

Part 828

Title 14 of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended by repealing the former Part 828 and adding a new Part 828 as follows:

OPIOID TREATMENT PROGRAM TITLE 14 NYCRR PART 828

[Statutory Authority: Mental Hygiene Law Sections 19.07(c), 19.07(e), 19.09(b), 19.16, 19.21(b), 19.21(d) 19.40, 32.01, 32.05(b), 32.07(a), 32.09(b)]

Notice: The following regulations are provided for informational purposes only. The Office of Alcoholism and Substance Abuse Services makes no assurance of reliability. For assured reliability, readers are referred to the *Office Compilation of Rules and Regulations*.

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Section 828.1 Background and intent

(a) This Part sets forth minimum standards for Opioid Treatment Programs (OTPs) certified by the Office of Alcoholism and Substance Abuse Services (OASAS). For purposes of this Part, opioid dependency is a chronic illness that can be treated effectively with approved medications; used consistent with their pharmacological efficacy and supportive services such as psychosocial counseling, treatment for co-occurring disorders, medical services, and vocational rehabilitation. Medication assisted treatment is an evidence based practice used for opioid dependency treatment.

Section 828.2 Legal base

- (a) Section 19.07(c) of the Mental Hygiene Law (MHL) charges the Office of Alcoholism and Substance Abuse Services (Office), with the responsibility to ensure that the care, treatment, and rehabilitation of persons that abuse or are dependent on alcohol and/or other substances and their families are provided with treatment that is of high quality and effectiveness.
- (b) Section 19.07(e) of the MHL authorizes the Commissioner to adopt standards including necessary rules and regulations pertaining to chemical dependence services.
- (c) Section 19.09(b) of the MHL authorizes the Commissioner to adopt regulations necessary and proper to implement any matter under his/her jurisdiction.
- (d) Section 19.16 of the MHL requires the commissioner to establish and maintain, either directly or through contract, a central registry for purposes of preventing multiple enrollments in methadone programs.
- (e) Section 19.21(b) of the MHL authorizes the Commissioner to establish and enforce regulations concerning the licensing, certification, and inspection of chemical dependency treatment services.
- (f) Section 19.40 of the MHL authorizes the Commissioner to issue operating certificates for

the provision of chemical dependence services.

(g) Section 32.01 of the MHL authorizes the Commissioner to adopt any regulation reasonably necessary to implement and effectively exercise the powers and perform the duties conferred by Article 32 of the MHL.

(h) Section 32.05(b) of the MHL provides that a controlled substance designated by the Commissioner of the New York State Department of Health as appropriate for such use may be used by a physician to treat a chemically dependent individual pursuant to section 32.09(b) of the MHL.

(i) Section 32.07(a) of the MHL authorizes the Commissioner to adopt regulations to effectuate the provisions and purposes of Article 32 of the MHL.

(j) Section 32.09(b) of the MHL provides that the commissioner may, once a controlled substance is approved by the Commissioner of the New York State Department of Health as appropriate for such use, authorize the use of such controlled substance in treating a chemically dependent individual.

Section 828.3 Applicability

(a) This Part applies to all OTPs unless the context indicates otherwise.

(b) To provide services pursuant to this Part, all OTPs must obtain and maintain:

- (1) certification from the Office;
- (2) approval from all other applicable regulatory entities; and
- (3) approval by a federally-approved accrediting body.

(c) The provision of opioid treatment services within local correctional facilities shall not require the approval of the Office; however, local correctional facilities must be in compliance with any other state and federal regulations. In addition, the Office shall reserve the right to review protocols, delivery of services and discharge planning procedures of opioid treatment services within local correctional facilities.

Section 828.4 Definitions

- (a) “Accrediting Body” means an entity approved by the Federal Substance Abuse Mental Health Services Administration to accredit OTPs pursuant to 42 CFR Part 8.1 through 8.6 using opioid agonist treatment medications.
- (b) “Admission” means the decision to admit a qualified individual for treatment in an OTP; such decision occurs on the date of administration of the initial methadone dose after satisfaction of all applicable requirements of this Part.
- (c) “Approved Medications” means methadone, buprenorphine or any other agent approved for opioid treatment by federal authorities.
- (d) “Central Registry System” means the central registry approved by the Office pursuant to section 19.16 of the Mental Hygiene Law and further defined in section 828.6 of this Part.
- (e) “Continuing Care Treatment” is a protocol that offers supportive services for an individual that has completed maintenance taper or who is no longer prescribed maintenance medication.
- (f) “Discharge” means the decision, in compliance with the requirements of this Part and Part 815 of this Title, to terminate treatment of a patient.
- (g) “Guest Medication Service” means a threshold visit to an OTP for opioid agonist medication by a patient admitted to a different OTP.
- (h) “Key Extended Entry Program” (KEEP) is a six-month medical treatment protocol designed to evaluate a patient’s long-term treatment needs by providing intensive medical and support services, resulting in a referral or transfer to address those long-term needs.
- (i) “Individualized Treatment” is a tailored clinical plan for each patient devised by a multi-disciplinary team with patient input that prioritizes and addresses needs on site or by referral, in

major life areas, including: health; housing; addiction; education; employment; legal; family; and leisure.

(j) “Medical Director” is a physician responsible for OTP medical services and the supervision of medical staff whose responsibilities cannot be delegated. All medical directors, hired subsequent to the promulgation date of this regulation, must hold a subspecialty board certification in addiction psychiatry from the American Board of Medical Specialties, or an addiction certification from the American Society of Addiction Medicine, or a subspecialty board certification in Addiction Medicine from the American Osteopathic Association. Physicians should be hired as probationary medical directors if not so certified, but must obtain certification within four years of being hired. In addition, the physician must become buprenorphine-certified within four months of employment, or within four months of this regulation if currently employed.

(k) “Occasion of Service” means the provision of any distinct and separate service in accordance with this Part.

