

Notice of Proposed Rulemaking Summary

Amend 14 NYCRR Part 800 OASAS TREATMENT SERVICES: GENERAL PROVISIONS

In addition to technical amendments updating this regulation consistent with Title 14, the Proposed Rule amends Part 800 as follows:

- §800.3 Incorporation by Reference. Adds incorporation by reference of Standards related to the Adolescent Endorsement proposed in Part 830 of this Title.
- §800.4 Definitions. Add and updates various definitions.
- §800.5 Access to Treatment. Adds individuals recently released from criminal justice settings to the list of individuals for which providers shall have priority admission policies.
- §800.6 Access to Medication for Addiction Treatment. Updates and clarifies provider expectations regarding the provision of medication for addiction treatment for substance use disorder and overdose prevention education and training.



Notice of Proposed Rulemaking Regulatory Impact Statement

Amend 14 NYCRR Part 800

OASAS TREATMENT SERVICES: GENERAL PROVISIONS

1. Statutory Authority:

- (a) Section 19.07(e) of the Mental Hygiene Law authorizes the Commissioner of the Office of Addiction Services and Supports to adopt standards including necessary rules and regulations pertaining to addiction services.
- (b) Section 19.09(b) of the Mental Hygiene Law authorizes the Commissioner of the Office of Addiction Services and Supports to adopt regulations necessary and proper to implement any matter under his or her jurisdiction.
- (c) Section 32.01 of the Mental Hygiene Law authorizes the Commissioner of the Office of Addiction Services and Supports to adopt any regulation reasonably necessary to implement and effectively exercise the powers and perform the duties conferred by Article 32 of the Mental Hygiene Law.
- (d) Section 32.07(a) of the Mental Hygiene Law authorizes the Commissioner of the Office of Addiction Services and Supports to adopt regulations to effectuate the provisions and purposes of Article 32 of the Mental Hygiene Law.
- (e) Article 15 of the Executive Law enacts the Human Rights Law prohibiting discrimination against various protected classes.
- 2. <u>Legislative Objectives:</u> The legislature has authorized OASAS to establish standards and regulations governing the provision of addiction services, including the provision of medications for addiction treatment, as well as standards for providers seeking to offer such services.
- 3. <u>Needs and Benefits:</u> OASAS is updating the language used in this regulation consistent with amendments made to other OASAS regulations to clarify provider requirements with respect to the provision of medication

for addiction treatment for substance use disorder and to update definitions consistent with other OASAS regulations.

Proposed amendments to Part 800 include updates to definitions and language used by all OASAS programs consistent with continued efforts and agency goals to reduce stigma and use person-first language for the delivery of addiction services. Additionally, provisions for medication for addiction treatment for substance use disorder are further clarified consistent with guidance issued by the Office and the medical standard of care for the treatment of substance use disorder. Finally, the agency has added to the list of high-risk populations for which programs must develop priority admissions policies. These amendments support OASAS overarching goals to ensure programs are responsive to community needs and provide person-centered care.

- 4. <u>Costs:</u> No additional administrative costs are anticipated for the State, local governments, or the agency. Costs for regulated providers should be minimal and are mostly related to updating policies and procedures. The requirements outlined in the regulation are already required in guidance (both for medication access and naloxone education and access) and in the standard of care for the treatment of substance use disorder.
- 5. <u>Paperwork:</u> There is no additional paperwork beyond what is already required. OASAS programs are required to review and update policies and procedures to ensure compliance with OASAS regulations and guidance and evolving standards of care for the treatment of substance use disorder and problem gambling. Programs will be expected to enter into agreements with Opioid Treatment Programs, which should not be difficult as many providers currently have agreements to facilitate linkage between different levels of care.
- 6. <u>Local Government Mandates</u>: There are no new local government mandates.
- 7. <u>Duplications</u>: This proposed rule does not duplicate, overlap, or conflict with any State or federal statute or rule.
- 8. <u>Alternatives</u>: The alternative is to leave the regulation as it currently reads, with language inconsistent across Title 14 regulations and providers unsure of their obligation to provide medication for addiction treatment for substance use disorders.
- 9. Federal Standards: This regulation does not conflict with federal standards.

10. <u>Compliance Schedule:</u> This rulemaking will be effective upon publication of a Notice of Adoption in the *State Register*.



OASAS [TREATMENT] SERVICES: GENERAL PROVISIONS TITLE 14 NYCRR PART 800

[Statutory Authority: Mental Hygiene Law Sections 19.07(e), 19.09(b), 32.01, 32.07(a), Executive Law, Article 15]

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Section 800.1 Applicability

The provisions of this Part shall apply to any program certified, funded, designated or otherwise authorized by the Office of Addiction Services and Supports (OASAS).

800.2 Legal base

- (a) Section 19.07(e) of the Mental Hygiene Law authorizes the Commissioner of the Office of Addiction Services and Supports to adopt standards including necessary rules and regulations pertaining to addiction services.
- (b) Section 19.09(b) of the Mental Hygiene Law authorizes the Commissioner of the Office of Addiction Services and Supports to adopt regulations necessary and proper to implement any matter under his or her jurisdiction.
- (c) Section 32.01 of the Mental Hygiene Law authorizes the Commissioner of the Office of Addiction Services and Supports to adopt any regulation reasonably necessary to implement and effectively exercise the powers and perform the duties conferred by Article 32 of the Mental Hygiene Law.
- (d) Section 32.07(a) of the Mental Hygiene Law authorizes the Commissioner of the Office of Addiction Services and Supports to adopt regulations to effectuate the provisions and purposes of Article 32 of the Mental Hygiene Law.

(e) Article 15 of the Executive Law enacts the Human Rights Law prohibiting discrimination against various protected classes.

800.3 Incorporation by reference

The following publications and/or federal laws and regulations are incorporated by reference where applicable to all Parts of this Chapter. Publications are filed with the Office of the Secretary of State of the State of New York, One Commerce Plaza, 99 Washington Ave., Albany, NY 12231-0001, and may be viewed at the law libraries of the New York State Supreme Court, the Legislative Library in the NYS Capitol, or viewed by appointment with the New York State Office of Addiction Services and Supports, Office of Counsel, 1450 Western Ave., Albany, NY. Copies are also available by writing to the NYS Office of Addiction Services and Supports, Office of Counsel, 1450 Western Avenue, Albany, NY 12203-3526; federal documents may be purchased from the Superintendent of Documents, Government Printing Office, Washington D.C. 20402. Copies of the Code of Federal Regulations (CFR) are also available at many public libraries and bar association libraries.

- (a) "The International Statistical Classification of Diseases and related Health Problems, Tenth Revision, Second Edition" published in 2004 by the World Health Organization.
- (b) "The OASAS Level of Care for Alcohol and Drug Treatment Referral Protocol 3.0" or "LOCADTR 3.0" or "level of care determination protocol", the various modules available and accompanying Guidelines for Level of Care Determination published by the Office and which is in the public domain.
- (c) 21 Code of Federal Regulations Part 1301.72, et seq. regarding regulatory requirements for controlled substances.
- (d) 42 Code of Federal Regulations Part 2, et. seq. regarding confidentiality of patient records.
- (e) "The Medicare Provider Reimbursement Manual" or "HIM 15" published by the U.S. Department of Health and Human Services' Centers for Medicaid and Medicare Services and available from: Centers for Medicaid and Medicare Services, Division of Communication Services, Production and Distribution Branch, Room 577, East High Rise Building, 6325 Security Boulevard, Baltimore, MD 21207.

- (f) The "American Psychiatric Association: Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition." Arlington, VA, published by the American Psychiatric Association, 2013.
- (g) "Health Insurance Portability and Accountability Act of 1996", 45 Code of Federal Regulations Part 160 and Subparts A and E of Part 164, et. seq. (HIPAA) regarding patient records.
- (h) The "Substance Use Disorder Counselor Scope of Practice" published in 2020 by the Office and which is in the public domain.
- (i) The "Telehealth Standards for OASAS Designated Providers" published in 2021 by the Office and which is in the public domain.
- (j) The "Lesbian, Gay, Bisexual, Transgender and Queer (LGBTQ) Affirming Program Endorsement Standards for OASAS-Certified Programs" published in 2021 by the Office and which is in the public domain.
- (k) The "Ambulatory Patient Groups (APG) Clinical and Medicaid Billing Guidance" published in 2021 by the Office and which is available in the public domain.
- (l) The "Medicaid State Plan Children and Family Treatment and Support Services Provider Manual for Children's Behavioral Health Early and Periodic Screening and Diagnostic Treatment (EPSDT) Services", published in January 2021 by the NYS Department of Health and which is available in the public domain.
- (m) The "Clinical Practice Standards for Adolescent Programs" (CPS-AP) Program endorsement standards for OASAS certified programs published in 2022 by the Office and which is in the public domain.

800.4 Definitions

The following terms are defined for purposes of all Parts of Chapter XXI of this Title, unless a term is defined and indicated as applicable only for purposes of a specific Part.

- (a) "Addiction disorder" means substance use disorder as defined in this Part and/or gambling disorder as defined in this Title and/or problem gambling as defined in this Title.
- (b) "Addiction services" means examination, evaluation, diagnosis, care, treatment, or rehabilitation of persons with substance use disorder, gambling disorder, or problem gambling and their families or significant others.

(c) "Approved medication" means any medication approved by state and federal authorities for the treatment of substance use disorder.

(d)[(a)]"Clinical staff" is staff who provide services directly to patients as prescribed in a treatment/recovery plan; clinical staff includes licensed medical staff, credentialed or licensed staff, non-credentialed staff, and student interns.

(e)[(b)] "Commissioner" means the Commissioner of the Office of Addiction Services and Supports unless otherwise indicated.

(f)[(e)] "Diagnosis" for purposes of admission, treatment and level of care transition planning (discharge planning) means the identification criteria contained in the most current editions of both the International Classification of Diseases, and the Diagnostic and Statistical Manual.

(g) "Full Opioid agonist" means methadone.

(h)[(d)] "Medical Director". (1) Each program must have a physician designated by the program sponsor to be the medical director. The medical director shall be a physician licensed and currently registered as such by the New York State Education Department and shall have at least one year of education, training, and/or experience in substance use disorder services. The medical director is a physician who has overall responsibility for the following (this overall responsibility may not be delegated):

- (i) medical services provided by the program;
- (ii) oversight of the development and revision of policies, procedures and ongoing training for matters including, but not limited to, routine medical care, specialized services, specialized medications, medical and psychiatric emergency care, screening for, and reporting of, communicable diseases and infection in accordance with law, public health education including prevention and harm reduction;
- (iii) collaborative supervision with the program director of non-medical staff in the provision of substance use disorder services;
 - (iv) supervision of medical staff in the performance of medical services;
- (v) assisting in the development of necessary referral and linkage relationships with other institutions and agencies including, but not limited to, general or specialty hospitals and nursing homes, health-related facilities, home health agencies, hospital outpatient departments, diagnostic and treatment facilities, laboratories and related resources;

- (vi) ensuring program compliance with all federal, state and local laws and regulations.
- (2) All medical directors, whether full-time or part-time, other than medical directors in place as of the effective date of this regulation, must hold a board certification in addiction medicine from a certifying entity appropriate to their primary or specialty board certification. Physicians may be hired as probationary medical directors if not so certified but must obtain certification within four (4) years of being hired. In addition, the medical director must have a federal DATA 2000 waiver to prescribe buprenorphine.
- (3) The medical director may serve as medical director of more than one program certified by the Office.
- (i)[(e)] "Medical staff" means physicians, nurse practitioners, registered physician assistants, and registered nurses licensed and certified by the State Education Department practicing within the scope of, and in accordance with, the terms and conditions of such licenses and certifications, and working with, or under the supervision of a physician, or other medical professional if required by law.
- (j) "Medication for addiction 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 optional counseling and behavioral therapies, as clinically appropriate.
- (k)[(f)] "Multi-disciplinary team" means a team of health professional staff including, at a minimum, one medical staff member (where applicable) as defined in this section, one credentialed alcoholism and substance abuse counselor (CASAC) and one other staff member who is a qualified health professional as defined in this section in a discipline other than alcohol and substance use disorder counseling. If the treatment service has a gambling designation on their operating certificate, the multi-disciplinary team must include Qualified Problem Gambling Professional (QPGP), consistent with this Chapter.
- (l) "Naloxone emergency overdose prevention kit" means a kit as prescribed or distributed pursuant to state law and is used to reverse an opioid overdose.
- (m)[(g)] "Office" or "OASAS" means the New York State Office of Addiction Services and Supports.

- (n) "Opioid agonist" means methadone or buprenorphine and/or buprenorphine/naloxone, or any other agonist medication that may be approved by the federal or state government for the treatment of opioid use disorder.
- (o) "Opioid antagonist" for purposes of substance use disorder treatment medication means naltrexone. Opioid antagonist for purposes of overdose prevention medication means naloxone.
- (p) "Partial Opioid agonist" means buprenorphine and/or buprenorphine/naloxone.
- (a)[(h)] "Peer advocate" is a Certified Recovery Peer Advocate (CRPA) who holds a certification from a certifying authority recognized by the Commissioner.
- <u>(r)</u>[(i)] "Prescribing professional" is any medical professional appropriately licensed under New York State law and registered under federal law to prescribe approved medications.
- (s)[(j)] "Program" means a location wherein a provider is authorized to provide addiction services.
- (t)[(k)] "Provider" means an individual, association, partnership, corporation, public or private agency sponsor, as "sponsor" is defined in this Part, other than an agency or department of the state, which provides addiction services via one or more Office certified, funded or otherwise authorized program.
- (u)[(1)] "Qualified Health Professional" means any of the professionals listed below, who are in good standing with the appropriate licensing or certifying authority, as applicable, with a minimum of one year of experience or satisfactory completion of a training program in the treatment of addiction:
- (1) a credentialed alcoholism and substance abuse counselor (CASAC) who has a current valid credential issued by the Office, or a comparable credential, certificate or license from another recognized certifying body as determined by the Office;
- (2) a counselor certified by and currently registered as such with the National Board for Certified Counselors;
- (3) a rehabilitation counselor certified by the Commission of Rehabilitation Counselor Certification;
- (4) a therapeutic recreation therapist certified by the National Council on Therapeutic Recreation or the American Therapeutic Recreation Association; or a person who holds a baccalaureate degree in a field allied to therapeutic recreation and, either before or after

receiving such degree, has five years of full-time, paid work experience in an activities program in a health care setting;

- (5) a professional licensed and currently registered as such by the New York State Education Department to include:
- (i) a physician who has received a doctor of medicine (M.D.) or doctor of osteopathy (D.O.) degree;
 - (ii) a physician['s] assistant (PA);
 - (iii) a certified nurse practitioner (NP);
 - (iv). a registered nurse (RN);
 - (v) a psychologist;
 - (vi) an occupational therapist;
- (vii) a social worker (LMSW; LCSW), including an individual with a Limited Permit Licensed Master Social Worker (LP-LMSW) only if such person has a permit which designates the OASAS-certified program as the employer and is under the general supervision of a LMSW or a LCSW; and
- (viii) a mental health practitioner including: a licensed mental health counselor (LMHC), a marriage and family therapist (LMFT), a creative arts therapist (LCAT), and licensed psychoanalyst; and any mental health practitioner with a Limited Permit.
- (v)[(m)] "Quality improvement" means an ongoing process by which an addiction service systematically assesses the adequacy and appropriateness of the addiction treatment services provided to patients and provides recommendations for improvement.
- (w)[(n)] "Significant other" is an individual who is admitted to treatment and manifests psychological, behavioral and/or emotional effects arising from another person's substance use disorder, regardless of whether the other individual is in treatment. A significant other must be determined to be able to participate actively in and benefit from the treatment process.
- $(\underline{x})[(o)]$ "Sponsor" (formerly "governing authority") means the provider of service or an entity that substantially controls or has the ability to control substantially the provider of service. For the purpose of this Part, factors used to determine whether there is substantial control shall include, but are not limited to, the following:
 - (1) the right to appoint and remove directors or officers;
 - (2) the right to approve bylaws or articles of incorporation;

- (3) the right to approve strategic or financial plans for a provider of service; or
- (4) the right to approve operating or capital budgets for a provider of service.

(v)[(p)]"Student Intern" means a person enrolled in a formal educational program which could lead to a degree, certification or credential which may qualify that person as a Qualified Health Professional.

(z)[(q)] "Substance use disorder" means a group of cognitive, behavioral, and physiological symptoms indicating that an individual continues using substances despite significant substance-related physical, psychological and social problems as determined through assessment and diagnosis using the most recent version of the DSM. Substance use disorder, or addiction, is a treatable, chronic medical condition. Substance use disorder treatment shall include alcoholism, alcohol abuse, substance abuse, substance dependence, chemical dependence, chemical abuse and/or chemical dependence.

(aa)[(r)] "Substance use disorder services" or "chemical dependence services" shall mean and include examination, evaluation, diagnosis, care, treatment, or rehabilitation of persons with substance use disorders and their families or significant others.

(bb)[(s)] "Utilization review" means a process by which a service systematically monitors the appropriateness of admissions, the need for continued stay, and the necessity for an alternative level of care.

- [(t) "Addiction services" means examination, evaluation, diagnosis, care, treatment, or rehabilitation of persons with substance use disorder, gambling disorder, or problem gambling and their families or significant others.
- (u) "Opioid agonist" as used in this Part means methadone or buprenorphine and/or buprenorphine/naloxone, or any other agonist medication that may be approved by the federal or state government for the treatment of opioid use disorder.
- (v) "Opioid full agonist" means methadone.
- (w) "Opioid partial agonist" means buprenorphine and/or buprenorphine/naloxone.
- (x) "Opioid antagonist" means naloxone or naltrexone.
- (y) "Naloxone emergency overdose prevention kit" means a kit as prescribed or distributed pursuant to state law and is used to reverse an opioid overdose.
- (z) Addiction disorder means substance use disorder as defined in this Part and/or gambling disorder as defined in this Title and/or problem gambling as defined in this Title.]

800.5 Access to Treatment

- (a) Efforts to reduce disparities in access to services: Programs shall develop policies and procedures to address and make efforts to reduce disparities in access, quality of care and treatment outcomes and which prohibit discrimination on the basis of age, race, creed, color, national origin, sexual orientation, gender identity or expression, military status, sex, marital status or disability in accordance with the NYS Human Rights Law, as well as specifically addressing policies and procedures for older adults, Veterans, individuals who are deaf & hard of hearing, individuals who are Limited English Proficient, immigrants, and individuals re-entering communities from criminal justice settings. Such policies and procedures shall include, but are not limited to the following:
 - ([i]1) increasing access to care and reducing barriers in accessing care;
 - ([ii]2) ensuring quality of care;
 - ([iii]3) increasing positive treatment outcomes;
 - ([iv]4) implementing written policies on affirmative action which are consistent with the affirmative action and equal employment opportunity obligations imposed by state and federal law for program staff;
 - ([+]5) employing staff that are proficient in the most prevalent languages spoken by services users.
- (b) Priority admission. All certified programs shall have priority admission policies and procedures which establish immediate admission preference for pregnant persons, people who inject drugs. [and] parent(s)/guardian(s) of children in or at risk of entering foster care and individuals recently released from criminal justice settings. If the individual does not meet admission criteria or is otherwise inappropriate for admission, the program rapidly must refer and engage the individual with an appropriate treatment provider.
- (c) Plan of safe care. All certified, licensed or otherwise authorized programs shall offer development of a plan of safe care to any pregnant patients in accordance with guidance issued by the Office.

(d) Records retention: Patient records must be retained for ten (10) 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.

800.6 Access to Medication for Addiction Assisted Treatment

- (a) All programs certified pursuant to this [Chapter] Title shall provide patient education on all available forms of approved medication for substance use disorder treatment and facilitate expeditious access to medication [assisted] for addiction treatment, based on the clinical need and preference of the patient, through direct provision of the medication, [or] contracting with private prescribing professionals or, where staffing structure or federal rules do not allow for direct provision of medication, linkage agreements with other Office certified programs. Such agreements must ensure rapid access sufficient to meet patient needs without undue barriers such as long waiting periods for appointments or waiting lists.
- (b) All [doctors]physicians, physician assistants and nurse practitioners employed in a treatment program certified pursuant to this [Chapter]Title must have a federal DATA 2000 waiver to prescribe buprenorphine.
- (c) All programs must allow for provision of medication [assisted] for addiction treatment and may not deny admission based on use of medication, patient intent to obtain medication for addiction treatment or patient preference for a specific medication. Programs must continue access to medications for addiction treatment [opioid full and partial agonist treatment] and plan for the continuity [of] for medication administration during admission and post-discharge.
- [(d) All programs must maintain an emergency medical kit at each certified or funded location; such kit must include basic first aid and naloxone emergency overdose prevention kit(s) in a quantity sufficient to meet the needs of the program and that are available for use during all program hours of operation.]
- (d) [(e)] Each program that dispenses medications must develop and implement a diversion control plan (DCP) as part of its quality improvement plan, such DCP must 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 program for carrying out the diversion control measures and functions described in the DCP.

- (e) Programs shall provide access to Medication for Addiction Treatment (MAT) for Substance Use Disorder in accordance with this Part, the Part under which the program is certified or otherwise authorized, and guidance issued by the Office.
- (1) All programs 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 the patient's 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, all programs 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) All programs shall provide FDA approved medications to treat substance use disorders 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) All programs shall provide education to an existing patient or prospective patient with substance use disorder about FDA 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 patient's record.
- (5) All programs shall ensure that the patient's discharge plan includes an appointment with a treatment provider or program that can continue the medication post-discharge.

- (f) Programs shall provide access to overdose prevention education, training and supplies in accordance with this Part, the Part under which the program is certified, funded or otherwise authorized and/or guidance issued by the Office.
- (1) All programs must maintain an emergency medical kit at each certified or funded location; such kit must include basic first aid and naloxone emergency overdose prevention kit(s) in a quantity sufficient to meet the needs of the program and that are available for use during all program hours of operation.
- (2) All programs shall provide overdose prevention education and naloxone education and training to a patient or prospective patient, and their significant other(s), in accordance with guidance issued by the Office.
- (3) All programs shall make available to patients and prospective patients, and their significant other(s), a naloxone kit or prescription as appropriate, in accordance with guidance issued by the Office.

800.7 Waiver

- (a) The Commissioner may grant a waiver of a Part 800-series addiction services regulatory requirement not specifically required by law, if the Commissioner determines that:
 - (1) meeting the requirement would impose an unreasonable hardship;
 - (2) the health and safety of patients/residents would not be diminished; and
 - (3) the best interests of the patients/residents and the service would be served.
- (b) In considering a request for a waiver, the Commissioner will consider such factors as the special needs of the population(s) to be served, geographic distances and transportation problems, staff availability, long range plans of the addiction services, alternatives and any other relevant information.
- (c) A request for a waiver must be submitted in writing, must contain substantial documentation to support the need for the waiver, and must include such other information as the Commissioner may require.
- (d) Special limits, conditions or restrictions may be established by the Commissioner in granting a waiver.
- (e) A waiver shall be in effect for no longer than the time period between granting of the waiver and the conclusion of the subsequent re-certification inspection and review.

800.8 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 which can be given effect without the invalid provisions or applications, and to this end the provisions of this Part are declared to be severable.





Notice of Proposed Rulemaking Summary

Amend 14 NYCRR PART 815 PATIENT RIGHTS

In addition to technical amendments updating this regulation consistent with Title 14, the Proposed Rule amends Part 815 as follows:

- §815.1 Legal Base. Updates to utilize appropriate language. Addition of reference to NYS Human Rights Law.
- §815.4 Provider requirements. Updates to utilize appropriate language, include references to personcentered and trauma informed care delivery. Clarification that providers may not base program admission on specific identification requirements. Clarification on the requirement for providers to have policies related to the provision of medication for addiction treatment for substance use disorder.
- §815.5 Patient rights. Updates to utilize appropriate language, include references to person-centered and trauma informed care delivery. Addition of provisions relating to non-discrimination in program admission. Clarification on a patient's right to access medication for addiction treatment for substance use disorder.
- §815.6 Patient responsibilities. Updates to utilize appropriate language, include references to personcentered and trauma informed care delivery.
- §815.7 Procedure at discharge. Updates to utilize appropriate language, include references to personcentered and trauma informed care delivery.
- §815.8 Toxicology testing. Updates to utilize appropriate language, include references to personcentered and trauma informed care delivery and consistent with OASAS guidance.
- §815.9 Patient use of prescription medication. Updates to utilize appropriate language, include references to person-centered and trauma informed care delivery.

- §815.10 Patient screening. Programs are explicitly prohibited from conducting body cavity searches Alternatives to body cavity searches are provided.
- §815.12 Research subjects. Updates to appropriate language references.
- §815.13 Staff and client relationships. Inclusion of reference to regular trainings regarding appropriate boundaries between staff and clients/patients.





Notice of Proposed Rulemaking Regulatory Impact Statement Amend 14 NYCRR PART 815 PATIENT RIGHTS

1. Statutory Authority:

- (a) Section 19.07(c) of the Mental Hygiene Law ("MHL") charges the Commissioner ("Commissioner") of the New York State Office of Addiction Services and Supports ("the Office") with the responsibility of ensuring that the personal and civil rights of persons receiving care, treatment and rehabilitation are adequately protected.
- (b) Section 19.07(e) of the MHL authorizes the Commissioner to adopt standards including necessary rules and regulations pertaining to addiction 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 19.20 of the MHL authorizes the Office to receive and review criminal history information from the Justice Center related to employees or volunteers of treatment facilities certified, licensed, funded or operated by the Office.
- (e) Section 19.20-a of the MHL authorizes the Office to receive and review criminal history information from the Justice Center related to persons seeking to be credentialed by the Office or applicants for an operating certificate issued by the Office.
- (f) Section 19.21(b) of the MHL authorizes the Commissioner to adopt regulations concerning the licensing, certification, inspection, and treatment standards of all facilities that provide addiction services.
- (g) Section 22.03 of the MHL requires the director of any addiction services program to establish, communicate and post patient rights, to include information about how to communicate with the Office and the Commissioner.
- (h) Section 22.07(c) of the MHL authorizes the Commissioner to adopt rules and regulations and take any other necessary action to ensure that the rights of individuals who have received or are receiving addiction 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 32.07(a) of the MHL authorizes the Commissioner to adopt regulations to effectuate the provisions and purposes of Article 32 of the MHL.
- (k) Section 32.05 of the MHL indicates that no provider of services shall engage in the provision of addiction services without an operating certificate issued by the Commissioner.
- (l) Section 492 of the Social Services Law established the Vulnerable Persons' Central Register.
- (m) The Protection of People with Special Needs Act (chapter 501 of the Laws of 2012) established the Justice Center for the Protection of People with Special Needs.
- (n) Section 32.06 of the MHL prohibits the offering or acceptance of a payment, benefit or consideration in any form, in exchange for the referral of any person as a potential patient for substance use disorder services.
- (o) Article 15 of the Executive Law enacts the Human Rights Law prohibiting discrimination against protected classes of New Yorkers including on the basis of sexual orientation and gender identity or expression.
- 2. <u>Legislative Objectives</u>: The legislature has authorized OASAS to establish standards and regulations governing the provision of addiction services, including the provision of medications for addiction treatment, as well as standards for providers seeking to offer such services. Additionally, OASAS is tasked with the responsibility of ensuring that the personal and civil rights of persons receiving care, treatment and rehabilitation are adequately protected.
- 3. <u>Needs and Benefits:</u> Proposed amendments to Part 815 include updates to definitions and language used by all OASAS programs consistent with continued efforts and agency goals to reduce stigma and use person-first language for the delivery of addiction services. Additionally, provisions for medication for addiction treatment for substance use disorder are further clarified consistent with guidance issued by the Office and the medical standard of care for the treatment of substance use disorder. These amendments support OASAS overarching goals to ensure programs are responsive to community needs and provide person-centered care.

Furthermore, the ability for OASAS certified programs to conduct body cavity searches are prohibited in all circumstances. OASAS has guidance for providers for recommended alternatives when a body cavity search may have otherwise been considered. OASAS, pursuant to mental hygiene law, is tasked with the responsibility of ensuring that the personal and civil rights of persons receiving care, treatment and rehabilitation are adequately protected.

4. <u>Costs:</u> No additional administrative costs to the State, local government or agency are anticipated. The requirements outlined in the regulation are already required in guidance (both for medication access and naloxone education and access) and in the standard of care for the treatment of substance use disorder.

Programs which formerly utilized body cavity searches in their patient search procedures will need to update their policies in accordance with this regulation as body cavity searches are explicitly prohibited.

- 5. <u>Paperwork:</u> There is no additional paperwork beyond what is already required. OASAS programs are required to review and update policies and procedures to ensure compliance with OASAS regulations and guidance and evolving standards of care for the treatment of substance use disorder and problem gambling. Some programs will be expected to enter into agreements with Opioid Treatment Programs, which should not be difficult as many providers currently have agreements to facilitate linkage between different levels of care.
- 6. Local Government Mandates: There are no new local government mandates.
- 7. <u>Duplications</u>: This proposed rule does not duplicate, overlap, or conflict with any State or federal statute or rule.
- 8. <u>Alternatives</u>: The alternative is to leave the regulation as it currently reads, with language inconsistent across Title 14 regulations and providers unsure of their obligation to provide medication for addiction treatment for substance use disorders. Additionally, body cavity searches, which have no therapeutic value, are permissible until such time as the regulation is updated.
- 9. Federal Standards: This regulation does not conflict with federal standards.
- 10. <u>Compliance Schedule:</u> This rulemaking will be effective upon publication of a Notice of Adoption in the *State Register*.

PART 815 PATIENT RIGHTS

(Statutory Authority: Mental Hygiene Law, §§ 19.07(c) and (e), 19.09(b), 19.20, 19.20-a, 19.21(b), 22.03, 22.07, 32.01, 32.07(a), 32.05; Social Services Law § 492; Protection of People with Special Needs Act (Chapter 501 of the Laws of 2012; Article 15 of the Executive Law))

Sec.

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Section 815.1 Background and intent.

This Part sets forth minimum standards to protect patient rights. For purposes of this Part, a patient is a person receiving services from a provider certified, funded or otherwise authorized by the Office. The term "patient" as used in this Part includes, but is not limited to, terms such as "client", "resident", "consumer", "customer", "participant" or such other term which applies to a current or former service recipient. All services shall be provided in a manner that is strength-based, person centered and trauma informed.

815.2 Legal base.

- (a) Section 19.07(c) of the Mental Hygiene Law ("MHL") charges the Commissioner ("Commissioner") of the New York State Office of <u>Addiction Services and Supports [Alcoholism and Substance Abuse Services]</u> ("the Office") with the responsibility of ensuring that the personal and civil rights of persons receiving care, treatment and rehabilitation are adequately protected.
- (b) Section 19.07(e) of the MHL authorizes the Commissioner to adopt standards including necessary rules and regulations pertaining to [ehemical dependence] addiction 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 19.20 of the MHL authorizes the Office to receive and review criminal history information from the Justice Center related to employees or volunteers of treatment facilities certified, licensed, funded or operated by the Office.
- (e) Section 19.20-a of the MHL authorizes the Office to receive and review criminal history information from the Justice Center related to persons seeking to be credentialed by the Office or applicants for an operating certificate issued by the Office.
- (f) Section 19.21(b) of the MHL authorizes the Commissioner to adopt regulations concerning the licensing, certification, inspection, and treatment standards of all facilities that **provide addiction services** [treat alcoholism and substance dependency].
- (g) Section 22.03 of the MHL requires the director of any [chemical dependency] addiction services program to establish, communicate and post patient rights, to include information about how to communicate with the Office and the Commissioner.
- (h) Section 22.07(c) of the MHL authorizes the Commissioner to adopt rules and regulations and take any other necessary action to ensure that the rights of individuals who have received or are receiving [ehemical dependence]addiction 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 32.07(a) of the MHL authorizes the Commissioner to adopt regulations to effectuate the provisions and purposes of Article 32 of the MHL.
- (k) Section 32.05 of the MHL indicates that no provider of services shall engage in <u>the provision of</u>

 <u>addiction services[any chemical dependence treatment activities]</u> without an operating certificate issued by the Commissioner.
- (1) Section 492 of the Social Services Law established the Vulnerable Persons' Central Register.
- (m) The Protection of People with Special Needs Act (chapter 501 of the Laws of 2012) established the Justice Center for the Protection of People with Special Needs.
- (n) Section 32.06 of the MHL prohibits the offering or acceptance of a payment, benefit or consideration in any form, in exchange for the referral of any person as a potential patient for substance use disorder services.

(o) Article 15 of the Executive Law enacts the Human Rights Law prohibiting discrimination against protected classes of New Yorkers including on the basis of sexual orientation and gender identity or expression.

815.3 Applicability.

This Part applies to any provider currently certified, funded or otherwise authorized by OASAS to provide addiction services.

815.4 Provider requirements.

- (a) The facility or provider agency as program sponsor shall establish policies and procedures to protect patient rights. Such policies and procedures shall be consistent with the requirements of the program's operating certificate, including, but not limited to:
- (1) standards governing staff conduct to ensure the protection of patient rights and to ensure the communication of such standards, rights and responsibilities to patients. When communicating, providers shall make every effort to accommodate patient differences in language and <u>language abilities</u> [disabilities] in accordance with applicable law.
- (2) Copies of a statement of the rights and responsibilities of patients shall be posted prominently and conspicuously throughout the provider's facility. This statement, at a minimum, shall include the requirements of sections 815.5 and 815.6 of this Part. Such postings shall also include contact information for the toll-free hotline to the Vulnerable Persons' Central Register, the provider's director, [as] the Commissioner, the Office patient advocate, and the Office toll-free telephone number.
- (3) The postings shall include the policy and procedures for addressing patient concerns or grievances with the provider and/or the Office. Such policy shall include, at a minimum, the following rights:
 - (i) to question a policy, voice a concern or grievance with the provider or the Office;
 - (ii) to receive a timely response and/or resolution;
 - (iii) to not suffer adverse consequences or retaliation as a result; and
- (iv) to communicate with the provider's director, medical director, board of directors, other responsible staff and the Commissioner.

- (4) A copy of this Part, and any other Part of Title 14 that is applicable to the provider, shall be provided to a patient upon request.
- (5) The provider shall develop policies and procedures to help patients follow their treatment/recovery plan. Such policies and procedures shall specify standards and expectations for patient conduct, <u>including</u> <u>conduct that may result in discharge</u>, [to-]achieve<u>ment of</u> goals consistent with the plan, and <u>procedures for reevaluating and revising the treatment plan when goals are not met.[consequences for failing to meet goals, including conduct which may result in discharge.] Policies and procedures shall, at a minimum, address patient conduct with timely [and appropriate] incremental interventions <u>that are strength-based, trauma-informed and</u> designed to assist patients in responding positively to treatment. Such incremental interventions shall be incorporated and delivered consistent with the patient's treatment/recovery plan; be time-limited, and documented in the patient's record. When a patient poses an imminent threat to others, immediate discharge may be warranted consistent with other provisions of this Part.</u>
- (6) The provider shall establish a policy and procedure for implementing quality improvements with respect to patient concerns and complaints, changes in regulatory requirements, or other factors, and shall review such policies no less frequently than once every two years. Documentation shall be kept of all such reviews.
- (b) Upon admission, each patient shall be given a written copy of provider services, including onsite and referral service, and <u>the</u> policy relating to the rights and responsibilities of the patient and the provider, and other provider rules and requirements. The patient shall acknowledge in writing the provision and understanding of these documents, and such attestation shall be kept in the patient's record. Patients shall be informed that if they wish to express a concern or grievance, they will be provided documents to initiate such grievance and resolution process upon request.
- (c) The provider shall make every effort to accommodate <u>patient differences in language and language</u>

 <u>abilities</u> and ensure effective communication [with patient language differences and/or disabilities] in accord<u>ance</u> with applicable law.
- (d) A patient's rights as a citizen of the United States or as a resident of the State of New York shall not be forfeited or abridged because of such patient's participation in addiction services as defined in Part 800 of this Title.

