.

(2) Any program licensed or funded by the Department shall implement a priority admissions policy for the treatment of drug dependent pregnant females which provides for immediate access to services for any such female applying for admission, which access shall be contingent only upon the availability of space. ~~Drug dependent pregnant females must be given priority for admission and services when a program has a waiting list for admissions and it is determined that the health of the mother and unborn child is more endangered than are the health of other patients awaiting services.~~ The program must coordinate the treatment of the pregnant female with appropriate health care providers monitoring the progress of the pregnancy. Pregnancy tests for females must be conducted at admission, unless otherwise indicated.

(3) No program may provide a bounty, free services, medication, or other reward for referral of potential patients to the program.

(4) No program may provide temporary discounted financial incentives to a potential patient that does not conform to the schedule of fees established by such program as required by these rules. No program shall provide discounted fees for services during the first ninety (90) days of treatment. This paragraph (4) shall not apply to drug dependent pregnant females.

(5~~4~~) Non-Admissions. The program shall maintain written logs that identify persons who were considered for admission or initially screened for admission but were not admitted. Such logs must identify the reasons why the persons were not admitted and what referrals were made for them by the program.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.13 Individual Treatment Plan

A program must develop a preliminary individual treatment plan for each patient within 10 days of admission, which includes an initial treatment recommendation. A complete individual treatment plan for each patient must be developed within 30 days of admission. Patients must be involved in the development of their treatment plans. Treatment plans must document a consistent pattern of substance abuse treatment services and medical care appropriate to individual patient needs and must meet the requirements of 42 C.F.R. § 8.12(f)(4).

(a) Medical care, including referral for necessary medical service, and evaluation and follow-up of patient complaints must be compatible with current and accepted standards of medical practice. All patients must receive a physical examination by the medical director, the program physician, or an appropriately licensed and qualified member of the medical staff at least annually. All other medical procedures performed at the time of admission must be reviewed by the medical staff on an annual basis, and all clinically indicated tests must be repeated. The medical director or program physician shall evaluate the results of this annual medical examination and review of patient medical records and document such evaluation in each patient's record.

(b) In recognition of the varied medical needs of patients, the case history and individual treatment plans must be reviewed at least every 90 days for patients in treatment less than one year and at least annually for patients in treatment more that one year. This review will be conducted by the medical director or program physician along with the primary counselor and other appropriate members of the treatment team for general quality controls and evaluation of the appropriateness of continuing the form of treatment on an ongoing basis. This review must also include an assessment of the current dosage and schedule and the rehabilitative progress of the patient, as part of determination of whether additional medical services are indicated. If such review results in a determination that additional or different medical services are indicated, the program must ensure that such services are made available to the patient and appropriate referrals for additional care are made.

(c) When the program physician prescribes other controlled substances to patients in the program, the program physician shall ensure that such prescriptions are in accordance with all applicable statutes and regulation and with current and accepted standards of medical practice. Such prescriptions shall not be issued to any patient unless the medical director, the program physician, or a member of the medical staff first sees the patient and assesses the patient's potential for abuse of such medications.

(d) As part of the rehabilitative services provided by the program, each patient must be provided with individual or group counseling appropriate to his or her needs. The frequency and duration of counseling provided to patients must be determined by appropriate program staff and be consistent with the individual treatment plan. Individual treatment plans must indicate a specific level of counseling services needed by the patient as part of the rehabilitative process.

(e) All patients shall receive HIV risk reduction education appropriate to their needs.

(f) When appropriate, each patient must be enrolled in an education program, or be engaged in a vocational activity (vocational evaluation, education, or skill training), or make documented efforts to seek gainful employment. Deviations from compliance with these requirements must be explained in the patient's record. Each program shall

take steps to ensure that a comprehensive range of rehabilitative services, including vocational, educational, legal, mental health, alcoholism, and social services are made available to patients who demonstrate a need for such services. The program can fulfill such responsibility by providing support services directly or by appropriate referral. Support services recommended and utilized must be documented in the patient record.

