

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 164.000: LICENSURE OF SUBSTANCE USE DISORDER TREATMENT PROGRAMS

Section

- 164.003: Scope
- 164.005: Definitions

PART ONE: LICENSING AND APPROVAL PROCEDURES AND REQUIREMENTS

- 164.006: Part One Scope
- 164.007: Application Requirements for Licensure or Approval
- 164.008: Application Submission
- 164.009: Evaluation of Application and Suitability of Applicant or Licensed or Approved Provider
- 164.010: Inspections
- 164.011: Issuance of Licenses and Approvals
- 164.012: Posting of a License or Approval
- 164.013: Transfer of Ownership
- 164.014: Change of Location
- 164.015: Change of Program Name
- 164.016: Correction Orders
- 164.017: Plan of Correction
- 164.018: Administrative Penalties
- 164.019: Grounds for Denial, Refusal to Renew, Restriction, Limitation, or Revocation of License or Approval
- 164.020: Hearings
- 164.021: Commissioner and Judicial Review
- 164.022: Providing Information to the Department
- 164.023: Waivers
- 164.030: Governance
- 164.031: Accreditation
- 164.032: Finances
- 164.033: Insurance
- 164.034: Qualified Service Organization Agreements
- 164.035: Required Notifications to the Department
- 164.036: Marketing of Services
- 164.038: Evaluation
- 164.039: Nondiscrimination and Accommodation
- 164.040: Written Policies
- 164.041: Personnel
- 164.043: Job Description and Evaluations
- 164.044: Training and Supervision
- 164.046: Personnel Records
- 164.047: Volunteers, Student Interns and Contract Agency Staff
- 164.048: Staffing Pattern
- 164.049: Physical Plant: Building Design
- 164.050: Required Certificates and Inspections
- 164.053: Building Maintenance
- 164.054: General Areas
- 164.055: Tobacco-free Environment
- 164.056: Restrooms
- 164.057: Communication Systems
- 164.058: First Aid
- 164.059: Child Safety
- 164.061: Internal Incident Investigation and Reporting
- 164.062: All Hazard and Emergency Planning and Procedures
- 164.070: Referrals and Admissions
- 164.071: Orientation
- 164.072: Assessment
- 164.073: Individual Treatment Plan
- 164.074: Minimum Treatment Service Requirements

Section: continued

- 164.075: Termination and Discharge
- 164.076: Aftercare
- 164.077: Post-discharge Follow-up
- 164.078: Behavior Management
- 164.079: Patients' and Residents' Rights
- 164.080: Grievances
- 164.081: Patient and Resident Policy Manual
- 164.082: Special Populations
- 164.083: Patient and Resident Records
- 164.084: Confidentiality
- 164.085: Transfer and Storage of Service Records
- 164.086: Interruption or Suspension of Service
- 164.087: Closure
- 164.099: Special Projects

PART TWO: REQUIREMENTS FOR SERVICE PROVISION

- 164.100: 24-hour Diversionary Services
- 164.101: Scope
- 164.103: Physical Plant
- 164.104: Meals and Food Handling
- 164.105: Safe Storage and Administration of Medications
- 164.106: Patient Personal Effects and Affairs
- 164.107: Required Agreements
- 164.108: Death of a Patient
- 164.110: Hours of Operation
- 164.131: 24-hour Diversionary Services Medically Managed Withdrawal Treatment
- 164.132: Scope
- 164.133: Provision of Services
- 164.134: Staffing Pattern
- 164.150: Clinical Stabilization Services
- 164.151: Scope
- 164.152: Provision of Services
- 164.153: Staffing Pattern
- 164.200: Outpatient Services
- 164.201: Scope
- 164.202: Provision of Services
- 164.205: Hours of Operation
- 164.206: Outpatient Withdrawal Treatment Services
- 164.207: Provision of Service
- 164.208: Staffing Pattern
- 164.209: Hours of Operation
- 164.211: First Offender Driver Alcohol or Controlled Substance Education
- 164.212: Provision of Services
- 164.215: Hours of Operation
- 164.223: Second Offender Alcohol or Controlled Substance Aftercare Treatment
- 164.224: Provision of Services
- 164.231: Day Treatment
- 164.232: Provision of Services
- 164.234: Hours of Operation
- 164.240: Acupuncture Withdrawal Management Treatment Services
- 164.241: Provision of Services
- 164.243: Staffing Pattern
- 164.245: Hours of Operation
- 164.250: Office-based Opioid Treatment
- 164.251: Provision of Services
- 164.255: Additional Service Requirements for Opioid Maintenance
- 164.260: Diversion Control
- 164.280: Mental Health Services

Section: continued

- 164.300: Opioid Treatment Programs
- 164.301: Scope
- 164.302: Authority to Operate an Opioid Treatment Program
- 164.303: Inspections
- 164.304: Required Notifications
- 164.305: Provision of Services – Opioid Treatment Providers
- 164.306: Additional Opioid Treatment Provider Requirements: Opioid Medically Supervised Withdrawal
- 164.307: Additional Service Requirements for Opioid Maintenance
- 164.308: Referral to Medication Unit
- 164.309: Drug Screening Policy and Procedure
- 164.310: Diversion Control
- 164.311: Involuntary Termination from an Opioid Treatment Program
- 164.312: Bureau Review of Program Decisions to Terminate
- 164.314: Staffing Pattern
- 164.315: Hours of Operation
- 164.316: Severe Weather Policy
- 164.317: Required Agreements
- 164.400: Residential Rehabilitation
- 164.401: Scope
- 164.402: Hours of Operation
- 164.404: Physical Plant
- 164.405: Meals and Food Handling
- 164.406: Safe Storage and Administration of Medications
- 164.407: Resident Personal Effects and Affairs
- 164.408: Required Agreements
- 164.409: Death of a Resident
- 164.420: Residential Rehabilitation for Adults
- 164.421: Scope
- 164.422: Provision of Services
- 164.423: Program Components
- 164.424: Staffing Pattern
- 164.430: Residential Rehabilitation for Adults with Their Families
- 164.431: Scope
- 164.432: Provision of Services
- 164.433: Staffing Pattern
- 164.440: Residential Rehabilitation for Adolescents and Transition Age Youth
- 164.441: Scope
- 164.442: Provision of Services
- 164.444: Staffing Pattern
- 164.450: Residential Programs for Operating under the Influence Second Offender Programs
- 164.451: Scope
- 164.452: Provision of Services
- 164.453: Notice to the Court
- 164.454: Staffing Pattern

PART THREE: DEPARTMENT OF MENTAL HEALTH LICENSEES, BUREAU OF
HEALTH CARE SAFETY AND QUALITY LICENSEES, AND
AGENCIES OF THE COMMONWEALTH

- 164.500: Licensure Requirements for Providers Licensed by the Department of Mental Health or the Bureau of Health Care Safety and Quality, or Operated by an Agency of the Commonwealth
- 164.505: Scope
- 164.507: Application Requirements for Licensure or Approval
- 164.508: Application Submission
- 164.509: Evaluation of Application and Suitability of Applicant or Licensed or Approved Provider
- 164.510: Inspections

Section: continued

- 164.511: Issuance of Licenses and Approvals
- 164.512: Posting of a License or Approval
- 164.513: Transfer of Ownership
- 164.514: Change of Location
- 164.515: Change of Program Name
- 164.516: Correction Orders
- 164.517: Plan of Correction
- 164.518: Administrative Penalties
- 164.519: Grounds for Denial, Refusal to Renew, Restriction, Limitation, or Revocation of License or Approval
- 164.520: Hearings
- 164.521: Commissioner and Judicial Review
- 164.522: Providing Information to the Department
- 164.523: Waivers
- 164.534: Qualified Service Organization Agreements
- 164.535: Required Notifications to the Department
- 164.536: Marketing of Services
- 164.539: Nondiscrimination and Accommodation
- 164.540: Written Policies
- 164.544: Training and Supervision
- 164.548: Staffing Pattern
- 164.570: Referrals and Admissions
- 164.572: Assessment
- 164.573: Individual Treatment Plan
- 164.574: Minimum Treatment Service Requirements
- 164.575: Termination and Discharge
- 164.576: Aftercare
- 164.579: Patients' and Residents' Rights
- 164.582: Special Populations
- 164.583: Patient and Resident Records
- 164.584: Confidentiality
- 164.586: Interruption or Suspension of Service
- 164.587: Closure
- 164.600: Approval Requirements for Substance Use Disorder Treatment Programs Operated by Penal Facilities
- 164.605: Scope
- 164.607: Application Submission for Approval and Provisional Approval
- 164.608: Renewal of Approval
- 164.609: Administrative Action on the Approval
- 164.612: Minimum Treatment Service Requirements
- 164.614: Inspections
- 164.616: Correction Orders
- 164.618: Plan of Correction
- 164.620: Required Notifications to the Department
- 164.623: Waiver
- 164.624: Patient Records
- 164.626: Confidentiality
- 164.700: Severability

164.003: Scope

105 CMR 164.000 governs the licensure or approval and operation of every substance use disorder treatment program subject to licensure or approval by the Department which includes separate, identifiable substance use disorder treatment programs within facilities licensed pursuant to M.G.L. c. 111, § 51 or M.G.L. c. 19, § 19. A department, agency or institution of the federal government, the Commonwealth or any political subdivision thereof is exempt from licensure except that a department, agency or institution of the Commonwealth or subdivision thereof is subject to approval by the Department. No person, corporation, trust, authority, governmental agency, political subdivision or any other entity subject to 105 CMR 164.000 shall operate a substance use disorder treatment program that does not comply with the requirements of 105 CMR 164.000. The Department may from time to time publish interpretations of 105 CMR 164.000 and guidelines as necessary to promote uniform application of 105 CMR 164.000, and make them available to those licensed and approved by the Department and to the public.

164.005: Definitions

The following definitions shall apply to 105 CMR 164.000, unless an alternative interpretation is specifically provided:

24-hour Diversionary Withdrawal Management Service. 24-hour substance use disorder treatment services provided in freestanding or hospital-based settings with 24-hour, seven-day per week nursing and medical supervision that include withdrawal symptom management as part of medically supervised withdrawal and/or induction onto maintenance treatment.

Accreditation. The process of evaluation and approval by an accrediting body.

Accreditation Survey. An on-site review and evaluation of a substance use disorder treatment program by an accrediting body.

Accrediting Body. An independent, not-for-profit organization or governmental entity that has been approved by the Commissioner to accredit substance use disorder treatment programs.

Acupuncture Withdrawal Treatment Services. A treatment program providing acupuncture services for individuals experiencing the dysfunctional effects of the use of alcohol and/or other drugs, whose primary need is to manage withdrawal symptoms, and thereafter, support services for maintenance of sobriety.

Acupuncturist. An individual licensed by the Board of Registration in Medicine in accordance with M.G.L. c. 112, §§ 150 through 156.

Administrator. The Executive Director, Program Director or other individual responsible for the day-to-day operations of a facility or program.

Adolescent. A child 13 through 17 years of age.

Advanced Practice Registered Nurse. An individual licensed by the Massachusetts Board of Registration in Nursing in accordance with M.G.L. c. 112, § 80B.

Advertisement. In accordance with Consumer Protection regulations 940 CMR 6.00: *Retail Advertising* (including the terms Advertise and Advertising), any oral, written, graphic, or pictorial representation made by a Licensed or Approved Provider in the course of the solicitation of consumers of services or which encourages a person to utilize services. Advertisement includes any representation made in any media including digital or electronic media, newspaper, magazine, or other publication or on radio or television or contained in any notice, handbill, sign, billboard, banner, poster, display, circular, pamphlet, catalog, or letter, or printed on or contained in any tag or label, which is attached to or accompanies any product offered for sale. Advertisement includes any representation disseminated within Massachusetts if the advertisement is directed to consumers in Massachusetts.

164.005: continued

Aftercare Coordinator. An individual responsible for identifying appropriate continuing care and post discharge services and resources while working to ensure a smooth transition to the next phase in the adolescent's or transition age youth's recovery plan.

Alcohol and Drug-free Housing or ADF Housing. A form of group housing, also known as a sober home or recovery residence, that provides an environment free from alcohol and drugs for individuals recovering from a substance use disorder who, as a condition of occupancy, agree not to use alcohol or other substances. ADF housing does not include a halfway house, residential rehabilitation unit, treatment unit, withdrawal management facility, or other facility licensed by the Department under 105 CMR 164.000.

American Psychiatric Association. A professional organization of psychiatrists which defines and codifies psychiatric conditions for purposes of diagnosis.

American Society of Addiction Medicine or ASAM. A medical society of physicians engaged in addiction treatment, education, research and program improvement.

Applicant. Anyone requesting or renewing a license or approval from the Department to operate a substance use disorder treatment program.

Application. Any application for initial or renewal licensure, approval, amendment or closure.

Approval. A certification, in writing, whether full or provisional, issued by the Department to a provider to operate within a facility or program licensed by the Department, or to a department, agency or institution of the Commonwealth or subdivision thereof, or to a penal facility, which authorizes it to operate a program subject to 105 CMR 164.000.

Approved Provider. Any entity holding an approval from the Department to operate a substance use disorder treatment program.

Audit. A professional independent review, examination and verification of financial and accounting records and supporting documents by a professional, such as a Certified Public Accountant, to verify their accuracy and render an opinion as to their fairness, consistency, and conformity with Generally Accepted Accounting Principles (GAAP) and to recommend necessary changes in controls, policies, or procedures.

Bureau. The Bureau of Substance Addiction Services of the Department of Public Health, including its staff.

Business Day. A day on which the offices of the Commonwealth are open for regular business.

Case Aide. An individual responsible for daily management within a 24-hour structured Substance Use Disorder treatment program.

Case Manager or Core Coordinator. An individual responsible for assisting patients or residents to obtain needed services by providing information, referral coordination and follow-up.

Case Record. A unified, comprehensive collection of documentation concerning a patient or resident in a substance use disorder treatment program.

Central Registry System. A centralized database for the collection and maintenance of records for the purposes of preventing multiple concurrent enrollments, ensuring accurate dosage delivery, and facilitating disaster management in Opioid Treatment Programs licensed in Massachusetts.

Certified Alcohol and Drug-free Housing. ADF housing provided by persons or entities trained and certified by a certifying body.

164.005: continued

Chain of Custody. A process of monitoring possession of samples, such as saliva, urine or blood, to prevent tampering with the sample or the results. Chain of custody begins with collection of the sample, and continues through final reporting of test results.

Child. Any person younger than 18 years old.

Children's Services Assistant. A person with, at minimum, an Associate in Arts or equivalent education and training in child development, child psychology, and childhood education and at least three years of experience working with families and children, substance use and mental health disorders who works under the supervision of the Child Service Coordinator and assists in developing the children's part of the service plan, overseeing the children's activities, parenting classes, and educational needs of the children.

Children's Services Coordinator. A person with, at minimum, a Bachelor's degree in Early Childhood Education, Special Education, Psychology, or a related field, or a Bachelor's degree in an unrelated field with four courses or 12 credits in Early Childhood Education, Special Education, Psychology, or a related field who has experience or knowledge of parent-child dyadic work.

Clinical Supervision. A regular and specified time set aside to provide training, education and guidance to direct care staff and to oversee the provision of patient and resident services. Supervision must be delivered by a staff member qualified to deliver supervision, preferably in the discipline of the supervisee; must be sufficient to meet the needs of supervised staff, patients, and residents; and may be provided on an individual or group basis.

Clinician. An individual with a minimum of:

- (1) a master's degree in one of the following disciplines or a closely related field: clinical psychology, education-counseling, medicine, psychology, psychiatric nursing, rehabilitative counseling, social work, and who has a minimum of one year of supervised substance use disorder counseling experience; or
- (2) a bachelor's degree in any of the listed disciplines and a minimum of two years of supervised substance use disorder counseling experience; or
- (3) a recognized certification or licensure including 4,000 hours of clinically supervised counseling of individuals with substance use disorders including at least 220 documented hours of supervision.

Commissioner. Commissioner of Massachusetts Department of Public Health or his or her designee.

Commonwealth. Every executive office, department, board, commission, division or authority of the Massachusetts state government or political sub-division of any of the foregoing.

Consultation. The presentation of specific patient cases to clinicians of equal or greater expertise for the purpose of feedback, direction and guidance.

Continuum of Care. A principle of substance use disorder treatment that includes a range of substance use disorder treatment services based on six dimensions established by the American Society of Addiction Medicine: alcohol intoxication/withdrawal potential; biomedical conditions and complications; emotional/behavioral conditions and complications; treatment acceptance/ resistance; relapse continued use potential; and recovery environment.

Co-occurring Disorders. Diagnosis of both a substance use disorder and one or more mental health disorders in one individual.

Co-occurring Enhanced. A program provided in a 24-hour, safe, structured environment, located in the community, which supports residents' recovery from addiction and moderate to severe mental health conditions as they reintegrate into the community and return to social, vocation/employment, and/or educational roles.

164.005: continued

Counselor. An individual who has a minimum of a high school diploma or equivalent and a minimum of one year supervised counseling experience in substance use disorder treatment or a closely related field.

Day Treatment. An intensive outpatient program providing direct patient services through group, individual, and family substance use disorder counseling a minimum of 3.5 hours per day three to seven days per week based upon patient needs.

Deemed Status. The acceptance by the Department of accreditation as evidence of compliance with one or more requirements of 105 CMR 164.000.

Department. The Massachusetts Department of Public Health.

Direct Care Staff. Personnel who provide direct individual, group, educational, clinical or case management services to patients or residents of substance use disorder treatment programs.

Disability. A physical or mental impairment that substantially limits one or more of the major life activities of an individual; a record of such an impairment; or being regarded as having such an impairment (28 CFR § 35.104, and M.G.L. c. 151B, § 1).

Educational Coordinator. An individual responsible for coordinating the educational progress of adolescents or transition age youth during treatment, who acts as a liaison between school districts or placements and the adolescents or transition age youth residents of residential treatment program, to ensure the residents are receiving and completing work and who support the residents in completing this educational work while at the residential treatment program.

Emergency. A sudden, calamitous event that seriously disrupts the functioning of a community or society and causes human, material, and economic or environmental losses that exceed the community's or society's ability to cope using its own resources.

Executive Director. The individual duly appointed by the governing body of the Licensed or Approved Provider, who is responsible for the overall operations of the Licensed or Approved Provider providing substance use disorder treatment services.

Facility. A substance use disorder intervention or treatment provider that is publicly or privately owned, for-profit or not-for-profit which is not part of or located at a penal institution and which is not operated by the federal government.

Family Therapist. An individual licensed by the Massachusetts Board of Registration of Allied Mental Health Professions in accordance with M.G.L. c. 112, § 165.

First Offender Driver Alcohol or Controlled Substance Education Services. An outpatient program providing psycho-educational and counseling interventions for individuals adjudicated by a court as first offenders of laws prohibiting driving under the influence of intoxicating liquor or controlled substances.

Food Service Personnel. Staff who prepare and serve meals, oversee food storage, and are responsible for sanitary care of food preparation and serving equipment.

Full-time Equivalent or FTE. A minimum of 35 hours per week per each staff position.

Induction. The process of initial dosing with medication for OUD treatment, until the patient reaches a state of stability; also called initiation.

Intensive 24-hour Diversionary Withdrawal Management. 24-hour substance use disorder treatment services provided in hospital-based settings that include daily medical management and primary nursing interventions with 24-hour, seven-day per week nursing and medical supervision that include withdrawal symptom management as part of medically supervised withdrawal and/or induction onto maintenance treatment.

164.005: continued

Interim Maintenance Treatment. Maintenance treatment provided in an opioid treatment program in conjunction with appropriate medical services while a patient is awaiting transfer to a program that provides comprehensive maintenance treatment.

License. Authorization, in writing, issued by the Department upon its determination that the applicant is responsible and suitable to operate a substance use disorder treatment program.

Licensed Alcohol and Drug Counselor (LADC). An individual who has applied for and has been deemed qualified under applicable sections of 105 CMR 168.000: *Licensure of Alcohol and Drug Counselors* and duly licensed by the Department to provide treatment for individuals with a substance use disorder as a Licensed Alcohol Drug Counselor I (LADC I), Licensed Alcohol Drug Counselor II (LADC II) or Licensed Alcohol Drug Counselor (LADC) Assistant.

Licensed Practical Nurse. An individual licensed by Massachusetts Board of Registration in Nursing in accordance with M.G.L. c. 112, § 74A.

Licensed Provider. Any entity, including its controlling parent (corporation) holding a license from the Department to operate a substance use disorder treatment program. In the case of a Licensed Provider which is not a natural person, the term Licensed Provider shall also mean any shareholder owning 5% or more of the outstanding stock; any limited partner owning 5% or more of the partnership interests and any general partner of a partnership Licensed Provider; any trustee of any trust Licensed Provider; any receiver or trustee in bankruptcy; any manager of a Limited Liability Company and any member of a Limited Liability Company with a 5% or more membership interest; any sole proprietor of any Licensed Provider which is a sole proprietorship; any mortgagee in possession; and any executor or administrator of any Licensed Provider which is an estate.

Limited Liability Company. An unincorporated organization formed under M.G.L. c. 156C.

Maintenance Treatment. Providing medications to achieve and sustain clinical remission of signs and symptoms of substance use disorder including, but not limited to, opioid use disorder, and support the individual process of recovery without a specific endpoint.

Massachusetts Prescription Awareness Tool (MassPAT). The online prescription monitoring program database created pursuant to M.G.L. c. 94C, § 24A.

Medical Clearance. Determination by the Provider's physician, nurse practitioner, physician assistant, registered nurse, or a licensed practical nurse duly licensed/certified in the Commonwealth of Massachusetts that treatment by the Provider is appropriate based upon an individual's condition, and that the individual is not exhibiting withdrawal or other medical symptoms that would require a higher level of care.

Medical Director. A physician licensed to practice medicine in the Commonwealth of Massachusetts, with specialized training in addiction medicine, who assumes responsibility for administering all medical services performed by the program, either by performing them directly or by delegating specific responsibility to authorized program physicians and qualified healthcare professionals functioning under the medical director's direct supervision.

Medically Supervised Withdrawal. Dispensing, administering, or prescribing of an FDA-approved medication for the treatment of substance use disorder including, but not limited to, opioid use disorder, in gradually decreasing doses to alleviate adverse physical or psychological effects incident to withdrawal from the continuous or sustained use of opioid drugs. The purpose of medically supervised withdrawal is to bring a patient maintained on maintenance medication to a medication-free state within a target period.

Medication for Addiction Treatment. Use of a medication approved by the federal Food and Drug Administration (FDA) for the treatment of a substance use disorder.

Medication for Treatment of Opioid Use Disorder. Use of a medication approved by the FDA for the treatment of an opioid use disorder.

164.005: continued

Medication Unit. A component of an OTP that is geographically separate from a brick-and-mortar OTP. As such, a medication unit engages in the treatment of opioid use disorder, including maintenance and/or detoxification treatment with narcotic drugs in Schedules II-V, at a location or locations remote from, but within the State as, the licensed, certified, and registered OTP, and operates under the licensure and certification of the Brick-and-Mortar OTP.

Mental and Behavioral Disorders Due to Psychoactive Substance Use. The variety of disorders defined by the World Health Organization which are attributable to the use of one or more psychoactive and/or addictive substances.

Mental Health. Any condition pertaining to mental health as defined by the current edition of the Diagnostic and Statistical Manual of Mental Disorders.

Mental Health Service. A separate, identifiable service providing diagnosis and treatment to individuals seeking treatment for mental health conditions, which may integrate treatment for co-occurring substance use disorder, and their families.

Mobile Opioid Treatment Program (Mobile OTP). An OTP operating from a motor vehicle that serves as a mobile component of the brick-and-mortar OTP. As such, a mobile OTP engages in the treatment of opioid use disorder, including maintenance and/or detoxification treatment with narcotic drugs in Schedules II-V, at a location or locations remote from, but within Massachusetts as, the licensed, certified, and registered OTP, and operates under the licensure, certification, and registration of the OTP. The Mobile OTP is described in DEA regulation 21 CFR Part 1300.

Office Based Addiction Treatment (OBAT). A type of outpatient service not subject to 105 CMR 164.000 providing medication for addiction that is provided outside of licensed or approved SUD treatment programs by appropriately licensed clinicians to patients with addiction. Includes, but is not limited to, MAT in a primary care office, MAT in a hospital clinic setting, and office based opioid treatment serving under 300 patients.