- (e) The provider shall comply with the federal confidentiality regulations at 42 Code of Federal Regulations (CFR) Part 2, the Health Insurance Portability and Accountability Act ("HIPAA"), the Public Health Law, and all other applicable law. At the time of admission, the provider shall inform each patient that federal and state law protects the confidentiality of all records of identity, diagnosis, prognosis, or treatment in connection with a person's attendance, participation, or receipt of addiction services. Such information shall be released only in accordance with applicable provisions of federal and state law.
- (f) The provider shall establish a policy and procedure for patient discharge pursuant to section 815.7 of this Part. Discharge decisions and appeal results shall be recorded, reviewed and incorporated into the provider's quality review and improvement process.
- (g) Participation in addiction services is voluntary and no provider shall force or coerce any person to enter or remain in any service. All patients shall be informed prior to admission that their participation is voluntary and that they are entitled to terminate their participation at any time. Providers may make <u>mutual</u> <u>help or</u> [anonymous] support-group services available to patients but shall not compel attendance. A patient's <u>inability [failure]</u> to complete treatment required by <u>a</u> judicial or child welfare mandate may have legal consequences to the patient under the terms of such mandate but, nevertheless, treatment remains voluntary.
- (h) The delivery and receipt of emergency <u>substance use disorder</u> [ehemical dependence] services for incapacitated persons shall be governed by Mental Hygiene Law section 22.09.
- (i) When admitting a patient to a facility or provider agency, the provider shall not add admission criteria not required by regulation, including, but not limited to, residency, **specific identification requirements** and/or citizenship status. Applicants not admitted to the program shall be given information concerning other service providers which can more appropriately meet the needs of the **patient** [individual] and, if clinically necessary, a referral and connection shall be made on the patient's behalf.
- (j) Office funded service providers must use a sliding scale when evaluating a self-pay patient that considers the patient's ability to pay. Admission to an Office funded provider agency may not be conditioned upon a patient's ability or inability to pay.
- (k) Providers shall [strictly] adhere strictly to the Confidentiality requirements of 42 CFR Part 2, and shall make each release form signed by a patient as specific as possible so as to ensure that clients are fully aware of who is receiving the information. Additionally, providers shall have a policy that ensures an end date to all release of confidential information forms. Copies of records shall be given to a patient or former patient

upon request, in accordance with applicable law, regulations, and the program's procedures, within fifteen (15) calendar days of a request.

- (l) The provider shall admit and treat minors in accordance with the requirements of Mental Hygiene Law section 22.11.
- (m) The provider shall establish guidelines to ensure that patients at inpatient and residential facilities may correspond, have reasonable access to telephones, and have regularly scheduled opportunities to meet with visitors consistent with treatment needs. Patient correspondence addressed to, or from, the Office, public officials, attorneys, and clergy shall be unrestricted and shall be forwarded promptly without being opened or read by provider staff.
- (n) The provider director or their designee may take temporary custody of a patient's personal property with the patient's written permission. Personal property retained by the provider shall, at the patient's direction, be returned to the patient when the patient leaves the service, sent to an address designated by the patient at the patient's expense, or donated to the provider. All property left by a patient will be disposed of as abandoned property within thirty (30) days, or in accordance with applicable law. Any interest on money received and held for a patient shall be the property of the individual patient and shall not accrue for the benefit of the provider or for the general welfare of all patients in a facility. A provider who serves as [which is] a representative payee for a patient pursuant to designation by a governmental entity or [which] assumes management responsibility over the funds of a patient shall maintain such funds in a fiduciary capacity to the patient.
- (o) The provider may submit reports or information to criminal justice entities regarding any patient only after receiving a request and executing a proper consent. Such reports shall be limited to only treatment or clinical information about the patient that is sufficient to satisfy the request, consistent with applicable law, and shall not contain any recommendation or suggestion of any legal action or consequence, such as: court intervention; remand; custody; violation; or incarceration.
- (p) Providers shall not offer or accept payment, benefit, or other consideration in any form, in exchange for the referral of any person as a potential patient for substance use disorder services and shall not advertise, or otherwise solicit patients, in false, deceptive or misleading ways.
- (q) Providers shall develop and implement policies and procedures consistent with the requirements for hiring and training all custodians, as such term is defined in Part 836 of this Title. Such procedures shall

include, but not be limited to, receipt of signed attestations that such custodian has been notified of, and understands, their obligations pursuant to chapter 501 of the Laws of 2012 and Justice Center regulations and that such custodian shall abide by the Code of Conduct for custodians as established by the Justice Center for the Protection of People with Special Needs; and provider's obligation to cooperate with any investigation of a custodian regarding a reportable or significant incident by the Justice Center as an agent of the Office.

- (r) Providers shall develop and implement policies and procedures to ensure the provision of culturally [competent]appropriate and affirming services for patients, including but not limited to, [consistent with their] sexual orientation and gender identity or expression.
- (s) Providers shall develop and implement policies and procedures to ensure access to approved medications for substance use disorder treatment as follows and in accordance with guidance issued by the Office:
 - (1) Medication for Addiction Treatment (MAT) for Substance Use Disorder:
- (i) Providers 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 the patient's consent, in accordance with federal and state rules and guidance issued by the Office. Such contact with the existing program or practitioner prescribing such medications shall be documented in the patient record.
 - (ii) 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, providers 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.

- (iii) Providers 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.
- (iv) Providers shall provide education to an existing patient or prospective patient with substance use disorder about FDA 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.
- (v) Providers shall ensure that the patient's discharge plan includes an appointment with a treatment provider or program that can continue the medication post-discharge.
 - (3) Overdose Prevention Education.
 - (i) Providers shall offer overdose prevention education and naloxone education and training to a patient, prospective patient, and/or their significant other(s), in accordance with guidance issued by the Office.
 - (ii) Providers shall offer a naloxone kit or prescription to patients, prospective patients, and/or their significant other(s), in accordance with guidance issued by the Office.
- (t) Providers shall document all formal agreements with Opioid Treatment Programs to facilitate patient access to opioid full agonist medication, where appropriate, and consistent with state and federal rules and guidance issued by the Office.

815.5 Patient rights.

- (a) Each patient has the following rights:
- (1) to receive services responsive to individual needs in accordance with an individualized treatment/recovery plan, which the patient helps develop and periodically update;

- (2) to receive services from provider staff who are competent, respectful of patient dignity and personal integrity, and in sufficient numbers to deliver needed services consistent with the requirements of the provider's operating certificate;
- (3) to receive services in a therapeutic environment that is safe, sanitary, and free from the presence of addictive substances;
- (4) to know the name, position, and function of any person providing treatment to the patient, and to communicate with the provider director, medical director, board of directors, other responsible staff or the Commissioner;
- (5) to receive information concerning treatment, such as diagnosis, condition or prognosis in understandable terms, and to receive services requiring a medical order only after such order is executed by <u>a</u> medical provider working within their scope of practice; [an appropriate medical professional;]
- (6) to receive information about provider services available on site or through referral, and how to access such services:
- (7) to receive a prompt and reasonable response to requests for provider services, or a stated future time to receive such services in accordance with an individual treatment/recovery plan;
- (8) to be informed of and to understand the standards that apply to their conduct, to receive timely warnings for conduct that could lead to discharge and to receive incremental interventions **that are strength-based**, **person centered and trauma-informed** for conduct contrary to program rules;
- (9) to receive in writing the reasons for a recommendation of discharge and to be informed of the process to appeal such discharge recommendation;
- (10) to voice a grievance, file a complaint, or recommend a change in procedure or service to provider staff and/or the Office, free from intimidation, reprisal or threat;
- (11) to examine, obtain a receipt, and receive an explanation of provider bills, charges, and payments, regardless of payment source;
 - (12) to receive a copy of the patient's records for a reasonable fee;
 - (13) to be free from physical, verbal or psychological abuse;
- (14) to be treated by provider staff who are <u>not under the influence of substances that would impair</u> their ability to perform the duties stated in their job description; [free from chemical dependence;]

- (15) to be free from any staff or patient coercion, undue influence, intimate relationships and personal financial transactions;
- (16) to be free from performing labor or personal services solely for provider or staff benefit, that are not consistent with treatment goals, and to receive compensation for any labor or employment services in accordance with applicable state and federal law; and
 - (17) the following rights apply to patients who reside in an inpatient/residential setting:
- (i) to practice religion in a reasonable manner not inconsistent with treatment/recovery plans or goals and/or have access to spiritual counseling if available;
 - (ii) to communicate with outside persons in accordance with the individualized treatment/recovery plan;
- (iii) to [freely] communicate freely with the Office, public officials, clergy, [and] attorneys and other persons identified by the patient;
- (iv) to receive visitors at reasonable times in relative privacy in accordance with the individualized treatment/recovery plan;
 - (v) to be free from restraint or seclusion;
- (vi) to have a reasonable degree of privacy in living quarters and a reasonable amount of safe personal storage space;
- (vii) to retain ownership of personal belongings, to the extent such belongings are not contrary to program rules; and
 - (viii) to have a balanced and nutritious diet.
- (18) participants referred to a faith-based provider have the right to be given a referral to a non-faith based provider.
- (19) Patients have the right to placement in gender segregated settings based on their gender identity or expression.
- (20) Patients have the right to culturally [competent] appropriate and affirming care and to be free from harassment and/or discrimination in accordance with the factors outlined in paragraph (21) of this subdivision[based on their sexual orientation or their gender identity or expression].
- (21) Prohibition against discrimination in admission. No individual that meets level of care criteria for admission shall be denied admission to any program based solely on the following factors, including but not limited to:

(i) prior treatment history;		
(ii) referral source;		
(iii) pregnancy;		
(iv) history of contact with the criminal justice system;		
(v) HIV 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 substance, including but not limited to, benzodiazepines; or		
(x) use of medications for substance use disorder prescribed and monitored by a appropriate practitioner;		
(xi) actual or perceived gender or gender identity;		
(xii) national origin;		
(xiii) race or ethnicity;		
(xiv) actual or perceived sexual orientation;		
(xv) marital status;		
(xvi) military status;		
(xvii) familial status; or		
(xviii) religion.		
(22) Patients have the following rights with regard to access to medication for addiction treatment:		

(1) Medication for Addiction Treatment (MAT) for Substance Use Disorder.

- (i) Patients have the right to be offered or maintained on all forms of approved medication for substance use disorder treatment when admitted or seeking admission to any Office certified program, in accordance with guidance issued by the Office.
- (ii) Patients have the right to be educated about all forms of FDA approved medications for the treatment of substance use disorders, including the benefits, risks and alternatives.
- (23) Overdose Prevention Education. (i) Patients have the right to receive overdose prevention education and naloxone education and training, and a naloxone kit or prescription, in accordance with guidance issued by the Office.

815.6 Patient responsibilities.

- (a) Participation in treatment for an addiction disorder presumes a patient's continuing desire to acquire healthy habits and requires each patient to act responsibly and cooperatively with provider staff, in accordance with an individual treatment/recovery plan and reasonable provider procedures. Therefore, each patient is expected to:
 - (1) work toward the goal of recovery, as defined by the patient;
 - (2) treat staff and other patients with courtesy and respect;
 - (3) respect other patients' right to confidentiality;
 - (4) participate in developing and following a treatment/recovery plan;
 - (5) become involved in productive activities according to ability;
 - (6) pay for services on a timely basis according to financial means;
- (7) participate in individual counseling and/or group and/or family counseling sessions as appropriate[applicable];
 - (8) inform medical staff if receiving [outside]other medical or psychiatric services;
 - (9) address all personal issues adversely affecting treatment; and
 - (10) act responsibly and observe all provider rules, regulations and policies. [;]
- (b) <u>Addressing</u> [Consequences for] patient non-<u>adherence</u>[compliance]. (1) Provider policies and procedures to address patient non-<u>adherence</u>[compliance] shall be <u>strength-based</u>, <u>trauma-informed and</u> designed to support a patient's positive response to treatment. Such policies and procedures must specify

standards and expectations for patient conduct, and any consequences of non<u>-adherence</u>[compliance], including conduct which may result in treatment termination.

- (2) Providers shall address patient non-<u>adherence</u>[eompliance] with timely and appropriate incremental interventions <u>that are strength-based</u>, <u>person centered</u>, <u>trauma-informed</u>, <u>and</u> designed to assist patients in responding positively to treatment. Such incremental interventions shall be incorporated in the patient's treatment/<u>recovery</u> plan, be time-limited, and be documented in the patient's record.
- (3) No treatment intervention or action can include delay or denial of any clinical, medical, or other required services vital to the health or recovery of the patient.
- (4) Providers shall first warn patients of any conduct that could result in a recommendation of discharge with continued non-<u>adherence</u>[eompliance], and must document such warning(s) in the patient's record.

815.7 Procedure at discharge.

- (a) The director of a facility or service provider shall be responsible for any recommendation to discharge a patient against the patient's wishes. The director or their designee shall implement such recommendations only after the director:
- (1) reviews the recommendation to discharge to ensure that the reason(s) is fair, not arbitrary or capricious, and is serious enough to warrant discharge;
- (2) reviews and evaluates the patient's total response to treatment, in light of the recommendation to discharge;
- (3) confers with staff at a multidisciplinary meeting to discuss the patient's response to treatment and the recommendation to discharge;
- (4) confirms that, within reasonable clinical judgment, all incremental <u>strength-based and trauma-informed</u> interventions have been tried <u>but without success[and failed]</u>, including consideration of transfer to another provider;
- (5) provides a written notice to the patient that indicates the reason(s) for the recommended discharge as well as required information on how to appeal;
- (6) if the patient appeals, meets with the patient to conduct the appeal no sooner than twenty-four (24) hours after provision of the notice, to allow the patient time to seek the advice of others, if desired, and discusses with the patient the reasons to implement or rescind the recommendation to discharge; and

- (7) informs the patient in writing of the decision to implement or rescind the recommendation to discharge no later than seventy-two (72) hours after the appeal is made;
- (i) if discharge is decided after the appeal, assures that the patient receives information about treatment and referral options, and connections to such referrals if desired;
- (ii) if rescission of the discharge is decided after the appeal, assure the patient full opportunity to continue treatment.
- (b) For providers of opioid full agonist medications, no dose taper shall begin until after completion of the aforesaid process and all efforts to transfer the patient to another provider of opioid full agonist medications have been exhausted.
- (c) For inpatient and residential providers, no patient shall be forced to leave the program until after completion of the aforesaid process. No patient shall be forced to leave the program between 6:00 P.M. and 8:00 A.M. unless appropriate arrangements have been made. Safe and appropriate transportation, travel arrangements, and travel costs shall be provided or arranged as needed.
- (d) The patient, and their family/significant other(s) shall be offered <u>overdose prevention education</u>, naloxone education and training and a naloxone kit or prescription.
- (e) None of the foregoing shall apply to an emergency discharge where the <u>patient [individual]</u> is[<u>reasonably</u>] determined <u>reasonably</u> to be a danger to others. A provider may make an emergency discharge immediately upon making such a determination, subject to the patient's right to appeal after the patient is discharged.
- (f) A discharge pursuant to a patient's refusal to consent to a proper request to screen in accordance with section 815.10 of this Part may be made immediately upon the refusal <u>but incremental strength-based and trauma informed interventions should be employed before a patient is discharged for the refusal</u>, subject to the patient's right to appeal after the patient is discharged.
- (g) All of the foregoing must be documented in the patient's record.

815.8 [Drug] Toxicology testing.

(a) The provider may administer <u>toxicology</u> tests to a patient to ascertain the use and/or presence of alcohol and/or other drugs, in accord<u>ance</u> with program policies for screening, applicable regulations, clinical judgment, **guidance issued by the Office** and mindful of patient dignity. The provider shall inform a patient of

each result and document all results in the patient's record. Supervised collection of a urine toxicology screen may only be conducted by persons of the same gender, or gender identity, as the patient. [Drug]Toxicology testing may not be used by a provider as a punitive tool.

(b) The provider must conduct such tests with reliable testing devices and administer such tests in accordance with manufacturer instructions and in compliance with all Department of Health requirements.

815.9 Patient use of prescription medicine.

- (a) Patients have the right to use lawfully prescribed and properly monitored medication, including controlled substances, from a duly-authorized medical practitioner(s). For all such patients:
- (1) The provider shall document the medication name, purpose, and administration frequency as well as the prescribing practitioner's name, phone number and, if applicable, affiliation;
- (2) The provider shall seek to obtain a proper consent from the patient, in accord with 42 CFR Part 2, so that the provider practitioner may consult with the prescribing practitioner and discuss:
 - (i) the patient's [total] medical condition(s) [and situation];
 - (ii) the prescribed medication(s)[ine], and available alternatives;
 - (iii) the best plan of services to be rendered by each practitioner, given the patient's concurrent treatment.
- (3) If the patient refuses to consent or if the practitioners cannot agree on concurrent treatment, the provider practitioner shall discuss with the patient the [probable]possible risks [and consequences] of continued concurrent treatment. If refusal to consent continues or if the patient opts to continue taking the prescribed medicine in light of the explained [probable consequences]possible risks, the provider may consider a recommendation for referral and connection to a more appropriate program.
- (b) Inpatient and residential providers shall develop policies and procedures governing the handling and storage of patients' medications, including controlled substances, in accordance with applicable law regulations and guidance issued by the Office. For such providers to take custody of such medicines lawfully, the provider must register with the New York State Department of Health as an Institutional Dispenser in accordance with the requirements of 10 NYCRR Part 80 and follow all applicable rules relating to storage of such medication.

(c) The provider shall not offer or withhold medical or pharmacological services, including prescribed medicines, for any reason other than medical necessity. The provider shall not delay, postpone, or withhold any prescribed medicine for a patient's non-adherence[compliance] with a program rule, policy, or procedure. Only duly-authorized medical staff may deliver medical services and/or administer prescribed medicines.

815.10 Patient screening.

- (a) The purpose of screening is to ensure a safe and therapeutic environment for all patients. However, patients shall be free from screening except as authorized pursuant to this section.
- (b) Subject to the following requirements, a provider may choose to screen patients by establishing written policies and procedures provided to each patient at admission. Such policies may include the following:
- (1) Routine screens of patients at admission or when returning to the service are permitted. Routine screening does not involve any physical contact between patient and staff; it does not involve having the patient remove all clothing; and the patient must consent to routine screening by the program. [consent for routine screening may be requested by a program and granted upon admission.]
- (2) Screening of a patient's room or a patient's belongings may be conducted at any time with reasonable cause; consent for room screening may be requested by a program and granted upon admission.
- (c) When a provider suspects that a patient may have items that may create an unsafe environment in the program, in lieu of a search that requires the patient to remove all clothing, or a body cavity search which is not permissible under any circumstances, providers should arrange for and have policies in place for extended close observation, in accordance with guidance issued by the Office.
- [(c) Under extenuating circumstances a provider may elect to conduct a body cavity search of a patient. Such a search must be:
- (1) based upon a good faith suspicion that the patient is harboring contraband;
- (2) authorized by the program director;
- (3) at the consent of the patient; and
- (4) conducted only by a member of the provider's medical staff. If the provider does not employ medical staff, the provider must utilize a physician, nurse practitioner, registered physician's assistant, registered nurse, or licensed practical nurse to conduct the search.

- (d) Any body-cavity search must be reported as a significant incident consistent with the requirements of Part 836 of this Title.]
- ([e]d) If a patient refuses to consent to <u>extended close observation they</u> [a proper request to conduct a screen or body cavity search, he or she] may be discharged in accordance with this Part.
- ([f]e) All [eontraband] items that may create an unsafe environment in the program must be disposed of in accordance with the applicable law including but not limited to 10 NYCRR Part 80.51, and 21 CFR Part 1307.21.

815.11 Research subjects.

- (a) A person may participate only in research which does not conflict with their individual treatment/recovery plan. Participation as a "subject at risk" in any research project or activity shall not deprive any patient of the rights, privileges, and protections provided to all patients by this Part. "Subject at risk" means any individual who may be exposed to the possibility of injury, including physical, psychological or social injury, as a consequence of participation as a subject in any research, development or related activity which departs from the application of those established and accepted methods necessary to meet their needs or which increases the risks of daily life. The research project or activity must be approved by an independent institutional review board and the approval kept on file.
- (b) Participation in any research project or activity and informed written consent.
- (1) The informed written consent of a patient who participates as a subject at risk in any human subjects' research project shall be obtained in accordance with 45 Code of Federal Regulations Part 46.
- (2) Prior to seeking consent required above, approval of any research placing human subjects at risk must be secured in accordance with 45 Code of Federal Regulations Part 46.
- (3) Research projects which involve placing patients <u>admitted to or enrolled in an [of a]</u> addiction service[s] at risk must be reported to the Office prior to initiation of the project.

815.12 Staff and client relationships

(a) Sexual contact prohibited. All sexual contact between OASAS program staff and a client is sexual abuse.

- (b) Sexual contact includes inappropriate touching, indecent exposure, sexual assault, taking or distributing sexually explicit pictures, voyeurism or other sexual exploitation.
- (c) A client is incapable of consenting to sexual contact if they are admitted to a program funded, certified or otherwise authorized by the Office.
- (d) All staff shall be regularly trained on and be provided with supervision about maintaining appropriate boundaries with clients.

815.13 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 provision or applications of this Part which can be given effect without the invalid provision or applications, and to this end the provisions of this Part are declared to be severable.



KATHY HOCHUL Governor CHINAZO CUNNINGHAM, MD Commissioner

Notice of Proposed Rulemaking Summary

Amend PART 816

SUBSTANCE USE DISORDER WITHDRAWAL AND STABILIZATION SERVICES

In addition to technical amendments updating this regulation consistent with Title 14, the Proposed Rule amends Part 816 as follows:

- §816.1 Background and intent. OASAS is removing the certification for medically monitored withdrawal and stabilization services and clarifying expectations, which are already included in guidance, for linkages to supportive services and other levels of care and the delivery of person centered, trauma informed services.
- §816.4 Definitions. Updates various definitions. Clarifies that detox services may be under the supervision of a nurse practitioner consistent with federal authority. Eliminates the definition for medically monitored withdrawal and stabilization services.
- §816.5 Standards applicable to all withdrawal and stabilization services. Various updates consistent with appropriate use of person-first terminology and consistent with other regulations. Clarification on the expectations regarding provision of medication for addiction treatment for substance use disorder. Reference added to current guidance on withdrawal and stabilization protocol guidance issued by the Office. Reference to psychosocial treatment requirements and prenatal care for pregnant persons for providers of these services.
- §816.7 Additional requirements for medically supervised inpatient withdrawal and stabilization services. Updates the qualifications on who may be a program director for this service.
- §816.8 Additional requirements for medically supervised outpatient withdrawal and stabilization services. Updates the qualifications on who may be a program director for this service. Removes the counselor ratio and instead references adequacy based on program objectives and outcomes.
- §816.9 Additional requirements for medically monitored services. This section is deleted.

§816.10 Standards pertaining to Medicaid reimbursement. Provisions updated to include mandate that programs deliver services consistent with this Part and Part 841 of this Title.

§816.11 Savings and renewal clause. Provision eliminated.





Notice of Proposed Rulemaking Regulatory Impact Statement

Amend PART 816

SUBSTANCE USE DISORDER WITHDRAWAL AND STABILIZATION SERVICES

1. Statutory Authority:

- (a) Section 19.09 of the Mental Hygiene Law authorizes the Commissioner to adopt regulations necessary and proper to implement any matter under their jurisdiction.
- (b) Section 19.15 of the Mental Hygiene Law bestows upon the Commissioner the responsibility of promoting, establishing, coordinating, and conducting programs for the prevention, diagnosis, treatment, aftercare, rehabilitation, and control in the field of substance use disorder.
- (c) Section 19.40 of the Mental Hygiene Law authorizes the Commissioner to issue operating certificates for the provision of substance use disorder services.
- (d) Section 22.09 of the Mental Hygiene Law directs the Commissioner to designate hospitals and other appropriate facilities as providers of emergency detoxification and stabilization services for persons needing or seeking emergency treatment.
- 2. <u>Legislative Objectives</u>: The legislature has authorized OASAS to establish standards and regulations governing the provision of addiction services, including the provision of medications for addiction treatment, as well as standards for providers seeking to offer such services.
- 3. <u>Needs and Benefits:</u> OASAS is updating the language used in this regulation consistent with amendments made to other OASAS regulations to clarify provider requirements with respect to the provision of medication for addiction treatment for substance use disorder and to update definitions consistent with other OASAS regulations. This level of service is very medically focused and is applicable to both hospital and community-

based detox programs. Provisions include reference to all appropriate medical, psychiatric and substance use protocols consistent with the medical standards of care and OASAS guidance and withdrawal protocols.

- 4. Costs: No additional administrative costs to the agency are anticipated.
- 5. Paperwork: There is no additional paperwork beyond what is already required.
- 6. <u>Local Government Mandates</u>: There are no new local government mandates.
- 7. <u>Duplications</u>: This proposed rule does not duplicate, overlap, or conflict with any State or federal statute or rule.
- 8. <u>Alternatives:</u> The alternative is to leave the regulation as it currently reads, with language inconsistent across Title 14 regulations and providers unsure of their obligation to provide medication for addiction treatment for substance use disorders. Additionally, while withdrawal protocols are included in guidance issued by the agency, the obvious preference for program operation is to identify such protocols in the regulation.
- 9. Federal Standards: This regulation does not conflict with federal standards.
- 10. <u>Compliance Schedule:</u> This rulemaking will be effective upon publication of a Notice of Adoption in the *State Register*.

PART 816 SUBSTANCE USE DISORDER WITHDRAWAL AND STABILIZATION SERVICES

(Statutory Authority: Mental Hygiene Law Sections 19.09, 19.15, 19.40, 22.09)

Sec.	
816.1	Background and intent
816.2	Legal base
816.3	Applicability
816.4	Definitions
816.5	[Standards applicable to all withdrawal and stabilization services]General
	program standards
816.6	Additional requirements for medically managed withdrawal and stabilization
	services
816.7	Additional requirements for medically supervised inpatient withdrawal and
	stabilization services
816.8	Additional requirements for medically supervised outpatient withdrawal and
	stabilization services
816.9	[Additional requirements for medically monitored withdrawal and stabilization
	services
816.10]	Standards pertaining to Medicaid reimbursement
816.1 <u>0</u> [1]	Savings and renewal clause
816.1 <u>1[2]</u>	Severability

Section 816.1 Background and intent.

- (a) These regulations set forth minimum standards for the provision of withdrawal and stabilization services for persons suffering from acute or crisis stages of substance use disorder.
- (b) The primary function of a withdrawal and stabilization service is the medical management and treatment of acute withdrawal, resulting in a referral to an appropriate level of [longer term] care. Certified providers of withdrawal and stabilization services may provide one or more of the following services as further defined in this Part:
 - (1) medically managed withdrawal and stabilization services;
 - (2) medically supervised inpatient withdrawal and stabilization services; and/or
 - (3) medically supervised outpatient withdrawal and stabilization services[; and/or
 - (4) medically monitored withdrawal and stabilization services].
- (c) Withdrawal and stabilization services can be the first step in the recovery process and must be provided in an atmosphere which protects the patient's dignity. Therefore, it is expected

that providers of withdrawal and stabilization services will establish meaningful linkages for supporting services, including appointments for admission, linkages to supportive services and those services identified by use of an Office designated level of care determination tool for the appropriate level of care [to the next appropriate level of care]. All services shall be provided in a manner that is person centered, strength based and trauma informed.

816.2 Legal base.

- (a) Section 19.09 of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to adopt regulations necessary and proper to implement any matter under their jurisdiction.
- (b) Section 19.15 of the Mental Hygiene Law bestows upon the Commissioner [of such Office] the responsibility of promoting, establishing, coordinating, and conducting programs for the prevention, diagnosis, treatment, aftercare, rehabilitation, and control in the field of substance use disorder.
- (c) Section 19.40 of the Mental Hygiene Law authorizes the Commissioner [of such Office] to issue operating certificates for the provision of [chemical dependence] substance use disorder services.
- (d) Section 22.09 of the Mental Hygiene Law directs the Commissioner [of such Office] to designate hospitals and other appropriate facilities as providers of emergency detoxification and stabilization services for persons needing or seeking emergency treatment.

816.3 Applicability.

- (a) This Part applies to any person or entity organized and operating pursuant to the provisions of this Title and certified, funded or otherwise authorized by the Office to provide a substance use disorder withdrawal and stabilization service.
- (b) Nothing in this Part shall be construed to limit the authority of a hospital licensed pursuant to Article 28 of the Public Health Law to provide detoxification and stabilization in a medical/surgical bed or emergency room.

816.4 Definitions.

- (a) "Detoxification" or "detox" means a medical withdrawal and stabilization regimen under the supervision of a physician <u>or nurse practitioner</u>, <u>consistent with federal authority</u>, to [systematically] reduce <u>systematically</u> the amount of an addictive substance <u>on which the</u> <u>patient is physiologically dependent [in a patient's body</u>], provide reasonable control of active withdrawal symptoms and/or avert a life-threatening medical crisis related to the [addictive] substance <u>on which the patient is physiologically dependent</u>.
- (b) "Discrete unit" means an OASAS program certified pursuant to Article 32 of the Mental Hygiene Law providing inpatient or outpatient substance use disorder treatment co-located in a facility licensed pursuant to Article 28 of the Public Health Law because such facility is providing treatment due to a consistent demand exceeding five (5) medical-surgical beds, or greater than 10% of overall patient days.
- (c) "Medically managed[2] withdrawal and stabilization services" are 24/7 services designed for individuals who are acutely ill from alcohol and/or substance related addictions or dependence, including the need for medical management of persons with severe withdrawal or risk of severe withdrawal symptoms, and may include individuals with or at risk of acute physical or psychiatric co-occurring conditions. This level of care includes the forty-eight (48) hour observation bed. Individuals who have stabilized in a medically managed detoxification service may transition to a medically supervised service within the same service setting or may be transferred to another service setting. [means 24/7 services designed for patients acutely ill from substance related dependence, experiencing severe withdrawal, or at risk of such conditions. This level of care includes the forty-eight (48) hour observation bed. Patients stabilized in a medically managed service may transition to a less intensive medically supervised inpatient service, a medically supervised outpatient service, or other appropriate level of care.]
- (d) "Medically supervised["]inpatient withdrawal and stabilization services" means services for the treatment of moderate withdrawal symptoms and non-acute physical or psychiatric complications. This service is physician directed and staffed 24/7 with medical staff and includes twenty-four (24) hour emergency medical coverage. Medically supervised withdrawal and stabilization services are appropriate for persons who are intoxicated by alcohol and/or substances, who are experiencing or who are expected to experience withdrawal symptoms that require medical oversight. Individuals who have

stabilized in a medically managed or medically supervised inpatient withdrawal service
may transition to a medically supervised outpatient service. [are appropriate for persons
suffering from mild to moderate withdrawal, coupled with situational crisis such as unstable
living environments, or who are unable to detox on their own without withdrawal complications.
Patients stabilized in a medically supervised service may transition to a less intensive medically
supervised outpatient service or other appropriate level of care.]

- (e) "Medically supervised outpatient" means services appropriate for persons who are suffering from mild to moderate withdrawal or persons experiencing non-acute physical or psychiatric complications associated with their substance use disorder and who are unable to detox on their own without withdrawal complications, but who retain a stable living environment.
- (f) ["Medically monitored" withdrawal and stabilization services are appropriate for persons who are suffering from mild withdrawal coupled with situational crises, or who are unable to detox on their own without withdrawal complications. Patients stabilized in medically managed or medically supervised services may transition to this service.
- (g) "Observation bed" means a service providing intensive assessment and treatment of withdrawal where the patient has continuous periodic evaluation for up to forty-eight (48) hours. The care given in an observation bed is a medically managed level of care.

816.5 Standards applicable to all withdrawal and stabilization services.

- (a) <u>Services applicable to all levels of care.</u> <u>Medically supervised withdrawal services</u> provide assessment, medical supervision of intoxication and withdrawal conditions, pharmacological services, individual and group counseling, level of care determination, and referral to other appropriate services.
- (b) Screening, linkages and referral. (1) All providers of withdrawal and stabilization services must provide onsite medical, mental health and substance use disorder services as well as screening, linkages and referral to other [appropriate]specialized providers of physical and behavioral health services if such services cannot be provided by the withdrawal and stabilization program.
- (2) All providers must develop referral sources and keep updated lists of regional programs which provide treatment and recovery services at all levels of care.

- (3) All providers must provide screening and referral for specialized physical conditions and/or mental health conditions.
- (4) All providers shall provide overdose prevention education and naloxone education and training to a patient or prospective patient, and their significant other(s), in accordance with guidance issued by the Office. Providers shall make a naloxone kit or prescription available to all patients or prospective patients.
- (c)[(b)] Policies and procedures. [(1)] The program sponsor must approve written policies, procedures and methods governing the provision of services in compliance with Office regulations and guidance, including a description of each service provided. [Providers of withdrawal and stabilization services must develop and implement written policies and procedures approved by the program sponsor]. Such policies and procedures must include, at a minimum, the following:
- (1) procedures and specific criteria for admission, retention, level of care transition(s), referrals and discharge;
- (2) level of care determinations utilizing a tool approved by OASAS to determine the appropriate level of care, treatment/recovery plans, and placement services;
- (3) staffing for sufficient coverage and task designation; at least 50% of all clinical staff must be qualified health professionals as defined in Part 800 of this Title;
- (4) the provision of medical services, including screening and referral for associated physical conditions;
- (5) the provision of mental health services, including the use of OASAS approved, validated screening instruments for co-occurring mental health conditions and behavioral health risks, including suicide risk, and referral for associated mental health conditions;
- (6) the provision of evidence-based SUD treatment services that are personcentered, strength-based and trauma-informed;
- (7) procedures for the coordination of care with other service providers including transfers, emergency care and transport;
 - (8) a schedule of fees for services rendered;
 - (9) infection control procedures;
- (10) cooperative agreements with other SUD treatment service providers or other providers of services that a patient may need;

- (11) 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 tuberculosis, viral hepatitis, sexually transmitted infections and HIV; regarding HIV, such education, counseling, prevention and treatment shall include condom use, testing, pre- and post-exposure prophylaxis and treatment;
 - (ii) the use toxicology tests consistent with OASAS guidance;
 - (iii) medication and the use of medication for addiction treatment;
- (iv) medication policies must ensure the appropriate continuation of medically appropriate and lawfully prescribed medication(s) taken by the patient prior to admission;
- (12) record keeping procedures which ensure that documentation is accurate, timely, prepared by appropriate staff, and in conformance with state and federal confidentially rules including 42 CFR Part 2;
- (13) utilization review and quality improvement. All programs must have a utilization review process, a quality improvement process, and a written plan that identifies key performance measures;
 - (14) medical and nursing procedures consistent with professional practice;
- (15) pharmacological services including storage and dispensing of medication pursuant to applicable state and federal regulations;
- (16) laboratory testing protocols, including alcohol screening and toxicology tests, such as breath tests and urine screening;
 - (17) toxicology policy;
 - (18) incident reporting and review in accordance with this Title; and
- (19) screening of patients and visitors and the disposal of any items that create an unsafe environment;
 - (i) programs must implement policies and procedures to prevent and address the presence of items that create an unsafe environment in a manner that is trauma-informed, person-centered, respectful of patient and visitor dignity, and that reasonably balances the well-being of the patients and visitors with contraband with the health and safety of other patients in the program.