(g) All programs will develop and implement policies for matching patient needs to treatment and providing treatment in accordance with current and accepted standards of medical practice. These policies shall include treatment phasing, in which the intensity of medical, counseling, and rehabilitative services provided to a patient varies depending upon the patient's phase of treatment. Phases of treatment may include intensive stabilization for new patients and those in need of acute care, graduated rehabilitation phases, and medical maintenance or appropriate treatment-tapering phases for long-term stable patients.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.14 Discharge and Aftercare Plans

(1) A program must complete, in accordance with accepted standards of practice, an individual discharge and aftercare plan prior to discharge for patients who leave the program with notice. The patient and, as applicable, his or her parents, guardian, or responsible persons must participate in discharge and aftercare planning.

(2) A discharge summary must be completed within seven days of discharge of a patient and must include a final assessment of the patient's status at the time of discharge and a description of aftercare plans for patients; and.

(3) The program must establish and maintain a formal plan of cooperation with other programs in the State to allow for continuity of care for drug dependent persons.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.15 Narcotic Drugs

Programs shall develop and implement written policies and procedures for prescription and administration of narcotic drugs and their security. These policies and procedures must include the following:

(a) Administration.

1. The program physician shall determine the patient's initial and subsequent dose and schedule. If the program physician did not perform the medical assessment required in Rule 111-8-53-.12, the program physician must consult with the person who performed the assessment before determining the patient's initial dose and schedule. The program physician shall communicate the initial and

subsequent doses and schedule to the pharmacy or the person supervising medication. The program physician may assign such dose and schedule by verbal order; however, the program physician must confirm all such orders in writing within 72 hours.

2. Individual doses shall be based on the clinical judgment of the program physician who has personally reviewed the patient's record and who has considered all available relevant information, including, but not limited to, drug screens, quantitative levels of methadone and related drugs, patient interview, and specific circumstances pertaining to the individual patient.

3. A program shall maintain current procedures that are adequate to ensure that the following dosage form and initial dosage requirements are met:

   (i) Methadone shall be administered or dispensed only in oral form and shall be formulated in such a way as to reduce its potential for parenteral abuse;

   (ii) For each new patient enrolled in a program, the initial dose of methadone shall not exceed 30 milligrams and the total dose for the first day shall not exceed 40 milligrams, unless the program physician documents in the patient's record that 40 milligrams did not suppress opiate abstinence symptoms; and

   (iii) For the use of any other approved opioid agonist treatment medication, the program shall ensure that the dosage form and initial dosage requirements are in accordance with currently accepted standards of treatment.

4. Patients are stabilized on methadone or a related drug when they are receiving a therapeutic dose that is sufficient to stop opioid use and sufficient to keep the patient comfortable for at least 24 hours with no need to resort to illicit opiates to satisfy opiate cravings.

5. The dose must either be administered by a licensed medical professional authorized by law to do so or be self-administered by the patient while under the supervision of a licensed medical professional. No methadone or any other drug may be administered unless the applicant has undergone all of the screening and admission procedures required, unless there is an emergency situation that is fully documented in the records. In that case, intake procedures must be completed on the next working day. No take-home medication may be given in such an emergency.

6. The program shall be responsible for ensuring that all dosages are within therapeutically acceptable limits;

(b) Any narcotic drug prescribed and administered shall be documented on an individual medication administration record that is maintained on site and stored when complete in the patient's clinical record. The record must include:

1. Name of medication;

2. Date prescribed;

3. Dosage;

4. Frequency;

5. Route of administration;

6. Date and time administered; and

7. Signed documentation of staff administering medication or supervising self-administration;

(c) Take-home doses of methadone shall be handled in accordance with applicable rules of SAMHSA or other applicable federal agency. A narcotic treatment program shall permit take-home doses of methadone according to these rules and the following restrictions:

1. During the first 90 days of treatment for a patient, the take-home supply shall be limited to a single dose per week, not to include any single take-home supply given to the patient for a day that the clinic is legitimately closed for business, including Sundays and state and federal holidays;

2. During the second 90 days of treatment for a patient, the take-home supply shall be limited to two doses per week, not to include any single take-home supply given to the patient for a day that the clinic is legitimately closed for business, including Sundays and state and federal holidays;

3. During the third 90 days of treatment for a patient, the take-home supply shall be limited to three doses per week, not to include any single take-home supply given to the patient for a day that the clinic is legitimately closed for business, including Sundays and state and federal holidays;

4. During the remaining months of the first year of treatment for a patient, the take-home supply shall be limited to no more than a six-day supply;

