Chapter 480-18 OPIOID TREATMENT PROGRAM CLINIC PHARMACIES

Rule 480-18-.01 Definitions

For purposes of this chapter, the following definitions apply:

(a) Administer. The term administer means to give one, single dose of a pharmacy prepared narcotic controlled substance.

(b) Board. Board means the Georgia State Board of Pharmacy.

(c) Compound. The term compound means to mix, prepare, package or change the dosage form of a narcotic controlled substance for use in or by an opioid treatment program.

(d) CSAT. CSAT means the Center for Substance Abuse Treatment.

(e) DEA. DEA means the United States Drug Enforcement Administration.

(f) DHR. DHR means the Georgia Department of Human Resources.

(g) Dispense. The term dispense refers to 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 an opioid treatment program.

(h) Director of Pharmacy Services. Director of Pharmacy Services shall be a pharmacist, licensed with the Board, who shall direct, oversee, establish protocols and be responsible for all pharmacy related transactions at an opioid treatment program clinic pharmacy.

(i) Emergency kit. An emergency kit is 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;

(j) GDNA. GDNA means the Georgia Drugs & Narcotics Agency.

(k) Licensed medical personnel. The term licensed medical personnel is used to describe employees of an opioid treatment program clinic licensed by the State of Georgia as health care professionals, i.e. physicians, pharmacists, nurses.

(l) Medication dosing station. The term medication dosing station is used to describe the location where doses of medication are administered.

(m) Medication order. The term medication order is used to describe the manner in which a physician orders, via written, verbal or

electronically transmitted means, the administration of a narcotic controlled substance to the ultimate user.

(n) Methadone clinic. Methadone clinic is defined the same as a narcotic treatment program clinic or an opioid treatment program clinic.

(o) Methadone treatment program. Methadone treatment program is defined the same as a narcotic treatment program or an opioid treatment program.

(p) Narcotic maintenance. The term narcotic maintenance means a treatment procedure in which individuals use an approved narcotic controlled substance over a period of time to relieve withdrawal symptoms and reduce narcotic craving in combination with rehabilitation services.

(q) Narcotic treatment program. Narcotic treatment program or NTP, also known as an opioid treatment program, is defined as a program licensed or otherwise authorized, by the State of Georgia Department of Human Resources (DHR), the Substance Abuse and Mental Health Services Administration (SAMHSA) and the U.S. Drug Enforcement Administration (DEA) to operate a narcotic substance abuse program using narcotic replacement procedures for individuals dependant on opium, morphine, heroin or any derivative or synthetic drug in that group.

(r) Narcotic treatment program clinic pharmacy. Narcotic treatment program clinic pharmacy, is defined as a pharmacy licensed by the Board which is designated as an on-site pharmacy department of a narcotic treatment program.

(s) On-site pharmacy. On-site pharmacy (OSP) is a licensed opoid treatment program clinic pharmacy.

(t) Opioid replacement center. Opioid replacement center (ORC) is an opioid treatment program.

(u) Opioid treatment program. Opioid treatment program (OTP), is an opioid replacement program or a narcotic treatment program licensed, or otherwise authorized by the State of Georgia Department of Human Resources, the Substance Abuse and Mental Health Services Administration, and the U.S. Drug Enforcement Administration. This program operates as a narcotic substance abuse program using narcotic replacement procedures for individuals dependant on opium, morphine, heroin or any derivative or synthetic drug in that group.

(v) Opioid treatment program clinic pharmacy. Opioid treatment program clinic pharmacy is a licensed pharmacy which is designated as an on-site pharmacy department located in and operated by any opioid treatment program or opiate replacement treatment program.

(w) Opioid treatment program clinic pharmacy license. An opioid treatment program clinic pharmacy license is issued by the Georgia State Board of Pharmacy to an opioid treatment program clinic pharmacy.

(x) Outpatient. Outpatient shall mean an opioid treatment program patient who is treated on an outpatient basis.

(y) SAMHSA. SAMHSA means the Substance Abuse and Mental Health Services Administration.

(z) Take-home dose. The term take-home dose means a quantity of a physician ordered narcotic controlled substance dispensed by an opioid treatment program clinic pharmacy which an individual can take away from the OTP clinic, as set forth in the Georgia Department of Human Resources rules.

Rule 480-18-.02 Licensure and Registration

(1) All opioid treatment program (OTP) clinics must have an on-site pharmacy. All such pharmacies shall obtain a license by registering with the Georgia State Board of Pharmacy (Board). Such license shall be renewed biennially with the Board. Before a Board license can be issued, an opioid treatment program clinic must meet all the requirements for licensure and registration as provided by both state and federal law and all Board rules.

