

14 NYCRR Part 822 is REPEALED and a new Part 822 is added to read as follows:

**PART 822
GENERAL SERVICE STANDARDS FOR CHEMICAL DEPENDENCE OUTPATIENT
(CD-OP) AND OPIOID TREATMENT PROGRAMS (OTP)**

[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), 22.07(c); Penal Law Section 220.78; Public Health Law Section 3309]

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822.1 Background

This Part contains requirements applicable to chemical dependence outpatient programs (CD-OP) and opioid treatment programs (OTP) certified by the Office of Alcoholism and Substance Abuse Services (Office) and the services provided by such programs. For purposes of this Part, chemical dependence is a chronic illness that can be treated effectively with counseling, approved medications used consistent with their pharmacological efficacy, and supportive services such as treatment for co-occurring disorders, medical services and vocational rehabilitation.

822.2 Legal base

- (a) Section 19.07(c) of the Mental Hygiene Law (MHL) charges the Office with the responsibility to ensure that persons who abuse or are dependent on alcohol and/or substances and their families are provided with care and treatment that is effective and of high quality.
- (b) Section 19.07(e) of the MHL authorizes the commissioner to adopt standards including necessary rules and regulations pertaining to chemical dependence treatment 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 opioid treatment programs (OTPs) and provide medication dosage information during an emergency situation, when displaced patients may seek treatment from an alternate OTP.
- (e) Section 19.21(b) of the MHL requires the commissioner to establish and enforce regulations concerning the licensing, certification, and inspection of chemical dependence treatment services.
- (f) Section 19.21(d) of the MHL requires the Office to establish reasonable performance standards for providers of services certified by the Office.
- (g) Section 19.40 of the MHL authorizes the commissioner to issue operating certificates for the provision of chemical dependence treatment services.
- (h) Section 22.07(c) of the Mental Hygiene Law authorizes the commissioner to promulgate rules and regulations to ensure that the rights of individuals who have received, and are receiving, chemical dependence services are protected.
- (i) 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.
- (j) Section 32.05(b) of the MHL provides that a controlled substance designated by the commissioner of the New York State Department of Health (DOH) 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.

- (k) 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.
- (l) Section 32.09(b) of the MHL provides that the commissioner may, once a controlled substance is approved by the commissioner of DOH as appropriate for such use, authorize the use of such controlled substance in treating a chemically dependent individual.
- (m) Section 220.78 of the Penal Law affords limited protections from prosecution for persons seeking medical attention for accidental overdose.
- (n) Section 3309 of the Public Health Law authorizes the DOH to establish standards for approval of any opioid overdose prevention program.

822.3 Applicability

- (a) Part 822 applies to any person or entity organized in accordance with this Part, operating pursuant to the provisions of this Title and certified by the Office to operate a CD-OP or an OTP. Except as indicated in subdivision (b) of this section, to provide services pursuant to this Part, each provider must obtain and maintain an operating certificate pursuant to Part 810 of this Title. OTPs must additionally obtain approval from a federally-approved accrediting body, and all other applicable regulatory entities.
- (b) The provision of opioid treatment services within local correctional facilities shall not require certification by the Office; however, local correctional facilities must be in compliance with any other applicable state and federal regulations. The Office reserves the right to review protocols, delivery of services and discharge planning procedures of OTPs within local correctional facilities.

822.4 Savings and renewal clause

Any operating certificate issued by the Office prior to the promulgation of this Part for the operation of a program subject to regulations of the former Part 822 shall remain in effect until the term of such operating certificate has been renewed or such operating certificate is suspended or revoked through process of law, at which time any recertification of such program or renewal of such operating certificate shall be pursuant to the provisions of this Part.

822.5 Definitions

As used in this Part, unless otherwise indicated, the following terms shall be applicable to both CD-OP and OTP programs:

- (a) “Accrediting Body” means an entity approved by the federal Substance Abuse Mental Health Services Administration (SAMHSA) to accredit all OTPs pursuant to 42 CFR Part 8.1 through 8.6 using opioid agonist treatment medications.
- (b) “Active treatment” is the period from admission through discharge.
- (c) “Admission assessment” is a face-to-face pre-admission service between a prospective patient and clinical staff for the purpose of determining a preliminary diagnosis, appropriateness for service, initial plan of treatment, including identifying problem areas to be addressed in the treatment/recovery plan, and the type and level of services needed by the patient.
- (d) “Ancillary withdrawal” is a service whereby patients in mild to moderate or persistent withdrawal receive symptom relief and/or addiction medications after an assessment of the level of withdrawal determined by the use of a standardized assessment instrument.
- (e) “Approved medications” means: (1) for an OTP, any agent approved for opioid treatment by federal authorities; and (2) for CD-OPs, buprenorphine or any medication appropriate for the treatment of chemical dependence in this setting (excluding methadone unless being used for pain management).
- (f) “Brief intervention” is a face-to-face pre-admission service between a prospective patient and clinical staff when screening results indicate at risk behavior. The brief intervention educates patients about their substance use, alerts them to possible consequences, and is intended to motivate them to change their behavior.
- (g) “Brief treatment” is a face-to-face service between an active patient and clinical staff and must include a target behavior and an evidence-based or clinical practice upon which the treatment is based. Brief treatment may be used throughout the course of treatment to meet specific goals, motivate patients or support medicated supported recovery.
- (h) “Central registry system” means the central registry established and maintained by the Office pursuant to section 19.16 of the Mental Hygiene Law.
- (i) “Chemical dependence outpatient rehabilitation services” (outpatient rehabilitation services) are services provided by a CD-OP which has been certified to provide outpatient rehabilitation services; such services are designed to assist individuals with more chronic

conditions who are typically scheduled to attend the outpatient rehabilitation program three to five days per week for at least four hours per day.

(j) “Chemical dependence outpatient program” (CD-OP) is an Office certified program which provides outpatient services that assist individuals who suffer from substance use disorder and their family members and/or significant others; CD-OPs may also provide outpatient rehabilitation services and/or intensive outpatient services (IOS).

(k) “Collateral person” is a member of a patient’s family or household, significant others, or persons who are directly affected by regular interaction with the patient, or who have the capability to affect both the patient’s chemical dependence and recovery.