5. After one year of continuous treatment for a patient, the take-home supply shall be limited to no more than a two-week supply; and

6. After two years of continuous treatment for a patient, the take-home supply shall be limited to no more than a one-month supply, provided that the patient makes at least one visit per month;

(d) Adverse drug reaction and medication administration errors must be documented and reported to a program physician immediately and corrective action initiated. The adverse reaction or error also must be recorded in the drug administration record and~~,~~ the nurse progress notes and ~~the individual treatment plan, and~~ the Medical Director ~~all persons who are authorized to administer medication or supervise self-medication~~ must be alerted;

(e) No drug shall be dispensed or administered except upon receipt of a medication drug order written by a licensed medical practitioner granted rights to prescribe such medication under the Rules and Regulations of the Georgia State Board of Pharmacy, Chapter 480-18-.07;

(fe) All medications must be appropriately stored in a locked safe when not being administered or self-administered; and

(gf) Emergency medications, such as NARCAN or other medically appropriate emergency narcotic antagonists, must be kept available for appropriate use.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.16 Drug-Screen Tests

The program shall develop and implement written policies and procedures for random drug-screen tests. These policies and procedures will be for the purposes of assessing the patient abuse of drugs and making decisions about the patient's treatment. These policies and procedures must include the following provisions:

(a) Clinically appropriate drug-screen tests done in accordance with current and accepted standards of medical practice must be conducted initially upon admission and on a random basis bi-weekly for new patients during the first 30 days of treatment and at least monthly thereafter. However, patients on a monthly schedule who fail the drug-screen tests will be returned to a bi-weekly schedule for at least two weeks or longer if clinically indicated;

(b) Each sample collected must be screened for opiates, oxycodone, methadone, methadone metabolite; amphetamines, cocaine, benzodiazepines, THC, and other drugs as indicated by individual patient use patterns or that are heavily used in the locale of the patient; and

(c) Programs shall develop and enforce policies for the proper collection and handling of drug-screen test samples to ensure that samples collected from patients are properly handled, are actually collected from the patient being tested, and are unadulterated. Such policies may include random direct observation, which shall be conducted professionally, ethically, and in a manner that respects patients' privacy.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.17 Quality Improvement

(1) Programs shall develop and implement a written quality improvement plan that provides for the delivery of care in accordance with accepted standards of practice. At a minimum, the plan must include the following areas:

(a) A service delivery assessment that evaluates appropriateness ~~-~~of treatment plans and services delivered, completeness of documentation in patient records, quality of and participation in staff training programs, linkage to and utilization of primary care and other out-of-program services, patient grievance procedures, ~~and~~ availability of services and medications for other conditions, and at least one indicator to evaluate the effectiveness of services at the program; and

(b) A documented ~~n~~ assessment of medication-related issues including take-home procedures, security, inventory, and dosage issues completed with the Director of Pharmacy Services or an appropriate delegate.~~.~~

(2) Such plan shall serve to continuously monitor the program's compliance with the requirements set forth in these rules. Responsibility for administering and coordinating the quality improvement plan must be delegated to a staff person who has been determined to be qualified by education, training, and experience to perform such tasks. The medical director shall be actively involved in the development, full implementation, and continuous monitoring of the plan ~~of the plan and its full implementation~~.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.18 Patient Rights, Responsibilities, and Complaints

(1) Programs shall develop and implement written policies and procedures regarding the rights and responsibilities of patients and the handling and resolution of complaints. These policies and procedures must include a written notice of rights and responsibilities provided to each patient at orientation. The required notice must contain the following items:

(a) Right to humane treatment that affords reasonable protection from harm, exploitation, and coercion;

(b) Right to be free from physical and verbal abuse;

(c) Right to be informed about the individual treatment plan and to participate in the planning, as able;

(d) Right to be promptly and fully informed of any changes in the plan of treatment;

(e) Right to accept or refuse treatment;

(f) Right to confidentiality of patient records;

(g) Right to be informed of the program's complaint policy and procedures and the right to submit complaints without fear of discrimination or retaliation and to have them investigated by the program within a reasonable period of time;

(h) Right to receive a written notice of the address and telephone number of the state licensing authority, i.e. the Department, and the right to file a complaint with the Department;

(i) Right to obtain a copy of the program's most recent completed report of licensing inspection from the program upon written request. The program is not required to release a report until the program has had the opportunity to file a written plan of correction for the violations as provided for in these rules; and

(j) Right to an informal review and appeal of any involuntary discharge.