(l) “Opioid Treatment Program” (OTP) means one or more Office-certified sites where methadone or other approved medications are administered to treat opioid dependency, following one or more medical treatment protocols as defined in this Part. This term encompasses medical and support services including counseling, educational and vocational rehabilitation. OTP also includes Narcotic Treatment Program (NTP), as defined by the Federal Drug Enforcement Agency (DEA) in 21 CFR 1301.

(m) “Opioid Detoxification” means a treatment procedure using approved medications administered in decreasing dosages over a limited period of time, for the purpose of detoxification from opioids consistent with an protocol that has been approved by the Office Medical Director.

(n) “Opioid Maintenance Treatment” means a medical treatment protocol utilizing approved

medications, administered at a stabilized dose over a period of time.

(o) “Opioid Medical Maintenance” (OMM) is a medical treatment program that is limited to patients who have demonstrated compliance with the specific criteria outlined within section 828.18 and who no longer require the structure or frequency of services provided in an OTP.

OMM dispenses a 30 day supply of medication and requires prior federal and state approval to operate. It is intended only for long-term stable patients that would benefit by extended take-home and no longer need the comprehensive services of an OTP.

(p) “Opioid Taper” means a medical treatment protocol that, after a period of stabilization, utilizes approved medications, in gradually decreasing dosages to the point of 0 milligrams (no dosage) followed by continuing care treatment as described in this Part, or discharge.

(q) “Program Sponsor” means a medical director or lay person named in the application for Office certification and described as responsible for the operation of the OTP, and who assumes responsibility for all its employees, including any practitioners, agents or other persons providing medical, rehabilitative, or counseling services at the program or any medication units.

(r) “Prescribing Professional” is any medical professional appropriately licensed under New York State law and registered under federal law to prescribe approved medications.

(s) “Specialized Opioid Service” is an approved medical treatment protocol that utilizes an approved pharmacological agent in the treatment of opioid addiction. The protocol must be research oriented and shall be provided in an ambulatory or residential environment.

(t) “Threshold Visit” means a period of attendance at the certified site of an OTP clinic during which at least one service is provided in accordance with this Part.

Section 828.5 Additional location

(a) A provider of OTP services may operate at one or more additional locations with the approval of the Commissioner pursuant to Part 810 of this Title, and all other legally mandated certifications including but not limited to 21 CFR 1300, 42 CFR Part 2, and

Article 28 DOH.

(b) For purposes of this section, an additional location is a place for the provision of OTP services which is dependent upon and subordinate to the main location of the provider of services for operation, administration and supervisory activities. The additional location must be operated in the same county or in a county contiguous to the main location and must not exceed 100 additional patients.

(c) Each additional location shall have adequate space to allow for the type and volume of services planned at the location. Policies and procedures shall be developed which describe the additional location's subordinate relationship to the main location, ensure that all operating regulations are met, and ensure that each patient served primarily at an additional location has access, as needed or desired, to the same character and quality of service available to persons served at any location.

Section 828.6 Central registry system

(a) Every OTP shall participate in the central registry system approved and authorized by the Office to prevent a patient's simultaneous enrollment in more than one OTP and in accordance with federal regulations.

(b) Each OTP shall initiate a clearance inquiry to the central registry system by submitting all required information prior to admitting an applicant to the OTP. The OTP must report all admissions, transfers, and discharges immediately to the central registry system. No OTP shall admit an applicant who is participating in another OTP.

(c) Any communication of patient information between an OTP and a central registry system is confidential and must be conducted in accordance with all applicable laws and regulations.

Section 828.7 Screening for admission

(a) Each OTP shall screen each applicant in person prior to admission to ensure that all

applicable criteria have been met based on this Part and consistent with the OTP accrediting body and the most recent version of the Diagnostic and Statistical Manual (DSM).

(b) Each OTP shall verify, to the extent possible, the identity of each applicant including name, address, date of birth, applicable insurance coverage information and other identifying data and shall include such information in the clinical record.

(c) Central registry verification that applicant is not presently enrolled in another OTP must be documented in the clinical record with date and time.

(d) A physical evaluation must be performed, by a physician, during the screening for admission to determine if the prospective patient has current physiological dependence on opioids for a minimum period of one year, and, to the extent possible, a medical determination of the total history should be taken of any chemical dependence and/or chemical use or abuse. An OTP shall admit an applicant who voluntarily completed treatment without confirming current opioid dependence if the OTP confirms the departure from an OTP was within two years, the previous treatment lasted at least six months, and a prescribing professional determines that treatment is medically and clinically indicated.

(e) A preliminary assessment of the applicant's medical and other needs must be performed to ensure the OTP is capable of addressing those needs directly or by referral.

(f) A toxicology test for drug use must be performed. A negative opioid toxicology test result will not preclude admission to the OTP where opioid dependence is verified through other indicators.

(g) Each OTP must document at least two prior treatment experiences at a chemical dependence withdrawal and stabilization service or inpatient service for all applicants less than 18 years of age.

(h) Applicants with a chronic immune deficiency condition, or who are pregnant and have a current opioid or past opioid dependency shall be screened and admitted on a priority basis. This

determination must be made by the physician and documented in the patient's clinical record within 72 hours of admission.

(i) Applicants who resided in a penal or chronic care facility for one month or longer, if screened within 14 days prior to release or discharge, or within six months after release or discharge, do not need documented evidence of opioid dependence if the applicant would have been eligible for admission prior to residing in such facility.

(j) Only applicants with a diagnosis of opioid dependency shall be admitted by an OTP. Applicants with only a primary medical diagnosis of a chronic pain condition must be referred to specialists qualified to treat chronic pain conditions and are not eligible for treatment in an OTP. Each OTP must comply with the provisions of section 815.9 of this Title for any patient prescribed medications by an outside prescriber.

(k) Each OTP shall advise each applicant determined to be ineligible for OTP admission, or determined to be more appropriate for admission to another chemical dependence service, of the reasons for such determination. The OTP shall inform an ineligible applicant of the appropriate chemical dependence service and refer accordingly.