Office Based Opioid Treatment (OBOT). A type of Office Based Addiction Treatment provided by a corporate entity, other than a hospital or clinic licensed under M.G.L. c. 111, § 51, or an opioid treatment program licensed under M.G.L. c. 111E, doing business in the Commonwealth, which has more than 300 patients receiving treatment for treatment of opioid dependence with an FDA-approved narcotic medication used for withdrawal management or maintenance by a qualified health care professional who is registered with the U.S. Department of Justice Drug Enforcement Agency, as required by 21 U.S.C. § 823(g) (known as DATA 2000), in a health care professional's office setting or in a primary care center, and is associated with the corporate entity by contract, fee for service, or other arrangement other than as members of the practice.

Opioid Treatment Program (OTP). A SAMHSA-certified program, usually comprised of a facility, staff, administration, patients, and services, that engages in supervised assessment and treatment, using approved medications, of individuals who are addicted to opioids.

Original License. A license, including a provisional license, issued to a facility not previously licensed; or a license issued to an existing facility, in which there has been a change in ownership or location.

Outpatient Counseling. An outpatient substance use disorder treatment service designed to help patients achieve changes in alcohol and/or drug use and addictive behaviors and often address issues that have the potential to undermine the patient's ability to cope with life tasks without the addictive use of alcohol, other drugs, or both. Outpatient counseling services may offer several therapies and service components, including individual and group counseling, motivational enhancement, family therapy, educational groups, occupational and recreational therapy, psychotherapy, MAT, or other skilled treatment services.

164.005: continued

Outpatient Withdrawal Treatment Service. A program of ambulatory substance use disorder treatment that provides clinical management of withdrawal symptoms through medical, ancillary treatment, treatment with FDA-approved medications for the treatment of addiction, and may include counseling.

Patient. A person applying for admission or admitted to a program providing acute or ambulatory substance use disorder services.

Penal Facility. An institution, or any part thereof, other than an institution, or any part thereof operated by the federal government, for the detention or confinement of persons accused or convicted of crime including, but not limited to, jails, prisons, houses of correction and correctional institutions, providing services especially designed for the treatment of drug dependent persons.

Pharmacist. An individual registered by the Massachusetts Board of Registration in Pharmacy in accordance with M.G.L. c. 112, § 24.

Physician. An individual licensed by the Massachusetts Board of Registration in Medicine in accordance with M.G.L. c. 112, § 2.

Physician Assistant. An individual who is registered by the Board of Registration of Physician Assistants in accordance with M.G.L. c. 112, § 9I.

Practitioner. A Physician, Physician Assistant, or Advanced Practice Registered Nurse as those terms are defined in 105 CMR 164.005, acting within applicable scope of service and pursuant to state and federal law.

Program. A substance use disorder treatment program.

Program Director. The individual employed by the Licensed or Approved Provider who is responsible for the administrative and programmatic day-to-day operations of a program of substance use disorder treatment services and may provide supervision of all non-clinical staff.

Program Sponsor. The person responsible for the operation of an opioid treatment program.

Provider. A substance use disorder treatment program, including units within a facility or program licensed by the Department of Mental Health or the Department, located within a penal facility, or operated by a department, agency or institution of the Commonwealth or subdivision thereof.

Provisional License. A license or approval granted by the Department to an applicant for a period not to exceed six months, in accordance with provisions of 105 CMR 164.011(F).

Psychiatrist. A physician licensed by the Massachusetts Board of Registration in Medicine and certified by the American Board of Psychiatry and Neurology or an equivalent body.

Psychologist. An individual licensed by the Massachusetts Board of Registration of Psychologists in accordance with M.G.L. c. 112, §§ 118 through 121.

Qualified Health Care Professional. A Practitioner, Registered Nurse, or Licensed Practical Nurse trained to do physical assessments, duly licensed, certified or registered as such in the Commonwealth of Massachusetts, and practicing within the scope of applicable Massachusetts and federal regulations.

Qualified Service Organization. An individual, partnership, corporation, federal, state or local government agency, or any other legal entity, which:

- (1) provides services to a Licensed or Approved Provider; and
- (2) has entered into a written agreement with the Licensed or Approved Provider.

164.005: continued

Qualified Service Organization Agreement (QSOA). A signed and dated document describing the agreed upon terms of a service relationship between the Licensed or Approved Provider and the qualified service organization, which meets the requirements of 42 CFR Part 2.

Recovery Home. A residential rehabilitation program that conforms to ASAM criteria for Medium-intensity Residential Services.

Recovery Specialist. A staff person who completes the orientation requirements pursuant to 105 CMR 164.044(B)(1) and population-specific addiction treatment training requirements pursuant to 105 CMR 164.004(B)(2)(f) to provide guidance and direction to residents or patients, and oversees resident or patient activities to ensure conformance with program policies.

Referral. A process through which a Licensed or Approved Provider directly refers a patient or resident for treatment or placement in a substance use disorder treatment program or other provider type upon securing the patient's or resident's treatment or placement in such a program or other provider type.

Registered Nurse. An individual licensed by the Massachusetts Board of Registration in Nursing in accordance with M.G.L. c. 112, § 74.

Resident. A person applying for admission or admitted to a Residential Rehabilitation program providing substance use disorder services.

Residential Rehabilitation. A Licensed or Approved Provider that provides a therapeutic, planned regimen of substance addiction treatment and education services for persons in the early stages of recovery from addiction who require safe and stable living environments in order to develop recovery skills. Services are provided in a 24-hour live-in setting, with 24-hour per day staffing.

Satellite Office. An office operating at a site physically separate from the main premises of a Licensed or Approved Provider that provides outpatient substance use disorder treatment services. A satellite office must be open to patients at least 20 hours per week and must offer a minimum of 40 staff hours a week of substance use disorder treatment services.

Second Offender Aftercare. An educational and treatment program of a licensed outpatient facility for individuals who have been convicted of a second Driving While Under the Influence offense and who have completed, or are awaiting placement in, a 14-day Driving Under the Influence (DUI) second offender residential program.

Senior Clinician. An individual who is a LADC I, or other independently licensed individual who has at least a master's degree in one of the following disciplines or a closely related field: clinical psychology, education-counseling, medicine, mental health, psychology, psychiatric nursing, rehabilitative counseling, social work; and two years of supervised substance use disorder counseling experience; and at least one year full time equivalent year of clinical supervisory experience.

- (1) Prior to January 1, 2026, Senior Clinicians may include an individual who possesses at least a master's degree in one of the following disciplines or a closely related field: clinical psychology, education-counseling, medicine, mental health, psychology, psychiatric nursing, rehabilitative counseling, social work; and two years of supervised substance use disorder counseling experience; at least one year full time equivalent year of clinical supervisory experience; and has acted as Senior Clinician for more than two years.
- (2) This role may also be known as the Clinical Director or the Clinical Supervisor.

Social Model Recovery Home. A Residential Rehabilitation program that conforms to the ASAM criteria for Low Intensity Residential Services.

State Opioid Treatment Authority (SOTA). Personnel of the Bureau authorized to approve requests for exceptions to limitations on take-home doses of methadone, and to review hearing decisions to terminate a patient from an opioid treatment program.

164.005: continued

Substance Use Education Program. An education program within a penal facility which focuses on reducing risk to recidivate and may include information about substance use prevention, misuse and addiction. Individuals enrolled in a Substance Use Education Program may simultaneously be enrolled in a Substance Use Disorder Treatment Program and/or receive individual medical treatment from a licensed provider for Substance Use Disorder management or treatment. Substance use education programs are not intended to provide treatment directly and therefore are not subject to licensure under 105 CMR 160.000.

Substance Use Disorder Treatment. An evidence based practice intended to assess status, reduce symptoms, or mitigate the effects of substance misuse, substance use disorders, that may also treat co-occurring disorders; reduce risk of relapse and associated harm; or restore or establish well-being for individuals and families; provided, that said practice shall include, but not be limited to, care coordination, case management, medical, pharmacological, psychological, psycho-educational, rehabilitative, or social services and therapies.

Substance Use Disorder Treatment License for Department of Mental Health Licensed Facility. Authorization, in writing, issued by the Department upon its determination that a mental health facility licensed by the Department of Mental Health (DMH) under M.G.L. c. 19, § 19, meets applicable requirements of 105 CMR 164.000 to ensure the safety and adequacy of the substance use disorder treatment program.

Substance Use Disorder Treatment Program. An organized system of services containing a mission, philosophy and model of substance use disorder treatment designed to address the needs of patients or residents.

Substance Use Disorder. Any condition pertaining to substance use disorder as defined by the current edition of the Diagnostic and Statistical Manual of Mental Disorders.

Supervision. A regular and specified time set aside to provide non-clinical training, education and guidance to staff. Supervision must be sufficient to meet the needs of supervised staff, patients, and residents, and may be provided on an individual or group basis.

Therapeutic Community. A Residential Rehabilitation program that conforms to ASAM criteria for High-intensity Residential Services.

Tobacco Free. An environment free of tobacco use, including e-cigarettes and the use of smokeless tobacco, such as snuff and chewing tobacco.

Training. Educational programs, workshops and other structured opportunities for staff aimed at improving skill, knowledge and service provision.

Transfer of Ownership shall include, but not be limited to, the following:

- (1) a transfer of a majority interest in the ownership of the substance use disorder treatment program;
- (2) in the case of a for profit corporation, transfer of a majority of any class of the stock thereof;
- (3) in the case of a partnership, transfer of a majority of the partnership interest;
- (4) in the case of a trust, change of the trustee or a majority of trustees;
- (5) in the case of a not-for profit corporation, such changes in the corporate membership and/or trustees as the Department determines to constitute a shift in control of the operation of the Licensed or Approved Provider; or
- (6) where foreclosure proceedings have been instituted by a mortgagee in possession.

Transfer of Ownership also means any change in the ownership interest or structure of a substance use disorder treatment program or the program's parent corporation(s) that the Commissioner determines to effect a change in control of the operation of the substance use disorder treatment program. The Commissioner may, in his or her discretion, determine a proposed transaction does not rise to the level of a transfer of ownership.

Transition Age Youth. A young person 16 through 25 years of age.

164.005: continued

Transitional Support Service. A short-term Residential Rehabilitation program.

Viral Hepatitis. For purposes of 105 CMR 164.000, viral hepatitis refers to Hepatitis A, Hepatitis B and Hepatitis C.

Withdrawal Symptom Management. The process of initial dosing with FDA-approved medication for the treatment of addiction including, but not limited to, opioid use disorder, until the patient reaches a state of stability. Withdrawal Symptom Management may also be referred to as induction.

World Health Organization. An agency of the United Nations which directs and coordinates UN authority on international public health, and which compiles classifications of diseases and disorders.

Written Notice.

- (1) a letter sent by registered or certified mail; or
- (2) a written statement, receipt of which is documented by dated signature of both the individual sending and the individual receiving the notice. The period of time stated in the written notice shall be calculated beginning on the first business day following receipt of written notice.

PART ONE: LICENSING AND APPROVAL PROCEDURES AND REQUIREMENTS

164.006: Part One Scope

The provisions of 105 CMR 164.006 through 105 CMR 164.087 apply to all substance use disorder treatment providers, except for those providers who currently hold a license from the Department of Mental Health or the Department of Public Health's Bureau of Health Care Safety and Quality, or those providers who are part of a facility or program operated by an agency of the Commonwealth (*See Part Three: Department of Mental Health Licensees, Bureau of Health Care Safety and Quality Licensees, and Agencies of the Commonwealth*).

164.007: Application Requirements for Licensure or Approval

No person or entity may operate a separate identifiable substance use disorder treatment program or hold themselves out or advertise as operating as a substance use disorder treatment program without a License or Approval from the Department.

Whoever knowingly operates such a program without obtaining a License or Approval may be subject to penalties up to a fine of \$500.00 for the first offense and up to \$1,000.00 for each subsequent offense or by imprisonment for not more than two years or both.

(A) Applications for licensure or approval shall be made in a form prescribed by the Department and include all supporting documents required by 105 CMR 164.000.

(B) An application for an original License or Approval shall not be approved until an applicant has been deemed suitable by the Department.

(C) An application for an original License or Approval shall include a sworn statement of the names and addresses of any person with an ownership or control interest in the facility or in the real property upon which the facility is located. For the purposes of 105 CMR 164.000, "person with an ownership or control interest" shall mean a person who:

- (1) has a direct or indirect ownership interest of 5% or more in the facility or the organization that holds the license;
- (2) is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the facility or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5% of the total property and assets of the facility or organization that holds the license;
- (3) is an officer or director of a corporate licensee;
- (4) is a partner of a licensee organized as a partnership; or
- (5) is the Trustee of a Trust.

164.008: Application Submission

- (A) Applications for licensure or approval shall be made in a format prescribed by the Department, together with the required fee and any other documents and materials required by 105 CMR 164.000 or that the Department deems appropriate.
- (B) A nonrefundable fee shall accompany each application and shall be as follows:
- (1) For each license application, excluding satellite offices and medication units, \$300;
 - (2) For each satellite office or medication unit, \$75.00.
 - (3) Licensed Providers seeking to add a service, satellite office or medication unit to an existing license shall submit documentation as required by the Department and an application fee of \$75 for each service, satellite office or medication unit.
 - (4) No fee shall be required when the applicant is the Commonwealth.
- (C) Applicants for renewal must submit to the Department completed forms and fees required by the Department at least 60 calendar days prior to the expiration of the current License or Approval. An application for renewal, if timely filed with the required fee, shall have the effect of a License or Approval from the date of License or Approval expiration until such time as the Department takes action on the application. If not timely filed, such an application will not have such effect and the License or Approval shall lapse.

164.009: Evaluation of Application and Suitability of Applicant or Licensed or Approved Provider

- (A) Upon receipt of a complete application the Department shall evaluate the suitability of the applicant or Licensed or Approved Provider including, but not limited to, the following factors. A negative determination with respect to any one of the factors constitutes an adequate ground for deeming an applicant or Licensed or Approved Provider unsuitable to establish or maintain a substance use disorder treatment program and upon which the Department may deny an initial or renewal application for a License or Approval.
- (1) Past performance as a provider of substance use disorder treatment services, based upon documentation of applicant's or Licensed or Approved Provider's:
 - (a) history of compliance with 105 CMR 164.000;
 - (b) history of providing substance use disorder treatment services or other health care services, including provision of services in other states;
 - (c) ability to provide substance use disorder treatment services;
 - (d) history of response to correction orders issued under 105 CMR 164.016;
 - (e) history of failure to provide services to any individual when licensed or approved to provide such services; and
 - (f) history of patient or resident abuse, mistreatment or neglect in any licensed health care program or facility.
 - (2) Whether the applicant's or Licensed or Approved Provider's financial resources are sufficient to provide substance use disorder treatment services for which the applicant seeks a license.
 - (3) Whether the Licensed or Approved Provider or applicant is in compliance with all laws of the Commonwealth including, but not limited to, laws relating to taxes and child support and whether the applicant has workers compensation and professional and commercial insurance coverage.
 - (4) The record of compliance for health care facilities in the Commonwealth or other jurisdictions, including any limitation on, suspension or revocation of, or refusal to grant or renew a health care license or certification for Medicaid or Medicare to the applicant or Licensed or Approved Provider.
 - (5) The adequacy of the applicant's or Licensed or Approved Provider's legal capacity to operate, as demonstrated by such documents as articles of incorporation and corporate by-laws.
 - (6) Any attempt to obtain a License or Approval by fraud, misrepresentation, or the submission of false information.
 - (7) Whether a new applicant can demonstrate the capacity to meet the requirements for licensing or approval as a substance use disorder treatment program.
 - (8) Whether the applicant is able to provide services to residents of the Commonwealth with public health insurance on a nondiscriminatory basis and able to report the facility's payer mix to the Department on a quarterly basis.

164.009: continued

- (9) Whether the applicant can demonstrate need for the services in accordance with 105 CMR 164.011(A).
- (10) Such other information as the Department may require.

(B) The application shall also include an attestation from the applicant confirming that any substance use disorder treatment program subject to licensure or approval under 105 CMR 164.000 operated by said applicant will:

- (1) Provide services on a nondiscriminatory basis to residents of the Commonwealth with public health insurance and report the substance use disorder treatment program's payer mix to the Department in a format prescribed by the Department on a quarterly basis, as required by M.G.L. c. 111E, § 7;
- (2) Provide medications for treatment of addiction, including all FDA-approved medications for addiction treatment, directly or through a QSOA;
- (3) Provide overdose prevention education as part of evidence-based practices; and
- (4) Provide data and other information as requested by the Department pursuant to 105 CMR 164.022.

164.010: Inspections

(A) The Department or its agents may visit at any time without prior notice and inspect the facility, its staff, activities, and records to determine compliance with 105 CMR 164.000 and applicable state and federal laws.

(B) Applicants and Licensed or Approved Providers shall provide Department inspectors with access to:

- (1) The entire physical plant, including those portions open to patients or residents and staff and those open only to staff; and
- (2) All information including, but not limited to: records, and documentation related to the provision of substance use disorder treatment services, and to the operation of the program, including personnel records and documents relating to the licensed legal entity. All such records and documentation shall be in English, legible, and current to within five business days of the most recent provision of service.

(C) Refusal to allow entry to Department inspectors shall constitute grounds to seek a warrant in district or superior court to authorize entry.

164.011: Issuance of Licenses and Approvals

(A) In accordance with M.G.L. c. 111E, § 7, the Department shall not approve an application for an original License unless the applicant can demonstrate need for the substance use disorder treatment program based upon the following factors:

- (1) The health needs of drug dependent persons and persons with alcohol use disorder, as defined in M.G.L. c. 111B, § 3, in the Commonwealth, including underserved populations and persons with co-occurring mental health conditions and substance use disorder; and
- (2) The demonstrated ability and history of a prospective Licensed or Approved Provider to meet the needs of such persons.

(B) In making this determination, the Department shall take into consideration the following factors:

- (1) Geographic access to the continuum of care;
- (2) Access to a balanced continuum of care in terms of proportion of each service type;
- (3) Program size is conducive to the health, safety, and well-being of the client population being served; and
- (4) Health disparities are addressed through access to services for underserved populations and persons with co-occurring mental health conditions and substance use disorder and the demonstrated ability and history to meet the needs of such populations.

(C) Providers who contract with the Department shall be deemed to have satisfied the requirements of 105 CMR 164.011(A) through (B).

164.011: continued

(D) The Department must determine the applicant suitable to establish or maintain the service in accordance with 105 CMR 164.009 prior to issuing a License or Approval.

(E) Upon satisfactory submission of an application and completion of an inspection(s), the Department may grant a license, approval, or renewal for a term of six months or two years. Every License and Approval shall state the name and address of the program if either differs from that of the Licensed or Approved Provider or approved entity; the period of Licensure or Approval; the specific service(s) that the program is Licensed or Approved to deliver; number of beds Licensed or Approved; and the name and address of any satellite location(s).

(F) Provisional Licenses and Approvals.

(1) When the Department finds that an applicant for an initial or renewal License or Approval has not complied with all applicable regulations, but is in substantial compliance and has submitted, within 90 days of notice of noncompliance from the Department, an acceptable plan for bringing the facility into full compliance with specific dates included, the Department may issue a Provisional License or Approval, provided that:

- (a) The applicant demonstrates to the Department's satisfaction a good faith intent to meet all the requirements;
- (b) The Department finds that the service offered protects or will protect the health, safety, and well-being of the facility's patients or residents; and
- (c) The Department finds that the applicant evidences the potential for full compliance within a reasonable period of time, not to exceed six months.

(2) A Provisional License or Approval is valid for a period not to exceed six months and may be renewed once for no more than six months.

(G) No License or Approval may be transferred or assigned to any other provider or location.

164.012: Posting of a License or Approval

Each Licensed or Approved Provider shall post the current License or Approval issued by the Department in a conspicuous public place at each service location.

164.013: Transfer of Ownership

(A) Circumvention. A transfer of ownership shall not be recognized and the new owner shall not be considered suitable for licensure when the Transfer of Ownership is proposed or made to circumvent the effect and purpose of 105 CMR 164.000. The Department shall consider the following factors in determining whether a Transfer of Ownership has been proposed or made to circumvent 105 CMR 164.000:

- (1) The transferor's record of compliance with Department licensure laws and regulations;
- (2) The transferor's current licensure status;
- (3) The transferor's familial, business or financial relation to the transferee; and
- (4) The terms of the transfer.

(B) Suitability. At least 90 calendar days in advance of any transfer of ownership, any applicant who intends to acquire a substance use disorder treatment program shall submit a Notice of Intent to the Department on a form supplied by it. The Department shall notify each applicant in writing of the date on which the form is deemed completed. Within 90 calendar days of such date, the Department shall complete its suitability review for licensure pursuant to the standards of 105 CMR 164.009. With the consent of the applicant, the Department may extend the 90-day suitability determination period for a maximum of 30 calendar days

(C) Application for Licensure. Upon a finding by the Department of suitability in accordance with 105 CMR 164.013(B), an applicant for licensure or approval as a result of any Transfer of Ownership shall file an application for licensure within two business days of the Transfer of Ownership, unless an extension of the two-business day period is granted by the Commissioner.

164.013: continued

(1) A License or Approval application filed as a result of a Transfer of Ownership, if timely filed, shall have the effect of a license or Approval from the date of transfer until such time as the Department takes action on the application. If not timely filed, an application will not have such effect and the License or Approval shall lapse.

(2) Any notice of hearing, order, or decision which the Department or Commissioner issues to a facility prior to a transfer of ownership shall be effective against the former owner prior to transfer and, where appropriate, the new owner following the transfer, unless the notice, order, or decision is modified or dismissed by the Department or the Commissioner.

164.014: Change of Location

(A) A Licensed or Approved Provider may not move the delivery of any services licensed pursuant to 105 CMR 164.000 to another location without receiving express prior approval by the Department for each proposed site.

(B) An application submitted by a Licensed or Approved Provider for a change in location must be filed with the Department at least 90 calendar days in advance in a manner prescribed by the Department and shall be subject to all requirements of initial licensure.

164.015: Change of Program Name

(A) A Licensed or Approved Provider may not change the name of any program licensed pursuant to 105 CMR 164.000 without receiving express prior approval by the Department.

(B) An application submitted by a Licensed or Approved Provider for a change in name must be filed with the Department at least 90 calendar days in advance in a manner prescribed by the Department and shall comply with all applicable provisions of 105 CMR 164.000.

164.016: Correction Orders

The Department shall prepare a written deficiency correction order for each violation of 105 CMR 164.000, M.G.L. c. 111E and M.G.L. c. 111B and send the deficiency correction order to the Licensed or Approved Provider of record. The deficiency correction order shall include a statement of the deficiencies found, the period within which the deficiency must be corrected, which shall not exceed 60 calendar days, except as provided for in 105 CMR 164.017(C), and the provision(s) of law and/or regulation relied upon.

164.017: Plan of Correction

(A) The Licensed or Approved Provider shall submit a plan of correction to address each deficiency within 14 calendar days, unless otherwise specified by the Department and, as provided in 105 CMR 164.017(B), shall remedy or correct each deficiency cited within 60 calendar days of receipt of the deficiency correction order. The Department may modify the plan of correction by providing notice to the Licensed or Approved Provider. The Licensed or Approved Provider may submit a written request for administrative reconsideration of the modified plan of correction, or any portion thereof, within seven calendar days of receipt of notice.

(B) The plan of correction shall set forth, with respect to each deficiency, the specific corrective step(s) to be taken, a timetable for each step, and the date by which full compliance will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible. The plan of correction shall be signed by either the Licensed or Approved Provider or his or her designee.

(C) Where, in the opinion of the Department, the deficiency is not capable of correction within 60 calendar days, the Licensed or Approved provider shall submit a written plan for correction of the deficiency in a reasonable manner within 14 calendar days of such determination by the Department. The plan of correction shall comply with 105 CMR 164.017(B). The Department may modify the plan of correction by providing notice to the Licensed or Approved Provider. The Licensed or Approved Provider may submit a written request for administrative reconsideration of the modified plan of correction, or any portion thereof, within seven calendar days of receipt of notice.

164.017: continued

(D) Fines. If a Licensed or Approved Provider fails to remedy or correct a cited deficiency by the date specified in the deficiency correction order or fails to remedy or correct a cited deficiency by the date specified in a plan of correction as accepted or modified by the Department, the Department may:

- (1) Suspend, limit, restrict or revoke the Provider's License or Approval;
- (2) Impose a civil fine upon the Licensed or Approved Provider not to exceed \$1,000 per deficiency for each day the deficiency continues to exist beyond the date prescribed for correction;
- (3) Pursue any other sanction as the Department may impose administratively upon the Licensed or Approved Provider; or
- (4) Impose any combination of the penalties set forth in 105 CMR 164.017(D)(1) through (3).