(2) Licensure and Applications. Certificates of registration or licensure shall be issued only to those opioid treatment program clinic pharmacies who meet the following requirements:

(a) Submission of an application with the following information:

1. The name, full business address, and telephone number of the licensee;
2. All trade or business names used by the licensee;
3. Address, telephone number, and the name of the Director of Pharmacy
4. The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship); and
5. The name(s) of the owner and/or operator of the licensee, including:

(i) If a person, the name of the person;

(ii) If a partnership, the name of the partnership and the name of each partner;

(iii) If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity; or

(iv) If a corporation, the corporate name, the name and title of each corporate officer and director, the state of incorporation; and the name of the parent company, if any.

(v) If operations are conducted at more than one location by a single opioid treatment program clinic pharmacy, each such location shall be licensed by the Board.

(3) Payment of an application fee. Application fees shall not be refundable.

(4) Applicant must file a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a license.

(5) Licenses become null and void upon the sale, transfer or change of mode of operation or location of the pharmacy.

(6) Licenses are required to be renewed June 30th of each odd numbered year and may be renewed upon the payment of the required fee for each pharmacy and the filing of an application for renewal. Said renewal is for a two year period. If the application for renewal is not filed with the Board and the fee paid before September 1st, of the odd numbered year, the license shall lapse and shall not be renewed. An application for reinstatement shall be required. Reinstatement shall be at the sole discretion of the Board.

(7) Changes in any licensee information pertaining to this rule shall be submitted in writing to the Board prior to such change.

(8) The Board will consider the following factors in determining eligibility for licensure of applicants in charge of the facility who are applying for an opioid treatment program clinic pharmacy license:

(a) Convictions of the applicant under any Federal, State, or local laws relating to wholesale or illegal distribution of dangerous drugs or controlled substances;

(b) Any felony convictions of the applicant under Federal, State, or local laws;

(c) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;

(d) Suspension or revocation by Federal, State, or local government of any pharmacist, pharmacy or other health care license currently or previously held by the applicant;

(e) Compliance with licensing requirements under previously granted licenses, if any;

(f) Compliance with requirements to maintain and/or make available to the State Licensing Authority or to Federal, State, or local law enforcement officials, those records required to be maintained by the opioid treatment program clinic pharmacies; and

(g) Other factors or qualifications the Board considers relevant to and consistent with the public health, safety and welfare.

(9) The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the best interest of the public.

(10) The pharmacist's wall certificate issued by the Georgia State Board of Pharmacy (Board), along with the current renewal license of each full-time pharmacist, employed at the pharmacy, shall be displayed in a conspicuous place, near the prescription department where such pharmacist is actively engaged in the practice of pharmacy.

(a) While employed in a pharmacy on a full-time basis, if a pharmacist has not yet received his/her Board issued pharmacist wall certificate, in its place such pharmacist shall post a copy of his/her current Board issued pocket license card;

(b) Any pharmacist employed on a part-time basis at a pharmacy shall post a copy of his/her current Board issued pocket license instead of posting his/her pharmacist wall certificate; and

(c) Any pharmacist employed as a relief or "prn" pharmacist need not post any type of Board issued license, but such pharmacist must maintain and present upon request his/her current Board issued pocket license.

(11) Any letter(s) from the Board which have granted a licensee any exception(s) and/or exemption(s) from this, or any other rule, must be posted and/or displayed next to the current Board of Pharmacy permit; and

(12) No pharmacist or intern/extern shall display his/ her license in any pharmacy where he or she is not employed or engaged in the practice of pharmacy, and shall not knowingly permit any other person to use his or her license for the purpose of misleading anyone to believe that such person is the holder or recipient of said license or intern certificate.

Rule 480-18-.03 Personnel

The personnel shall be as follows:

(a) Director of Pharmacy Services. Each OTP clinic pharmacy shall be under the direction of a Director of Pharmacy Services, hereafter referred to as the Director. The Director shall:

1. Direct, oversee and be responsible for all activities related to pharmacy transactions at an opioid treatment program clinic pharmacy;
2. Be a pharmacist licensed by the Board to practice;
3. Be charged with meeting all of the requirements of applicable state and federal laws and rules;
4. Be employed on a full-time or part-time basis consistent with the need and objectives of the OTP clinic.
5. Shall have such other duties and responsibilities as set forth in this chapter.