Section 828.8 Admission procedures

(a) Each person admitted to an OTP shall be evaluated within 24 hours but no longer than 72 hours when necessary

(b) When at capacity, an OTP shall maintain a waiting list of eligible applicants who would otherwise be admitted if openings were available. When an opening is available, the OTP must make at least one good faith attempt to contact the next applicant on the waiting list.

(c) For admission purposes only, an OTP shall exclude, to the extent possible, from certified capacity the number of current patients who are confirmed to be maintained on approved medications in a hospital, nursing home or correctional facility and who are expected to return to

the OTP upon discharge or release within 12 months.

(d) A physician must substantiate the determination of a history of opioid dependence and current physical dependence. The physician makes the decision to admit all patients to an OTP.

(e) Each OTP shall complete all of the following with each new patient:

(1) a physician must obtain the patient's written informed consent to participate in opioid treatment which includes the risks and benefits of a prescribed medicine. The patient must sign the informed written consent prior to treatment being initiated at admission;

(2) staff must obtain medical, addiction, and mental health information in the development of the comprehensive treatment plan within two weeks of admission;

(3) the prescribing professional shall meet with a patient within one week of admission to assess need and the potential for abuse prior to prescribing medications or issuing prescriptions to treat any medical problem or condition;

(4) the prescribing professional must conduct a comprehensive physical examination within the first week after admission to determine the patient's overall health, including dependency on other substances and the necessity for treatment for addiction as well as any medical condition or disease;

(5) required laboratory tests include; (i) complete blood count and differential; (ii) routine and microscopic urinalysis; (iii) comprehensive testing for drugs of abuse; (iv) multiphasic chemistry profile; (v) intradermal skin or blood-based PPD and follow up; and (vi) Hepatitis A, B or C within one week of admission;

(6) additionally, tests for sexually-transmitted diseases; EKG; chest or other x-ray; pregnancy test; or tetanus immunization review should be completed as necessary;

(7) each OTP shall issue a photo-identification card to each patient, within two weeks after admission; patients may carry the identification or, at the patient's option, have the identification maintained at the OTP;

(8) each OTP shall orient each patient to treatment within one week of admission by providing necessary education and information to support patient rehabilitation including: pharmacology of approved medications, available services, operating and medicating hours, alternative medicating procedures for emergencies, treatment expectations, and key OTP procedures and guidelines;

(9) a notation must be entered in the patient record within two weeks of admission indicating the patient received a copy of the OTP service's rules and regulations, including patient rights, a summary of federal confidentiality requirements, and a statement that notes that such rules were discussed with the patient and that the patient indicated that he/she understood them; and

(10) all patients must be informed that admission is on a voluntary basis and that a patient shall be free to discharge him/herself from the service at any time. For patients under an external mandate, the potential consequences for premature discharge must be explained, but this shall not alter the voluntary nature of admission and continued treatment. This provision shall not be construed to preclude or prohibit attempts to persuade a patient to remain in the service in his/her own best interest.

(f) A prescribing professional must annually repeat the physical examination required at admission. A patient can choose to have a non-OTP licensed practitioner complete the annual physical examination to determine health condition with all required results, including ordered tests, recorded in the patient's chart.

(g) Each OTP need not repeat admission procedures for any patient who is being re-admitted within three months of discharge and need not repeat a medical and laboratory examination if the patient received a medical and laboratory exam within the previous year. The patient's prior medical records must be combined with the new medical records within 30 days of the patient's readmission.

(h) Each OTP must immediately re-admit clients who were previously discharged from that OTP due to a stay of 30 days or more in a hospital, nursing home, or other health care facility, if such patient is still being maintained on an approved medication, and meets the eligibility requirements when released.

(i) Any patient discharged from an OTP after an extended incarceration is entitled to readmission to the OTP of record when released if clinically appropriate.

(j) Any patient referred back to an OTP by a KEEP service located within a correctional facility must be re-admitted to the OTP upon release with full resumption of treatment including approved medications.

(k) Each OTP shall develop procedures to complete the permanent transfer of patients which shall incorporate all of the following:

(1) OTP administrators are responsible for effective implementation;

(2) each OTP shall not deny a reasonable request for transfer;

(3) each OTP shall not include “temporary-to-permanent” conditions;

(4) each OTP will regard transfer patients as continuing in treatment by original admission date and incorporating treatment plans from the sending OTP. Neither admission procedures nor physical exams need repeating for transfer patients;

(5) OTPs will send or receive the reason for transfer and provide the most current medical, counseling, and laboratory information within fourteen (14) days of the request.

Receipt of this information is not required prior to acceptance and the failure to receive this information does not preclude acceptance; and

(6) each OTP shall continue the patient’s approved medication dosage and take-home schedule unless new medical or clinical information requires medical staff to review and subsequently order a change; any such change shall be explained to the patient prior to implementation and documented in the clinical record.

(1) Each OTP shall develop procedures for the temporary transfer of patients that shall incorporate the following:

(1) OTP administrators will be responsible for effective implementation, not limited to forwarding information on fees, contact person, date/time and dose of medication to the receiving clinic;

(2) each OTP will send or receive prior to the patient's arrival, the reason for the temporary transfer, inclusive temporary dates, and approved medication dose;

(3) each OTP shall not deny a reasonable request for a temporary transfer;

(4) the sending OTP remains responsible for the patient's overall treatment. The receiving OTP may deliver any necessary service after consultation with the sending OTP;

(5) the receiving OTP prescribing professional must write an order to continue the patient's medication dose and take home schedule, if applicable, in accordance with directions from the sending OTP prescribing professional; and

(6) the sending OTP cannot bill Medicaid for non-threshold visits nor collect fees from self-pay patients during the temporary treatment period. The receiving OTP may charge a nominal fee to self-pay patients for the temporary transfer period or bill Medicaid for threshold visits for Medicaid covered patients.