(E) Administrative Reconsideration of Civil Fines.

- (1) Request for Administrative Review. The Licensed or Approved Provider may submit a written request for administrative reconsideration within seven calendar days of receipt of notice of the fine on forms approved by the Department. The request for review must fully state and support the reasons why a waiver or reduction of a fine is warranted, including specific reference to all relevant factors under 105 CMR 164.000 and any and all supporting documentation.
- (2) The Department shall conduct an administrative review, based solely on the evidence presented within the written request and Department records, and shall issue a written decision. This decision shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A, § 14.
- (3) The failure to file an appeal requesting administrative review within seven calendar days of receipt of the notice constitutes a waiver of the right to request reconsideration and all fines set forth in the notice shall be imposed. The payment of a fine constitutes a waiver of the right to appeal.

164.018: Administrative Penalties

(A) Summary Suspension. The Department may summarily suspend a License or Approval prior to a hearing if:

- (1) In the opinion of the Department, the violation of rules, regulation, deficiency correction orders, or plans of correction jeopardizes the health, safety, and well-being of patients or the public or seriously limits the capacity of a facility to provide adequate care; or
- (2) Where the violation of such rules, regulation, deficiency correction orders, or plans of correction is the second or subsequent such violation occurring during a period of 12 months.

(B) The suspension shall remain in effect until the Department rescinds or amends such requirements or if the Department's decision is otherwise modified on appeal.

164.019: Grounds for Denial, Refusal to Renew, Restriction, Limitation, or Revocation of License or Approval

In addition to 105 CMR 164.017(E) and 164.018, each of the following, in and of itself, shall constitute full and adequate grounds to deny, revoke, limit, restrict, or refuse renewal of a License or Approval:

- (A) Failure to meet the applicable requirements for licensure or approval as specified in 105 CMR 164.000.
- (B) Failure to meet the requirements of applicable federal or state law or regulations.
- (C) Violating any applicable requirement of 105 CMR 164.000.
- (D) Failure to give proper care to patients or residents.
- (E) Denying entry to agents of the Department or attempting to impede the work of a duly authorized representative of the Department.

164.019: continued

(F) Knowingly making an omission of material information or providing false or misleading statements orally or in writing to the Department.

(G) Operating the facility without a required License or Approval or after the expiration of a License or Approval where the applicant or Licensed or Approved Provider has not timely submitted an application for renewal.

(H) There is a reasonable basis for the Department to conclude that there is a discrepancy between the representations by a facility as to the treatment services to be afforded patients and the treatment services actually rendered or to be rendered.

(I) Conviction of an applicant or Licensed or Approved Provider, or a person with ownership or control interest in the program, of Medicare or Medicaid fraud or other criminal offense related to operating the program.

(J) Conviction of an applicant or Licensed or Approved Provider, or a person with ownership or control interest in the program, of a violent crime against a person, which indicates that operation of the program may endanger the public health or safety.

164.020: Hearings

(A) If the Department refuses to renew, suspends, restricts, limits, or revokes licensure or approval, the Department shall notify the applicant in writing of the following:

- (1) the intended action;
- (2) the reason(s) and ground(s) for the action; and
- (3) the aggrieved provider's right to file a written request for an adjudicatory hearing in accordance with M.G.L. c. 30A and the Standard Adjudicatory Rules and Practice and Procedure, 801 CMR 1.01: *Formal Rules*.

(B) The aggrieved provider may request a hearing on the Department's decision. A written request for a hearing shall be submitted within 14 calendar days of receipt of the notice. Upon receipt of an aggrieved provider's request for a hearing, the Department shall provide an opportunity for a hearing in accordance with M.G.L. c. 30A, and 801 CMR 1.01: *Formal Rules*.

164.021: Commissioner and Judicial Review

(A) The Commissioner shall review the recommended decision of the hearing officer in any adjudicatory proceeding conducted pursuant to 801 CMR 1.01: *Formal Rules*. The decision of the Commissioner shall constitute a final agency decision in an adjudicatory proceeding, and is subject to judicial review pursuant to M.G.L. c. 30A, § 14.

(B) An aggrieved provider or applicant that fails to exercise the right to an adjudicatory proceeding pursuant to 105 CMR 164.020 waives both the right to administrative review by the Commissioner and the right to judicial review pursuant to M.G.L. c. 30A, § 14.

164.022: Providing Information to the Department

(A) Each Licensed or Approved Provider shall timely submit management information data in a manner prescribed by the Department including, but not limited to, admissions, discharges, patient or resident characteristics, services and outcomes, and staff patterns and characteristics. It shall also submit to the Department such data, statistics, schedules, or information as the Department may require for the purposes of licensing and/or monitoring and evaluating a service as well as data required to meet federal reporting requirements including, but not limited to, outcome data.

(B) Each Licensed or Approved Provider is responsible for requesting patient or resident authorizations to ensure the timely submission of data to the Department.

(C) All information submitted pursuant to the requirements of 105 CMR 164.000 or otherwise required by the Department shall be kept current by each Licensed or Approved Provider.

164.023: Waivers

(A) The Department may, in its discretion, waive the applicability of one or more of the requirements of 105 CMR 164.000 as requested by a Licensed or Approved Provider, upon a written finding that:

- (1) compliance would cause undue hardship to the provider, as documented by the Licensed or Approved Provider in a manner defined by the Department;
- (2) the provider is in substantial compliance with the spirit of the requirement and has instituted compensating features that are acceptable to the Department;
- (3) the provider's noncompliance does not jeopardize the health, safety, or well-being of its patients or residents and does not limit the provider's capacity to provide the service; and
- (4) the provider provides to the Department written documentation supporting its request for a waiver.

(B) The Department may, in its discretion, rescind or impose a time limit on any waiver it grants.

164.030: Governance

(A) The Licensed or Approved Provider shall have a governing body which shall include members representative of the communities served. The Licensed or Approved Provider shall maintain updated articles of organization and by-laws, partnership, agreement or trust instrument, as appropriate. The documents shall specify the organizational structure of the governing body, and the methods of selecting its members. In addition, the Licensed or Approved Provider shall maintain updated lists of the names and addresses of the members of the governing body as well as minutes of all meetings of the governing body and its members.

(B) If the Licensed or Approved Provider's governing body is located outside of Massachusetts, the governing body shall establish an advisory board in Massachusetts comprised of Massachusetts residents representative of the community served.

(C) The Licensed or Approved Provider shall maintain, and make available to any employee, patient, or resident an organizational chart and written policy that describe the organizational structure including lines of authority, responsibility, communication, and staff assignment.

164.031: Accreditation

Licensed or Approved Providers who are subject to accreditation by any state, federal or national organization shall obtain and maintain their accreditation and shall provide documentation of the accreditation to Department.

164.032: Finances

(A) All Licensed or Approved Providers shall keep and maintain an accurate record of the finances of the facility in accordance with state requirements and its bylaws which demonstrates the Licensed or Approved Provider's financial capacity to operate the facility for the licensing period. Such records shall include an annual operating budget with documentation of approval by its governing body.

(B) All Licensed or Approved Providers shall establish written policies and procedures for all fiscal operations, including fee arrangements with patients or residents, provided that the Licensed or Approved Provider shall provide services to patients or residents with public health insurance on a nondiscriminatory basis. In the event of patient or resident nonpayment, prior to moving to discharge the patient or resident, the provider shall:

- (1) make reasonable efforts to secure payment from a third-party payment source; and
- (2) offer a reasonable payment plan which takes into account the patient's or resident's income and resources.

164.033: Insurance

Each Licensed or Approved Provider shall maintain evidence of general and professional liability insurance, as well as workers' compensation insurance coverage required by M.G.L. c. 152, § 25C, covering all service delivery and administrative sites.

164.034: Qualified Service Organization Agreements

Each Licensed or Approved Provider must establish written agreements with any qualified service organization providing services, programs, agencies, or facilities to the Licensed or Approved Provider. The qualified service organization agreements (QSOAs) shall:

- (A) be signed by both parties;
- (B) be renewed at a minimum of every five years;
- (C) require the qualified service organization to agree to be bound by requirements of 42 CFR Part 2;
- (D) specify the services, programs, agencies or facilities to be provided; and
- (E) if the qualified service organization provides services to the Licensed or Approved Provider's patients or residents, specify the method of referral and review of treatment plans.

164.035: Required Notifications to the Department

(A) Legal Proceedings. The Licensed or Approved Provider shall report to the Department in a manner prescribed by the Department any civil action or criminal charge that is initiated against the Licensed or Approved Provider or any person employed or contracted by the Licensed or Approved Provider that relates to the delivery of the service or may affect the continued operation of the facility. The report shall be provided no later than one business day after the initiation of any legal action.

(B) Closure. When a Licensed or Approved Provider plans to cease operation, said Provider shall notify the Department, patients, and residents pursuant to 105 CMR 164.087.

(C) Interruption or Suspension of Service. If a Licensed or Approved Provider determines that the health, safety or well-being of patients or residents is in imminent danger as a result of conditions existing within the program, the Licensed or Approved Provider shall notify the Department immediately upon becoming aware of the danger to patients or residents and comply with 105 CMR 164.086.

(D) Change of Program or Service Provision. A Licensed or Approved Provider shall notify the Department in a manner prescribed by the Department at least 30 calendar days before any change in program or service provision. The Department shall determine whether such change requires relicensure.

(E) Change of Administrator, Executive or Program Director. A Licensed or Approved Provider shall notify the Department at least 14 calendar days before a planned change of Administrator, Executive or Program Director. In the event of an unplanned departure of a director, the Licensed or Approved Provider shall notify the Department upon the next business day of the change of director in a manner prescribed by the Department.

(F) Death, Serious Incident, Accident or Fire.

(1) The Licensed or Approved Provider shall notify the Department, in a manner prescribed by the Department, immediately upon any of the following occurring at the program

- (a) learning of the death of any person currently admitted to the program, regardless of where the death occurs;
- (b) full or partial evacuation of the facility for any reason;
- (c) fire;
- (d) suicide;
- (e) criminal acts alleged to have been committed by patients, residents, contractors, or staff members;
- (f) pending or actual strike action by its employees, and contingency plans for operation of the program;

164.035: continued

- (g) alleged abuse or neglect, or physical or sexual assault, or prohibited interaction which occurs between or among patients and/or residents currently or previously treated by the program, or which occurs between or among such patients or residents and current or former staff regardless of location, including any incident which is reported to another agency or law enforcement;
 - (h) alleged abuse or neglect at the program which includes the following:
 - 1. any reports of child abuse or neglect made under M.G.L. c. 119, § 51A;
 - 2. any reports of elder abuse or neglect made under M.G.L. c. 19A, § 15; and
 - 3. any reports of abuse of a disabled person made under M.G.L. c. 19C.
 - (i) any condition at the program which poses a threat to the health, safety, or well-being of patients, residents, or staff;
 - (j) confirmed cases among staff or patients and residents of communicable diseases which are reportable under 105 CMR 300.000: *Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements*; or
 - (k) elopements of patients committed under M.G.L. c. 123 § 35;
 - (l) elopements of adolescent patients; or
 - (m) any other serious incident or accident as specified in guidelines of the Department.
- (2) The program shall report to the Department any other serious incident occurring on premises covered by the License or Approval that seriously affects the health, safety, or well-being of a patient(s) or that causes serious physical injury to a patient(s) within five business days of the date of occurrence of the event.

164.036: Marketing of Services

A Licensed or Approved Provider may not engage in advertising which:

- (1) is false, deceptive or misleading;
- (2) has the effect of intimidating or exerting undue pressure;
- (3) guarantees a cure; and/or
- (4) makes claims of professional superiority which a Licensed or Approved Provider cannot substantiate.

164.038: Evaluation

The Licensed or Approved Provider shall implement an evaluation plan that enables it to measure progress toward the achievement of its established goals and objectives. The evaluation plan shall be prepared annually by the Licensed or Approved Provider and reviewed with the governing body. The plan shall address methods for reviewing appropriateness of patient or resident care, utilization of service components, methods for achieving compliance with the federal and state disability laws, and other data and information necessary for analyzing and improving the efficiency and effectiveness of program services. The Licensed or Approved Provider shall designate the individual(s) responsible for completing the evaluation plan, and shall document the application of the evaluation findings to its efforts to improve program services.

164.039: Nondiscrimination and Accommodation

(A) No Licensed or Approved Provider shall discriminate in the provision of service against any person on the basis of race, color, ethnicity, religious creed, national origin, sex, sexual orientation, gender identity, age, disability, genetic information, ancestry or status as a veteran.

(B) No Licensed or Approved Provider shall discriminate in the provision of service against any Medicaid recipient.

(C) Program space, including satellites and medication units, used for patients or residents shall be accessible to individuals with disabilities and shall comply with all federal, state and local requirements for accessibility.

164.040: Written Policies

(A) Each Licensed or Approved Provider shall have written policies and procedures consistent with and implemented in accordance with the requirements established in 105 CMR 164.000, Department administrative guidelines, accepted standards of care for substance use disorder treatment services and applicable laws. All policies required under 105 CMR 164.000 shall be in writing, and available to staff, patients, residents and Department inspectors, and shall at a minimum address the following areas:

- (1) organizational structure including lines of authority, responsibility, communication, personnel practices, supervisory mechanisms for staff, and staff assignment;
- (2) statement of goals and objectives of the program;
- (3) types of services offered;
- (4) fiscal management including establishment and collection of fees;
- (5) criteria for admission, treatment, termination and discharge planning, involuntary termination, aftercare, post-discharge and follow-up, including for patients or residents who leave the program without notice;
- (6) program rules;
- (7) prohibition of alcohol and drugs, other than those medications properly prescribed or ordered by a patient's practitioner, are prohibited on the premises.
- (8) confidentiality in accordance with 105 CMR 164.084;
- (9) security of and access to patient and resident records, and patient and resident information;
- (10) personnel policies, including:
 - (a) the criteria and procedures for hiring, assigning, promoting, and suspending or dismissing a staff member;
 - (b) the procedure for handling staff complaints and grievances;
 - (c) prohibition of sexual harassment and procedures for handling and investigating sexual harassment complaints;
 - (d) prohibited interactions between staff and patients or residents, and between patients or residents;
 - (e) provisions for vacations, holidays, paternity and maternity leave, educational leave, sick leave, other leaves of absence, and fringe benefits;
 - (f) staff member accident and safety procedures;
 - (g) employee assistance plan;
 - (h) restrictions on the use of tobacco products and vaping;
 - (i) requirements of 42 CFR Part 2 (federal confidentiality regulations) and 45 CFR Parts 160, 162 and 164 (Health Insurance Portability and Accountability Act, HIPAA), where applicable;
 - (j) annual tuberculosis screening, and testing as indicated by the results of the screening; and
 - (k) provision of employee assistance, which shall include the following provided directly or through QSOAs:
 1. Confidential assessment and referral for services related to personal or professional difficulties which affect the employee's ability to perform assigned duties, including substance use disorders, gambling or other addictive behaviors, and domestic violence.
 2. Response for employees who experience injury or stress related to workplace incidents.
 3. Information about tobacco treatment programs, and encouragement of staff to utilize resources.
- (11) development and implementation of policies to ensure equitable access to services on a non-discriminatory basis in accordance with state and federal law;
- (12) when providing 24-hour diversionary services and residential services: care of patient and resident possessions, safe storage, administration and disposal of medication, handling of patient and resident mail, visits and communication;
- (13) transfer or referral of a patient or resident to another program or for additional services not provided by the Licensed or Approved Provider directly or through a QSOA;
- (14) ensuring patient safety, including adequate patient and resident oversight and periodic patient and resident safety checks;
- (15) behavior management;
- (16) grievances;
- (17) staff response to patient and resident threats to harm self or others;

164.040: continued

- (18) submission of mandated reports of child abuse or neglect under M.G.L. c. 119, § 51A, elder abuse under M.G.L. c. 19A, § 15, and abuse of a disabled person under M.G.L. c. 19C, § 4 and maintenance of records of any such reports made by staff;
- (19) staff response and reporting requirements in accordance with 105 CMR 164.035;
- (20) procedures for conducting internal investigations for any alleged or suspected serious incident at or under circumstances connected with the program involving the health, safety, or well-being of the patients or residents.
- (21) all-hazard and emergency planning and procedures;
- (22) employee assistance;
- (23) orientation and supervision of staff from contract or temporary agencies;
- (24) for Licensed or Approved Providers providing opioid treatment services, severe weather;
- (25) controlling access to records and to information pertaining to HIV/AIDS testing pursuant to M.G.L. c. 111, §70F;
- (26) care and treatment protocols developed in accordance with all applicable federal regulation;
- (27) clinical supervision of direct care staff by appropriately licensed staff qualified to deliver supervision;
- (28) storing, prescribing, and administering medications including methadone and buprenorphine take home medication; and
- (29) monitoring safe sleep conditions in client rooms as well as conducting periodic safety checks with parents and children overnight and during any napping times.

(B) Standards for the content of required policies may be set by administrative requirements issued from time to time by the Department.

(C) Each Licensed or Approved Provider shall ensure all policies and procedures are complied with.

164.041: Personnel

(A) 105 CMR 164.041 through 164.046 apply to all staff, including volunteers, contractors, and interns.

(B) The Licensed or Approved Provider shall, as part of its orientation, inform and train all staff members, in writing, of confidentiality requirements in accordance with 105 CMR 164.084. Evidence of this notification and training shall be included in personnel records.

(C) The Licensed or Approved Provider shall comply with all state and federal anti-discrimination laws including Equal Employment Opportunity Laws and M.G.L. c. 151B, §§ 3A and 4.

(D) A Licensed or Approved Provider who serves a community in which a majority of the population do not speak English as a first language shall make and document efforts to employ staff in direct service positions who speak the language(s) of the community served.

(E) The Licensed or Approved Provider shall comply with the hiring restrictions established by the Executive Office of Health and Human Services under 101 CMR 15.00: *Criminal Offender Record Checks*.

(F) A Licensed or Approved Provider serving individuals younger than 18 years old, or serving families with children younger than 18 years old, shall require volunteers, students, employees, and employment candidates being considered for hire to sign a consent form allowing the Department of Children and Families to release information about the volunteer, student, employee, or employment candidate, including whether their name appears on the Registry of Alleged Perpetrators, to the Licensed or Approved Provider.

164.043: Job Description and Evaluations

(A) The Licensed or Approved Provider shall make available job descriptions for all positions, which shall include current salary ranges. Job descriptions shall specify responsibilities, supervision received, supervision provided to others, degree of authority to execute job responsibilities, and qualifications.

(B) The Licensed or Approved Provider shall evaluate the job performance of all staff members. Each evaluation shall be completed at least annually, and a copy shall be placed in the employee's personnel record.

(C) The Licensed or Approved Provider shall include the following job descriptions, which may be incorporated into descriptions for other positions:

- (1) Access Coordinator: responsible for development and implementation of the Licensed or Approved Provider's evaluation, plan and annual review of the Licensed or Approved Provider's performance in ensuring equitable access to services as required by 105 CMR 164.040(A)(11).
- (2) HIV/AIDS Coordinator: responsible for overseeing confidential HIV risk assessment and access to counseling and testing; staff, patient, and resident HIV/AIDS and hepatitis education; and Department requirements for admission, service planning and discharge of HIV positive patients or residents;
- (3) Tobacco Education Coordinator: responsible for assisting staff in implementing BSAS guidelines for integrating tobacco assessment, education and treatment into program services.

164.044: Training and Supervision

(A) The Licensed or Approved Provider shall provide ongoing staff training and supervision to all staff, including clinical staff, qualified health care professionals, relief staff, interns, volunteers, contractors and others, in accordance with 105 CMR 164.044(B). The Licensed or Approved Provider shall have a written plan for supervision sufficient to meet the needs of staff, patients and residents which shall specify the frequency and goals of supervision for all staff, and which shall provide that all direct care staff requiring clinical supervision receive clinical supervision from appropriately licensed staff qualified to deliver supervision, and that supervision is documented.

(B) The Licensed or Approved Provider shall have a written plan for ongoing in-service training of all personnel. The plan shall include the following:

- (1) orientation and ongoing supervision of employees regarding policies and procedures of the program, including at a minimum program operations; state and federal confidentiality laws; professional ethics, including staff-patient and staff-resident boundaries and boundaries for relationships between and among patients and residents; behavioral management; record keeping; internal incident reporting and investigation; and the reporting of abuse and neglect of children, the elderly and disabled persons; and
- (2) over the course of a year, monthly scheduled in-service training sessions in accordance with Department guidance on, at a minimum:
 - (a) program's All Hazards Emergency Response Plan;
 - (b) HIV/AIDS, sexually transmitted infections (STIs) and Viral Hepatitis;
 - (c) universal health precautions and infection control;
 - (d) substance use disorders including tobacco and nicotine addiction, clinical assessment and diagnosis; treatment planning; relapse prevention and aftercare planning; overdose risk assessment and prevention;
 - (e) co-occurring disorders, including mental health disorders, gambling and other addictive behaviors, and mechanisms for ensuring coordination of care related to all co-occurring disorders, including risk assessments and creation of safety plans;
 - (f) other topics specific to the requirements of the service type and/or the population served;
 - (g) effects of substance use disorders on the family and related topics such as the role of the family in treatment and recovery;
 - (h) cultural competency including culturally and linguistically appropriate services (CLAS) or standards;
 - (i) the benefits and risks of all clinically appropriate medication for addiction treatment options, as well as the risks and benefits of not receiving treatment;

164.044: continued

- (j) abuse and neglect reporting requirements; and
- (k) professional ethics, including staff-patient and staff-resident boundaries and boundaries for relationships between and among patients and residents.

(C) The Licensed or Approved Provider shall provide specific training, as specified by the Department, for the Access, HIV/AIDS and Tobacco Education Coordinators.

(D) The Licensed or Approved Provider shall maintain a record of all in-service training sessions provided, including topic, date, duration and attendance.

164.046: Personnel Records

The Licensed or Approved Provider shall maintain a personnel record for each employee which includes at a minimum evidence of any required license or registration number; documentation of any specialty certification, education, and job experience; and evidence of training received, as specified in 105 CMR 164.044(B).

164.047: Volunteers, Student Interns and Contract Agency Staff

(A) Volunteers and student interns may be used only as an adjunct to regular paid staff and not as a substitute for the staffing requirements of 105 CMR 164.000. Student interns and volunteers providing individual and/or group counseling shall be screened, oriented, trained, and supervised in a manner consistent with 105 CMR 164.041(E) and 105 CMR 164.044.

(B) When a Licensed or Approved Provider uses staff who are employed by a contract or temporary agency, the Licensed or Approved Provider shall ensure the following:

- (1) the Licensed or Approved Provider has established a qualified service organization agreement with the contract or temporary agency which specifies that the contract or temporary agency has complied with hiring restrictions established by the Executive Office of Health and Human Services under 101 CMR 15.00: *Criminal Offender Record Checks*.
- (2) the Licensed or Approved Provider has established a written policy and procedure to ensure such staff receive orientation and supervision, and to document such orientation and supervision.

164.048: Staffing Pattern

(A) The Licensed or Approved Provider shall provide an adequate number of qualified personnel to fulfill the service objectives and needs of each patient or resident served based upon acuity, patient assessments, treatment plans, and other relevant factors as determined by the Licensed or Approved Provider. At a minimum, such staffing shall include:

- (1) A program director who shall administer the day-to-day operations of the facility and who shall be on the premises during regular business hours. In his or her absence a professional staff person shall be designated to act in his or her place. The Licensed or Approved Provider shall provide the designee with contact information for the administration in the event of an emergency.
- (2) A multidisciplinary team that includes professionals sufficient to meet the needs of each patient or resident served with recognized expertise in a variety of areas of substance use disorder treatment. The team may include the Licensed or Approved Provider's staff as well as other treatment professionals through QSOAs, as necessary to care for patients and residents served. The team may include, but is not limited to, physicians, psychiatrists, psychologists, acupuncturists, advanced practice registered nurses, physician assistants, registered nurses, licensed practical nurses, licensed social workers, psychiatric nurses, substance use disorder counselors with master's or bachelor's degrees in a related field and certified or licensed substance use disorder counselors, licensed mental health counselors, case managers, care coordinators, recovery coaches, and peers.
 - (a) The multidisciplinary team shall review assessments, treatment plans and other patient- and resident-specific issues to ensure quality of services and to provide education and training to staff.
 - (b) The Licensed or Approved Provider shall ensure that the multidisciplinary team is incorporated into the staffing plan.

164.048: continued

(B) In addition, the Licensed or Approved Provider shall ensure that on each shift specific staff members are designated to:

- (1) Initiate an emergency response as described in 105 CMR 164.062; and
- (2) Perform cardio-pulmonary resuscitation.