(2) These policies and procedures shall also include provisions for patients and others to present complaints to the program, either orally or in writing, and to have their complaints addressed and resolved as appropriate in a timely manner.

(3) The program shall provide services in a manner that respects the rights and responsibilities of patients.

(4) The program shall post the name and phone number of the Complaint Intake Line for the Department of Community Health and the most recent inspection report issued by the Department in an area visible to the patients.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.19 Central Registry

(1) To prevent simultaneous enrollment of a patient in more than one program, all programs shall participate in the Central Registry approved by the Department and operated by the Department of Behavioral Health and Developmental Disabilities and shall comply with any policies, procedures or rules of the Department of Behavioral Health and Developmental Disabilities which are associated with the Central Registry.~~.~~ The Central Registry shall require each program to provide the social security number and other identifying information of each patient. Patients must be informed of the program's participation in the Central Registry, and prior to initiating a Central Registry inquiry, the program must obtain the patient's signed consent. ~~Within 72 hours of admission~~Within 24 hours of accepting a patient for treatment, and prior to the administration of any medication, the program shall initiate a clearance inquiry by submitting to the approved Central Registry the patient's name, date of birth, social security number, anticipated date of admission, and any other relevant information required for the clearance procedure. All such information shall be considered confidential. No individual shall receive medication from a program if that individual is reported by the Central Registry to be participating in another such program. In the event a dual enrollment is discovered, the patient must be discharged from one program in order to continue enrollment at another program. Reports received by the Central Registry shall be treated as confidential and shall not be released except to a licensed program or as required by law. Information made available by the Central Registry to programs shall also be treated as confidential.

(2) To prevent simultaneous enrollment of persons in different programs located in different states, if a program operates within 125 miles of any adjoining state and that state also has a Central Registry, the program shall participate in the Central Registry of the adjoining state, if available.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.20 Reporting to the Department

(1) A narcotic treatment program shall report to the Department within 24 hours and also follow the Department of Behavioral Health and Developmental Disabilities reporting protocol whenever any of the following incidents involving patients occurs or the program has reasonable cause to believe that such an incident involving a patient has occurred:

(a) Any death of a patient;

(b) Any rape that occurs in the program;

(c) Any serious injury to a patient while at the program that requires medical attention;

(d) Any assault on a patient, any battery on a patient, or any abuse, neglect, or exploitation of a patient by program staff; and

(e) An external disaster or other emergency situation that affects the continued safe operation of the program.

(2) The report shall be received by the Department in confidence and shall include at least:

(a) The name of the program and the name of the administrator or clinical director;

(b) The date of the incident and the date the program became aware of the incident;

(c) The type of incident suspected, with a brief description of the incident; and

(d) Any immediate corrective or preventative action taken by the program to ensure against the replication of the incident.

(3) Where the Department determines that a rule violation related to the incident has occurred, the Department will initiate a separate complaint investigation of the incident. The complaint investigation report and the report of any rule violation compiled by the Department arising either from the initial report received from the program or an independent source shall be subject to disclosure in accordance with applicable laws.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.21 Enforcement and Penalties

(1) When the Department finds that an applicant for a license fails to fulfill the requirements of these rules, the Department may, subject to notice and opportunity for a hearing, refuse to grant the license. The Department is not required to hold a hearing prior to taking such action.

(2) When the Department finds that any licensed program violates any requirements of these rules, the Department may, subject to notice and opportunity for a hearing, suspend or revoke the license.

(a) License Suspension.

1. The Department may suspend any license for a definite period calculated by the period necessary for the facility to implement long-term corrective measures and for the facility to be deterred from lapsing into noncompliance in the future. As an alternative to suspending a license for a definite period, the Department may suspend the license for an indefinite period in connection with the imposition of any condition or conditions reasonably calculated to elicit long-term compliance with licensing requirements that the program must meet and demonstrate before it may regain its license.

2. In lieu of a full suspension, the Department, in its discretion, may suspend the authority of the narcotic treatment program to operate a portion of the program, e.g. granting take-home medication privileges or admitting new patients.