- (1) Use of standardized withdrawal evaluation instruments;
- (2) staffing for sufficient coverage and task designation; at lease50% of all clinical staff must be qualified health professionals as defined in Part 800 of this Title;
 - (3) screening and referral for physical conditions and/or mental disabilities;
 - (4) infection control;
- (5) procedures for public health education and screening with regard to tuberculosis, sexually transmitted diseases, hepatitis, and HIV prevention and harm reduction;
- (6) procedures for the coordination of care with other service providers including transfers, emergency care and patient transport;
 - (7) quality assurance and utilization review procedures;
 - (8) medical and nursing procedures consistent with professional practice;
 - (9) admission and planning for level of care transitions;
- (10) pharmacological services including storage and dispensing medication pursuant to applicable state and federal regulations and ensuring appropriate continuation of medications prescribed to the patient prior to admission;
 - (11) laboratory testing protocols;
 - (12) records and reporting;
 - (13) incident reporting
 - (14) screening of patients and visitors and the disposal of contraband;
 - (15) compliance with other applicable federal and state regulations and Office guidance.]
- (d) <u>Medical Protocols for Withdrawal Management.</u> (1) Providers of withdrawal management and stabilization services must develop and implement written withdrawal management and stabilization protocols that are consistent with the following criteria, in accordance with guidance from the Office:
 - (i) objective monitoring;
 - (ii) safety;
 - (iii) involvement of medical professionals;
 - (iv) stabilization on medication for addiction treatment;
 - (v) patient comfort;
 - (vi) level of care assessment; and
 - (vii) transition to continued care.

- (2) Providers of withdrawal management and stabilization services must obtain and maintain approval of medical protocols for withdrawal management from the OASAS Chief Medical Officer (CMO) or CMO designee by attesting that their protocols meet the criteria identified herein and in guidance issued by the Office when seeking new certification for, or continued operation of, withdrawal management and stabilization services.
 - (i) Medical protocols are subject to review at any time by OASAS.
- (ii) Medical protocols not in compliance with this Chapter and guidance issued by the Office and/or do not meet the standard of care for withdrawal management and stabilization services may result in corrective and/or disciplinary action in accordance with this Title.
- [(e)](e) Co-location. Substance use disorder[(1) Chemical dependence] withdrawal and stabilization services may be co-located with other [ehemical dependence] substance use disorder services to ensure improved coordination of care and linkage.
- [(2) Patients enrolled in a medically monitored withdrawal and stabilization service may participate in another level of care if clinically and medically appropriate.]

 [(d)](f) Capacity. Capacity approved by the Office may not be exceeded at any time except with written permission from the Office.
- (g) <u>Emergency medical kit</u>. Each program shall maintain an emergency medical kit in accordance with the provisions of Part 800 and applicable guidance.
- [(e)](h) Admission requirements for all programs. (1) Admission shall be based upon a diagnosis of substance use disorder pursuant to the most recent edition of either the Diagnostic and Statistical Manual of the American Psychiatric Association, or the International Classification of Diseases.
- (2) A level of care determination must be made using the OASAS level of care assessment tool as defined in Part 800 of this Title and documented in the patient record.
- (3) The admission assessment or decision to admit must include identification of initial services needed until the development of the treatment/recovery plan.
- (4) An individual who presents to the withdrawal and stabilization service seeking or having been referred for treatment or assessment shall have an initial determination

made and documented in a written record by a qualified health professional, or other clinical staff under the supervision of a qualified health professional, which states that:

- (i) the individual appears to be in need of withdrawal and stabilization services; and
- (ii) the individual appears to be free of serious communicable disease that could be transmitted through ordinary contact; and
- (iii) the individual appears not to need acute hospital care, acute psychiatric care, or other intensive services which cannot be provided in conjunction with withdrawal and stabilization services or which would prevent them from participating in substance use disorder treatment. [Medication policies must ensure the appropriate continuation of medically appropriate and lawfully prescribed medication taken by the patient prior to admission.]
- [(4)](5) Each person admitted to the withdrawal and stabilization service must receive a medical evaluation as soon as possible, but no later than the first twenty-four (24) hours.
- [(5) A provider of withdrawal and stabilization services may provide maintenance on opioid agonist medications while a patient is being detoxified from other substances and/or tapering from such agonist medications, provided the program administering such service meets all federal and state requirements which regulate the use of approved opioid full agonist treatment.
- (6) All admissions shall be consistent with Part 815 of this Title. Admission is voluntary and a patient shall be free to discharge themselves from the service at any time, provided however, this provision shall not preclude or prohibit attempts to persuade a patient to remain in the service in their own best interest.
- (i) Any person who desires to leave the service should be offered an examination as soon as possible by medical personnel of the service.
- (ii) If the medical personnel determine upon examination that such person is incapacitated by alcohol and/or substances to the degree that they may endanger themselves or other persons, or that there is an acute need for medical or psychiatric intervention, a referral must be made to a provider designated by the Office to provide emergency services pursuant to section 22.09 of the mental hygiene law or to another appropriate provider.]

(6) Decision to admit, notice to patient.

(i) If determined appropriate for withdrawal and stabilization services, the patient shall be admitted, consistent with Part 815 of this Title.

- (ii) The decision to admit a patient 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) of the qualified health professional working within their scope of practice and include the basis for admitting the patient;
- (iii) there must be a notation in the patient record that the patient received a copy of the withdrawal and stabilization service's rules and regulations, including patient's rights, a summary of federal confidentiality requirements, and a statement that such rules were discussed with the patient and the patient indicated that they understood them;
- (iv) all patients shall be informed that admission is voluntary and that a patient shall be free to discharge themselves from the service at any time, provided however, this provision shall not preclude or prohibit attempts to persuade a patient to remain in the service in their own best interest.
- (A) For prospective or admitted 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.
- (B) Any patient who desires to leave the service should be offered a physical examination as soon as possible by medical personnel of the service.
- (7) If the medical personnel determine upon examination that such patient does not pose a danger to themselves or other persons because they are not incapacitated by a substance(s) to a degree that they may endanger themselves or other persons, or that there is no need for medical or psychiatric intervention, the patient and their family/significant other shall receive the following prior to leaving the program:
- (i) education about the medical consequences of untreated substance(s) withdrawal.
- (ii) instructions for obtaining emergency medical care for substance(s) withdrawal, should such care be necessary;
- (iii) prescriptions for all medications, including medications for addiction treatments for substance use disorder(s);
- (iv) referrals to ensure ongoing access to medications, including medication for addiction treatment for substance use disorder(s); and

(v) overdose prevention education, naloxone education and training, and a naloxone kit or prescription regardless of substance use disorder diagnosis.

(A) the patient record must document that the patient, and their family/significant other(s) were provided education about the medical consequences of untreated substance(s) withdrawal, instructions for obtaining emergency medical care for substance(s) withdrawal, prescriptions and/or other arrangements to ensure access to medications, including medication for addiction treatment for substance use disorder(s), and overdose prevention education, naloxone education and training, and a naloxone kit or prescription consistent with this Part.

- (B) The patient record must document the reasons why education about the medical consequences of untreated substance(s) withdrawal, instructions for obtaining emergency medical care for substance(s) withdrawal, prescriptions and/or other arrangements to ensure access to medications, including medication for addiction treatment for substance use disorder(s), and overdose prevention education, naloxone education and training, and a naloxone kit or prescription were not offered, if the program is unable to provide these services or if the patient declines these services.
- (8) If an individual does not meet admission criteria for the withdrawal and stabilization service, a referral to a service that can meet the individual's treatment needs must be made, unless the individual is already receiving substance use disorder services from another provider. Individuals who do not meet admission criteria shall be informed of the reason.
- (9) The admission assessment or decision to admit shall contain a statement documenting the individual is appropriate for this level of care, identify the assignment of a named clinical staff member with the responsibility to provide orientation to the individual, and include a preliminary schedule of activities, therapies and interventions.
- [(f)](i) Initial <u>assessment</u> [services; initial evaluation]. (1) Except as otherwise provided in paragraph (2) of this subdivision, an initial [evaluation] assessment must be conducted by a clinical staff member. [In addition to patient identifying and emergency contact information the following clinical and psycho-social information is required:
- (i) withdrawal evaluation, including patient's history and recent use of alcohol and/or substances, treatment history, medical history, high risk behaviors, mental status and psychiatric

history, living arrangements, level of self-sufficiency, supports, and barriers to treatment services; and

(ii) any information concerning a disability which may affect communication or other functioning.

(2)]

(2) The initial assessment must be completed within twenty-four (24) hours of admission and shall include whatever relevant information is necessary to develop an individualized, person-centered, interdisciplinary treatment/recovery plan. The initial assessment shall comprise of a written report of findings and conclusions and shall include the names of any staff or other persons participating in the assessment.

(3) The initial assessment shall include:

- (i) the patient's identifying and emergency contact information; and
- (ii) the patient's history and recent use of substances, substance use disorder treatment history, medical history, psychiatric history, high risk behaviors, mental status, living arrangements, level of self-sufficiency, supports, and barriers to treatment services; and
- (iii) any information concerning a medical or psychological condition that may affect communication or other functioning; and
- (iv) communicable disease risk assessment (HIV, tuberculosis, viral hepatitis, sexual transmitted infections, and other communicable diseases).
- (4) If the patient had previously been admitted to the same service within thirty (30) days of the current admission, the previous [evaluation]assessment may be utilized, provided that such documentation has been reviewed and determined to be current and accurate.[it is appropriately updated.]
- [(3)](5) Except for patients admitted to a medically supervised outpatient service, no patient may be continued in the withdrawal and stabilization service longer than seven (7) days after admission unless there is a reasonable probability that discharge criteria will be met within an additional seven (7) days. Current evidence must document a level of instability requiring continued stay for adjustment of medication or attainment of a level of stability to enable functioning outside a structured setting; and **one of the following**[either]:

- (i) there is medical evidence of moderate to severe organ damage related to [alcohol and/or other] substance use; or
- (ii) the patient is pregnant and continued stay is necessary to ensure stabilization and/or complete[d] referral to continuing treatment; or
- (iii) there is evidence of other medical complications warranting continued care in a withdrawal and stabilization service.

(6) Medical History and Physical Examination.

(i) A medical history shall be taken, and a physical examination performed by a physician, physician assistant, or nurse practitioner within twenty-four (24) hours of admission. The physical examination will include but shall not be limited to the investigation of, and if appropriate, screenings for infectious diseases; pulmonary, cardiac or liver abnormalities; and physical and/or psychological conditions or limitations which may require special services or attention during treatment. The physical examination shall also include the following laboratory tests:

(A) complete blood count and differential;

(B) routine and microscopic urinalysis, as clinically indicated, and in accordance with guidance from the Office;

(C) if medically or clinically indicated, urine toxicology test;

(D) blood-based tuberculosis test;

(1) an intradermal PPD may be given in those circumstances when a blood-based tuberculosis test cannot be performed; this test is given and interpreted by the medical staff unless the patient is known to be PPD positive;

(E) pregnancy test for persons of child-bearing potential; or

(F) any other tests the examining physician, physician assistant, nurse practitioner or other medical staff member deems to be necessary, including, but not limited to, an ECG or a chest X-ray.

(ii) If a medical history has been taken and a physical examination has been performed within the last twenty-four (24) hours, the existing medical history and physical examination documentation, including the results of laboratory and other diagnostic tests, for the patient may be used to comply with the requirements of this Part, provided that such documentation has been reviewed and determined to be current and accurate.

(A) A focused medical history shall be taken and/or physical examination shall be performed and/or laboratory tests and other diagnostic tests shall be ordered if the examining physician or other medical staff determine that elements of the existing medical history and/or physical examination and/or the results of laboratory and other diagnostic tests require reevaluation based on the clinical judgment of the examining physician or other medical staff.

(B) A focused medical history and/or physical examination shall be performed and/or laboratory, and other diagnostic tests shall be ordered if the patient has a physical complaint(s) that was not addressed in the existing medical history and /or physical examination, and/or the patient has a new physical complaint(s) that has developed since the existing medical history was taken and existing physical examination was performed.

(iii) Patient records shall include a summary of the results of the physical examination, laboratory test, and other diagnostic tests and shall also demonstrate that appropriate medical care, including psychiatric care, is recommended to any patient whose health status indicates the need for such care.

(j) Initial Services

(1) The initial assessment shall include an identification of initial withdrawal and stabilization intervention services needed, and schedules of individual and group counseling to address the needed services until the development of the treatment/recovery plan. The initial services shall be based on the withdrawal protocols that may be needed as well as the goals the patient identifies for treatment.

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

(i) 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.

- (ii) 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.
- (iii) 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.
- (iv) 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.
- (v) 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.
 - (3) Psychosocial Treatment Requirements.
- (i) Group and individual psychosocial treatment modalities must be offered.

 (ii) These interventions must be evidenced-based, trauma-informed, personcentered, and individualized to the needs of the patient per the clinical assessment, in
 accordance with guidance and standards from the Office.
- <u>Treatment/recovery plan.[Recovery/Care plan.]</u> (1) <u>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</u>

identified by the patient as supportive to recovery goals. The treatment plan begins with the assessment incorporated into the patient record and is regularly updated with progress notes. The plan must be completed within twenty-four (24) hours of admission and shall be based on the initial [evaluation]assessment conducted. The plan shall:

- (i) be developed [in collaboration with the patient] by the responsible clinical staff member(s), in collaboration with the patient and anyone identified by the patient as supportive to recovery and signed and dated by all parties [including the patient] when completed and agreed upon;
- (ii) provide goals for <u>the</u> outcome of [the] treatment, the protocols to be followed for medical withdrawal and the **clinical** care **services** to be provided;
- (iii) be updated as appropriate and as required by the level of care should additional problems requiring immediate treatment be identified;
- (iv) reflect coordination of medical, [and/or] psychiatric, substance use care, and/or the provision of other services provided concurrently either directly or through a secondary provider; [and]
- (v) be incorporated in the patient's case record along with written orders, prescriptions and the provision of withdrawal and stabilization services; and
- (vi) include provisions for prenatal care for all patients who are pregnant. If a pregnant patient refuses or does not obtain such care, the provider must have the patient acknowledge in writing that prenatal 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 and such offer should be noted in the patient record.
 - (2) <u>Continuing review of treatment/recovery plan.</u> [Review of recovery/care plan.]
- (i) The clinical staff shall ensure that all treatment is provided in accordance with the individual treatment/recovery plan. The treatment/recovery plan must be reviewed through the ongoing assessment process and regular progress notes. [All components of the recovery/care plan shall be reviewed by the responsible clinical staff as often as necessary consistent with the level of care, and at least once in the first seven (7) days; in the event that an individual's stay is extended beyond seven (7) days, the entire recovery/ care plan must be reviewed and modified accordingly every subsequent three (3) days during the course of the

extended stay.] Revisions to the [recovery / care] treatment/recovery plan shall be reflected in the patient's progress notes [case record], signed and dated by the responsible clinical staff.

- (3) Progress Notes. Progress notes are intended to document the patient's clinical status. Such progress notes shall provide a chronology of all significant withdrawal, stabilization and SUD services delivered to the patient, their progress related to the initial services or the goals established in the treatment/recovery plan and be sufficient to delineate the course and results of treatments/services. 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 treatment/service delivered to or on behalf of a patient, described and verified as follows:
- (i) be written, signed (physically or electronically) and dated by the clinical staff member or another clinical staff member familiar with the patient's care.
- (ii) record the relationship to the patient to the patient's developing treatment goals described in the treatment/recovery plan; and
- (ii) include, as appropriate and relevant, any recommendations, communications, or determinations for initial, continued, or revised patient goals and/or treatment; and
- (iv) include all individual, medical, and psychiatric contacts for the purpose of assessing, diagnosing, or treating the patient.
- (v) Unless additional requirements apply to specific levels of withdrawal and stabilization services, progress notes shall be documented no less often than once per shift for the first five (5) days and no less often than once per day thereafter.
- (vi) If a patient's condition necessitates more frequent documentation, the appropriate staff must document the provision of those services and/or care in the patient's progress notes.
- (vii) 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.

[Progress notes shall be written, signed and dated by clinical staff members; give a chronological picture of the patient's progress; and must be sufficiently detailed to delineate the course and results of the patient's progress in treatment.

- (i) Unless additional requirements apply to specific levels of withdrawal and stabilization services, progress notes shall be documented no less often than once per shift for the first five (5) days and no less often than once per day thereafter.
- (ii) If a patient's condition necessitates more frequent documentation, the appropriate staff must document the provision of those services and/or care in the patient's case record.]

 [(h)](k) Discharge and planning for level of care transitions. (1) Discharge and planning for level of care transitions. (1) Discharge and planning for level of care transition and shall be considered part of the treatment/recovery planning process. The plan for discharge or level of care transition shall be developed by the clinical staff member(s) with primary responsibility for the patient in collaboration with the patient and anyone identified by the patient as supportive to recovery. [involve consultation with the patient; p]Planning must provide a framework for a long-term, patient-driven treatment/recovery plan and link the patient to appropriate level of care transition services to support the plan; and include detailed information on referral and plan specifics. [Except for unplanned discharges, n]No patient shall be discharged until the plan is complete and identifies a staff member assigned to follow up on referrals. .

 Documentation detailing why a discharge or level of care transition plan was not provided to the patient must be placed in the medical record, if the patient did not receive a plan.
 - (2) Discharge and/or level of care transitions should occur when:
- (i) the patient meets criteria documented by the OASAS level of care determination protocol for an alternate level of care and has been medically withdrawn from a substance(s) they are physiologically dependent on, has been stabilized on a medication(s) for addiction treatment if such treatment(s) were initiated during admission, has co-occurring medical and/or psychiatric symptoms that have been stabilized, and has developed a discharge or level of care transition plan;
- (ii) the patient and the medical and clinical staff agree that the patient has received maximum benefit from the withdrawal and stabilization services provided by the program; or
- (iv) the patient does not adhere to the program's written behavioral standards, provided that the patient is offered a referral and connection to another treatment program.

(A) discharge for behavioral reasons with a referral and connection to another treatment program shall only occur after the program has utilized behavioral interventions to help the patient manage their behavior in a less disruptive manner and discharge must be consistent with the provisions of Part 815 of this Title.

- [(2)](3) The plan shall include, but not be limited to at least the following:
- (i) an evaluation of the patient's living arrangement, level of self-sufficiency and available support systems;
- (ii) identification of substance use disorder treatment and other services the patient will need after discharge including alternative medical and [psychological] mental health providers; and
 - (iii) a list of current medications.
- [(3)](A) A member of the clinical and medical staff who participated in preparing the plan, and the patient, shall sign and date the plan upon its completion. Except for medically monitored withdrawal and stabilization services, the program physician shall also sign and date the plan.
- [(4)](B) The plan shall be <u>discussed with the patient</u>, given to the patient upon discharge and with appropriate patient consent, the [care] plan, including level of care transition planning, shall be forwarded to any subsequent service providers. The patient and their family/significant other(s) shall be offered [naloxone]overdose prevention education, naloxone education and training, and a naloxone kit or prescription.
- [(5)](C) For a patient transitioning directly from a withdrawal and stabilization service to another service within the same facility, a transfer plan may take the place of a discharge plan. To ensure sufficient information is available to the new service, a transfer plan must include information about the patient's immediate needs, medical and psychiatric diagnoses, medications and plan for meeting those needs.
- [(i)](I) [Case] <u>Patient</u> records. (1) Providers must keep individual <u>patient</u> [ease] records for each patient admitted. These records must include, at a minimum, all information and documentation required in this Part, including but not limited to:

(i) identifying information about the patient and their family;

- (ii) the source of referral, date of commencing service, and names of clinical staff who have primary responsibility for the patient's care;
- (iii) a notation that the patient received a copy of the program's rules and regulations, including patient's rights consistent with Part 815 of this Title and a summary of the federal confidentially 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 they understood them;
- (iv) the admission diagnosis, including substance-related, medical, and psychiatric diagnoses in official nomenclature with associated diagnostic codes in the most recent version of the Diagnostic and Statistical Manual (DSM) or the International Classification of Diseases (ICD);
- (v) any clinical and non-clinical documentation or determination applicable to the delivery of withdrawal and stabilization treatment services for a patient and/or supporting the patient's evolving recovery treatment/recovery plan;
- (vi) the individual treatment/recovery plan and all reviews and updates thereto through progress notes;
 - (vii) reports of all assessments performed, including findings and conclusions;
- (viii) reports of all examinations performed, including but not limited to X-rays and/or other imaging studies, clinical laboratory tests, clinical psychological tests, electroencephalograms, and psychometric tests
- (ix) documentation of public health education and screening with regard to tuberculosis, sexually transmitted infections, hepatitis, and HIV prevention and harm reduction.
 - (x) summaries of case conferences, and special consultations held.
- (xi) dated and signed prescriptions or orders for all medications with notation of termination dates;
- (xii) documentation that the patient, and their family/significant other(s), were offered overdose prevention education, naloxone education and training and a naloxone kit or prescription;
- (xiii) documentation should include, if applicable, the reasons why overdose prevention education, naloxone education and training, and/or a naloxone kit or

prescription were not offered or the reasons why the patient declined overdose prevention, naloxone education and training and/or a naloxone kit or prescription.

(xiv) the discharge plan;

- (xv) any other documents or information regarding the patient's condition, treatment, and results of treatment; and
- (xvi) signed forms consenting to treatment and for obtaining or releasing confidential information in accordance with 42 Code of Federal Regulations Part 2 or other applicable law.
- (2) Patient records shall be maintained, shared with other clinical staff involved in the treatment of a patient and with professional staff or other providers involved in the care of such patient, and released in accordance with state and federal laws and regulations governing confidentiality.
- (i) evaluation at admission;
 - (ii) recovery care plan and all revisions including progress notes and discharge plan;
- (iii) documentation of public health education and screening with regard to tuberculosis, sexually transmitted diseases, hepatitis, and HIV prevention and harm reduction;
 - (iv) documentation of contacts with a patients family and/or significant other(s); and
 - (v) signed releases of consent for information, if any.
- (2) Patient records shall be maintained, shared with other staff involved in the treatment of a patient and with professional staff of other providers involved in the care of such patient, and released in accordance with state and federal laws and regulations—governing confidentiality.
- (3) If the service denies admission due to lack of available capacity or resources, it shall provide a referral to the most appropriate available service.]
- [(j) Utilization review and quality improvement. Each withdrawal and stabilization service must have a utilization review process, a quality improvement process, and a written plan that identifies key performance measures for that particular program.]
- [(k)](m) Staffing. (1) Staff may be either specifically assigned to the withdrawal and stabilization service or may be part of the staff of the facility within which the service is located, provided that:

- (i) they have specific training in the <u>diagnosis and</u> treatment of substance use disorder <u>including person-centered</u>, <u>trauma-informed principles</u>; and
- (ii) the service identifies and documents the percentage of time each shared staff member is assigned to each service.
- (2) A withdrawal and stabilization service shall have regular, scheduled, and documented training made available in the following subject areas, or as determined by the Office:
 - (i) **diagnosing** substance use disorder and other addictive disorders;
 - (ii) signs and symptoms of withdrawal **from all classes of substances**; [and]
 - (iii) complications of withdrawal **from all classes of substances**; [and]
- (iv) public health education and screening with regard to tuberculosis, sexually transmitted [diseases]infections, viral hepatitis, and HIV prevention and harm reduction, and,[-]

(v) certification in cardiopulmonary resuscitation from the American Red Cross, the American Heart Association or an equivalent nationally recognized organization within one year of hire, to be renewed as needed.

- (3) Each service shall have a qualified individual designated as the Health Coordinator to ensure the provision of education, risk reduction, counseling and referral services to all patients regarding HIV[-and AIDS], tuberculosis, <u>viral</u> hepatitis, sexually transmitted [diseases]infections, and other communicable diseases.
- (4) Clinical staff shall have primary responsibility for implementing the [care]treatment/recovery plan.
- (5) Medical staff shall have primary responsibility for coordinating medical care including, but not limited to, physical examination, prescription, dispensing, and/or administration of medications, observation of symptoms, and vital signs and the provision of nursing care.
- (6) Additional staffing requirements specific to the type of withdrawal and stabilization service provided pursuant to applicable sections of this Part.

816.6 Additional requirements for medically managed withdrawal and stabilization services.

(a) Unless otherwise authorized medically managed withdrawal and stabilization services, as defined in [section 816.4(c) of] this Part, shall only be provided in facilities certified by the

Office and [eertified] licensed by the Department of Health as a general hospital pursuant to Article 28 of the Public Health Law.

- (b) *Required services*. Medically managed services must provide, at a minimum, all of the following services:
 - (1) medical management of acute intoxication and withdrawal conditions;
- (2) an observation period for up to <u>forty-eight (48)</u> hours of admission. Patients found to be stable and able to step-down to a lower level of care shall be transferred within or <u>to</u> <u>another[without the]</u> facility, with specific discharge instructions, as soon as possible:[.-]
 - (3) medically supervised inpatient withdrawal services.
- (c) Staffing. (1) The medical director of a medically managed withdrawal and stabilization service, whether full or part time, may also serve as director of another service provided by the same program sponsor.
 - (2) A physician must be on duty or on call at all times[-and available if needed].
- (3) There must be a physician, nurse practitioner and/or physician assistant under the supervision of a physician, on-site sufficient hours to perform the initial medical <u>history and physical examination of all patients</u> [examination of all patients] and to prescribe any and all necessary medications necessary to ensure safe withdrawal.
- (4) There shall be registered nursing personnel immediately available to all patients at all times. Nursing services shall be under the direction of a registered [professional] nurse who has at least one year of experience in the nursing care and treatment of substance use disorders and related medical and psychiatric illnesses.
- (5) There shall be sufficient hours of [qualified] psychiatric <u>provider</u> time to meet the [evaluation]assessment and treatment needs of those patients with other psychiatric disorders in addition to substance use disorders.
- (6) There shall be sufficient clinical staff **both** to [both] maintain a ratio of one counselor for each 10 beds and be scheduled [so as] to be available for one and one-half shifts, seven (7) days per week.
- (7) One of the full time equivalent qualified health professionals employed by the service shall be designated to provide discharge and <u>treatment/recovery planning</u> to persons <u>admitted</u> <u>to the service.</u> [suffering from chemical dependence as needed.]

Additional requirements for medically supervised inpatient withdrawal and stabilization services.

- (a) Medically supervised withdrawal services can [only] be delivered only by a provider of services certified by the Office to provide a continuum of care encompassing: residential, inpatient or outpatient substance use disorder treatment services in order to ensure appropriate continuation in treatment.
- (b) Each inpatient medically supervised withdrawal service shall have a director who is a qualified health professional with at least [one year]two years of full-time clinical work experience in the treatment of substance use disorder prior to appointment. The director may also serve as director of another service provided by the same governing authority.

816.8 Additional requirements for medically supervised outpatient withdrawal and stabilization services.

- (a) Unless otherwise authorized by the Office medically supervised outpatient services may [only] be delivered only by an OASAS certified provider of residential, inpatient and outpatient services in order to assure appropriate continuation in treatment.
- (b) Required services. (1) All providers of outpatient medically supervised services must, at a minimum, provide the following services in addition[al] to those otherwise required [pursuant to section 816.5 of]by this Part:
- [(i)](2) patients must be seen by the physician, nurse practitioner, physician assistant or registered nurse daily unless otherwise specified by the physician based on the patient's physical and [emotional]psychiatric conditions; and
- [(ii)](3) The provider of services must provide or make available a twenty-four (24) hour telephone crisis line[-to help facilitate the provision of this information].
- (c) Staffing. (1) Each outpatient medically supervised service shall have a service director who is a qualified health professional as defined by this Title. Such service director shall have at least [one year] two years of full-time work experience in the [ehemical dependence] substance use disorder treatment field prior to appointment as service director and may also serve as director of another service provided by the same program sponsor.
- (2) [There shall be sufficient qualified clinical staff to achieve a ratio of one counselor to 15 patients. 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 shall 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.

[(4)](3) Progress notes shall be documented no less often than once per visit.

[816.9 Additional requirements for medically monitored services.

- (a) Medically monitored services are designed for persons intoxicated by alcohol and/or substances, or who are suffering from mild withdrawal coupled with situational crisis, or persons who have previously been unable to withdraw without complications. Such services do not require physician direction or direct supervision by a physician, and are designed to provide a safe environment with medical monitoring in which a person may complete withdrawal and secure a referral to the next level of care.
- (b) All medically monitored services must provide at least all of the following services:
 - (1) assessment;
 - (2) monitoring of withdrawal symptoms and vital signs; and
 - (3) individual and group counseling
- (c) A patient may be retained in the medically monitored withdrawal and stabilization service if he or she is awaiting a scheduled admission into appropriate treatment upon discharge. Such retention must be documented and may not exceed twenty-one (21) days from date of admission.
- (d) Staffing. (1) Each medically monitored service of 10 beds or more shall have a full-time program director who is a qualified health professional. Such director shall have at least one year of full-time work experience in the field of substance use disorder prior to appointment. A medically monitored service with fewer than 10 beds shall have a similarly qualified director who shall serve on at least a part-time basis.
- (2) Each medically monitored withdrawal and stabilization service shall employ a sufficient number of staff to adequately serve all patients and to meet the requirements of this Part.
- (i) There shall be at least two patient care staff on duty at all times.

- (ii) There shall be sufficient clinical staff to achieve a ratio of one counselor for each 10 beds, scheduled so as to be on duty at least one and one-half shifts per day, seven (7) days per week.
- (iii) All patient care staff of the service shall have current certification in cardiopulmonary resuscitation from the American Red Cross, the American Heart Association or an equivalent nationally recognized organization within 90 days after hiring and thereafter, to be renewed as needed.]

816.9[10] Standards pertaining to Medicaid reimbursement.

- [(a)] Medicaid reimbursement [will]shall be provided in accordance with the provisions of 14 NYCRR Part 841.
- [(b) The following services are not eligible for Medicaid reimbursement on a fee for service basis:
- (1) visits to the premises of a withdrawal and stabilization service for the sole purpose of attending meetings of a self-help group; and/or
 - (2) any visits which include only companionship, recreation, and/or social activity:[;]
 - [(3) treatment provided in a medically monitored withdrawal and stabilization service.]

816.11 Savings and renewal clause.

Any operating certificate which has been issued by the Office pursuant to Part 816 of this Title and before that Part has been repealed shall remain in effect until its term has expired at which time any renewal of such operating certificate will be issued pursuant to this Part 816.

816.<u>10[12]</u> 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.



Notice of Proposed Rulemaking Summary

Amend 14 NYCRR Part 817 SUBSTANCE USE DISORDER RESIDENTIAL REHABILITATION SERVICES FOR YOUTH

In addition to technical amendments and updating terminology used across all regulations for consistency in Title 14, the Proposed Rule amends Part 817 as follows:

- §817.2 General program standards. Added references to the provision of person centered, trauma informed care. Updated provisions regarding medication for addiction treatment for substance use disorder and naloxone access consistent with the needs of the program.
- §817.3 Admission procedures. Removed list of non-discrimination categories and added reference to Part 815.
- §817.5 Treatment/recovery plan. Added reference to requirement for post-discharge appointment(s) to continue medication access.



Notice of Proposed Rulemaking Regulatory Impact Statement

Amend 14 NYCRR Part 817 SUBSTANCE USE DISORDER RESIDENTIAL REHABILITATION SERVICES FOR YOUTH

1. Statutory Authority:

- (a) Section 19.07(e) of the Mental Hygiene Law authorizes the Commissioner to adopt standards including necessary rules and regulations pertaining to addiction services.
- (b) Section 19.09(b) of the Mental Hygiene Law authorizes the Commissioner to adopt regulations necessary and proper to implement any matter under their jurisdiction.
- (c) Section 19.15(e) of the Mental Hygiene Law authorizes the Commissioner to implement programs of children and youth.
- (d) Section 19.40 of the Mental Hygiene Law authorizes the Commissioner to issue operating certificates for the provision of addiction services.
- (e) Section 32.01 of the Mental Hygiene Law 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 Mental Hygiene Law.
- (f) Section 32.07(a) of the Mental Hygiene Law authorizes the Commissioner to adopt regulations to effectuate the provisions and purposes of Article 32 of the Mental Hygiene Law.
- (g) Section 32.09 of the Mental Hygiene Law authorizes the Commissioner to issue operating certificates for services that treat individuals with a substance use disorder.
- (h) Section 3309 of the Public Health Law authorizes the DOH to establish standards for approval of any opioid overdose prevention program.
- (i) Article 27F of the Public Health Law defines the rules governing HIV testing and treatment in New York.

- 2. <u>Legislative Objectives</u>: The legislature has authorized OASAS to establish standards and regulations governing the provision of addiction services, including the provision of medications for addiction treatment, as well as standards for providers seeking to offer such services.
- 3. <u>Needs and Benefits:</u> OASAS is updating the language used in this regulation consistent with amendments made to other OASAS regulations and OASAS guidance to clarify provider requirements with respect to the provision of medication for addiction treatment for substance use disorder and to update definitions consistent with other OASAS regulations.
- 4. <u>Costs:</u> No additional administrative costs to the agency are anticipated.
- 5. <u>Paperwork:</u> There is no additional paperwork beyond what is already required.
- 6. <u>Local Government Mandates</u>: There are no new local government mandates.
- 7. <u>Duplications</u>: This proposed rule does not duplicate, overlap, or conflict with any State or federal statute or rule.
- 8. <u>Alternatives:</u> The alternative is to leave the regulation as it currently reads, with language inconsistent across Title 14 regulations and providers unsure of their obligation to provide medication for addiction treatment for substance use disorders.
- 9. Federal Standards: This regulation does not conflict with federal standards.
- 10. <u>Compliance Schedule:</u> This rulemaking will be effective upon publication of a Notice of Adoption in the *State Register*.



TITLE 14 NYCRR PART 817

SUBSTANCE USE DISORDER RESIDENTIAL REHABILITATION SERVICES FOR YOUTH (RRSY)

[Statutory Authority: Mental Hygiene Law Sections 19.07(e), 19.09(b), 19.15(e),19.40, 32.01, 32.07(a),[and]

32.09 and Public Health Law sections 33.09, Article 27f]

Section:

- 817.1 Legal base
- 817.2 General service standards
- 817.3 Admission procedures
- 817.4 Post admission procedures
- 817.5 Treatment / recovery plan
- 817.6 Patient records
- 817.7 Staffing
- 817.8 Severability
- [817.9 Savings and Renewal clause]

817.1 Legal base

- (a) Section 19.07(e) of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to adopt standards including necessary rules and regulations pertaining to [chemical dependence] addiction services.
- (b) Section 19.09(b) of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to adopt regulations necessary and proper to implement any matter under their jurisdiction.
- (c) Section 19.15(e) of the Mental Hygiene Law authorizes the Commissioner to implement programs of children and youth.
- (d) Section 19.40 of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to issue operating certificates for the provision of [chemical dependence] addiction services.

