Georgia Department of Behavioral Health &
Developmental Disabilities

Kevin Tanner, Commissioner

Office of General Counsel

PUBLIC NOTICE OF PROPOSED RULES

Rules and Regulations for Narcotic Treatment Programs, GA COMP. R. & REGS. 82-11-1

To All Interested Persons:

Pursuant to the Georgia Administrative Procedures Act, Official Code of Georgia Annotated (O.C.G.A.) § 50-13-1, et seq., the Georgia Department of Department of Behavioral Health and Developmental Disabilities (DBHDD) is required to provide public notice of its intent to adopt, amend, or repeal certain rules other than interpretative rules or general statements of policy. Accordingly, DBHDD hereby provides notice of its intent to adopt **Rules and Regulations for Narcotic Treatment Programs, GA COMP. R. & REGS. 82-11-1.**

These rules and regulations are being proposed pursuant to the authority granted to DBHDD in O.C.G.A. § § 37-13-1 and 26-5-40 *et seq*. These rules and regulations amend the rules and regulations previously located in **GA COMP. R. & REGS. 111-8-53.** This notice and the proposed rules and regulations are posted on the DBHDD website at https://dbhdd.georgia.gov/organization/be-informed/privacy-rules-regulations.

ECONOMIC IMPACT STATEMENT

The following economic impact statement is included pursuant to O.C.G.A. § 50-13-4(a)(1).

ANTICIPATED IMPACT(S) TO SMALL BUSINESSES:

This rule impacts small businesses that operate or seek to operate a Narcotic Treatment Program that provides treatment for chronic heroin or opiate-like drug-dependent individuals in a rehabilitative context. In crafting the rule, DBHDD sought to minimize impacts to small businesses by including only those facilities which DBHDD is charged with licensing or inspecting under O.C.G.A. § 26-5-40 *et seq*.

ANTICIPATED COSTS:

Small businesses operating a Narcotic Treatment Program or seeking licensure may incur costs related to developing materials (e.g., written policies and procedures)

required in the application; submitting criminal background checks; and demonstrating the facility's ability to receive approval or certification for controlled substance security from the appropriate federal and state agencies (e.g., Substance Abuse and Mental Health Services Administration, Drug Enforcement Agency, Georgia Board of Pharmacy, etc.)

In accordance with O.C.G.A. § 50-13-4(a)(5), DBHDD sought to establish licensure requirements that represent the least burdensome method to achieve the minimum standards required for Narcotic Treatment Program quality and services under O.C.G.A. § 25-5-42. Because of the minimum standards established by federal and state agencies (e.g., Substance Abuse and Mental Health Services Administration, Drug Enforcement Agency, Georgia Board of Pharmacy, etc.) and the fact that Narcotic Treatment Programs necessarily involve the management of controlled medications, certain minimum standards must apply to all Narcotic Treatment Programs regardless of the size of the business. For example, withdrawal management services must meet standards established by the Substance Abuse and Mental Health Services Administration, and pharmacy services at Narcotic Treatment Programs must comply with requirements established by the Georgia State Board of Pharmacy and the Drug Enforcement Agency.

ANTICIPATED IMPROVEMENTS IN EFFECTIVENESS:

Updates to this rule increase the effectiveness of Narcotic Treatment Programs by modernizing and aligning, where applicable, licensure rules and the requirements of state and federal agencies to promote accountability and effectiveness in the program overall. This rule establishes procedures requiring Narcotic Treatment Programs to report incidents that involve an immediate threat to the care, health, or safety of a client, as well as procedures for investigations and reviews by DBHDD. Additionally, there are requirements for treatment plans and discharge, and aftercare plans to ensure clients receive appropriate post-treatment support, which is anticipated to improve the effectiveness of treatment outcomes.

ANTICIPATED STREAMLINING EFFECTS:

Due to the transition of licensure activities to DBHDD effective January 1, 2026, DBHDD now has oversight of all facilities licensed as Narcotic Treatment Programs. This transition reduces any inconsistencies related to having oversight under different state agencies. The rules were also aligned with the minimum requirements of state and federal agencies to maintain consistency across regulations.

OPTION CHOSEN UNDER O.C.G.A. § 50-13-4(a)(3):

In accordance with O.C.G.A. § 50-13-4(a)(3), DBHDD chose the least burdensome rules that were "legal and feasible in meeting the stated objectives of the statutes

which are the basis of the proposed rule." Because DBHDD is statutorily required to regulate specific aspects of Narcotic Treatment Programs and must achieve desired treatment outcomes for clients, DBHDD was limited in its ability to further exempt small businesses. *See* O.C.G.A. §§ 37-1-20; 37-13-2; and 37-13-4.

SYNOPSIS AND PURPOSE

STATEMENT OF PURPOSE:

The purpose of these rules and regulations is to incorporate changes to licensure of Narcotic Treatment Programs (NTP) with the passage of House Bill 584 from the 2025 Legislative Session which transferred NTP licensing authority from the Department of Community Health to the Department of Behavioral Health and Developmental Disabilities (DBHDD), and to make administrative updates. These rules and regulations are being proposed pursuant to the authority granted to DBHDD in O.C.G.A. §37-13-1, *et seq*. These rules and regulations amend the rules and regulations previously located in 111-8-53.

MAIN FEATURES OF THE PROPOSED RULES AND REGULATIONS:

The proposed rules and regulations provide the minimum operating requirements for Narcotic Treatment Programs.

1. Rule 82-11-1-.03 provides definitions for the terms in the rule.
2. Rule 82-11-1-.04 provides requirements for the governing body.
3. Rule 82-11-1-.05 provides the general requirements for licensure, including requiring compliance with the requirements of other state and federal agencies, requirements to be met with a change in ownership, and procedures for inspection upon application for a new license.
4. Rule 82-11-1-.06 provides requirements for provisional licenses.
5. Rule 82-11-1-.07 provides for the license application process.
6. Rule 82-11-1-.08 requires reportable incidents to be reported to the Department within twenty-four (24) hours and provides for that process.
7. Rule 82-11-1-.09 provides for the Department to conduct inspections and investigations, requires corrective action plans to correct violations cited, and provides for a process to dispute violations cited.
8. Rule 82-11-1-.10 provides the general requirements for the administration of an NTP, including establishing the written policies

and procedures and facility description. The rule also provides for NTP finances, fees, patient records, personnel records, referral to other facilities, closing of a facility, hours of operation, and community liaison and concerns.

9. Rule 82-11-1-.11 provides for criminal background checks of owners, administrators, and employees.
10. Rule 82-11-1-.12 provides the staffing requirements, including ratios, the requirements for each of the staffing positions, staffing training and orientation, and employee drug testing.
11. Rule 82-11-1-.13 provides for the physical plant and safety requirements.
12. Rule 82-11-1-.14 provides for the patient screening, assessment, and admission processes.
13. Rule 82-11-1-.15 requires individual treatment plans.
14. Rule 82-11-1-.16 requires discharge and aftercare plans.
15. Rule 82-11-1-.17 provides the requirements regarding medications for opioid use disorder.
16. Rule 82-11-1-.18 provides requirements for dug screen tests.
17. Rule 82-11-1-.21 provides the patient rights and the complaint process.

COMMENT INSTRUCTIONS:

Individuals wishing to comment in writing on any of the proposed changes should do so on or before **Friday, October 2, 2026, at 5:00 P.M.** To expedite the review of comments, DBHDD encourages the submission of written public comments via email to the following email address: legal@dbhdd.ga.gov

Any comments not able to be submitted via email may be submitted via regular mail to the following address:

Brenda Woodard, Esq., General Counsel
Georgia Department of Behavioral Health and
Developmental Disabilities
200 Piedmont Avenue, S.E.
Suite 1406, West Tower
Atlanta, GA 30334-9026

DBHDD will review all comments, and may contact commenters to discuss their suggestions, and, after the comment period has closed, intends on promulgating final

rules. DBHDD will consider the proposed rules for adoption at the **DBHDD Board Meeting at 1:00 P.M. on Thursday, October 22, 2026**, at the offices of the Department of Behavioral Health and Developmental Disabilities at 200 Piedmont Avenue, S.E. West Tower, 5th Floor, Board Room 512 Atlanta, Georgia 30303.

Notice and a copy of the final rules adopted will be emailed to persons who have made a special request and will be made available on our website at https://dbhdd.georgia.gov/organization/be-informed/privacy-rules-regulations.