(C) The Licensed or Approved Provider shall establish a staffing pattern sufficient to meet the program's patient or resident acuity, which includes paid staff in numbers, qualifications and shift coverage to ensure:

- (1) required services are provided;
- (2) safety of patients, residents and staff; and
- (3) the program operates in accordance with 105 CMR 164.000.

(D) The Department may issue guidance specifying minimum numbers of staff, and may determine that a staffing pattern is insufficient to ensure 105 CMR 164.048(C)(1) through (3). Providers must make every reasonable effort to provide sufficient staff in order to guarantee admissions up to their licensed capacity.

164.049: Physical Plant: Building Design

(A) The design, construction, and maintenance of the building shall comply with all federal and state laws and local ordinances pursuant to 105 CMR 164.050 including, but not limited to, 780 CMR and 521 CMR.

(B) The Licensed or Approved Provider must ensure that any locking system on any door in the facility can be opened by a master key or specialized tool in the event of an emergency.

(C) All sites where services are delivered shall comply with the Americans with Disabilities Act.

(D) Each site shall have sufficient and appropriate space for storage of patient and resident records which shall be maintained in compliance with 105 CMR 164.083.

164.050: Required Certificates and Inspections

The Licensed or Approved Provider shall maintain valid certificates from the applicable local or state authority or authorities including, but not limited to, building, fire and sanitary code inspection certificates. Such certificates shall be made available to Department inspectors upon request. Further, all documentation in connection with any inspections shall be maintained on-site and provided to the Department upon request.

164.053: Building Maintenance

(A) All Licensed or Approved Providers shall provide sufficient maintenance and housekeeping personnel to ensure that the building is in good repair and in a safe, clean, and sanitary condition and free from accumulation of refuse. Residential rehabilitation programs may require residents to maintain sleeping quarters in clean and safe condition and to perform light housekeeping tasks. Residential rehabilitation programs shall not require residents to serve as substitutes for maintenance and housekeeping personnel.

(B) Each building shall have adequate space for storage of equipment and bulk office supplies and all storage areas, attics, and cellars shall be kept safe and free from accumulations of refuse. Combustibles, whose storage is permissible under relevant state and local regulations, shall be kept in metal cabinets.

(C) All areas around the buildings, sidewalks, and patios shall be kept clear of debris, ice and snow.

164.054: General Areas

(A) Each building shall have sufficient and separate space for reception and office areas, including:

164.054: continued

- (1) reception and waiting areas;
- (2) administrative and staff offices; and
- (3) storage of patient and resident records.

(B) Program service areas shall be designated and furnished in a manner consistent with their use and so as to safeguard patient and resident confidentiality, dignity and privacy.

(C) Toxic substances including, but not limited to, alcohol-based products, cleaning supplies and paints, shall be kept in locked storage areas.

(D) Alcohol and drugs, other than those medications prescribed or ordered or patient's practitioner, are prohibited on the premises.

164.055: Tobacco-free Environment

(A) Tobacco and e-cigarette use is prohibited throughout the entire facility with no exceptions subject to M.G.L. c. 270, § 22 for acute care residential substance use disorder treatment centers. The prohibition shall include program-owned and/or leased vehicles, and personal vehicles when used to transport patients or residents. Such prohibition shall apply to everyone, including employees, patients, residents, consumers, contractors, and visitors.

(B) The Licensed or Approved Provider may establish restricted exterior smoking and vaping areas away from main entrances to the building. The Licensed or Approved Provider shall establish separate exterior smoking and vaping areas, or separate smoking and vaping times, for patients or residents and staff.

164.056: Restrooms

(A) Restrooms shall be conveniently located and accessible throughout the building, and shall be designed to:

- (1) permit opening a locked door from the outside in an emergency;
- (2) ensure privacy through the use of partitions and doors; and
- (3) provide adequate ventilation through windows and/or by exhaust fans.

(B) Restrooms shall be cleaned frequently and maintained in good repair and in a sanitary manner.

(C) Restrooms shall have sufficient supplies, including soap, paper towels, and toilet paper, at all times.

(D) Licensed or Approved Providers shall provide an adequate number of restroom facilities which are adapted for use by and accessible to individuals with disabilities or wheelchairs.

(E) Restrooms shall be equipped with flashing lights to signal fire or other alarms for hearing impaired persons.

164.057: Communication Systems

Licensed or Approved Providers shall establish and maintain telephone and electronic equipment necessary to ensure efficient communication for staff, patients, and residents. Telephone systems shall include Telecommunication Device for the Deaf (TDD)/Teletypewriter (TTY) equipment, Videophone (VP) systems, relay systems or other technology approved by the Department. Licensed and Approved Providers shall ensure that all staff who may be responsible for receiving incoming communications are trained in the use of relay systems at a minimum, and other technologies as applicable.

164.058: First Aid

The Licensed or Approved Provider shall ensure first aid kits meeting the American National Standards Institute Z308.1-2015 requirements are available including, at a minimum, one Class B Kit and one or more Class A Kits.

164.059: Child Safety

If children are permitted on the premises for any reason, the Licensed or Approved Provider shall ensure that children on site are supervised at all times by an adult, and that the premises are safe for children.

(A) Safety provisions shall include:

- (1) floors and walls free from dangerous protruding objects;
- (2) intact banisters and balusters;
- (3) tall or top-heavy furniture bolted to the floor or wall;
- (4) electrical cords secured to baseboard or floor;
- (5) toys in children's play areas sanitized daily with written cleaning procedures posted;
- (6) in facilities with kitchens, children younger than six years old shall not be permitted in kitchen areas, and kitchen cabinets and refrigerators shall be equipped with child-proof locking mechanisms;
- (7) protective covers on radiators;
- (8) If children younger than six years old are present, provisions shall also include:
 - (a) covers larger than 1x4 inches installed on all electrical outlets;
 - (b) diaper changing areas with a safety strap and adequate supplies for cleaning the surface with a disinfectant after each use;
 - (c) safety bars on windows above the first floor, and on any other hazardous window accessible to children; and
 - (d) gates placed across top and bottom of stairways.

(B) If the Licensed or Approved Provider provides a separate area for children and restricts children's access to other parts of the premises, provisions under 105 CMR 164.059(A) shall apply to the separate children's areas only.

(C) Licensees providing residential services for children, or allowing overnight visitation, shall ensure the parent is or will be educated on safe sleep procedures. The program shall ensure no children younger than two years old be allowed to co-sleep with their parent.

164.061: Internal Incident Investigation and Reporting

(A) Unless otherwise approved by the Department, all internal investigation reports shall be completed no later than ten business days from the date of the incident or from the date the Licensed or Approved Provider knew or should have known about the incident. All internal investigation reports shall include a root cause analysis of the incident.

(B) The Licensed or Approved Provider shall maintain and store in a central and readily accessible location all internal incident reports and investigatory documentation, for review by the Department upon request. Such records shall include a log and documentation related to all incidents that effect, or could potentially effect, the health and safety of patients or cause physical injury.

164.062: All Hazard and Emergency Planning and Procedures

(A) The Licensed or Approved Provider shall establish a written plan for response to emergencies, which must include:

- (1) Said plan shall be formulated on an all-hazards approach: provide for response to internal, local, community, state, regional or national emergencies, regardless of cause (natural or man-made).
- (2) The plan shall include a mechanism for review of all services furnished by the Licensed or Approved Provider, and how those services will be affected by and changed to address the emergency to which they would potentially respond.
- (3) The plan shall document the Licensed or Approved Provider's communications with community emergency management and response agencies.
- (4) The plan shall include at a minimum the provisions described in 105 CMR 164.062(B)(1) through (8).

(B) Specification of roles and responsibilities of program staff in the event of an emergency, including the sequence of authority in the event executive leadership is unavailable. The chain of command shall describe duties related to emergencies, including:

164.062: continued

- (1) internal communication and notification of the emergency, including notice to all staff, patients, residents, and the Department;
- (2) instructions related to use of alarm systems and signals;
- (3) instructions for evacuation of the building;
- (4) notification of and liaison to local emergency management and response agencies;
- (5) where evacuation of the locality is necessary, overseeing evacuation of patients or residents and staff to designated evacuation/relocation sites;
- (6) where evacuation of the facility is not appropriate, shelter-in-place procedures and plans to implement any procedures that are responsive to an extended state of emergency;
- (7) ensuring security of program records; and
- (8) controlling access to the facility.

(C) Facility offices and waiting areas must display the names and telephone number of individuals, such as physicians, hospitals, emergency medical technicians, who should be contacted in case of emergency or utilize 911 or similar local emergency resources. A mechanism to address patient medical or psychiatric emergencies occurring outside of program hours of operation must be provided, including the establishment of an emergency contact system to obtain dosage levels and other pertinent patient information on a 24-hour, seven-days-a-week basis, as appropriate under confidentiality regulations.

- (D) Establishment of an emergency communication system specifying responsibility for:
- (1) notifying staff;
 - (2) notifying patients and residents; and
 - (3) notifying the Department.

(E) Identification of local and state emergency management and response agencies, including location, phone numbers and emergency contact information.

(F) Relocation of Staff and Patients and Residents in the Event of an Evacuation. Such plan shall identify the local evacuation sites and procedures, and shall specify provisions for evacuation of individuals whose mobility is impaired and/or who require adaptive equipment. The Licensed or Approved Provider shall determine, and document, any restrictions that may apply to evacuation sites.

(G) Maintenance of Essential Services. Licensed or Approved Providers who store and/or dispense medications shall include provisions for safe storage of medication as well as for continuity of service to patients and residents. Licensed or Approved Providers must ensure continuity of essential services through modification of operations, subject to approval by the Department, which are specific to the type of the applicable emergency.

(H) Provision for Continuity of Care for Existing Residents and Patients. Licensed or Approved Providers may develop cooperative plans with other substance abuse treatment programs in the community to provide for continuity of care.

(I) Safe Storage and Retrieval of Program Records. This plan shall include provision for regular backup and separate fireproof storage of electronic records.

(J) Preparation of staff, patients, and residents through periodic training, drills, and review and active updating of procedures. Training and drills must be responsive to a reasonable variety of emergencies.

(K) Licensed or Approved Provider's response to community need for substance use disorder treatment service as a result of the emergency. Said response may be established in coordination with other substance use disorder treatment services, programs or facilities in the Licensed or Approved Provider's community.

164.070: Referrals and Admissions

(A) Admission and Eligibility Criteria.

- (1) The Licensed or Approved Provider shall establish written admission eligibility criteria and procedures, provided such criteria and procedures do not impose any restrictions that act

164.070: continued

as a barrier to treatment access including, but not limited to, discrimination against patients and residents with public health insurance.

(2) Such criteria and procedures shall describe the Licensed or Approved Provider's method of determining, for each prospective patient or resident, whether the Licensed or Approved Provider's services and program are suitable for the prospective patient or resident.

(3) Such eligibility criteria shall not establish a category of automatic exclusion that is defined by a history of criminal conviction or type of primary substance used, mental health diagnosis, or prescribed medication including FDA-approved medications for the treatment of addiction.

(4) The Licensed or Approved Provider shall make the criteria and procedures available to prospective patients or residents upon the patient's or resident's application for admission.

(5) Admission eligibility criteria shall be posted in a conspicuous, public area.

(B) The Licensed or Approved Provider shall comply with all applicable state and federal anti-discrimination laws such that the Provider equally evaluates all potential admissions regardless of the source of payment, and may not deny admission on the basis of disability, race, color, ethnicity, religious creed, national origin, sex, sexual orientation, gender identity, age, genetic information, ancestry, or status as a veteran, except that Licensed or Approved Providers providing a service designed for a specific population, *e.g.*, women or adolescents, may limit admissions to members of that population.

(C) Where consistent with the program of services, admission eligibility criteria shall specifically address priority populations defined by the Department including, but not limited to, Medicaid patients or residents.

(D) The Licensed or Approved Provider shall gather and record all pertinent information needed to evaluate eligibility and service need, and to complete the Department's information system form(s).

(E) Licensed and Approved Providers shall directly connect individuals who do not meet eligibility requirements or who are inappropriate for the Licensed or Approved Provider's services to the appropriate level of care. The Licensed or Approved Provider shall collaborate, as appropriate, with care managers, case managers, health plans, and any others necessary to obtain an appropriate placement for the patient. Additionally, the Licensed or Approved provider must maintain a log of applications denied, reasons for denial and direct referrals made, and shall make this documentation available to the Department for inspection.

(F) Upon admission into treatment, or as soon as the patient or resident is medically cleared, the Licensed or Approved Provider shall obtain and make a part of the patient or resident record:

(1) a consent to treatment form signed by the patient or resident;

(2) name and contact information of a person to contact on patient's or resident's behalf in an emergency, including patient's or resident's consent to such contact. Refusal to provide an emergency contact shall be documented in the patient's or resident's record;

(3) name of patient's or resident's health insurance carrier;

(4) documentation of information provided to the patient or resident in accordance with 105 CMR 164.070(D), including patient's or resident's signed receipt of such information; and

(5) Documentation of patient or resident consent to provide treatment information to the patient or resident's primary care provider or release information to the receiving provider prior to or upon patient transfer. In the event the patient or resident refuses such consent, the Licensed or Approved Provider shall document such refusal in the patient's or resident's record.

(G) The Licensed or Approved Provider may not deny admission to an individual solely because the individual uses medication prescribed by a practitioner outside the Licensed or Approved Provider's service or facility, including any FDA-approved medication for addiction treatment and any FDA-approved medications used to treat mental health conditions.

(1) Programs may not require a designated amount of medication for admission.

(a) Programs must accept prospective patients or residents who arrive with medication(s) remaining on current prescription(s), and facilitate the ability to refill such prescription(s).

164.070: continued

- (b) Programs cannot deny admission to prospective patients or residents who lack current prescription refills and must work with such patients or residents to coordinate medication refills.
 - (c) Programs cannot deny admission based upon the types of medication a patient or resident is prescribed.
- (2) Programs may not deny admission to or exclude prospective patients or residents who lack an official state identification card.
- (H) Licensed or Approved Providers may deny admission to individuals who refuse to provide information necessary to complete an assessment and treatment plan, provided the Licensed or Approved Provider shall maintain a log of applications denied, reasons for denial and referrals made, and shall make this documentation available to the Department for inspection.
- (I) The Licensed or Approved Provider may not deny readmission to any person solely because that person
- (1) withdrew from treatment against clinical advice on a prior occasion;
 - (2) relapsed from earlier treatment; or
 - (3) filed a grievance regarding an action or decision of the Licensed or Approved Provider.
- (J) The Licensed or Approved Provider shall not admit patients or residents in excess of the number of beds approved by the Department and listed on the License or Certificate of Approval document.

164.071: Orientation

The Licensed or Approved Provider shall provide each new or returning patient or resident with an orientation that will familiarize him or her with the patient's and resident's rights, and with rules, procedures, activities, policies, and philosophy of the program, including program requirements for participation, disciplinary action, termination, and grievance procedures. Written orientation materials shall be included in the Patient and Resident Policy Manual, as required by 105 CMR 164.081. Written documentation of this orientation shall appear in the clinical records.

164.072: Assessment

- (A) The Licensed or Approved Provider shall complete an assessment for each patient and resident that includes the following elements, as well as elements prescribed for each service type in 105 CMR 164.000:
- (1) Appropriateness of Licensed or Approved Provider's service type in relation to patient's or resident's treatment needs.
 - (2) A history of the use of alcohol, tobacco and other drugs, including age of onset, duration, patterns and consequences of use; history of overdose, including witnessing an overdose; use of alcohol, tobacco and other drugs by family members; and types of and responses to previous treatment.
 - (3) An assessment of the patient's or resident's psychological, social, health, economic, educational/vocational status; co-occurring mental health and/or physical health conditions; trauma history; and history of compulsive behaviors such as gambling. The assessment must be completed before a comprehensive treatment plan is developed for the patient.
 - (4) An assessment of the patient's or resident's HIV risk status.
 - (5) An assessment of the patient's or resident's TB risk status.
 - (6) An assessment of the patient's or resident's cultural and linguistic needs.
- (B) Patient or resident treatment may begin prior to completing the assessment upon obtaining sufficient information to initiate treatment for the acute problem at the time of presentation and that the assessment is subsequently completed in a reasonable timeframe; provided that a Qualified Healthcare Professional must see such a patient or resident prior to initiating an FDA-approved medication for treatment of addiction.
- (C) When the assessment indicates a need for further evaluation, the program shall conduct necessary testing, physical examination and/or consultation by qualified professionals, or make

164.072: continued

appropriate referrals for such testing, physical examination and/or consultation by qualified professionals provided the program continues to provide treatment to the patient or resident in the interim.

(D) The assessment shall be reviewed and signed by a Senior Clinician, Clinician, or Practitioner. If conducted by a Clinician, it must be approved in writing by a Senior Clinician or Practitioner.

(E) The assessment shall conclude with:

- (1) a diagnosis of the status and nature of the patient's or resident's substance use disorder, using standardized definitions established by the American Psychiatric Association, or a mental or behavioral disorder due to use of psychoactive substances, as defined by the World Health Organization; and
- (2) an offer to the patient or resident to initiate medication for treatment of addiction, including any FDA-approved medications for the treatment of addiction.

164.073: Individual Treatment Plan

For each patient and resident admitted, the Licensed or Approved Provider shall complete an individual treatment plan based on the patient's or resident's treatment, medical, psychiatric and social histories, which includes the following elements, as well as elements prescribed for each service type in 105 CMR 164.000.

(A) The treatment plan, and all subsequent updates, shall include documentation of at a minimum the following information:

- (1) A statement of the patient's or resident's strengths, needs, abilities and preferences in relation to his or her substance use disorder treatment, described in behavioral terms;
- (2) Evidence of the patient's or resident's involvement in formulation of the treatment plan, in the form of the patient's or resident's signature attesting agreement to the plan;
- (3) Service to be provided;
- (4) Service goals, described in measurable, behavioral terms, with time lines;
- (5) Clearly defined staff, patient, and resident responsibilities and assignments for implementing the plan;
- (6) Description of discharge plans and aftercare service needs;
- (7) Aftercare goals;
- (8) The date the plan was developed and revised;
- (9) Signatures of staff involved in the formulation or review of the plan;
- (10) Documentation of disability, if any, which requires a modification of policies, practices, or procedures and record of any modifications made; and
- (11) Plan for initiating, coordinating, managing, and referring to:
 - (a) concurrent additional substance use disorder treatment that may require the use of medication, such as medication for addiction treatment when a patient or resident is enrolled in outpatient counseling or residential rehabilitation;
 - (b) treatment of co-occurring disorders;
 - (c) primary medical care; and
 - (d) recovery supports and resources.
- (12) Such plan shall identify providers of care and responsibilities of each, specifying method(s) for coordination and communication, and method(s) for ensuring that sharing of information is consistent with the requirements of 105 CMR 164.084. With patient consent, treatment plans may be submitted from the discharging provider to the admitting provider during the referral process.

(B) The Licensed or Approved Provider shall ensure that individual treatment plans are reviewed with the patient or resident and amended as necessary. As treatment progresses, further assessment and diagnostic information must be gathered and documented so as to inform longitudinal treatment planning. The patient or resident and staff reviewing the plan shall sign it, and it shall be incorporated into the patient's or resident's record. If there has been no patient or resident contact over a three-month period, the patient or resident shall be discharged from care and the case closed.

(C) All treatment plans shall be reviewed and signed by the Senior Clinician.

164.074: Minimum Treatment Service Requirements

The Licensed or Approved Provider shall provide directly or through with Qualified Service Organizations, Business Associate Agreement, or other applicable agreement in compliance with 42 CFR part 2 the following services:

- (A) Medications for treatment of addiction, including all FDA-approved medications for addiction treatment;
- (B) Overdose prevention education as part of evidence-based practices;
- (C) Substance use disorder therapies;
- (D) Counseling and education as clinically indicated which conform to accepted standards of care, uses evidence-based practices, and monitors progress and outcomes;
- (E) HIV education and counseling;
- (F) TB screening, education and treatment;
- (G) Tobacco education and counseling;
- (H) Case management including:
 - (1) directly connecting patients and residents to appropriate providers based on continuum of care and patient and resident educational, vocational, financial, legal and housing; and
 - (2) updating the patient or resident's primary care provider on treatment and progress, such as by providing the patient's or resident's record to the primary care provider upon the patient's or resident's documented authorization in accordance with 105 CMR 164.070(F)(5);
- (I) Mental health services, including screening, crisis intervention, and psychopharmacological services, for individuals with co-occurring disorders;
- (J) Health services, including primary care, oral health, and family planning services requested by the patient or resident;
- (K) Services for individuals with compulsive behaviors such as compulsive gambling;
- (L) Relapse prevention and recovery maintenance counseling and education and shall:
 - (1) include monitoring of the patient's or resident's behavior;
 - (2) address risks specific to the patient or resident, including, where applicable, risk of overdose; and
 - (3) include services intended to maintain the patient or resident in treatment and support recovery;
- (M) Planning for patient's or resident's completion of treatment, and identification of transitional, discharge and aftercare supports the patient or resident may require; and
- (N) Family support services, including family therapy, or social or education services.

164.075: Termination and Discharge

- (A) The Licensed or Approved Provider shall establish written termination and discharge policies and procedures and shall make these available to prospective patients or residents at the time of admission. These shall include:
 - (1) Written criteria defining:
 - (a) Successful completion of treatment;
 - (b) Voluntary termination prior to program completion, except in the case of an individual committed to treatment under M.G.L. c. 123, § 35;
 - (c) Involuntary termination, including:
 - 1. emergency termination when the program director or Practitioner reasonably determines that the patient's or resident's continued presence in the program presents an immediate and substantial threat of physical harm to other patients or residents, program personnel, or property; and

164.075: continued

2. nonemergency termination, including notice to the patient or resident of the reasons for termination and the right to grieve the decision as required by 105 CMR 164.080 prior to termination; and
 - (d) Procedures for determining, in consultation with the patient or resident, referrals needed to ensure a continuum of care, reduction of risk of relapse, and reduction of risks to patient's or resident's well-being, provided the patient or resident is directly connected to such services prior to or within a reasonable time following discharge. Such referrals may include, but are not limited to:
 1. certified alcohol and drug-free housing;
 2. additional substance use disorder treatment;
 3. treatment of co-occurring disorders;
 4. continued care coordination and management with the patient's or resident's medical and psychiatric care providers;
 5. community based overdose prevention programs;
 6. employment resource;
 7. community and social supports, including family support services; and
 8. providers of medication for addiction treatment.
 - (2) Procedures for planning the discharge in consultation with the patient or resident when one of the following conditions is met and discharge will not create an immediate safety risk for the patient:
 - (a) Patient or resident has received optimum benefit from treatment and further progress requires either the patient's or resident's return to the community or the patient's or resident's referral to another type of treatment program;
 - (b) Patient or resident is ready to transition to different service type, which may be more or less intensive than the current program;
 - (c) Patient or resident voluntarily requests discharge from treatment, in which case procedures shall include review of risks and benefits of terminating treatment; or
 - (d) Patient or resident is involuntarily terminated on a nonemergency basis.
 - (3) A written discharge summary, including:
 - (a) Description of services provided, patient's or resident's response to such services, and progress in attaining treatment plan goals;
 - (b) Patient's or resident's substance use at discharge, including risk of overdose and recommendations for follow-up services;
 - (c) Patient's or resident's current vocational, educational and financial status;
 - (d) Reason for termination;
 - (e) Direct referrals provided;
 - (f) Supports and services available to the patient or resident after discharge, provided by the Licensed or Approved Provider or by others;
 - (g) Documentation of efforts made by the Licensed or Approved Provider to prevent discharge of a patient or resident to a shelter for the homeless;
 - (h) Documentation of patient's or resident's participation in discharge planning, or of patient's or resident's refusal to participate; and
 - (i) An aftercare and follow-up plan, including method for contacting patient or resident if the patient or resident consents to contact.
- (B) The Licensed or Approved Provider shall establish procedures for discharge if a patient or resident leaves the program against clinical advice or is involuntarily discharged from the program including, but not limited to, an appeal process for an involuntary discharge. The Licensed or Approved Provider shall refer the patient or resident to another facility/program for treatment if necessary or appropriate.
- (C) Licensed or Approved Providers may discharge patients or residents who refuse to provide information required for necessary coordination of treatment or in an emergency situation where the patient's or resident's continuation in the program presents an immediate and substantial threat of physical harm to other patients or residents, program personnel or property; provided the Licensed or Approved Provider shall maintain documentation related to involuntary discharges, to include reasons for involuntary discharge and referrals made, and shall make this documentation available to the Department for inspection.
- (D) Licensed or Approved Providers providing Opioid Treatment Services shall establish additional termination and discharge procedures as specified in 105 CMR 164.311.