- (e) Section 32.01 of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to adopt any regulation reasonably necessary to implement and effectively exercise the powers and perform the duties conferred by Article 32 of the Mental Hygiene Law.
- (f) Section 32.07(a) of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to adopt regulations to effectuate the provisions and purposes of Article 32 of the Mental Hygiene Law.
- (g) Section 32.09 of the Mental Hygiene Law authorizes the Commissioner to issue operating certificates for services that treat [ehemically dependent] individuals with a substance use disorder.
- (h) Section 3309 of the Public Health Law authorizes the DOH to establish standards for approval of any opioid overdose prevention program.
- (i) [Section 2781] Article 27F of the Public Health Law defines the rules governing HIV testing and treatment in New York.

817.2 General program standards

- (a) Policies and procedures. The program sponsor must approve written policies, procedures and methods governing the provision of services that are strength-based, person centered and trauma informed to patients in compliance with Office regulations including a description of each service provided and the overall approach to service delivery and a description of evidence-based practices employed in group, individual and family treatment. Such policies and procedures shall address, at a minimum, the following:
 - (1) procedures and specific criteria for admission, retention, transfer, referrals and discharge;
- (2) level of care determinations utilizing the OASAS level of care determination protocol, treatment/recovery plans, and placement services;
- (3) staffing, including but not limited to, training, supervision, and use of student interns, peers, and volunteers:
- (4) the provision of medical and psychiatric services, including screening and referral for associated physical or mental health conditions;
 - (5) a schedule of fees for services rendered;
 - (6) infection control procedures;

- (7) cooperative agreements with other substance use disorder services providers and other providers of services that the patient may need;
- (8) 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 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 as clinically appropriate; and
 - (iii) medication and the use of medication [assisted] for addiction treatment;
 - (iv) if acupuncture is provided it must be provided in accordance with Part 830 of this Title;
 - (v) the use of a problem gambling screen approved by OASAS.
- (9) record keeping procedures which ensure that documentation is accurate, timely, prepared by appropriate staff, and in conformance with the federal confidentiality regulations contained in 42 Code of Federal Regulations Part 2; and
- (10) 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.
 - [(11) Providers must comply with all applicable laws regarding the use of restraint and seclusion.]
- (b) *Program goals*. The program shall have as its goals:
- (1) the improvement of functioning and development of coping skills necessary to enable the patient to be safely, adequately and responsibly treated in the least intensive environment; and
- (2) the development of individualized plans to support the maintenance of recovery, attain self-sufficiency, and improve the patient's quality of life.
- (c) *Minimum services*. An array of services shall be provided including, but not limited to, those listed below. The services must be clinically indicated and specified in the individualized treatment/recovery plan.
- (1) Clinical services including:
- (i) Counseling services: trauma-informed, person centered individual, group and family counseling as appropriate; 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; activities therapy;

- (ii) Assessment and referral services for patients and significant others;
- (iii) Medical and psychiatric consultation;
- (iv) HIV and AIDS, hepatitis C, tuberculosis, and other communicable diseases education, risk assessment, supportive counseling and referral;
 - (2) Recovery support services including:
- (i) [chemical dependence]substance use education, awareness and recurrence [re-occurrence] prevention;
- (ii) education about, orientation to, and the opportunity for participation in, available and relevant self-help and [sober/]peer support groups including Alternative Peer Groups;
 - (iii) holistic health practices; socialization skills;
- (3) Educational assessment and educational services, as appropriate and as required by law, either directly or by arrangement with local school districts including:
 - (i) Vocational assessment and vocational services;
 - (ii) life skills training.
- (d) Medication for Addiction [Assisted] Treatment. [A program must provide services to an individual who is receiving approved opiate full agonist maintenance or detoxification. Opiate maintenance or detoxification services must be provided through a written agreement with an appropriately certified outpatient provider of opioid full agonist treatment in accordance with applicable federal and state requirements including, but not limited to, regulations of the federal Center for Substance Abuse Treatment, the United States Drug Enforcement Administration, the New York State Department of Health, and Part 822 of this Title.]
- (1) All programs 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.
- (e) Emergency medical kit. Pursuant to Part 800 of this Title, all programs must maintain an emergency medical kit at each certified or funded location; such kit must include basic first aid and [at least one] naloxone emergency overdose prevention kit in a quantity sufficient to meet the needs of the program. Programs must develop and implement a plan to have staff trained in the prescribed use of a naloxone overdose prevention 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 naloxone overdose prevention kit and the authorized administering staff.
- (2) 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.
- (f) Food and nutrition. (1) Each facility shall provide to each patient three (3) nutritious meals each day which furnish sufficient nutrients and calories to meet normal needs as well as the special needs of persons in recovery.
 - (2) The facility shall have available snacks and beverages between meals.

- (3) A dietician or dietetic technician acting within their scope of practice shall provide menu planning services. Other suitable staff shall be responsible for the procurement of food supplies and the training and directing of food preparation and serving personnel.
- (g) *Certified capacity*. The certified bed capacity of each RRSY program shall not be exceeded at any time except with the written approval of the Office.
- (h) *Medicaid*. Providers seeking Medicaid reimbursement must comply with the requirements of **this Part** and Part 841 of this Title.
- (i) Segregation. All patients must at all times be kept physically separated from patients of non-Part 817 services. In accordance with a provider-specific plan approved by the Office prior to implementation, certain groups of patients shall be kept physically separated within the facility based upon clinically appropriate age, gender and developmental grouping.
- (k) <u>Telehealth.</u>[Telepractice.] Services may be delivered using <u>telehealth</u>[telepractice] consistent with Part 830 of this [Chapter] <u>Title</u>.

817.3 Admission procedures

- (a) *Initial determination*. (1) An individual who appears at the service seeking treatment or evaluation shall have an initial determination made and documented in a written record by a qualified health professional, or other clinical staff under the supervision of a qualified health professional, which states the following:
- (i) that the individual is documented as less than <u>twenty-one (21)</u> years of age on the date of admission and appears to be in need of [chemical dependence] <u>substance use disorder</u> services;
- (ii) that the individual appears to be free of serious communicable diseases that can be transmitted through ordinary contact; and
- (iii) that the individual appears not to be in need of acute hospital care, acute psychiatric care, Part 816 crisis services or other services which cannot be provided in conjunction with treatment at the facility or would prevent them from participating in substance use disorder treatment.
- (2) The initial determinations made pursuant to the above shall be based upon provider records, reports from other providers and face-to-face contact with the individual, all of which must be documented.
- (b) Level of care determination. If an individual is determined to be appropriate for substance use disorder treatment services, a level of care determination utilizing the OASAS level of care determination protocol, shall

be made by a clinical staff member. The level of care determination shall be made no later than one patient day after the patient's first on-site visit to the program and documented in the patient record.

- (c) Prohibition against discrimination. <u>Individual's may not be denied admission to the service</u>

 <u>consistent with the provisions of Part 815 of this Title.</u> [No individual shall be denied admission to the service based solely on the individual's:
 - (1) prior treatment history;
 - (2) referral source;
 - (3) pregnancy;
 - (4) history of contact with the criminal justice system;
 - (5) HIV and AIDS status;
 - (6) physical or mental disability; or
 - (7) lack of cooperation by significant others in the treatment process.]
- (d) Additional requirements for the admission of Medicaid eligible individuals. A provider must obtain preadmission approval as follows prior to admitting Medicaid eligible individuals to the program.
- (1) The Office shall establish a pre-admission review team ("ART") that shall use the requirements of this Section to review each individual candidate to determine their appropriateness for admission. If deemed appropriate for admission, the ART shall certify that the individual seeking admission is in need of this level of residential treatment for substance use disorder[ehemical dependence]. The ART shall be operated in accordance with the procedures established by the Office and shall at a minimum consist of a Physician, a Social Worker licensed and currently registered as such by the New York State Education Department, and a Credentialed Alcoholism and Substance Abuse Counselor (CASAC).
- (2) Except in emergency circumstances, the service provider must obtain approval from the ART prior to admitting a Medicaid eligible individual. Emergency admissions are authorized only when an individual appears for treatment meeting the admission criteria and meets one of the following conditions:
 - (i) the individual has a history of <u>recurrent use</u> [re-occurrence] outside of a structured 24-hour setting;
 - (ii) the individual is unable to access transitional services in the community; or
 - (iii) the individual is without appropriate housing.

- (3) Under no circumstances should an individual be admitted on an emergency basis or otherwise if they are in medical or psychiatric crisis or if they are in need of withdrawal services and an appropriate referral for such services is made.
- (e) Admission criteria. (1) To be admitted to the program it must be determined that ambulatory services in the community do not meet the needs of the individual recipient or the individual's environment is not conducive to recovery.
- (2) If the individual is deemed inappropriate for service, unless the individual is already receiving [ehemical dependence]substance use disorder services from another provider, a referral and connection to a more appropriate service provider shall be made. The reasons for denial of admission must be provided to the individual and documented in a written record maintained by the service provider.
- (3) The decision to admit shall be made by a staff member who is a qualified health professional authorized by the program sponsor to admit individuals. The name of the qualified health professional who made the admission decision, along with the date of admission, must be documented in the patient record.
- (4) There must be a notation in the case record that the patient received a copy of the program's rule and regulations, including patient rights and a summary of federal confidentiality requirements, and a statement that notes that such rules were discussed with the patient, and that the patient indicated that they understood them.
- (5) 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 and continued treatment.
- (6) Individuals under the age of eighteen may be admitted without the consent of a parent or legal guardian under certain circumstances in accordance with Mental Hygiene Law Section 22.11.

817.4 Post Admission Procedures

- (a) Post-admission. (1) As soon as possible after admission, for all patients, all programs must:
 - (i) offer viral hepatitis testing; testing may be done on site or by referral;
- (ii) offer HIV testing; testing may not be conducted without patient written informed consent except in situations specifically authorized by law; testing 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.

- (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 <u>infections[diseases]</u>; 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 any blood and skin test results to the patient.
- (b) *Initial evaluation*. (1) The goal of the initial evaluation shall be to obtain information from such sources, including family members where appropriate, as necessary to develop an individualized patient-centered treatment/recovery plan.
- (2) No later than three (3) days after admission, staff shall complete the initial evaluation which shall include a written report of findings and conclusions and shall include the names of any staff participating in the evaluation and be signed by the qualified health professional responsible for the evaluation.
- (c) Initial services. The initial evaluation shall include an identification of initial services needed, and schedules of individual[s] and group counseling to address the needed services until the development of the treatment/recovery plan. The initial services shall be based on goals the patient identifies for treatment and shall include substance use and any other priority issues identified in the admission assessment and initial evaluation.
- (d) Medical history. (1) For those patients who have not had a physical examination or mental health history taken within one year prior to admission, each such patient must either be assessed face-to-face 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 [ehemical dependence]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, the

following shall be offered regardless of a documented history within the previous twelve months: HIV and viral hepatitis testing.

- (2) Patient records shall include a summary of the results of the physical examination and shall also demonstrate that appropriate medical care is recommended to any patient whose health status indicates the need for such care.
- (e) Referral and connection (1) If the initial evaluation and medical history indicates that the individual needs services beyond the capacity of the program to provide either alone or in conjunction with another program, referral and connection to appropriate services shall be made. Identification of such referrals and the results of those referrals to identified program(s) shall be documented in the patient record.
- (2) If a patient is referred directly to the program from another service provider certified by the Office or is readmitted to the same service provider within sixty (60) days of discharge, the existing level of care determination and initial evaluation may be used, provided that documentation is maintained demonstrating a review and update.

817.5 Treatment / recovery plan

- (a) Treatment / recovery plan. Each patient must have a written patient-centered treatment/recovery plan developed by clinical staff and patient as soon as possible after admission but not later than ten (10) calendar days after admission. Standards for developing a treatment/recovery plan include, but are not limited to:
- (1) 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.
- (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 ten (10) days of transfer.
- (b) Treatment/recovery plan. 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, approved, signed and dated by the physician within fourteen (14) days after admission.
- (5) Where a service is to be provided by any other program off-site, the treatment/recovery plan must contain a description of the nature of the service, a record that referral for such service has been made, and the results of the referral.
- (c) Continuing review of treatment plans. (1) The clinical staff shall ensure that the treatment/recovery plan is included in the patient record and that all treatment is provided in accordance with the individual treatment/recovery plan.
- (2) If, during the course of treatment, revisions to the treatment/recovery plan are determined to be clinically necessary, the plan shall be revised accordingly by the clinical staff member.
- (3) The treatment/recovery plan must be reviewed, and revised if necessary, at least once within every **thirty** (30) calendar days from the date of admission. 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 shall be signed (physical or electronic signature) by a physician.
- (d) *Progress notes.* (1) A progress note shall be written, signed and dated by the clinical staff member or another clinical staff member familiar with the patient's care no less often than once per week. Such progress note shall provide a chronology of the patient's participation in all significant services provided, their progress related to the initial services or the goals established in the treatment/recovery plan and be sufficient to delineate the course and results of treatment/services.
- (e) Discharge and planning for level of care transitions. (1) The discharge planning process shall begin as soon as the patient is admitted and shall be considered a part of the treatment planning process. The plan for discharge and level of care transitions shall be developed in collaboration with the patient and any significant other(s) the patient chooses to involve. If the patient is a minor, the 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.
 - (2) Discharge should occur when:
- (i) the patient meets criteria documented by the OASAS level of care determination protocol for an alternate level of care and has attained skills necessary to identify and manage cravings and urges to use

substances, stabilized psychiatric and medical conditions, and has identified a plan for returning to their community;

- (ii) the patient has received maximum benefit from the service provided by the program; or
- (iii) the individual is disruptive and/or fails to comply with the program's reasonably applied written behavioral standards, provided the individual is offered a referral to another treatment program and discharge is otherwise in accordance with Part 815 of this Title.
- (3) No patient shall be discharged without a discharge plan which has been completed and reviewed by the multi-disciplinary team prior to the discharge of the patient. This review may be part of a regular treatment/recovery plan review. The portion of the discharge plan which includes the referrals for post-discharge shall be given to the patient. This requirement shall not apply to patients who leave the program without permission, refuse continuing care planning, or otherwise fail to cooperate.
- (4) The discharge plan shall be developed by the clinical staff member, who, in the development of such plan, shall consider the patient's self-reported confidence in maintaining their health and recovery and following an individualized <u>recurrence safety</u> [re-occurrence prevention] plan. The clinical staff member shall also consider an assessment of the patient's home and family environment, vocational/educational/employment status, and the patient's relationships with significant others. The purpose of the discharge plan shall be to establish the level of clinical and social resources available to the individual post-treatment and the need for the services for significant others. The plan shall include, but not be limited to, the following:
- (i) identification of any other treatment, rehabilitation, self-help and vocational, educational and employment services the patient will need after discharge;
 - (ii) identification of the type of residence, if any, that the patient will need after discharge;
 - (iii) identification of specific providers of these needed services;
 - (iv) specific referrals and initial appointments for these needed services; [and]
- (v) the patient, and their family/significant other(s) shall be offered naloxone education and training and a naloxone kit or prescription[-]; and

(vi) an appointment with a community based provider to continue access to medication for addiction treatment.

(5) A discharge summary which includes the course and results of care and treatment must be prepared and included in each patient's case record within twenty (20) days of discharge.

817.6 Patient records

- (a) <u>Patient</u>[Case] Records. (1) Programs must maintain individual <u>patient</u>[ease] records for each patient served. Patient records [maintained by inpatient services] are confidential and may only be disclosed in conformity with federal regulations regarding the confidentiality of records related to persons receiving treatment for substance use disorder as set forth in 42 Code of Federal Regulations Part 2, or other applicable state and federal laws.
- (2) There shall be a single individual record for each person admitted to the program which shall include, at a minimum:
 - (i) identifying information about the patient and their family;
 - (ii) the source of referral, date of commencing service and name of primary counselor;
- (iii) the admission diagnosis, including [chemical dependence-]substance use related, medical, and psychiatric diagnoses in official nomenclature with associated diagnostic codes;
 - (iv) reports of all evaluations performed, including findings and conclusions;
- (v) reports of all examinations performed, including but not limited to X-rays, clinical laboratory tests, clinical psychological tests, electroencephalograms, and psychometric tests;
 - (vi) the written and signed individual treatment plan, including all reviews and updates;
- (vii) progress notes informative of the patient's condition and response to treatment, written and signed by staff members;
- (viii) summaries of case conferences, treatment plan updates, and special consultations and communications held;
 - (ix) dated and signed prescriptions or orders for all medications with notation of termination dates;
 - (x) the discharge and level of care transitions plan;
- (xi) any other documents or information regarding the patient's condition, treatment, and results of treatment; and
- (xii) signed forms consenting to treatment and for obtaining or releasing confidential information in accordance with 42 Code of Federal Regulations Part 2 or other applicable law.

- (b) *Disclosures*. Disclosure of HIV [and AIDS] related information contained in a patient's record shall be made in accordance with the Article [24]27f of the Public Health Law, other applicable state and federal statutes and regulations, and subject to the additional disclosure requirements of 42 Code of Federal Regulations Part 2.
- (c) Reporting to Office. Statistical information shall be reported to the Office as required and on the prescribed forms therefor.

817.7 Staffing

- (a) Medical Director and medical staff. (1) The medical director, as defined in Part 800 of this Title, shall oversee the development and revision of medical policies, procedures and ongoing training for matters such as routine medical care, specialized services, and medical and psychiatric emergency care, and supervision of medical staff.
- (2) Programs providing treatment for persons with co-existing medical or psychiatric conditions in addition to their substance use disorder shall have an appropriately qualified physician, physician['s] assistant, nurse practitioner, psychiatrist or psychologist on-site or through <u>telehealth</u>[telepractice], pursuant to Part 830 of this Title, for a sufficient number of hours each week to provide evaluation, treatment and supervision of such other services for these patients.
- (3) There shall be at least one full-time registered professional nurse and additional licensed practical nurses, registered nurses, registered physician's assistants, and nurse practitioners sufficient to provide the services required. Such personnel shall be available to all patients at all times.
- (4) The medical director may also serve as a physician of another service which is provided by the facility. The general severity of the condition of the population served, including comorbid conditions, complications and general functioning, may indicate the need for staff in addition to those identified in this section.
- (b) Staff sharing. Staff may be either specifically assigned to the inpatient service or may be part of the staff of the facility within which the inpatient service is located. However, if these staff members are part of the general facility staff, they must have specific training and experience in the treatment of substance use disorder specific to the services provided. The percentage of time that each shared staff is assigned to the inpatient service must be documented.

- (c) Supervision and training. 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.
- (d) *Program director*. There shall be a director of the program who is a qualified health professional with at least:
 - (1) four (4) years experience in the human services field;
 - (2) two (2) years experience in the provision of substance use disorder treatment services;
 - (3) two (2) years of administration and supervisory experience prior to appointment as director; and
 - (4) two (2) years of adolescent services experience.
- (e) Other clinical staff. (1) At least 50 percent of all clinical staff shall be qualified health professionals as defined in Part 800 of this Title. CASAC Trainees may be counted towards satisfying the 50 percent requirement provided, however, that such individuals shall not be considered qualified health professionals for any other purpose under this Part.
- (2) Clinical staff members who are not qualified health professionals shall have qualifications appropriate to their assigned responsibilities as set forth in the inpatient service's written personnel policies, shall be subject to appropriate staff supervision, and shall receive regular and continuing education and training.
- (3) There shall be at least one clinical staff member, as defined in Part 800 of this Title, designated to provide activities therapy;
- (4) There shall be at least one counselor for every eight (8) patients, at least 50 percent of whom shall be qualified health professionals. Counseling staff shall be scheduled for a minimum of one and one-half shifts five days per week, and one shift per day for the remaining two days per week;
- (5) There shall be clinical staff available to all patients at all times. During late evening and night shifts, there shall be at least two clinical staff members on duty. This staff shall be awake at all times, make frequent rounds and be available to patients who awaken during the night;
 - (6) There shall be at least one full time equivalent Licensed Mental Health Counselor or Social Worker licensed and currently registered as such by the New York State Education Department experienced in [ehemical dependence]substance use treatment and adolescents. If qualified to do so, this individual may also perform the family therapist function required in paragraph (7) below.

- (7) There shall be at least one full time equivalent Family Therapist who is a Social Worker licensed and currently registered as such by the New York State Education Department or a licensed Marriage and Family Therapist. If qualified to do so, this individual may also perform the social worker function required in paragraph (6) above.
- (8) There shall be sufficient clinical staff to achieve an overall ratio of at least one full time equivalent staff for each four (4) patients.
- (f) Additional required staff. (1) Maintenance and security. There shall be sufficient staff available to ensure that the program facility and all equipment utilized therein is maintained in such a manner as to provide patients with a clean and safe environment.
- (2) Volunteers and interns. In addition to staffing requirements of this Part, a program may utilize volunteers, students and trainees, on a salaried or non-salaried basis. Such personnel shall be provided close professional staff supervision and appropriate education from both internal and external sources.
- (3) Health coordinator. Each program shall have a qualified individual designated as the Health Coordinator who will ensure the provision of education, risk reduction, counseling and referral services to all patients regarding HIV[—and—AIDS], tuberculosis, hepatitis, sexually transmitted <u>infections[diseases]</u>, and other communicable diseases.
- (4) Community Support Specialist. There shall be at least one Community Support Specialist for every thirty (30) patients or portion thereof who shall be responsible for coordinating care for the patient and assisting in discharge planning.
- (5) Intake/admissions coordinator. There shall be one staff member designated to perform an Intake/Admissions Coordinator function.

817.8 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 provision or applications of this Part which can be given effect without the invalid provision or applications, and to this end the provisions of this Part are declared to be severable.

[817.9 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 818 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.]



Notice of Proposed Rulemaking Summary

Amend 14 NYCRR Part 818 SUBSTANCE USE DISORDER INPATIENT REHABILITATION SERVICES

In addition to technical amendments and updating terminology used across all regulations for consistency in Title 14, the Proposed Rule amends Part 818 as follows:

- §818.2 General program standards. Added references to the provision of person centered, trauma informed care. Updated provisions regarding medication for addiction treatment for substance use disorder and naloxone access consistent with the needs of the program.
- §818.3 Admission procedures. Removed list of non-discrimination categories and added reference to Part 815.
- §818.5 Treatment/recovery plan. Added reference to requirement for post-discharge appointment(s) to continue medication access.
- §818.10 Savings and renewal clause. Removed.



Notice of Proposed Rulemaking Regulatory Impact Statement

Amend 14 NYCRR Part 818 SUBSTANCE USE DISORDER INPATIENT REHABILITATION SERVICES

1. Statutory Authority:

- (a) Section 19.07(e) of the Mental Hygiene Law authorizes the Commissioner to adopt standards including necessary rules and regulations pertaining to substance use disorder services.
- (b) Section 19.09(b) of the Mental Hygiene Law authorizes the Commissioner to adopt regulations necessary and proper to implement any matter under his or her jurisdiction.
- (c) Section 19.40 of the Mental Hygiene Law authorizes the Commissioner to issue operating certificates for the provision of substance use disorder services.
- (d) Section 32.01 of the Mental Hygiene Law 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 Mental Hygiene Law.
- (e) Section 32.07(a) of the Mental Hygiene Law authorizes the Commissioner to adopt regulations to effectuate the provisions and purposes of Article 32 of the Mental Hygiene Law.
- (f) Section 3309 of the Public Health Law authorizes the DOH to establish standards for approval of any opioid overdose prevention program.
- (g) Article 27f of the Public Health Law defines the rules governing HIV testing and treatment in New York.
- 2. <u>Legislative Objectives:</u> The legislature has authorized OASAS to establish standards and regulations governing the provision of addiction services, including the provision of medications for addiction treatment, as well as standards for providers seeking to offer such services.

- 3. <u>Needs and Benefits:</u> OASAS is updating the language used in this regulation consistent with amendments made to other OASAS regulations and OASAS guidance to clarify provider requirements with respect to the provision of medication for addiction treatment for substance use disorder and to update definitions consistent with other OASAS regulations.
- 4. Costs: No additional administrative costs to the agency are anticipated.
- 5. <u>Paperwork:</u> There is no additional paperwork beyond what is already required.
- 6. Local Government Mandates: There are no new local government mandates.
- 7. <u>Duplications</u>: This proposed rule does not duplicate, overlap, or conflict with any State or federal statute or rule.
- 8. <u>Alternatives:</u> The alternative is to leave the regulation as it currently reads, with language inconsistent across Title 14 regulations and providers unsure of their obligation to provide medication for addiction treatment for substance use disorders.
- 9. Federal Standards: This regulation does not conflict with federal standards.
- 10. <u>Compliance Schedule:</u> This rulemaking will be effective upon publication of a Notice of Adoption in the *State Register*.

PART 818 SUBSTANCE USE DISORDER INPATIENT REHABILITATION SERVICES

Statutory Authority: Mental Hygiene Law Sections 19.07(e), 19.09(b), 19.40, 32.01, 32.07(a) and Public Health Law sections 33.09, Article 27f

Sec.	
818.1	Legal base
818.2	General program standards
818.3	Admission procedures
818.4	Post admission procedures
818.5	Treatment/recovery plan
818.6	Record keeping
818.7	Staffing
818.8	Severability
[819.9	Savings and renewal clause.

Section 818.1 Legal base.

- (a) Section 19.07(e) of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to adopt standards including necessary rules and regulations pertaining to substance use disorder services.
- (b) Section 19.09(b) of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to adopt regulations necessary and proper to implement any matter under his or her jurisdiction.
- (c) Section 19.40 of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to issue operating certificates for the provision of substance use disorder services.
- (d) Section 32.01 of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to adopt any regulation reasonably necessary to implement and effectively exercise the powers and perform the duties conferred by Article 32 of the Mental Hygiene Law.
- (e) Section 32.07(a) of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to adopt regulations to effectuate the provisions and purposes of Article 32 of the Mental Hygiene Law.

- (f) Section 3309 of the Public Health Law authorizes the DOH to establish standards for approval of any opioid overdose prevention program.
- (g) [Section 2781] Article 27f of the Public Health Law defines the rules governing HIV testing and treatment in New York.

818.2 General program standards.

- (a) Policies and procedures. The program sponsor must approve written policies, procedures and methods governing the provision of **strength based, person centered, trauma informed** services to patients in compliance with Office regulations including a description of each service provided and a description of evidence-based practices employed in **all aspects of service delivery including but not limited to** group, individual and family treatment. Such policies and procedures shall address, at a minimum, the following:
 - (1) procedures and specific criteria for admission, retention, transfer, referrals and discharge;
- (2) level of care determinations utilizing the OASAS level of care determination protocol, treatment/recovery plans, and placement services;
- (3) staffing, including but not limited to, training, supervision, and use of student interns, peers, and volunteers;
- (4) the provision of medical and psychiatric services, including screening and referral for associated physical or mental health conditions;
 - (5) a schedule of fees for services rendered;
 - (6) infection control procedures;
- (7) cooperative agreements with other [ehemical dependence] substance use disorder service providers and other providers of services that the patient may need;
- (8) 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 [diseases]infections 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 as clinically appropriate; and
 - (iii) medication and the use of medication [assisted] for addiction treatment;

- (iv) if acupuncture is provided it must be provided in accordance with Part 830 of this Title;
- (v) the use of a problem gambling screen approved by OASAS.
- (9) record keeping procedures which ensure that documentation is accurate, timely, prepared by appropriate staff, and in conformance with the federal confidentiality regulations contained in 42 Code of Federal Regulations Part 2; and
- (10) Utilization review and quality improvement. All programs must have a utilization review process, a quality improvement process, and a written plan that identifies key performance measures.
- (b) *Program goals*. An inpatient program shall have as its goals:
- (1) the improvement of functioning and development of coping skills necessary to enable the patient to be safely, adequately and responsibly treated in the least intensive environment; and
- (2) the development of individualized plans to support the maintenance of recovery, attain self-sufficiency, and improve the patient's quality of life.
- (c) *Minimum services*. Inpatient programs shall provide, at a minimum, the following **strength based**, **person centered**, **trauma informed** services as clinically indicated and specified in the individualized treatment/recovery plan:
- (1) trauma-informed individual and group counseling and activities therapy. 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;
- (2) skills to identify and manage craving and urges to use, anticipate <u>recurrent substance use</u>[reoccurrence], and develop a [prevention]safety plan;
- (3) education about, orientation to, and the opportunity for participation in, available and relevant self-help groups and other forms of peer support;
 - (4) assessment and referral services for patients and significant others;
 - (5) HIV [and AIDS] education, risk assessment, supportive counseling and referral:
 - (i) offer viral hepatitis testing; testing may be done on site or by referral;
- (ii) offer HIV testing; testing may not be conducted without patient written informed consent except in situations specifically authorized by law; testing 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;

- (6) vocational and/or educational assessment; and
- (7) medical and psychiatric consultation.
- (d) Medication [Assisted] for Addiction Treatment. [A provider of inpatient services must provide services to an individual who is receiving approved opioid full agonist medication maintenance or detoxification through a written agreement with a certified outpatient provider of opioid full agonist medication treatment in accordance with applicable federal and state requirements.]
- (1) All programs 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.

- (e) Emergency medical kit. Pursuant to Part 800 of this Title, all programs must maintain an emergency medical kit at each certified or funded location; such kit must include basic first aid and [at least one] naloxone emergency overdose prevention kits sufficient to meet the needs of the program. Programs must develop and implement a plan to have staff trained in the prescribed use of a naloxone overdose prevention 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 naloxone overdose prevention kit and the authorized administering staff.
- (2) 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.
- (f) Food and nutrition. (1) Each facility shall provide to each patient three (3) nutritious meals each day which furnish sufficient nutrients and calories to meet normal needs as well as the special needs of persons in recovery.
 - (2) The facility shall have available snacks and beverages between meals.
- (3) A dietician or dietetic technician acting within their scope of practice shall provide menu planning services. Other suitable staff shall be responsible for the procurement of food supplies and the training and directing of food preparation and serving personnel.
- (g) *Certified capacity*. The certified bed capacity of each inpatient program shall not be exceeded at any time except with the written approval of the Office.
- (h) Educational and child care services. Each inpatient program which provides services to school-age [ehildren]youth must make arrangements to ensure the availability of required basic educational and child care services.
- (i) *Medicaid*. Providers seeking Medicaid reimbursement must comply with the requirements of **this Part** and Part 841 of this Title.
- (j) *Medical emergencies*. Each inpatient program shall have written agreements with general hospitals for the immediate transfer of patients or prospective patients in need of acute hospital care, unless the inpatient program is co-located in a general hospital.

(k) <u>Telehealth</u> [*Telepractice*]. Services may be delivered using <u>telehealth</u>[telepractice] consistent with Part 830 of this <u>Title</u>[Chapter].

818.3 Admission procedures.

- (a) Admission requirements for all programs. (1) The admission assessment or decision to admit must include identification of initial services needed until the development of the treatment/recovery plan.
- (2) 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);
- (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.
- (4) An individual who appears at the inpatient program seeking or having been referred for treatment or evaluation shall have an initial determination made and documented in a written record by a qualified health professional, or other clinical staff under the supervision of a qualified health professional, which states that the individual appears to not need acute hospital care, acute psychiatric care, or other intensive services which cannot be provided in conjunction with inpatient care or which would prevent them from participating in substance use disorder treatment.
- (b) Level of care determination. If an individual is determined to be appropriate for substance use disorder treatment services, a level of care determination utilizing the OASAS level of care determination protocol, shall be made by a clinical staff member. The level of care determination shall be made no later than twenty-four (24) hours after the patient's first on-site visit to the program.
- (c) Prohibition against discrimination. No individual shall be denied admission to the inpatient program consistent with the provisions in Part 815 of this Title. [(1) No individual shall be denied admission to the inpatient 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	y) HIV and AIDS status;
(v	vi) physical or mental disability; or
(v	viii) lack of cooperation by significant others in the treatment process.
(i :	x) toxicology test results; or
——— (X	() use of medications for substance use disorder prescribed and monitored by a physician, physician's
assistant	or nurse practitioner.

- (2) 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 and continued treatment.
- (d) Admission criteria. (1) If the individual is deemed inappropriate for inpatient services, unless the individual is already receiving substance use disorder treatment services from another provider, a referral and connection to a more appropriate service shall be made. The reasons for a denial of admission must be provided to the individual and documented in a written record maintained by the program.
- (2) There must be a notation in the case record that the patient received a copy of the inpatient program's rules and regulations, including patient rights and a summary of federal confidentiality requirements, and a statement that notes that such rules were discussed with the patient, and that the patient indicated that they understood them.

818.4 Post-admission procedures.

- (a) *Post-admission.* (1) As soon as possible after admission, for all patients, all programs must:
 - (i) offer viral hepatitis testing; testing may be done on site or by referral;
- (ii) offer HIV testing; testing may not be conducted without patient written informed consent except in situations specifically authorized by law; testing 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.
 - (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 [diseases]infections; 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 any blood and skin test results to the patient.
- (b) *Initial evaluation*. (1) The goal of the initial evaluation, to be completed within twenty-four (24) hours of admission, shall be to obtain whatever relevant information is necessary to develop an individualized patient-centered treatment/recovery plan. The initial evaluation shall comprise a written report of findings and conclusions and shall include the names of any staff or other persons participating in the evaluation.
- (2) *Initial services*. The initial evaluation shall include an identification of initial services needed, and schedules of individuals and group counseling to address the needed services until the development of the treatment plan. The initial services shall be based on goals the patient identifies for treatment.
- (c) *Medical history*. (1) For those patients who do not have available a medical history and no physical examination has been performed within twelve (12) months, within three (3) days after admission the patient's medical history shall be recorded and placed in the patient's case record and the patient shall receive a physical examination by a physician, physician's assistant, or a nurse practitioner. The physical examination may include but shall not be limited to the investigation of, and if appropriate, screenings for infectious diseases; pulmonary, cardiac or liver abnormalities; and physical and/or mental limitations or disabilities which may require special services or attention during treatment. The physical examination shall also include the following laboratory tests:
 - (i) complete blood count and differential;
 - (ii) routine and microscopic urinalysis;
 - (iii) if medically or clinically indicated, urine screening for drugs;
- (iv) intradermal PPD, given and interpreted by the medical staff unless the patient is known to be PPD positive;

- (v) or 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.
- (2) If the patient has a medical history available and has had a physical examination performed within twelve (12) months prior to admission, or if the patient is being admitted directly to the inpatient service from another [ehemical dependence]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 Part, provided that such documentation has been reviewed and determined to be current and accurate.
- (3) Patient records shall include a summary of the results of the physical examination and shall also demonstrate that appropriate medical care is recommended to any patient whose health status indicates the need for such care.
- (d) Referral and connection. (1) If the initial evaluation indicates that the individual needs services beyond the capacity of the inpatient program to provide either alone or in conjunction with another program, referral and connection to appropriate services shall be made. Identification of such referrals and connections and the results of those referrals to identified program(s) shall be documented in the patient record.
- (2) If a patient is referred directly to the inpatient program from another program certified by the Office, or is readmitted to the same program within sixty (60) days of discharge, the existing level of care determination and evaluation or treatment/recovery plan may be used, provided that documentation is maintained demonstrating a review and update.