NOTICE IS HEREBY GIVEN THIS 31st DAY OF AUGUST 2026

Brenda King Woodard, Esq., DBHDD General Counsel

DEPARTMENT OF BEHAVIORALHEALTH AND DEVELOPMENTAL DISABILITIES

[PROPOSED] CHAPTER 82-11-1

Narcotic Treatment Programs

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82-11-1 RULES AND REGULATIONS FOR NARCOTIC TREATMENT PROGRAMS

82-11-1-.01 Legal Authority

These rules are adopted and published pursuant to the Official Code of Georgia Annotated (O.C.G.A.) § 26-5-2 *et seq.*

Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.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. § 26-5-40 *et seq.*

82-11-1-.03 Definitions

In these rules, unless the context otherwise requires, the words and phrases set forth herein shall mean the following:

(1) “Administer” means to give one, single dose of a pharmacy prepared narcotic controlled substance.

(2) "Administrative action" means the initiation of a contested case as defined in the Georgia Administrative Procedures Act (APA), O.C.G.A. § 50-13-2(2).

(3) “Administrator” means the individual designated by a Narcotic Treatment Program's governing body who is responsible for the ongoing 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.

(4) “Applicant” means a person applying to be an employee at a facility, as the term “employee” is defined in these rules.

(5) “Clinic pharmacy” means a licensed pharmacy which is designated as an on-site pharmacy department located in and operated by any Narcotic Treatment Program.

(6) “Change of ownership” means any transfer of any ownership interest in a governing body, facility, or license candidate.

(7) "Clinical director" means the individual designated by the facility's governing body who is responsible for the ongoing and day-to-day clinical aspects of treatment for those patients admitted to the facility.

(8) "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.

(9) “Conviction” means a finding or verdict of guilty or a plea of guilty, including a plea of guilty pursuant to O.C.G.A. § 42-8-60, regardless of whether an appeal of the conviction has been sought.

(10) “Corrective action plan” or “CAP” means a plan developed by the facility in response to a violation identified on a written report of inspection or investigation that contains the steps or actions that have been taken, or are planned, to address or correct the violation and the anticipated date of the correction.

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

(12) “Counselor in training” means a person who works in the field while gaining experience and education needed for full certification. Counselors in Training must be under direct supervision by a certified counselor, such as an NCACI, CACI, CACII, CADCI, CADCII, CAADC, NCACII, LCSW, LMFT, LPC, RN, APRN, Addictionologist, Psychologist, Psychiatrist or other licensed behavioral health providers.

(13) “Crime,” in connection with any criminal background check required by these rules, has the same meaning as the term “crime” in any applicable criminal background check rules and regulations enforced by the Department.

(14) “Criminal background check” has the same meaning as the term “criminal background check” in any applicable criminal background check rules and regulations enforced by the Department.

(15) “Criminal record” has the same meaning as the term “criminal record” in any applicable criminal background check rules and regulations enforced by the Department.

(16) "Department" means the Georgia Department of Behavioral Health and Developmental Disabilities, or its successor.

(17) "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.

(18) “Dispense” means the actions of a pharmacist when he/she fills a prescription drug order and prepares either a single dose or multiple doses in patient-specific take-home containers with narcotic controlled substances for a Narcotic Treatment Program.

(19) “Diversion control plan” means a set of documented procedures that reduce the possibility that controlled medications will be transferred or otherwise shared with others to whom the medication was not prescribed or dispensed.

(20) “Eligible determination” means a written determination that a person for whom a criminal background check was performed was found to have no criminal record.

(21) “Emergency kit” means a kit containing drugs which may be required to meet the immediate therapeutic needs of patients and which are not available from any other authorized source within the clinic in sufficient time to prevent risk of harm to patients.

(22) “Employee” means any individual who is hired by a facility through employment, or through a contract with such facility, including, but not limited to, clinical directors medical directors program physicians, physician assistants, nurse practitioners, advanced practice registered nurses, registered nurses, licensed practical nurses, other nurses, medical staff, and clinical staff; counselors and counselors in training; any person who will have direct access to controlled substances maintained by the facility; and any volunteer who has duties that are equivalent to the duties of an employee providing such services. Such term shall not include a person who contracts with the facility, whether personally or through a company, to provide utility, construction, communications, general accounting, quality assurance, human resource management, information technology, legal, or other services if the contracted services are not directly related to providing services to a patient or client of the facility and the person is not otherwise specifically included in this definition.

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(23) “FBI” means the Federal Bureau of Investigation.

(24) “Facility” means a Narcotic Treatment Program required to be licensed pursuant to Article 2 of Chapter 5 of Title 26 of the Official Code of Georgia.

(25) "Facility 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.

(26) “GCIC” means the Georgia Crime Information Center established under Article 2 of Chapter 3 of Title 35 of the Official Code of Georgia.

(27) "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 the Narcotic Treatment Program.

(28) “Indirect ownership interest” means an ownership interest in a corporation, partnership, legal entity, or association which owns an ownership interest in another corporation, partnership, legal entity, or association. This term includes an ownership interest in any corporation, partnership, legal entity, or association that has an indirect ownership interest in a facility or in a license candidate.

(29) "Individual treatment plan" means a patient-centered plan, developed with patient participation and shared decision-making, that identifies the patient's treatment goals, medical and behavioral health needs, recovery supports, harm-reduction needs, and services to be provided or coordinated consistent with current SAMHSA standards.

(30) “Individualized dose” means the dose of a medication for opioid use disorder, orders by the Narcotic Treatment Program practitioner and dispensed to a patient, that sufficiently suppresses opioid withdrawal symptoms. Individualized doses may also include split doses of a medication for opioid use disorder, where such dosing regimens are indicated.

(31) “Ineligible determination” means a written determination that a person for whom a criminal background check was performed was found to have a criminal record.(33) "Inspection" means any monitoring visit or other inquiry by the Department of Behavioral Health and Developmental Disabilities, or its representatives, of a facility, including, but not necessarily limited to, the premises, staff, persons in care, and documents pertinent to initial and continued licensing so that the Department may determine whether a facility is operating in compliance with licensing requirements or has violated any licensing requirements. Inspections may be announced or unannounced at the discretion of the Department.

(32) “Investigation” means any examination by the Department of Behavioral Health and Developmental Disabilities, or its representatives, of a facility, including but not necessarily limited to the premises, staff, persons in care, and documents pertinent to an allegation(s) of non-compliance or a reportable incident. Investigations may be initiated at any time and may be announced or unannounced at the discretion of the Department.

(33) "License" means the official permit issued by the Department that authorizes the holder to operate a Narcotic Treatment Program for the term provided therein.

(34) “License candidate” means a person, corporation, partnership, legal entity, or association applying for a license to operate a facility.

(35) "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 opioid use disorder.

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(36) "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 facility physician or medical director.

(37) “Medications for opioid use disorder” or “MOUD” means medications, including opioid agonist medications, 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 opioid use disorder.

(38) “Medication order” means the manner in which a physician’s order, via written, verbal or electronically transmitted means, results in the administration of a narcotic controlled substance to the ultimate user.

(39) "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 opioid use disorder.

(40) "Narcotic Treatment Program" or “NTP” 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.

(41) “Opioid use disorder” means a cluster of cognitive, behavioral, and physiological symptoms associated with a problematic pattern of opioid use that continues despite clinically significant impairment or distress within a 12-month period.

(42) “Owner” means a person with an ownership interest in a facility or license candidate or with an ownership interest in a corporation, partnership, legal entity, or association which has any ownership interest in a facility or license candidate, including an indirect ownership interest.

(43) “Ownership interest” means the possession of equity in the capital, stock, or profits of either a:

(a) Facility or license candidate; or

(b) Corporation, partnership, legal entity or association that holds a license for a facility.

(44) "Patient" means any individual who undergoes treatment in a Narcotic Treatment Program.

(45) “Pharmacy director” or “Director of pharmacy services” means a pharmacist, licensed with the Georgia State Board of Pharmacy, who shall direct, oversee, establish protocols and be responsible for all pharmacy related transactions at a Narcotic Treatment Program pharmacy.

(46) “Physician extender” means a licensed Physician Assistant (PA) or Advanced Practice Registered Nurse (APRN), qualified by training and experience as determined by the supervising physician, who conduct assessments, develop treatment plans, manage documentation and communicate with other healthcare providers under a designated supervising physician through an approved job description (for PAs) or nurse protocol agreement (for APRNs).