(b) Supportive Personnel. The Director of an OTP clinic pharmacy shall be assisted by a sufficient number of licensed pharmacists and other personnel as may be required to operate such pharmacy competently, safely, and to meet the needs of the outpatients of the OTP clinic pharmacy.

(c) Secretary and clerical personnel shall be provided to assist with record keeping, report submission, and other administrative duties, provided such personnel do not perform any dispensing duties.

(d) Supervision. All of the activities and operations of each OTP clinic pharmacy shall be personally and directly supervised by the Director or his/her pharmacist designee.

1. All functions and activities of supportive personnel shall be supervised by an adequate number of registered pharmacists to insure that all such functions and activities are performed competently, safely, and without risk of harm to patients;
2. Personal supervision can only be accomplished by the physical presence of a licensed pharmacist in the OTP clinic pharmacy.
3. The Director of Pharmacy shall insure that all supportive personnel will be trained in the matters of an opioid treatment program clinic pharmacy.
4. The Director of Pharmacy 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.

Rule 480-18-.04 Absence of a Pharmacist

The following regulations shall be followed in the absence of a pharmacist:

(1) General. Access to drugs in the absence of a licensed pharmacist shall be limited to specifically authorized licensed medical personnel consistent with policies and procedures of the Director. Such areas shall be sufficiently secure to deny access by unauthorized persons. The Director shall, in conjunction with the appropriate committee of the narcotic treatment program clinic, develop a list of the drugs to be accessible and shall ensure that:

(a) Such drugs available therein, are properly labeled, with drug name, strength, lot number and expiration date;

(b) Only prepackaged drugs are available therein, in amounts sufficient for immediate therapeutic requirements;

(c) Whenever access to such area shall have been gained, written physician's orders and proof of use for controlled substances are provided;

(d) All drugs therein are inventoried no less than once per week. A system of accountability must exist for all drugs contained therein; and

(2) Written policies and procedures are established to implement the requirements of this subsection.

(3) Emergency Kits. Drugs may be provided for use by authorized licensed health care personnel by emergency kits, provided such kits meet the following requirements:

(a) Drugs included. The Director and the medical staff of the clinic shall jointly determine the drugs, by identity and quantity, to be included in the emergency kits. Such drugs shall also be approved by the Board or its authorized agent;

(b) Storage. Emergency kits shall be stored in limited access areas and sealed to prevent unauthorized access, and to insure a proper environment for preservation of the drugs within them;

(c) Labeling-exterior. 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. In addition, a listing of the drugs contained therein, including name, strength, quantity, and expiration date of each drug shall be attached. Nothing

in this section shall prohibit another method of accomplishing the intent of this section, provided such method is approved by the Board upon a recommendation of the GDNA.

(d) Labeling-interior. All drugs contained in emergency kits shall be labeled in accordance with such state and federal laws and regulations which pertain thereto; and shall also be labeled with such other and further information as may be required by the medical staff of the clinic to prevent misunderstanding or risk of harm to the patients;

(e) Removal of drugs. 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;

(f) Notification. Whenever an emergency kit is opened, the pharmacy shall be notified; and the pharmacy shall replace or re-stock and reseal the kit within a reasonable time so as to prevent risk of harm to patients. In the event the kit is opened in an unauthorized manner, the pharmacy and other appropriate personnel of the facility shall be notified;

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

(4) Access to pharmacy. Whenever any drugs are not available from an afterhours
safe or emergency kit(s), and such drugs are required to treat the immediate needs of a patient whose health would otherwise be jeopardized, such drugs may be obtained from the pharmacy pursuant to the physician's order and the requirements of this subsection.

(a) At any given time, there may be only one licensed health care professional who is designated in the policies and procedures, to have access to the pharmacy and to remove drugs therefrom.

(b) Such licensed health care professional shall be designated in writing by the Director of the OTP clinic pharmacy and shall, prior to being permitted to obtain access to the pharmacy, receive thorough education and training by the Director or his or her designee in the proper methods of access, removal of drugs, and records and procedures required.

(c) Such licensed healthcare professional shall at a minimum record on a suitable form the name of any drug, the strength, amount, date and time removed from the pharmacy and his or her signature and title.

(d) Such licensed healthcare professional shall place the container from which the drug is removed in a conspicuous place in the pharmacy to be promptly reviewed and inspected by a pharmacist.

(e) Procedures. The Director, in conjunction with the medical staff of the clinic, shall develop and implement written policies and procedures to insure compliance with the provisions of this subsection.