818.5 Treatment / recovery plan.

- (a) Treatment / recovery plan. (1) Each patient must have a written person-centered treatment/recovery plan developed by clinical staff and patient no later than seven (7) 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 the patient's parent or guardian unless the minor is being treated without parental consent as authorized by Mental Hygiene Law section 22.11.

- (3) 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 twenty-four (24) hours of transfer.
- (b) *Treatment/recovery plan.* 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, signed and dated by the physician within ten (10) days of admission.
- (5) Where a service is to be provided by any other program off site, the treatment/recovery plan must contain a description of the nature of the service, a record that referral for such service has been made, and the results of the referral.
- (c) Continuing review of the treatment/recovery plan. (1) The clinical staff shall ensure that the treatment/recovery plan is included in the patient record and that all treatment is provided in accordance with the individual treatment/recovery plan.
- (2) If, during the course of treatment, revisions to the treatment/recovery plan are determined to be clinically necessary, the plan shall be revised accordingly by the clinical staff member.
- (d) *Progress notes*. A progress note shall be written, signed and dated by the clinical staff member or another clinical staff member familiar with the patient's care no less often than once per week. Such progress note shall provide a chronology of the patient's participation in all significant services provided, their progress related to the initial services or the goals established in the treatment/recovery plan and be sufficient to delineate the course and results of treatment/services.
- (e) Discharge and planning for level of care transitions. (1) The discharge planning process shall begin as soon as the patient is admitted and shall be considered a part of the treatment planning process. The plan for discharge and level of care transitions shall be developed in collaboration with the patient and any significant other(s) the patient chooses to involve. If the patient is a minor, the discharge 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.

- (2) Discharge should occur when:
- (i) the patient meets criteria documented by the OASAS level of care determination protocol for an alternate level of care and has attained skills in identifying and managing cravings and urges to use substances, stabilized psychiatric and medical conditions, and has identified a plan for returning to their community;
 - (ii) the patient has received maximum benefit from the service provided by the program; or
- (iii) the individual is disruptive and/or fails to comply with the program's written behavioral standards, provided that the individual is offered a referral and connection to another treatment program and discharge is otherwise in accordance with Part 815 of this Title.
- (3) No patient shall be discharged without a discharge plan which has been completed and reviewed by the multi-disciplinary team prior to the discharge of the patient. This review may be part of a regular treatment/recovery plan review. The portion of the discharge plan which includes the referrals for continuing care shall be given to the patient upon discharge. This requirement shall not apply to patients who leave the program without permission, refuse continuing care planning, or otherwise fail to cooperate.
- (4) The discharge plan shall be developed by the clinical staff member, who, in the development of such plan, shall consider the patient's self-reported confidence in maintaining their health and recovery and following an individualized [re-occurrence prevention]recurrent use safety plan. The clinical staff member shall also consider an assessment of the patient's home and family environment, vocational/educational/employment status, and the patient's relationships with significant others. The purpose of the discharge plan shall be to establish the level of clinical and social resources available to the individual post-treatment and the need for the services for significant others. The plan shall include, but not be limited to, the following:
- (i) identification of any other treatment, rehabilitation, self-help and vocational, educational and employment services the patient will need after discharge;
 - (ii) identification of the type of residence, if any, that the patient will need after discharge;
 - (iii) identification of specific providers of these needed services;
 - (iv) specific referrals and initial appointments for these needed services; [and]

(v) the patient, and their family/significant other(s) shall be offered naloxone education and training and a naloxone kit or prescription[-]; and

(vi) an appointment with a community based provider to continue access to medication for addiction treatment.

(5) A discharge summary which includes the course and results of care and treatment must be prepared and included in each patient's case record within twenty (20) days of discharge.

818.6 Patient Records.

- (a) <u>Patient</u>[Case] Records. (1) Inpatient programs must maintain individual <u>patient</u>[ease] records for each patient served. Patient records maintained by inpatient programs are confidential and may only be disclosed in <u>accordance</u>[conformity] with federal regulations regarding the confidentiality of records related to persons receiving treatment for substance use disorder as set forth in 42 Code of Federal Regulations Part 2, or other applicable <u>state and federal</u> laws.
- (2) There shall be a single individual patient record for each person admitted to the inpatient program which shall include, at a minimum:
 - (i) identifying information about the patient and their family;
 - (ii) the source of referral, date of commencing service and name of primary counselor;
- (iii) the admission diagnosis, including [ehemical dependence-] <u>substance use</u> related, medical, and psychiatric diagnoses in official nomenclature with associated diagnostic codes;
 - (iv) reports of all evaluations performed, including findings and conclusions;
- (v) reports of all examinations performed, including but not limited to X-rays, clinical laboratory tests, clinical psychological tests, electroencephalograms, and psychometric tests;
 - (vi) the written and signed individual treatment/recovery plan, including all reviews and updates;
- (vii) progress notes informative of the patient's condition and response to treatment, written and signed by staff members;
 - (viii) summaries of case conferences, treatment plan updates, and special consultations held;
 - (ix) dated and signed prescriptions or orders for all medications with notation of termination dates;
 - (x) the discharge plan;

- (xi) any other documents or information regarding the patient's condition, treatment, and results of treatment; and
- (xii) signed forms consenting to treatment and for obtaining or releasing confidential information in accordance with 42 Code of Federal Regulations Part 2 or other applicable law.
- (b) *Disclosures*. Disclosure of HIV[-and-AIDS] related information contained in a patient's record shall be made in accordance with the Article [24]27f of the Public Health Law, other applicable state and federal statutes and regulations, and subject to the additional disclosure requirements of 42 Code of Federal Regulations Part 2.
- (c) Reporting to Office. Statistical information shall be reported to the Office as required and on the prescribed forms therefor.

818.7 Staffing.

- (a) Medical Director and medical staff. (1) The medical director, as defined in Part 800 of this Title, shall oversee the development and revision of medical policies, procedures and ongoing training for matters such as routine medical care, specialized services, and medical and psychiatric emergency care, and supervision of medical staff.
- (2) Programs providing treatment for persons with co-existing medical or psychiatric conditions in addition to their substance use disorder shall have an appropriately qualified physician, physician's assistant, nurse practitioner, psychiatrist or psychologist on-site or through telepractice, pursuant to Part 830 of this Title, providing coverage as adequate and necessary to provide evaluation, treatment and supervision of such other services for these patients.
- (3) There shall be at least one full-time registered professional nurse and additional licensed practical nurses, registered nurses, registered physician's assistants, and nurse practitioners sufficient to provide the services required. Such personnel shall be available to all patients at all times.
- (4) The medical director may also serve as a physician of another service which is provided by the facility.
- (b) Staff sharing. Staff may be either specifically assigned to the inpatient service or may be part of the staff of the facility within which the inpatient service is located. However, if these staff members are part of the general facility staff, they must have specific training and experience in the treatment of substance use

disorder specific to the services provided. The percentage of time that each shared staff is assigned to the inpatient service must be documented.

- (c) Supervision and training. 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.
- (d) *Program director*. There shall be a director of the program who is a qualified health professional with at least three (3) years-experience in the provision of [alcoholism, substance abuse, and/or chemical dependence] substance use disorder services, and at least two (2) additional years of supervisory experience prior to appointment as director.
- (e) Other clinical staff. (1) At least 50 percent of all clinical staff shall be qualified health professionals as defined in Part 800 of this Title. CASAC Trainees may be counted towards satisfying the 50 percent requirement provided, however, that such individuals shall not be considered qualified health professionals for any other purpose under this Part.
- (2) Clinical staff members who are not qualified health professionals shall have qualifications appropriate to their assigned responsibilities as set forth in the inpatient service's written personnel policies, shall be subject to appropriate staff supervision, and shall receive regular and continuing education and training.
- (3) There shall be at least one clinical staff member, as defined in Part 800 of this Title, designated to provide activities therapy;
- (4) There shall be at least one counselor for every eight (8) patients, at least 50 percent of whom shall be qualified health professionals. Counseling staff shall be scheduled for a minimum of one and one-half shifts five days per week, and one shift per day for the remaining two days per week;
- (5) There shall be clinical staff available to all patients at all times. During late evening and night shifts, there shall be at least two clinical staff members on duty. This staff shall be awake at all times, make frequent rounds and be available to patients who awaken during the night;
- (6) There shall be sufficient clinical staff, allocated based on clinical demands of each shift, to achieve an overall program ratio of at least the following:
 - (i) if the program has 80 patients or more, one full time equivalent staff for each four (4) patients;

- (ii) if the program has between 31 and 79 patients, at least one full time equivalent staff for each three and one-half patients; and
- (iii) if the program has 30 or fewer patients, at least one full time equivalent staff for each three patients.
- (g) Additional required staff. (1) Maintenance and security. There shall be sufficient staff available to ensure that the inpatient program and all equipment utilized therein is maintained in such a manner as to provide patients with a clean and safe environment.
- (2) Volunteers and interns. In addition to staffing requirements of this Part, an inpatient service may utilize volunteers, students and trainees, on a salaried or non-salaried basis. Such personnel shall be provided close professional staff supervision and appropriate education from both internal and external sources.
- (3) Health coordinator. Each inpatient program shall have a qualified individual designated as the Health Coordinator who will ensure the provision of education, risk reduction, counseling and referral services to all patients regarding HIV[-and-AIDS], tuberculosis, hepatitis, sexually transmitted [diseases]infections, and other communicable diseases.

818.9 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 provision or applications of this Part which can be given effect without the invalid provision or applications, and to this end the provisions of this Part are declared to be severable.

[818.10 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 818 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.]





Notice of Proposed Rulemaking Summary

Amend Part 819 CHEMICAL DEPENDENCE RESIDENTIAL SERVICES

In addition to technical amendments updating this regulation consistent with Title 14, the Proposed Rule amends Part 819 as follows:

- §819.2 Definitions. A new section addressing definitions applicable to this Part is added.
- §800.3 Standards applicable to all residential service providers. Adds and updates requirements applicable to residential service providers consistent with other OASAS residential programs including the development of policies and procedures, access to medications for addiction treatment for substance use disorders and service provision.
- §819.4 Admission procedures. Updates consistent with appropriate use of terminology. Provisions relating to non-discrimination are removed and reference is added to compliance with Part 815.
- §819.5 Post admission procedures. Updates consistent with appropriate use of terminology related to medical and clinical assessments post-admission. Treatment planning and discharge provisions are updated consistent with OASAS updates to all certified programs.
- §819.6 Record keeping. Updates consistent with appropriate use of terminology and record keeping requirements around medications for addiction treatment.
- §819.8 General staffing. Updates consistent with appropriate use of terminology consistent with OASAS regulations. Reference is added to appropriate duties that may fall to residents consistent with OASAS guidance. Staff training requirements are amended to occur every year instead of every three years and the list of appropriate trainings are updated consistent with other certified program requirements.





Notice of Proposed Rulemaking Regulatory Impact Statement

Amend Part 819 CHEMICAL DEPENDENCE RESIDENTIAL SERVICES

1. Statutory Authority:

- (a) Section 19.07(e) of the Mental Hygiene Law authorizes the Commissioner of the Office of Addiction Services and Supports to adopt standards including necessary rules and regulations pertaining to substance use disorder services.
- (b) Section 19.09(b) of the Mental Hygiene Law authorizes the Commissioner of the Office of Addiction Services and Supports to adopt regulations necessary and proper to implement any matter under their jurisdiction.
- (c) Section 19.40 of the Mental Hygiene Law authorizes the Commissioner of the Office of Addiction Services and Supports to issue operating certificates for the provision of substance use disorder services.
- (d) Section 32.01 of the Mental Hygiene Law authorizes the Commissioner of the Office of Addiction Services and Supports to adopt any regulation reasonably necessary to implement and exercise effectively the powers and perform the duties conferred by Article 32 of the Mental Hygiene Law.
- (e) Section 32.07(a) of the Mental Hygiene Law authorizes the Commissioner of the Office of Addiction Services and Supports to adopt regulations to effectuate the provisions and purposes of Article 32 of the Mental Hygiene Law.
- 2. <u>Legislative Objectives</u>: The legislature has authorized OASAS to establish standards and regulations governing the provision of addiction services, including the provision of medications for addiction treatment, as well as standards for providers seeking to offer such services.
- 3. <u>Needs and Benefits:</u> OASAS is updating the language used in this regulation consistent with amendments made to other OASAS regulations to clarify provider requirements with respect to the provision of medication for addiction treatment for substance use disorder and to update definitions consistent with other OASAS

regulations. Medical and clinical requirements for providers of substance use disorder residential services are updated consistent with requirements in other residential services programs.

- 4. <u>Costs:</u> No additional administrative costs to the agency are anticipated.
- 5. Paperwork: There is no additional paperwork beyond what is already required.
- 6. <u>Local Government Mandates</u>: There are no new local government mandates.
- 7. <u>Duplications</u>: This proposed rule does not duplicate, overlap, or conflict with any State or federal statute or rule.
- 8. <u>Alternatives:</u> The alternative is to leave the regulation as it currently reads, with language inconsistent across Title 14 regulations and providers unsure of their obligation to provide medication for addiction treatment for substance use disorders. Additionally, similar residential services programs will have inconsistent regulatory provisions and requirements.
- 9. Federal Standards: This regulation does not conflict with federal standards.
- 10. <u>Compliance Schedule:</u> This rulemaking will be effective upon publication of a Notice of Adoption in the *State Register*.

PART 819

SUBSTANCE USE DISORDER [CHEMICAL DEPENDENCE] RESIDENTIAL SERVICES

(Statutory Authority: Mental Hygiene Law Sections 19.07(e), 19.09(b), 19.40, 32.01, 32.07(a))

Sec.

- 819.1 Legal base
- 819.2 **Definitions** [Standards applicable to all residential service providers]
- 819.3 Standards applicable to all residential service providers [Admission procedures]
- 819.4 Admission Procedures [Post admission procedures]
- 819.5 Post-admission procedures [Record keeping]
- 819.6 Record keeping[Quality improvement and utilization review]
- 819.7 Quality improvement and utilization review
- 819.8[7] General staffing
- 819.9[8] Additional requirements for intensive residential rehabilitation
- 819.10[9] Additional requirements for community residential services
- 819.11[0] Additional requirements for supportive living services
- 819.12[4] Severability

Section 819.1 Legal base.

- (a) Section 19.07(e) of the Mental Hygiene Law authorizes the Commissioner of the Office of <u>Addiction Services and Supports</u> [Alcoholism and Substance Abuse Services] to adopt standards including necessary rules and regulations pertaining to <u>substance use disorder</u> [chemical dependence] services.
- (b) Section 19.09(b) of the Mental Hygiene Law authorizes the Commissioner of the Office of <u>Addiction Services and Supports</u> [Alcoholism and Substance Abuse Services] to adopt regulations necessary and proper to implement any matter under <u>their</u> [his or her] jurisdiction.
- (c) Section 19.40 of the Mental Hygiene Law authorizes the Commissioner of the Office of Addiction Services and Supports [Alcoholism and Substance Abuse Services] to issue operating certificates for the provision of substance use disorder [ehemical dependence] services.
- (d) Section 32.01 of the Mental Hygiene Law authorizes the Commissioner of the Office of Addiction Services and Supports [Alcoholism and Substance Abuse Services] to adopt any regulation reasonably necessary to implement and [effectively] exercise effectively the powers and perform the duties conferred by Article 32 of the Mental Hygiene Law.

(e) Section 32.07(a) of the Mental Hygiene Law authorizes the Commissioner of the Office of <u>Addiction Services and Supports</u> [Alcoholism and Substance Abuse Services] to adopt regulations to effectuate the provisions and purposes of Article 32 of the Mental Hygiene Law.

819.2 <u>Definitions [Standards applicable to all residential service providers.]</u> For purposes of this Part, the following definitions are applicable:

- (a) Substance use disorder residential service or residential service means a substance use disorder residential service providing an array of services for persons with substance use disorders, which may be provided directly or through cooperative relationships with other community service providers.
- (b) Levels of service. There are three levels of service that can be offered in a residential setting which are distinguished by the complement of services available on site as well as the functional capacity of the patient served in each setting:
- [(a) For purposes of this Part, Chemical dependence residential service or residential service means a chemical dependence residential service providing an array of services for persons [suffering from chemical dependence. Such services may be provided directly or through cooperative relationships with other community service providers. This Part applies to any entity certified by the Office to provide a chemical dependence residential service and governs all residential programs formerly certified by the Division of Alcoholism and Alcohol Abuse and/or the Office pursuant to Part 375 of this Title and all residential programs formerly licensed by the Division of Substance Abuse Services and/or the Office pursuant to Part 1030 of this Title. There are three levels of service that can be offered in a residential setting: intensive residential rehabilitation services, community residential services, and supportive living services. Each is distinguished by the complement of services available on site as well as the degree of dysfunction of the individual served in each setting. The three levels of residential services are defined as follows:1
- (1) Intensive residential rehabilitation services means <u>substance use disorder</u> residential services requiring twenty four hours a day, seven days per week treatment in a structured environment for individuals whose potential for independent living in recovery is contingent upon [<u>substantial</u>] social habilitation or rehabilitation. An integral part of this service is the case management of additional services from other providers that are needed by the resident. This level of residential service requires established written agreements with other appropriately certified providers to furnish <u>physical and mental</u> [<u>psychiatric and</u>] health <u>treatment [care]</u> services, in addition to educational, social and vocational services. These services are appropriate for individuals who require <u>substance use disorder</u> [<u>chemical dependence</u>] services in a residential setting [<u>due to previous non-compliance</u>, or relapse, in outpatient service settings] as

<u>determined by utilizing the OASAS level of care determination protocol</u> [, or their life skills deficits require sustained intensive rehabilitation].

- (2) Community residential services means <u>substance use disorder</u> [chemical dependence] residential services providing supervised services to persons making the transition to <u>independent</u> [abstinent-] living. Persons appropriate for this service require the support of a <u>substance</u> [drug and alcohol]-free environment while receiving either outpatient services or educational and/or vocational services. These transitional residential services are for individuals who are completing or have completed a course of treatment, but who are not [yet] ready for independent living <u>yet</u> due to <u>unresolved</u> [outstanding] clinical issues or unmet needs for personal, social or vocational skills development. These services are appropriate for individuals who require ongoing clinical support.
- (3) Supportive living services means <u>substance use disorder</u> [chemical dependence] treatment services which are designed to promote independent living in a supervised setting for individuals who have completed another course of treatment, are making the transition to independent living, and whose need for services does not require staffing on site <u>twenty-four</u> <u>hours a day</u> [on a twenty four hour a day basis]. These treatment services are for individuals who either require a long-term supportive environment following care in another type of residential service for an undetermined length of stay, or who are in need of a transitional living environment prior to establishing independent community living.
- (c) Resident, for purposes of this Part, means the individual admitted to and receiving services from the residential service provider certified pursuant to this Part.

§819.3 Standards applicable to all residential service providers.

- (a)[(b)] The <u>program sponsor must approve</u>[governing authority shall determine and establish] written policies, procedures and methods governing the provision of services to residents <u>in compliance with Office regulations and guidance</u> which shall include a description of each service provided, including procedures for making appropriate referrals to and from other services, when necessary. These policies, procedures, and methods[, which require review and approval by the governing authority], shall address, at a minimum, the following:
- (1) <u>procedures and specific criteria for</u> admission, retention, <u>transfers</u>, <u>referrals</u>, and discharge, [including specific criteria relating thereto, as well as transfer procedures];
- (2) level of care determinations <u>utilizing the OASAS level of care determination</u> <u>protocol</u>, comprehensive evaluations, treatment/<u>recovery</u> plans, and placement services;

- (3) staffing <u>including</u>, <u>but not limited to, training and the use of students, peers, and</u> [<u>plans</u>, <u>including the use of</u>] volunteers, <u>and appropriate criminal history reviews as</u> <u>otherwise required by this Title</u>;
- (4) <u>the provision of medical services, including</u> screening and referral procedures for associated physical [or psychiatric] conditions;
- (5) the provision of psychiatric services, including the use of OASAS approved, validated screening instruments for co-occurring mental health conditions, and referral procedures for associated mental health conditions;
 - (6) a schedule of fees for services rendered;
 - [(5) the determination of fees for services rendered;]
 - (7) [(6)] infection control procedures;
- [(7) public [health education and screening with regard to tuberculosis, sexually transmitted diseases, hepatitis, AIDS and HIV prevention and harm reduction];
- (8) cooperative agreements with other <u>substance use disorder</u> [ehemical dependence service] <u>treatment</u> providers and other providers of services that the resident may need;
- (9) <u>compliance with other requirements of applicable local, state, and federal laws and regulations, OASAS guidance documents and standards of care regarding:</u> [a requirement that if acupuncture is provided as an adjunct to the services provided by the service, it must be provided in accordance with Part 830 of this Title;]
- (i) education, counseling, prevention, and treatment of communicable diseases, including tuberculosis, viral hepatitis, sexually transmitted infections, HIV, and other infectious diseases, in accordance with guidance from the Office. Regarding HIV, such education, counseling, prevention and treatment shall include condom use, testing, and preand post-exposure prophylaxis and treatment;
 - (ii) the use of toxicology tests, in accordance with guidance issued by the Office;
 - (iii) medication and the use of medication for addiction treatment;
- (iv) if acupuncture is provided as an adjunct to the services provided by the program, it must be provided in accordance with Part 830 of this Title.
- [(10) a requirement that when HIV and AIDS education, testing and counseling are provided, such services must be provided in accordance with Article 27-F of the Public Health Law and this Title;]
- (11) the use of alcohol and other drug screening tests, such as breath testing, urine screening and/or blood tests];]
- (10) [(12)] procedures for the ordering, procuring, and disposing of medication, as well as the self-administration of medication;
 - (11) [(13)] quality improvement and utilization review;
 - (12) [(14)] clinical supervision and related procedures;
 - (13) [(15)] procedures for emergencies;
 - (14) [(16)] incident reporting and review in accordance with Part 836 of this Title;

(15) [(17)] record keeping procedures which ensure that documentation is accurate, timely, prepared by appropriate staff, and in conformance with the federal confidentiality regulations contained in 42 Code of Federal Regulations Part 2;

[(18) personnel;]

- (16) [(19)] procedures by which required educational services are provided for school age children who are in residence as either an individual who is receiving treatment or as part of a family unit; [and]
 - (17) [(20)] procurement, storage, and preparation of food; [-]and (18) record retention.
- (b) Emergency Medical Kit. Pursuant to Part 800 of this Title, all programs must maintain an emergency medical kit at each certified or funded location; such kit must include basic first aid items and naloxone emergency overdose prevention kits sufficient to meet the needs of the program. Programs must develop and implement a plan to have staff and residents, where appropriate, trained in the prescribed use of a naloxone overdose prevention kit such that it is available for use during all program hours of operation, in accordance with guidance from the Office.
- (1) All staff and residents should be notified of the existence of the naloxone prevention kit and the authorized administering staff.
- (2) Nothing in this Part shall preclude residents 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) A provider of residential services may provide residential services to an individual who is on methadone or other approved opiate maintenance, or is being detoxified from methadone. Opiate maintenance or detoxification services must be provided through a written agreement with an appropriately certified methadone/opiate provider in accordance with applicable federal and state requirements including, but not limited to, regulations of the federal Center for Substance Abuse Treatment, the United States Drug Enforcement Administration, the New York State Department of Health, and the Office, including but not limited to Part 828 of this Title.]
- (c) Medication for Addiction Treatment (MAT) for Substance Use Disorder (SUD)
- (1) All programs 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.
- (d) A substance use disorder residential service shall have as its goals: [(d) A chemical dependence residential service shall have as its goals:
- (1) the promotion and maintenance of abstinence from alcohol and other mood-altering drugs and substances except those lawfully prescribed by a physician, physician's assistant, or nurse practitioner; however, if a residential service objects to a resident's continued use of such prescribed drugs or substances, the residential service shall document each of the following:
- (i) obtain a signed consent form in accordance with the requirements of 42 Code of Federal Regulations Part 2 which authorizes the release of patient identifying information to the physician, physician's assistant, or nurse practitioner who prescribed the drug or substance to the resident ("the prescribing professional");

- (ii) consult with the prescribing professional to ascertain their knowledge and awareness of the resident's history of chemical dependence, and if the prescribing professional is unaware of the resident's
- -history of chemical dependence, inform the prescribing professional accordingly; and
- (iii) after the required consultation in (ii) above, if the prescribing professional believes that the resident should be permitted to continue to use the drug or substance, the resident must be permitted to

continue to use the drug or substance;]

- (1) [(2)] the improvement of functioning and development of coping skills necessary to enable the resident to be <u>treated</u> safely, adequately and responsibly [treated] in the least intensive environment; and
- (2) [(3)] the utilization of individualized treatment/<u>recovery</u> [service] plans to support the maintenance of recovery and the attainment of self-sufficiency, including, where appropriate, the ability to be [functionally] employed <u>functionally</u>, and the improvement of the resident's quality of life.
- (e) All residential services shall provide, either directly or through referral to appropriate agencies, habilitative and rehabilitative services consistent with identified needs and treatment/recovery plans for services for individual residents. The following services shall be provided to residents as clinically indicated:
- (1) <u>Psychosocial Treatment</u> [Counseling]. Each residential service shall make available to its residents individual, group and family [counseling] services <u>as appropriate that are</u> evidence-based, person-centered, and trauma-informed [as appropriate].
- (i) 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 resident experience, and assessing group efficacy. These sessions shall contain no more than fifteen residents. [A group therapy session shall contain no more than fifteen persons].
- (ii) These treatments must be evidence-based, person-centered, and trauma-informed, and individualized to the needs of the resident per the clinical assessment, in accordance with guidance and standards from the Office.
- (iii) [(ii)] Evidence-based, person-centered, trauma informed [Chemical dependence] individual, group and family counseling must be provided by a [elinical] staff member operating within their scope of practice.
- (iv) [(iii)] Family counseling services that include [services to] significant others are provided by program staff with appropriate training or by referral to community providers with this expertise.
- (v) [(iv)] Peer support may occur in a peer group setting where the group is facilitated by residents who have greater experience or seniority within the service. Such counseling must be [directly] supervised directly by a clinical staff member in attendance.

- (2) Supportive services. Each service shall ensure that a comprehensive and appropriate range of support services are available to each resident. Such services shall include, as needed and as appropriate, legal, **medical**, mental health, **recovery**, **wellness**, and social services, as well as vocational assessment and **activities** [eounseling].
- (3) Educational and childcare services. Each residential service <u>that</u> [which] provides services to school-age children must make arrangements to ensure the availability of required educational and childcare services.
- (4) Structured activity and recreation. Residents shall be afforded the opportunity to participate in <u>recovery and wellness</u> activities designed to develop skills to enable them to make effective use of leisure time as well as improve social skills, self esteem and responsibility.
- (5) Orientation to community services. Each <u>substance use disorder</u> [ehemical dependence] residential service shall provide orientation <u>to</u>, [advice] and instruction in identifying and obtaining needed community <u>recovery and wellness</u> services, including housing and other necessary case management services, to each resident.
- (f) The certified bed capacity of each residential service may not be exceeded at any time except in cases of emergency and unexpected surges in demand where no alternative options are available, when the failure to [temporarily] accept individuals temporarily into the service would jeopardize their immediate health and safety, and where the excess of capacity would be time limited. Standards and procedures for such exceptions that are based upon the availability of adequate space, supplies and staff must be established with the prior approval of the Office.

 (g) Food and nutrition.
- (1) Intensive residential rehabilitation services shall ensure the availability of three meals each day to each resident and community residences shall ensure the availability of two meals each day to each resident. Such meals shall furnish sufficient nutrients and calories to meet normal needs as well as the special needs of persons in recovery. Supportive living services shall ensure the availability of adequate food to all participants.
- (2) <u>Intensive</u> [For intensive] residential rehabilitation services and community residences[, the facility] shall have available snacks and beverages between meals. A qualified dietician, dietetic technician, nutritionist, or other appropriately qualified personnel <u>working within their scope of practice</u> shall provide menu planning services. Other suitable staff shall be responsible for the procurement of food supplies and the training and directing of food preparation and serving personnel. Copies of menus shall be kept on file for a period of one year.

819.[3]4 Admission procedures.

- (a) Admission requirements for all programs.
- (1) The admission assessment or decision to admit must include identification of initial services needed until the development of the treatment/recovery plan.
- (2) 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

<u>version of the Diagnostic and Statistical Manual (DSM) or the International Classification of Diseases (ICD), as incorporated by reference in Part 800 of this Title.</u>

- (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) of the qualified health professional and include the basis for admitting the individual. [An individual who appears at the residential service seeking or having been referred for treatment or evaluation shall have an initial determination made and documented in a written record by a qualified health professional, or other clinical staff under the supervision of a qualified health professional, which states the following:
- (1) that the individual appears to be in need of chemical dependence services;
- (2) that the individual appears to be free of serious communicable disease that can be transmitted through ordinary contact; and
- (3) that the individual appears to be not in need of acute hospital care, acute psychiatric care, or other intensive services which cannot be provided in conjunction with residential care or would prevent him/her from participating in a chemical dependence service.
- (b) The determinations made pursuant to the above shall be based upon service provider records, reports from other providers and/or through a face-to-face contact with the individual, all of which must be documented.
- (c)] (b) Level of care determination. If an individual is determined to meet criteria [be appropriate] for [ehemical dependence] substance use disorder residential services, a level of care determination shall be made by a clinical staff member who shall be provided clinical oversight by a qualified health professional. The level of care determination shall be signed and dated by the clinical staff member. The level of care determination shall be made promptly [and in no event not later than one day] after the individual's [resident's] first on site contact with the service.
- [(d)] (c) The level of care determination process must be in accordance with the governing authority's policy and procedures and incorporate the use of the OASAS Level of Care for Alcohol and Drug Treatment Referral Protocol (LOCADTR) or another Office-approved protocol.
- [(e)] (d) Prohibition against discrimination. Individuals that meet level of care criteria for residential services, in accordance with this Part, may not otherwise be denied admission in accordance with the provisions of Part 815 of this Title. [No individual shall be denied admission to the residential service based solely on the individual's:
- (1) prior treatment history;
- (2) referral source;
- (3) [maintenance on methadone or other medication prescribed and monitored by a physician, physician's assistant or nurse practitioner; however, if a residential service objects to an individual's continued use of such prescribed drugs or substances, the residential service shall document each of the following:

- (i) obtain a signed consent form in accordance with the requirements of 42 Code of Federal Regulations Part 2 which authorizes the release of patient identifying information to the physician, physician's assistant, or nurse practitioner who prescribed the drug or substance to the individual ("the prescribing professional"); (ii) consult with the prescribing professional to ascertain their knowledge and awareness of the individual's history of chemical dependence, and if the prescribing professional is unaware of the individual's history of chemical dependence, inform the prescribing professional accordingly; and (iii) after the required consultation in (ii) above, if the prescribing professional believes that the individual should be permitted to continue to use the drug or substance, the individual must be permitted to continue to use the drug or substance; (4)] (3) pregnancy; [(5)] (4) history of contact with the criminal justice system; <u>[(6)] (5) HIV and AIDS status;</u> [(7)] (6) physical or mental disability; or [(8)] (7) lack of cooperation by significant others in the treatment process. (8) toxicology test results; (9) use of medications for the treatment of substance use disorders prescribed and monitored by a physician, physician's assistant or nurse practitioner; (10) use of any illicit or prescribed substance, including but not limited to, benzodiazepines; or (11) prior ineligibility for admission for other than behavioral concerns including, but not limited to, a history of violent or self-harming behavior or suicide attempts, in accordance with clinical guidance issued by the Office. [(f)] (e) Admission criteria. To be admitted for residential services, the individual must be determined to [be able to achieve or maintain abstinence and] have recovery goals with the application of residential services and [÷ (1) the individual must meet the admission criteria identified in this Part for the applicable level of service. [Section 819.8 for intensive residential rehabilitation services; or (2) the individual must meet the admission criteria identified in Section 819.9 for community residential services; or (3) the individual must meet the admission criteria identified in Section 819.10 for
- [(g)] (f) If the individual does not meet admission criteria [is deemed inappropriate] for residential services, unless the individual already is [already] receiving substance use disorder treatment services [chemical dependence services] from another provider, a referral to a [more appropriate] service that can meet the individual's treatment needs shall be made. The reasons for denial of any admission to the residential service must be provided to the individual and documented in a written record maintained by the residential service.

supportive living services.

- [(h) If determined appropriate for the residential service, the individual shall be admitted. The decision to admit an individual shall be made by a clinical staff member who is a qualified health professional authorized by the policy of the governing authority to admit individuals. The name of the qualified health professional who made the admission decision, along with the date of admission, must be documented in the case record].
- [(i)] (g) There must be a notation in the <u>resident's</u> [ease] record that <u>they</u> [the resident] received a copy of the residential service's rules and regulations, including resident rights and a summary of federal confidentiality requirements, and a statement that notes that such rules were discussed with the resident, and that the resident indicated that <u>they</u> [he/she] understood them.
- [(j)] (h) All prospective residents shall be informed that admission is on a voluntary basis and that a resident shall be free to discharge themselves [himself or herself] from the service at any time. For prospective residents under an external mandate, the potential consequences for premature discharge shall be explained, including that the external mandate does [but this shall] not alter the voluntary nature of admission and continued treatment. This provision shall not be construed to preclude or prohibit attempts to persuade a resident to remain in the service in their [his or her] own best interest.

819.5[4] Post admission procedures.

- (a) As soon as possible after admission, if not completed already, all programs must:
 - (1) offer viral hepatitis testing (testing may be done by referral);
 - (2) offer HIV testing (testing may not be conducted without a resident's written informed consent in accordance with public health law and may be done on site or by referral). Residents on a regimen of pre- or post- exposure prophylaxis must be permitted to continue the regimen until consultation with the prescribing professional occurs.
 - (3) <u>Screen for co-occurring mental health conditions and behavioral health risks, including suicide risk, using validated screening instruments approved by the Office.</u>
 - (4) If clinically appropriate, all programs must:
 - (i) conduct a blood-based tuberculosis test (testing may be done on site or by referral with results as soon as possible after testing); residents with a positive test result should be referred for further tuberculosis evaluation;
 - a. an intradermal PPD may be placed in those circumstances when a blood-based tuberculosis test cannot be performed unless the patient is known to be PPD positive;
 - b. PPD placement may done on site with medical staff interpreting the results or by referral with results as soon as possible after testing

- (ii) <u>offer testing for other sexually transmitted infections (testing may</u> be done on site or by referral);
- (iii) offer immunizations either on site or by referral;
- (iv) <u>offer pregnancy tests to persons of childbearing potential (testing</u> may be done on site or by referral);
- (v) <u>provide or recommend any other tests the examining physician or other medical staff member working within their scope of practice deems necessary including, but not limited to, an ECG, a chest X-ray or other diagnostic tests.</u>
- (5) As soon as possible after testing, programs must review and discuss any blood, urine, and skin test results, ECG results, chest X-ray results, or other diagnostic test results where applicable with the residents.
- (6) Any significant medical issues, including risk of communicable diseases, identified prior to or after admission must be addressed in the treatment/recovery plan and documented in the resident's record.