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

(48) “Records check application” has the same meaning as the term “records check application” in any applicable criminal background check rules and regulations enforced by the Department.

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

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(50) “Registry check” has the same meaning as the term “registry check” in any applicable criminal background check rules and regulations enforced by the Department.

(51) “Reportable incident” means any event that involves an immediate threat to the care, health or safety of a facility’s client which either happens at the facility or is connected with the care that the client received from the facility. (52) “Split dosing” means dispensing of a single dose of a medication for opioid use disorder as separate portions to be taken within a 24-hour period. Split dosing is indicated among, but not limited to, those patients who possess a genetic variant which increases methadone metabolism, concurrently take other medications or drink alcohol that also induce hepatic enzymes leading to more rapid metabolism of methadone; who are pregnant; or for whom methadone or buprenorphine are being used to treat a concurrent pain indication in addition to the diagnosis of opioid use disorder. This leads to more stable, steady-state medication levels.

(52) "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.

(53) “State opioid treatment authority” or “SOTA” means the agency designated by the Governor of the State of Georgia, or other appropriate official designated by the Governor, to exercise the responsibility and authority within the State for governing the treatment of opioid use disorder with medication for opioid use disorder in Narcotic Treatment Programs.

(54) “Take-home dose” means a quantity of a physician ordered narcotic controlled substance dispensed by a Narcotic Treatment Program clinic pharmacy which a patient can take away from the clinic.

(55) “Telemedicine” means the practice of medicine in accordance with applicable federal and state laws and regulations by a practitioner who is at a location remote from the patient and is communicating with the patient, or a health care professional who is treating the patient, using a two-way, real time interactive and secure electronic communication system.

(56) "Withdrawal management" means medically supervised services for management of withdrawal, consistent with current SAMHSA standards. The term replaces outdated references to "detoxification" where used clinically.

Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.04 Governing Body

(1) Each licensed facility shall have a clearly identified governing body that accepts responsibility for operating the Narcotic Treatment Program in accordance with applicable laws, rules, and regulations.

(2) The governing body shall ensure that the program maintains current SAMHSA certification, DEA registration, required accreditation, Georgia Board of Pharmacy compliance, state licensure, patient rights protections, controlled substance security, and a quality improvement program.

(3) Owners of governing bodies must complete criminal background checks in accordance with these rules. If there is a change of ownership of the governing body, each new owner must complete a criminal background check in accordance with these rules. If the governing body wishes to transfer ownership or operation of the facility to a different governing body, the new governing body must complete a license application and obtain a license before operating the facility.

Authority: O.C.G.A. § 26-5-40 *et seq.*

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82-11-1-.05 License

(1) No governing body may operate a Narcotic Treatment Program in the State of Georgia without first obtaining a license from the Department of Behavioral Health and Developmental Disabilities.

(2) **License.** A license will be issued upon presentation of evidence satisfactory to the Department that the facility is in compliance with these rules and all applicable federal and state laws for the handling, storing, administering, dispensing, and accounting 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 facility'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 82-11-1-.07.

(3) **Compliance with requirements of other state and federal agencies.** To obtain a license, a facility 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.

(4) **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 facility may be subjected to an on-site visit by the Department prior to the issuance of a license at the discretion of the Department.

(5) **Change of Ownership.** The governing body must notify the Department of any change of ownership, i.e., any transfer of any ownership interest in the governing body, facility, or license candidate.

(6) **Inspections Upon New License Application.** Upon application for an additional facility 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. Such inspections are in addition to all other application requirements for an additional facility application by the licensee.

Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.06 Provisional License

(1) Except as otherwise provided in these Rules, provisional licenses may be issued:

(a) To the governing body of a new Narcotic Treatment Program that is in substantial compliance with these rules; or

(b) At the discretion of the Department, to an existing facility that has been found to be out of compliance with these rules but is actively developing and implementing a corrective action plan with the Department's approval; or

(c) To an existing facility that has unpaid fees or fines, provided that such fees or fines must be fully paid prior to the expiration of the provisional license.

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

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(3) Provisional licenses may be renewed at the discretion of the Department only in cases of extreme hardship and in no case for longer than one (1) year.

Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.07 License Application

(1) **Mandatory information forum.** Potential license candidates must send at least one (1) 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 license candidate from consideration during open enrollment.

(2) **Letter of intent.** License candidates must submit a letter of intent stating the 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 open enrollment period shall be held in the month of December of each 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 policies and procedures that demonstrate an organizational capability to meet these rules;

(c) Biographical information and qualifications of the governing body, owners, administrators, medical directors, clinical director, director of pharmacy services, counselors, and other required staff;

(d) A listing of all currently licensed Narcotic Treatment Programs within the region of proposed location and within a 75-mile radius, whether such other facilities are outside of the region. (The region is designated by county in accordance with O.C.G.A. § 26-5-48.);

(e) Patient levels of currently licensed facilities 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 facility location;

(g) License candidate’s experience operating a Narcotic Treatment Program or working at such facility, including complete history of such experience both within this state and in any other state;

(h) Facility ownership in other locations, if any, including a complete and accurate description of Narcotic Treatment Program experience, including whether the license candidate currently holds, has held, or had revoked any licenses, registrations, enrollments, accreditations, contracts, and network memberships. The license candidate shall disclose any adverse actions against the license candidate while employed by or as a result of ownership of a Narcotic Treatment Program;

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(i) Evidence the license candidate sought community input for the proposed location from substance use disorder 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 facility location;

(k) Proof of notification of intent to file an application with all drug courts within a 75-mile radius of the proposed facility 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 physical plant and parking arrangements for staff and patients;

(n) A complete report identifying every owner of the license candidate, as the term “owner” is defined in these rules;

(o) Assurances satisfactory to the Department that the facility 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; and

(p) **Approval by SAMHSA, the DEA, and the Georgia State Board of Pharmacy.** An application must include assurances satisfactory to the Department that the facility will meet the requirements for approval by SAMHSA or other applicable federal agency, the DEA, and the Georgia State Board of Pharmacy. All licenses and approvals must be obtained before any services are provided and no later than twelve (12) months following the issuance of the Narcotic Treatment Program license.

(5) **Criminal Background Checks for Applicant/Owner.** Prior to the issuance of any new license, the owners, administrators, and employees of the license candidate shall submit a records check application so as to permit the Department to obtain a criminal background check, in accordance with the applicable rules and regulations for criminal background checks being enforced by the Department. After initial licensure, owners and administrators shall be required to submit to a criminal background check every three (3) years and upon any change of ownership or change/addition of an administrator.

(a) A Narcotic Treatment Program license shall not be issued, and any issued license shall be revoked, where it has been determined that an owner, administrator, or employee has received an ineligible determination involving any of the covered crimes, as defined in any applicable criminal background check rules and regulations enforced by the Department.

(b) An owner, administrator, or employee of a licensed Narcotic Treatment Program who, subsequent to the effective date of the license, acquires a criminal record for any of the crimes listed in any applicable criminal background check rules and regulations enforced by the Department, shall disclose the criminal record to the Department.

(c) If at any time the Department has reason to believe an owner, administrator, or employee of a licensed Narcotic Treatment Program has been arrested, charged, or convicted of any of the covered crimes listed in any applicable criminal background check rules and regulations enforced by the Department , or in the course of an investigation or inspection of the Narcotic Treatment Program, the Department shall require such owner, administrator, or employee to submit a records check application immediately for determination of whether a revocation action is necessary.

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(6) The license candidate shall promptly notify the Department of any changes in the information provided in the letter of intent or the application prior to the issuance of a license.

(7) Facilities shall cooperate with potential license candidates by providing the information detailed in paragraph (4)(e) above within a reasonable period of time.

(8) **False or misleading information.** An application for a license must be truthfully and fully completed. If the Department has reason to believe that an application has not been completed truthfully, the Department may require additional verification of the information 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.

(9) **History of compliance.** When an existing licensee applies to operate another facility, the Department will consider the licensee's history of compliance in the State of Georgia and may consider the licensee's compliance in any other state when determining the licensee's eligibility for another license. When a license candidate that has previously operated a facility applies to operate a new facility, the Department will consider the compliance history of the license candidate in the State of Georgia and may consider the compliance history of the license candidate in any other state.

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

(11) **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 paragraphs (4) and (5) 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) Facility structure for successful service delivery; and

(d) Impact on the delivery of opioid treatment services of the license candidate in the applicable population.

