

PART 822
GENERAL SERVICE STANDARDS FOR SUBSTANCE USE DISORDER
OUTPATIENT PROGRAMS

[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, 2781; 42 CFR Part 8]

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822.1 Background

This Part contains requirements applicable to substance use disorder (SUD) outpatient programs certified, licensed, funded or otherwise authorized by the Office and the services provided by such programs. For purposes of this Part, addiction or substance use disorder 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 and psychiatric services, vocational rehabilitation and family intervention and support.

All services shall be strength-based, person-centered and trauma informed.

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 have a substance use disorder 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 substance use disorder treatment services.
- (c) Section 19.09(b) of the MHL authorizes the commissioner to adopt regulations necessary and proper to implement any matter under their 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 and provides medication dosage information during an emergency, when displaced patients may seek such treatment from an alternate program.
- (e) Section 19.21(b) of the MHL requires the commissioner to establish and enforce regulations concerning the licensing, certification, and inspection of substance use disorder 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 substance use disorder 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, substance use disorder 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 prescribing professional to treat an individual with a substance use disorder 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 an individual with a substance use disorder.

- (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.
- (o) Section 2781 of the Public Health Law defines the rules governing HIV testing in New York.
- (p) 42 CFR Part 8 relates to the federal oversight and regulation of medication **for addiction** [~~assisted~~] treatment for opioid use disorders.

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, funded or otherwise authorized by the Office to operate an outpatient treatment program. 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. Programs providing **full** opioid [~~full~~] agonist treatment medications must additionally obtain approval from a federally-approved accrediting body, and all other applicable regulatory entities.
- (b) The provision of treatment services within local correctional facilities shall not require certification by the Office; however, local correctional facilities must follow any other applicable state and federal regulations. The Office reserves the right to review protocols, delivery of services and discharge planning procedures of programs providing medications for substance use disorders 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 all programs providing outpatient services:

- (a) “Accrediting Body” means an entity approved by the federal Substance Abuse Mental Health Services Administration (SAMHSA) to accredit all programs pursuant to 42 CFR Part 8.1 through 8.6 using opioid full agonist treatment medications.
- (b) “Active treatment” is the period from pre-admission through discharge.
- (c) “Admission assessment” is a service between a prospective patient and clinical staff for the purpose of determining a preliminary diagnosis, appropriateness for service, person-centered initial plan of treatment, including type(s) of services and frequency of services.
- (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 using a standardized assessment instrument. Providers must receive Office approved designation to provide this service.
- (e) “Approved medications” means any medication approved by state or federal authorities for the treatment of substance use disorder.
- (f) “Brief intervention” is a 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 encourage healthier choices.
- (g) “Brief treatment” is a service between an active patient and clinical staff and must include a target behavior or health need 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) “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 substance use disorder and recovery.
- (j) “Collateral visit” is a 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.

(k) “Complex care coordination” is an ancillary service provided to a patient when a critical event occurs, or the individual’s condition requires significant coordination with other service providers. Complex care coordination is distinguished from routine case coordination activities.

(l) “Continuing care treatment” is a treatment protocol that offers clinical support for the ongoing substance use~~[disease]~~ management needs of patients. Patients have either completed the goals of active treatment and are discharged with referral to continuing care or opt for continuing care any time after discharge.

(m) “Group counseling” is a 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 be structured in size and duration to maximize therapeutic benefit for each participant. Program policies must include a process for determining group size, group purpose, monitoring patient experience, and assessing group efficacy.

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

(o) “Initial services or pre-admission services” are services prior to admission as the first step in developing a treatment/recovery plan, focusing on issues that need to be addressed to ensure successful engagement and admission into treatment and any other urgent or emergent issues. Initial/pre-admission services address priority goals based on presenting problem(s) identified during the patient’s assessment and provide focus for the critical period of treatment engagement. Services which may be delivered preadmission will be identified by the Office.

(p) “Intensive outpatient services” (IOS) is an outpatient treatment service 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 must make available individual and group counseling, family counseling when appropriate, skills to mitigate reoccurrence, and coping skills training, including as appropriate, Dialectical and Behavioral Therapy (DBT), Motivational Enhancement Therapy (MET), Cognitive Behavioral Therapy (CBT) and increased connections to recovery supports and other evidence based practices as proven effective in meeting patient needs.

(q) “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.