164.075: continued

(E) Licensed or Approved Providers providing residential services, whether acute or rehabilitation, shall not develop a discharge plan which provides for discharge of a patient or resident or patient to a shelter for the homeless.

164.076: Aftercare

The Licensed or Approved Provider shall establish written policies and procedures for provision of aftercare for patients or residents who are discharged, which shall include provisions for patient and resident participation in developing the aftercare plan, a method for contacting the patient or resident, and ensuring the patient's or resident's ability to continue any prescribed medications. Aftercare services shall include:

(A) Directly connecting the patient or resident to an appropriate provider to ensure a continuum of care for the patient or resident, including arrangements for further substance use disorder treatment and post-discharge counseling and other supportive services;

(B) Providing information concerning available community-based service agencies and programs, which shall include a description of services, addresses, phone numbers and the names of contact persons;

(C) Referrals, the aftercare plan and information provided to the patient or resident shall be documented in the patient's or resident's record; and

(D) If a patient or resident refuses aftercare services, the Licensed or Approved Provider shall document the refusal in the patient's or resident's record.

164.077: Post-discharge Follow-up

The Licensed or Approved Provider shall establish written policies and procedures for follow-up patient and resident contact. Such policies shall describe circumstances under which a patient or resident may be contacted after discharge and shall require that patient's or resident's permission for such contact be documented in the patient's or resident's record.

164.078: Behavior Management

The Licensed or Approved Provider shall establish and maintain written policies and procedures for managing disruptive behavior including, but not limited to, aggression, harm or threats of harm to self or others, destruction of property and refusal to comply with program policies. The policies and procedures shall be posted and shall:

(A) Describe the safeguards for the emotional, physical and psychological well-being of the population served;

(B) Describe the measures used to promote appropriate behavior;

(C) Define and explain the behavior management procedures used in the facility including, where applicable:

(1) level/point systems of privileges, including procedures for the patient's or resident's progress in the program;

(2) the type and range of restrictions a staff member can authorize for misbehavior of residents; and

(3) behavioral interventions to be used in response to angry or aggressive patients or residents, including de-escalation techniques.

(D) Prohibit use of physical restraints in any form, except in the case of an individual committed to treatment under M.G.L. c. 123, § 35;

(E) Include criteria for the transfer or discharge of any patient or resident whose aggressive behavior presents a danger or threat of danger to the resident or to other patients, residents or staff;

164.078: continued

- (F) Describe the Licensed or Approved Provider's grievance process; and
- (G) Describe the process for filing complaints with the Department.

164.079: Patients' and Residents' Rights

(A) The Licensed or Approved Provider shall safeguard the legal and civil rights of each patient and resident at all times during treatment and throughout the discharge process. Each Licensed or Approved Provider shall adopt and maintain an updated set of rules, which set forth the responsibilities and the rights of patients and residents regarding treatment and discharge.

(B) The Licensed or Approved Provider shall guarantee the patient or resident, at a minimum, the following rights:

- (1) freedom from physical and psychological abuse;
- (2) freedom from strip searches and body cavity searches;
- (3) control over his or her bodily appearance; provided, however, on program premises, the Licensed or Approved Provider may prohibit attire and personal decoration which interfere with treatment;
- (4) access to his or her patient or resident record in the presence of the administrator or designee, unless there is a determination that access to parts of the record could cause harm to the patient or resident;
- (5) the right to challenge information in his or her patient or resident record by inserting a statement of clarification or letter of correction signed by both the clinician and the patient or resident;
- (6) the right to obtain a copy of the patient's or resident's records as specified in 105 CMR 164.083;
- (7) the right to have the confidentiality of his or her records secured as required by 105 CMR 164.084;
- (8) the right to terminate treatment at any time, except in the case of an individual committed to treatment under M.G.L. c. 123, § 35;
- (9) freedom from coercion;
- (10) treatment provided on a nondiscriminatory basis;
- (11) treatment in a manner sensitive to individual needs and which promotes dignity and self-respect;
- (12) full disclosure regarding fee charged and, in residential rehabilitation programs, any patient or resident benefits to be contributed;
- (13) the right to grieve actions or decisions of the Licensed or Approved Provider regarding the patient's or resident's treatment;
- (14) freedom to practice his or her religious faith;
- (15) the right to request referral to a facility which provides treatment in a manner to which the patient or resident has no religious objection;
- (16) drug screens conducted in a manner which preserves the patient's or resident's dignity and, when the drug screen is by urine sample, accommodates any medically confirmed inability to give urine by providing for an alternate effective means of screening such as oral swab; and
- (17) the right to contact the Department.

(C) The Licensed or Approved Provider shall provide for translations of rights, rules and manuals for patients and residents who do not read English.

164.080: Grievances

The Licensed or Approved Provider shall establish written policy and procedures for the resolution of patients' or residents' disagreement(s) or dispute(s) arising in relation to treatment or program requirements. The policy and procedures shall specify:

- (A) Patients' and residents' right to grieve actions and/or decisions of the Licensed or Approved Provider regarding the patient's or resident's treatment;
- (B) Steps to be taken to resolve the matter; and

164.080: continued

(C) Provisions for a hearing on the matter presided over by an impartial grievance officer who may be any staff or other person(s) not directly involved in the facts of the incident giving rise to the action grieved or in the decision to commence the action; provided that the persons involved in either the facts of the incident or in the decision to commence the proceedings shall not have authority over the hearing officer(s). Grievance officers shall be selected based upon their expertise in issues being grieved (*e.g.*, medical officer/medical grievance, administrative officer/administrative grievance). All hearings may be conducted by telephone or using an audio-visual, real-time, two-way interactive communication system.

164.081: Patient and Resident Policy Manual

(A) Each Licensed or Approved Provider shall adopt and maintain a current policy manual for patients and residents containing clear and concise statements regarding:

- (1) Program description, including:
 - (a) goals and objectives,
 - (b) type of services provided, including aftercare and follow-up;
 - (c) qualifications for service delivery staff;
 - (d) restrictive criteria for receipt of specific services, if any;
 - (e) scheduling restrictions; and
 - (f) overall hours of program operation.
- (2) Orientation materials provided to patients and residents at admission, including information about treatment options, such as medication for addiction treatment, and about family support services;
- (3) Admission requirements and intake procedures, including a list of the minimum information that is collected at the intake session;
- (4) Fee policies including:
 - (a) method used to determine fee, including reduced fees for persons of low income; and
 - (b) whether or not the program accepts public or private third-party reimbursement or funding.
- (5) Procedures regulating access to patient and resident records;
- (6) Program rules, including:
 - (a) all patient and resident expectations and responsibilities, and process for maintaining safety and accountability;
 - (b) restrictions on use of tobacco and vaping products;
 - (c) prohibition of sexual harassment and procedures for addressing and investigating sexual harassment complaints;
 - (d) prohibited interactions between staff and patients or residents, and among patients or residents;
 - (e) criteria for termination;
 - (f) procedures for involuntary terminations;
 - (g) grievance procedure for the resolution of any other patient or resident related problem or dispute; and
 - (h) visitation and communication policies that encourage and support family visits, mail, telephone calls, and other forms of communication with family, friends, or other persons provided that no such policy authorizes the Licensed or Approved Provider to hold mail or restrict the sending of mail or open patient or residents' mail; however, such policy may require patients or residents to open letters or packages in the presence of staff.
- (7) Policies, practices, and procedures to ensure compliance with the ADA;
- (8) Patients' and residents' rights; and
- (9) Contact information for the Department's Bureau of Substance Addiction Services complaint line.

(B) The policy manual and contact information for the Department's Bureau of Substance Addiction Services complaint line shall be:

- (1) placed visibly in a public area frequented by all patients or residents or kept at a central location, with a notice of its availability conspicuously posted in a public area frequented by all patients or residents; and
- (2) given to each new patient or resident during the admission process or subsequently upon his or her request, and to any interested party upon request.

164.081: continued

(C) Whenever the Licensed or Approved Provider makes a change in policy, it shall issue a written change to the policy manual; the change shall not take effect until placed in the manual and distributed as provided for in 105 CMR 164.081(B).

(D) When furnishing a patient or resident with a copy of the policy manual or of any changes to the policy manual, the Licensed or Approved Provider shall secure a dated and signed receipt, which shall be placed in the patient or resident record.

(E) The Licensed or Approved Provider may charge for the cost of copying and assembling the policy manual for an interested party or for a second copy to a patient or resident.

164.082: Special Populations

Licensed and Approved Providers providing services to special populations listed in 105 CMR 164.082(A) through (E) shall make additional provisions as specified:

(A) Pregnant Women. Licensed and Approved Providers serving pregnant women shall:

- (1) establish in writing clinically appropriate medical protocols for pregnant women;
- (2) designate a hospital for emergency obstetrical and medical back-up; however, patients or residents may elect to choose their own medical providers;
- (3) coordinate care with obstetrical or other maternity care providers as appropriate;
- (4) provide for appropriate parent or legal guardian-child services directly or through a QSOA; and
- (5) be available to serve women in all three trimesters of pregnancy.

(B) Adolescents and Transition Age Youth. Licensed and Approved Providers serving Adolescents and/or Transition Age Youth shall:

- (1) ensure that assessments as required in 105 CMR 164.072 include an evaluation of:
 - (a) developmentally age-appropriate behaviors;
 - (b) cognitive functioning;
 - (c) physical maturation;
 - (d) existing peer and family supports, peer group and family functioning;
 - (e) experience of trauma;
 - (f) history of mental health diagnoses;
 - (g) availability of and access to recovery supports;
 - (h) social maturity; and
 - (i) educational needs.
- (2) determine the person's custody status if younger than 18 years old;
- (3) ensure that staff providing services for children and adolescents have specific training in child and teen development, including a minimum of five college credit hours in courses related to the topic;
- (4) ensure that services for adolescents are supervised by a Senior Clinician with at least two years post-master's experience working with adolescents with substance use disorders;
- (5) ensure available parent or care-giver support and education services;
- (6) ensure that adolescents are served in programs which are separate from programs serving adult populations; and
- (7) prior to providing any services to persons younger than 18 years old, inform the Department of the nature and scope of any services provided to adults in the same facility as those intended for services for adolescents. The Department shall determine whether such proximity of adult services constitutes a risk to adolescents.

(C) Persons with Co-occurring Disorders. Licensed and Approved Providers serving persons with co-occurring disorders shall:

- (1) establish policies and procedures for referrals for specialized mental health care care; and
- (2) if the Licensed or Approved Provider is not also licensed or approved to provide mental health services, establish QSOAs providing for mental health interventions and coordinated care.

(D) Elders. Licensed and Approved Providers serving persons 60 years of age or older shall establish QSOAs with local organizations providing services for the elderly.

164.082: continued

(E) Persons with Disabilities. Licensed and Approved Providers serving persons with disabilities shall:

- (1) establish policies and procedures that identify any specialized programming for persons with disabilities;
- (2) establish policies and procedures for referrals as appropriate to specialized services for persons with disabilities; and
- (3) establish QSOAs with state and local organizations providing services and/or care coordination for persons with disabilities.

164.083: Patient and Resident Records

(A) The Licensed or Approved Provider shall maintain separate records for each patient and resident in a secure and confidential manner consistent with state and federal law, including 42 CFR Part 2. Records shall be legible and up to date no later than five business days from the date of last patient or resident contact.

(B) The written individual patient or resident record shall include, but not be limited to, the following information:

- (1) name, unique patient or resident identifier, date of birth, sex, race/ethnicity, relationship status, and primary language, if other than English;
- (2) name and contact information of the referring agency, court or person;
- (3) presenting problem(s);
- (4) all necessary authorizations, consents, and updates;
- (5) patient or resident assessment as required by 105 CMR 164.072;
- (6) insurance coverage information;
- (7) individual treatment plan and service plan reviews;
- (8) signed patient or resident confirmation of receipt of program policy manual, information regarding maintenance of client confidentiality, and contact information for the Department's Bureau of Substance Addiction Services complaint line;
- (9) signed and dated progress notes entered by patient's or resident's counselor after every patient and resident contact or attempted contact;
- (10) documentation of STD, TB, Viral Hepatitis, HIV/AIDS risk assessment;
- (11) documentation of STD, TB, Viral Hepatitis, HIV/AIDS education;
- (12) record of any threat made by patient or resident to harm self or another, and the action taken by Licensed or Approved Provider in response to threat(s);
- (13) record of multidisciplinary team reviews concerning patient or resident, including plan for coordination with other substance use disorder treatment, mental health, and physical health care services;
- (14) discharge summary;
- (15) aftercare service plan;
- (16) record of attempts at post-discharge follow-up by letter, phone call, home visit or through contacts with aftercare providers;
- (17) records of any warnings, disciplinary actions, grievances or complaints, and actions taken by Licensed or Approved Provider;
- (18) patient and resident fee information, including method by which fee was determined, and documentation of all fees paid by patient or resident; and
- (19) record of care coordination, including relevant releases of information.

(C) Progress notes shall be current, legible, dated, and signed by the individual making the entry. Group counseling and educational-session progress notes may describe the session in general, but the patient's or resident's record must also include in each progress note specific comments on the patient's or resident's participation and progress in the group.

(D) All patient or resident cases reviewed by a Clinician and Counselor shall receive a quarterly record review by his or her supervisor. Evidence of this review shall be documented in the clinical record.

(E) All patient and resident records shall be marked confidential and kept in a secure, locked location, accessible only to authorized staff. Electronic records shall be secured through firewall and password protection and shall be accessible only to authorized staff.

164.083: continued

(F) Except as otherwise provided in 105 CMR 164.000 or by applicable state or federal law, access to patient and resident records shall be limited to the patient or resident or his or her designee pursuant to patient's or resident's written authorization, and to those staff members authorized by the administrator. The Licensed or Approved Provider shall have a written procedure regulating and controlling access to patient and resident records by staff members whose responsibilities require access.

(G) Upon a patient's or resident's request, the Licensed or Approved Provider shall provide, in a timely manner, to the patient or resident, another Licensed or Approved Provider or other specifically authorized person:

- (1) The opportunity to inspect the patient's or resident's records;
- (2) A copy of such record, except in circumstances described in 243 CMR 2.07(13)(e): *Psychiatric Records* governing licensed physicians engaged in the practice of psychiatry; and
- (3) A copy of any previously completed report required for third-party reimbursement.

(H) The Department shall have access to patient and resident records for the purposes of reviews required under 105 CMR 164.000. The Licensed or Approved Provider shall obtain any signed consent from its patients or residents that it deems necessary to provide such access.

164.084: Confidentiality

Patient- and resident-specific information shall be privileged and confidential and shall be made available only in conformity with all applicable state and federal laws and regulations regarding the confidentiality of patient and resident records including, but not limited to, 42 CFR Part 2, and 45 CFR Parts 160 and 164 (HIPAA Privacy and Security Rules) if applicable.

164.085: Transfer and Storage of Service Records

(A) The Licensed or Approved Provider shall maintain patient and resident records in a secure place for a minimum of seven years from the date of patient's or resident's termination of services unless required by law to do so for a longer period. Bureau-approved programs licensed under M.G.L. c. 111, § 51 as a hospital or clinic shall maintain patient and resident medical records for 20 years, as required by M.G.L. c. 111, § 70. The Licensed or Approved Provider shall ensure that clinical records accompany patients or residents upon transfer. Transfer of records shall be made in accordance with federal and state confidentiality law and regulations. A signed consent from each patient and resident must be obtained prior to the transfer of such records.

(B) When closing a program, service or facility, the Licensed or Approved Provider shall ensure that all records not transferred to a new facility with the patient or resident be securely stored for the remainder of the seven-year period mandated for each record. For all current patients and residents of the Licensed or Approved Provider at the time of closure, the Licensed or Approved Provider shall also make every effort to provide a copy of the record to the patient or resident at the time of closure, if the record is not transferred with the patient or resident to a new treatment program. Public notice shall be given regarding the date of service termination and the site at which such records shall be securely stored. The Licensed or Approved Provider shall prepay the full cost of such storage and shall contract to ensure that the records are appropriately maintained for the entire period and that the records are destroyed at the end of the period in a manner that protects their confidential nature.

164.086: Interruption or Suspension of Service

(A) If the Department determines there is a need to interrupt or suspend a service or program because the health, safety, or well-being of patients or residents is in imminent danger as a result of conditions existing within the service, program, or facility, the Licensed or Approved Provider shall:

- (1) notify patients and residents of the interruption or suspension;
- (2) provide for continuity of care for patients and residents during the period of interruption or suspension; and
- (3) provide for the secure storage or safe transfer of patient or resident records, with patient or resident authorization.

164.086: continued

(B) Within five calendar days of the interruption or suspension of services or program, the Licensed or Approved Provider shall notify the Department in writing of its plans to resume service, or for transfer of services to another program or facility.

164.087: Closure

(A) Except as provided by 105 CMR 164.087(D), the Licensed or Approved Provider shall notify the Department, each patient and resident, each staff member of the program, and each labor organization that represents the facility's workforce at the time of notice, orally and in writing of the impending termination at least 90 calendar days prior to the termination of service or program that the service or program will close, and document the notification in each patient's or resident's record. Notification shall specify the date of closure.

(B) The Licensed or Approved Provider shall develop a written referral plan in collaboration with each patient and resident that includes a plan for continuing the patient's or resident's substance use disorder treatment, including directly connecting patients and residents to an appropriate provider for continued treatment. If insufficient time remains to ensure an appropriate referral plan with respect to an involuntary closure, the Licensed or Approved Provider shall cooperate with the Department and the patient or resident to ensure an appropriate referral, if required.

(C) The Commissioner may waive the 90-day time frame for initial notification of closure in circumstances where the Commissioner has determined such a waiver is necessary to protect the health, safety, and well-being of the patients and residents served by the program.

(D) The Department may grant permission for the temporary closure of the service or program provided that:

- (1) the Licensed or Approved Provider has submitted a plan for continued substance use disorder treatment for all patients and residents during the temporary closure; and
- (2) the Licensed or Approved Provider may only close after approval from the Department.

PART TWO: REQUIREMENTS FOR SERVICE PROVISION

164.099: Special Projects

(A) The Department will consider proposals for Special Projects for the innovative delivery of substance use disorder services. No such proposal shall be implemented without prior written approval of the Department. Special projects may be time limited and may be subject to conditions by the Department.

(B) Special projects shall include an organized system of substance use disorder treatment services delivered in a model that meets the immediate need(s) for a special population that is determined to be underserved by existing licensed substance use disorder treatment models.

(C) Services provided by special projects shall not pose a threat to patient health and safety, and shall be delivered in an evidence-based, trauma-informed manner while demonstrating positive outcomes for patients.

(D) Any proposal for a special project approval from the Department must meet the definition of Substance Use Disorder Treatment and Substance Use Disorder Treatment Program under 105 CMR 164.005.

(E) An application for a special project approval must be submitted in a manner prescribed by the Department. The application shall:

- (1) Demonstrate the need for the service;
- (2) Describe the innovative delivery of the service and how it will satisfy the current need;
- (3) Meet all applicable requirements in 105 CMR 164.000 Part One;
- (4) Include one or more treatment service components within 105 CMR 164.000 Part Two;
- (5) Demonstrate that the innovative service delivery model is evidence-based and consistent with medical efficacy; and
- (6) Comply with all applicable state and federal requirements.

164.100: 24-hour Diversionary Services164.101: Scope

24-hour Diversionary Services medically manage withdrawal symptoms of patients on a 24-hour diversionary service basis, and include 24-hour diversionary service forms of Acute Treatment Services (ATS) and Clinical Stabilization Services (CSS). Acute Treatment Services encourage the patient's continued participation in treatment after discharge, and conclude by directly connecting the patient to appropriate recovery and rehabilitation services. In addition to all provisions of 105 CMR 164.000: *Part One*, the provisions of 105 CMR 164.103 through 105 CMR 164.110 apply to all Licensed or Approved Providers providing 24-hour Diversionary Services. A Licensed or Approved Provider that meets the requirements for a determined service type under 105 CMR 164.100 through 105 CMR 164.153 may also deliver services to lower acuity patients, provided that the Licensed or Approved Provider meets all applicable staffing and service requirements for each additional service type.

164.103: Physical Plant

(A) Building Design. Each program shall provide adequate space to accommodate the number of patients served, including sufficient and separate space for the following, which may not be used as bedrooms for patients or staff:

- (1) Individual and group counseling sessions;
- (2) A living room or common area;
- (3) A visiting area;
- (4) A kitchen area and a dining area; and
- (5) Recreation and/or exercise area.

(B) Compliance with Building Standards. The Licensed or Approved Provider shall comply with the standards specified in 780 CMR: *State Board of Building Regulations and Standards*, and those standards in 105 CMR 410.000: *Minimum Standards of Fitness for Human Habitation (State Sanitary Code: Chapter II)* regarding heating, electricity, lighting, plumbing and sanitary facilities.

(C) Bathrooms and Personal Hygiene. The Licensed or Approved Provider shall ensure that:

- (1) Female and male patients have separate toilet and bathroom facilities;
- (2) Rooms containing a toilet or shower shall be separate and allow for privacy;
- (3) All showers and tubs are equipped with a nonslip surface or mat; and
- (4) All toilets have seats.

(D) Sleeping Rooms. The Licensed or Approved Provider shall ensure that:

- (1) All sleeping rooms are conveniently located near toilet and bathing facilities;
- (2) Female and male residents have separate sleeping quarters;
- (3) Sleeping rooms are designed to promote comfort and provide adequate space and privacy, and meet the following requirements:
 - (a) accommodate no more than six persons per sleeping area;
 - (b) a separate bed for each patient; and
 - (c) may not be an unfinished attic, stairway, hall or room commonly used for other purposes.
- (4) The sleeping area has the following basic equipment and supplies:
 - (a) a twin-size bed with a fire-retardant twin-size mattress in good condition and waterproof mattress cover. Each mattress shall be cleaned or replaced when soiled or when not in good condition. Each mattress pad shall be cleaned when soiled and at least every three months, and replaced when not in good condition. Cots may not be used;
 - (b) adequate drawer and closet space;
 - (c) an adequate supply of bed linens, blankets, pillows, washcloths and towels, which are in good condition. Linens, blankets, washcloths and towels shall be laundered before each new admission, or once a week, whichever occurs sooner; and
 - (d) a toothbrush, toothpaste and basic hygiene supplies.

164.104: Meals and Food Handling

(A) Inspections. The Licensed or Approved Provider shall ensure that food storage and preparation areas meet the standards defined in 105 CMR 590.000: *Minimum Standards for Food Establishments*, and that the food service is inspected and receives a food service permit by the local board of health, where applicable.

(B) Purchased Food Services. A Licensed or Approved Provider shall purchase only from a licensed food service establishment. A Licensed or Approved Provider that purchases from a food service shall obtain from the food service provider documentation of all required inspections, licenses, and conformance with sanitary standards. Such documentation shall include copies of a current license and the most recent inspection report.

(C) Meals. The Licensed or Approved Provider shall provide a nourishing well-balanced diet to all patients, and shall provide the following:

- (1) Dining areas that are clean, well-lit, ventilated and appropriately furnished;
- (2) A dining room large enough so all patients may eat at an appropriate hour, but not necessarily simultaneously;
- (3) Three meals each day;
- (4) Food and beverages for snacks;
- (5) Menus for each week planned prior to the start of the week, dated and maintained for three months; and
- (6) Means to provide for patients with special dietary needs, including food allergies.

164.105: Safe Storage and Administration of Medications

(A) Licensed and Approve Providers providing medically managed or medically monitored withdrawal treatment services shall comply with all federal and state laws and regulations relating to the procurement, storage, dispensing, administration, recording and disposal of medications and shall comply with the following:

- (1) Written Policy and Procedure. The Licensed or Approved Provider shall establish a written policy and procedure governing the storage and administration of patients' prescription medications.
- (2) Storage. All medications shall be maintained in a locked, secure cabinet, accessible only to designated staff positions. The titles of designated positions shall be posted on the cabinet. The Licensed or Approved Provider shall ensure that patients do not have direct access to the medication cabinet.
- (3) Approval of Medication. The Licensed or Approved Provider shall take possession of a patient's prescription and over-the-counter medication upon admission. The medical director or their delegated qualified healthcare professional shall assess such medication(s) in light of the medical examination and medical services to be provided to determine whether the patient should continue to take these medications and based upon this determination shall implement a process for adjusting the medication regimen.
- (4) Medications brought by patients to the program shall be stored in a locked, secure cabinet separate from the facility's supply, except that patients shall retain medications required to treat acute episodes, such as asthma attacks or allergic reactions.
 - (a) If injectable drugs are used, Licensed and Approved Provider shall provide containers for safe storage, and proper disposal of sharps.
 - (b) Medications requiring refrigeration shall be kept in a refrigerator in the same area where other medications are stored. Medications shall not be stored in kitchen refrigerators.
 - (c) The Licensed or Approved Provider shall also establish a record of medications which remain in the possession of patients for treatment of acute episodes.
- (5) Prescription medication presented by a patient shall bear a pharmacy label, which shows the date of filling, the pharmacy name and address, the filling pharmacist's initials, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, the name of the prescribed medication, directions for use and cautionary statements, if any, contained in such prescription or required by law, and if tablets or capsules, the number in the container. All over-the-counter medications shall be kept in the original containers containing the original label, which shall include the directions for use.