(12) **Notice of intent to issue license/notice of appeal rights.** Facilities selected for licensure by the Application Review Committee shall receive a notice of the Department's intent to issue a license. Facilities 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 facility.

(13) **Waiver applications under O.C.G.A. § 26-5-48(f).** The Department, in its discretion, may grant a waiver to a license candidate to allow an application to be submitted for review in a region that has four (4) or more licensed Narcotic Treatment Programs. The Application Review Committee shall consider such waiver applications based on criteria developed by the Department with emphasis on the needs assessment and/or justification for the establishment of a new facility (including identification of treatment gaps), as well as community stakeholder support.

Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.08 Reporting Incidents to the Department

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(1) The facility shall report all reportable incidents to the Department within twenty-four (24) hours; provided, however, that legal action involving the juvenile justice system is not required to be reported.

(2) Reportable incidents include the following incidents involving a patient:

(a) Death of a patient;

(b) Serious injury to a patient while at the facility that requires medical attention beyond first aid;

(c) Rape that occurs in the facility;

(d) Assault on a patient;

(e) Battery on a patient;

(f) Abuse of a patient by facility staff;

(g) Neglect of a patient by facility staff;

(h) Exploitation of a patient by facility staff; and

(i) External disaster or other emergency situation that affects the continued safe operation of the facility.

(3) Reports of reportable incidents shall be made in a form acceptable to the Department, and the Department may specify a methodology and/or an online platform or system through which such reports must be electronically submitted.

(4) The Department may request the facility to conduct an investigation of any reportable incident. If so requested, the facility shall provide the Department with a detailed investigative report within seven (7) days of the Department's request. At the request of the facility, and for good cause shown, the Department may, in its discretion, allow the facility additional time to complete and submit such investigative report.

(5) Where required by O.C.G.A. § 30-5-4, the facility shall also report incidents to an appropriate law enforcement agency or prosecuting attorney.

Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.09 Inspection, Investigation and Corrective Action Plan

(1) **Inspection.** The Department is authorized to conduct an inspection to determine whether a facility is operating in compliance with licensing requirements or has violated any licensing requirements. Such inspections may be initiated at any time, in the discretion of the Department, and may continue during the pendency of any action initiated by the Department. After initial licensure, the Department shall conduct on-site inspections of each facility on an annual basis. The Department may authorize third party audits or inspections of facilities for the purpose of determining whether or not a facility is in compliance with these rules.

(2) **Investigation.** Where the Department determines that a rule violation related to a complaint or a reportable incident may have occurred, the Department may initiate an investigation. Such investigations may be initiated at any time, in the discretion of the Department, and may continue during the pendency of any action initiated by the Department.

(3) **Cooperation with inspection and investigation.** Facility staff shall cooperate with any inspection or investigation conducted by the Department and shall provide, without delay, reasonable and meaningful access to the facility's premises, and information pertinent to licensure including staff and patients/clients. The Department shall have the authority to require the production of any documents, including but not

limited to patient records and employee records, related to the initial and continued licensing of any facility. 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.

(4) **Violations report.** If violations of any licensing rules are identified, the facility will be given a written report of the violation that identifies the rule violated; provided however, that the names and identifying information regarding the complainants are classified as confidential. Nothing in this rule shall be construed to require the Department to release the name or identifying information regarding a complainant without first obtaining proper authorization from such complainant. Nor shall this rule be construed to require the Department to release any other confidential or privileged information without first obtaining proper authorization.

(5) **Corrective Action Plans.** If violations of these licensing rules are identified, the facility must develop a written corrective action plan within fifteen (15) days of an inspection or investigation report to correct each of the violations identified. The facility must correct all violations cited.

(6) **Violations dispute.** The facility may offer an explanation or dispute the Department's finding of a violation of licensing rules within ten (10) days of an inspection or investigation report showing such finding(s). When the Department transmits the inspection or investigation report to the facility, the Department shall include instructions for how such an explanation or dispute can be made, and the facility must make such explanation or dispute as directed in those instructions. At a minimum, the instructions must include directions on how the facility can initiate an administrative action (as defined in Section .03); provided, however, that the Department may (but is not required to) provide for a prior process of administrative review by the Department before the matter is ripe for administrative action before agencies or courts outside the Department.

Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.10 Administration

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

(2) **Facility description.** A licensed facility shall develop and fully implement written policies and procedures that describe the range of treatment and services provided by the facility. 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 facility description must show what services are provided directly by the facility 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 facility 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. Facilities must organize and coordinate patient records in a manner that

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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 dependence prior to entry into the facility;

(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 82-11-1-.14(7)(a);

(h) Documentation of Central Registry clearance as required in Rule 82-11-1-.19;

(i) Documentation of orientation as required in Rule 82-11-1-.14(7)(c);

(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 ongoing licensure of the facility.

(7) **Personnel records.** A facility shall maintain written and verified records for each employee. Each employee file shall include:

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

(b) A five (5) year employment history or a complete employment history if the person has not worked for five (5) years;

(c) Evidence of an eligible determination from a fingerprint-based criminal background check, as required in Rule 82-11-1-.11;

(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, without restrictions, sanctions, or other limitations related to their job responsibilities.

(8) **Referral to other facilities.** Each facility shall have arrangements for referral of patients to other facilities that offer different treatment modalities. Facilities must be able to document a referral agreement with a local hospital or health care facility.

(9) **Closing of a facility.** A facility that intends to close the facility voluntarily shall notify the Department no later than sixty (60) days prior to closure. Any facility that closes, either voluntarily or involuntarily, shall submit satisfactory evidence to the Department that the facility 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 facility is closing. Such notice shall be provided to patients at least thirty (30) days prior to closure and shall include information on other facilities in close proximity which have availability to treat new patients;

(b) Coordination with other facilities to ensure continuity of care for patients that need assistance in locating a new Narcotic Treatment Program;

(c) Use of the Central Registry, as required in Rule 82-11-1-.19, to transfer patients to the receiving facility;

(d) A plan for the transfer of appropriate clinical/treatment records to the receiving facility 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.

(10) **Hours of operation.** Facility hours of operation shall accommodate persons involved in activities such as school, homemaking, childcare, and variable-shift work.

(a) A facility must be open at least six (6) days per week except for state and federal holidays. Appropriate treatment arrangements must be made for patients to ensure continuity of care when the facility is closed. Any requests to operate less than the required six (6) days per week must be made in writing to the State Opioid Treatment Authority and a variance application must be submitted to the Department.

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(b) Facilities shall offer comprehensive services, including, but not limited to, individual and group counseling, medical services, and referral services, at least five (5) days per week.

(c) In order to accommodate patients for whom take-home medication has not been authorized, the facility shall dispense medication at least seven (7) days per week when necessary.

(d) Facilities shall further develop a plan for contingencies, emergencies, etc., including twenty-four (24) hour emergency services during non-operating hours to assist patients in crisis situations.

(11) **Community liaison and concerns.** A facility 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. § 26-5-40 *et seq.*

82-11-1-.11 Criminal Background Check

(1) **Owners.** The Department is authorized to conduct state-level and nationwide criminal background checks by the submission of fingerprints the Georgia Crime Information Center and the Federal Bureau of Investigation. In order to determine the suitability of an owner, the Department shall require such person to furnish a full set of fingerprints to enable a criminal background check to be conducted. The Department shall be responsible for review of the criminal background check to determine the owner's fitness to have responsibility for the safety and well-being of persons receiving services and to convey that determination to the licensed Narcotic Treatment Program, as prescribed in any applicable criminal background check rules and regulations enforced by the Department.

(a) Prior to the criminal background check, the facility must perform a registry check and professional licensing board check (as applicable), as prescribed in any applicable criminal background check rules and regulations enforced by the Department.

(b) A record check application and criminal background check shall be required:

1. For each owner upon application for a new license; and

2. For each owner upon application for a change of ownership.

(c) After the initial eligibility determination, the owner shall be required to submit to a registry check, professional licensing board check (as applicable), and criminal background check, to be conducted by the Department, every three (3) years.

(d) An owner with a valid Narcotic Treatment Program license who acquires a criminal record for any of the crimes listed in applicable criminal background check rules and regulations enforced by the Department subsequent to the effective date of the license shall disclose the criminal record to the Department.

(e) A Narcotic Treatment Program license shall not be issued, and any issued license shall be revoked, where it has been determined that an owner, administrator, or applicant has received an ineligible determination involving any of the covered crimes, as defined in any applicable criminal background check rules and regulations enforced by the Department.