Section 828.9 Individualized treatment

(a) Each OTP shall arrange for, or directly deliver, individual and group counseling services required by the patients' individual treatment plan.

(b) Each OTP shall not adopt maximum medication dosage limits.

(c) Each OTP shall render individualized treatment to each patient including at least one individual counseling session each month.

(d) Within 30 days of admission to the OTP a written comprehensive individualized patient-centered treatment plan for each patient based on the comprehensive evaluation shall be

developed by the primary counselor and reviewed and approved by the multidisciplinary team, as documented by their dated signatures. Each comprehensive treatment plan shall include a description of the type and frequency of counseling needed for implementation, including individual, group and family counseling in accordance with patient needs. For the first three months following admission, the patient shall be provided counseling at least weekly and the plan shall specify the type and frequency of such counseling.

(e) Each OTP must include provisions for pre-natal care in comprehensive treatment plans for all patients who are or become pregnant. If a pregnant patient refuses or fails to obtain such care, a prescribing professional must have the patient acknowledge in writing that pre-natal care was offered but refused.

(f) Each comprehensive treatment plan, once established, shall be thoroughly reviewed and revised at least quarterly for the first year and every six months thereafter, based on date of admission or transfer. Treatment plan reviews must be prepared by the primary counselor in consultation with the patient, and reviewed, signed and dated by at least three members of the multi-disciplinary team. The names of all reviewing individuals shall be recorded in the treatment plan. A summary of the patient's progress in each of the specified treatment plan goals shall be prepared and documented in the patient's record as part of the treatment plan review.

(g) A summary of the content and outcome of all counseling services shall be entered in the patient's record at least monthly. Remarkable or notable occurrences shall be recorded in immediate notations.

(h) In providing group counseling, groups shall contain no more than 15 patients.

(i) Each OTP shall conduct multidisciplinary team meetings at least monthly. Patients who are non-responsive to treatment shall have their treatment plans revised. If the treatment plan is not modified then the OTP must notate the reason.

Section 828.10 Recordkeeping

- (a) Each OTP shall maintain an individual case record for each patient. The case record must demonstrate a chronological pattern of delivered medical and treatment services consistent with the individualized comprehensive treatment plan.
- (b) Each record shall contain:
- (1) information required in screening and admission;
 - (2) all treatment plans and revisions;
 - (3) all physical examinations and lab results;
 - (4) current approved medication dose and justification for any changes;
 - (5) all drug toxicology results;
 - (6) documentation of all counseling services, immediate notations, and summaries;
 - (7) discharge information, including but not limited to, a complete medication list, reason for discharge, and any referrals made; and
 - (8) any other patient information.
- (c) Any medical professional licensed under the appropriate state law and registered under the appropriate state and federal laws shall sign and date each approved medication order and dose change on an order sheet that is displayed in the chart.
- (d) Each OTP must follow all state and federal regulations regarding dispensing and inventory control procedures for approved medications and other controlled substances.
- (e) Documentation of all activities required by this Part shall be completed within 30 days of occurrence unless otherwise specified.
- (f) Each OTP must retain all patient records at least six years after discharge or contact, or three years after the patient reaches the age of 18, whichever time period is longer.
- (g) If death occurs to a patient while enrolled in the OTP, details must be reported to the Office and other authorities, as required.

Section 828.11 Medication administration

- (a) A physician shall determine a patient's initial medication dose and schedule of administration and document such orders in the patient's record. A prescribing professional shall report such orders to the pharmacy or to the licensed medical staff.
- (b) Any subsequent change in approved medications, dose or schedule shall similarly be reported to the pharmacy or to the medical staff and documented in the record before administration. The prescribing professional shall issue verbal orders in emergencies only and must document such orders in writing within 48 hours.
- (c) Patients shall be informed of their approved medication dose or of any adjustment prior to administration. Patients may waive receiving this information by written consent.
- (d) The initial dose of methadone shall not exceed 30 milligrams on the first day. Additional amounts may only be given if the physician determines, and immediately documents in the patient record, that a 30 milligram dose is ineffective to relieve withdrawal symptoms. Only in unusual circumstances, which are immediately documented in the patient record, shall the total methadone dose for the first day exceed 40 milligrams.
- (e) The initial dose of buprenorphine shall not exceed 8-12 milligrams on the first day. Additional amounts may only be given if the physician determines and immediately documents in the patient record that the dose is insufficient to relieve opioid withdrawal symptoms.
- (f) Patients must be properly stabilized with a therapeutic dose of approved medications; a therapeutic dose means an amount sufficient to maintain comfort for at least 24 hours, alleviate opioid craving for narcotic drugs and to stop continued opioid use. To ensure effectiveness, measuring plasma levels and/or administering split methadone doses, and/or conducting psychiatric evaluations should be considered as clinically indicated. Split methadone doses require prior Office approval. Tests for plasma levels must be taken prior to a request to the Office for split dosing.

(g) The procedure for methadone administration shall be as follows:

(1) Acceptable methadone formulation is either tablets or liquid form. Administration of methadone at all OTPs must be in liquid form, and in single doses, including take home doses.

Take home bottles shall be labeled in accordance with applicable state and federal law.

(2) Medical staff shall confirm that the correct dose of ordered methadone is administered to the right patient. Medical staff shall observe and verify ingestion.

(3) Patients approved to receive take home medication of 13 or more days may be administered take-home doses in tablet form.

(h) A patient's approved medication shall not be withheld to enforce patient compliance with clinic rules or procedures, including but not limited to, rules on submitting to toxicology tests.

(i) If any medical staff member observes any condition or behavior on the part of a patient that may contraindicate a regularly scheduled dose of an opioid agonist medication, such staff member must contact the prescribing professional immediately and advise of the necessity warranting the approved medication delay, withholding or adjustment. The prescribing professional must provide the medical direction regarding the dosage for the patient. The prescribing professional must provide follow-up consistent with emergency verbal orders as required by this section.