164.105: continued

(6) Upon admission the Licensed or Approved Provider shall document in writing the number of tablets or capsules, or the approximate amount of liquid in each prescribed medication brought by the patient. The Licensed or Approved Provider shall ensure that a similar count is conducted for all Schedule II through Schedule V medications by two staff persons at the beginning of each shift.

(7) The Licensed or Approved Provider shall maintain documentation of all medications stored and disposed of.

(8) Self-administration of Medications. Medications shall be self-administered by the patient, unless the Licensed or Approved Provider employs qualified health care professionals authorized to administer medications. Patients must be able to administer their own medications and, unless the Licensed or Approved Provider employs qualified health care professionals for this purpose, staff shall not administer medication to any patient. However, staff shall observe the patient ingesting the prescribed dose. Medications may not be provided to any patient if other patients are in the storage or office area. Licensed and Approved Providers shall make provision to provide a supply of medications to patients who plan to be absent from the facility when they would normally take a medication. The Licensed or Approved Provider shall maintain documentation of all administrations of medication, which shall include:

(a) Name of patient to whom medication was provided;

(b) Name of staff person observing the patient take the medication, or providing needed supply;

(c) Date and time medication was provided; and

(d) Patient initials confirming that the medication was provided and taken.

(9) Disposing of Medications. Programs shall comply with all federal and state laws and regulations relating to the procurement, storage, dispensing, administration, recording and disposal of medications.

(10) Improper Use. The Licensed or Approved Provider shall establish a policy regarding improper use of medication which:

(a) may impose corrective actions on patients who do not take medications in accordance with prescribed dose and frequency; and

(b) shall impose corrective actions on patients who illegally obtain and use prescription medications.

164.106: Patient Personal Effects and Affairs

(A) Written Policy and Procedure. The Licensed or Approved Provider shall establish a written policy and procedure governing care of patient personal belongings and support of patient personal affairs.

(B) Safekeeping. The Licensed or Approved Provider may allow patients to bring monies and valuables into the program, if the licensee provides for the secure, locked storage of the personal property.

(C) Right to Confiscate. All patients shall be notified that by accepting admission they authorize the Licensed or Approved Provider to:

(1) confiscate and dispose of any alcohol or drugs (other than those properly provided by prescription) or paraphernalia for the use of illegal drugs found in the possession of the patient;

(2) confiscate any weapons or other articles found in the possession of the patient, which may constitute a threat to the life, health, safety, or well-being of the patient, the staff or public, and to turn over any guns to the police.

(D) The Licensed or Approved Provider shall establish a record of any items confiscated or turned over to the police.

(E) The Licensed or Approved Provider shall establish written procedures governing patients' use of telephones, cell phones or other communication devices, and sending and receiving mail. The Licensed or Approved Provider may not hold mail or restrict the sending of mail. The Licensed or Approved Provider may not open residents' mail, but may require that residents open letters or packages in the presence of staff.

164.107: Required Agreements

Licensed and Approved Providers providing medically monitored or medically managed withdrawal services shall have QSOAs for the provision of the following services as needed:

- (A) Psychiatric consultative, diagnostic and evaluative services;
- (B) Acute 24-hour diversionary service medical or psychiatric hospitalization;
- (C) Emergency medical and psychiatric services; and
- (D) Any specialized services a program provides through special arrangement, purchase or contract.

164.108: Death of a Patient

The Licensed or Approved Provider shall develop procedures to be followed in the event of the death of a patient. These procedures shall conform with laws governing the report of death to local authorities and the requirements of 105 CMR 164.035(F), and shall include the following:

- (A) Local emergency services (911) shall be notified immediately.
- (B) The Licensed or Approved Provider shall comply with all laws concerning declaration of death and moving the deceased.
- (C) The Licensed or Approved Provider shall make reasonable efforts to notify the deceased's emergency contact. A written record of these efforts shall be included in the patient's record.

164.110: Hours of Operation

The Licensed or Approved Provider shall provide admission and services 24 hours per day, seven days per week.

164.131: 24-hour Diversionary Medically Managed Withdrawal Management Services

164.132: Scope

Provisions of 105 CMR 164.133 through 105 CMR 164.134 apply to 24-hour diversionary withdrawal management services (ASAM Level 3.7 and 4.0). The Licensed or Approved Provider shall also comply with all provisions of 105 CMR 164.000: *Part One*, 105 CMR 164.103 through 105 CMR 164.110, and, for any Licensed or Approved Provider who is also a federally-certified Opioid Treatment Provider, the provisions of 105 CMR 164.300 through 105 CMR 164.317. Licensed or Approved Providers approved to provide these services may also provide a less intensive service, provided that the Provider has the required programming and required staff.

164.133: Provision of Services

(A) Admission.

(1) The Licensed or Approved Provider shall determine the appropriate type of 24-hour diversionary service based upon the following:

(a) Intensive 24-hour Diversionary Withdrawal Management Services (ASAM Level 4): Intensive 24-hour diversionary withdrawal management services are provided to patients who require this service type because:

1. current and potential withdrawal symptoms are severe, constitute a risk to the patient's health and well-being and require frequent medical attention; and
2. the patient's incapacity results from a substance use disorder or a mental or behavioral disorder due to psychoactive substance use.

(b) 24-hour Diversionary Withdrawal Management Services (ASAM Level 3.7): 24-hour diversionary withdrawal management services are provided to patients who require this service type because:

164.133: continued

1. the patient's current or potential withdrawal symptoms constitute a risk to the patient's health and well-being and require medical monitoring; and
 2. the patient's incapacity results from a substance use disorder or a mental or behavioral disorder due to psychoactive substance use.
- (2) Initial Physical Assessment. Immediately upon admission a brief physical assessment of the patient shall be made by a qualified health care professional.

(B) Assessments. Pursuant to 105 CMR 164.072(B), the Licensed or Approved Provider may initiate patient treatment prior to completion of the assessment required by 105 CMR 164.072 upon obtaining sufficient information to initiate treatment for the acute problem at the time of presentation and that the assessment is subsequently completed in a reasonable timeframe, provided that a Qualified Healthcare Professional must see such a patient or resident prior to initiating an FDA-approved medication for treatment of addiction.

(C) In addition to the assessment required by 105 CMR 164.572, the Licensed or Approved Provider shall ensure an initial medical examination, which conforms to principles established by the American Society of Addiction Medicine, is completed for all patients within 24 hours of admission.

- (1) The physical examination shall include:
 - (a) tests for the presence of opioids, alcohol, benzodiazepines, cocaine, all FDA-approved medications for addiction treatment, and any other drugs the Licensed or Approved Provider determines are clinically indicated or as approved by the Commissioner and listed in Department guidance;
 - (b) a brief mental status exam; and
 - (c) an assessment of pulmonary, liver, and cardiac abnormalities; dermatological and neurological sequelae of addiction; possible infectious serologies if indicated; possible concurrent surgical problems; and any other relevant laboratory studies as clinically indicated.

These laboratory tests are not required to be completed prior to the initiation of medication for addiction treatment. Any relevant laboratory findings shall be documented and reviewed with the Medical Director and findings reviewed with the patient. Evidence of direct referrals to address findings shall be properly documented. The Licensed or Approved Provider shall ensure laboratory tests are completed by licensed facilities that comply with all applicable federal and state licensure and certification requirements.

(2) The license Licensed or Approved Provider shall also ensure the patient's current prescription medications are assessed in relation to interactions with medication prescribed in the course of treatment including, but not limited to, a review of MassPAT. Prior to prescribing, dispensing or administering an approved opioid agonist medication, the Licensed or Approved Provider shall ensure the approved medication is not contraindicated by the patient's current prescribed medications or health status.

(3) For women of child-bearing age, the Licensed or Approved Provider shall include a pregnancy test in the physical examination.

(4) If the examination is conducted by a qualified health care professional who is not a physician, the results of the examination and any recommendations arising from the examination shall be reviewed by the Medical Director or their delegated qualified healthcare professional prior to implementation.

(5) All medical orders shall be signed by the Medical Director or their delegated qualified healthcare professional.

(6) When readmitting a patient who had been admitted within the previous three months, the timing, frequency and interval of a complete physical examination shall be subject to Practitioner discretion, providing that no more than three months elapse between physical examinations.

(7) If, within 30 calendar days of admission to 24-hour diversionary withdrawal management treatment, a patient is transferred to a different level of withdrawal management care, the Licensed or Approved Provider to whom the patient is transferred shall, with the patient's consent, request:

- (a) results of the physical examination described in 105 CMR 164.133(C)(1); and
- (b) for women of child-bearing age, results of the pregnancy and related tests described in 105 CMR 164.133(C)(3).

164.133: continued

(D) Diversion Control. The Licensed or Approved Provider shall maintain a diversion control plan using measures to reduce the possibility of diversion of controlled substances that are FDA-approved for the treatment of opioid dependency.

(E) Treatment Services.

- (1) The Licensed or Approved Provider shall provide managed withdrawal treatment services as determined by the physical examination.
- (2) Once the patient receives medical clearance to participate, the Licensed or Approved Provider shall provide the patient with at least four hours of service programming each day. The programming shall include services specified in 105 CMR 164.074, and may be provided directly or through QSOAs.
- (3) The Licensed or Approved Provider shall provide at least one multidisciplinary team review for each patient stay.

(F) Termination and Discharge. In addition to the termination and discharge requirements delineated in 105 CMR 164.075, the Licensed or Approved Provider's written procedures shall include the following provisions and shall incorporate these provisions into the policies as described in 105 CMR 164.040 and 105 CMR 164.081:

- (1) Criteria for medical discharge; and
- (2) Procedures for emergency and involuntary terminations in accordance with the following:
 - (a) In an emergency situation, where the patient's continuation in the program presents an immediate and substantial threat of physical harm to other patients, program personnel or property or where the continued treatment of a patient presents a serious medical risk to the patient as determined by the medical director or the nurse-in-charge, the Licensed or Approved Provider may suspend a patient immediately and without provision for further withdrawal management or Referral. The patient shall be afforded the right to an appeal as described in the program policies and as required by 105 CMR 164.080.
 - (b) In a nonemergency situation, wherein the patient's continuation does not present the immediate and substantial threat or serious medical risk described in 105 CMR 164.133(F)(2)(a), the Licensed or Approved Provider may not terminate the patient without first affording the patient the procedural rights defined in 105 CMR 164.079 and 105 CMR 164.080.

164.134: Staffing Pattern

(A) The Licensed or Approved Provider shall designate a Medical Director who shall be responsible for administering all medical services performed by the program. The Medical Director shall have documented clinical experience with opioid-dependent, alcohol, and other drug-dependent persons or 40 hours of documented continuing education credit in addiction medicine and medications for treatment of addiction, including all FDA-approved medications for treatment of opioid use disorder. The Medical Director shall be responsible for:

- (1) Ensuring that each patient receives a medical evaluation, including a medical history;
- (2) Ensuring that appropriate laboratory studies have been performed; and
- (3) Establishing an individualized signs of life check protocol for each patient to be documented in the medical record.

(B) In addition to the staffing requirements of 105 CMR 164.048, the Licensed or Approved Provider shall establish a staffing pattern in sufficient numbers and positions necessary for the service type provided. Any program which serves persons who identify as male or female must have a plan in place for ensuring at least one direct care staff person on-site who identifies as female and one direct care staff person who identifies as male on each overnight shift. Staffing pattern shall include the following positions:

- (1) A full-time equivalent Senior Clinician among direct service staff who shall be responsible for the clinical/educational operation of the substance use disorder service;
- (2) Licensed psychiatrist or licensed psychologist on staff or available through QSOAs;
- (3) Registered nurse, advanced practice registered nurse, or physician assistant;
- (4) Licensed practical nurse, case aides and case management staff;
- (5) If serving pregnant women, an obstetrician/gynecologist available on staff or through a QSOA;

164.134: continued

- (6) Food personnel trained in safe and sanitary food handling and preparation, as specified in 105 CMR 590.000: *Minimum Sanitation Standards for Food Establishments* and 150 CMR 590.003: *Management and Personnel*. Food service permits, where required, shall be current and available for review by Department personnel; and
- (7) Sufficient staff coverage on all shifts to ensure patient needs are met. Such staffing shall include the following staffing minimums, which shall be adjusted upward in order to address patient acuity and programmatic need:
- (a) Licensed nursing staff shall be on-site for a minimum of eight hours per shift, provided that each day and evening shift includes at least one registered nurse seven days per week;
 - (b) The Provider must provide a minimum one recovery specialist for all shifts, seven days per week; and
 - (c) The Provider must provide at least two case managers providing services over a 12-hour time period, seven days per week.
- (8) Any Provider who treats patients younger than 18 years old must have a Case Manager on staff and provide sufficient staff coverage on all shifts to ensure patient needs are met. Such staffing shall include the following staffing minimums, which shall be adjusted upward in order to address patient acuity and programmatic need:
- (a) A minimum of one full-time registered nurse responsible for supervision of all nursing staff, or a Licensed Practical Nurse (LPN) or other Qualified Health Care Professional provider defined under 105 CMR 164.005 who possesses the skills and supervision experience as determined by program and/or meets the requirements under professional licensure; provided, however that the supervisor shall be educationally prepared at or above the level of the nursing staff under his or her supervision;
 - (b) A minimum of one full-time recovery specialist for all shifts;
 - (c) Case manager staffing such that there is a minimum of eight hours of case management services provided at least five days per week;
 - (d) Counselors on-site for a minimum of 12 hours per day, seven days per week; and
 - (e) One full-time Clinical Director that meets the definition of a Senior Clinician on-site a minimum of five days per week to provide supervision and oversight of the provision of clinical services.

(C) Clinical Supervision. In addition to supervision requirements set forth in 105 CMR 164.044, the Licensed or Approved Provider shall ensure that supervision of nursing staff is overseen by a Practitioner, a registered nurse, or a Licensed Practical Nurse (LPN) or other Qualified Health Care Professional provider defined under 105 CMR 164.005 who possesses the skills and supervision experience as determined by program and/or meets the requirements under professional licensure; provided, however that the supervisor shall be educationally prepared at or above the level of the nursing staff under his or her supervision.

(D) The Licensed or Approved Provider shall ensure a qualified Practitioner is available 24 hours per day, seven days per week, on site, through a QSOA, or by the use of telemedicine as appropriate and in the discretion of the Practitioner, to provide consultation to staff. If services are to be available through an agreement, this agreement shall be reaffirmed at minimum every five years.

164.150: Clinical Stabilization Services

164.151: Scope

Clinical Stabilization Services (ASAM Level 3.5) are provided in a nonmedical setting and include 24 hour per day supervision, observation and support. Provisions of 105 CMR 164.152 through 105 CMR 164.153 apply to Clinical Stabilization Services. The Licensed or Approved Provider shall also comply with all provisions of 105 CMR 164.00: *Part One*, 105 CMR 164.103 through 105 CMR 164.110 and, for any Licensed or Approved Provider who is also a federally-certified Opioid Treatment Provider, the provisions of 105 CMR 164.300 through 105 CMR 164.317.

164.152: Provision of Services

(A) At the time of admission, the Licensed or Approved Provider shall determine that the patient requires this service type because:

- (1) the patient's current and potential withdrawal symptoms are not severe; and
- (2) the patient's incapacity results from a substance use disorder or dual diagnosis.

(B) Assessment. Pursuant to 105 CMR 164.072(B), the Licensed or Approved Provider may initiate patient treatment prior to completion of the assessment required by 105 CMR 164.072 upon obtaining sufficient information to initiate treatment for the acute problem at the time of presentation and that the assessment is subsequently completed in a reasonable timeframe, provided a Qualified Healthcare Professional must see such a patient prior to initiating an FDA-approved medication for treatment of addiction.

(C) Initial Medical Examination. In addition to the assessment required by 105 CMR 164.072, the Licensed or Approved Provider shall ensure each patient has an initial medical examination, which conforms to principles established by the American Society of Addiction Medicine and is completed for all patients within 24 hours of admission. The Medical Director can defer as clinically indicated any of the requirements below if a patient is directly referred from a practitioner who has completed an examination, or components of an examination, which fulfill the requirements of 105 CMR 164.152(C)(1)(a) through (c).

(1) The examination shall include:

- (a) tests for the presence of opioids including, but not be limited to, buprenorphine, methadone, and fentanyl; alcohol; benzodiazepines; cocaine; and any other drugs the Licensed or Approved Provider determines are clinically indicated or as approved by the Commissioner and listed in Department guidance;
- (b) a brief mental status exam; and
- (c) an assessment of pulmonary, liver, and cardiac abnormalities; dermatological and neurological sequelae of addiction; possible infectious serologies if indicated; and possible concurrent surgical problems. These laboratory tests are not required to be completed prior to the initiation of medication for addiction treatment. Any relevant laboratory findings shall be documented and reviewed with the patient and medical director. Evidence of direct referrals to address findings shall be properly documented. The Licensed or Approved Provider shall ensure laboratory tests are completed by licensed facilities that comply with all applicable federal and state licensure and certification requirements.

(2) The Licensed or Approved Provider shall also ensure the patient's current prescription medications are assessed in relation to interactions with medication prescribed in the course of treatment including, but not limited to, a review of MassPat. When appropriate, prior to prescribing, dispensing or administering an approved opioid agonist medication the Licensed or Approved Provider shall ensure the approved medication is not contraindicated by the patient's current prescribed medications or health status.

(3) For women of child-bearing age, the Licensed or Approved Provider shall include a pregnancy test in the physical examination.

(4) If the examination is conducted by a qualified health care professional who is not a physician, the results of the examination and any recommendations arising from the examination shall be reviewed by the medical director or their delegated qualified healthcare professional prior to implementation.

(5) All medical orders shall be signed by the medical director or their delegated qualified healthcare professional.

(6) When readmitting a patient who had been admitted within the previous three months, the timing, frequency and interval of a complete physical examination shall be subject to physician discretion, providing that no more than three months elapse between physical examinations.

(D) Treatment Services.

(1) Once the patient receives medical clearance to participate, the Licensed or Approved Provider shall provide the patient with at least four hours of service programming each day. The programming shall include services specified in 105 CMR 164.074, and may be provided directly or through QSOAs.

(2) The Licensed or Approved Provider shall provide at least one multidisciplinary team review for each patient stay.

164.152: continued

(E) Termination and Discharge. In addition to the termination and discharge requirements delineated in 105 CMR 164.075, the Licensed or Approved Provider's written procedures shall include the following provisions and shall incorporate these provisions into the policies as described in 105 CMR 164.040 and 105 CMR 164.081:

- (1) Criteria for medical discharge;
- (2) Procedures for emergency and involuntary terminations in accordance with the following:
 - (a) In an emergency situation, where the patient's continuation in the program presents an immediate and substantial threat of physical harm to other patients, program personnel or property or where the continued treatment of a patient presents a serious medical risk to the patient as determined by the medical director or the nurse-in-charge, the Licensed or Approved Provider may suspend a patient immediately and without provision for further withdrawal management or Referral. The patient shall be afforded the right to an appeal as described in the program policies and as required by 105 CMR 164.080.
 - (b) In a nonemergency situation, wherein the patient's continuation does not present the immediate and substantial threat or serious medical risk described in 105 CMR 164.133(E)(2)(a), the Licensed or Approved Provider may not terminate the patient without first affording the patient the procedural rights defined in 105 CMR 164.079 and 164.080.

164.153: Staffing Pattern

(A) The Licensed or Approved Provider shall designate a physician as Medical Director who shall be responsible for administering all medical services performed by the program. The Medical Director shall have documented clinical experience or 40 hours of documented continuing education credit in addiction medicine and medications for treatment of addiction, including all FDA-approved medications for treatment of opioid use disorder. The Medical Director or designee shall be responsible for:

- (1) Ensuring each patient receives a medical evaluation, including a medical history;
- (2) Ensuring appropriate laboratory studies have been performed; and
- (3) Establishing an individualized signs of life check protocol for each patient to be documented in the medical record.

(B) The Licensed or Approved Provider shall establish a staffing pattern in sufficient numbers and positions necessary for the service type provided. Staffing pattern shall include the following positions:

- (1) A full-time equivalent Senior Clinician among direct service staff who shall be responsible for the clinical/educational operation of the substance use disorder service;
- (2) Licensed psychiatrist or licensed psychologist on staff or available through QSOAs;
- (3) Registered nurse, nurse practitioner, licensed practical nurse or physician assistant;
- (4) At least one full time counselor, recovery specialist and case management/care coordinator staff;
- (5) If serving pregnant women, an obstetrician/gynecologist available on staff or through a QSOA;
- (6) Food personnel trained in safe and sanitary food handling and preparation, as specified in 105 CMR 590.000: *Minimum Sanitation Standards for Food Establishments*, and 105 CMR 590.003: *Management and Personnel*. Food service permits, where required, shall be current and available for review by Department personnel; and
- (7) Sufficient staff coverage on all shifts to ensure patient needs are met. Such staffing shall include the following staffing minimums, which shall be adjusted upward to address patient acuity and programmatic need:
 - (a) Licensed nursing staff shall be on-site for a minimum of four hours per day, seven days per week;
 - (b) The Provider must provide, at minimum, one recovery specialist on all shifts;
 - (c) The Provider must provide, at minimum, the full-time equivalent of 2.5 counselors to be present at the program over a 12-hour span, seven days per week;
 - (d) The Provider must provide, at minimum, the full-time equivalent of one care coordinator to be present at the program five days per week; and
 - (e) Any provider with a program serving persons who identify as male or female must have a plan in place ensuring at least one direct care staff person on-site who identifies as female, and one direct care staff person who identifies as male.

164.153: continued

(C) The Licensed or Approved Provider shall ensure a qualified physician is available 24 hours per day, seven days per week, on-site, through a QSOA, or by the use of telemedicine as appropriate and in the discretion of the Practitioner, to provide consultation to staff. If services are to be available through an agreement, this agreement shall be reaffirmed at a minimum every five years.

164.200: Outpatient Services

Outpatient Services encompass provision of services to patients who can participate in organized ambulatory services including withdrawal symptom management, intensive day treatment services, counseling, educational services for driving under the influence first offenders, and office-based opioid treatment. Programs may provide services through telemedicine as appropriate and based on federal guidance.

164.201: Scope

Provisions of 105 CMR 164.202 through 164.205 apply to outpatient substance use disorder treatment services provided by Program. The Licensed or Approved Provider shall also comply with all provisions of 105 CMR 164.000: *Part One*. A Licensed or Approved Provider that meets the requirements for a determined service type under 105 CMR 164.200 through 105 CMR 164.280 may also deliver other outpatient service types, provided that the Licensed or Approved Provider meets all applicable staffing and service requirements for each additional service type.

164.202: Provision of Services

(A) Admission. At the time of admission, the Licensed or Approved Provider shall determine whether outpatient counseling services are appropriate based on:

- (1) the existence of a substance use disorder or a mental or behavioral disorder due to psychoactive substance use;
- (2) ability to engage and remain in treatment; and
- (3) availability of community support for recovery.

(B) Assessment. Pursuant to 105 CMR 164.072(B), the Licensed or Approved Provider may initiate patient treatment prior to completion of the assessment required by 105 CMR 164.072 upon obtaining sufficient information to initiate treatment for the acute problem at the time of presentation and that the assessment is subsequently completed in a reasonable timeframe, provided that a Qualified Healthcare Professional must see such a patient prior to initiating an FDA-approved medication for treatment of addiction.

(C) Treatment. The Licensed or Approved Provider shall provide individual, group, couple and family therapies. The Licensed or Approved Provider shall provide individual and group therapies directly, and shall provide couple and family therapies directly or through QSOAs.