(f) 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 any applicable criminal background check rules and regulations enforced by the Department, the Department shall require the owner to submit a records check application immediately for determination of whether a revocation action is necessary.

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(g) An owner holding a valid Narcotic Treatment Program license issued prior to May 4, 2017, shall not be subject to any of the requirements of any applicable criminal background check rules and regulations enforced by the Department. However, if there is a change in the governing body of a facility licensed prior to May 4, 2017, any new individuals with an ownership interest in the facility shall be subject to the requirements of any applicable criminal background check rules and regulations enforced by the Department.

(2) **Administrators.** The Department is authorized to conduct state-level and nationwide background checks by the submission of fingerprints the Georgia Crime Information Center and the Federal Bureau of Investigation. In order the determine the suitability of an administrator, the Department shall require such person to furnish a full set of fingerprints to enable a criminal background check to be conducted. The Department shall be responsible for review of the criminal background check to determine the administrator's fitness to have responsibility for the safety and well-being of persons receiving services and to convey that determination to the licensed Narcotic Treatment Program, as prescribed in any applicable criminal background check rules and regulations enforced by the Department.

(a) Prior to the criminal background check, the facility must perform a registry check and professional licensing board check (as applicable), as prescribed in applicable criminal background check rules and regulations enforced by the Department.

(b) A record check application and criminal background check shall be required:

1. For each administrator upon application for a new license;

2. For each administrator upon application for employment as administrator or prior to placement in the position of administrator.

(c) After the initial eligibility determination, the administrator shall be required to submit to a registry check, professional licensing board check (as applicable), and criminal background check, to be conducted by the department, every three (3) years.

(e) A person with an ineligible determination must not serve as an administrator of a Narcotic Treatment Program. Failure to satisfy this requirement may result in enforcement action against the facility as prescribed in any applicable criminal background check rules and regulations enforced by the Department.

(f) The administrator must immediately submit to an additional criminal 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 had acquired a criminal record as defined by these rules; or

2. The criminal background check is required in connection with an investigation being conducted by the Department.

(3) **Employees.** The facility must obtain evidence of a satisfactory fingerprint-based criminal history background check determination for each person being considered for employment that reflects the individual does not have any convictions of a crime, as defined in applicable criminal background check rules and regulations enforced by the Department, within the previous five (5) years.

(a) For employees working in an administrative capacity who are not providing care to patients, the fingerprint-based criminal background check may be deemed satisfactory if it includes conviction of a nonviolent crime such as those listed in applicable criminal background check rules and regulations enforced by the Department

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(b) **Peer counselors.** For employees working as peer counselors, the fingerprint-based criminal record check may be deemed satisfactory if it includes conviction of a nonviolent crime such as those listed in applicable criminal background check rules and regulations enforced by the Department

(4) Except as provided in subsection (c) of O.C.G.A. § 37-1-148, nothing in these rules shall be construed to limit the responsibility or ability of a facility to screen owners, applicants, administrators, and employees through additional methods.Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.12 Staffing

(1) **Staff ratios.** The facility's organizational structure shall be adequate to ensure quality patient care and to meet the requirements of all pertinent federal, state, and local laws and regulations.

(a) When the facility is open to provide treatment, there shall be a minimum of one (1) clinical staff member and at least one (1) additional staff member on site at all times.

(b) Patient to 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.

(2) Each person engaged in the treatment of opioid use disorder must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions.

(a) All practitioners and other licensed/certified health care providers, including counselors, must comply with the credentialing and maintenance of licensure and/or certification requirements of their respective professions.

(b) All licensed health care providers shall maintain their licenses in good standing and without restrictions, sanctions, or other limitations to their job responsibilities.

(3) **Administrator.** The governing body of each facility shall designate in writing an administrator. The administrator shall be responsible for the ongoing and day-to-day operations of the facility, for overall compliance with federal, state, and local laws and regulations regarding the operation of Narcotic Treatment Programs, and for all facility employees including practitioners, agents, or other persons providing services at the facility.

(a) The administrator must be at least 21 years of age, must have at least one (1) year of supervisory and administrative experience in the field of substance use disorder treatment, and must have at least one (1) year of experience working in a Narcotic Treatment Program.

(b) Facilities must notify the State Opioid Treatment Authority in writing within ten (10) calendar days whenever there is a change in administrator.

(4) **Director of pharmacy services.** Each Narcotic Treatment Program clinic pharmacy shall be under the direction of a director of pharmacy services who is employed on a full-time or part-time basis consistent with the need of the Narcotic Treatment Program.

(a) All of the activities and operations of the Narcotic Treatment Program clinic pharmacy shall be personally and directly supervised by the director of pharmacy services or his/her pharmacist designee.

(b) All functions and activities of supportive personnel shall be supervised by an adequate number of registered pharmacists to ensure that all such functions and activities are performed competently, safely, and without risk of harm to patients. Personal supervision can only be accomplished by the physical presence of a licensed pharmacist in the Narcotic Treatment Program clinic pharmacy.

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(c) The director of pharmacy services must be licensed by the Georgia State Board of Pharmacy.

(d) The director of pharmacy services shall ensure that all supportive personnel will be trained in the matters of a Narcotic Treatment Program clinic pharmacy.

(e) The director of pharmacy services shall develop and implement written policies and procedures to specify the duties to be performed by such supportive personnel. These policies and procedures shall, at a minimum, specify that supportive personnel are personally and directly supervised by a licensed pharmacist while on duty in the pharmacy, and that supportive personnel are not assigned duties which may be performed only by licensed pharmacists.

(5) **Clinical director.** The governing body of each facility shall designate in writing a clinical director.

(a) The clinical director shall be responsible for the day-to-day and ongoing clinical aspects of the facility and of the treatment for those patients admitted to the facility.

(b) All clinical directors must be currently licensed to: practice medicine in the State of Georgia; licensed as a practitioner to provide treatment, therapeutic advice, or counseling for the treatment of opioid use disorder in compliance with state practice acts; or, certified as an addiction counselor, and must be at least 21 years of age, and must have at least one (1) year of supervisory and administrative experience in the field of substance use disorder treatment.

(c) Within ten (10) calendar days of any change in clinical director, the facility must notify the State Opioid Treatment Authority in writing and update the contact information in the Central Registry.

(6) **Medical director.** The governing body of each facility shall designate in writing a medical director to be responsible for the administration of all medical and behavioral health services performed by the Narcotic Treatment Program, including compliance with all federal, state, and local laws and regulations regarding the medical treatment of opioid use disorder.

(a) All medical directors shall be licensed to practice medicine in the State of Georgia.

(b) A physician may serve as medical director of no more than two (2) Narcotic Treatment Programs provided that all such facilities are in substantial compliance with these rules and are within fifty (50) miles of the physician's primary residence or primary office location.

(c) All medical directors shall have had, at a minimum, twelve (12) hours of training in opioid use disorder treatment within the twelve (12) months preceding the date of hire when hired after the effective date of these rules.

(d) Facilities must notify the State Opioid Treatment Authority in writing within ten (10) calendar days whenever there is a change in medical director.

(7) **Facility physician.** Facilities are required to provide sufficient physician coverage to provide the medical treatment and oversight necessary to serve patient needs. A facility physician's responsibilities for each patient include, but are not limited to, performing medical history and physical exams, determination of diagnosis under current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria, determination of an opioid use disorder, 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.

(a) All facility physicians must be licensed to practice medicine in the State of Georgia.

(b) All facility physicians must have had, at a minimum, twelve (12) hours of training in opioid use disorder treatment within the twelve (12) months preceding the date of hire when hired after the effective date of these rules.

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(c) If the facility physician has not had such training, he or she must be working under the direction of a medical director with an acceptable training plan, completed within twelve (12) months of the date of hire, that consists of a combination of continuing education in addiction medicine and in-service training by the medical director.

(d) At all times a facility is open and a physician is not present on site, a facility physician must be available on call for consultation and emergency orders.

(e) Any facility physician who is not a medical director must work under the supervision of the medical director.

(8) **Physician extenders.** Licensed physician's assistants and certified nurse practitioners may be employed by facilities and perform any functions permitted under Georgia law.

(a) All physician extenders must be licensed to practice their respective professions in the State of Georgia.

(b) All physician extenders must have twelve (12) hours of training in opioid use disorder treatment within the twelve (12) months preceding the date of hire when hired after the effective date of these rules.