(r) “Medication **for addiction** [~~assisted~~] treatment” (MAT) means treatment of substance use disorder i.e., substance use disorder and concomitant conditions with medications requiring a prescription or order from an authorized prescribing professional with counseling and behavioral therapies, as clinically appropriate.

(s) “Medication management” is a 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.

(t) “Naloxone emergency overdose prevention kit” means a kit as prescribed pursuant to state law and is used to reverse an opioid overdose.

(u) “Opioid medical maintenance” is a designated Office-based opioid treatment (“OBOT”) program limited to patients who meet specific criteria as described in this Part.

(v) “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.

(w) “Patient” **for purposes of this Part** is an individual including a significant other who meets with clinical and/or peer staff for the purpose of engagement, assessment or treatment.

“Active patient” means a patient who is admitted to a program and has an active treatment/recovery plan.

(x) “Peer support service” is provided by a peer advocate as defined in Part 800 of this Title. Peer support services are services for the purpose of outreach for engaging an individual to consider entering treatment, reinforcing current patients’ engagement in treatment, and connecting patients to community-based recovery supports consistent with treatment/recovery and discharge plans.

(y) “Person centered care” is a collaborative care approach to individualized treatment resulting in the development of treatment/recovery plan goals and service provision 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. Person and family centered care planning is strength-based and focuses on individual capacities, preferences and goals. It supports patient preferences and a recovery orientation and is developed within the professional responsibilities of providers and care teams.

(z) “Progress note” is documentation of each service delivered and serves as the treatment/recovery plan as it evolves to support person centered goals and ongoing service and care planning. Progress notes identify patient’s clinical status, type of services, and may also include updates to goals, methods of treatment and types of services provided and includes challenges and achievements identified.

(aa) “Screening” is a pre-admission service with a clinical staff member for the purpose of identifying patients who have problems with substance use. Screening results must be shared by the clinical staff with the patient.

(ab) “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.

(ac) “Substance use disorder outpatient rehabilitation services” (outpatient rehabilitation services) are services offered by programs which have been certified to provide outpatient rehabilitation services; such services are designed to assist individuals with more chronic conditions as further defined in this Part who are typically scheduled to attend the outpatient rehabilitation program three to five days per week for at least two hours per day.

(ad) “Substance use disorder outpatient program” is an Office certified program which provides outpatient services that assist individuals with a substance use disorder and their family members and/or significant others and may also provide outpatient rehabilitation services and/or intensive outpatient services (IOS); and sites where addiction medications are administered to treat opioid use disorder, as well as other SUDs following one or more medical treatment protocols as defined in this Part. This term encompasses medical and comprehensive support services including counseling, educational and vocational rehabilitation. The term also includes

the Narcotic Treatment Program (NTP) as defined by the federal Drug Enforcement Agency (DEA) in 21 CFR Section 1301. An NTP or Opioid Treatment Program (OTP) requires federal and state approval.

(ae) “Transfer” is an intra-program function (i.e., between outpatient and outpatient rehabilitation within the same provider or between different Program Reporting Units (PRUs) of the same provider); and

may also be an inter-program function (i.e., between two different providers).

(af) “Treatment/recovery plan” is the plan developed by clinical staff with the patient and based on the admission assessment and initial services and includes goals, type and frequency of services and methods. Treatment/recovery plans shall be regularly updated using progress notes.

(ag) “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 (regardless of whether such significant other is connected to a current patient with a diagnosed substance use disorder).

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

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

(d) 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.

(e) 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.

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;

(4) a schedule of fees for services rendered;

(5) compliance with other requirements of applicable local, state and federal laws and regulations, OASAS guidance documents and standards of care regarding, but not limited to:

(i) education, counseling, prevention and treatment of communicable diseases, including viral hepatitis, sexually transmitted **infections** [~~diseases~~] and HIV[~~/AIDS~~]; regarding HIV, such education, counseling, prevention and treatment shall include condom use, testing, pre- and post-exposure prophylaxis and treatment;

(ii) the use of alcohol and other drug screening and toxicology tests; and

(iii) medication and the use of medication **for** addiction [~~assisted~~] treatment; and

(iv) the use of a problem gambling screen approved by the Office.

(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.