(j) If a patient misses more than two consecutive scheduled medication visits, upon the patient's next attendance a medical assessment must be made by the prescribing professional to determine whether a change in dose is indicated. The prescribing professional shall write an appropriate order.

(k) Each OTP must comply with patients' rights pursuant to section 815.9 of this Title upon learning that a patient is receiving medical treatment or prescribed medications from an outside source.

Section 828.12 Take-home medication

(a) Each patient should be on an OTP visit schedule that is most appropriate to clinical need, conducive to treatment progress, and supportive of rehabilitation. A prescribing professional can reduce a patient's OTP visit schedule, when clinically indicated, only after assessing patient responsibility in handling approved medication and taking reasonable precautions to prevent possible misuse. A physician shall review and confirm the appropriateness for take-home medication at least each time the comprehensive treatment plan is reviewed.

(b) Patients shall be granted take-home medication after a clinical review and consideration of the criteria below and in accordance with (a) above:

(1) adherence to a comprehensive treatment plan;

(2) progress in maintaining a stable lifestyle, evidenced by:

(i) absence of patterned drug use including alcohol;

(ii) regular OTP attendance;

(iii) absence of criminal activity and/ or serious behavioral issues;

(iv) stability of home environment and social relationships;

(v) employment or other productive activity;

(vi) whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion; and

(vii) assurance that take-home medication shall be safely stored;

(3) The length of time in treatment:

(i) if less than three months, then a seven times per week OTP visit schedule is required unless the OTP is open only six days a week in which case one take-home dose may be issued weekly;

(ii) if more than three months but less than nine months, up to a three times per week OTP visit schedule is permitted, and no more than two take-home doses should be issued at any one visit;

(iii) if nine months but less than one year, up to twice per week OTP visit schedule is permitted, and no more than three take-home doses should be issued at any one visit;

(iv) if one year, but less than two years, a once per week OTP visit schedule is permitted, and no more than six take-home doses should be issued at any one visit;

(v) if two years but less than three years, a twice per month OTP visit schedule is permitted, and no more than 13 take-home doses should be issued at any one visit; and

(vi) if more than three years, a once per month OTP visit schedule is permitted, and no more than 30 take-home doses should be issued at any one visit.

(c) Notwithstanding the requirements of this section, a provider can use the practice of recall to detect diversion of opioid medication. Recall occurs when OTP staff has reasonable cause to require a particular patient to return to the OTP unexpectedly, within a day or two, prior to the next scheduled visit, and bring in all remaining take-home doses. Remaining doses must match the prescribed schedule to avoid suspected misuse.

(d) Notwithstanding the requirements of this section, a patient can be provided with extra medication without prior Office approval if the patient's regular OTP visit schedule falls on a legal or clinic holiday. Designation of an OTP holiday must be approved annually by the Office at least 30 days in advance of such holiday.

(e) Notwithstanding the requirements of this section, a prescribing professional, based on reasonable clinical judgment, can order up to 30 take-home doses at any one time if a patient is unable to conform to the applicable mandatory schedule requirements due to exceptional circumstances such as illness, personal or family crisis, travel, employment, medical, or hardship, and the prescribing professional determines that the patient is also responsible in handling approved medication. Such order cannot be construed as a permanent schedule change. The prescribing professional shall immediately document in the patient record the reasons for the order.

(f) Medical staff may release medication to a designated third party other than the patient only when the patient is considered physically compromised and unable to attend the OTP. The decision to permit such release to a third party such as a visiting nurse or nursing home personnel must be based on the reasonable clinical judgment of the prescribing professional and the consent of the patient, both of which must be documented in the patient's record. The need to continue this arrangement must be re-evaluated at least monthly by the prescribing professional. All other designated third parties, such as a parent, spouse, non-minor child, legal guardian, or significant other must receive prior Office approval.

(g) Patients re-admitted to an OTP after an approved voluntary discharge may be granted the same take-home schedule at the time of discharge provided that all criteria other than length of treatment are satisfied.

Section 828.13 Toxicology

(a) Each OTP shall conduct toxicology tests for the presence of benzodiazepines, cocaine, methadone, opioids, and shall alternate randomly the fifth panel among the recognized list of illicit drugs.

(b) Each OTP shall review and discuss with the patient each positive toxicology result for illicit drugs or negative toxicology results for approved medications; however, no significant treatment decision shall be based solely on a single test result.

(c) Each OTP shall inform patients of positive toxicology test results for illicit drugs or negative toxicology results for approved medications, and after two or more consecutive confirmed positive toxicology results or multiple confirmed positive results within a three month period, and in combination with counseling sessions and other clinical indicators, shall develop an individualized treatment plan to address the issue. A treatment plan review should be scheduled within three months after a series of such confirmed positive toxicology results to evaluate patient functioning.

(d) Each OTP shall conduct toxicology tests as often as necessary but at least weekly for all new patients during the first three months in treatment and at least bi-weekly thereafter, except as follows:

(1) An OTP shall conduct monthly tests only for those patients who complete at least three months of bi-weekly tests that show no positive illicit results and who are on a 30 day take-home schedule.

(2) An OTP shall resume bi-weekly or more frequent testing, for those patients who show positive illicit test results within a three month period. A patient's take-home schedule must be changed accordingly.

(e) Each OTP shall implement procedures, such as random collection of samples, to effectively minimize the possibility of false samples.

(f) All toxicology testing must be performed by laboratories approved by the New York State Department of Health or, in the City of New York, the New York City Department of Health and Mental Hygiene.

(g) Each OTP must use a method approved by the Food and Drug Administration (FDA) and Center for Substance Abuse Treatment (CSAT) for toxicology testing. Each OTP using urine toxicology tests must develop policy and procedures that require:

(1) monthly supervised collection, if falsification is suspected;

(2) random supervised collection of toxicology samples of all patients;

(3) environmental controls to maximize validity of urine toxicology samples; and

(4) only same sex staff shall supervise the collection of a urine sample.