(c) If any physician extender 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 twelve (12) months of the date of hire, that consists of a combination of continuing education in addiction medicine and in-service training by the medical director.

(9) **Nurses.** Facilities shall ensure that nursing care is provided at all times the facility is in operation and that an appropriately licensed health care professional is present at all times medication is administered at the facility.

(a) Facilities that do not employ a registered nurse to supervise the nursing staff must ensure that licensed practical nurses adhere to written protocols within their scope of service and are supervised by the medical director to ensure that nursing services are being appropriately delivered.

(b) When licensed practical nurses are supervised by the medical director, the supervision 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 of the facility;

2. Changes made to policies and procedures; and

3. Other areas identified by administrator, clinical director, director of pharmacy services, medical director or facility physician as requiring training for all licensed practical nurses.

(10) **Counselors.** There must be at least one full-time counselor for every fifty (50) patients. To be considered "full-time," a counselor must work a minimum of thirty-five (35) hours per week. All counselors, including counselors in training, must be certified in addiction counseling pursuant to O.C.G.A. § 43-10A-7(b)(15) within three (3) years of employment by the facility. Such certification must be obtained pursuant to Section 7(b)(16) of Chapter 10A of Title 43 of the Official Code of Georgia, from a certification agency that has demonstrated to the Department that it:

(a) Has been in continuous operation for at least five (5) years or has had its certifications accepted by the Department prior to the effective date of this Rule; and

(b) Meets the requirements of O.C.G.A. § 43-10A-7(b)(16) and any other applicable law for the certification of addiction counselors.

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(11) **Counselors in training.** The facility shall assign no more than forty (40) patients to a counselor in training who is not yet certified.

(12) **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 facility'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 sixteen (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 opioid use disorder 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 polysubstance use disorder; opioid use disorder treatment during pregnancy; HIV and other infectious diseases; co-morbid psychiatric conditions; and referring patients for primary care or other specialized services.

(c) Facilities shall maintain records documenting that each staff member has received the required annual training including evidence of hours and content covered in each training.

(13) **Employee drug testing.** Facilities shall establish and implement written policies and procedures for pre-employment and ongoing random drug testing of all facility 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, tetrahydrocannabinol (THC), fentanyl, and other drugs with satisfactory documentation of the results retained by the facility.

Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.13 Physical Plant and Safety

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

(2) A facility 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 to people with disabilities and constructed and maintained in a safe manner in accordance with these rules.

(4) A facility shall have appropriate and sufficient space to meet the programmatic needs of its patients and carry out the facility'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.

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(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 naloxone, or other medically appropriate emergency narcotic antagonists, available on site when care is being provided to patients.

Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.14 Patient Screening, Assessment, and Admission

(1) A facility may only admit and retain patients whose known needs can be met by the facility in accordance with its facility purpose and description and applicable federal and state laws and regulations.

(2) Written policies and procedures for patient referral, intake, screening, physical assessment, psychosocial assessment, and admission must be established and implemented and must include the following provisions or requirements.

(3) The screening may be completed via audio-visual telehealth if a licensed and qualified member of the medical staff determines that an adequate evaluation of the patient can be accomplished via telehealth. Audio-only telehealth shall be acceptable only if a visual telehealth platform is unavailable and the patient is in the presence of a licensed practitioner who is registered to prescribe and dispense controlled medications.

(4) **Screening.** All persons applying for facility admission must be initially screened to determine eligibility for admission.

(a) No person applying for facility admission 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 patient record.

(b) The screening must be completed by an appropriately licensed practitioner. If the licensed practitioner is not a Narcotic Treatment Program practitioner, the screening examination must be completed no more than seven (7) days prior to Narcotic Treatment Program admission. Where the screening is performed outside of the Narcotic Treatment Program, the written results and narrative of the examination, as well as available lab testing results, must be transmitted, consistent with applicable privacy laws, to the Narcotic Treatment Program, verified by a Narcotic Treatment Program practitioner, and recorded in the patient record.

(c) The screening must include:

1. Verification, to the extent possible, of the person'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. Verification that there are no contradictions to treatment with a medication for opioid use disorder;

4. If a person applying for facility admission has been previously discharged from treatment at another Narcotic Treatment Program, the admitting facility must initiate an investigation into the person's prior treatment history, including the last facility attended and the reasons for discharge from treatment;

5. Explanation of treatment options, detoxification rights, and facility charges, including fee agreement, signed by the person applying for facility admission.

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(d) Assuming there are no contraindications, a person may commence treatment with medications for opioid use disorder after the screening has been completed.

(e) No person under eighteen (18) years of age may be admitted to maintenance treatment unless a parent, legal guardian, or responsible party consents in writing to such treatment.

(5) **Physical Assessment.** A full, in-person physical assessment must be completed within fourteen (14) calendar days following a patient's admission to the Narcotic Treatment Program. The physical assessment can be completed by a non-Narcotic Treatment Program practitioner, if the exam is verified by a licensed Narcotic Treatment Program practitioner as being true and accurate. The physical assessment must be documented in the patient record and include:

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

(b) Psychiatric history and current medical status examination;

(c) A determination, using accepted medical criteria, that the person meets diagnostic criteria for moderate to severe opioid use disorder, has an active or in remission moderate to severe opioid use disorder, or is at high risk for recurrence or overdose.

(d) Lab testing as determined to be required by an appropriately licensed practitioner.

1. A patient's refusal to undergo lab testing for co-occurring physical health conditions should not preclude them from access to treatment, provided such refusal does not have potential to negatively impact treatment with medications for opioid use disorder. The reason for refusal must be documented in the clinical record, and attempt(s) must be made at a later time to obtain lab testing.

2. Lab testing drawn not more than thirty (30) days prior to admission to the Narcotic Treatment Program may form part of the physical assessment.

(e) Subsequent physical assessments must occur at least annually, be documented in the clinical record, and include a review of the medication for opioid use disorder dosing, treatment response, other opioid use disorder treatment needs, responses and patient-identified goals, and other relevant physical and psychiatric treatment needs and goals.

(6) **Psychosocial Assessment.** Each patient admitted to a Narcotic Treatment Program shall be given a psychosocial assessment within fourteen (14) calendar days following admission.

(a) The psychosocial assessment must be conducted by appropriately licensed/credentialed personnel.

(b) The psychosocial assessment must include screening for imminent risk of harm to self or others, education, vocational training, and employment; and the medical and psychiatric, psychosocial, economic, legal, housing, and other recovery support services that a patient needs and wishes to pursue.

(7) **Admission.** A facility shall not admit a patient for a maintenance program unless it is the most appropriate treatment modality.

(a) **Informed 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 clinical record:

1. All relevant facts concerning the use of medications for opioid use disorder;

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2. The facility's services and treatment;

3. The specific condition that will be treated;

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

5. The facility's rules regarding patient conduct and responsibilities.

(b) **Admission Clearance.** No person may receive medications unless the facility first conducts an inquiry with the Central Registry in accordance with Rule 82-11-1-.19 and receives clearance from the Central Registry that the person is not simultaneously enrolled in another facility.

(c) **Orientation.** The facility shall provide orientation to patients who are admitted for treatment within twenty-four (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 facility. Facilities shall ensure that each patient signs a statement confirming that the following has been explained to the patient, and that the patient receives a written copy of the orientation information to include, at a minimum:

1. The expected benefits of the treatment that the patient is expected to receive;

2. The patient's responsibilities for adhering to the treatment regimen and the consequences of non-adherence;

3. An explanation of individual treatment planning;

4. The identification of the staff person who is expected to provide treatment or coordinate the treatment;

5. Facility rules including requirements for conduct and the consequences of infractions, including involuntary discharge;

6. Patient's rights and responsibilities;

7. Procedures for complaining to the facility and to the Department;

8. Drug screening policies and procedures;

9. HIV education; and

10. Community awareness.

(8) **Special services for pregnant patients.** Any facility 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.

(a) Pregnancy must be confirmed.

(b) Evidence-based treatment protocols for the pregnant patient, such as split dosing regimens, may be instituted after assessment by a Narcotic Treatment Program practitioner and documentation that confirms the clinical appropriateness of such an evidence-based treatment protocol.

(c) Prenatal care and other sex-specific services, including reproductive health services, for pregnant and postpartum patients must be provided and documented either by the Narcotic Treatment Program or by referral to appropriate healthcare practitioners.

(d) The facility must coordinate the treatment of the pregnant female with appropriate health care providers monitoring the progress of the pregnancy.