(9) Certified Capacity. In determining certified capacity for an OTP, such programs may:

(i) Exclude patients confirmed to be maintained on appropriate medications in a hospital, nursing home or correctional facility and who are expected to return to the program within 12 months upon discharge from such facility;

(ii) Programs may include patients previously deemed ineligible for admission for reasons other than behavioral concerns;

(iii) Exclude patients maintained on buprenorphine or naltrexone; in continuing care not receiving medication; or, enrolled in auxiliary withdrawal management; and

(iv) Exclude a significant other(s).

(10) Each program must maintain a policy on toxicology.

(b) Emergency medical kit. (1) All programs must maintain an emergency medical kit at each certified location; such kit must include basic first aid and [~~at least one~~] naloxone emergency overdose prevention kits **in a quantity sufficient to meet the needs of the program.** Programs must develop and implement a plan to have staff trained in the use of a naloxone overdose prevention kit such that it is available for use during all program hours of operation.

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

(3) Nothing in this regulation shall preclude patients from becoming authorized in the administration of the naloxone 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.

(d) Continuous services. Programs must develop necessary procedures, including disaster plans, to assure continuous services in emergencies or disruption of operations in accordance with Office guidelines and accreditation standards.

(e) Community relations. Programs 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.

- (f) Required services. Each program must directly provide the following:
- (1) admission assessment, including, if clinically indicated, a screen for problem gambling;
 - (2) treatment/recovery planning and review;
 - (3) trauma-informed individual and group counseling;
 - (4) medication **for addition** [~~assisted~~] treatment;
 - (5) toxicology testing (not required for significant others unless clinically indicated):
 - (i) Each program must conduct toxicology tests to be determined by the provider as clinically appropriate provided, however, at least eight random toxicology tests must be conducted per year for each patient in an OTP.
 - (ii) Each program must review and discuss with the patient the toxicology result.
 - (iii) 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.
 - (iv) 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) post-treatment planning;
 - (7) medication administration and observation;
 - (8) medication management;
 - (9) brief intervention and brief treatment;
 - (10) collateral visits;
 - (11) complex care coordination;
 - (12) outreach; [~~and~~]
 - (13) peer support services[~~;~~];
 - (14) overdose prevention education and naloxone education and training; and**
 - (15) safety plan development.**
- (g) Optional Services. Each program may, at its option, directly provide any of the following:
- (1) intensive outpatient services (IOS);
 - (2) ancillary withdrawal (requires Office approved designation); or
 - (3) other services which may be identified by the Office from time to time.

(h) Problem gambling. A program that treats an individual and/or a significant other who has been affected by problem gambling, shall be designated and provide such services in accordance with Part 857 of this Title.

(i) Medication for Addiction Treatment (MAT) for Substance Use Disorder (SUD)

(1) The program shall maintain a patient with substance use disorder on approved medication, including those federal Food and Drug Administration (FDA) approved medications to treat substance use disorder, if deemed clinically appropriate and in collaboration with the patient's existing provider, and with patient consent, in accordance with federal and state rules and guidance issued by the Office. The program shall document such contact with the existing program or practitioner prescribing such medications.

(2) To facilitate access to full opioid agonist medication for patients who are maintained on such medication at the time of admission or who choose to start such medication during admission, the program shall develop a formal agreement with at least one Opioid Treatment Program (OTP) certified by the Office to facilitate patient access to full opioid agonist medication, if clinically appropriate. Such agreements shall address the program and the OTPs responsibilities to facilitate patient access to such medication in accordance with guidance issued by the Office.

(3) The program shall provide FDA approved medications to treat substance use disorder to an existing patient or prospective patient seeking admission to an Office certified program in accordance with all federal and state rules and guidance issued by the Office.

(4) The program shall provide education to an existing patient or prospective patient with substance use disorder about approved medications for the treatment of substance use disorder if the patient is not already taking such medications, including the benefits and risks. The program shall document such discussion and the outcome of such discussion, including a patient's preference for or refusal of medication, in the patients record.

(5) The program shall ensure that the patient's discharge plan includes an appointment with a treatment provider or program that can continue the medication post-discharge.

(j) Telehealth~~[Telepractice]~~. Any services authorized to be delivered **via telehealth** ~~[using telepractice]~~ shall be provided consistent with Part 830 of this Title.