Section 828.14 Staffing

(a) OTP staffing and staff hours must be sufficient to meet the medical and clinical needs of patients. For purposes of this section, full-time employment is 35 hours per week. Volunteers

are excluded as staff members.

(b) All OTP staff must have appropriate licenses and necessary experience and meet standard requirements for any position, in accordance with state and federal laws, the OTP accrediting body and Office regulations.

(c) Each OTP must have a medical director.

(d) Prescribing professionals may be used to meet physician staffing requirements, provided that no less than one-third of the required 35 hours per 300 patients is fulfilled by the attendance of the physician and that no more than two-thirds of the time is filled by prescribing professionals. In addition, at all times a clinic is open and a physician is not present, a physician must be available for consultation and emergency attendance.

(e) Each OTP must have a full-time administrator whose responsibilities shall include, but are not limited to, the following:

(1) ensuring adherence to all sections of this Part, to all state and federal laws, and to standards of the OTP accrediting body;

(2) ensuring that all administrative and clinical policies and procedures are implemented appropriately and effectively; and

(3) ensuring that medical and other services to which patients shall be referred are known to staff and made available to patients.

(f) Each OTP shall have a part-time administrator only if the OTP's certified capacity is less than 100 and the OTP is part of a multiple OTP system or part of a larger health, mental health or chemical dependence service. Such an OTP shall designate and assign all administrator responsibilities to another staff member qualified and capable of completing all duties.

(g) Each OTP shall have on staff a total number of nurses commensurate with the OTP hours of operation and number of patients to ensure that adequate nursing care and effective methadone administration is provided at all times. Adequate nursing care shall include:

(1) no less than the equivalent of two full-time nurses for up to 300 patients, at least one of whom is a registered nurse. Where specific approval to serve over 300 patients has been granted, there shall be one nurse for each additional 100 patients or fraction thereof;

(2) the registered nurse shall be responsible for the general supervision of the nursing staff; and

(3) a nurse shall be present at all times medication is administered at the OTP. As a Licensed Practical Nurse (LPN) cannot practice independently, a registered nurse or nurse practitioner must be present on the premises or immediately available by telephone when professional services are given by a LPN. The degree of supervision should be appropriate to the circumstance.

(h) Each OTP shall have on staff the total number of counselors necessary to ensure the effective delivery of counseling services. There shall be at least one full-time equivalent primary counselor or primary therapist for every 50 patients based on overall program census. Caseloads may vary dependent upon patient profile and frequency of counseling visits. Student interns, volunteers, or other counseling staff shall not be counted in the staff to patient ratio.

(i) At least fifty percent of all counselors on staff must be Qualified Health Professionals (QHPs) or CASAC trainees. For the period commencing on the effective date of this Part and ending one year thereafter, at least thirty five percent of the aggregate of the clinical staff shall be QHPs or CASAC trainees. For the period commencing one year and one day after the effective date of this Part and ending two years after the effective date of this Part, at least forty percent of the aggregate clinical staff shall be QHPs or CASAC trainees. After the two year period following the effective date of this Part, and for all times thereafter, at least fifty percent of the aggregate of the clinical staff shall be QHPs or CASAC trainees.

(j) Each OTP is required to have a qualified individual designated as the Health Care Coordinator who will ensure the provision of education, risk reduction, counseling and referral services to all patients regarding HIV and AIDS, tuberculosis, hepatitis, sexually transmitted diseases, and other communicable diseases. In addition, each OTP shall ensure and document that all clinical staff receive training from but not limited to the following categories: communicable diseases such as tuberculosis, sexually transmitted diseases, hepatitis and HIV and AIDS.

(k) Each OTP can employ security guards to provide security for the OTP, its occupants and operations. Security guards are not clinical staff and shall not have any clinical responsibilities or be involved in clinical services or clinical activities. However, since security guards interact with patients, security guards must receive training on the confidential nature of patient information and of chemical dependence treatment, and must adhere to all applicable confidentiality requirements.

(l) Security guards can be utilized to conduct community patrols to ensure that patients are not loitering; however, when security guards are used in this manner they must receive appropriate training and be advised not to confront individuals outside of the OTP, but rather that clinical staff must address the matter within the OTP.

(m) Each OTP must ensure that, upon hiring, all staff, including medical staff, receive information and training regarding opioid treatment and additional training thereafter at regular intervals but at least every two years; such additional training shall include but not limited to the efficacy of methadone and other approved agents; the efficacy of other addiction treatment; the development of comprehensive treatment plans; patient rights; and all confidentiality requirements.

(n) The medical staff shall be trained in cardiopulmonary resuscitation and in the use of resuscitation equipment, and shall have regular refresher courses/drills on handling such

emergencies.

(o) Each OTP must notify the Office of any change in medical director, physician(s) onsite, and program sponsors within seven days once the OTP knows of the change.

Section 828.15 Medication security

(a) Access to controlled substances, including approved medications, shall be limited to authorized persons in accordance with applicable state and federal law.

(b) The areas where controlled medication stocks are maintained, dispensed, or administered shall be physically separated and secure from patient areas in accordance with applicable state and federal law.

(c) Each OTP shall conduct frequent and regular checks of medication, in addition to frequent spot checks and maintain a daily narcotic inventory.

(d) The medical area of the clinic shall contain, at least, the following equipment and supplies:

(1) supplies and medical instruments suitable for required examinations and foreseeable emergency procedures, including, at a minimum, stethoscope and ophthalmoscope;

(2) resuscitation equipment consisting of, at a minimum, ambu-bag and mask, and oral pharyngeal airways; and

(3) emergency drug consisting of, at a minimum, Narcan in single dose vials, aspirin, and epi-pen.

(e) Immediately after administration, containers must be purged by rinsing, inversion, or by an acceptable alternative method which shall effectively prevent the accumulation of residual methadone. Containers used in the OTP or for take-home medications cannot be reused and shall be destroyed. Each OTP shall ensure that patients take-home bottles and used containers are disposed of properly. Patients should return take-home bottles before receiving take-home

medication.