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

(10) No facility may provide temporary discounted financial incentives to a potential patient that does not conform to the schedule of fees established by such facility as required by these rules. No facility shall provide discounted fees for services during the first ninety (90) days of treatment. This paragraph (10) shall not apply to pregnant females with an opioid use disorder.

(11) Paragraphs (9) and (10) above do not preclude facilities from providing services allowed specifically for grants or other funding for patients who meet eligibility for the funding source (e.g., patients who are uninsured or underinsured).

(12) **Non-Admissions.** The facility 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 person was not admitted and what referrals were made by the facility.

Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.15 Individual Treatment Plan

(1) Treatment plans must document a consistent pattern of substance use disorder treatment services and medical care appropriate to individual patient needs and must meet the requirements of 42 C.F.R. § 8.12(f)(4).

(2) A facility must develop a preliminary individual treatment plan for each patient within fourteen (14) days of admission, which includes an initial treatment recommendation.

(3) A complete individual treatment plan for each patient must be developed and signed by the patient, medical director, and counselor within thirty (30) days of admission. Patients must be involved in the development of their treatment plans.

(4) In recognition of the varied medical needs of patients, the case history and individual treatment plans must be reviewed at least every ninety (90) days for patients in treatment less than one (1) year and at least annually for patients in treatment more than one (1) year. This review will be conducted by the medical director or facility 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 facility must ensure that such services are made available to the patient and appropriate referrals for additional care are made.

(5) As part of the rehabilitative services provided by the facility, each patient must be provided with individual and/or group substance use disorder counseling and psychoeducation as clinically necessary and agreed upon, including harm-reduction education and recovery-oriented counseling.

(a) The frequency and duration of counseling provided to patients must be determined by appropriate facility 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.

(b) Counseling shall be provided by a facility counselor, qualified by education, training, or experience to assess the psychological and sociological background of patients, and engage with patients to contribute to the appropriate care plan for the patient and to monitor and update patient progress.

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(c) Patient refusal of counseling shall not preclude them from receiving medication for opioid use disorder.

(6) Narcotic Treatment Programs must provide counseling on preventing exposure to, and the transmission of, human immunodeficiency virus (HIV), viral hepatitis, and sexually transmitted infections (STIs) and either directly provide services and treatments or actively link to treatment each patient admitted or readmitted to treatment who has received positive test results for these conditions from initial and/or periodic medical examinations.

(7) 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 clinical record.

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

(9) All facilities will develop and implement policies for matching patient needs to treatment and providing treatment in accordance with current and accepted standards of medical practice.

(a) 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.

(b) Patients who choose to taper from medications are provided the opportunity to do so with informed consent, as documented in the clinical record, and at a rate mutually agreed upon with the prescriber and patient that minimize taper-related risks.

Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.16 Discharge and Aftercare Plan

(1) A facility must complete, in accordance with accepted standards of practice, an individual discharge and aftercare plan prior to discharge for patients who leave the facility 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 three (3) days of discharge of any 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.

(3) The facility must establish and maintain a formal plan of cooperation with other facilities in the State of Georgia to allow for continuity of care for persons with opioid use disorder.

(4) An individual’s discharge and transfer to another facility may not be delayed or withheld for any reason, including outstanding fees due to the facility. Facilities must actively participate in coordination of care for the individual’s transition and may not interfere by withholding information about the individual.

Authority: O.C.G.A. § 26-5-40 *et seq.*

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82-11-1-.17 Medications for Opioid Use Disorder

(1) Narcotic Treatment Programs shall use only those medications for opioid use disorder (MOUD) that are 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 opioid use disorder.

(a) Narcotic Treatment Programs that are fully compliant with the protocol of an investigational use of a drug and other conditions set forth in the application may administer a drug that has been authorized by the Food and Drug Administration under an investigational new drug application under section 505(i) of the Federal Food, Drug, and Cosmetic Act for investigational use in the treatment of opioid use disorder.

(b) The following MOUD are approved by the Food and Drug Administration (FDA) for use in the treatment of opioid use disorder:

1. Methadone;

(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 Narcotic Treatment Program, the initial dose of methadone shall be individually determined and shall include consideration of the type(s) of opioid(s) involved in the patient's opioid use disorder, other medications or substances being taken, medical history, and severity of opioid withdrawal.

(iii) The total dose for the first day shall not exceed fifty (50) milligrams, unless the facility physician documents in the patient's record sufficient medication rationale that fifty (50) milligrams did not suppress opiate abstinence symptoms, including but not limited to if the patient is transferring from another Narcotic Treatment Program on a higher dosage that has been verified.

2. Buprenorphine and buprenorphine combination products that have been approved for use in the treatment of opioid use disorder;

3. Naltrexone; and

4. Any other FDA-approved medication for opioid use disorder in the dosage form and requirements in accordance with currently accepted standards of treatment.

(2) **Policies and procedures.** Facilities shall develop and implement written policies and procedures for prescribing, dispensing, administration, and security of MOUD. These policies and procedures must include the following a current Diversion Control Plan that contains specific measures to reduce the possibility of diversion of dispensed MOUD, and that assigns specific responsibility to the Narcotic Treatment Program clinical and administrative staff for carrying out the diversion control measures and functions described in the plan, including identifying and responding to theft or diversion of take-home doses.

(b) **Prescribing MOUD.** The Narcotic Treatment Program shall be responsible for ensuring that all dosages are within therapeutically acceptable limits.

1. Individual doses shall be based on the clinical judgment of the facility 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 drug levels, patient interview, and specific circumstances pertaining to the individual patient. For the use of any other approved opioid agonist treatment

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medication, the facility shall ensure that the dosage form and initial dosage requirements are in accordance with currently accepted standards of treatment.

2. The facility physician shall determine the patient's initial and subsequent dose and schedule. If the facility physician did not perform the physical assessment required in Rule 82-11-1-.14, the facility physician must consult with the person who performed the assessment before determining the patient's initial dose and schedule.

3. The facility physician shall communicate the initial and subsequent doses and schedule to the pharmacy or the person supervising medication.

4. Any adjustment to a patient's dosage regimen shall be considered a new medication order. Such orders shall be written per protocol developed by the medical director and signed by the ordering physician within 72 hours.

5. Patients are stabilized on MOUD when they are receiving a therapeutic dose that is sufficient to stop opioid use and sufficient to keep the patient comfortable for at least twenty-four (24) hours with no need to resort to illicit opiates to satisfy opiate cravings.

6. **Verbal orders.** A verbal order may be given by a licensed medical practitioner granted rights to prescribe in a Narcotic Treatment Program. All verbal and telephone orders must include the medication name, explicit instructions, and the prescriber's name. Only licensed healthcare professionals, such as nurses and pharmacists, specifically authorized by the facility may receive and transcribe a verbal order. Verbal orders must be signed by the prescriber within 72 hours.

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.

(i) The 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.

(ii) Where computerized systems are used, authentication procedures will be strictly enforced.

(iii) 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.

(iv) The perpetual inventory must be totaled and recorded in milligrams daily.

(v) MOUD shall be counted and reconciled with the written inventory at the beginning and end of each dosing day with all discrepancies satisfactorily resolved.

(c) **Dispensing MOUD.** No drug shall be dispensed 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.

1. MOUD shall be dispensed by a pharmacist, physician, or physician extender.

2. The pharmacy must receive an electric or mechanical copy of a physician's order before the first dose of medication is dispensed.

3. Detailed records of all controlled substances received and dispensed shall be maintained, with a biennial inventory.

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4. MOUD dispensed by the Narcotic Treatment Program clinic pharmacy shall be dispensed in appropriate containers and adequately labeled as required by the Rules and Regulations of the Georgia State Board of Pharmacy, Chapter 480-18-.06.

5. The Narcotic Treatment Program clinic pharmacy shall not dispense or administer prescription medications other than MOUD.

6. The director of pharmacy services shall develop and implement policies and procedures to ensure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition.

(d) **Administration of MOUD.** No drug shall be 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.

1. MOUD shall be administered by authorized licensed personnel in accordance with policies and procedures specified by the director of pharmacy services and by usual and customary standards of good medical practice which protect the public health, safety and welfare. Only licensed personnel shall administer medications.

2. MOUD may be self-administered by the patient while under the supervision of a licensed medical professional.

3. No MOUD may be administered unless the person applying for facility admission has undergone the required screening, 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.