3. If the sanction of license suspension is finally imposed, as defined by a final administrative decision, the program must return its license to the Department. Upon the expiration of any period of suspension, and upon a showing by the program that it is capable of achieving compliance with licensing requirements, the Department shall reissue the program license. Where the license was suspended for an indefinite period in connection with conditions for the re-issuance of a license, once the program can show that any and all conditions imposed by the Department have been met, the Department shall reissue the program license.

(b) License Revocation. If the sanction of license revocation is finally imposed, as defined by a final administrative decision, the program must return its license to the Department.

(c) Notice. The Department shall provide notice of its actions to revoke the license or seek an emergency suspension of the program's license to operate to patients and to their legal guardians, if any, as follows:

1. The notice, together with the Department's complaint intake phone number and website, shall be provided to patients and to their legal guardians, if any, through the following methods:

(i) The posting of the official notice of the revocation or emergency suspension action and any final resolution at the program by Departmental staff in an area that is visible to the patients and to their legal guardians, if any;

(ii) The posting of the official notice of the revocation or emergency suspension action and any final resolution on the Department's website; and

(iii) The distribution by Departmental staff of a brief notice of the initial filing of actions to revoke or suspend the program's license to the patients and to their legal guardians, if any, who are receiving services at the program location at the time that the notice of revocation or emergency suspension is posted by the Department;

2. The Department may share any notice of the revocation or emergency suspension action and any information pertaining thereto with any other agencies that may have an interest in the welfare of the patients in care at the program;

3. When the Department has posted a notice of the revocation and/or emergency suspension actions in the program, the program shall ensure that the notice at the program continues to be visible to the patients and to their legal guardians, if any, throughout the pendency of the revocation and emergency suspension actions including any appeals;

4. The program shall have posted at the program in an area that is readily visible to the patients and to their legal guardians, if any, any inspection reports that are prepared by the Department during the pendency of any revocation or emergency suspension action; and

5. It shall be a violation of these rules for the program to permit the removal or obliteration of any notices of revocation, emergency suspension action, resolution, or inspection survey reports posted by the Department on the premises of the program during the pendency of any revocation or emergency suspension action.

(3) The Department is authorized to take emergency actions against any program when it determines that the public health, safety, or welfare requires such action.

(4) All enforcement actions shall be administered in accordance with Chapter 13 of Title 50 of the Official Code of Georgia Annotated, the "Georgia Administrative Procedure Act" and the Rules and Regulations for Enforcement of General Licensing and Enforcement Requirements, Chapter 111-8-25. Any requests for hearings in response to enforcement actions must be in writing and must be submitted to the Department no later than 10 calendar days from the date of receipt of any notice of intent by the Department to impose an enforcement action.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.22 Variance and Waiver~~Severability~~

(1) The Department may, in its discretion, grant variances and waivers of specific rules upon application or petition filed on forms provided by the Department. The Department may establish conditions which must be met by the program in order to operate under the variance or waiver granted.

(a) **Variance**. A variance may be granted by the Department upon a showing by the applicant or petitioner that the particular rule or regulation that is the subject of the variance request should not be applied as written because strict application of the rule would cause undue hardship. The applicant or petitioner must also show that adequate standards affording protection for the health, safety, and care of patients exist and will be met in lieu of the exact requirements of the rule or regulations in question. The Department may require additional documentation by the program to support its application for a variance or waiver.

(b) **Waiver.** The Department, in its discretion, may dispense entirely with the enforcement of a rule or regulation by granting a waiver upon a showing by the applicant or petitioner that the purpose of the rule or regulation is met through equivalent standards affording equivalent protection for the health, safety, and care of patients.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.

Rule 111-8-53-.23 Severability

In the event that any rule, sentence, clause, or phrase of any of these rules and regulations may be construed by any court of competent jurisdiction to be invalid, illegal, unconstitutional, or otherwise unenforceable, such determination or adjudication shall in no manner affect the remaining rules or portions thereof. The remaining rules or portions of rules shall remain in full force and effect, as if such rule or portions thereof so determined, declared, or adjudged invalid or unconstitutional were not originally a part of these rules.

Authority: O.C.G.A. §§ 26-5-2 et. seq., 31-2-5 and 31-2-7.