(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 clinical director working within their scope of practice, 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 substance use disorder field, at least one year of which must be supervisory, prior to appointment as clinical director. A program which is part of a provider comprised of multiple health, mental health or substance use disorder treatment programs may share this position provided clinical director responsibilities have been delegated to another qualified staff member and shared to the extent such assignment is sufficient to meet patient need.

(2) Medical Director. Each program must have a Medical Director as defined in Part 800 of this Title.

(3) Medical staff, as defined in Part 800 of this Title.

(i) The medical staff must be trained in emergency response treatment and must complete regular refresher courses/ drills on handling emergencies.

(ii) A physician, registered physician's assistant or nurse practitioner must provide on-site, or through telepractice, coverage as adequate and necessary.

(iii) In an OTP, anytime such program is open, and a physician is not present, a physician must be available for consultation, prescribing, dispensing and to attend to any emergency situation.

(iv) An OTP 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 always be present when medication is being administered.

(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~~] (including pre- and post-exposure prophylaxis), tuberculosis, viral hepatitis, sexually transmitted infections [~~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' stability and progress in treatment.

(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, that maintains a professional license other than a CASAC.

(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 of any change in medical director, on-site physician(s), or program sponsors (pursuant to Part 810 of this Title).

(1)[~~(k)~~] Other staffing requirements. (1) If other specialized services are directly provided by the program, staff must be appropriately qualified to provide such services.

(2) Volunteers and student interns. In addition to staffing requirements of this Part, a program may utilize volunteers and 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) Certified Recovery Peer Advocates (CRPA). CRPAs, as defined in Part 800 of this Title, must be supervised by a clinical staff member who is credentialed or licensed and

participate in a training plan appropriate to their needs. CRPAs may provide peer support services based on clinical needs as identified in the patient's treatment/recovery plan.

(4) Security staff. Programs may employ security staff who are not clinical staff and may not be involved in clinical services and must receive training on confidentiality of patient information and adhere to such federal laws.

(5) All clinical staff should be provided training related to, including but not limited to, crisis interventions, dealing with special populations, quality improvement, agency policies and procedures. Additional subject areas appropriate for training may from time to time be identified by the Office.

(6) A clinical or non-clinical staff person shall be identified to serve as the program's Lesbian, Gay, Bisexual, Transgender, Questioning/Queer (LGBTQ) liaison.

(m)(4) Program hours of operation. Each program must operate at least five (5) days per week providing structured treatment services in accordance with treatment/recovery plans. Programs should make every effort to provide services outside of normal business hours, including evening and weekend hours. OTPs must be open at least six (6) days per week and must provide flexible dosing hours that meet patient needs, providing access for patients with varying schedules. Patients must be given an appointment for all visits including medication dispensing. Appointment times must allow for program operation with limited wait times.

822.8 Patient Records/Treatment Planning

(a) General requirements for all patient records. All programs must maintain a patient record (either electronic or paper) for each patient who receives services. The patient 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, updated regularly through progress notes. The patient record shall also include:

(1) the source of referral, if applicable;

(2) 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, including their ability to designate individuals to be notified in case of an emergency and that the patient indicated he/she understood them;

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

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

(5) signed releases of consent for information;

(6) documentation of services in accordance with this Part;

(7) documentation of level of care determinations using the OASAS level of care protocol for admission and level of care transition;

(8) transition planning, including medication list, circumstances/reason, and referrals made;

(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.

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

(11) all lab results;

(12) current approved medication doses and justification for any changes; and

(13) include an order sheet that is displayed in the patient 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.

(b) Admission requirements applicable to all programs:

(1) Diagnosis. (i) Unless otherwise authorized, 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).

(ii) For a significant other, the program must document that the individual is determined to have a diagnosis consistent with the presenting concerns related to a close relationship with someone who has a substance use disorder.

(2) 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.

(3) Documentation of admission must:

(i) include the level of care determination;

(ii) include an assessment, initial services and diagnosis that form the basis of the treatment/recovery plan;

(iii) be made by a clinical staff member who is a qualified health professional and must be documented by the dated signature (physical or electronic) of the qualified health professional working within their scope of practice and include the basis for admitting the patient; and

(iv) be approved by the dated signature (physical or electronic) of a physician, physician's assistant, nurse practitioner, licensed psychologist, or licensed clinical social worker.

(4) Patients being admitted to an OTP must be documented to have a minimum 12-month opioid use disorder (OUD) accompanied by a physical evaluation. A comprehensive physical examination must be completed within fourteen days, or otherwise in accordance with federal rules.