(l) “Collateral visit” is a face-to-face service between a clinical staff member and a collateral person for the purpose of providing an intervention in the service of the primary patient’s progress in treatment.

(m) “Complex care coordination” is a service provided to or on behalf of a patient when a critical event occurs or the patient’s condition requires significant coordination with other service providers. Complex care coordination is distinguished from routine case coordination and must occur within five working days of another service.

(n) “Continuing care treatment” is a treatment protocol that offers clinical support for the ongoing disease management needs of patients. In an OTP the individual is admitted, has completed a taper or is no longer receiving prescribed maintenance; in a CD-OP the individual has completed the goals of active treatment.

(o) “Group counseling” is a face-to-face service between one or more clinical staff and multiple patients at the same time, to be delivered consistent with patient treatment/recovery plans, their development or emergent issues. Group counseling sessions must contain no more than 15 patients.

(p) “Individual counseling” is a face-to-face service between a clinical staff member and a patient focused on the needs of the patient to be delivered consistent with the treatment/recovery plan, its development or emergent issues.

(q) “Initial services” are services provided between admission and the development of the treatment/recovery plan, focusing on issues that need to be addressed to ensure successful engagement in treatment and any other urgent or emergent issues. Initial services address one or

two priority goals based on presenting problem(s) identified during the patient's admission assessment and provide focus for the critical period of treatment engagement.

(r) "Intensive outpatient services" (IOS) is an outpatient treatment service authorized by the Office and provided by a team of clinical staff for patients who require a time-limited, multi-faceted array of services, structure, and support to achieve and sustain recovery. Programs that offer intensive outpatient treatment schedule a minimum of 9 service hours per week delivered during the day, evening or weekends. The treatment service must make available individual and group counseling, family counseling when appropriate, relapse prevention and coping skills training, motivational enhancement, and drug refusal skills training.

(s) "Medication administration and observation" is face-to-face administration or dispensing of a medication by medical staff, to be delivered in conjunction with observation of the patient prior to the administration and after, as appropriate to the medication and patient's condition.

(t) "Medication supported recovery" (previously "medication assisted treatment") means treatment of chemical dependence abuse and concomitant conditions with medications requiring a prescription or order from an authorized prescribing professional.

(u) "Medication management" is a face-to-face service with a prescribing professional for one of the following purposes:

(1) evaluation, monitoring, observation or dosage change to a patient's medication;

(2) a comprehensive medication review of a new patient or any patient who requires a more extensive review; or

(3) the induction of a patient to a new medication requiring a period of patient observation.

(v) "NARCAN (naloxone) emergency overdose prevention kit" means a kit as prescribed pursuant to state law.

(w) "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 the Narcotic Treatment Program (NTP) as defined by the federal Drug Enforcement Agency (DEA) in 21 CFR Section 1301.

- (x) “Opioid detoxification” means a treatment procedure using approved medications administered in decreasing doses over a limited period of time, for the purpose of detoxification from opioids consistent with a protocol that has been approved by the Office’s Medical Director.
- (y) “Opioid medical maintenance” is a designated Office-based opioid treatment (“OBOT”) program operated by a certified OTP and is limited to patients who meet specific criteria.
- (z) “Opioid taper” means a medical treatment protocol that, after a period of stabilization, utilizes approved medications in gradually decreasing doses to the point of 0 milligrams (no dose) followed by continuing care treatment as described in this Part, or discharge.
- (aa) “Outreach” is a face-to-face service with a patient provided by clinical staff or a peer advocate for the purpose of increasing motivation to participate in clinically indicated treatment for chemical dependence. Patients identified for this intervention must be current patients who have failed to appear for sessions at the program and are judged to be at risk for prematurely discontinuing treatment or persons transitioning from another Office-certified program.
- (ab) “Patient” is an individual including a significant other who meets with clinical and/or peer staff for the purpose of assessment or treatment. “Active patient” means a patient who is admitted to either a CD-OP or OTP and has an active treatment plan.
- (ac) “Patient-centered” is a collaborative care approach to individualized treatment resulting in a treatment/recovery plan that is respectful of the patient’s needs and choices. It is guided by patients and produced in partnership with care providers for treatment and recovery. It supports patient preferences and a recovery orientation.
- (ad) “Peer support service” is a face-to-face service provided by a peer advocate to a current patient. Peer support services are services for the purpose of connecting patients to community based recovery supports consistent with the treatment/recovery plan.
- (ae) “Screening” is a face-to-face pre-admission service with a clinical staff member for the purpose of identifying patients who have alcohol or substance misuse problems through the use of an Office-approved screening tool. The screening tool may be completed as part of an interview using a computer or in written format. The results must be shared by the clinical staff in an individual face-to-face session.
- (af) “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 must be provided in an ambulatory or residential environment.

(ag) “Transfer” means:

(1) in a CD-OP, transfer is an intra-program function (i.e., between outpatient and outpatient rehabilitation within the same provider); and

(2) in an OTP, transfer may be both an inter-program function (i.e., between two different providers) or an intra-program function (between different PRUs of the same provider).

(ah) “Treatment/recovery plan” is the plan developed by the responsible clinical staff member with the patient and based on the admission assessment and initial services.

(ai) “Visit” means one or more services provided to a patient and/or collateral person on a single day.

822.6 Standards pertaining to Medicaid reimbursement

(a) For purposes of Medicaid billing, a claim may be submitted for services delivered to a patient, collateral person, or significant other.

(b) Only services delivered by an Office-certified or authorized program are eligible for Medicaid reimbursement.

(c) The content and/or outcome of all services must be fully documented in the patient’s case record consistent with section 822.11 of this Part.

(d) Services must be provided under the direction of the medical director or another physician employed by the CD-OP or OTP.

(e) In order to qualify for reimbursement, each 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 meet the standards established in Part 841 of this Title;

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

(f) The following services alone do not constitute a service eligible for Medicaid reimbursement:

(1) nutrition services;

(2) educational and vocational services;

(3) recreational and social activity services;

(4) group meetings, workshops or seminars that are primarily informational or organizational;

- (5) acupuncture;
- (6) services that are not provided pursuant to this Part.