(e) **Unsupervised or take-home medication doses.** Take-home doses of MOUD 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 MOUD according to these rules and the following restrictions. The dispensing restrictions below do not apply to buprenorphine and buprenorphine products.

1. Any patient under comprehensive treatment may receive their individualized take-home doses as ordered for days that the facility is closed for business, including one (1) weekend day (e.g., Sunday) and State of Georgia and Federal holidays, no matter their length of time in treatment.

2. In determining which patients may receive unsupervised medication doses, the medical director or medical staff shall consider, among other pertinent factors that indicate that the therapeutic benefits of unsupervised doses outweigh the risks, the following criteria, as documented in the patient's medical record:

(i) Absence of active substance use disorders, other physical or behavioral health conditions that increase the risk of patient harm as it relates to the potential for overdose, or the ability to function safely;

(ii) Regularity of attendance for supervised medication administration;

(iii) Absence of serious behavioral problems that endanger the patient, the public or others;

(iv) Absence of known recent diversion activity;

(v) Whether take-home medication can be safely transported and stored; and

(vi) Any other criteria that the medical director or medical staff considers relevant to the patient's safety and the public's health.

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3. The following dispensing restrictions for take-home doses shall apply, exclusive of any dosage for closure days:

(i) During the first fourteen (14) days of treatment, the take-home supply is limited to seven (7) days.

(ii) From fifteen (15) to thirty (30) days of treatment, the take-home supply is limited to fourteen (14) days.

(iii) From 31 days of treatment, the take-home supply provided to a patient is not to exceed 28 days.

(f) **Documentation of administration.** Any MOUD 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.

1. The record must include:

(i) Name of medication;

(ii) Date prescribed;

(iii) Dosage;

(iv) Frequency;

(v) Route of administration;

(vi) Date and time administered; and

(vii) Signed documentation of the licensed medical professional administering medication or supervising self-administration.

2. Suspected adverse drug reactions and medication administration errors must be reported to the ordering physician and pharmacist immediately and corrective action initiated. The adverse reaction or error also must be recorded in the drug administration record and the nurse’s progress notes and the medical director must be alerted.

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(g) **Emergency kit.** Emergency medications, such as naloxone or other medically appropriate emergency narcotic antagonists, must be kept available for appropriate use. Emergency kits must meet the following requirements:

1. The director of pharmacy services and the medical staff shall jointly determine the drugs, by identity and quantity, to be included in the emergency kits and location of the emergency kit in a limited access area.

2. The exterior of emergency kits shall be labeled so as to clearly and unmistakably indicate that it is an emergency drug kit and is for use in emergencies only, and have an inventory attached.

3. All drugs in emergency kits shall be labeled in accordance with such state and federal laws.

4. Drugs shall be removed from emergency kits only pursuant to a valid physician's order, by authorized licensed clinic personnel, or by a pharmacist for the clinic pharmacy.

5. Each emergency kit shall be opened and its contents inspected by a pharmacist at least once every ninety (90) days. Upon completion of inspection, the emergency kit shall be re-sealed.

(h) **Accountability for controlled substances.** All medications must be appropriately stored in a locked safe when not being administered or self-administered.

1. The Narcotic Treatment Program clinic pharmacy shall be capable of being locked by key or combination so as to prevent unauthorized access except by force. Only authorized persons shall be permitted to enter these areas.

(i) All drugs shall be stored to ensure proper sanitation, temperature, light, ventilation, and moisture control.

(ii) Storage for Schedule II controlled substances shall be in an enclosed room or space with controlled limited access or a safe or lockable metal cabinet that is permanently affixed to the structure.

(iii) Whenever the Narcotic Treatment Program clinic pharmacy is not under the personal and direct supervision of authorized licensed personnel, the area shall be locked and secured.

2. Perpetual inventory of Schedule II controlled substances shall be required to indicate the date used, name of shipper or drug recipient, corresponding serial number of a drug order, invoice or proof of use form, and quantity received or issued.

3. Proof of use controlled substance forms shall be provided by the pharmacy. Each form shall display the name of the patient to or for which it has been issued and an indication that the drugs are for general or emergency use and a serial number. Each proof of use form shall provide space to record the administration information necessary to account for each dose of medication to include:

(i) Drug name, strength and dosage form;

(ii) Dose administered;

(iii) Prescriber;

(iv) Patient's first and last name;

(v) Date and time of administration to patient;

(vi) Full signature and title of the licensed medical professional administering the dose;

(vii) Documentation of destruction of all unused portions by the signature of two licensed healthcare professionals;

(viii) Proof of receipt of medication bearing identifying serial numbers; and

(ix) Date the medication was issued and date the proof of use form was returned.

Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.18 Drug-Screen Tests

(1) The facility 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 thirty (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 (2) weeks or longer if clinically indicated.

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

(c) Drug-screen test samples must be properly collected and handled to ensure that samples are actually collected from the patient being tested and are unadulterated.

(2) When conducting random drug testing, Narcotic Treatment Programs must use drug tests that have received the FDA marketing authorization for commonly used and misused substances that may impact patient safety, recovery, or otherwise complicate substance use disorder treatment.

(3) These requirements do not preclude distribution of legal harm reduction supplies that allow an individual to test their personal drug supply for adulteration with substances that increase the risk of overdose.

(4) 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. § 26-5-40 *et seq.*

82-11-1-.19 Central Registry

(1) To prevent simultaneous enrollment of a patient in more than one facility, all facilities shall participate in the Central Registry approved and operated by the Department of Behavioral Health and Developmental Disabilities and shall comply with any policies, procedures or rules of the Department which are associated with the Central Registry.

(2) The Central Registry shall require each facility to provide the social security number and other identifying information of each patient.

(3) Patients must be informed of the facility's participation in the Central Registry, and prior to initiating a Central Registry inquiry, the facility must obtain the patient's signed consent. Within twenty-four (24) hours of accepting a patient for treatment, and prior to the administration of any medication, the facility 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.

(4) No individual shall receive medication from a facility if that individual is reported by the Central Registry to be participating in another such facility. In the event a dual enrollment is discovered, the patient must be discharged from one facility in order to continue enrollment at another facility.

(5) Reports received by the Central Registry shall be treated as confidential and shall not be released except to a licensed facility or as required by law. Information made available by the Central Registry to facilities shall also be treated as confidential.

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

Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.20 Quality Improvement

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(1) Facilities 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-facility services, patient grievance procedures, availability of services and medications for other conditions, and at least one (1) indicator to evaluate the effectiveness of services; and

(b) A documented 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 facility'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.

(3) The medical director shall be actively involved in the development, full implementation, and continuous monitoring of the plan.

Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.21 Patient Rights and Complaints

(1) Facilities 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 receive treatment without discrimination in the quality of service based on age, gender, race, physical or mental disability, religion, sexual orientation, national origin, marital status, or the source of payment for the service;

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

(c) Right to be free from abuse, neglect, and exploitation;

(d) Right to be free from punishment or harassment;

(e) Right to fully participate in the planning of his/her care, including the right to be informed about the plan of treatment and any changes in the plan of treatment.

(f) Right to accept or refuse treatment;

(g) Right to confidentiality of patient records;

(h) Right to timely access to patient records when transferring or discharging from a facility;

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

(j) Right to receive a written notice of the method for filing a complaint with the Department, including the address and telephone number of the state licensing authority, i.e., the Department;

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

(l) Right to a review of any involuntary discharge.

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

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

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

Authority: O.C.G.A. § 26-5-40 *et seq.*

82-11-1-.22 Enforcement and Sanctions

(1) When the Department finds that a license candidate 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 facility violates any requirements of these rules, the Department may, subject to notice and opportunity for a hearing, impose one or more sanctions as outlined in the Rules and Regulations for Licensure Enforcement and Sanctions, Chapter 82-14-1.

(3) 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 Licensure Enforcement and Sanctions, Chapter 82-14-1. Any requests for hearings in response to enforcement actions must be in writing and must be submitted to the Department no later than ten (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. § 26-5-40 *et seq.*

82-11-1-.23 Waivers and Variances

(1) The Department may, in its discretion, grant waivers and variances 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 facility in order to operate under the waiver or variance granted.

(2) **Variance.** A variance may be granted by the Department upon a showing by the license candidate 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 license candidate 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 facility to support its application for a variance.

(3) **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 license candidate or petitioner that the purpose of

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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. § 26-5-40 *et seq.*

82-11-1 -.24 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. § 26-5-40 *et seq.*

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