(f) Any theft or loss of bulk approved medications must be immediately reported in accordance with applicable state and federal law.

Section 828.16 Program operations

(a) Each outpatient OTP shall:

(1) be open at least six days per week;

(2) have program and medication hours flexible enough to permit patients sufficient time to receive services without jeopardizing their employment and arranged so as to permit a free flow of patients;

(3) obtain prior approval of the Office before changing program or medication hours and shall provide patients at least one month notice prior to implementing the approved change; and

(4) develop necessary procedures to ensure continuous OTP services in emergencies or disruption of operations such as fire, weather, power outage, union or transit strike or other disaster in accordance with Office guidelines and accreditation standards.

(b) An inpatient OTP shall:

(1) comply with all applicable requirements of this Part;

(2) comply with all requirements of this Title regarding inpatient rehabilitation services;

(3) not dispense take-home medications to any patient; and

(4) include material and schedules for development and review of individual comprehensive treatment plans as required by regulations applicable to inpatient rehabilitation services rather than requirements of this Part.

(c) An intensive residential OTP shall:

- (1) comply with all applicable requirements of this Part;
- (2) comply with all requirements of this Title applicable to chemical dependence residential services;
- (3) not dispense take-home medications to any patient; and
- (4) include material and schedules for development and review of individual comprehensive treatment plans shall be as required by regulations applicable to chemical dependence residential services, rather than the requirements of this Part.

(d) A withdrawal and stabilization service certified by the Office that uses opioid agonist medication for short-term detoxification from other opioid substances shall meet all applicable requirements of this Part. Any OTP certified in accordance with this Part that includes a special unit, service or program providing short-term detoxification shall also comply with the requirements of the Title applicable to chemical dependence withdrawal and stabilization services.

Section 828.17 Opioid taper

(a) Voluntary Taper

(1) Opioid treatment is voluntary and all patients are free to leave treatment at any time. Each OTP shall provide an opioid taper at the OTP or pre-arrange for taper at another OTP or in a facility approved to provide tapering as is medically and clinically appropriate. Each OTP may also discharge patients who are unresponsive to treatment in accordance with the requirements of Part 815.

(2) Patients may request a voluntary taper at any time and may discuss reasons and circumstances with OTP staff who shall provide clinical feedback regarding patient readiness based on past treatment response. After discussions that address and resolve any problematic

issues, taper must begin with approval and continued oversight of a prescribing professional.

(3) Each OTP shall administer a voluntary taper at a pace tailored to the patient's individual needs, based on clinical judgment, medical evaluation, patient input and feedback at the start of the taper and continuously throughout. A prescribing professional can allow the patient to guide the pace of the taper.

(4) A patient's request for a voluntary taper may be contraindicated based on past treatment response or unresolved medical or clinical reasons. A prescribing professional must inform such a patient of current contraindications. After continued informed discussions, a prescribing professional must make a taper available to the patient if the patient wishes. Each OTP must document when the patient consents to taper against medical advice.

(5) Each OTP shall provide treatment information or referral assistance regarding other programs and/or support groups to all patients discharged.

(6) A voluntary methadone taper is generally designed to help a patient reach zero milligrams in a time frame in accordance with the patients' wishes and abilities. A 5-10 milligrams decrease of methadone per week or month is considered appropriate for voluntary tapers. Taper decreases of two and one-half milligrams or one milligram should also be made available. Once at zero milligrams, a patient can remain enrolled in continuing care treatment or be discharged from the OTP in accordance with the taper treatment plan. Under no circumstance shall a voluntary opioid taper with methadone occur faster than ten milligrams every three days.

(7) For a voluntary buprenorphine taper, if a patient is being tapered with buprenorphine, the dosage shall not be reduced by more than one to two milligrams every three days without the prior approval of the Office.

(b) Involuntary Taper:

(1) Each OTP may discharge a patient who is unresponsive to treatment in accordance with the requirements of the Part 815 of this Title and shall provide an opioid taper

onsite, or prearrange for taper at another OTP, or in a facility approved to provide tapering.

(2) If an onsite taper is contraindicated due to a patient's imminent violence or threat thereof, an OTP must pre-arrange for taper at an alternate site and inform the patient of such arrangements at least one day before. If the patient does not appear at the alternate site on the pre-arranged date, or creates a disturbance at the alternate site, the OTP responsibility for the taper shall have been fulfilled.

Section 828.18 Opioid medical maintenance

(a) Opioid medical maintenance (OMM) is an OTP that is limited to long-term stable patients who do not require routine OTP services and would benefit from receiving a 30 day supply medication and medical services monthly directly from a physician, and not in a traditional OTP clinic setting, and who meet specific OMM criteria.

(b) Minimum OMM criteria are:

- (1) four years of continuous treatment in an OTP;
- (2) three years of no drug abuse including alcohol;
- (3) three years of no criminal involvement;
- (4) three years of continuous gainful employment or productive activity;
- (5) three years of emotional stability;
- (6) intent to continue maintenance treatment; and
- (7) verified safe and secure medication storage.

(c) An OMM service requires federal and state approval and is granted regulatory exemptions from portions of this Part pertaining to counseling, and recordkeeping requirements. Records are maintained at least on a quarterly basis and monthly toxicology tests are taken.

(d) The 30 day medication supply should be dispensed in dry medication diskettes in one single bottle.

(e) An OMM patient shall be returned to an OTP when, in the physician's clinical judgment,

the patient needs OTP services.

(f) An OMM service has no Office certified capacity but each OMM must follow all requirements regarding central registry system communications.

Section 828.19 Continuing care treatment

(a) Each OTP must make continuing care treatment available to patients who meet the following criteria:

- (1) recent completion of a voluntary opioid taper within the last three months;
- (2) no drug abuse including alcohol;
- (3) demonstrated responsible behavior; and
- (4) commitment to keep OTP appointments at least every two weeks for the first two

months and as needed thereafter.