Rule 480-18-.05 Physical Requirements and Equipment

(1) Physical Area. An OTP clinic pharmacy shall have within the clinic which it serves, sufficient floor space allocated to it to insure that drugs are prepared in sanitary, well-lighted and enclosed space, and which meet the other requirements of this section, the Georgia Pharmacy laws, and other applicable state and federal laws and rules. Such space shall be at a minimum 150 square feet. Such space shall include all areas which are assigned and under the direct control of the Director.

(2) Minimum equipment. No OTP clinic pharmacy licensed in accordance with O.C.G.A. Title 26, Ch. 4 shall engage in the practice of filling, compounding or dispensing prescription drugs for an OTP Clinic unless it shall possess the following items:

(a) Copies of and/or electronic access to current reference materials appropriate to the practice of pharmacy related to OTP. These reference materials shall be authoritative on at least the topics of drug interactions; patient counseling; compounding and pharmaceutical calculations; and generic substitution.

(b) Authoritative, current antidote information as well as the telephone number of the regional poison control information center shall be posted or readily available in areas both inside and outside of the pharmacy where drugs are stored, or patients are being cared for.

(c) Current copies or electronic or computer access to the following:

1. The Georgia Pharmacy Practice Act/Drug and Cosmetic Act, O.C.G.A. §§26-4 and 26-3;

2. The Georgia Controlled Substances Act/Dangerous Drug Act, O.C.G.A. §16-13;

3. The official rules of the Georgia State Board of Pharmacy.

(d) Equipment:

1. Sink in working condition with both hot and cold running water;

2. Two spatulas;

3. One oral solid counting tray;

4. Typewriter, word processor or computer with label printer;

5. A refrigerator in working order with a thermometer.

6. Any other equipment the Board may deem necessary for a specialized practice setting where such a specialized practice takes place.

(e) Weighing and labeling:

1. Appropriate prescription labels consistent with the requirements of O.C.G.A. §§16-13, 26-3 and 26-4; and

2. Appropriate auxiliary labels that should be used in the pharmacist's professional judgement.

3. A class A balance with metric and apothecary weights or an electronic class I or II balance.

(f) An adequate supply of drugs used in an OTP Clinic setting.

(g) Assorted sizes and types of appropriate dispensing containers.

(3) The Director in an OTP clinic pharmacy may submit to the Board a typed request for a variance to the provisions relating to the minimum equipment requirements.

(a) The reason for requesting each variance must be included in the typed request;

(b) A variance shall be granted by the Board only when, in the judgement of the Board, there are sound reasons for doing so which relate to the necessary or efficient delivery of health care.

(c) Any variance granted by the Board shall be in writing, and the variance must be posted in the pharmacy next to the current Board issued license certificate.

Rule 480-18-.06 Drug Distribution and Control

(1) General. A drug distribution system is the entirety of that mechanism by which a physician's drug order is executed, from the time the practitioner transmits the order either orally, in writing, or electronically to a licensed health care professional to the time the ordered drug is administered to the patient or delivered to the patient for self-administration. No drugs can be dispensed or administered without a physician's medication drug order.

(2) Responsibility. The Director shall be responsible for the safe and efficient distribution, control, and accountability for drugs. The other professional staff, including the physicians, at the OTP clinic shall cooperate with the Director in meeting this responsibility and in ordering, administering, and accounting for the drugs and devices so as to achieve this purpose.

(a) The Director shall establish written policies and procedures for the distribution of medications including emergency kits, etc. to achieve this goal.

1. The drugs must be identified up to the point of administration;

2. The pharmacy must receive a direct, electronic (only for drugs to be administered on site) or mechanical copy of a physician's order before the first dose of medication is dispensed as defined by the clinic stat order policy.

3. At a minimum, the pharmacy must maintain a patient profile for each OTP clinic patient for use in prospective and retrospective drug reviews, for comparing with the central registry as required by the DHR and to report violators to the GDNA and DHR, for discharge from another OTP, and for urine or blood tests to check for drug positive test results.

4. Records of all transactions of the OTP clinic pharmacy, such as daily drug dosing summaries, daily drug inventory sheets, patient medication profiles, and bulk drug inventory records must be maintained by the clinic pharmacy as may be required by law, and as may be necessary to maintain accurate control over and accountability for all drugs and devices within the scope of the clinic practice.

5. All drug invoices must be attached to their accompanying DEA form 222 order form and must be filed separately from all other drug records. A biennial inventory of all controlled substances on hand must be taken every two years from the date of the pharmacy opening for business. This inventory must be an accurate count of all such drugs, signed in indelible ink by the pharmacist taking the inventory and dated on the date it is taken.