822.7 General program standards

(a) Policies and procedures. The program sponsor must approve written policies, procedures, and methods governing the provision of services to patients in compliance with Office regulations including a description of each service provided. These policies, procedures, and methods must address, at a minimum:

(1) admission and discharge, including specific criteria relating thereto, as well as transfer and referral procedures;

(2) treatment/recovery plans;

(3) services to be provided by contract or subcontract including methods for coordinating service delivery and a description of core groups offered and procedures for coordinating group, individual, and family treatment (if offered);

(4) a schedule of fees for services rendered;

(5) compliance with other requirements of state and federal laws, regulations and OASAS guidance documents including HIV/AIDS education, testing and counseling and the use of alcohol and other drug screening and toxicology tests, and medication and the use of medication supported recovery;

(6) infection control procedures;

(7) staffing, including but not limited to, training and use of student interns, peers and volunteers;

(8) Waiting lists. Programs must maintain a waiting list of eligible prospective patients. When an opening is available programs must make at least one good faith attempt to contact the next prospective patient on the waiting list.

(i) In determining certified capacity, OTPs may exclude continuing care patients, patients confirmed to be maintained on appropriate medications in hospital, nursing home or correctional facility and are expected to return to the OTP within 12 months upon discharge from such facility;

(ii) CD-OPs may include patients previously deemed ineligible for admission for reasons other than behavioral concerns.

(b) Emergency medical kit. All programs must maintain an emergency medical kit at each certified location; such kit must include basic first aid and at least one Narcan emergency overdose prevention kit the use of which is subject to applicable laws and regulations. Programs must develop and implement a plan to have staff trained in the prescribed use of a Narcan kit such that it is available for use during all program hours of operation.

(1) All staff and patients should be notified of the existence of the Narcan overdose prevention kit and the authorized administering staff.

(2) Nothing in this regulation shall preclude patients from becoming authorized in the administration of the Narcan emergency overdose prevention kit, provided however, the program director must be notified of the availability of any additional authorized users.

(c) Utilization review and quality improvement. All programs must have a utilization review process, a quality improvement committee, and a written plan that identifies key performance measures for that particular program.

(d) OTP diversion control. Each OTP must develop and implement a diversion control plan (DCP) as part of its quality improvement plan, such DCP to include specific measures to reduce the possibility for diversion of controlled substances from legitimate treatment use, and shall assign specific responsibility to the medical and administrative staff of the OTP for carrying out the diversion control measures and functions described in the DCP.

(e) OTP continuous services. OTPs must develop necessary procedures to assure continuous OTP services in emergencies or disruption of operations in accordance with Office guidelines and accreditation standards.

(f) OTP community relations. OTPs must develop and implement a community relations plan that describes actions responsive to reasonable community needs; such plans may include, but not be limited to, formation of community patrols to ensure that patients are not loitering, and formation of a Community Committee that meets regularly to discuss actions to improve community relations.

(g) Required services. Each program must directly provide the following:

- (1) admission assessment;
- (2) treatment/recovery planning and review;
- (3) individual counseling;
- (4) group counseling;

(5) toxicology testing (not required for significant others unless clinically indicated):

(i) Each program must conduct toxicology tests for the presence of benzodiazepines, cocaine, opioids, and a 4th panel to be determined by the provider. At least eight random toxicology tests must be conducted per year, per patient in treatment, in accordance with federal regulations. For OTPs, if during a three month period, toxicology testing indicates use of illicit drugs, a patient's take home schedule and treatment/recovery plan must be changed accordingly as clinically indicated.

(ii) Each program must review and discuss with the patient each positive toxicology result for illicit drugs or negative toxicology results for approved medications.

(iii) Each program must inform patients of positive toxicology test results for illicit drugs or negative toxicology results for approved medications.

(iv) Each program must implement procedures, such as random collection of samples, to effectively minimize the possibility of false samples.

(v) Laboratories used for toxicology testing must be 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.

(vi) Each program must use a method approved by the Food and Drug Administration (FDA) and Center for Substance Abuse Treatment (CSAT) for toxicology testing.

(6) discharge planning; and

(7) OTPs must provide:

(i) medication administration and observation; and

(ii) medication management.

(h) Optional Services. Each program may, at its option, directly provide any of the following:

(1) brief intervention;

(2) brief treatment;

(3) collateral visits;

(4) complex care coordination;

(5) outreach;

(6) peer support services;

(7) screening;

(8) medication administration and observation;

- (9) medication management;
 - (10) intensive outpatient services (IOS);
 - (11) ancillary withdrawal; or
 - (12) other services which may be identified by the Office from time to time.
- (i) Problem gambling. A CD-OP program that has been granted a waiver to admit and treat individuals for problem gambling only (persons who do not have a co-occurring chemical dependency diagnosis) and/or a significant other who has been affected by problem gambling, shall provide services in accordance with Part 857 of this Title.
- (j) Telepractice. The Office may designate services that may be provided by the use of telepractice as such practice may be defined by the Office.
- (k) Staffing. Each program must provide clinical supervision and ensure and document a plan for staff training based on individual employee needs. Subject areas appropriate for training shall be identified by the Office. Staffing requirements include:
- (1) Clinical Director. Each program must have a qualified health professional designated as the full-time on-site clinical director who is responsible for the daily activities and supervision of services provided. Such person must have at least three years of full-time clinical work experience in the chemical dependence field, at least one year of which must be supervisory, prior to appointment as clinical director. An OTP may have a part-time on-site clinical director only if the OTPs certified capacity is less than 100 patients 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 must designate and assign all clinical director responsibilities to another staff member qualified and capable of completing all duties.
 - (2) Medical Director. Each program must have a Medical Director as defined in Part 800 of this Title.
 - (3) Medical staff.
 - (i) The medical staff must be trained in emergency response treatment and must complete regular refresher courses/ drills on handling emergencies.
 - (ii) In a CD-OP a physician, registered physician's assistant or nurse practitioner must provide on-site coverage for a minimum of one hour per week for up to 25 active patients and an additional hour for each additional 25 active patients or part thereof.

(iii) In OTPs, 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 no more than two-thirds of such time is filled by other prescribing professionals. In addition, anytime an OTP is open and a physician is not present, a physician must be available for consultation and to attend to any emergency situation.