(b) Patients in continuing care do not need to comply with sections 828.9 and 828.10 regarding individualized counseling services and recordkeeping requirements. Patient records are maintained at least monthly. Continuing care patients are not included in an OTP certified capacity.

(c) Patients can choose to return to maintenance treatment at any time. OTP staff shall honor such a choice and resume full delivery of all required services.

(d) A continuing care patient shall return to an OTP when, in the prescribing professional's clinical judgment, the patient needs OTP maintenance treatment services.

(e) Continuing care services must be limited to no more than four months

(f) Continuing care services should include discharge planning and possible referral to an alternate level of care, dependent on a patient's continuing treatment needs.

Section 828.20 Specialized opioid services

(a) Specialized opioid services are those not defined in this Part and are generally research-oriented in nature. Such specialized services shall be reviewed and approved by the Office prior

to implementation and operation in accordance with Office policy, procedures, and requirements.

Section 828.21 Community relations

(a) Each OTP shall be responsible for ensuring good community relations and that patients do not cause community disruptions. Patients who consistently cause community disruptions are subject to discharge in accordance with the OTP community relations policy described in subdivision (b) of this section and pursuant to Part 815 of this Title.

(b) Each OTP shall develop and implement a community relations policy that describes plans to avoid community disruptions and actions to take in response to reasonable community needs. The Office shall require such policy to include forming a community committee, which meets regularly to discuss actions to improve community relations.

Section 828.22 Quality improvement

(a) Each OTP must maintain current quality assurance and quality control plans (i.e., Quality Improvement Plan) that includes, but is not limited to, annual review of program policies and procedures and ongoing assessment of patient outcomes. The OTP administrator shall maintain responsibility for the Quality Improvement Plan (QIP).

(b) Each OTP must implement a QIP that identifies OTP problem areas, patient trends and needs, and includes recommendations to address, implement and/or promote changes in problem areas, including the resolution of patient complaints.

(c) Each OTP must maintain a current Diversion Control Plan (DCP) as part of its Quality Improvement Plan that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use and that assigns specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP.

(d) Each OTP shall implement a patient advisory committee comprised of current patients to advise the OTP on matters of concern about policies and services.

Section 828.23 Standards pertaining to Medicaid reimbursement

- (a) Each OTP may receive the Medicaid OTP weekly fee for any weekly period (defined as Sunday through Saturday) in which the admitted patient receives at least one threshold unit of service. The OTP may not bill for any week in which the admitted patient does not receive a Part 828 OTP threshold unit of service. The OTP program cannot bill Medicaid for an admitted patient during the time the patient is receiving take home medication and is not physically visiting the OTP.
- (b) A threshold unit occurs each time an admitted patient crosses the threshold of an OTP to receive OTP care without regard to the number of services provided during that visit and includes any distinct and separate occasion of OTP service provided in accordance with this Part.
- (c) For purposes of this section, a patient shall mean an individual who is admitted to program certified by the Office to provide services pursuant to this Part. The Medicaid weekly OTP fee is available for admitted patients only. The Medicaid weekly OTP fee is not available for individuals presenting for an admission assessment.
- (d) To qualify as a threshold unit of service or visit, the occasion of service must meet the standards established in this Part.
- (e) Reimbursement is allowed only for visits where there is a face-to-face contact between an admitted patient and treatment staff and that visit takes place at the certified OTP.
- (f) The content and/or outcome of all visits must be fully documented in the individual admitted patient's treatment record.
- (g) The following services alone shall not constitute a visit eligible for reimbursement:
- (1) nutrition services;

(2) educational and/or vocational services;

(3) recreational/or social activity services;

(4) urinalysis services;

(5) group meetings, workshops or seminars which are primarily informational or organizational;

(6) acupuncture; and

(7) if patient received services from two OTP programs in a week, the program in which s/he is an admitted client is the only program that shall bill. The other OTP program is considered to have provided "guest medication services" as a courtesy; or

(8) services that are not provided pursuant to this Part.

(h) In order to qualify for reimbursement, each occasion of service must be documented as a covered Medicaid service in accordance with the following:

(1) the service must meet the standards established in this Part;

(2) the service must be documented in the patient's record as required in this Part;

(3) the service must be provided by staff as required in this Part;

(4) services must be approved by the medical director or another physician employed by the OTP program, recorded in the initial treatment plan of the patient, and subject to utilization review procedures; and

(5) the service must not be in excess of the clinical needs of the patient.

Section 828.24 Incorporation by reference

The provisions of the *Code of Federal Regulations* which have been incorporated by reference in this Part have been filed in the Office of the Secretary of State of the State of New York, the publication so filed being the booklet entitled *Code of Federal Regulations*, title 42, Part 8, revised as of January 17, 2001, and Title 21 CFR, Part 1300-1399 revised as of April 1, 2006, published by the Office of the Federal Register,

National Archives and Records Administration, as a special edition of the *Federal Register*. The regulations incorporated by reference may be examined at the Office of the Department of State, One Commerce Plaza, 99 Washington Ave., Albany, NY 12231, at the law libraries of the New York State Supreme Court, the Legislative Library, or the New York State Office of Alcoholism and Substance Abuse Services, Office of Counsel, 1450 Western Ave., Albany, NY 12203. They may also be purchased from the Superintendent of Documents, Government Printing Office Washington, DC 20402. Copies of the *Code of Federal Regulations* are also available at many public libraries and bar association libraries.

Section 828.25 Severability

If any provision or application of this Part to any person or circumstance is held invalid, such invalidity shall not affect any other provision or applications of this Part which shall be given effect without the invalid provision or applications, and to this end the provisions of this Part are declared to be severable.

Section 828.26 Savings Clause

Any operating certificate which has been issued by the Office pursuant to Part 828 of this Title and before that Part has been repealed shall remain in effect until its term has expired at which time any renewal of such operating certificate will be issued pursuant to this Part 828.