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

(6) No individual that meets level of care criteria may be denied admission to a program **consistent with the provisions of Part 815 of this Title.**~~[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;~~

~~_____ (viii) toxicology test results;~~

~~_____ (ix) use of any illicit or prescribed substance, including but not limited to, benzodiazepines; or~~

~~_____ (x) use of medications for substance use disorder prescribed and monitored by a physician, physician's assistant or nurse practitioner.]~~

(7) All prospective patients must be informed that admission to a program is on a voluntary basis and a prospective patient is free to discharge themselves 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, continued treatment, and toxicology screening.

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

(c) Post-admission. (1) As soon as possible after admission, if not already complete, every patient must be:

(i) offered viral hepatitis testing; testing may be done on site or by referral;

(ii) offered HIV testing; testing must be conducted with patient consent in accordance with public health law and may be done on site or by referral; individuals on a regimen of pre- or post-exposure prophylaxis, must be permitted to continue the regimen until consultation with the prescribing professional occurs;

(iii) screened for co-occurring mental health conditions and behavioral health risk including suicide risk using validated screening instruments approved by the Office.

(2) If clinically indicated, all programs must:

(i) 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 testing; for patients with a positive test result, refer the patient for further tuberculosis evaluation.

(ii) offer testing for other sexually transmitted **infections** ~~[diseases]~~; testing may be done on site or by referral;

(iii) provide or recommend any other tests the examining physician or other medical staff member deems to be necessary including, but not limited to, an EKG, a chest X-ray, or a pregnancy test.

(3) As soon as possible after testing programs must explain or ensure that the provider has explained, any blood and skin test results to the patient.

(4) For those patients who have not had a physical examination within one year prior to admission, each such patient must either be assessed by a member of the medical staff 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 substance use disorder 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. Notwithstanding the foregoing, HIV and viral hepatitis testing shall be offered regardless of a documented history within the previous twelve months. OTPs are exempt from this requirement but must provide physical examinations in accordance with federal rules.

(d) 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 822.10 of this Part to be admitted to an outpatient rehabilitation service.

(e) Additional admission requirements for OTPs. (1) The decision to admit a prospective patient for treatment is finalized on the date of administration or prescription 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. No person under the age of 16 may be admitted without the prior approval of the Office. The following requirements must be met for an individual to be admitted:

(2) In order to administer the first medication dose, a patient must have an in-person evaluation, including a physical evaluation, to determine that they have had a physiological dependence on opioids for at least the previous 12-month period, and must diagnose and document such, provided however:

(i) a prospective patient may be admitted who voluntarily completed treatment in another program without confirming current opioid dependence if the program 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 treatment episodes within a 12-month period and a dependence on opioids;

(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.

(3) A physician, or other practitioner with federal approval, 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 an opioid treatment program, which shall include notice of the risks and benefits of a prescribed medicine.

(4) 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 program.

(f) Readmissions to OTPs. Programs need not repeat admission procedures for any patient who is being re-admitted within three (3) 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 program must immediately readmit patients who were previously discharged from that program:

(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) Transfers between OTPs. (1) Each program must develop procedures regarding the transfer of patients which must ensure that the program shall:

(i) not deny a reasonable request for a temporary or permanent transfer;

(ii) not include “temporary-to-permanent” conditions, whereby a patient is temporarily provided guest medication and then evaluated as to whether or not the OTP will permanently admit, unless otherwise authorized by the Office;

(iii) regard transferred patients as continuing in treatment by incorporating their length of treatment and treatment/recovery plans from the referring program;

(iv) send or receive the reason for the 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 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 program must develop procedures for the temporary transfer of patients which must ensure that the:

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

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

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

(iv) transferring program remains responsible for the patient’s overall treatment.

The receiving program may deliver any necessary service after consultation with the transferring program; and

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

(h) Treatment/recovery plan. (1) Each patient must have a written person-centered treatment/recovery plan developed by the clinical staff person with primary responsibility for the patient, in collaboration with the patient and anyone identified by the patient as supportive to recovery goals. The treatment/recovery plan begins with the assessment incorporated into the patient record and is regularly updated with progress notes.

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

(ii) Immediate transfer: 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 to reflect patient goals as appropriate.