(iv) OTPs must have at least the equivalent of two full-time on-site nurses for up to 300 patients, one of whom shall be a registered nurse. Programs approved to serve more than 300 patients must have one additional full-time nurse for each additional 150 patients or part thereof. A nurse must be present at all times when medication is being administered. A registered nurse or nurse practitioner must be present or immediately available by telephone when services are provided by a licensed practical nurse.

(4) Health coordinator. Each program must designate a health coordinator to assure the provision of education, risk reduction, counseling and referral services to all patients regarding HIV/AIDS, tuberculosis, hepatitis, sexually transmitted diseases, and other communicable diseases.

(5) Counselors. In every program there must be an adequate number of counselors sufficient to carry out the objectives of the program and to assure the outcomes of the program are addressed. The Office will review factors in determining whether the program's outcomes are being addressed, which may include but shall not be limited to:

(i) retention of patients in treatment;

(ii) patients' successful completion of treatment or referral to more appropriate levels of care; and

(iii) attainment of remission from substance use disorder.

(6) Full-time staffing requirements. There must be at least one full-time Credentialed Alcoholism and Substance Abuse Counselor (CASAC); and there must be at least one full-time qualified health professional, as defined in Part 800 of this Title, qualified in a discipline other than substance use disorder counseling.

(7) Qualified health professional requirements. At least 50 percent of all clinical staff must be qualified health professionals. CASAC trainees (CASAC-T) may be counted towards satisfying the 50 percent requirement; however such individuals may not be considered qualified health professionals for any other purpose under this Part. Clinical staff members who are not

qualified health professionals must have qualifications appropriate to their assigned responsibilities as set forth in the personnel policies of the program and must be subject to appropriate staff supervision and continuing education and training.

(8) Each program must notify the Office within seven (7) days of any change in medical director, on-site physician(s), or program sponsors.

(1) Other staffing requirements.

(1) If other specialized services are directly provided by the program, staff must be appropriately qualified to provide such services.

(2) Unpaid volunteers and student interns. In addition to staffing requirements of this Part, a program may utilize unpaid volunteers and unpaid student interns. Such volunteers or student interns must receive supervision, training, or didactic education consistent with their assigned tasks and the services they are expected to provide.

(3) Peer Advocates. Peer advocates must be supervised by a clinical staff member who is credentialed or licensed and participate in a training plan appropriate to their needs. Peer advocates may provide peer support and outreach services based on clinical needs as identified in the patient's treatment/recovery plan.

(4) OTP security guards. OTPs may employ security guards who are not clinical staff to protect persons, property and program operations. Security guards may not be involved in clinical services and must receive training on confidentiality of patient information and adhere to such federal laws.

(m) Program hours of operation. Each CD-OP must operate at least five days per week providing structured treatment services in accordance with treatment/recovery plans. OTPs must be open at least six days per week and must obtain prior approval of the Office before changing program or medication hours and must provide patients at least one month notice prior to implementing the approved change.

822.8 Admission, Initial Services, Transfers and Readmissions

(a) Admission requirements for all programs. The admission assessment or decision to admit must include identification of initial services needed until the development of the treatment/recovery plan.

(1) If the presenting individual is determined to be inappropriate for admission to the program, a referral to a more appropriate service must be made, unless the individual is already receiving chemical dependence services from another provider. Individuals deemed ineligible for admission must be informed of the reason.

(2) No individual may be denied admission to a program based solely on the individual's:

(i) prior treatment history;

(ii) referral source;

(iii) pregnancy;

(iv) history of contact with the criminal justice system;

(v) HIV and AIDS status;

(vi) physical or mental disability;

(vii) lack of cooperation by significant others in the treatment process; or

(viii) medication supported recovery for opioid dependence prescribed and monitored by a physician, physician's assistant or nurse practitioner.

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

(4) Prior to admission, all programs must:

(i) conduct a communicable disease risk assessment (HIV/AIDS, tuberculosis, hepatitis, or other communicable diseases);

(ii) check the Prescription Monitoring Program ("PMP") regarding any medications which may be prescribed to a patient or prospective patient;

(iii) conduct a toxicology screen pursuant to provisions of this Part as clinically appropriate or required by federal law.

(5) As soon as possible after admission, and as clinically appropriate, all programs must:

(i) recommend HCV testing; testing may be done on site or by referral;

(ii) conduct an intradermal skin or blood based Tuberculosis test; testing may be done on site or by referral with results as soon as possible after admission but no later than finalization of the treatment recovery plan;

(iii) recommend HIV testing; testing may not be conducted without patient written informed consent except in situations specifically authorized by law. HIV testing may be done on site or by referral;

(iv) explain any blood and skin test results to the patient within 3 weeks of the test.

(6) Any significant medical issues identified prior to or after admission must be addressed in the treatment recovery plan and documented in the patient case record.

(7) A significant other may be admitted to a program regardless of whether the abusing/dependent individual with whom they are associated is in treatment. A significant other is not appropriate for admission to an outpatient rehabilitation service.

(b) Additional admission requirements to a CD-OP.

(1) The program must document that the individual is determined to have a substance use disorder based on the criteria in the most recent version of the Diagnostic and Statistical Manual (DSM) or the International Classification of Diseases (ICD). If an individual has been referred by an Office approved Driving While Intoxicated (DWI) provider/practitioner, any assessment created by such provider which meets the requirements of this section may be used to admit the patient.

(2) Physical health. For those patients who have not had a physical examination within one year prior to admission, each such patient must either be assessed face-to-face by a member of the medical staff (except LPN) to ascertain the need for a physical examination or referred for a physical examination. For those patients who have had a physical examination within one year prior to admission, or for those patients being admitted directly to the outpatient program from another chemical dependence service authorized by the Office, the existing medical history and physical examination documentation may be used to comply with the requirements of this subdivision, provided such documentation has been reviewed by a medical staff member and determined to be current.

(3) The decision to admit an individual must be made by a clinical staff member who is a qualified health professional and must be documented by the dated signature (physical or

electronic signature) of the qualified health professional and include the basis for admitting the patient.

(c) Additional admission requirements for outpatient rehabilitation services. In addition to the requirements of paragraph (a) of this section, an individual must also meet the criteria in Section 822.15 of this Part to be admitted to an outpatient rehabilitation service.