 Treatment/recovery plans must include provisions for the prevention, care, and treatment of HIV, viral hepatitis, tuberculosis, sexually transmitted infections, and other infectious diseases when present. If a resident chooses not to obtain such care and treatment, the provider must have the resident acknowledge in writing that such care and treatment were offered and declined.
- (b) Comprehensive evaluation.
- (1) The goal of the comprehensive evaluation shall be to obtain <u>information from the</u> resident and other sources, including family members and significant others if possible and where appropriate, that is necessary to develop an individualized, person-centered treatment/recovery plan [that information necessary to develop an individual treatment plan].
- (2) [The comprehensive evaluation shall obtain that information necessary to determine whether a diagnosis of alcohol related or psychoactive substance related use disorder in accordance with the International Classification of Diseases, Ninth Revision or another Office approved protocol is indicated.
- (3) Each comprehensive evaluation shall be based, in part, on clinical interviews with the resident, and may also include interviews with significant others, if possible and appropriate.
- (4)] No later than fourteen days after admission, staff shall complete the resident's comprehensive evaluation which shall include a written report of findings and conclusions addressing, at a minimum, the resident's:
 - (i) identifying and emergency contact information;
- (ii) the source of referral, date of commencing service, and name of the clinical staff member with primary responsibility for the resident;
 - ____(iii) both recent and history of substance use;
 - (iv) substance use disorder treatment history;

$(v_{\overline{H}})$ comprehensive psychosocial history, including, but not limited to the following:

- [(i) chemical use, abuse and dependence history;
- (ii) history of previous attempts to abstain from chemicals and previous treatment experiences;
- (iii) comprehensive psychosocial history, including, but not limited to, the following:
 - (A) legal **history** [involvements];
- (B) <u>communicable disease risk assessment (HIV [-and AIDS]</u>, tuberculosis, <u>viral</u> hepatitis, <u>sexually transmitted infections</u>, <u>and other communicable diseases</u> [or other <u>communicable disease risk assessment</u>];
- (C) relationships with, history of the use of chemicals by, and the impact of the use of chemicals on, significant others;]
- [(D)] an assessment of the resident's individual, social and educational strengths <u>and</u> <u>limitations</u> [and weaknesses], including, but not limited to, the resident's literacy level, daily living skills and use of leisure time;
- [(E)] (D) the resident's current medical conditions, current mental health conditions, past medical history, past mental health history, and an assessment of the resident's risk of harming self or others. [medical history, mental health history, current status, and the resident's lethality (danger to himself/herself or to others) assessment; and]

 (F) a specific diagnosis of alcohol related or psychoactive substance related use disorder in accordance with the International Classification of Diseases, Ninth Revision or another Office approved protocol.]
- (3) The comprehensive evaluation must include diagnoses, including substance-related, medical, and psychiatric diagnoses in official nomenclature with associated diagnostic codes in the most recent version of the Diagnostic and Statistical Manual (DSM) or the International Classification of Diseases (ICD).
- [(5)] (4) The comprehensive evaluation shall bear the names of the <u>clinical</u> staff members who <u>evaluated[participated in evaluating]</u> the <u>resident [individual]</u> and must be signed (<u>physically or electronically</u>) and <u>dated</u> by the qualified health professional responsible for the evaluation.
- [(b)] (c) Medical history and physical examination. Providers shall make every effort to execute appropriate consents to obtain and share medical information with the resident's other medical providers as appropriate.
- (1) [For those r]Residents who do not have an available [a] medical history and have not had a [no] physical examination [has been] performed within the last 12 months prior to admission must have a medical history recorded, and a physical examination performed and documented in the resident's record by a physician, physician assistant, or a nurse practitioner working within their scope of practice within forty five days after admission.[5] within forty-five days after admission the resident's medical history shall be recorded and placed

in the resident's case record and the resident shall receive a physical examination by a physician, physician's assistant, or a nurse practitioner.] The physical examination may include but shall not be limited to the investigation of, and if appropriate, screenings for infectious diseases; pulmonary, cardiac or **gastrointestinal** [liver] abnormalities; and physical. neurological, and/or psychological [and/or mental-] limitations or disabilities which may require special services or attention during treatment. The physical examination shall also include the following laboratory tests:

- (a) complete blood count and differential;
- (b) routine and microscopic urinalysis;
- (c) if medically or clinically indicated, urine toxicology test [screening for drugs];
- (d) pregnancy test for persons of childbearing potential;
- [(d)] (e) blood-based tuberculosis test
- (i) an intradermal PPD may be placed in those circumstances when a blood-based tuberculosis test cannot be performed, with the results [given and] interpreted by the medical staff working within the scope of their practice unless the resident is known to be PPD positive;
- [(e)] (f) [or] any other tests the examining physician or other medical staff members working within their scope of practice [member] deem[s] to be necessary, including, but not limited to, an ECG [EKG], a chest X-ray, or other diagnostic tests [a pregnancy test].
- (2) If the <u>resident</u> [patient] has a medical history available and has had a physical examination performed within 12 months prior to admission, or if the resident [is being] <u>has</u> <u>been</u>-admitted directly to the residential service from another <u>substance use disorder</u> [ehemical dependence] service authorized by the Office, the existing medical history and physical examination documentation may be used to comply with the requirements of this Part, provided that such documentation has been reviewed and determined to be current and accurate.

Notwithstanding the forgoing, the following shall be offered regardless of a documented history within the previous twelve months: HIV and viral hepatitis testing.

- (a) a focused medical history shall be taken and/or physical examination shall be performed and/or laboratory tests and other diagnostic tests shall be ordered if the examining physician, physician assistant, or nurse practitioner working within the scope of their practice determine that the elements of the existing medical history and/or physical examination and/or results of laboratory and other diagnostic tests require reevaluation based on the clinical judgment of the examining physician or other medical staff;
- (b) a focused medical history shall be taken and/or physical examination shall be performed and/or laboratory and other diagnostic tests shall be ordered if the resident has a physical complaint that was not addressed in the existing medical history and/or physical examination, and/or the resident has a new complaint that developed since the existing medical history was taken and/or existing physical examination was performed.
- (3) Resident records shall include a summary of the <u>medical history and the</u> results of the physical examination, <u>laboratory tests</u>, and other <u>diagnostic tests</u> and shall also demonstrate

that appropriate medical care, including mental health care, is recommended to any resident who needs [whose health status indicates the need for] such care.

- (c) After the comprehensive evaluation is completed, a resident shall be retained in such treatment [only] if the resident[:
- (1)] has a diagnosis of <u>a substance use disorder in accordance with the most recent</u> edition of the Diagnostic and Statistical Manual (DSM) or the International Classification of Diseases (ICD) and [alcohol related or psychoactive substance related use disorder in accordance with the International Classification of Diseases, Ninth Revision or another Office approved protocol];
 - [(2)] continues to meet the admission criteria <u>required by</u> [in] this Part.[;
- (3) is free of serious communicable diseases that can be transmitted through ordinary contact with other residents;
- (4) has no medical or surgical condition or mental disability requiring acute care in a general or psychiatric hospital;
- (5) is not in need of medically managed detoxification; and
- (6) can benefit from continued treatment in a residential service.
- (d) If the comprehensive evaluation indicates that the <u>resident</u> [individual] needs services beyond the capacity of the residential service to provide either alone or in conjunction with another program, referral to appropriate services shall be made. Identification of such referrals and the results of those referrals to identified program(s) shall be documented in the resident record.
- (e) If a resident is referred directly to the residential service from another service certified by the Office, or is readmitted to the same service within sixty (60) days of discharge, the existing level of care determination and comprehensive evaluation may be used, provided that the documentation has been reviewed and, if necessary, updated within fourteen (14) days of transfer [documentation is maintained demonstrating a review and update].
- (f) Treatment/recovery plan. [An] A person-centered, initial treatment/recovery[service] plan addressing the resident's individual needs must be developed within three days of admission, or readmission [read mission], to the substance use disorder [ehemical dependence] residential service. The treatment/recovery plan shall be developed by the clinical staff member with primary responsibility for the resident ("the responsible clinical staff member") in collaboration with the resident and anyone identified by the resident as supportive of their recovery goals. [and shall be prepared in consultation with the resident, as documented by the resident's signature on the treatment/service plan.] This initial treatment/recovery[service] plan must contain a statement which documents that the resident [individual] meets admission criteria [is appropriate] for this level of care, identifies the assignment of a named clinical staff member with the responsibility to provide orientation to the resident [individual], and includes a preliminary schedule of activities, therapies and interventions.

- (g) A <u>treatment/recovery plan</u>, [comprehensive treatment/service plan ("treatment/service plan"),] based on the admitting evaluation, shall be prepared within thirty days of development of the initial treatment/<u>recovery</u>[service] plan to meet the identified needs of the resident, and shall take into account cultural and social factors as well as the particular characteristics, conditions and circumstances of each resident. For [individuals] <u>residents</u> moving directly from one <u>substance use disorder</u> [chemical dependence] service to another, <u>the existing</u> <u>treatment/recovery plan may be used if there is documentation that it has been reviewed and, if necessary, updated to reflect the resident's goals as appropriate [an updated treatment/service plan shall be acceptable if it is in conformance with the requirements of this Section].</u>
 - (h) The treatment/<u>recovery</u>[service] plan shall:
- (1) be developed by the responsible clinical staff member(s) in collaboration with the resident and anyone identified by the resident as supportive of their recovery goals [in collaboration with the resident as evidenced by the resident's signature thereon];
- (2) be based on the admitting evaluations specified above and any additional evaluation(s) **the resident has received or is** determined to be required;
 - (3) specify measurable treatment goals for each problem identified;
- (4) specify the objectives <u>that</u> [to be achieved while the resident is receiving services which] shall be used to measure progress toward attainment of goals;
- (5) include schedules for the provision of all services prescribed; where a service is to be provided by any other service or facility offsite, the treatment/recovery plan must contain a description of the nature of the service, a record that referral for such service has been made, the results of the referral, and procedures for ongoing care coordination and discharge planning;
- (6) identify the <u>responsible</u> [single member of the] clinical staff [responsible] for coordinating and managing the resident's <u>treatment</u>, who shall approve and sign (physically or electronically) such plan [care ("the responsible clinical staff member")];
- (7) reference any significant medical and mental health issues, including applicable medications, identified as part of the medical assessment process;
 - [(7)] (8) include each [the] diagnosis for which the resident is being treated; [and]
- (9) be reviewed, approved, signed (physically or electronically), and dated by the supervisor of the responsible clinical staff member within seven (7) days after the finalization of the treatment/recovery plan. If the supervisor of the responsible clinical staff member is not a qualified health professional, another qualified health professional must be designated to sign (physically or electronically) the plan; and
- (10) Pregnancies. Treatment/recovery plans must include provisions for prenatal care for all residents who are pregnant or become pregnant. If a pregnant resident chooses not to obtain such care, the provider must have the resident acknowledge in writing that prenatal care was offered, recommended, and declined. The program should offer to

develop a plan of safe care with the resident and anyone identified by the resident, and such offer should be noted in the resident's record.

- (11) Communicable disease. Treatment/recovery plans must include provisions for the prevention, care, and treatment of HIV, viral hepatitis, tuberculosis, and/or sexually transmitted infections when present. If a resident chooses not to obtain such care and treatment, the provider must have the resident acknowledge that such care and treatment were offered, recommended, and declined.
- (j) Treatment according to the treatment/recovery plan. The responsible clinical staff member shall ensure that the treatment/recovery plan is included in the resident record and that all treatment is provided in accordance with the treatment/recovery plan.
- (1) If, during the course of treatment, revisions to the treatment/recovery plan are determined to be clinically necessary, a multidisciplinary case conference will be held with the resident to determine what revisions to the treatment plan are needed to help the resident achieve their goals.
- [(8) be signed by the responsible clinical staff member and approved and signed by the clinical staff member's supervisor or another supervising QHP within seven days.
- (i) Where a service is to be provided by any other service or facility off site, the treatment/service plan must contain a description of the nature of the service, a record that referral for such service has been made, the results of the referral, and procedures for ongoing coordination of care.
- (j) Treatment according to the treatment/service plan. The clinical staff member shall ensure that the treatment/service plan is included in the resident record and that all treatment is provided in accordance with the treatment/service plan.
- (k) The case of any resident who is not responding to treatment, is not meeting goals defined in the comprehensive treatment/service plan, including educational and vocational goals, or who is disruptive to the service must be discussed at a case conference, or by the clinical supervisor and the clinical staff member in a supportive living service, and the treatment/service plan revised accordingly.]
- (1) Documentation of service

(k) Progress notes.

- (1) Progress notes shall be written, signed (physically or electronically) and dated by the responsible clinical staff member or another clinical staff member familiar with the resident's care no less often than once every two weeks. Progress towards all treatment/recovery plan goals that are made during the two-week period must be documented in the applicable progress note [All treatment plan life areas that are addressed in the two-week period must be documented in the applicable progress note].
- (2) Progress notes shall provide a chronology of the resident's progress related to the goals established in the treatment/recovery[service] plan and be sufficient to delineate the course and

results of treatment[/services]. The progress notes shall indicate the resident's participation in all significant services that are provided.

(m) Resident deaths. If a resident dies while in active treatment any known details must be documented in the resident record.

- [(m)] (n) Discharge planning. Discharge planning shall begin upon admission and shall [as soon as the resident is admitted,] be considered [as] part of the treatment/recovery[service] planning process.[7] The plan for discharge shall be developed by the responsible clinical staff member in collaboration with the resident and anyone the resident identifies as supportive of their recovery. [and be provided by the responsible clinical staff member. The discharge plan shall be developed in collaboration with the resident and any significant other(s) the resident chooses to involve.] If the resident is a minor, the discharge plan must also be developed in consultation with their [his or her] parent or guardian, unless the minor is being treated without parental consent as authorized by Section 22.11 of the Mental Hygiene Law. Information pertaining to testing and treatment of sexually transmitted infections including HIV cannot be shared with applicable laws and regulations.
- (1) A resident discharged from the program must be discharged for a documented reason. Residents discharged involuntarily must be discharged consistent with Part 815 of this Title.
- [(1)] (2) The discharge plan shall be based on the <u>resident's</u> [individual's] self-reported confidence in <u>their recovery</u> [maintaining abstinence] and following an individualized <u>recovery support</u> [relapse prevention] plan, an assessment of the resident's home environment, suitability of housing, vocational/educational/employment status, and relationships with significant others to establish the level of social resources available to the resident and the need for services to significant others. <u>In accordance with guidance and standards issued by the Office</u>, [The] <u>the</u> discharge plan shall include but not be limited to:
- (i) identification of continuing <u>substance use disorder</u> [ehemical dependence] services, <u>medical and mental health services</u>, [and any other treatment,] rehabilitation, <u>recovery</u>, <u>wellness</u>, [self-help-]and vocational, educational and employment services the resident will need after discharge;
 - (ii) identification of specific providers of these needed services; and
- (iii) specific referrals with appointment dates and times for any needed services; [and initial appointments for these needed services.]
 - (iv) identification of the type of residence that the resident will need after discharge;
- (v) prescriptions and/or other arrangements to ensure access to medications including medications for addiction treatment for substance use disorders; and
- (vi) overdose prevention education, naloxone education and training, and a naloxone kit or prescription for the resident and their family/significant other(s).
- (n) No resident shall be discharged without a discharge plan [which] that has been reviewed and approved by the responsible clinical staff member and the clinical supervisor

or designee prior to the discharge of the resident. [This does not apply to residents who leave the service without permission or otherwise fail to cooperate in the discharge planning process. A] The portion of the discharge plan [which] that includes referrals for continuing care shall be given to the resident upon discharge. Documentation detailing why a discharge plan was not provided to the resident prior to discharge must be placed in the resident record if the resident did not receive the plan.

- (o) Discharge criteria. A resident shall be appropriate for discharge from the residential service and shall be discharged when <u>they</u> [he or she] meet[s] one or more of the following criteria:
- (1) the resident has accomplished the goals and objectives which were identified in the **treatment/recovery plan** [comprehensive treatment/service plan];
 - (2) the resident <u>declines</u> [refuses] further care;
- (3) the resident has been referred to other <u>treatment that meets their individual needs</u> <u>and cannot be provided in conjunction with the residential service</u> [appropriate treatment which cannot be provided in conjunction with the residential service];
- (4) the resident has been removed from the service by the criminal justice system or other legal process;
 - (5) the resident has received maximum benefit from the service; and/or
- (6) the resident does not adhere to the written behavioral standards of the facility, provided that the resident is offered a referral and connection to another treatment program. A discharge for behavioral reasons with a referral and connection to another treatment program shall occur only after the program has utilized interventions to help the resident manage their behavior in a manner consistent with the written behavioral standards of the facility, and in accordance with guidance from the Office. [is disruptive to the service and/or fails to comply with the reasonably applied written behavioral standards of the facility.]
- (p) A <u>discharge</u> summary which includes the course and results of <u>treatment</u>[eare] must be prepared and included in each resident's record within thirty (30) days of discharge.

819.6[5] Record keeping.

- (a) <u>Substance Use Disorder</u> [Chemical dependence] residential services must maintain individual [case] records for each resident served. These <u>resident</u> records must, at a minimum, include the information required in this Part, as well as the source of referral, documentation of any case conferences or case reviews, reports of other evaluations and case consultations, medical orders, if applicable, and consent forms.
- (1) the resident record shall include documentation that the resident and their family/significant other(s) were offered overdose prevention education, naloxone education and training, and a naloxone kit or prescription.
- (i) documentation should include the reasons why overdose prevention education, naloxone education and training, and a naloxone kit or prescription were not

offered, if applicable, or the reasons why the resident and their family members/significant other(s) declined overdose prevention education, naloxone education and training, and a naloxone kit or prescription.

- (b) Resident records maintained by <u>substance use disorder</u> [ehemical dependence] residential services are confidential and <u>only</u> may [only] be disclosed <u>consistent</u> [in conformity] with <u>the Health Insurance Portability and Accountability Act (HIPAA) and the</u> federal regulations <u>governing</u> [relating to] the confidentiality of <u>patient/resident</u> records as set forth in 42 Code of Federal Regulations Part 2 and other applicable law.
- (c) Any medical <u>and/or mental health treatments provided [procedures required]</u>, including [<u>use of any</u>] medication<u>s</u>, shall be maintained in accord<u>ance</u> with the requirements of federal and state law and approved policies and procedures.
- (d) All medical <u>or psychiatric</u> services provided must be provided pursuant to <u>the orders</u> <u>of a physician['s]</u>, physician assistant['s], or nurse practitioner <u>working within their scope of practice ['s order</u>].
- (e) In the event that more than one <u>substance use disorder</u> [chemical dependence] service is offered by a facility, the resident record shall identify the service in which the resident is [currently] participating <u>currently</u>.
- (f) Statistical information shall be reported to the Office as required and on the prescribed forms therefor.

819.7[6] Quality improvement and utilization review.

- (a) Each <u>substance use disorder</u> [ehemical dependence] residential service shall establish and implement a quality improvement plan and utilization review plan in accordance with this section. The utilization review requirement may be met by the following:
 - (1) the service may perform its utilization review process internally; or
- (2) the service may enter into an agreement with another organization, competent to perform utilization review, to complete its utilization review process.
- (b) The utilization review plan shall include procedures for ensuring that admissions are **based on the program's admission criteria** [appropriate,] that retention and discharge criteria are met, and that services are appropriate. The utilization review plan shall consider each resident's need for continued treatment, the **severity** [extent] of the resident's **substance use disorder(s)** [ehemical dependence problem], and the continued effectiveness of, and progress in, treatment.
- (c) Each residential service shall establish a written quality improvement plan in accordance with this section.
- (1) The quality improvement plan shall identify clinically relevant quality indicators that are based upon professionally recognized standards of care. This process shall include but not be limited to:

- (i) no less than quarterly self-evaluations which may include an independent peer review process as discussed below, to ensure compliance with applicable regulations and performance standards;
- (ii) findings of other management activities, including but not limited to; utilization reviews, incident reviews, and reviews of staff training, development and supervision needs;
 - (iii) surveys of resident satisfaction; and
 - (iv) analysis of treatment outcome data.
- (2) The residential service shall prepare an annual report and submit it to the governing authority. This report shall document the effectiveness and efficiency of the service in relation to its goals and indicate any recommendations for improvement in its services to residents, as well as recommended changes in its policies and procedures.
- (3) The purpose of independent peer review is to review the quality and appropriateness of residential services. The review is to focus on such services and the <u>substance use disorder</u> [<u>chemical dependence</u>] service system rather than on the individual practitioners. The intent of the independent peer review process is to [<u>continuously</u>] improve <u>continuously</u> the residential services <u>provided</u> to [<u>chemically dependent</u>] individuals <u>with substance use disorders</u>.

819.8[7] General staffing.

(a) General Staffing Requirements.

- (1) Former residents. Staff members shall not be former residents who recently have received treatment in the program and/or who have completed the program less than one year prior to their employment application, per guidance and standards issued by the Office.
- (2) Adequate coverage. There shall be sufficient staff to ensure that there is adequate coverage of all critical tasks necessary to the safe care of residents in the program, per guidance and standards issued by the Office.
- (i) Residents in the program shall not be asked or required to perform staff duties. For valid therapeutic reasons and when included in the treatment/recovery plan, residents may be asked to perform certain duties under the direct supervision of staff members, in accordance with guidance and standards issued by the Office.
 - (A) Residents shall not operate motor vehicles belonging to the program under any circumstances.
 - (B) Residents shall not serve as overnight awake staff.
- (ii) Programs shall have arrangements with outside entities such as staffing agencies to ensure adequate staffing coverage during times of staff shortages.
- [(a)] (b) Staff may be [either specifically] assigned either specifically to the substance use disorder [chemical dependence] residential service or may be part of the staff of the facility within which the substance use disorder [chemical dependence] residential service is located. However, if these staff members are part of the general facility staff, they must have specific training and experience in the treatment of substance use disorders [chemical use, abuse and

dependence] specific to the services provided. The percentage of time that each shared staff is assigned to the **substance use disorder** [ehemical dependence] residential service must be documented.

[(b)] (c) Staff Training. Each residential program must provide clinical supervision and ensure and document that all clinical staff have training plan based on individual employee needs. Such training may be provided directly or through outside arrangements and must be provided at least every one vear [three years]. Training must be ongoing and documented in each employee's personnel record. Training in suggested relevant topics includes, but it not limited to: [chemical dependence; individual, group and family counseling;]

(i) substance use disorders;

(ii) evidence-based, trauma-informed, and person-centered individual, group and family counseling;

- (iii) child abuse and domestic violence;
- (iv) therapies and other activities supportive of recovery;
- (v) co-occurring disorders;
- (vi) communicable diseases such as tuberculosis, sexually transmitted <u>infections</u> [diseases], <u>viral</u> hepatitis, HIV[/AIDS];
 - (vii) infection control procedures;
 - (viii) clinical supervision;
 - (ix) quality improvement;
 - (x) vocational rehabilitation and employment preparation services;
 - (xi) cultural diversity and cultural competence;
 - (xii) tobacco <u>use disorder</u> [dependence];
 - (xiii) problem gambling; [and]
 - (xiv) community based recovery supports and services[-];
 - (xv) trauma-informed care;
 - (xvi) medications for addiction treatment;
 - (xvii) overdose prevention education;
 - (xviii) naloxone and naloxone administration; and
 - (xix) agency policies and procedures.
- (c) All <u>substance use disorder</u> [ehemical dependence] residential services shall identify a clinical supervisor who shall be responsible for the day-to-day clinical operation of each residence and provide routine supervision for the staff. The clinical supervisor shall be a qualified health professional with at least three years of administrative and clinical experience in <u>substance use disorder</u> [ehemical dependence] residential services.
- (d) All <u>substance use disorder</u> [chemical dependence] residential services shall have sufficient clinical staff who have received training in, and are designated by the clinical supervisor to perform, the following tasks:

- (1) evaluation of resident needs, development and implementation of individualized treatment/<u>recovery</u> [service] plans for each resident, including individual, group and family counseling;
- (2) participation with staff and, as necessary, other services and agencies to assure the development, management and implementation of comprehensive services for each resident, reflecting **substance use disorder treatment needs** [both chemical dependence issues] and other habilitation or rehabilitation needs; and
 - (3) preparation and maintenance of case records for each individual resident.
- (e) At least twenty-five per cent of all clinical staff members shall be qualified health professionals. [For three years following the effective date of this Part, when determining the number of qualified health professionals pursuant to the foregoing, a residential service may count all of the qualified health professionals that are employed by, or at the direction of, the residential service at all of the residential service's facilities located within the State of New York, including Public Health Law Article 28 facilities. Individuals who have completed a minimum of 350 education and training clock hours in the areas required by Part 853 of this Title governing Credentialed Alcoholism and Substance Abuse Counselors, as well as individuals who have completed a minimum of 4000 hours of appropriate work experience and a minimum of 85 clock hours of education and training related to knowledge of [alcoholism and | substance use disorders [abuse] as required by Part 853 of this Title governing Credentialed Alcoholism and Substance Abuse Counselors, may be counted towards satisfying the twentyfive percent requirement provided that such individuals, also known as CASAC Trainees, may not be considered qualified health professionals for any purpose under this Part. Notwithstanding the foregoing, during the three year period following the effective date of this Part, each residential service shall have sufficient qualified health professional staffing levels to meet the requirements of this Part which mandate that certain duties be performed by, under the supervision of, or at the direction of, a qualified health professional.
- (f) Each residential service shall have a qualified individual designated as the Health Coordinator who will ensure the provision of education, risk reduction, counseling and referral services to all residents regarding HIV [and AIDS], tuberculosis, viral hepatitis, sexually transmitted infections [diseases], and other communicable diseases.
- (g) There shall be sufficient staff available to ensure that the space and equipment of the service is clean and maintained in working order to minimize the need for treatment staff to perform nontreatment functions and to optimize operational efficiency.
- (h) Clinical staff members who are not qualified health professionals shall have qualifications appropriate to their assigned responsibilities as set forth in the service's personnel policies and shall be subject to appropriate professional staff supervision and continuing education and training.

(i) In addition to staffing requirements of this Part, a residential service may utilize volunteers, students or trainees, on a salaried or non-salaried basis if such volunteers, students or trainees are provided close professional staff supervision and necessary didactic education from both internal and external sources.

819.9[8] Additional requirements for intensive residential rehabilitation.

- (a) Admission criteria. In addition to the admission criteria applicable to residential services generally, an individual admitted to intensive residential rehabilitation services must meet the following criteria:
- (1) The individual must have demonstrated an inability to participate in [or comply with] treatment outside of a twenty-four hour setting as indicated by one or more of the following:
 - (i) recent unsuccessful attempts at abstinence; or
- [(ii) a history of prior treatment episodes, including a demonstrated inability to complete outpatient treatment; or
- (iii) (ii) substantial <u>limitations</u> [deficits] in functional skills evidencing the need for extensive habilitation or rehabilitation in order to achieve lasting recovery in an independent setting.
- (b) Clinical services. Intensive residential services are required to provide a minimum of forty hours per week within a structured therapeutic environment, consisting of the services identified in Section 819.4 of this Part and include the following:
 - (1) Rehabilitation and/or habilitation services.
- (i) Each service shall ensure that a comprehensive and appropriate range of rehabilitative services are available to each resident. Such services include, but are not limited to:
- (A) vocational services such as vocational assessment, job skills training, and employment readiness training;
 - (B) educational remediation services; and
 - (C) life, parenting and social skills training.
 - (ii) These services may be provided directly by the service or by referral.
- (iii) These services shall be reflected in the resident's comprehensive treatment/<u>recovery</u> [service] plan and the resident's progress shall be documented <u>in the</u> resident's record.
- (2) Personal, social, and community skills training and development. Residents shall receive training in community **and adult** living skills, [personal hygiene and personal care skills] as needed by each individual. Such skill development shall include, but is not limited to, social interaction and leisure activities.
 - (c) Comprehensive treatment/recovery plan update.

- (1) Each comprehensive plan, once established, must be reviewed and revised at least every three months thereafter by the responsible clinical staff member in consultation with the resident and reviewed and signed (physically or electronically) by the supervisor.
- (2) A summary of the resident's progress in each of the specified goals shall be prepared and documented in the resident's record as part of the plan update.
 - (d) Staffing.
- (1) Each residential facility shall have a full-time <u>on-site Director</u> [manager on site] whose duties shall include overseeing the day-to-day operations of the service.
- (2) There shall be sufficient staff available to all residents at all times. During late evening and night shifts, there shall be at least one responsible staff person awake and on duty.
- (3) In addition to the twenty four hour per day, seven day per week coverage, all intensive residential rehabilitation services shall have sufficient staff to **ensure**[insure] that counseling and rehabilitation services are available and responsive to the needs of each **resident**[individual]. An intensive residential rehabilitation service will have no less than one clinical staff member for every fifteen residents.
- (4) For those residential rehabilitation services that serve children, at least one clinical staff member with training and experience in childcare shall be available.

819.10[9] Additional requirements for community residential services.

- (a) Admission criteria. In addition to the admission criteria applicable to residential services generally, an individual admitted to community residential services must meet the following criteria:
- (1) The individual must be homeless or must have a living environment not conducive to recovery.
- (2) The individual must be determined to need outpatient treatment services and/or other support services such as vocational or educational services, in addition to the residential services provided by the community residence.
 - (b) Clinical services.
- (1) In addition to the service elements required of all residential services, community residential services are [specifically] required specifically to provide a structured therapeutic environment designed to facilitate the individual's progress toward recovery from a substance use disorder(s)[chemical dependence or abuse].
- (2) The service shall maintain a focus on the development and improvement of the skills necessary for recovery.
 - (3) Specific services to be provided shall include the following:
- (i) Each community residential service shall ensure that its residents have access to **evidence-based, person-centered, and trauma-informed** individual, group and family counseling services as needed and appropriate.

- (ii) Each community residence shall have written referral agreements with one or more **substance use disorder**[ehemical dependence] outpatient services to provide outpatient treatment services, as necessary.
- (iii) The community residence shall ensure that such services are integrated with the <u>recovery and wellness</u> activities and services provided by the residence and incorporated in the individual's service plan.
- (iv) Each community residence shall ensure that a comprehensive and appropriate range of rehabilitative procedures are available to each resident. Such services include but are not limited to:
 - (A) vocational services such as vocational assessment(s);
 - (B) job skills training, and employment readiness training;
 - (C) educational remediation; and
 - (D) life, parenting and social skills training.
 - (4) Rehabilitation services may be provided directly by the service or by referral.
- (5) Rehabilitation services shall be identified in the resident's comprehensive **treatment/recovery** [service] plan.
- (6) Personal, social, and community skills training and development. Residents shall receive training in community living skills and adult living [personal hygiene and personal eare] skills as needed by each resident. Such skill development shall include, but is not limited to, a program of social interaction and leisure activities.
 - (c) Treatment/recovery [Service] plan review.
- (1) Each <u>treatment/recovery</u> [service]plan, once established, must be [<u>completely</u>] reviewed <u>completely</u> and revised at least every three months thereafter by the responsible clinical staff member in consultation with the resident and reviewed and signed by the supervisor.
- (2) Any resident who is having challenges meeting agreed upon goals defined in the treatment/recovery plan shall be engaged in a case conference with members of the multidisciplinary team who will collaborate with the resident to create revisions to the treatment/recovery plan that meet the resident's treatment needs [not responding to treatment, is not meeting goals defined in the comprehensive service plan, including educational and vocational goals, or who is disruptive to the service, shall have the same noted in the case file and the circumstances addressed at a case conference, and the service plan revised accordingly].
- (d) Staffing.
- (1) Each community residence shall have a full time **house** manager responsible for the day-to-day operation of the service.
 - (2) There shall be staff on site twenty-four hours per day, seven days per week.
- (3) All community residential services shall have sufficient staff to insure that supportive and rehabilitation services are available and responsive to the needs of each resident. In

addition to the twenty-four **hours** a day coverage, community residential services will have at least one clinical staff member for every fifteen residents.

819.11[10] Additional requirements for supportive living services.

- (a) Admission criteria. In addition to the admission criteria applicable to residential services generally, an individual admitted to a supportive living service must meet the following criteria:
- (1) the individual requires support of a residence that provides <u>a substance-</u> [an alcoholand drug-] free environment;
 - (2) the individual requires the peer support of fellow residents to maintain abstinence;
- (3) the individual does not require twenty-four hour a day on-site supervision by clinical staff; and
- (4) the individual exhibits the skills and strengths necessary to maintain <u>recovery</u> [abstinence] and readapt to independent living in the community while receiving the minimal clinical and peer support provided by this residential environment.
- (b) Clinical services. There shall be scheduled clinical interaction at least one time per week designed to support residents in their efforts to <u>readapt to independent living in the</u> <u>community while maintaining their recovery and wellness</u> [maintain abstinence and reduce the probability of relapse].
- (c) <u>Treatment/recovery</u> [Service] plan review. Each <u>treatment/recovery</u> [service] plan, once established, must be reviewed at least every six months thereafter, at which time the progress toward accomplishing the goals and objectives is reviewed. <u>Any resident who is having challenges meeting agreed upon goals described in the treatment/recovery plan shall be engaged in a case conference where members of the multidisciplinary team will collaborate with the resident to create revisions to the treatment/recovery plan. [The case of any resident who is not making progress toward accomplishing goals or who is disruptive to the service must be discussed and the service plan revised accordingly. The service plan must be signed by the resident and the clinical staff member].</u>
 - (d) Staffing. Supportive living services shall be staffed as follows:
- (1) there shall be at least one full-time equivalent clinical staff member for each fifteen residents; and
- (2) there shall be sufficient clinical staff members to ensure at least one visit to each supportive living service once per week, in order to assure the proper maintenance of the living site and that residents are maintaining an environment and schedule appropriate to and supportive of each [individual]resident's [abstinent,] independent living; and
- (3) there shall be sufficient clinical staff members to ensure that each resident is contacted personally at least once a week by staff to assure safety, adherence to the established service plan and support for daily independent living, through guidance, training, and assistance, as necessary.

819.<u>12</u>[11] 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 which can be given effect without the invalid provisions or applications, and to this end the provisions of this Part are declared to be severable.





Notice of Proposed Rulemaking Summary

Amend Part 820 Residential Services

In addition to technical amendments and updating terminology used across all regulations for consistency in Title 14, the Proposed Rule amends Part 817 as follows:

§820.2 Applicability. Adds reference to person centered, trauma informed services. §820.3 Definitions. Adds definition of patient/resident consistent with this Part. §820.5 General program standards. Added references to the provision of person centered, trauma informed care. Updated provisions regarding medication for addiction treatment for substance use disorder and naloxone access consistent with the needs of the program. §820.7 Admission, screening, assessment. Removed list of non-discrimination categories and added reference to Part 815. §820.9 Discharge. Added reference to requirement for post-discharge appointment(s) to continue medication access. §820.12 Additional requirements for community reintegration services in a residential setting. Added requirement for programs obligation to ensure access to medication for addition treatment. Standards pertaining to Medicaid reimbursement. Updated provisions consistent with Part 841. §820.13





Notice of Proposed Rulemaking Regulatory Impact Statement

Amend Part 820 Residential Services

1. Statutory Authority:

- (a) Section 19.07(e) of the Mental Hygiene Law authorizes the Commissioner to adopt standards including necessary rules and regulations pertaining to addiction services.
- (b) Section 19.09(b) of the Mental Hygiene Law authorizes the Commissioner to adopt regulations necessary and proper to implement any matter under his or her jurisdiction.
- (c) Section 19.40 of the Mental Hygiene Law authorizes the Commissioner to issue operating certificates for the provision of addiction services.
- (d) Section 32.01 of the Mental Hygiene Law 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 Mental Hygiene Law.
- (e) Section 32.07(a) of the Mental Hygiene Law authorizes the Commissioner to adopt regulations to effectuate the provisions and purposes of article 32 of the Mental Hygiene Law.
- (f) Article 27F of the Public Health Law defines the rules governing HIV testing and treatment in New York.
- 2. <u>Legislative Objectives</u>: The legislature has authorized OASAS to establish standards and regulations governing the provision of addiction services, including the provision of medications for addiction treatment, as well as standards for providers seeking to offer such services.
- 3. <u>Needs and Benefits:</u> OASAS is updating the language used in this regulation consistent with amendments made to other OASAS regulations and OASAS guidance to clarify provider requirements with respect to the provision of medication for addiction treatment for substance use disorder and to update definitions consistent with other OASAS regulations.