(2) The treatment/recovery plan must:

(i) include the assessment, which identifies each diagnosis for which the patient is being treated;

(ii) be incorporated into the patient record through regular progress notes, including initial services to be offered prior to completion of the initial assessment;

(iii) address patient goals as identified through the assessment process and regularly updated as needed through progress notes;

(iv) 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;

(v) reference to any significant medical and psychiatric issues, including all medications, by acknowledging review of medical/psychiatric assessment and progress notes, as well as coordination with mental and psychiatric providers; and

(vi) be reviewed and approved by the clinical staff person responsible for developing the plan, the patient and the clinical supervisor.

(i) Continuing review of treatment/recovery plans. The treatment/recovery plan must be reviewed through the ongoing assessment process and regular progress notes.

(j) Progress Notes. Progress notes are intended to document the patient's clinical status. Service delivery should be documented in the patient record through regular progress notes that include, unless otherwise indicated, the type, content, duration and outcome of each service delivered to or on behalf of a patient, 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; and

(4) include, as appropriate and relevant, any recommendations, communications, or determinations for initial, continued or revised patient goals and/or treatment.

(k) 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.

(l) 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, recommended, and refused. The program should also offer to develop a plan of safe care with the patient and anyone identified by the patient, such offer should be noted in the patient record.

(m) Communicable disease. Treatment/recovery plans must include provisions for the prevention, care and treatment of HIV[/~~AIDS~~], viral hepatitis, tuberculosis and/or sexually transmitted **infections**[~~diseases~~] when present. If a patient refuses to obtain such care, the provider must have the patient acknowledge in writing that such care was offered, recommended, and refused.

(n) Transfers. If patients are transferred between a SUD outpatient program and outpatient rehabilitation services within the same provider, a single patient 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, if necessary, signed (physical or electronic signature) by a clinical staff member and their supervisor.

(o) Confidentiality. Patient 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 patients' records as set forth in 42 CFR Part 2 and other applicable law.

(p) Records retention. Patient records must be retained for **ten (10)** [~~six (6)~~] years after the date of discharge or last contact, or three (3) years after the patient reaches the age of eighteen, whichever time period is longer.

(q) Patient deaths. If a patient dies while in active treatment any known details must be documented in the patient record.

(r) Transition or discharge criteria. (1) Patients having no contact or intent to continue accessing services from a program should be discharged after a period not exceeding sixty (60) days unless reason for continuing treatment past that period is identified and documented in the patient record.

(2) Individuals entering treatment should progress by meeting treatment milestones including: stabilization; engagement; goal setting; and attainment of patient-centered goals. Individuals should be considered for transitions to the community or another level of care once they have stabilized and attained the support necessary to support their goals. If an individual leaving treatment expresses a preference for a level of care or services that preference should be included in the patient record.

(3) Individuals who are discharged involuntarily must be discharged consistent with Part 815 of this Title.

(4) Transition plan.

(i) A transition plan must be developed in collaboration with the patient and any collateral person(s) the patient chooses to involve. Such plan shall specify needed referrals with appointment dates and times, all known medications (including frequency and dosage) and recommendations for continued care.

(ii) **The transition plan shall include an appointment with an appropriate provider to continue access to approved medications to treat the patient's substance use disorder.**

(iii) If the patient is a minor, the plan must also be developed in consultation with their parent or guardian, unless the minor is being treated without parental consent as authorized by Mental Hygiene Law section 22.11; information pertaining to the testing and treatment of sexually transmitted **infections** [~~diseases~~] cannot be shared with the minor patient's parent or guardian without the patient's consent, in accordance with applicable laws and regulations.

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

continuing care must be given to the patient prior to leaving the program. The patient, and their family/significant other(s), shall be offered overdose prevention education and training, and a naloxone kit or prescription.

(s) Continuing Care. Individuals may be admitted to continuing care when they require a less intensive amount of support and services and there is a documented clinical need for ongoing clinical support to maintain gains made in treatment.

(1) The purpose of 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 treatment.

(2) Individuals in continuing care may receive counseling or peer services, rehabilitative support services including case management and medication management services as needed.

(3) Patients receiving OTP services are not appropriate for continuing care as defined herein.

822.9 Additional locations

(a) A certified provider of an outpatient program may operate at one or more additional locations with the approval of the commissioner pursuant to Part 810 of this Title. For purposes of this section, an “additional location” is a provider site providing outpatient addiction treatment services which reports to a primary certified program for its operation, administration and supervisory activities.