(d) Additional requirements for admission to an OTP.

(1) The decision to admit a prospective patient for treatment is finalized on the date of administration of the initial approved medication dose after satisfaction of all applicable requirements of this Part. Prospective patients with a chronic immune deficiency or prospective patients who are pregnant and have a current opioid or past opioid dependency must be screened and admitted on a priority basis. A prospective patient 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 admission to an OTP. No person under the age of 16 may be admitted to an OTP without the prior approval of the Office. The following requirements must be met for an individual to be admitted to an OTP:

(2) In order to provide the first medication dose, a physician must make an in person evaluation of each prospective patient within 72 hours of the first on-site visit to determine that the prospective patient has had a physiological dependence on opioids for at least the previous 12-month period, and must diagnose and document an addiction or dependence, provided however:

(i) a prospective patient may be admitted who voluntarily completed treatment in another OTP without confirming current opioid dependence if the OTP confirms that the:

(A) voluntary completion of treatment occurred within the previous 24 months; and

(B) previous treatment lasted at least 6 months;

(ii) a prospective patient who is less than 18 years of age may be admitted if such patient has had at least two prior unsuccessful treatment episodes at a chemical dependence withdrawal and stabilization service or inpatient service within a 12-month period and a current physiological dependence to opioids for a minimum period of 24 months;

(iii) a prospective patient who resided in a correctional or chronic care facility for at least one month, if assessed within 6 months after release or discharge, may be admitted if the prospective patient would have been eligible for admission prior to residing in such facility.

(e) Initial services in an OTP.

(1) The prescribing professional must conduct a full physical examination, including required laboratory tests or screens, and any other test as clinically indicated or as may be required by the Office, during the first week after admission to determine the patient's overall health. A prescribing professional must annually repeat the physical examination required at admission. A patient may choose to have a licensed practitioner outside the OTP complete the annual physical examination to determine health condition and OTP clinical staff shall make diligent efforts to record all required results, including ordered tests, in the patient's case record.

(2) Each OTP must orient each patient to treatment within one week after admission by providing education and information to support patient rehabilitation including pharmacology of approved medications (methadone and buprenorphine must be included in this review), available services, operating and medicating hours, alternative medicating procedures for emergencies, treatment expectations, hepatitis B and C (incidence, detection and treatment options) and key OTP procedures and guidelines. A physician must ensure that prior to first dose; the prospective patient is provided and signs (physical or electronic signature) an informed written consent to participate in opioid treatment, which shall include notice of the risks and benefits of a prescribed medicine.

(3) Each OTP must 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.

(f) OTP Readmissions. Opioid treatment programs 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, provided:

(1) The patient's prior medical records must be combined with the new medical records within thirty days of the patient's readmission;

(2) each OTP must immediately readmit patients who were previously discharged from that OTP:

(i) after 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/or meets the eligibility requirements when released; or

(ii) after an extended incarceration (including KEEP), if clinically appropriate when such patient is released.

(g) OTP transfers. (1) Each OTP must develop procedures regarding the permanent transfer of patients which must ensure that the OTP shall:

(i) not deny a reasonable request for transfer;

(ii) not include “temporary-to-permanent” conditions;

(iii) regard transferred patients as continuing in treatment by incorporating their length of treatment and treatment/recovery plans from the referring OTP. Admission procedures and physical exams need not be repeated for transferring patients if medical/lab exam were completed within the previous year;

(iv) send or receive the reason for the transfer and provide the most current medical, counseling, and laboratory information within 14 days of the request. Receipt of this information is not required prior to acceptance and the failure to receive this information will not preclude acceptance; and

(v) 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.

(2) Each OTP must develop procedures for the temporary transfer of patients which must ensure that the:

(i) transferring OTP forward information on fees, contact person, time and dose of medication to the receiving OTP;

(ii) OTPs sends or receives prior to the patient’s arrival the reason for the temporary transfer including temporary dates and approved medication dose;

(iii) OTPs shall not deny a reasonable request for a temporary transfer;

(iv) transferring OTP remains responsible for the patient’s overall treatment. The receiving OTP may deliver any necessary service after consultation with the transferring OTP; and

(v) receiving OTP prescribing professional must write an order to continue the patient’s medication dose and take-home schedule.

822.9 Treatment / recovery plan

(a) Each patient must have a written patient-centered treatment/recovery plan developed by the responsible clinical staff member and patient as soon as possible after admission but not later than 30 calendar days after admission. Standards for developing a treatment/recovery plan include, but are not limited to:

(1) If the patient is a minor, the treatment/recovery plan must also be developed in consultation with his/her parent or guardian unless the minor is being treated without parental consent as authorized by Mental Hygiene Law section 22.11.

(2) For patients moving directly from one program to another, the existing treatment/recovery plan may be used if there is documentation that it has been reviewed and, if necessary, updated within 14 days of transfer.

(b) The treatment/recovery plan must:

(1) include each diagnosis for which the patient is being treated;

(2) address patient identified problem areas specified in the admission assessment and concerns which may have been identified subsequent to admission, and identify methods and treatment approaches that will be utilized to achieve the goals developed by the patient and primary counselor;

(3) identify a single member of the clinical staff responsible for coordinating and managing the patient's treatment who shall approve and sign (physical or electronic signature) such plan; and

(4) be reviewed and approved by the patient and supervisor of the responsible clinical staff member within 10 days of the development of the treatment plan. If the supervisor of the responsible clinical staff member is not a Qualified Health Professional (QHP), another QHP must be designated to sign (physical or electronic signature) the plan. For patients whose services are reimbursed by fee-for-service Medicaid, the plan shall be signed (physical or electronic signature) by either a physician, licensed psychologist, nurse practitioner, or licensed clinical social worker.

(c) Continuing review of treatment/recovery plans. The treatment/recovery plan must be reviewed, and revised if necessary, at least once within every 90 calendar days from the date of admission for the first year and at least once within every 180 calendar day window period thereafter. Reviews should occur more frequently when a patient is not responding to treatment

as planned or if a significant incident occurs. Reviews of the treatment plan should be signed (physical or electronic signature) by the supervisor of the responsible clinical staff member (or other designated QHP). For patients whose services are reimbursed by fee-for-service Medicaid, the plan shall be signed (physical or electronic signature) by either a physician, licensed psychologist, nurse practitioner, or licensed clinical social worker.