(D) Staffing Pattern. The Licensed or Approved Provider shall establish a staffing pattern in sufficient numbers and positions necessary for the service type provided. Staffing pattern shall include the following positions:

- (1) A full-time equivalent Senior Clinician among other clinical and direct service staff who shall be responsible for the clinical/educational operation of the substance use disorder service;
- (2) Licensed psychiatrist or licensed psychologist, licensed mental health counselor, or licensed social worker on staff or available through a QSOA;
- (3) Additional direct service clinical staff, as needed, to ensure service is provided through a multidisciplinary team as required by 105 CMR 164.048(A)(2);
- (4) Staffing in sufficient numbers to provide coverage on all shifts; and
- (5) A Senior Clinician or Clinician to provide group education sessions where the Licensed or Approved Provider provide Driver Alcohol or Controlled Substance Education Services.

164.205: Hours of Operation

The program shall be open to provide services 40 hours per week. At least seven hours shall be at a time other than between 9:00 A.M. to 5:00 P.M. Monday through Friday. Satellite office

164.205: continued

shall be open to patients at least 20 hours a week and offer more than 40 staff hours a week of substance use disorder treatment services to patients.

164.206: Outpatient Withdrawal Treatment Services

Provisions of 105 CMR 164.206 through 105 CMR 164.209 apply to outpatient substance use disorder withdrawal management treatment services. The Licensed or Approved Provider shall also comply with all provisions of 105 CMR 164.000: *Part One*, 105 CMR 164.201 through 105 CMR 164.205, and, for any Licensed or Approved Provider who is also a federally-certified Opioid Treatment Provider, the provisions of 105 CMR 164.300 through 105 CMR 164.317.

164.207: Provision of Service

(A) Admission. Pursuant to 105 CMR 164.072(B), the Licensed or Approved Provider may initiate patient treatment prior to completion of the assessment required by 105 CMR 164.072 upon obtaining sufficient information to initiate treatment for the acute problem at the time of presentation and that the assessment is subsequently completed in a reasonable timeframe, provided that a Qualified Healthcare Professional must see such a patient prior to initiating an FDA-approved medication for treatment of addiction.

(B) In addition to the assessment required by 105 CMR 164.072, the Licensed or Approved Provider shall make as part of the patient record a medical evaluation by a Practitioner, psychiatrist, registered nurse, or licensed practical nurse, which confirms that the patient requires outpatient withdrawal management services based on:

- (1) an assessment of the current and potential withdrawal symptoms of the patient;
- (2) the patient's need for a structured program with frequent contact in order to engage in treatment; and
- (3) an assessment as to whether the community in which the patient resides poses a threat to the patient's abstinence.

(C) Medical Examination. In addition to the assessment requirements of 105 CMR 164.072, the Licensed or Approved Provider shall ensure an initial medical examination, which conforms to principles established by the American Society of Addiction Medicine, is completed for all patients within 24 hours of admission.

- (1) The physical examination shall include:
 - (a) tests for the presence of opioids including, but not be limited to, buprenorphine, methadone, and fentanyl; alcohol; benzodiazepines; cocaine; and any other drugs the Licensed or Approved Provider determines are clinically indicated or as approved by the Commissioner and listed in Department guidance;
 - (b) a brief mental status exam; and
 - (c) an assessment of pulmonary, liver, and cardiac abnormalities; possible infectious serologies if indicated; dermatological and neurological sequelae of addiction; possible concurrent surgical problems; and any other relevant laboratory studies as clinically indicated. When indicated, laboratory tests for these conditions shall be ordered.

These laboratory tests are not required to be completed prior to the initiation of medication for addiction treatment. Any relevant laboratory findings shall be documented and reviewed with the patient and medical director. Evidence of direct referrals to address findings shall be properly documented. The Licensed or Approved Provider shall ensure laboratory tests are completed by licensed facilities that comply with all applicable federal and state licensure and certification requirements.

- (2) The Licensed or Approved Provider shall ensure the patient's current prescription medications are assessed in relation to interactions with medication prescribed in the course of treatment. Prior to prescribing, dispensing or administering an approved opioid agonist medication, the Licensed or Approved Provider shall ensure the approved medication is not contraindicated by the patient's current prescribed medications or health status.
- (3) For women of child-bearing age, the Licensed or Approved Provider shall include a pregnancy test in the physical examination.
- (4) If the examination is conducted by a qualified health care professional who is not a physician, the results of the examination and any recommendations arising from the examination shall be reviewed by the nursing supervisor prior to implementation.

164.207: continued

- (5) All medical orders shall be signed by the medical director or their designated practitioner pursuant to their scope of practice.
- (6) When re-admitting a patient who had been admitted within the previous three months, the timing, frequency and interval of a complete physical examination shall be subject to Practitioner discretion, provided that no more than three months elapses between physical examinations.

(D) Treatment.

- (1) The Licensed or Approved Provider shall provide withdrawal management services after determining through physical examination such services are required.
- (2) Upon receiving medical clearance to participate in treatment services, the Licensed or Approved Provider shall provide each patient with at least nine hours of service programming each week.
- (3) Treatment shall include services specified in 105 CMR 164.074, and shall be provided either directly or through QSOAs. Services must also include:
 - (a) a primary counselor to provide case management and motivational counseling that focus on engaging the patient to remain in withdrawal management services; and
 - (b) supportive counseling during the relapse prevention phase to motivate the patient to utilize ongoing substance use disorder outpatient treatment and self-help groups.

(E) Diversion Control. The Licensed or Approved Provider shall maintain a diversion control plan using measures to reduce the possibility of diversion of controlled substances that are FDA-approved for the treatment of opioid dependency, which shall include:

- (1) For patients who test positive for any FDA approved medications treatment of opioid use disorder at admission, procedures for determining whether patients are enrolled in an opioid treatment program or are prescribed any medications for treatment of opioid use disorder, and documentation of actions taken in patient records;
- (2) Assignment of specific responsibility to the Medical Director and administrator for carrying out the diversion control measures and functions described in the plan; and
- (3) Initial review of the patient's prescription history through the MassPAT.

164.208: Staffing Pattern

(A) The Licensed or Approved Provider shall designate a Medical Director who shall be responsible for administering all medical services performed by the program. The Medical Director shall have documented clinical experience with opioid-dependent, alcohol and other drug-dependent persons and medications used for treatment of addiction, including all FDA-approved medications for treatment of opioid use disorder. The Medical Director shall be responsible for:

- (1) Ensuring each patient receives a complete physical examination, including a medical history;
- (2) Ensuring appropriate laboratory studies have been performed; and
- (3) Establishing an individualized signs of life check protocol for each patient to be documented in the medical record.

(B) The Licensed or Approved Provider shall establish a staffing pattern in sufficient numbers and positions necessary for the service type provided. Staffing pattern shall include the following positions:

- (1) Senior Clinician among direct service staff, who shall be responsible for the clinical/educational operation of the substance use disorder service;
- (2) Licensed psychiatrist or licensed psychologist on staff or available through QSOAs;
- (3) Registered nurse, advanced practice registered nurse, or physician assistant on staff and on-site during hours of operation of the service;
- (4) Licensed practical nurse, case aides and case management staff;
- (5) If serving pregnant women, an obstetrician/gynecologist available on staff or through a QSOA; and
- (6) Sufficient staff coverage on all shifts to ensure patient needs are met.

164.208: continued

(C) Supervision. In addition to supervision requirements set forth in 105 CMR 164.044 Training and Supervision, the Licensed or Approved Provider shall ensure supervision of nursing staff is overseen by either a registered nurse, or a Licensed Practical Nurse (LPN) or other Qualified Health Care Professional provider defined under 105 CMR 164.005 who possesses the skills and supervision experience as determined by program and/or meets the requirements under professional licensure; provided, however that the supervisor shall be educationally prepared at or above the level of the nursing staff under his or her supervision.

(D) The Licensed or Approved Provider shall ensure a qualified Practitioner is available during all hours when service is provided, either on-site or through a QSOA, to provide consultation to staff. If services are to be available through an agreement, this agreement shall be reaffirmed every five years.

164.209: Hours of Operation

The program shall be open to provide admission to outpatient services as well as to provide treatment seven days per week and four hours per day, at a minimum.

164.211: First Offender Driver Alcohol or Controlled Substance Education

Provisions of 105 CMR 164.211 through 105 CMR 164.215 apply to first offender driver alcohol or controlled substance education services. The Licensed or Approved Provider shall also comply with all provisions of 105 CMR 164.000: *Part One*, 105 CMR 164.201 through 105 CMR 164.205.

164.212: Provision of Services

(A) Admission and Referral.

(1) Referral. The Licensed or Approved Provider shall admit patients referred by a Massachusetts court, or, for patients younger than 21 years old, by the Registrar of Motor Vehicles, as provided for by M.G.L. c. 90, § 24P.

(2) Individuals admitted for first offender driver alcohol or controlled substances education services are not required to have a substance use disorder diagnosis.

(B) Assessment. When admitting a patient younger than 21 years old, the Licensed or Approved Provider shall also assess the patient's developmental status, including social, emotional and cognitive functioning, to determine whether the patient is able to participate in programming designed for adults.

(C) Treatment. The Licensed or Approved Provider shall provide treatment service to each patient in accordance with protocols established by the Department. Services shall include:

(1) Group education sessions which address:

- (a) consequences of patient's substance use;
- (b) dangers of drinking and/or using drugs and driving;
- (c) modifying substance use habits; and
- (d) impact of driving under the influence on others, including victims.

(2) When the assessment of a patient younger than 21 years old establishes that the patient is not developmentally able to participate in programming for adults, the Licensed or Approved Provider shall provide alternative programming addressing concerns pertinent to youth. Alternative programming shall be submitted to the Department for approval at the time of application for a license or renewal. The Department shall provide its determination approving or denying the alternative programming in writing.

(3) Special programming, either directly, through QSOAs or by referral to other programs to accommodate:

- (a) patients who do not speak English;
- (b) patients' employment, military, school and/or child care schedules; and
- (c) patients suffering from mental health disorders, which limit their ability to participate in the Licensed or Approved Provider's group programming.

(4) Referral to community-based self help group meetings.

164.212: continued

(D) Individual Treatment Plan. The treatment plan required by 105 CMR 164.073 shall be reviewed at mid-point in the group educational programming.

(E) Termination and Discharge.

(1) Involuntary Termination. the Licensed or Approved Provider shall include in its termination policy a provision for immediately notifying the referring body of the termination of any patient for failure to comply with program rules, intoxication and/or disruptive behavior.

(2) Upon completion of the treatment program, the Licensed or Approved Provider shall conduct an exit interview, and shall make referrals available to the patient to ensure a continuum of care. If the patient refuses referrals, the refusal shall be documented in the patient record.

(3) In an emergency situation, where the patient's continuation in the program presents an immediate and substantial threat of physical harm to other patients, program personnel or property or where the continued treatment of a patient presents a serious medical risk to the patient as determined by the Program Director or Senior Clinician, the Licensed or Approved Provider may discharge the patient without providing a Referral.

164.215: Hours of Operation

In addition to the requirements of 105 CMR 164.205, the Licensed or Approved Provider shall be open as necessary to provide the required services on a schedule that ensures patient access to day and evening programs, including at least one group available in the evening or on weekends.

164.223: Second Offender Alcohol or Controlled Substance Aftercare Treatment

Provisions of 105 CMR 164.223 through 105 CMR 164.224 apply to second offender alcohol or controlled substance aftercare treatment services. The Licensed or Approved Provider shall also comply with all provisions of 105 CMR 164.000: *Part One*, 105 CMR 164.201 through 105 CMR 164.205.

164.224: Provision of Services

(A) Individuals may be admitted for aftercare services following completion of a 14-day residential driving under the influence program or while awaiting placement in such a program.

(B) Counseling services shall emphasize consequences of alcohol and/or drug use while driving.

(C) The Licensed or Approved Provider shall provide regular reports of the patient's status to the referring court or other referring agency. The Licensed or Approved Provider shall provide to the referring court or agency a complete evaluation of the patient's compliance with the service plan 30 calendar days prior to the end of one complete year of outpatient treatment. One year of outpatient treatment must follow adjudication. All such reports shall comply with 105 CMR 164.084.

(D) The Licensed or Approved Provider shall ensure alcohol and drug screening is conducted on a random basis.

164.231: Day Treatment

Provisions of 105 CMR 164.231 through 105 CMR 164.234 apply to day treatment services. The Licensed or Approved Provider shall also comply with all provisions of 105 CMR 164.000: *Part One*, 105 CMR 164.201 through 105 CMR 164.205, and, for any Licensed or Approved Provider who is also a federally-certified Opioid Treatment Provider, the provisions of 105 CMR 164.300 through 105 CMR 164.317.

164.232: Provision of Services

(A) Admission. At the time of admission the Licensed or Approved Provider shall determine

164.232: continued

that day treatment services are appropriate for the patient based on:

- (1) the patient's substance use disorder;
- (2) absence of withdrawal risk; and
- (3) presence of substantial relapse risk and need for a structured program in order to engage and remain in treatment. This determination shall be made during the first visit.

(B) Treatment. The Licensed or Approved Provider shall provide each patient with:

- (1) 3.5 hours per day three to seven days per week based upon patient needs. Such service program shall meet the requirements of 105 CMR 164.074 and also include counseling, psychoeducational groups, and family counseling; and
- (2) Case management services to ensure a continuum of care for the patient, encouragement of patient use of self-help groups or other sources of community support for recovery, and aftercare service planning; provided the Licensed or Approved Provider directly connects the patient to such services.

164.234: Hours of Operation

In addition to the requirements of 105 CMR 164.205, the Licensed or Approved Provider shall ensure day treatment services are provided at a minimum of 3.5 hours per day three to seven days per week based upon patient needs.

164.240: Acupuncture Withdrawal Management Treatment Services

Provisions of 105 CMR 164.241 through 164.245 apply to acupuncture withdrawal management services. The Licensed or Approved Provider shall also comply with all provisions of 105 CMR 164.000: *Part One* and 105 CMR 164.201 through 105 CMR 164.205, and, for any Licensed or Approved Provider who is also a federally-certified Opioid Treatment Provider, the provisions of 105 CMR 164.300 through 105 CMR 164.317.

164.241: Provision of Services

(A) Assessment. Pursuant to 105 CMR 164.072(B), the Licensed or Approved Provider may initiate patient treatment prior to completion of the assessment required by 105 CMR 164.072 upon obtaining sufficient information to initiate treatment for the acute problem at the time of presentation and that the assessment is subsequently completed in a reasonable timeframe, provided that a Qualified Healthcare Professional must see such a patient prior to initiating an FDA-approved medication for treatment of addiction. In addition to the assessment required by 105 CMR 164.072 and prior to admission, the Licensed or Approved Provider shall conduct a screening to determine acupuncture is not contraindicated. The screening shall include, at a minimum:

- (1) patient's history of seizures, delirium tremens or other life-threatening withdrawal symptoms, which constitute a risk to the patient's health or well-being;
- (2) neurological evidence of an appropriate level of consciousness; and
- (3) vital signs.

(B) Admission. Upon conclusion of the assessment required by 105 CMR 164.072, the Licensed or Approved Provider shall only admit those patients with a substance use disorder who are not in a current or potential state of withdrawal that constitutes a risk to the patient's health and well-being, which requires medical attention or medical monitoring beyond the scope of the Licensed or Approved Provider's services.

(C) Treatment. The Licensed or Approved Provider shall provide intensive acupuncture administration of six treatments per week for withdrawal purposes, followed by less intensive treatment of two to three times per week for relapse prevention.

164.243: Staffing Pattern

In addition to the staffing requirements of 105 CMR 164.048, the Licensed or Approved Provider shall provide an adequate number of qualified personnel to fulfill the services objectives and patient needs. At a minimum, such staffing shall include:

164.243: continued

- (A) An acupuncturist on-site during the hours of operation.
- (B) Consultation to staff available from a fully qualified clinician, and a Practitioner, psychiatrist, registered nurse or licensed practical nurse either on-site or through an affiliation agreement. If services are to be available through a QSOA, the QSOS shall be reaffirmed every two years.
- (C) Supervision. In addition to supervision requirements set forth in 105 CMR 164.044, the Licensed or Approved Providers shall ensure supervision of nursing staff is overseen by either a registered nurse, or a Licensed Practical Nurse (LPN) or other Qualified Health Care Professional provider defined under 105 CMR 164.005 who possesses the skills and supervision experience as determined by program and/or meets the requirements under professional licensure; provided, however that the supervisor shall be educationally prepared at or above the level of the nursing staff under his or her supervision.

164.245: Hours of Operation

The Licensed or Approved Provider shall provide services a minimum of six days per week, 52 weeks per year. Daytime hours shall include morning services and ensure maximum accessibility to patients without an appointment. Hours shall include at least seven hours per week that shall be at time other than the regular 9:00 A.M. to 5:00 P.M., Monday through Friday schedule.

164.250: Office-based Opioid Treatment

Provisions of 105 CMR 164.250 through 164.260 in addition to provisions of 105 CMR 164.000: *Part One* and 105 CMR 164.201 through 105 CMR 164.205, apply to all licensed or approved for Office-based Opioid Treatment.

164.251: Provision of Services

- (A) Admission.
 - (1) Evidence of Physiologic Opioid Dependence. The Licensed or Approved Provider shall obtain evidence of a diagnosis of opioid use disorder through reliable methods such as physical examination, laboratory tests and substance use history.
 - (2) Prior to initiating treatment, the Licensed or Approved Provider shall:
 - (a) complete an assessment of patient's current prescription medications prior to prescribing, dispensing or administering an FDA-approved medication for opioid dependence to ensure the approved medication is not contraindicated by the patient's current prescribed medications or health status;
 - (b) for women of child bearing age, complete a pregnancy test before dispensing or administering or prescribing an FDA-approved medication for opioid dependence; and
 - (c) review the patient's prescription history through the MassPAT.
 - (3) Consent to Treatment. The Licensed or Approved Provider shall ensure the patient voluntarily chooses treatment. The information listed in 105 CMR 164.251(A)(3)(a) through (f) shall be provided to the patient and recorded on a consent form, which shall be signed by the patient, and a copy shall be provided to the patient. The information shall also be provided orally:
 - (a) the nature of FDA-approved medication used in opioid treatment, including benefits and risks, and the benefits and risks of not receiving treatment;
 - (b) approximate length of each type of treatment;
 - (c) a clear statement of the goals of each type of treatment, and the tasks necessary to reach those goals;
 - (d) need for the patient to inform the Licensed or Approved Provider of current medical conditions and medications the patient is currently taking;
 - (e) acknowledgement the patient may withdraw voluntarily from treatment and discontinue use of medications; and

164.251: continued

- (f) for women of child-bearing age, acknowledgement of the benefits and risks of treatment during pregnancy, and importance of informing the Licensed or Approved Provider if she is or becomes pregnant.
- (4) Consent to Treatment by Minors. Minors 12 through 17 years of age may consent to treatment without the consent of the parent or guardian upon a finding of two or more physicians that the minor is drug dependent.
- (B) Assessment. Pursuant to 105 CMR 164.072(B), the Licensed or Approved Provider may initiate patient treatment prior to completion of the assessment required by 105 CMR 164.072 upon obtaining sufficient information to initiate treatment for the acute problem at the time of presentation and that the assessment is subsequently completed in a reasonable timeframe, provided that a Qualified Healthcare Professional must see such a patient prior to initiating an FDA-approved medication for treatment of addiction.
- (C) Initial Medical Examination. In addition to the assessment required by 105 CMR 164.072, the Licensed or Approved Provider shall ensure each patient has an initial medical examination by a physician, or by a qualified health-care professional under the supervision of a program physician prior to administration of the first dose of medication. Licensed or approved providers may utilize a medical examination conducted within the last 12 months, provided there are no medical issues or changes that require examination per the clinical discretion of the facility provider and review of such a medical examination is documented in the patient's record. The examination shall include:
- (1) a brief mental status exam;
 - (2) tests for the presence of opioids including, but not be limited to, buprenorphine, methadone, and fentanyl; alcohol; benzodiazepines; cocaine; and any other drugs the Licensed or Approved Provider determines are clinically indicated or as approved by the Commissioner and listed in Department guidance; and
 - (3) an assessment of pulmonary, liver, and cardiac abnormalities; dermatological and neurological sequelae of addiction; possible infectious serologies if indicated; possible concurrent surgical problems as clinically indicated; and any other relevant laboratory studies as clinically indicated. The assessment shall include the following laboratory tests, results of which must be returned no later than 14 calendar days after admission.
- These laboratory tests are not required to be completed prior to the initiation of medication for addiction treatment. Any relevant laboratory findings shall be documented and reviewed with the patient and medical director. Evidence of direct referrals to address findings shall be properly documented. The Licensed or Approved Provider shall ensure such laboratory tests are completed by licensed facilities, which comply with all applicable federal and state laboratory licensure and certification requirements.
- (D) Documentation. In addition to the requirements of 105 CMR 164.083, a Practitioner shall:
- (1) ensure evidence of current physiological dependence is entered in the patient record;
 - (2) ensure a medical evaluation, including a medical history, is recorded;
 - (3) ensure appropriate laboratory results are documented;
 - (4) ensure a list of prescription medication, prescribed dosage(s) of all medications, the plan for changing prescribed medications if necessary, including the planned rate of withdrawal management, when applicable, are documented in the record;
 - (5) sign or countersign all medical orders;
 - (6) document program verifications made in accordance with 105 CMR 164.305(B)(3)(a); and
 - (7) document status of initial and periodic MassPAT review.
- (E) Upon Department approval, a Licensed or Approved opioid treatment provider may provide interim maintenance in accordance with federal requirements.

164.255: Additional Service Requirements for Opioid Maintenance

- (A) Drug Screening. The Licensed or Approved Provider shall provide for the following:
- (1) An initial drug-screening completed for each prospective patient as required by 105 CMR 164.305(D)(2).

164.255: continued

(2) Results of drug screening are to be used as a clinical tool and not as the sole factor in the diagnosis and treatment of the patient and for monitoring the patient's drug-use patterns before and during treatment. The Licensed or Approved Provider's Medical Director shall ensure drug screen results are not used to force a patient out of treatment, but are used as an aid in making treatment decisions.

(3) Drug screening may be done by one of the following: blood, oral swab, urine testing, or other method as defined by the Department.

(B) Pregnant Women.

(1) The Licensed or Approved Provider shall ensure each pregnant woman is fully informed concerning the possible benefits and risks of opioid treatment to herself and to the fetus. The Licensed or Approved Provider shall document provision of this information in the patient's record.

(2) The Licensed or Approved Provider shall establish a QSOA for prenatal, obstetrical and gynecological services, unless licensee provides these services directly.

(C) Medically Supervised Withdrawal Rate. The rate of medically supervised withdrawal shall be determined by a practitioner employed or contracted by the Licensed or Approved Provider, to be appropriate to the patient's medical and psychiatric conditions and the dosage level at which the patient was being medicated before the decision was made to terminate. In determining the appropriate course of dosage reduction, the medical director shall review the patient's record, and consider the patient's physical and mental health status, and with consent of the patient, may take into account the opinions of the patient's other practitioners and medical providers.

164.260: Diversion Control

The Licensed or Approved Provider shall maintain a diversion control plan using measures to reduce the possibility of diversion of controlled substances that are FDA-approved for the treatment of opioid dependency, which shall include:

(A) Random callbacks;

(B) For patients who test positive for any FDA approved medications for treatment of opioid use disorder at admission, procedures for determining whether patients are enrolled in an opioid treatment program or are prescribed any medications for treatment of opioid use disorder, and documentation of actions taken in patient records;

(C) Random drug screening; and

(D) Initial and periodic review of patient's prescription history through the MassPAT.

164.280: Mental Health Services

To provide Mental Health Services, as that term is defined in 105 CMR 164.005, a Licensed or Approved Provider must meet the applicable Mental Health Service programmatic and staffing requirements set forth in 105 CMR 140.000: *Licensure of Clinics*. The Licensed or Approved Provider shall also comply with all provisions of 105 CMR 164.000: *Part One*, 105 CMR 164.201 through 105 CMR 164.205, and, for any Licensed or Approved Provider who is also a federally-certified Opioid Treatment Provider, the provisions of 105 CMR 164.300 through 105 CMR 164.317.

164.300: Opioid Treatment Programs

Opioid treatment programs are SAMHSA-certified organized addiction treatment for opioid addicted persons, providing FDA-approved medications and counseling and other services needed to assist the patient in achieving stability. Opioid treatment includes interim maintenance, maintenance, and medically supervised withdrawal.