- 4. Costs: No additional administrative costs to the agency are anticipated.
- 5. <u>Paperwork:</u> There is no additional paperwork beyond what is already required.
- 6. Local Government Mandates: There are no new local government mandates.
- 7. <u>Duplications</u>: This proposed rule does not duplicate, overlap, or conflict with any State or federal statute or rule.
- 8. <u>Alternatives:</u> The alternative is to leave the regulation as it currently reads, with language inconsistent across Title 14 regulations and providers unsure of their obligation to provide medication for addiction treatment for substance use disorders.
- 9. Federal Standards: This regulation does not conflict with federal standards.
- 10. <u>Compliance Schedule:</u> This rulemaking will be effective upon publication of a Notice of Adoption in the *State Register*.

PART 820 RESIDENTIAL SERVICES

(Statutory Authority: Mental Hygiene Law Sections 19.07(e), 19.09(b), 19.40, 32.01, 32.07(a), Public Health Law <u>Article 27f</u>[Section 2781])

Section:	
820.1	Legal base
820.2	Applicability
820.3	Definitions
820.4	Assignment of services
820.5	General program standards
820.6	Staffing
820.7	Admission, screening and assessment
820.8	Treatment/recovery plan development and review
820.9	Discharge
820.10	Additional requirements for stabilization in a residential setting
820.11	Additional requirements for rehabilitation services in a residential setting
820.12	Additional requirements for community reintegration services in a residential setting
820.13	Standards pertaining to Medicaid reimbursement
820.14	Severability

Section 820.1 Legal base.

- (a) Section 19.07(e) of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to adopt standards including necessary rules and regulations pertaining to [chemical dependence] addiction services.
- (b) Section 19.09(b) of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to adopt regulations necessary and proper to implement any matter under his or her jurisdiction.
- (c) Section 19.40 of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to issue operating certificates for the provision of [chemical dependence] addiction services.
- (d) Section 32.01 of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to adopt any regulation reasonably necessary to implement and effectively exercise the powers and perform the duties conferred by article 32 of the Mental Hygiene Law.

- (e) Section 32.07(a) of the Mental Hygiene Law authorizes the Commissioner [of the Office of Alcoholism and Substance Abuse Services] to adopt regulations to effectuate the provisions and purposes of article 32 of the Mental Hygiene Law.
- (f) [Section 2781] Article 27F of the Public Health Law defines the rules governing HIV testing in New York.

820.2 Applicability.

- (a) This Part applies to any program certified by the office pursuant to this Part to provide residential services. These services are designed to help persons who lack a safe and supportive residential option in the community to achieve changes in their substance use disorder ("SUD") behaviors within a safe and supportive setting. Such services **shall be strength based, person centered and trauma informed and** may focus treatment on one or more of the following treatment/recovery elements: stabilization, rehabilitation, or community reintegration in congregate or scatter-site settings and may be provided directly on program site or through cooperative relationships with other service providers. Clinical services in residential programs are delivered on an individual or group basis in a variety of settings.
- (b) Residential substance use disorder (SUD) services include medically necessary care and supportive services both on and off-site according to assessed needs including:
 - (1) assessment and clinical treatment/recovery plan or service plan_development;
- (2) skill development for coping with and managing symptoms and behaviors associated with SUDs;
- (3) counseling to address a beneficiary's major lifestyle, attitudinal, and behavioral problems; and
- (4) medication [assisted] for addiction treatment for substance use disorder when medically necessary.

820.3 Definitions.

Unless otherwise indicated, the following terms shall be applicable to all programs certified pursuant to this Part.

(a) <u>"Residential services"</u> are 24/7 structured treatment/recovery services in a residential setting provided by office certified programs to persons recovering from substance use disorder.

Services correspond to elements in the treatment/recovery process and are distinguished by the configuration of services, staffing patterns, degree of dysfunction of the individual served in each setting, and patient readiness to transition to a less restrictive program or element of treatment/recovery. Certified residential programs may provide residential services corresponding to one or more of the following elements of the treatment/recovery process:

- (1) stabilization;
- (2) rehabilitation;
- (3) reintegration in congregate or scatter-site settings.
- (b) <u>"Stabilization"</u> provides a safe environment in which a person may stabilize withdrawal symptoms, severe cravings, psychiatric and medical symptoms before referral or transition to another program or element of structured treatment/recovery. Stabilization requires the supervision of a physician and clinical monitoring.
- (c) <u>"Rehabilitation"</u> provides a structured environment for persons whose potential for independent living is seriously limited due to significant functional impairment including social, employment, cognitive and ability to follow social norms that requires restructuring social supports and behaviors in order to develop sufficient skills; these persons require a course of rehabilitative services in a structured environment with staffing to provide monitoring and support and case management.
- (d) <u>"Reintegration"</u> provides a community living experience in either congregate or scattersite settings with limited supervision and/or case management; persons appropriate for these services are transitioning to long term recovery from substance use disorder and independent living in the community.
- (e) "Patient" or "Resident", for purposes of this Part, means an individual that is receiving services from a program certified pursuant to this Part.

820.4 Assignment of services.

(a) Programs will be certified for a maximum number of beds for a certified capacity. The level of care is attributed to the patient based on a patient-centered assessment and the OASAS level of care for alcohol and drug treatment referral protocol based on individual risk and resources. Programs will be certified pursuant to Part 810 of this Title for residential services and

will have noted on the operating certificate each of the services (stabilization, rehabilitative and/or reintegration) approved for delivery at the certified residential site.

- (b) Bed distribution will be determined by patient population demand. At any given time, the bed type is defined by the element of care to which the patient has been assigned. Distribution of bed types will not be fixed; however, the program must meet OASAS reporting requirements for transitions from one element of care to the next.
- (c) All programs must submit an application with specific staffing structure, treatment approach, and other policies and procedures as requested by the $[\bullet]$ Office for each element of residential services the program intends to provide. Upon approval of the application the service to be provided will be approved and designated on the residential program's operating certificate.

820.5 General program standards.

- (a) Policies and procedures. The program sponsor must approve written policies, procedures, and methods governing the provision of services 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 transfer and referral procedures;
 - (2) treatment/recovery plans, including service plans where appropriate;
- (3) staffing including, but not limited to, training and use of student interns, peers and volunteers, and compliance with Part 805 of this Title;
 - (4) screening and referral procedures for associated physical or psychiatric conditions;
 - (5) a schedule of fees for services rendered;
 - (6) infection control procedures;
- (7) cooperative agreements with other [ehemical dependence] substance use disorder service providers and other providers of services a resident may need;
- (8) 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 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) medication [assisted] for addiction treatment;
- (9) the use of alcohol and other drug screening tests, such as breath testing, urine screening;
- (10) procedures for the ordering, procuring, and disposing of medication, as well as the self-administration of medication;
 - (11) quality improvement and utilization review;
 - (12) procedures for emergencies;
 - (13) incident reporting and review in accordance with Part 836 of this Title;
 - (14) record keeping;
- (15) procedures whereby required educational services are provided for school age children who are in residence as either an individual who is receiving treatment or as part of a family unit;
 - (16) procurement, storage, preparation of food and nutritional planning;
- (17) records retention. Case records must be retained for [six]ten years after the date of discharge or last contact, or three years after the patient reaches the age of 18, whichever time period is longer.
- (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 (]naloxone[)] emergency overdose prevention kits sufficient to meet the needs of the program. [the use of which is subject to applicable laws and regulations.] Programs must develop and implement a plan to have staff and residents, where appropriate, trained in overdose prevention education and naloxone education including the prescribed use of naloxone[a Narcan kit such that it is available, to the maximum extent possible,] which shall be available for use during all program hours of operation.
- (1) All staff and residents should be notified of the existence of the [Narcan]naloxone overdose prevention kit and the authorized administering staff.
- (2) Nothing in this regulation shall preclude residents from becoming authorized in the administration of the [Narean] 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) Medication <u>for addiction</u> [assisted] treatment. [A provider of residential services may provide residential services to an individual who is on methadone or other approved opiate maintenance, or is being detoxified from methadone. Opiate maintenance or detoxification services may be provided through a written agreement with an appropriately certified methadone/opiate provider in accordance with applicable Federal and State requirements including, but not limited to, regulations of the Federal Center for Substance Abuse Treatment, the United States Drug Enforcement Administration, the New York State Department of Health, and the office, including but not limited to Part 822 of this Title.]
- (1) All programs 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.
- (e) Services. All residential programs shall make available, either directly or through referral to appropriate agencies, the following services as clinically and programmatically indicated:
- (1) Supportive services: availability of a range of support services appropriate to resident needs including legal, mental health, and social services, vocational assessment and counseling.
- (2) Educational and child care services: availability of required educational and childcare services in each program which provides services to school-age children.
- (3) Structured activity and recreation: opportunities for residents and family members, where appropriate, to participate in activities designed to foster effective use of leisure time, to improve social skills, develop self-esteem and encourage personal responsibility.
- (4) Orientation to community services: orientation for each resident including advice and instruction in identifying and obtaining needed community services such as housing and other necessary case management services.
- (5) Medication for addiction treatment, consistent with this Part and guidance issued by the Office.
- (6) Overdose prevention education and naloxone education and training and a naloxone kit or prescription, consistent with guidance issued by the Office.
- (f) Certified capacity. The certified bed capacity of each residential program may not be exceeded at any time except:
- (1) in cases of emergency and unexpected surges in demand where no alternative options are available; and

- (2) failure to temporarily accept individuals into the program would jeopardize their immediate health and safety; and
 - (3) where the excess of capacity would be time limited.
- (g) Recordkeeping and reporting. (1) All residential services must maintain individual case records for each resident served. These records must, at a minimum, include the information required in this Part, as well as the source of referral, documentation of any case conferences or case reviews, reports of other evaluations and case consultations, medical orders, if applicable, and consent forms.
- (2) Statistical information shall be reported to the office as required and on the prescribed forms therefor.

820.6 Staffing.

- (a) Any residential program of 10 beds or more shall have a full-time program director who is a qualified health professional as defined in Part 800 of this Title. The program director shall have at least five years of full-time work experience in SUD, or related treatment field, prior to appointment as program director. A residential program with fewer than 10 beds shall have a similarly qualified program director who shall serve on at least a part-time basis.
- (b) General and clinical staffing. (1) General and clinical staffing shall be on-site or on-call sufficient to meet the emergent needs of the resident population receiving services in a particular treatment element. Staff may be either specifically assigned to the residential service or may be part of the staff of the facility or program within which the residential service is located. However, if the staff is part of the general facility or program staff, they must have specific training and experience in the treatment of chemical use, abuse and dependence specific to the services provided.
- (2) Applicable only to stabilization and rehabilitation services, staff "sufficient to meet the emergent needs of the resident population" shall include:
- (i) registered nurse and weekend nursing staff sufficient to resident need, on-site daily and to supervise LPN;
- (ii) LPN available on-site daily for support to residents for support and documentation of self-medication;

- (iii) physician, nurse practitioner and or physician assistants to meet the medical assessment and treatment needs of each resident. Each service shall have identified a medical director whose qualifications and responsibilities are defined in Part 800 of this Title;
- (iv) psychiatrist and/or psychiatric nurse practitioner to evaluate all residents who have a history of mental health disorder or who are exhibiting symptoms of a mental health disorder.
- (v) LMSW/LCSW/LMHC or family therapist in sufficient numbers to provide psychotherapy to all residents who are in need of such services in a frequency sufficient to meet the assessed need;
- (vi) clinical staff in sufficient numbers to serve as the primary counselors. Each resident shall be assigned a clinical staff member as his/her primary counselor to provide individual counseling and treatment/recovery plan preparation, monitoring and review;
- (vii) CASACs, CASAC-T and other clinical and milieu staff in sufficient numbers to facilitate activities of daily living, community meetings, engagement, carry out of treatment planning in milieu; at least one CASAC available at all times to intervene to help provide therapeutic interactions to foster residents' social, cognitive and behavioral skill development. CASAC staff will provide supervision of milieu staff;
- (viii) milieu staff all shifts in sufficient numbers available within the community to model and provide pro-social behavioral interventions at all times. Milieu staff are included in the treatment planning process and are aware of the treatment goals of each resident; they will carry out activities that will support goal attainment through the natural interactions within the milieu.
 - (ix) at least two staff per overnight shift, one of which must be a clinical staff member;
 - (x) vocational counselor;
- (xi) case manager to develop the treatment/recovery plan and to meet regularly to identify needs and progress.
- (3) All residential services shall have sufficient clinical staff that have been trained in, and are designated by the clinical supervisor to perform, the following tasks:
- (i) evaluation of resident needs, development and implementation of individualized treatment/recovery plans for each resident, including individual, group and family counseling;
- (ii) participation with staff and, as necessary, other services and agencies to assure the development, management and implementation of comprehensive services for each resident,

reflecting both [ehemical dependence] substance use issues and other habilitation or rehabilitation needs; and

- (iii) preparation and maintenance of case records for each individual resident.
- (4) There shall be sufficient staff available to ensure that the space and equipment of the service is clean and maintained in working order to minimize the need for treatment staff to perform non-treatment functions and to optimize operational efficiency.
- (c) Clinical supervision. (1) Each residential 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.
- (2) All residential services shall identify a clinical supervisor who shall be responsible for the day-to-day clinical operation of each residence and provide routine supervision for the staff. The clinical supervisor shall be a qualified health professional as defined in Part 800 of this Title with at least three years of clinical experience in [ehemical dependence]substance use disorder treatment.
- (3) Clinical staff members who are not qualified health professionals shall have qualifications appropriate to their assigned responsibilities as set forth in the service's personnel policies and shall be subject to appropriate professional staff supervision and continuing education and training.
- (4) All clinical staff should be provided with and document training, including but not limited to, crisis interventions, working with special populations, medication assisted treatment, trauma informed care, quality improvement, agency policies and procedures. Additional subject areas appropriate for training may from time to time be identified by the Office.
- (d) Health coordinator. Each residential service shall have a qualified individual designated as the health coordinator who will ensure the provision of education, risk reduction, counseling and referral services to all residents regarding HIV[-and AIDS] (including pre-and post-exposure prophylaxis), tuberculosis, viral hepatitis, sexually transmitted [diseases] and other communicable diseases.
- (e) Volunteers, peers, students or trainees. A residential service may utilize volunteers, peers, students or trainees, on a salaried or non-salaried basis if such volunteers, peers, students or trainees are provided close professional staff supervision and necessary didactic education from

both internal and external sources, and comply with the requirements of Part 805 where appropriate.

820.7 Admission, screening and assessment.

- (a) Admission procedures. (1) Initial determination. An individual seeking residential services shall have an initial determination based upon face-to-face contact plus any other available records and made by a qualified health professional or other clinical staff under the supervision of a qualified health professional; such determination shall document in writing that:
- (i) the individual appears to be in need of [ehemical dependence] substance use disorder services; and
- (ii) the individual appears to be free of serious communicable disease which can be transmitted through ordinary contact; and
- (iii) the individual appears to not need acute hospital care, acute psychiatric care, or other intensive services which cannot be provided in conjunction with residential services or would prevent him/her from appropriate participation in a residential service.
- (2) Level of care determination. If the initial determination indicates the person is appropriate for residential services, a level of care determination shall be made by a clinical staff member supervised by a qualified health professional no later than 24 hours after the resident's first on-site contact with the program. The level of care report generated by the level of care protocol must be documented in the resident [ease]patient record. To be admitted for residential services at the appropriate level of care the individual must meet the level of care protocol criteria for the residential services and must be provided the services which match the resident's need for either stabilization, rehabilitative, or reintegration services.
- (3) No individual may be denied admission to a program consistent with 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/recovery process; or

 (viii) medication assisted treatment for opioid dependence prescribed and monitored by a physician, physician's assistant or nurse practitioner.
- (4) Decision to admit; notice to residents. (i) If determined appropriate for the residential service, the individual shall be admitted. The decision to admit shall be included in the resident case record, dated and signed by a staff member who is a qualified health professional authorized by program policies to admit individuals; and
- (ii) there must be a notation in the resident [ease] <u>patient</u> record that the resident received a copy of the residential service's rules and regulations, including resident rights, a summary of Federal confidentiality requirements, and a statement that such rules were discussed with the resident and the resident indicated that he/she understood them; and
- (iii) all residents shall be informed that admission is on a voluntary basis and that a resident is free to discharge him or herself from the service at any time.
- (iv) If the presenting individual is determined to be inappropriate for admission to the residential service, a referral 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.
- (v) The admission assessment or decision to admit must contain a statement documenting the individual is appropriate for this level of care, identify the assignment of a named clinical staff member with the responsibility to provide orientation to the individual, and include a preliminary schedule of activities, therapies and interventions.
- (b) Assessment. (1) Prior to admission, all programs must:
- (i) conduct a communicable disease risk assessment (HIV[/AIDS], tuberculosis, viral hepatitis, sexually transmitted diseases, and other communicable diseases);
 - (ii) conduct a toxicology screen as clinically appropriate or required by Federal law.
 - (2) As soon as possible after admission, for all residents, programs must:
 - (i) offer viral hepatitis testing; testing may be done on site or by referral;
- (ii) offer HIV testing; testing 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.
 - (3) If clinically indicated, as soon as possible after admission, 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 diseases and referrals for immunization; 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.
- (4) As soon as possible after testing programs must explain any blood and skin test results to the resident.
- (5) Any significant medical issues, including risk for communicable diseases, identified prior to or after admission must be addressed in the treatment/recovery plan and documented in the patient case record. Treatment/recovery plans must include provisions for the prevention, care and treatment of HIV, viral hepatitis, tuberculosis and/or sexually transmitted [diseases]infections. If a resident refuses to obtain such care, the provider must have the resident acknowledge in writing that such care was offered but refused.
- (c) Medical history. (1) If the resident has a medical history available and has had a physical examination performed within 12 months prior to admission, or if the resident is being admitted directly to the residential service from another office certified SUD program, the existing medical history and physical examination documentation may be used to comply with the requirements of this subdivision, provided that such documentation has been reviewed and determined to be current and accurate; such determination shall be dated and recorded in the resident record. Notwithstanding the foregoing, the following shall be offered to all patients regardless of a documented history within the previous twelve (12) months: HIV and HCV[ep-C] testing.
- (2) Stabilization services. (i) Within 24 hours after admission, programs providing stabilization services must complete a general assessment which identifies immediate problem areas, substantiates appropriate resident placement and is signed by a qualified professional. If withdrawal symptoms or other potentially life threatening behavior or conditions are present, the patient must be assessed immediately for safety by a medical staff person who is working within

the scope of practice. A physician must be available by phone at all times to respond to immediate crises.

- (ii) Within 24 hours after admission programs providing stabilization services must conclude a medical assessment and, if necessary, a full physical no later than 7 days after admission. All residents shall receive a physical exam by a physician, physician's assistant or nurse practitioner if they do not have available a medical history and no physical examination has been performed within the prior 12 months. Residents who have a medical history shall receive an evaluation within 7 days.
- (3) Rehabilitation services. Within seven days after admission, programs providing rehabilitation services must conclude a medical assessment and, if necessary, a full physical no later than 45 days after admission. All residents shall receive a physical exam by a physician, physician's assistant or a nurse practitioner if they do not have available a medical history and no physical examination has been performed within the prior 12 months. Residents who have a medical history shall receive an evaluation within 21 days.
- (4) Reintegration services. (i) Residents admitted to reintegration services should have an identified primary care physician (PCP) in the community and have a physical exam if one has not been completed within the prior 12 months, or, if the resident is admitted to an outpatient SUD clinic [(CD-OP)] or opioid treatment program (OTP), then within 30 days the reintegration program shall obtain the medical history, physical and treatment plan from the outpatient provider.
- (ii) The physical examination shall include review of any physical and/or mental limitations or disabilities which may require special services or attention during treatment.

820.8 Treatment/recovery plan development and review.

- (a) Programs providing residential services for any or all elements of care must:
- (1) as soon as possible after admission, develop a patient-centered, interdisciplinary **person centered** treatment/recovery plan [or service plan], which includes problem formulation and short-term, measurable treatment/recovery goals and activities designed to achieve those goals. This plan should be developed in collaboration with the resident; and

- (2) review and revise, if necessary, the treatment/recovery plan or service plan in collaboration with the resident monthly (rehabilitation and reintegration) and weekly (stabilization) after admission and document accordingly.
- (b) Treatment/recovery plan. (1) Each resident must have a written **person**[patient]-centered treatment/recovery plan, or a service plan where appropriate, developed by the responsible clinical staff member and resident as soon as possible after admission. Standards for developing a treatment/recovery plan include, but are not limited to:
- (i) for residents moving directly from one program to another, or being readmitted to the same program within 60 days of discharge, 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;
- (ii) if the resident 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) The treatment/recovery plan must:
 - (i) include each diagnosis for which the resident is being treated;
- (ii) address resident 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 resident and primary counselor;
- (iii) identify a single member of the clinical staff responsible for coordinating and managing the resident's treatment who shall approve and sign (physical or electronic signature) such plan;
- (iv) be reviewed and approved by the supervisor of the responsible clinical staff member within 10 days after the finalization of the treatment/recovery or service 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; and
- (v) include schedules for the provision of all services prescribed; where a service is to be provided by any other service or facility off site, the treatment/recovery plan must contain a description of the nature of the service, a record that referral for such service has been made, the results of the referral, and procedures for care coordination and discharge planning.

- (c) Treatment according to the treatment/recovery plan. (1) The responsible clinical staff member shall ensure that the treatment/recovery plan is included in the resident record and that all treatment and services are provided in accordance with the treatment/recovery plan.
- (2) Progress notes. (i) Progress notes shall be written, signed and dated by the responsible clinical staff member on a frequency appropriate to the element of care and consistent with policies and procedures and must include all clinical and milieu services delivered and the response of the resident to treatment. All individual and medical contacts for the purpose of assessing, diagnosing or treating the resident shall be documented in the resident record by the staff member delivering the service(s).
- (ii) Progress notes shall provide a chronology of the resident's progress related to the goals established in the treatment/recovery plan and be sufficient to delineate the course and results of treatment/recovery.
- (iii) The progress notes shall indicate the resident's participation in all significant services provided.

820.9 Discharge.

- (a) Discharge planning. (1) Discharge planning shall begin as soon as the resident is admitted. 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.
- (2) 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.
- (3) Patients and significant other(s) shall be offered overdose prevention education and naloxone education and training and a kit or prescription for naloxone.

(4) Programs shall develop a safety plan in collaboration with the patient.

(b) Discharge criteria. A resident shall be appropriate for discharge from the residential service and shall be discharged when he or she meets one or more of the following criteria:

- (1) the resident has accomplished the goals and objectives identified in the comprehensive treatment/recovery plan;
 - (2) the resident refuses further care;
- (3) the resident has been referred to other appropriate treatment which cannot be provided in conjunction with the residential service;
- (4) the resident has been removed from the service by the criminal justice system or other legal process;
 - (5) the resident has received maximum benefit from the service; and/or
- (6) the resident is disruptive to the service and/or fails to comply with the reasonably applied written behavioral standards of the facility.
- (c) Discharge plan. (1) A discharge plan must be developed in collaboration with the resident and any collateral person(s) the resident 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.

(2) The discharge plan must include an appointment with a community-based provider to continue approved medications for substance use disorder treatment.

- (3) If the resident 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 22.1; information pertaining to testing and treatment of sexually transmitted diseases including HIV, cannot be shared with the minor patient's parent or guardian without the patient's consent, in accordance with applicable laws and regulations.
- (4)[(3)] No resident 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 residents 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 resident upon discharge.
- (5)[(4)] Residents should be discharged to the level of care indicated by the level of care protocol and may be moved between services within the residential program as long as the program is approved to provide the service and the resident meets the level of care for that service. Clinical staff should utilize the level of care protocol whenever a change in level of care is considered.

(6)[(5)] No later than 30 days after discharge, a discharge summary must be finalized and included in each resident's record. The discharge summary must address and measure progress toward attainment of treatment goals.

820.10 Additional requirements for stabilization in a residential setting.

- (a) Stabilization services are appropriate for residents who present with mild withdrawal or expected withdrawal and psychiatric symptoms that cause acute impairment; medical conditions, emotional or cognitive impairment that can be managed in a residential setting where medical staff are available on an on-call basis. Stabilization services may be provided by any certified provider of residential services designated by the office to provide stabilization services.
- (1) Residential providers will be required to have medication management protocols, approved by the OASAS Medical Director, to qualify to provide stabilization services.
- (2) All programs offering stabilization services shall have ancillary withdrawal and addiction medication management available as clinically indicated.
- (b) Staffing. (1) In addition to staffing required of all residential services pursuant to section 820.6 of this Part, stabilization services approved by the office must provide medical staff, as defined in Part 800 of this Title, on site or on-call, and staff available sufficient to meet the emergent needs of the resident population including any or all of the staff identified in Section 820.6(b)(2) of this Part. The percentage of time that each shared staff is assigned to the residential service must be documented.
- (c) Services. In addition to the required services for all residential programs, stabilization services must include:
- (1) Medical assessment of the SUD symptoms and medical treatment of mild to moderate withdrawal symptoms, urges and cravings using a protocol approved by the OASAS Medical Director.
- (2) Medical assessment of physical and mental health conditions and medical treatment to stabilize these conditions.
- (3) Psychiatric assessment and medication management of co-occurring psychiatric conditions which can be managed within the residential setting.

(4) [Psych-social] Psychosocial interventions which teach skills for coping with urges, craving, impulsive behavior and cognitive distortions in thinking, motivational interviewing techniques to engage the resident in treatment.

Additional requirements for rehabilitation services in a residential setting.

- (a) Rehabilitation services are appropriate for individuals who do not have significant withdrawal symptoms, are free of severe cravings to use substances and, if present, psychiatric and medical conditions are stable. Individuals have functional impairment in cognitive, emotional regulation, social and role functioning.
- (b) Staffing. In addition to staffing required of all residential services pursuant to section 820.6 of this Part, rehabilitation services approved by the [office] office must provide medical staff, as defined in Part 800 of this Title, on site or on-call, and staff available sufficient to meet the emergent needs of the resident population including any or all of the staff identified in section 820.6(b)(2) of this Part. The percentage of time that each shared staff is assigned to the residential service must be documented.
- (c) Services. In addition to the services required of all residential programs, rehabilitation services must provide:
- (1) individual, group and family counseling as appropriate to [resident]patient needs; provided by clinical staff as clinical staff are defined in Part 800 of this Title.
 - (i) a group therapy session shall contain no more than 15 persons;
 - (ii) family counseling services include services to significant others;
- (iii) peer support may occur in a peer group setting where the group is facilitated by residents who have greater experience or seniority within the service. Such counseling must be directly supervised by a clinical staff member in attendance;
 - (iv) multi-family group counseling and psycho-education;
- (2) medical assessment of physical and mental health conditions and medical treatment to enable the **patient** [resident] to manage chronic health and mental health conditions including treatment of physical health conditions that are routine;
- (i) psychiatric assessment and medication management of co-occurring psychiatric conditions which can be managed within the residential setting;

- (ii) psycho-social interventions which teach skills for coping with urges, craving, impulsive behavior and cognitive distortions in thinking, motivational interviewing techniques to engage the [resident]patient in treatment;
- (iii) planned interactions with [residents]patients within the milieu intended to build social, emotional, and behavioral functioning including: increased empathy, successful social interactions, increase in self-efficacy, confidence, control over impulses, managing of urges and cravings to use and the skill in use of social supports available within the community.

Additional requirements for community reintegration services in a residential setting.

- (a) Resident profile. Reintegration services are provided in a supervised congregate or scattered site setting to persons making the transition [to sustained remission from SUD in]into the community. Persons appropriate for this service are stable in SUD, psychiatric and medical conditions and have adequate functioning in cognitive, emotional regulation, social and role functioning.
- (b) Admission criteria. In addition to the admission criteria applicable to residential services generally, an individual admitted to a reintegration residential service must meet the following criteria:
- (1) the individual must be homeless or must have a living environment not conducive to recovery; and
- (2) the individual must be determined to need outpatient treatment services and/or other support services such as vocational or educational services.
- (c) Services. (1) In addition to services required of all residential services, reintegration residential services are specifically required to provide a structured therapeutic environment designed to facilitate the individual's progress toward recovery from SUD and maintain a focus on the development and improvement of the skills necessary for recovery.
 - (2) Services to be provided shall include the following:
- (i) each reintegration residential service shall ensure that its residents have access to individual, group and family counseling services as needed and appropriate;
- (ii) each reintegration residential service shall have written referral agreements with one or more SUD outpatient services to provide outpatient treatment services, as necessary;

- (iii) the reintegration residential service shall ensure that such services are integrated with the activities and services provided by the residence and incorporated in the individual's comprehensive service plan;
- (iv) each reintegration residential service shall ensure that a comprehensive and appropriate range of services are available to each resident. Such services include but are not limited to:
 - (a) vocational services such as vocational assessment;
 - (b) job skills training, and employment readiness training;
 - (c) educational remediation; and
 - (d) life, parenting and social skills training.
 - (3) Services may be provided directly by the service or by referral.
 - (4) Services shall be identified in the resident's service plan.
- (5) Personal, social, and community skills training and development. Residents shall receive training in community living skills, personal hygiene and personal care skills as needed by each resident. Such skill development shall include, but is not limited to, a program of social interaction and leisure activities.

(3) Programs shall ensure access to medication for addiction treatment.

- (d) Service plan review. In addition to the required periodic review, each service plan, once established, must be thoroughly reviewed and updated by the responsible clinical staff member in consultation with the resident whenever a change in services requires; all updates must be reviewed and signed by the supervisor.
- (e) Staffing. (1) Each reintegration residential service shall have a full time manager responsible for the day-to-day operation of the service.
- (2) For community reintegration services in a congregate setting, there shall be staff on site twenty-four hours per day, seven days per week.
- (3) All reintegration residential services shall have sufficient staff to insure that supportive services are available and responsive to the needs of each resident.
- (4) For community reintegration services in a scattered site setting, there shall be sufficient clinical staff members to ensure at least one visit to each resident per week, in order to assure the proper maintenance of the living site and that residents are maintaining an environment and schedule appropriate to and supportive of recovery and independent living.

820.13 Standards pertaining to Medicaid reimbursement.

(a) Services must be delivered in accordance with <u>the signed treatment/recovery plan, this</u>

Part and Part 841 of this Title.

[(1) Treatment/recovery plans should be signed by the responsible clinical staff member
and the resident. Activities included in the service plan must be intended to achieve identified
treatment/recovery plan goals or objectives and identify the following:
(i) medical or remedial services intended to reduce the condition;
(ii) anticipated outcomes for the resident;
(iii) frequency, amount and duration of the services.
(2) Treatment/recovery plans shall specify a timeline for plan reevaluation at least
annually and be reevaluated at any time clinically necessary.]
(b) Non-covered services. [(1)] Components that are not provided to, or directed exclusively
toward the treatment of the Medicaid beneficiary, are not eligible for Medicaid reimbursement.
[(2) Services provided at a work site must not be job task oriented and must be directly
related to treatment of a resident's treatment needs.
(3) No more than one per diem rate may be billed a day for residential SUD programs,
however bills may be submitted for allowable medical procedures in accordance with CPT
approved coder set per the national correct coding initiative.
(c) Court ordered services. (1) Assessments and testing for individuals who are Medicaid
eligible, including any laboratory tests and urine tests.
(2) Drug court diversion treatment programs are eligible for Medicaid funding.
(3) Laboratory procedures which the practitioner refers to an outside laboratory must be
billed by the laboratory.
(d) Service reimbursement. Reimbursements for services are based upon a Medicaid fee
schedule established by the State of New York. OASAS reimbursement rates and information
may be found on the OASAS website and in Part 841 of this Title.]

820.14 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 which can be

given effect without the invalid provisions or applications, and to this end the provisions of this Part are declared to be severable.





Notice of Proposed Rulemaking Summary

Amend Part 822

GENERAL SERVICE STANDARDS FOR SUBSTANCE USE DISORDER OUTPATIENT PROGRAMS

In addition to technical amendments and updating terminology used across all regulations for consistency in Title 14, the Proposed Rule amends Part 822 as follows:

- §822.1 Background. Adds reference to person centered, trauma informed services.
- §822.7 General program standards. Updated provisions regarding medication for addiction treatment for substance use disorder and overdose prevention education and training and naloxone access.
- §822.8 Patient records/treatment planning. Removed list of non-discrimination categories and added reference to Part 815. Added reference to requirement for post-discharge appointment(s) to continue medication access.



Notice of Proposed Rulemaking Regulatory Impact Statement

Amend Part 822

GENERAL SERVICE STANDARDS FOR SUBSTANCE USE DISORDER OUTPATIENT PROGRAMS

1. Statutory Authority:

- (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 treatment for opioid use disorders.
- 2. <u>Legislative Objectives:</u> The legislature has authorized OASAS to establish standards and regulations governing the provision of addiction services, including the provision of medications for addiction treatment, as well as standards for providers seeking to offer such services.
- 3. <u>Needs and Benefits:</u> OASAS is updating the language used in this regulation consistent with amendments made to other OASAS regulations and OASAS guidance to clarify provider requirements with respect to the provision of medication for addiction treatment for substance use disorder and to update definitions consistent with other OASAS regulations.

- 4. Costs: No additional administrative costs to the agency are anticipated.
- 5. <u>Paperwork:</u> There is no additional paperwork beyond what is already required.
- 6. Local Government Mandates: There are no new local government mandates.
- 7. <u>Duplications</u>: This proposed rule does not duplicate, overlap, or conflict with any State or federal statute or rule.
- 8. <u>Alternatives:</u> The alternative is to leave the regulation as it currently reads, with language inconsistent across Title 14 regulations and providers unsure of their obligation to provide medication for addiction treatment for substance use disorders.
- 9. Federal Standards: This regulation does not conflict with federal standards.
- 10. <u>Compliance Schedule:</u> This rulemaking will be effective upon publication of a Notice of Adoption in the *State Register*.

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]

Section:	
822.1	Background
822.2	Legal base
822.3	Applicability
822.4	Savings and renewal clause
822.5	Definitions
822.6	Standards pertaining to Medicaid reimbursement
822.7	General program standards
822.8	Patient records/Treatment planning
822.9	Additional locations
822.10	Additional requirements for substance use disorder outpatient rehabilitation services
822.11	Additional requirements for opioid treatment programs
822.12	Severability

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 <u>for addiction</u> [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 <u>full</u> 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.
- (1) "Continuing care treatment" is a treatment protocol that offers clinical support for the ongoing 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 <u>for addiction [assisted]</u> 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" <u>for purposes of this Part</u> 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 <u>infections [diseases]</u> 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) <u>Medication for Addiction Treatment (MAT) for Substance Use Disorder (SUD)</u>
- (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.