(d) The program's multidisciplinary team, as defined in Part 800 of this Title, shall meet on a regularly scheduled basis for the purpose of reviewing a sample of cases for the purpose of clinical monitoring of practice. This meeting shall be documented as to date, attendance, cases reviewed and recommendations.

(e) Referrals and Readmissions. If a patient is referred directly to the CD-OP from another service certified by the Office, including an office approved DWI provider/practitioner, or is readmitted to the same CD-OP within 60 days of discharge, any assessment created by such provider may be used, provided documentation is maintained demonstrating a review and update.

(f) Pregnancies. Treatment/recovery plans must include provisions for pre-natal care for all patients who are pregnant or become pregnant. If a pregnant patient refuses or fails to obtain such care, the provider must have the patient acknowledge in writing that pre-natal care was offered but refused.

822.10 Case records

(a) All programs must maintain a case record (either electronic or paper) for each patient who receives services. The case record must demonstrate a chronological pattern of delivered medical and treatment services consistent with the patient's prior treatment history, if any, and the patient's evolving treatment/recovery plan.

(b) The case record must include, at a minimum, the following:

(1) a notation that, prior to the first treatment visit, the patient received a copy of the program's rules and regulations, including patient's rights (Part 815) and a summary of the federal confidentiality requirements, that such rules and regulations were discussed with the patient, and that the patient indicated he/she understood them;

(2) the source of referral, if applicable;

(3) any clinical or non-clinical documentation or determination applicable to the delivery of medical and treatment services for a particular patient and/or supporting the patient's evolving treatment/recovery plan;

(4) the individual treatment/recovery plan and all reviews and updates thereto;

(5) signed releases of consent for information;

(6) documentation of services in accordance with 822.12.

(7) the level of care in which the patient is currently participating if more than one level of care is offered by a program.

(8) discharge plan and summary, including the circumstances of the discharge; and

(9) if the patient is a minor being treated without parental consent, documentation establishing that the provisions of Mental Hygiene Law section 22.11 have been met.

(c) In addition to the requirements of subdivision (b) of this section OTPs must also include in the patient record, and document within 30 days of occurrence unless otherwise specified:

(1) information and documentation required in screening and admission;

(2) all lab results;

(3) current approved medication dose and justification for any changes;

(4) include an order sheet that is displayed in the case record and signed (physical or electronic signature) by any medical professional licensed under the appropriate state law authorizing such change and noting the date for each approved medication order and dose change; and

(5) discharge information, including but not limited to, a complete medication list, reason for discharge and any referrals made.

(d) Transfers. If patients are transferred between CD-OPs and outpatient rehabilitation services within the same provider, a single case record may be maintained provided that it includes clinical justification for the transfer, the effective date of the transfer and a revised treatment/recovery plan, signed (physical or electronic signature) by the responsible clinical staff member and their supervisor within seven days of the transfer.

(e) Confidentiality. Case records maintained by the program are confidential and may only be disclosed consistent with the Health Insurance Portability and Accountability Act (HIPAA) and the federal regulations governing the confidentiality of alcohol and drug abuse patients' records as set forth in 42 CFR Part 2 and other applicable law.

- (f) Records retention. Case records must be retained for six years after the date of discharge or last contact.
- (g) Patient deaths. If a patient dies while in active treatment any known details must be documented in the case record.

822.11 Documentation of services

(a) Unless otherwise indicated, the type, content, duration and outcome of each service delivered to or on behalf of a patient must be documented in the patient's case record, described and verified as follows:

- (1) be written and signed (physical or electronic signature) by the staff member providing the service;
- (2) indicate the date the service was delivered;
- (3) record the relationship to the patient's developing treatment goals described in the treatment/recovery plan;
- (4) include any recommendations or determinations for initial, continued or revised patient goals and/or treatment.

822.12 Discharge planning

(a) Discharge criteria. Individuals entering treatment should progress by meeting treatment milestones including: stabilization; engagement; goal setting; remission of substance use disorder; and attainment of goals supporting recovery. Individuals should be considered for discharge once they have stabilized, met remission criteria for substance use disorder, and attained the support necessary to support long term remission. An individual discharged from a program must be discharged for a documented reason. Individuals discharged involuntarily must be discharged consistent with Part 815 of this Title.

(b) A discharge plan must be developed in collaboration with the patient and any collateral person(s) the patient chooses to involve. The discharge plan shall specify needed referrals with appointment dates and times, all known medications (including frequency and dosage) and recommendations for continued care. If the patient is a minor, the discharge plan must also be

developed in consultation with his or her parent or guardian, unless the minor is being treated without parental consent as authorized by Mental Hygiene Law section 22.11.

(c) No patient may be discharged without a discharge plan which has been reviewed and approved by the responsible clinical staff member and the clinical supervisor prior to the discharge. This requirement does not apply to patients who stop attending, refuse continuing care planning, or otherwise fail to cooperate. That portion of the discharge plan which includes referrals for continuing care must be given to the patient upon discharge.

(d) Within 45 days of discharge, a discharge summary must be prepared and included in each patient's record. The discharge summary must address and measure progress toward attainment of treatment goals.

822.13 Continuing care in CD-OP

(a) Individuals may be admitted to continuing care when they have been discharged from active treatment and there is a documented clinical need for ongoing clinical support to prevent relapse or to maintain gains made in active treatment.

(b) The purpose of admission to continuing care is to provide ongoing disease management services including management of life stressors, urges and cravings, mood and interpersonal relationships and to maintain gains made in active treatment.

(c) Individuals in continuing care may receive counseling or peer services once per month.

(d) Individuals in continuing care may receive rehabilitative support services including case management and medication management services as needed.

822.14 Additional locations

(a) A certified provider of a CD-OP service may operate at one or more additional locations with the approval of the commissioner pursuant to Part 810 of this Title.

(1) For purposes of this section, an “additional location” is a provider site providing chemical dependence outpatient treatment services which reports to a primary certified program for its operation, administration and supervisory activities. The additional location must be operated in the same county or in a county contiguous to the primary certified program and may not exceed the volume of services provided at the primary certified program.