(b) The provisions of this section shall not apply to certified providers of outpatient rehabilitation services.

(c) Opioid Treatment Programs must comply with federal statutes, regulations and guidance regarding the development of additional locations and are not subject to the provisions of 822.7(f) of this Chapter.

822.10 Additional requirements for substance use disorder outpatient rehabilitation services

(a) These requirements are in addition to those contained in 822.7 of this Chapter and other sections applicable to all programs.

- (b) As defined in 822.5 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 programs. It is expected that services will be provided three to five days per week for at least two hours per day.
- (c) Programs must be certified by the Office to provide outpatient rehabilitation services.
- (d) 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.
- (e) If a program 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.
- (f) A provider of outpatient rehabilitation services must assure the availability of one meal to each patient who receives outpatient rehabilitation services.

822.11 Additional requirements for opioid treatment programs

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

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

(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 such program and this verification must be documented in the clinical record; a program may not admit an applicant who is participating in another such program; 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. Another designated practitioner, such as a nurse practitioner or physician's assistant may determine a patient's initial medication dose and schedule of administration if a federal waiver has been approved.

(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 seventy-two (72) hours.

(3) 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 twenty-four (24) hours, alleviate opioid craving and stop continued opioid use. Split medication doses require prior Office approval.

(4) If any medical staff member observes any condition or behavior on the part of a patient that may contraindicate a regularly scheduled dose of 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.

(c) Unsupervised or take-home medication. (1) Each patient must be on a 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 visit schedule, when clinically indicated, to accommodate patient changes in need, progress, or rehabilitation.

(2) Each patient's take-home schedule must comply with the federal regulatory time in treatment requirements (42 CFR Part 8.12), unless there is a clinical justification that takes into consideration the federal eight (8) point criteria, as to why the person is not stable enough to be granted the applicable take home schedule. The Medical Director must review and confirm the appropriateness for take-home medication. Federal time in treatment criteria do not apply to the provision of buprenorphine or naltrexone.

(3) 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.

(4) Such determinations shall be documented in the patient's medical record. Time-in-treatment requirements do not apply to buprenorphine take-home medication per federal rules.

(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 require a patient to visit the program when concerned with diversion of medication. When this occurs the patient shall be required to bring in all remaining take-home doses. Remaining doses must match the prescribed schedule.

(7) Holidays. Notwithstanding the requirements of this subdivision, a patient may be provided with extra medication without prior Office approval if the patient's next regular visit falls on a legal or program holiday. Designation of a program holiday that is not a federal holiday must be approved annually by the Office at least thirty (30) days in advance.

(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 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. Program medical staff may release medication to a designated third party other than the patient only when the patient is physically unable to attend the program. The decision to permit such release to a designated third party must be based on the clinical judgment of the prescribing professional and with the consent of the patient, both of which must be documented in the patient's record. All designated third parties must also receive prior Office approval.

(10) Patients readmitted to a program 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) 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 medication. Containers used in the program or for take-home medications must be in child resistant packaging, may not be reused and must be destroyed. Each program 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.

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

(e) Residential programs providing opioid full agonist treatment medications. Such a residential program shall:

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

(2) comply with all requirements of this Title applicable to substance use disorder 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 substance use disorder residential services, rather than the requirements of this Part.

(f) Opioid taper. (1) MAT is the standard of care for OUD; however an opioid taper may be appropriate in limited clinical situations and upon patient request.

(2) Voluntary Taper. Each program must provide an opioid taper at the program or arrange for taper at another program or in a facility approved to provide tapering as is medically and clinically appropriate:

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

(ii) Each program 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.

(g) Opioid medical maintenance (OMM). (1) An OMM program requires federal and state approval. Patients admitted to OMM must meet specific criteria including:

(i) four (4) years of continuous treatment in a program providing opioid full agonist treatment;

(ii) three (3) years of no **substance use**~~[drug abuse]~~ including alcohol;

(iii) three (3) years of no criminal involvement;

(iv) three (3) years of continuous gainful employment or productive activity;

(v) three (3) years of emotional stability;

(vi) intent to continue maintenance treatment; and

(vii) verified stability in the Prescription Monitoring Program ("PMP").

(2) The individual patient 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.

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

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

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

(h) 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.

822.12 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