- <u>(i)</u> Telehealth[Telepractice]. Any services authorized to be delivered <u>via telehealth</u> [<u>using</u> telepractice] shall be provided consistent with Part 830 of this Title.
- (k)[(j)] 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 <u>infections</u> [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).
- $\underline{\mathbf{\Pi}}[(k)]$ 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)[(+)] 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 <u>Patient Records/Treatment Planning</u>

- (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 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,
benzodiazepir	nes; 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 <u>infections</u> [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 dose₂ 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 <u>infections[diseases]</u> 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 <u>ten (10) [six (6)]</u> 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 <u>infections</u> [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



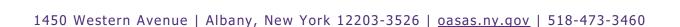
Notice of Proposed Rulemaking Summary

Amend 14 NYCRR Part 830 **Designated Services**

In addition to technical amendments updating this regulation consistent with Title 14, the Proposed Rule amends Part 830 as follows:

§800.7 Adolescent Outpatient Program Endorsement. Adds standards for programs to obtain an optional Adolescent Endorsement.

§800.8 Ancillary Withdrawal Outpatient Designation. Adds standards for programs to obtain an optional Ancillary Withdrawal Outpatient Designation.





Notice of Proposed Rulemaking Regulatory Impact Statement

Amend 14 NYCRR Part 830

DESIGNATED SERVICES

1. Statutory Authority:

- (a) Section 1.03(6) of the Mental Hygiene Law defines "facility" as any place in which services for the mentally disabled are provided.
- (b) Section 19.07(c) of the Mental Hygiene Law authorizes the commissioner to adopt standards ensuring the personal and civil rights of persons seeking and receiving addiction services, care, treatment and rehabilitation are adequately protected.
- (c) Section 19.07(e) of the Mental Hygiene Law authorizes the commissioner to adopt standards including necessary rules and regulations pertaining to chemical dependence services.
- (d) Section 19.09(b) of the Mental Hygiene Law authorizes the commissioner to adopt regulations necessary and proper to implement any matter under his or her jurisdiction.
- (e) Section 19.21(d) of the MHL requires the Office to establish reasonable performance standards for providers of services certified by the Office.
- (f) Section 32.01 of the Mental Hygiene Law 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 Mental Hygiene Law.
- (g) 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.
- (h) 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.
- (i) 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.
- (j) Article 160 of the Education Law provides for the licensure or certification of acupuncturists and limited practice of unlicensed persons in treatment of substance use disorder.

- (k) Article 29-G of the Public Health Law relates to reimbursement for health care services delivered via "telehealth."
- (l) Section 3351 of the Public Health Law authorizes the prescribing or dispensing of controlled substances for the purposes of substance use disorder treatment.
- (m) Section 829 of Title 21 of the United States Code governs the law concerning internet prescribing of controlled substances.
- (n) Article 15 of the Executive Law enacts the Human Rights Law prohibiting discrimination against protected classes of New Yorkers including on the basis of sexual orientation and gender identity or expression.
- 2. <u>Legislative Objectives</u>: The legislature has authorized OASAS to establish standards and regulations governing the provision of addiction services, including the provision of medications for addiction treatment, as well as standards for providers seeking to offer such services. The amendments to Part 830 add two new designations for providers to obtain if they meet the standards and wish to do so. They include the Adolescent Endorsement and the Ancillary Withdrawal Endorsement.
- 3. <u>Needs and Benefits:</u> Both the adolescent endorsement and the ancillary withdrawal endorsement allow programs the option of meeting the standards for an additional program endorsement. The regulatory amendments serve as a formal means of identifying adolescent programs in the OASAS system, and/or those that offer ancillary withdrawal services in outpatient settings for providers certified pursuant to Part 822 and meet the standards in the regulation. The addition of these optional endorsements will make it easier for those seeking OASAS services to obtain the appropriate services.
- 4. Costs: No additional administrative costs to the agency are anticipated.
- 5. <u>Paperwork:</u> There is no additional paperwork beyond what is already required. The adolescent endorsement and ancillary withdrawal endorsement are optional for providers and therefore any additional paper work required will not create additional burdens.
- 6. <u>Local Government Mandates</u>: There are no new local government mandates.
- 7. Duplications: This proposed rule does not duplicate, overlap, or conflict with any State or federal statute or rule.
- 8. <u>Alternatives:</u> The alternative is to leave the regulation as it currently reads, without options for either the adolescent endorsement or ancillary withdrawal endorsement. Not creating a distinction for OASAS certified programs that meet these additional requirements for the endorsements may have the effect of limiting access to appropriate care.
- 9. Federal Standards: This regulation does not conflict with federal standards.

10. <u>Compliance Schedule:</u> This rulemaking will be effective upon publication of a Notice of Adoption in the *State Register*.





4 NYCRR PART 830: Designated Services

(Statutory authority: Mental Hygiene Law §§1.03(6), 19.07(c), 19.07(e), 19.09(b), 19.21(d), 32.01, 32.02, 32.05(b), 32.07(a) and 32.09(b); Education Law, Article 160; Public Health Law §3351(5), Article 29G; Executive Law, Article 15; 21 USC 829.)

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am Endorsement

§ 830.1 Applicability

The provisions of this Part are applicable to all OASAS certified, approved or otherwise authorized programs seeking to offer or provide certain services or therapies including, but not limited to, acupuncture and telehealth, or other such services, therapies or program endorsements as may be defined in this Part. Such services may require application for an operating certificate "designation" indicating approval by the Office to provide such services.

§ 830.2 Legal base

(a) Section 1.03(6) of the Mental Hygiene Law defines "facility" as any place in which services for the mentally disabled are provided.

- (b) Section 19.07(c) of the Mental Hygiene Law authorizes the commissioner to adopt standards ensuring the personal and civil rights of persons seeking and receiving addiction services, care, treatment and rehabilitation are adequately protected.
- (c) Section 19.07(e) of the Mental Hygiene Law authorizes the commissioner to adopt standards including necessary rules and regulations pertaining to addiction services.
- (d) Section 19.09(b) of the Mental Hygiene Law authorizes the commissioner to adopt regulations necessary and proper to implement any matter under his or her jurisdiction.
- (e) Section 19.21(d) of the MHL requires the Office to establish reasonable performance standards for providers of services certified by the Office.
- (f) Section 32.01 of the Mental Hygiene Law 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 Mental Hygiene Law.
- (g) 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 an individual with a substance use disorder pursuant to section 32.09(b) of the MHL.
- (h) 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.
- (i) 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.
- (j) Article 160 of the Education Law provides for the licensure or certification of acupuncturists and limited practice of unlicensed persons in treatment of substance use disorder.
- (k) Article 29-G of the Public Health Law relates to reimbursement and requirements for health care services delivered via "telehealth."
- (l) Section 3351 of the Public Health Law authorizes the prescribing or dispensing of controlled substances for the purposes of substance use disorder treatment.
- (m) Section 829 of Title 21 of the United States Code governs the law concerning internet prescribing of controlled substances.
- (n) Article 15 of the Executive Law enacts the Human Rights Law prohibiting discrimination against protected classes of New Yorkers including on the basis of sexual orientation and gender identity or expression.

830.3 Definitions

As used in this Part, the following terms shall have the following meanings:

- (a) "Acupuncture therapist" means licensed, certified, or unlicensed clinical staff who have documented successful completion of acupuncture training for the treatment of substance use disorder in an educational program acceptable to the Education Department pursuant to Article 160 of the Education Law.
- (b) "Telehealth" means the use of two-way real-time interactive telecommunication system for the purpose of providing addiction services at a distance.
- (c) "Designated program" means a certified, approved or otherwise authorized program which has complied with the requirements of this Part and any applicable standards and guidance issued by the Office and has received an operating certificate designation indicating Office approval.
- (d) For purposes of Telehealth, the following terms shall have the following meanings:
- (1) "Distant site" means the site at which the practitioner delivering the service is located at the time the service is provided via the interactive telecommunications system, which may include the practitioner's place of residence, office, or other identified space within the United States.
- (2) "Originating site" means the site at which the patient is located at the time the service is being provided via the interactive telecommunications system, which may include the patient's place of residence, other identified location, or other temporary location out-of-state.
 - (3) "Practitioner" means:
 - (i) a prescribing professional eligible to prescribe buprenorphine pursuant to federal regulations;
- (ii) other staff credentialed or approved by the Office providing addiction services consistent with their scope of practice and as authorized pursuant to this Part and Article 29G of the public health law.
- (4) "Telecommunication system" means a dedicated secure interactive audio and/or video linkage system approved by the Office to transmit data between an originating and distant site for purposes of providing services delivered via telehealth[-services].
- (e) "Gender identity or expression" means a person's actual or perceived gender-related identity, appearance, behavior, expression, or other gender-related characteristics regardless of the sex assigned to that person at birth, including, but not limited to, the status of being transgender. One's gender identity may also innately reside somewhere in between the ends of the gender binary (man/woman) or somewhere outside the boundaries of the gender binary and can be fluid for some individuals. Gender identity and expression may be expressed in self-image, physical appearance, and with behavior.
- (f) "Program Endorsement" means a designation offered pursuant to the requirements of this Part and any Standards and guidance issued by the Office. It is a demonstration of a program's proficiency in meeting additional standards identified by the Office.
- (g) "Adolescent" for purposes of this Part, means an individual under the age of twenty-one (21).

830.4 Acupuncture therapy

- (a) *Initial services*. Acupuncture may be effective in some patients to reduce cravings and relieve anxiety, thereby assisting patients in achieving and sustaining recovery from substance use disorder.
- (1) Acupuncture shall not be the exclusive method of treatment for any patient. In an outpatient program, when acupuncture is provided it must be part of an office visit including at least one other service.
- (2) Acupuncture therapy, administered pursuant to this section, may be an initial service provided on demand to stabilize and engage a patient during the period of treatment/recovery plan development or a service included in and administered pursuant to a patient's treatment/recovery plan.
- (b) *Physician approval; monitoring*. (1) A program's medical director shall, in consultation with the acupuncturist, develop a protocol to determine if a patient requires a medical evaluation prior to acupuncture therapy. No patient requiring a medical evaluation in accordance with such protocol shall receive acupuncture therapy unless a physician has reviewed the patient's medical condition and provided written authorization for acupuncture therapy.
- (2) Any patient receiving acupuncture therapy shall be monitored by a clinical staff member during the conduct of an acupuncture therapy session to ensure counseling and clinical intervention as necessary.
- (3) All acupuncture therapy sessions must be documented in a patient case record and signed by both the therapist and the monitoring clinical staff member.
- (c) *Treatment/Recovery plan.* (1) Acupuncture therapy is limited to the treatment of addictive disorders as indicated in the treatment/recovery plan.
- (2) The individual treatment/recovery plan must contain a schedule of acupuncture sessions tailored to the patient's initial and evolving needs including, frequency, duration and clinical justification.
- (3) Acupuncture therapy must be provided either immediately preceding or following an otherwise permissible clinical service.
- (d) *Staffing*. Acupuncture therapy in OASAS certified facilities shall only be performed by the following persons:
- (1) a licensed or certified Acupuncturist who has had at least one year of employment experience in the treatment of addictive disorders or completed a training program in the treatment of addictive disorders during the first six (6) months of employment; or
- (2) an acupuncture detoxification therapist who is not licensed or certified but who is a clinical staff member who has successfully completed a course of acupuncture training acceptable to the state Education Department under Article 160 of the Education Law and who practices acupuncture under the supervision of:
 - (i) a licensed or certified Acupuncturist pursuant to paragraph (1) of this subdivision; and
 - (ii) the clinical supervisor or medical director of the program.

- (e) *Policies*. Programs providing acupuncture therapy must develop and implement policies and procedures in consultation with the program Medical Director including, but not limited to, the following:
 - (1) training of all acupuncture therapists regarding infection control, body fluids;
 - (2) recommended vaccinations;
 - (3) regular on-site clinical supervision of licensed and unlicensed acupuncture therapists;
 - (4) written patient informed consent;
 - (5) space requirements;
- (6) use of and disposal of needles or other acupressure implements consistent with NYS public health law and environmental conservation law.

§ 830.5 Telehealth

- (a) Limitations. (1) Services delivered via Telehealth[-services], as defined in this Part, may be authorized by the Office for the delivery of addiction services provided by practitioners employed by, or pursuant to a contract or Memorandum of Understanding (MOU) with a program certified by the Office. All services may be delivered via telehealth unless otherwise specified by the Office in the *Telehealth Standards for OASAS Designated Providers*, as incorporated in this Title (hereafter the *Telehealth Standards*), posted on the Office website.
- (2) The Office supports the use of telehealth as an appropriate component of the delivery of addiction services to the extent that it is in the best interests of the person receiving services; is performed in compliance with applicable federal and state laws and regulations, [and-]the provisions of this Part, and the *Telehealth*Standards in order to address legitimate concerns about privacy, security, patient safety, and interoperability; and is delivered by appropriate staff working within their scope of practice [does not replace the preferred option of an in person exchange between patient and practitioner].
- (3) Services may be <u>delivered[provided]</u> via telehealth by a practitioner from a site distant from the location of the patient, provided both practitioner and patient are located in sites approved by the Office pursuant to the policies and procedures submitted by a certified program in an application for a telehealth designation.
- (4) Telehealth does not include an electronic mail message, a text message or facsimile transmission between a program and a patient or a consultation between two practitioners, although these activities may support the delivery of services via telehealth.
- (5) An Office certified program must obtain prior written authorization from the Office pursuant to this section before implementing telehealth service; services shall be limited to those authorized and approved by the Office.

- (b) *Designation*. (1) Requests for designation to provide telehealth services shall be in the form of policies and procedures and an attestation, found in the *Telehealth Standards* posted on the agency website, and submitted by a certified provider to the Office Bureau of Certification and the Regional Office serving the area in which the applicant site is located. Such Regional Office may make an on-site visit to either or both linked sites prior to final approval and designation which will be issued by the Bureau of Certification.
- (2) Office approval and operating certificate designation will be based on review of the policies and procedures and attestation addressing the following criteria, including but not limited to:
- (i) <u>service delivery via</u> telehealth [<u>services</u>] must be conducted via telecommunication systems employing acceptable authentication and identification procedures by both the sender and the receiver; applicant must document a relationship with a credible technology service provider;
- (ii) delivery of services <u>via telehealth</u> meet federal and state confidentiality requirements including, but not limited to, 42 C.F. R. Part 2, and 45 C.F.R. Parts 160 and 164 (HIPAA Security Rules);
- (iii) confidentiality requirements applicable to written medical records shall apply to <u>services delivered</u>

 <u>via</u> telehealth [services] including the actual transmission of the service, any recordings made during the transmission, and any other electronic records;
- (iv) spaces occupied by the patient and the practitioner must both meet minimum privacy standards consistent with patient-practitioner interaction and confidentiality;
- (v) culturally competent <u>and affirming interpretation and</u> translation services must be provided when the patient and practitioner do not speak the same language;
- (vi) a written procedure detailing the availability of <u>in-person services</u>[face to face assessments] by medical staff in an emergency situation;
- (vii) written procedures for a contingency plan in the event of a transmission failure or other technical difficulties which may render the service undeliverable;
- (viii) when applicable, a written and executed contract or MOU between an applicant provider and an individual practitioner or a corporate entity encompassing multiple practitioners regarding the above criteria and including billing, payment, record sharing, background checks, and any other relevant details necessary for implementation;
- (ix) a practitioner must be licensed or credentialed to practice in New York State and be in good standing with the appropriate licensing or credentialing authority and be physically located in the USA when providing services via telehealth;
- (x) the provision of buprenorphine prescribing and monitoring via telehealth must comply with applicable state and federal laws and regulations; additional guidance may be found in <u>the</u> *Telehealth Standards*.

- (c) *Implementation*. (1) The patient shall be <u>seeking services from</u>[admitted to, or seeking admission to,] a program certified by the Office.
- (i) [If the patient is admitted to or seeking admission to a program, t] The practitioner shall prepare appropriate documentation of the service and, [admission or progress notes and,] if appropriate, securely forward said documentation [them] to the designated program as a condition of reimbursement;
- (ii) If <u>services delivered via</u> telehealth [<u>services</u>] are a regular part of an admitted patient's treatment/recovery plan, the practitioner must coordinate with the responsible professional at the patient's designated program to prepare and/or update the treatment/recovery plan in accordance with this Title to permit the patient's program to be reimbursed for continuing services;
- (iii) The patient must be provided basic information about telehealth including alternatives, possible delays in service, possible need to travel to an approved originating site to receive services, risks associated with not having the services provided; the patient must acknowledge in writing having received such information;
 - (iv) The patient may refuse to receive services via telehealth.
- (v) Patients and prospective patients must be evaluated to determine if <u>service delivery via</u> telehealth is appropriate; additional evaluations may be required for medication <u>for addiction</u> [assisted] treatment using controlled substances.
 - (2) Service delivery via telehealth [services] must be included in a provider's quality review process.
 - (3) The distant site practitioner must directly render the <u>service delivered via</u> telehealth [service];
- (4) If the distant site is a hospital, the practitioner must be credentialed and privileged by such hospital, consistent with applicable accreditation standards.
- (5) Telehealth sessions shall not be recorded without the patient's consent, which shall be documented in the clinical record.
- (6) Unless otherwise required, persons receiving services via telehealth may be accompanied by a staff member during the session or may be alone. If the initial evaluation or a subsequent treatment/recovery plan recommends that the patient be accompanied during telehealth sessions, the [person]patient must be accompanied for the session to be reimbursed.
- (d) *Medicaid Reimbursement*. (1) For purposes of billing for Medicaid reimbursement, both the practitioner and/or facility employing the practitioner, and the designated program must be Medicaid enrolled
- (2) For purposes of this subdivision, <u>services delivered via</u> telehealth [services] shall be considered face-to-face contacts.
- (3) To be eligible for Medicaid reimbursement, <u>services delivered via</u> telehealth [<u>services</u>] must meet all requirements applicable to [<u>assessment and treatment</u>] service[s] <u>delivery in accordance with</u> [of] Part 841

and the Part pursuant to which the designated program operating certificate is issued and must exercise the same standard of care as services delivered on-site or in-community.

- (4) <u>Services delivered via</u> telehealth [services] will be reimbursed at the same rates for identical procedures provided by practitioners in person and delivered on-site or in-community unless otherwise specified by the Office.
- (5) The designated program is the primary billing entity; reimbursement for practitioners at a distant site must be pursuant to a contract or MOU. Delivery of services via telehealth are covered when medically necessary and under the following circumstances:
- (i) the patient is located at an originating site and is seeking <u>a service(s) from [or contemplating</u> admission, or is admitted to,] a certified program;
 - (ii) the practitioner is employed by or contracted with a program certified by the Office;
 - (iii) the patient or significant other is present during the telehealth session;
- (iv) the request for a telehealth session and the rationale for the request are documented in the patient's case record:
- (v) the patient case record includes documentation that the telehealth session occurred and the results and findings were communicated to the designated provider.
- (6) If the person receiving services or a significant other are not present during the telehealth **session**[service], the service is not eligible for third party reimbursement and any incurred costs remain the responsibility of the designated provider.
- (7) <u>Services delivered via</u> telehealth [services] may only be delivered via technological means approved by the federal Center for Medicaid and Medicare Services (CMS), provided such means are compliant with federal confidentiality requirements.
- (8) If all or part of a [telehealth] service delivered via telehealth is undeliverable due to a failure of transmission or other technical difficulty, reimbursement shall not be provided.
- (e) Contracts or Memorandum of Understanding (MOU) for the Provision of Telepractice services. (1) Prior approval of the Office is not required before entering into such contracts or MOU; however, notice of such contracts or agreements must be provided by the OASAS certified provider to the Office Bureau of Certification within thirty (30) days after execution of such contract or MOU or as part of the application for designation.
- (2) The designated OASAS program is the default billing entity. Reimbursement of practitioners for **services delivered via** telehealth [services] shall be pursuant to such contract or MOU; services are not separately billable by the practitioner unless agreed to in writing in advance of any service delivery.

- (3) Designated programs or approved practitioners shall not engage in any service[s] <u>delivery</u> via telehealth not <u>otherwise</u> authorized by the Office.
- (4) Practitioners under contract or MOU with a certified and designated program must comply with the provisions of Part 805 of this Title related to criminal history information reviews or provide documentation that such security checks have been conducted and satisfied.
- (5) Designated programs shall notify the Office Bureau of Certification of any change in practitioners pursuant to a contract or MOU and compliance with provisions of Part 805 of this Title.
- (f) *Telehealth Standards*. The Office shall post standards on its public website to assist in compliance with the provisions of this Part and in achieving treatment goals through the provision of **service delivery via** telehealth. Such standards shall include, but not be limited to:
 - (1) Technology guidelines, including:
- (i) The minimum technology thresholds (i.e., equipment, bandwidth, videoconferencing software, network specifications, carrier selection, hub/bridge, and security specifications), which shall be updated as new technology is approved; and
 - (ii) The form or format regarding the technology and communications to be used.
- (2) Clinical standards, including but not limited to, the prescribing of medication <u>for addiction</u> [assisted] treatment (MAT), including controlled substances, via telehealth.
- (g) *Policies and procedures*. A program designated to deliver services via telehealth must have written policies and procedures submitted by the program for designation approval, and the applicable requirements of this Part.
- (h) *Medication* [Assisted] *Treatment*. Initiation and prescribing of [addiction] medications for addiction treatment must be done in accordance any and all applicable federal rules and regulations; guidance may be found in the *Telehealth Standards* posted on the agency website.

§830.6 Lesbian, Gay, Bisexual, Transgender, Queer and Questioning Program Endorsement

(a) Intent. All OASAS providers must meet minimum requirements for the provision of culturally competent and appropriate services for Lesbian, Gay, Bisexual, Transgender, Queer and Questioning (LGBTQ) patients or clients in accordance with state and federal law, this Title, Local Services Bulletins, Standards and guidance issued by the Office. This program endorsement identifies additional criteria programs must meet as outlined in the *LGBTQ Affirming Program Endorsement Standards for OASAS-Certified Programs* (hereafter the *LGBTQ Standards*), as incorporated in this Title, for the provision of LGBTQ affirming addiction treatment services.

- (b) Application. Requests for the LGBTQ Program Endorsement shall be in the form of a written application, to include a program self-assessment and attestation found in the *LGBTQ Standards* posted on the agency website, and submitted by a certified program to the Office Bureau of Certification and the appropriate Regional Office serving the area in which the applicant is located. Office staff may make an on-site visit to the program prior to issuing the Program Endorsement Designation.
- (c) Approval. Office approval and operating certificate designation will be based on submission of the attestation and the program self-assessment as well as any additional documentation requested by the Office and as set forth by the Office in this Part and the applicable *Standards* and guidance.
- (d) Certification. Programs receiving the endorsement remain subject to all applicable rules and regulations pertaining to the Part under which they are certified.
- (e) Program Self-Assessment. Programs seeking the LGBTQ Program Endorsement designation shall develop and implement policies and procedures consistent with the *LGBTQ Standards* set forth by the Office, including but not limited to:
- (1) Physical environment. The program shall cultivate a welcoming and affirming physical environment for LGBTQ patients, staff, and family members.
- (2) Program staff. The program shall establish an inclusive, non-discriminatory workplace environment for LGBTQ employees and actively recruit LGBTQ staff.
- (i) At least one staff person identified as the LGBTQ Liaison is tasked with monitoring compliance with all required staff training and maintaining a resource directory and creating referral relationships with LGBTQ affirming providers.
 - (ii) All program staff shall receive training as identified in the *Standards*.
- (iii) Non-discrimination. Providers shall have policies addressing non-discrimination and encouraging diversity, in hiring and compensation and benefits.
- (3) Patient Rights. The program shall implement policies prohibiting discrimination in the delivery of services to LGBTQ patients and their families. Agency Patient Rights will reflect LGBTQ affirming policies and shall be linguistically appropriate.
- (4) Service Provision. Staff and patient interaction shall be inclusive, affirming, and meet the needs of LGBTQ patients of all ages and their families, as indicated by:
 - (i) use of culturally appropriate and affirming language;
- (ii) all forms and electronic health record (EHR) use inclusive language and provide for optional selfidentification related to, at a minimum, name, gender marker, pronoun(s), sexual orientation, gender identity or expression, legal and correct name and partnership/marital status;

- (iii) availability of referrals for LGBTQ patients and their families to providers within and outside of the agency.
- (5) Patient interaction. The program shall address and identify staff responsibilities in creating a welcoming atmosphere and responding to negative patient interactions, including opportunities for addressing harassment among patients.
- (6) Confidentiality. The program shall ensure the confidentiality of all patient data, including information about sexual orientation, gender identity or expression, gender pronoun information, legal name and any other identifying information.
- (f) Agency Forms. All agency forms shall be updated to include LGBTQ affirming language.

§830.7 Adolescent Outpatient Program Endorsement

- (a) Intent: Developmentally informed treatment is recognized as reducing substance use symptomology and assists in achieving and sustaining person-centered recovery from a substance use disorder. Programs certified pursuant to Part 822 of this Title seeking to implement adolescent initial and ongoing services in accordance with the Clinical Practice Standards for Adolescent Programs for OASAS Designated Providers (hereinafter the Adolescent Endorsement Standards), incorporated by reference in this Title, are eligible to apply for an Adolescent Endorsement.
- (b) Application Process. (1) Requests for designation for the Adolescent Program Endorsement shall be in the form of an application and attestation, found in the Adolescent Endorsement Standards posted on the agency website, incorporated by reference in this Title, and submitted by a certified outpatient program to the Office Bureau of Certification and the Regional Office serving the area in which the applicant site is located. Programs are required to submit Policies and Procedures in accordance with the aforementioned Adolescent Endorsement Standards. Office Adolescent Services and Regional Office staff may make an on-site visit prior to final approval and designation which will be issued by the Bureau of Certification.
- (2) Office approval and operating certificate designation will be based on a review of the application, policies and procedures, and attestation addressing the following criteria, including but not limited to:
 - (1) Policies and procedures specific to the adolescent population addressing at a minimum:
 - i. Outreach, engagement, and retention strategies;
 - ii. HIPAA messaging compliance (if applicable);
 - iii. Mental health treatment;
 - iv. Reporting for injuries and emergencies;
 - v. Filing of client complaints;

- vi. Emotional and physical safety of youth, including bullying;
- vii. Availability and use of Medication for Addiction Treatment for youth.
- (2) Staff Qualification and training. Accessible staff includes providers such as a psychologist, psychiatrist, or nurse practitioner with knowledge of the adolescent population and at least one Master's level clinician. Staff shall have ongoing training on the principles of emerging best practices relevant to trauma-informed care and other trainings relevant to youth treatment and recovery.
- (3) Treatment services are available to adolescents in a developmentally appropriate manner including using appropriate Evidenced Based Practices, age-appropriate grouping of patients for group services and prosocial activities, and presenting information based on patient maturity level.
- (4) Formal and informal services for the family and/or significant others identified by adolescent patients.
 - (5) Mental Health services are available on site or by referral.
- (6) Availability of Medication for Addiction Treatment, including appropriate linkage with a certified Opioid Treatment Program.

§830.8 Ancillary Withdrawal Outpatient Designation

- (a) Intent. Ancillary Withdrawal utilizes medication management to address the symptoms of mild to moderate or persistent withdrawal in outpatient settings. In combination with other outpatient services, Ancillary Withdrawal allows individuals to physically tolerate their symptoms while staying in their treatment/recovery community where they can continue to build long term support.
- (b) Application for Designation. (1) Providers certified pursuant to Part 822 of this Title shall submit a request to the Office Bureau of Certification on the Attestation Form for Withdrawal Management Medical protocols at OASAS Certified Programs, which can be found on the Office website. On such form providers shall attest to compliance with Office issued guidance in the following areas, where there are deviations from the Office guidance providers shall submit an explanation on said form:
 - (i) Objective monitoring;
 - (ii) Safety;
 - (iii) Involvement of medical professionals;
 - (iv) Stabilization of medication for addiction treatment;
 - (v) Patient comfort;
 - (vi) Level of care assessment; and,

(vii) Transition to continued care.

(2) Providers agree to service delivery consistent with the Guidance on Medical Protocols for Withdrawal Management for OASAS Certified Programs, posted on the OASAS website.

§830.9[7] Revocation of Designation

- (a) Failure to maintain minimum standards for designation, implementation and/or reimbursement may result in disciplinary action against a program's operating certificate. In the event the Office determines that a designation must be revoked, the Office will notify the program in writing. The program may request an administrative review of such decision pursuant to this paragraph.
- (i) The program must request such review in writing within fifteen (15) days of receipt of the notice of revocation of designation. The request shall state the reasons the program considers the revocation of designation incorrect and shall include any supporting documentation;
- (ii) the commissioner shall notify the program, in writing, of the results of the administrative review within twenty (20) days of receipt of the request for review. Failure to notify the program within twenty (20) days shall be deemed confirmation of revocation of a designation.
- (iii) The commissioner's determination after administrative review shall be final and not subject to further review.

§830.<u>10</u>[**8**] 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 which can be given effect without the invalid provision or applications, and to this end the provisions of the Part are declared to be severable.



Notice of Proposed Rulemaking Regulatory Impact Statement

Amend 14 NYCRR Part 836 INCIDENT REPORTING IN OASAS CERTIFIED, LICENSED, FUNDED, OR OPERATED SERVICES

1. Statutory Authority:

- (a) Section 19.07(c) of the Mental Hygiene Law charges the Office with the responsibility for seeing that persons in need of treatment for addiction services receive high quality care and treatment, and that the personal and civil rights of persons receiving care, treatment and rehabilitation are adequately protected.
- (b) Section 19.07(e) of the Mental Hygiene Law authorizes the Commissioner ("Commissioner") of the Office to adopt standards including necessary rules and regulations pertaining to addiction services.
- (c) Section 19.09(b) of the Mental Hygiene Law authorizes the Commissioner to adopt regulations necessary and proper to implement any matter under their jurisdiction.
- (d) Section 19.20 of the Mental Hygiene Law (Protection of People with Special Needs Act, added by Chapter 501 of the Laws of 2012) authorizes the Office to receive and review criminal history information related to certain prospective employees and volunteers.
- (e) Section 19.20-a of the Mental Hygiene Law (Protection of People with Special Needs Act, added by Chapter 501 of the Laws of 2012) authorizes the Office to receive and review criminal history information related to persons seeking to be credentialed or applicants for an operating certificate issued by the Office.
- (f) Section 19.21(b) of the Mental Hygiene Law requires the Commissioner to establish and enforce certification, inspection, licensing and treatment standards for addiction services facilities and staff.
- (g) Section 19.40 of the Mental Hygiene Law authorizes the Commissioner to issue operating certificates for the provision of addiction 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, addiction services are protected.
- (i) Section 32.01 of the Mental Hygiene Law 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 Mental Hygiene Law.
- (j) Section 32.02 of the Mental Hygiene Law authorizes the Commissioner to adopt regulations necessary to ensure quality services to those suffering from compulsive gambling.
- (k) Section 32.07(a) of the Mental Hygiene Law authorizes the Commissioner to adopt regulations to effectuate the provisions and purposes of Article 32 of the Mental Hygiene Law.
- (1) Sections 33.16(a)(6) and 33.16(b)(4) of the Mental Hygiene Law define a "qualified person" as an individual receiving services, their legal guardian, or a parent, spouse or adult child who has authority to provide consent for care and treatment.
- (m) Section 33.23 of the Mental Hygiene Law requires directors of facilities certified by OASAS to provide telephone notification to a "qualified person" of an incident involving a client within twenty-four (24) hours of the initial report.
- (n) Section 33.25 of the Mental Hygiene Law requires facilities to release records to "qualified persons", upon request, relating to allegations and investigations of client abuse or mistreatment.
- (o) Section 491 of the Executive Law requires mandated reporters to immediately report allegations of reportable incidents to the Vulnerable Persons' Register upon discovery.
- (p) Section 492 of the Social Services Law establishes the Vulnerable Persons' Register to which reports of allegations of reportable incidents must be submitted in a manner and on forms approved by the executive director of the Justice Center.
- (q) Article 6, Title 6 of the Social Services Law requires the reporting of suspected abuse or maltreatment of persons under 18 years of age to the New York Statewide Central Register of Child Abuse and Maltreatment (hereinafter, "Statewide Central Register").
- (r) Section 413 of the Social Services Law identifies persons required to report cases of suspected child abuse or maltreatment to the Statewide Central Register.

- 2. <u>Legislative Objectives</u>: The legislature has authorized OASAS to establish standards and regulations governing incident management and oversight of addiction services in certified, funded or otherwise authorized programs, consistent with various NYS laws, regulations and rules for the protection of individuals seeking and receiving services in the OASAS system.
- 3. <u>Needs and Benefits:</u> OASAS is explicitly prohibiting any certified, funded or otherwise authorized program from conducting a body cavity search of a patient for any reason. There is no therapeutic value in conducting a body cavity search and could potentially cause harm to individuals that have a history of trauma.
- 4. <u>Costs:</u> No additional administrative costs to the agency are anticipated.
- 5. <u>Paperwork:</u> There is no additional paperwork beyond what is already required.
- 6. <u>Local Government Mandates</u>: There are no new local government mandates.
- 7. <u>Duplications</u>: This proposed rule does not duplicate, overlap, or conflict with any State or federal statute or rule.
- 8. <u>Alternatives:</u> The alternative is to leave the regulation as it currently reads, with language permitting body cavity searches.
- 9. Federal Standards: This regulation does not conflict with federal standards.
- 10. <u>Compliance Schedule:</u> This rulemaking will be effective upon publication of a Notice of Adoption in the *State Register*.

PART 836

INCIDENT REPORTING IN OASAS CERTIFIED, LICENSED, FUNDED, OR OPERATED SERVICES

(Statutory Authority: Mental Hygiene Law Sections 19.07(c), 19.07(e), 19.09(b), 19.20, 19.20-a, 19.21(b), 19.40, 22.07(c), 32.01, 32.02, 32.07(a), 33.16, 33.23, 33.25; Executive Law sections 296, 491 and 495, ; Civil Service Law section 50; Corrections Law Article 23-A; Protection of People with Special Needs Act (Chapter 501 of the Laws of 2012)

Section:

836.1	Background and intent
836.2	Legal base
836.3	Applicability
836.4	Definitions
836.5	Incident management plan and incident review committee
836.6	Incident reporting, notice, and investigations in facilities and provider agencies
certified, licen	sed or operated by the Office
836.7	Incident reporting, notice, and investigations in programs funded, but not certified
	or licensed, by the Office
836.8	Additional notice and reporting requirements for reportable incidents
836.9	Recordkeeping and release of records to qualified persons
836.10	Duty to cooperate and inspection of facilities
836.11	Severability

Section 836.4(d)(3)(ii) is amended as follows:

(ii) Body cavity search; which is explicitly prohibited pursuant to Part 815 of this Title [must be with client consent];

Section 836.8 (c) is amended as follows:

(c) In the event of a client's death in an inpatient or residential program under any circumstances or within 30 days of such client's discharge, immediate notification must be made to both the VPCR and the Justice Center's Mortality Review Unit (subject to the provisions of 42 CFR Part 2), the process for which can be found on the Justice Center's website [here: https://www.justicecenter.ny.gov/mortality-review], the local coroner or medical examiner, or any other state or local agency identified under state laws requiring the collection of health or other vital statistics.