(2) The primary certified provider must apply for additional location approval by completing an application approved by the commissioner and clearly indicating the need for access to outpatient services at the site proposed, the financial and programmatic ability to provide such service, the characteristics of the space, the schedule of services, and the staffing. The application will be reviewed in accordance with the administrative review process pursuant to Part 810 of this Title.

(b) Each additional location must directly provide the following:

- (1) assessment;
- (2) treatment/recovery planning; and
- (3) individual and/or group counseling.

(c) The provisions of this section shall not apply to:

- (1) certified providers of outpatient rehabilitation services; or
- (2) certified providers of opioid treatment services.

822.15 Additional requirements for chemical dependence outpatient rehabilitation services

(a) As defined in 822.6 of this Part, outpatient rehabilitation services for individuals with more chronic conditions emphasize development of basic skills in prevocational and vocational competencies, personal care, nutrition, and community competency. The individual must have an inadequate support system and either substantial deficits in interpersonal and functional skills or health care needs requiring attention or monitoring by health care staff. These services are provided in combination with all other clinical services provided by CD-OPs. It is expected that services will be provided three to five days per week for at least four hours per day.

(b) Programs must be certified by the Office to provide outpatient rehabilitation services.

(c) Staffing. There must be at least one full-time equivalent counselor or therapist for every 20 patients receiving outpatient rehabilitation services. If volunteers or student interns are used, they may not be counted in the counselor-to-patient ratio. In addition to the staffing required in section 822.7 of this Part, the following additional staff members are required:

- (1) at least one half-time therapeutic recreation therapist or occupational therapist or vocational specialist, certified as a rehabilitation counselor or qualified health professional with

one year of experience and/or training in providing recreation, occupation and/or rehabilitation services; and

(2) at least one part-time nurse practitioner, registered physician's assistant, or registered nurse, or a licensed practical nurse supervised by a registered nurse employed by the governing authority.

(d) If a CD-OP is providing outpatient rehabilitation services, the following services must be available either directly or through written agreements:

(1) socialization development;

(2) skill development in accessing community services;

(3) activity therapies; and

(4) information and education about nutritional requirements, including but not limited to planning, food purchasing, preparation and clean-up.

(e) A provider of outpatient rehabilitation services must assure the availability of one meal to each patient who receives outpatient rehabilitation services for four or more hours per day.

822.16 Additional requirements for opioid treatment programs

(a) Central registry system. Each OTP must participate in the central registry system established and maintained by the Office to prevent a patient's simultaneous enrollment in more than one OTP and ensure accurate dispensing of medication in accordance with federal regulations. Each OTP must:

(1) initiate a clearance inquiry to the central registry system by submitting all required information prior to admitting an applicant to the OTP;

(2) report all admissions, transfers, and discharges immediately to the central registry system;

(3) verify with the central registry system that the prospective patient is not presently enrolled in another OTP and this verification must be documented in the clinical record; OTPs may not admit an applicant who is participating in another OTP; and

(4) report any other information deemed necessary by the Office to comply with state and federal laws and regulations.

(b) Medication administration. (1) A physician must determine a patient's initial medication dose and schedule of administration and document such orders in the patient's record. OTPs shall not adopt maximum medication dosage limits.

(2) A prescribing professional may report such orders to the registered or licensed medical personnel supervising medication administration; any subsequent change in approved medications, dose or schedule must similarly be reported to the pharmacy or to the medical staff and documented in the record before administration. The prescribing professional may issue verbal orders in emergencies only and must document such orders in writing within 72 hours.

(3) Unless waived in writing, patients must be informed of their approved medication dose and of any adjustment prior to administration.

(4) The initial dose of methadone administered for a patient should not exceed 30 milligrams, provided however, the initial dose may exceed 30 milligrams when the physician documents that the dose is ineffective for relief of withdrawal symptoms. In no circumstances may the total methadone dose administered to a patient on the first day exceed 40 milligrams.

(5) Unless immediately documented as ineffective for relief of withdrawal symptoms by a physician, the initial dose of buprenorphine administered to a patient must not exceed 12 milligrams on the first day.

(6) 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 and stop continued opioid use. To assure effectiveness, measuring plasma levels and/or administering split methadone doses, and/or conducting psychiatric evaluations may 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.

(7) The procedure for methadone administration must be as follows:

(i) Administration of methadone at all OTPs must be in liquid form and in single doses except as permitted in subparagraph (iii) of this paragraph. Take-home bottles must be labeled in accordance with applicable state and federal law;

(ii) medical staff must observe and verify ingestion to confirm that the correct dose of ordered methadone is administered to the patient; and

(iii) patients approved to receive take-home medication of 13 or more days may be administered take-home doses in dry tablet form in a single bottle.

(8) 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 patient's condition which may warrant an approved medication delay, withholding or adjustment. The prescribing professional must:

- (i) approve any medication delay, withholding or adjustment; and
- (ii) provide follow up consistent with emergency verbal orders as otherwise required by this section

(9) 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 and the prescribing professional must write an appropriate order.

(c) Unsupervised or Take-home medication. (1) Each patient must be on an OTP visit schedule that is most appropriate to clinical need, conducive to treatment progress, and supportive of rehabilitation. A prescribing professional may reduce a patient's OTP visit schedule, when clinically indicated, to accommodate patient changes in need, progress, or rehabilitation only after assessing patient responsibility in handling approved medication and taking reasonable precautions to prevent possible misuse.

(2) Any patient may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

(3) A physician must review and confirm the appropriateness for take-home medication. Patients may be granted take-home medication pursuant to the provisions of this subdivision and consideration of the criteria below:

- (i) Absence of recent abuse of drugs (opioid or non-narcotic), including alcohol;
- (ii) Regularity of clinic attendance;
- (iii) Absence of serious behavioral problems at the clinic;
- (iv) Absence of known recent criminal activity, e.g., drug dealing;
- (v) Stability of the patient's home environment and social relationships;
- (vi) Length of time in comprehensive maintenance treatment;
- (vii) Assurance that take-home medication can be safely stored within the patient's home; and

(viii) Whether the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion.