6. Any drug compounded by the pharmacy must be accounted for by use of a compounding log form. This form, at a minimum must display the date the drug was compounded, the name of the drug, the strength, quantity made, manufacturer's lot number, manufacturer's expiration date, and the signature of the pharmacist compounding the drug.

7. Nothing in this section shall prohibit the use of computerized records, where such records meet all other requirements of the law. An OTP clinic pharmacy may not dispense or administer prescription medications other than OTP program medications; and

8. The pharmacy must participate in those aspects of the OTP clinic patient care evaluation program which relate to drug and device utilization and effectiveness.

(b) All records must be maintained by the pharmacy for a minimum of two years and be readily retrievable upon request by an agent of the Board.

(3) Labeling:

(a) For use inside the clinic, all drugs dispensed by an OTP clinic pharmacy, including those for use in an afterhours safe or emergency kit shall be dispensed in appropriate containers and adequately labeled so as to identify at a minimum:

1. Brand name or generic name of the drug;
2. Drug strength;
3. Lot number assigned by either the drug manufacturer or the clinic pharmacy; and
4. Expiration date assigned either by the drug manufacturer or the clinic pharmacy.

(b) Any drug container dispensed by the pharmacy for take-home use by an OTP clinic patient must display a label which contains at least the following:

1. Patient name;
2. Name of the prescribing physician;
3. Name, address and telephone number of the OTP clinic pharmacy;
4. Drug name (either brand or generic name);
5. Drug strength;
6. Date of dispensing;
7. Expiration date of the drug as determined by the pharmacy;
8. "Federal Caution" for controlled substances;
9. Clinic Pharmacy serial number for that specific prescription drug order;
10. Any other labeling or information as required by the DEA;

(c) All take-home medication dispensed by the pharmacy, including one-time use containers, must be in child-proof containers which meet the requirements of the U.S. Consumer Product Safety Commission.

(4) Discontinued drugs. The Director shall develop and implement policies and procedures to insure that discontinued and outdated drugs and containers with worn, illegible, or missing labels are returned to the pharmacy for proper disposition.

(5) Accountability of controlled substances.

(a) Nothing shall prohibit the use of controlled substance drugs issued via proof of use forms for general or emergency use for specific patients. Proof of use controlled substances forms shall be provided by the pharmacy.

(b) Each proof of use 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. The form shall also show the date the form was issued and the signature of the pharmacist issuing the form and the signature of the licensed medical practitioner receiving the form for storage in the after-hour safe. A detachable receipt reflecting all the previous information must be returned and filed by the pharmacy as a safeguard to prevent drug diversion.

(c) Each proof of use sheet shall provide space to record the administration information necessary to account for each dose of medication. This information shall specify at a minimum:

1. Drug name, strength, and dosage form;
2. Dose administered;
3. Name of prescriber. This shall include, at a minimum, the first initial and complete last name of the prescriber;
4. First and last name of the patient;
5. Date and time of administration to patient;
6. Signature of individual administering the dose, which shall include at a minimum, the first and last name and title;
7. Documentation of destruction of all unused portions by two signature verifications of licensed healthcare professionals;
8. Proof of receipt of medication bearing identifying serial numbers;
9. Date the medication was issued and date the proof of use form was returned.

(6) Any OTP clinic pharmacy licensed by the Board may make on-premises destruction of small quantities of controlled substances prepared for oral administration provided:

(a) The controlled substance is the remainder of a single-dose unit; and,

(b) The single-dosage unit from which the ordered dose was prepared is the nearest possible size to the dose ordered.

(7) Perpetual inventory of Schedule II controlled substances shall be required and accountability of said drugs shall be by an appropriate form indicating at a minimum 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.

(8) Recall. The Director shall develop and implement a recall policy and procedure to assure that all drugs within the clinic included on the recall are returned to the pharmacy for proper disposition.

(9) Suspected adverse drug reactions. All suspected adverse drug reactions shall be reported immediately to the ordering physician, the pharmacy, and to the appropriate committee of the clinic. An appropriate entry on the patient's pharmacy profile shall also be made.

(10) Security. All areas occupied by an OTP clinic pharmacy shall be capable of being locked by key or combination, so as to prevent unauthorized personnel access except by force. Such areas shall meet the security requirements of all applicable Federal and State laws and rules. Only those persons so authorized shall be permitted to enter these areas.