(4) Such determinations and the basis for such determinations consistent with the criteria outlined in paragraph (3) of this subdivision shall be documented in the patient's medical record. If it is determined that a patient is responsible in handling opioid drugs, beyond the 1-day dose for clinic closure, the following restrictions apply (*Note: the following requirements pertain only to the use of methadone; take-home considerations for buprenorphine are not dependent on the following time-in-treatment requirements. However, when determining take-home schedules for patients treated with buprenorphine, OTPs must articulate/document sound clinical judgment that the patient is appropriate for the amount of buprenorphine dispensed*):

(i) During the first 90 days of treatment, the take-home supply is limited to a single dose each week and the patient shall ingest all other doses under appropriate supervision pursuant to this Part.

(ii) In the second 90 days of treatment, the take-home supply is two doses per week.

(iii) In the third 90 days of treatment, the take-home supply is three doses per week.

(iv) In the remaining months of the first year, a patient may be given a maximum 6-day supply of take-home medication.

(v) After 1 year of continuous treatment, a patient may be given a maximum 2-week supply of take-home medication.

(vi) After 2 years of continuous treatment, a patient may be given a maximum one-month supply of take-home medication, but must make monthly visits.

(5) No medications shall be dispensed to patients in short-term detoxification treatment or interim maintenance treatment for unsupervised or take-home use.

(6) Notwithstanding the requirements of this subdivision, a provider may 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.

(7) Holidays. Notwithstanding the requirements of this subdivision, a patient may be provided with extra medication without prior Office approval if the patient's regular OTP visit

schedule falls on a legal or OTP holiday. Designation of an OTP holiday must be approved annually by the Office at least 30 days in advance of such holiday.

(8) Exceptional circumstances. Notwithstanding the requirements of this subdivision, a prescribing professional, based on reasonable clinical judgment, may order up to thirty (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 the patient is also responsible in handling approved medication. Such order shall not be construed as a permanent schedule change. The prescribing professional must immediately document in the patient record the reasons for the order.

(9) Release of medication to designated third party. OTP 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 non-OTP medical staff 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. All designated third parties must receive prior Office approval.

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

(d) Medication security. (1) Access to controlled substances, including approved medications, shall be limited to authorized persons in accordance with applicable state and federal law. The areas where controlled medication stocks are maintained, dispensed, or administered must be physically separated and secure from patient areas in accordance with applicable state and federal law.

(2) Each OTP must conduct frequent and regular checks of medication and maintain a daily narcotic inventory.

(3) The medical area of the OTP must contain, at least, the following equipment and supplies:

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

(ii) resuscitation equipment consisting of, at a minimum, two (2) ambu-bag and masks, and oral pharyngeal airways.

(4) Immediately after administration, drug containers must be purged by rinsing, inversion, or by an acceptable alternative method that must effectively prevent the accumulation of residual methadone. Containers used in the OTP or for take-home medications may not be reused and must be destroyed. Each OTP must assure patients' take-home bottles and used containers are disposed of properly. Patients should return take-home bottles before receiving any subsequent take-home medication.

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

(e) Residential OTPs. A 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 treatment/recovery plans as required by regulations applicable to chemical dependence residential services, rather than the requirements of this Part.

(f) Opioid taper. (1) Voluntary Taper. Each OTP must provide an opioid taper at the OTP or arrange for taper at another OTP or in a facility approved to provide tapering with methadone as is medically and clinically appropriate:

(i) Patients may request a voluntary taper at any time and may discuss reasons and circumstances with OTP staff who must provide clinical feedback regarding patient readiness. No reasonable request shall be denied;

(ii) Each OTP must 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;

(iii) 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. The OTP must document when the patient's voluntary taper is against medical advice.

(iv) A voluntary methadone taper is generally designed to help a patient reach zero milligrams in accordance with the patients' wishes and abilities. Once at zero milligrams, a patient may remain enrolled in continuing care treatment or be discharged from the OTP in accordance with the taper treatment/recovery plan. The pace of a voluntary taper is determined by the prescribing physician in consultation with the patient.

(v) For a voluntary buprenorphine taper, the dosage may not be reduced by more than one to two milligrams every three days without the prior approval of the Office.

(2) Involuntary Taper. Each OTP may discharge a patient who is unresponsive to treatment in accordance with the requirements of Office regulations regarding patient rights and must provide an opioid taper onsite, or prearrange for taper at another OTP, or in a facility approved to provide tapering with methadone, as is medically and clinically appropriate. Under no circumstance may an involuntary opioid taper occur faster than 10 milligrams every three days.

(g) Opioid medical maintenance (OMM). (1) Patients admitted to OMM must meet specific criteria including:

- (i) four years of continuous treatment in an OTP;
- (ii) three years of no drug abuse including alcohol;
- (iii) three years of no criminal involvement;
- (iv) three years of continuous gainful employment or productive activity;
- (v) three years of emotional stability;
- (vi) intent to continue maintenance treatment; and
- (vii) verified stability in the Prescription Monitoring Program ("PMP").

(2) An OMM program requires federal and state approval. The provisions of sections 822.11, 822.12 and 822.13 regarding individualized counseling services and recordkeeping requirements do not apply to patients in OMM. The individual case record for a patient in OMM must be updated at least monthly and toxicology tests and/or a check of the PMP must be conducted as clinically indicated. Programs must verify safe and secure medication storage.

(3) The 30 day medication supply may be dispensed in dry tablet form in a single bottle.

(4) An OMM patient must return to an OTP when, in the prescribing professional's clinical judgment, the patient needs OTP maintenance treatment services.

(5) An OMM program has no Office-certified capacity.

(h) Continuing Care Treatment. (1) Each OTP must make continuing care treatment available to patients who meet the following criteria:

(i) recent completion of a voluntary opioid taper within the last three months;

(ii) absence of patterned drug use, including alcohol;

(iii) demonstrated responsible behavior; and

(iv) commitment to keep OTP appointments at least once per month.

(2) The provisions of sections 822.11, 822.12 and 822.13 regarding individualized counseling services and recordkeeping requirements do not apply to patients in continuing care treatment. The individual case record for a patient in continuing care treatment must be updated at least once a month.

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

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

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

(i) Specialized opioid services. 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.

822.17 Severability

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