(a) All drugs shall be stored in designated areas within the clinic pharmacy or all dispensing medications shall be stored in designated areas within the clinic which are sufficient to insure proper sanitation, temperature, light, ventilation, moisture control, segregation, and security. Drug storage areas shall be locked or otherwise secured when licensed health care professionals are not present.

(b) Storage for Schedule II controlled substances shall be in an enclosed room or space with controlled limited access capable of showing forced entry is preferable. However, a safe or a lockable metal cabinet that is permanently affixed to the structure is acceptable.

(c) Whenever any area of an OTP clinic pharmacy is not under the personal and direct supervision of authorized licensed personnel, such areas shall be locked and secured.

(11) Reports and records. The Director shall maintain access to and submit, as appropriate, such records and reports as are required to insure patient health, safety and welfare. Such records shall be readily available and subject to inspections by the Board, the GDNA or its designated agents. All such records shall be maintained for a

minimum of two years. These shall include, at a minimum, the following:

(a) Patient profile, chart or other appropriate record;

(b) Proof of use forms for controlled substances;

(c) Reports of suspected adverse drug reactions;

(d) Inventories of after hours safe(s) and emergency drug kits,

(e) All perpetual inventories maintained by the pharmacy, and all other records pertaining to controlled substances, including a biennial controlled substances inventory;

(f) Such other records and reports as may be required by Federal or State laws and/or rules;

(12) The compounding, labeling and quality control of large volumes of opioid treatment medication is the responsibility of a pharmacist and shall be prepared within the on-site pharmacy.

Rule 480-18-.07 Delivery of Drugs, General

(1) No drug shall be dispensed or administered except upon receipt of a medication drug order written by a licensed medical practitioner granted rights to prescribe in an OTP.

(a) A licensed medical practitioner must write an initial dosing medication order for each patient prior to any medication being dispensed or prepared by the OTP clinic pharmacy.

(b) In emergency situations, a verbal order may be given by the physician and it must be signed by the physician within 72 hours, or such order would be considered a violation of these rules.

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

(2) Drugs shall be administered by authorized licensed personnel in accordance with policies and procedures specified by the Director of Pharmacy Services under applicable laws and rules and regulations, and by usual and customary standards of good medical practice which protect the public health, safety and welfare. Only licensed personnel shall administer medications.

Rule 480-18-.08 Drugs From Outside Sources

(1) The Director shall establish policies and procedures relating to drugs brought into the OTP clinic by outside sources. Such drugs shall not be administered unless they can be precisely identified. Administration shall be pursuant only to an authorized practitioner's prescription drug order. These medications shall be kept in the pharmacy. If such drugs are not to be administered, the medication shall be returned to an adult member of the patient's family or stored by the pharmacy and returned to the patient upon discharge. Nothing in this section shall prohibit another method of accomplishing the intent of this section provided such method is approved by the Board.

Rule 480-18-.09 Inspections

(1) Board Inspection. The Board, through either the GDNA or by its qualified designee, shall, at a minimum, inspect each OTP clinic pharmacy once every two (2) years to verify compliance with the laws and these rules and regulations.

(a) The Director shall maintain a copy of the inspection report in the OTP clinic pharmacy and shall submit a copy of the report to the DHR Methadone Authority.

(b) Any discrepancies or deficiencies noted shall be corrected within thirty (30) days of the inspection.

(c) Written notice of such corrections or a plan of action to correct deficiencies shall be filed with the GDNA within thirty (30) days after receipt of the inspection report.

(2) Director inspections. The Director shall no less than once each month, either personally or by qualified designee, inspect all matters within the jurisdiction and responsibility of the pharmacy and make appropriate written records of such inspections. Such inspections shall, at a minimum, verify that:

(a) Drugs are dispensed only by licensed pharmacists or licensed pharmacy interns/externs acting under the direct supervision of a licensed pharmacist;

(b) Non-licensed pharmacy personnel are properly directed and supervised;

(c) Drugs for external use are stored separately and apart from drugs for internal use or injection;

(d) Drugs requiring special storage conditions to insure their stability are properly stored;

(e) No outdated drugs are stocked in the OTP clinic pharmacy or the facility it serves;

(f) Distribution and administration of controlled substances are properly and adequately documented and reported by both pharmacy and other licensed medical personnel;

Rule 480-18-.10 Notification Required by the Georgia Department of Human Resources

Whenever the DHR central registry determines that a patient is improperly utilizing more than one OTP at the same time, and notifies the Director, the Director shall notify the Board and the GDNA.