164.301: Scope

Provisions of 105 CMR 164.302 through 164.317, in addition to provisions of 105 CMR 164.000: *Part One*, apply to all opioid treatment with the exception of entities subject to licensure under 105 CMR 164.250.

164.302: Authority to Operate an Opioid Treatment Program

(A) Compliance with Other Laws, Rules, Regulations and Standards. In addition to 105 CMR 164.000, the Licensed or Approved Provider shall comply with the following:

- (1) M.G.L. c. 94C governing controlled substances and 105 CMR 700.00: *Implementation of M.G.L. c. 94C* governing controlled substance registration; and
- (2) 21 CFR Parts 1300 through 1399 of the U.S. Department of Justice, Drug Enforcement Administration (DEA) regulations requiring registration under the Controlled Substances Act.

(B) Current Certification. The Licensed or Approved Provider shall have a current valid certificate from the Substance Abuse and Mental Health Services Administration of the U.S. Department of Health and Human Services, in compliance with 42 CFR Part 8.

(C) Accreditation. The Licensed or Approved Provider shall be accredited by an accrediting organization approved by the Substance Abuse and Mental Health Service Administration. If the Licensed or Approved Provider has operated an opioid treatment program for less than one year, the Licensed or Approved Provider shall obtain accreditation by the end of the first year of operation.

(D) State Opioid Treatment Authority Approval. No one may operate an opioid treatment program in the Commonwealth of Massachusetts without Department and State Opioid Treatment Authority Approval, except for opioid treatment programs operated by the Veterans Administration or programs directly operated by the federal government. Persons who hold a current Department-issued License or Approval and State Opioid Treatment Authority Approval to operate an opioid treatment program may not open a new or relocated facility, or transfer ownership, without applying for and receiving a new License or Approval and State Opioid Treatment Authority Approval.

- (1) Upon receipt of the Request for State Opioid Treatment Authority to Operate an Opioid Treatment Program, the Department shall review and make a determination as to whether the applicant has met all state and federal standards and the interests of public health would be served by the establishment of the opioid treatment program. Should the Department determine the applicant meets all such requirements, the Department will approve the Request and shall forward the State Opioid Treatment Authority Approval to the SAMHSA.
- (2) Upon State Authority Approval, the Department shall issue a Provisional License valid for six months and shall sign and forward it to the SAMHSA.
- (3) The Department may review the program's operations during the provisional licensing period. Following the provisional period, the Department shall make a recommendation regarding the issuance of a two-year license.
- (4) If the Department determines that the applicant has not met the requirements of state and federal regulations and/or the interests of public health are not served by the establishment of the opioid treatment program at the proposed site, the Department shall deny State Authority Approval of the application in writing, citing specific reasons for denial, and forward its denial to the SAMHSA. If denied, the applicant may request an adjudicatory hearing, pursuant to M.G.L. c. 30A and 801 CMR 1.01(7): *Motions*.
- (5) The State Authority may make a request to SAMHSA to revoke SAMHSA approval of a opioid treatment program for cause.

(E) Deemed Status.

- (1) License Renewal Based on Accreditation. In considering an application for renewal of a license to operate an opioid treatment program pursuant to 105 CMR 164.008, the Department may in its complete discretion accept accreditation as evidence of compliance with one or more requirements of 105 CMR 164.000, and grant deemed status to the Licensed or Approved Provider, provided that:
 - (a) The Licensed or Approved Provider's accreditation is not provisional;
 - (b) The Licensed or Approved Provider meets all requirements of 105 CMR 164.000;

164.302: continued

(c) The Licensed or Approved Provider submits documentation to the Department as follows:

1. the accreditation letter;
2. the accrediting body's explanation of its survey findings; and
3. the Licensed or Approved Provider's response to the accrediting body's explanation, submitted to the Department at the same time it is submitted to the accrediting body.

(d) The Licensed or Approved Provider provides written consent to permit the Department to observe the accrediting body's summation conference(s); and

(e) The Licensed or Approved Provider agrees in writing to release to the Department any other accreditation information requested.

Licensed or Approved Providers requesting renewal based on accreditation shall submit this request on an approved form obtained from the Department, in a manner prescribed by the Department.

(2) Department's Decision. The Department's decision to deny a request for deemed status is not subject to review or hearing pursuant to 105 CMR 164.020. If the Department denies the request for deemed status, the Licensed or Approved Provider shall provide full evidence of compliance by submitting an application for renewal as required by 105 CMR 164.008.

(3) Required Notifications. Licensed or Approved Providers granted deemed status shall, during the term of the license:

(a) provide the Department with the following documentation within ten business calendar days of receipt of such documentation by the Licensed or Approved Provider:

1. accreditation renewal letter(s);
2. accrediting body's explanation(s) of survey findings related to accreditation renewal; the Licensed or Approved Provider shall submit its response(s) to the accrediting body's explanation(s) to the Department at the same time it is submitted to the accrediting body; and
3. notice(s) of any changes to the Licensed or Approved Provider's accreditation status.

(b) notify the Department immediately upon loss of accreditation.

(4) Department's Authority. In granting deemed status, the Department retains all authority described in 105 CMR 164.000, including authority to evaluate applications; to conduct inspections; and to suspend, deny, refuse to renew, restrict, limit or revoke a license.

(5) Additional Grounds for Suspension, Denial, Refusal to Renew, Restriction, Limitation or Revocation of License: In addition to the grounds for such action specified in 105 CMR 164.018 and 105 CMR 164.019, the Department may suspend, deny, refuse to renew, restrict, limit or revoke any license granted by deemed status if:

- (a) the Licensed or Approved Provider loses its accreditation status;
- (b) the Licensed or Approved Provider fails to comply with one or more conditions of accreditation; or
- (c) the Licensed or Approved Provider's accreditation is made provisional.

164.303: Inspections

In addition to inspections specified in 105 CMR 164.010 and 105 CMR 164.302, the Licensed or Approved Provider shall permit the following inspections:

(A) The Licensed or Approved Provider shall allow inspections by duly authorized employees of the State Authority, Drug Enforcement Agency, and SAMHSA at any time.

(B) A hospital or Department of Mental Health licensed facility subject to 105 CMR 164.500 shall permit the State Authority and Drug Enforcement Agency to inspect supplies of opioid drugs for opioid addiction treatment which are located at the hospital or facility at any time and to evaluate how the drug(s) are being used. In addition, records on receipt, storage, and distribution of opioid medication are subject to inspection.

164.304: Required Notifications

Licensed and Approved Providers shall notify the Department of the following:

164.304: continued

(A) Change in Program Sponsor or Medical Director. The opioid treatment program must provide written notice to the State Authority of a replacement of a program sponsor or Medical Director within two weeks of any replacement of these personnel.

(B) Closure or Cessation of Operation. The opioid treatment program must provide written notice to the State Authority 90 calendar days in advance of discontinuing a program in which medication is administered or dispensed. In addition to requirements of 105 CMR 164.035(B) and 105 CMR 164.087, the Licensed or Approved Provider shall include in its notice its plan for storage, transfer or disposal of its supply of opioids. Such plan shall be subject to approval by the Department.

164.305: Provision of Services – Opioid Treatment Programs

(A) Central Registry System.

(1) All Opioid Treatment Programs shall participate in the Central Registry System to expedite the admission process by verification of medication and dose, prevent a patient's simultaneous enrollment in more than one Opioid Treatment Program, facilitate disaster response and allow access to treatment during emergencies throughout the State, and ensure accurate dispensing of medication in accordance with state and federal laws and regulations.

(2) The Program Director and at least two other employees designated by the Program Director shall have access to the Central Registry System and be properly trained in the Central Registry System.

(3) Each Opioid Treatment Program must:

(a) Upon admission, inform all patients of the Opioid Treatment Program's participation in the Central Registry System;

(b) Prior to initiating a Central Registry System inquiry, obtain the patient's written consent;

(c) Include information about the Central Registry System in the Client Handbook and as part of patient orientations;

(d) Ensure evidence of the written consent and orientation is included in the patient's medical record;

(e) Initiate a clearance inquiry to the Central Registry System by submitting all information required by the State Opioid Treatment Authority prior to admitting a patient to the Opioid Treatment Program;

(f) Verify with the Central Registry System that the prospective patient is not presently enrolled in another Opioid Treatment Program, and document this verification in the patient's record;

(g) Report any other information required by the Department; and

(h) Report all admissions, transfers, and discharges, and any other required information as soon as possible, but not more than 72 hours later into to the Central Registry System.

(4) No person who is reported by the Central Registry System to be participating in another Opioid Treatment Program shall be admitted to an Opioid Treatment Program. In the event a dual enrollment is found by either Opioid Treatment Program in which the patient is participating, the patient shall be discharged from one Opioid Treatment Program in order to continue enrollment at another Opioid Treatment Program.

(5) The Opioid Treatment Program shall notify the State Opioid Treatment Authority within 24 hours of any patient who is found by an Opioid Treatment Program to be simultaneously enrolled in another Opioid Treatment Program.

(6) Information made available by the Central Registry System to Opioid Treatment Programs as approved by the State Opioid Treatment Authority shall also be treated as confidential in accordance with all state and federal regulations including, but not limited to, 42 CFR Part 2 and shall not be shared with others, including state or federal agencies, unless permitted by confidentiality laws and regulations.

(7) Opioid Treatment Programs shall not disclose any information to a treating provider that is a non-member of the Central Registry System regardless of whether there is a treating provider relationship, unless there is a patient specific authorized consent which complies with 42 CFR Part 2.

(8) The Opioid Treatment Program shall develop policies and procedures for:

(a) Orienting patients and staff to the Central Registry System; and

(b) Training for staff to ensure compliance with 105 CMR 164.305(A). Evidence of this training shall be documented in staff's personnel files.

164.305: continued

(9) All Hazard and Emergency Planning and Procedures plan. Opioid Treatment Programs shall include use of the Central Registry System to ensure patient access to care, accuracy and efficiency in dosing services during an emergency by ensuring medication dosing information can be shared between licensed and/or certified Opioid Treatment Programs and the State Opioid Treatment Authority and/or their delegate.

(B) Admission.

(1) Prior to admitting a patient into treatment, the Licensed or Approved Provider shall determine that the patient has a current physiologic dependence on opioids of at least a 12-month duration. If the exact term of physiologic dependence cannot be determined, the medical director, or designee, may admit the patient to treatment if there is sufficient evidence to reasonably conclude that there was physiologic dependence one year prior to admission. The 12-month duration may be waived if the patient:

- (a) is pregnant;
- (b) is seeking opioid withdrawal services;
- (c) has been released from a penal institution within the previous six months; or
- (d) has been discharged from opioid treatment within the previous two years.

(2) Evidence of Physiologic Opioid Dependence. The Licensed or Approved Provider shall obtain evidence of a diagnosis of opioid use disorder through reliable methods such as physical examination, laboratory tests and substance use history.

(3) Prior to initiating treatment, the Licensed or Approved Provider shall:

- (a) verify that the patient with a positive drug screen for methadone is not enrolled in an opioid treatment program;
- (b) complete an assessment of patient's current prescription medications prior to prescribing, dispensing or administering an FDA-approved medication for opioid dependence to ensure that the approved medication is not contraindicated by the patient's current prescribed medications or health status;
- (c) for women of child bearing age, complete a pregnancy test before dispensing or administering or prescribing an FDA-approved medication for opioid dependence; and
- (d) review the patient's prescription history through the MassPAT.

(4) Consent to Treatment. The Licensed or Approved Provider shall ensure that the patient voluntarily chooses treatment. The information listed in 105 CMR 164.305(B)(4)(a) through (h) shall be provided to the client and recorded on a consent form, which shall be signed by the patient, and a copy shall be provided to the patient. If the patient is younger than 18 years old, the consent form shall be signed by the patient and the patient's parent or legal guardian. The information shall also be provided orally:

- (a) the nature of FDA-approved medication used in opioid treatment, including benefits and risks, and the benefits and risks of not receiving treatment;
- (b) the distinction between withdrawal and maintenance and the availability of short-term withdrawal treatment for a period not less than 30 calendar days nor more than 180 calendar days;
- (c) approximate length of each type of treatment;
- (d) a clear statement of the goals of each type of treatment, and the tasks necessary to reach those goals;
- (e) need for the patient to inform the Licensed or Approved Provider of current medical conditions and medications the patient is currently taking;
- (f) acknowledgement that the patient may withdraw voluntarily from treatment and discontinue use of medications;
- (g) the options available to both the patient and the program as a result of either a voluntary or involuntary termination, including medically supervised withdrawal; and
- (h) for women of child-bearing age, acknowledgement of the benefits and risks of treatment during pregnancy, and importance of informing the Licensed or Approved Provider if she is or becomes pregnant.

(C) Assessment. Pursuant to 105 CMR 164.072(B), the Licensed or Approved Provider may initiate patient treatment prior to completion of the assessment required by 105 CMR 164.072 upon obtaining sufficient information to initiate treatment for the acute problem at the time of presentation and that the assessment is subsequently completed in a reasonable timeframe, provided that a Qualified Healthcare Professional must see such a patient prior to initiating an FDA-approved medication for treatment of addiction.

164.305: continued

(D) Initial Medical Examination. In addition to the assessment required by 105 CMR 164.072, the Licensed or Approved Provider shall ensure that each patient has an initial medical examination by a Practitioner, or by a qualified healthcare professional under the supervision of a program physician prior to administration of the first dose of medication. The examination shall include:

- (1) a brief mental status exam;
- (2) tests for the presence of opioids including, but not be limited to, buprenorphine, methadone, and fentanyl; alcohol; benzodiazepines; cocaine; and any other drugs the Licensed or Approved Provider determines are clinically indicated or as approved by the Commissioner and listed in Department guidance;
- (3) an assessment of pulmonary, liver, and cardiac abnormalities; dermatological and neurological sequelae of addiction; possible infectious serologies if indicated; possible concurrent surgical problems; and any other relevant laboratory studies as clinically indicated. The full medical examination including the results of serology and other tests must be returned no later than 14 calendar days after admission.
- (4) These laboratory tests are not required to be completed prior to the initiation of medication for addiction treatment. Any relevant laboratory findings shall be documented and reviewed with the patient and Medical Director and findings reviewed with the patient. Evidence of direct referrals to address findings shall be properly documented. The Licensed or Approved Provider shall ensure that such laboratory tests are completed by licensed facilities which comply with all applicable federal and state laboratory licensure and certification requirements.

(E) Treatment Plan. In addition to the requirements of 105 CMR 164.073, the treatment plan shall include the following information:

- (1) Dosage. The Medical Director shall ensure all dosing of an opioid agonist treatment medication is ordered in accordance with federal requirements; and
- (2) Services. The Licensed or Approved Provider shall provide services as specified in 105 CMR 164.074.

(F) Documentation. In addition to the requirements of 105 CMR 164.083, the Medical Director, or other authorized health care professional, shall:

- (1) ensure that evidence of current physiological dependence is entered in the patient record;
- (2) ensure that a medical evaluation, including a medical history, is recorded;
- (3) ensure that appropriate laboratory results are documented;
- (4) ensure that a list of prescription medication, prescribed dosage(s) of all medications, the plan for changing prescribed medications if necessary, including the planned rate of withdrawal, when applicable, are documented in the record;
- (5) sign or countersign all medical orders;
- (6) review and countersign treatment plans at least annually;
- (7) ensure that the reasons for any changes in dosage and changes in the permitted number of take-home doses are documented;
- (8) document program verifications made in accordance with 105 CMR 164.305(B)(3)(a); and
- (9) document status of initial and periodic MassPAT review.

(G) Upon Department approval, a Licensed or Approved opioid treatment provider may provide interim maintenance in accordance with federal requirements.

164.306: Additional Opioid Treatment Provider Requirements: Medically Supervised Withdrawal

(A) Admission. In accordance with federal requirements:

- (1) When admitting an individual for opioid medically supervised withdrawal management, the Licensed or Approved Provider shall obtain and include in the patient's record a medical evaluation by a Practitioner or psychiatrist which confirms the appropriateness of outpatient medically supervised withdrawal management for the patient.
- (2) A program physician shall conduct an assessment to determine the appropriate form of treatment. Should such physician determine treatment other than opioid medically supervised withdrawal is necessary, the physician shall directly connect the patient with a provider for such treatment.

164.306: continued

(3) A program physician may determine persons younger than 18 years old may be admitted upon determination such individual is currently physiologically dependent upon opioids as defined in 105 CMR 164.305(B)(2).

(4) Patients with two or more unsuccessful episodes of supervised withdrawal within a 12-month period may not be admitted to opioid medically supervised withdrawal management treatment.

(5) A waiting period of at least one week is required between withdrawal attempts. An authorized staff physician shall document in the patient record that the patient continues to be or is again physiologically dependent on an opioid drug.

(B) Treatment. The Licensed or Approved Provider shall ensure the following provisions are met:

(1) A program physician shall determine for each patient the rate at which the opioid drug is to be decreased;

(2) At least one drug screening shall be performed upon admission to opioid medically supervised withdrawal treatment. If the withdrawal management period exceeds 30 calendar days, the Licensed or Approved Provider shall obtain at least one drug screen per month for the duration of medically supervised withdrawal treatment;

(3) Treatment plans shall be reviewed with the patient periodically and as needed to determine the appropriate accommodation of treatment and services;

(4) The Licensed or Approved Provider shall dispense opioid agonist treatment medications to the patient daily at the facility under the direct supervision of a physician or other qualified medical person; and

(5) The Licensed or Approved Provider shall not provide take-home medication for withdrawal management.

164.307: Additional Service Requirements for Opioid Maintenance

(A) Admission of Persons Younger than 18 Years Old. Licensed and Approved Providers may not admit a person younger than 18 years old to opioid maintenance treatment, unless that person has two documented unsuccessful attempts at short-term withdrawal or drug-free treatment within a 12-month period, or is pregnant.

(B) Drug Screening. The Licensed or Approved Provider shall provide for the following:

(1) An initial drug-screening completed for each prospective patient as required by 105 CMR 164.305(D)(2).

(2) An opioid treatment provider must conduct additional random drug screens according to federal requirements. Such drug screens shall, at a minimum, test for opioids including, but not be limited to, buprenorphine, methadone, and fentanyl; cocaine; benzodiazepines; alcohol; and any other drugs the Licensed or Approved Provider determines are clinically indicated or as approved by the Commissioner and listed in Department guidance. The Licensed or Approved Provider shall document measures taken to prevent adulteration of samples and to ensure a chain of custody.

(3) Results of drug screening are to be used as a clinical tool and not as the sole factor in the diagnosis and treatment of the patient and for monitoring the patient's drug-use patterns before and during treatment. The Licensed or Approved Provider's Medical Director shall ensure that drug screen results are not used to force a patient out of treatment, but are used as an aid in making treatment decisions.

(4) Drug screening may be done by one of the following: blood, oral swab, urine testing, or other method as defined by the Department.

(C) Administration of Opioid Maintenance. The Licensed or Approved Provider shall provide for the following:

(1) All patients who begin opioid maintenance treatment shall present themselves daily for medication so the Licensed or Approved Provider may observe the patient ingesting the prescribed dosage of opioid agonist medication on a daily basis.

(2) The Medical Director may reduce the number of times patients must present themselves for observed ingestion of medication by providing take-home doses. In determining whether to provide take-home doses to a patient, the Medical Director shall ensure all decisions comply with federal take-home criteria and schedule including, but not limited to, 42 CFR Part 8.12(h)(4)(i)(1) through (5). The results of such assessment shall be documented in the patient's record.

164.307: continued

(3) The Licensed or Approved Provider shall adhere to federal limits for providing take home doses of any opioid agonist or partial agonist, including that any patient in opioid maintenance treatment may receive a single take-home dose for a day the program is closed, such as on Sundays and state and federal holidays.

(4) The Licensed or Approved Provider may not exceed federally established take-home limits without written permission from the Department. Requests for such permission shall be submitted to the Department in writing in a form required by the State Opioid Treatment Authority and, where required, by the federal government.

(5) Take-home doses shall be dispensed to patients in locked containers. Licensed and Approved Providers may require patients to provide their own locked container.

(6) The Licensed or Approved Provider shall instruct patients receiving a take-home dose, or take-home doses, of the dangers of ingesting methadone to children, pets, and others for whom methadone is not prescribed, and of the dangers of ingesting more than the prescribed dose. Such instruction shall include information on safe storage of methadone in the home. The Licensed or Approved Provider shall document that this instruction has been provided.

(7) Take-home status may be revoked or suspended if the patient does not maintain the behavior which supported approval of take-home privileges. Suspension or revocation of take-home privileges are not subject to appeal to the Department.

(8) The Licensed or Approved Provider shall support patients on opioid maintenance treatment when they are admitted to to a 24-hour settings or during a time of clinical need in obtaining take-home doses in accordance with all state and federal requirements.

(D) Pregnant Women.

(1) Pregnant women, regardless of age, who have had a documented opioid dependency in the past and who may be in direct jeopardy of returning to opioid dependency may be placed on a maintenance regimen. For such patients, evidence of current physiological dependence on opioid drugs is not needed if an authorized staff physician certifies the pregnancy and, using reasonable clinical judgment, finds such treatment to be medically justified in accordance with best medical practices considering the health of the woman and impact on the pregnancy. Evidence of all findings shall be recorded in the patient record.

(2) The Licensed or Approved Provider shall ensure that each pregnant woman is fully informed concerning the possible benefits and risks of opioid treatment to herself and to the fetus. The Licensed or Approved Provider shall document provision of this information in the patient's record.

(3) The Licensed or Approved Provider shall establish a QSOA for pre-natal, obstetrical and gynecological services, unless Licensed or Approved Provider provides these services directly.

(E) Blind Dosage Reduction. Patients who are undergoing medically supervised withdrawal as a planned goal in a maintenance program may request a blind dosage reduction, *i.e.* a gradual decrease of dosage without prior notice to the patient of the decrease. Such blind dosage reduction shall be undertaken only with written consent of the patient and Licensed or Approved Provider. Such consents shall be renewed only by mutual agreement on a regular basis.

(F) Voluntary Termination. Upon request of a patient, or when deemed medically advisable and with the patient's consent, the Licensed or Approved Provider shall initiate the following services:

(1) Discuss with the patient the benefits and risks of medically supervised withdrawal, including possibility of relapse;

164.307: continued

- (2) Provide relapse prevention services;
- (3) Provide medically supervised withdrawal services directly or by referral; and
- (4) Make referrals as necessary to ensure a continuum of care for the patient, including continued counseling and other services, including risk reduction and outreach, as long as necessary to assure stability.

(G) Medically Supervised Withdrawal Rate. The rate of medically supervised withdrawal shall be determined by a program physician to be appropriate to the patient's medical and psychiatric conditions and the dosage level at which the patient was being medicated before the decision was made to terminate. In determining the appropriate course of dosage reduction, the physician shall review the patient's record, and consider the patient's physical and mental health status, and with consent of the patient, may take into account the opinions of the patient's other practitioners and medical providers.

(H) Annual Medical Exam. The Licensed or Approved Provider shall ensure that each patient has a medical examination by a Practitioner, or by a qualified health-care professional, under the supervision of a program physician once each year. The examination shall include:

- (1) a brief mental status exam;
- (2) tests for the presence of opioids, cocaine, benzodiazepines, alcohol, all FDA-approved medications for addiction treatment, and any other drugs the Licensed or Approved Provider determines are clinically indicated or as approved by the Commissioner and listed in Department guidance.
- (3) an assessment of pulmonary, liver, and cardiac abnormalities; dermatological and neurological sequelae of addiction; possible infectious serologies if indicated; possible concurrent surgical problems; and any other relevant laboratory studies as clinically indicated. The assessment shall include laboratory tests as needed. The Licensed or Approved Provider shall ensure that any necessary laboratory tests are completed by licensed facilities which comply with all applicable federal and state laboratory licensure and certification requirements. Any relevant laboratory findings shall be documented and reviewed with the physician and findings reviewed with the patient. Evidence of direct referrals to address findings must be properly documented.
- (4) Licensed or approved providers may utilize a medical examination conducted within the last 12 months, provided there are no medical issues or changes that require examination per the clinical discretion of the facility provider, and review of such a medical examination is documented in the patient's record.

164.308: Referral to Medication Unit

In referring patients to a medication unit, the Licensed or Approved Provider shall ensure that:

- (A) Medication unit is staffed and equipped to assess patients' dosage levels;
- (B) Patients continue to receive all OTP required services as described in their treatment plans.

164.309: Drug Screening Policy and Procedure

The Licensed or Approved Provider shall provide for testing and analysis for drugs of misuse, and shall establish written policies and procedures for guarding against adulteration of such tests.

164.310: Diversion Control

The Licensed or Approved Provider shall maintain a diversion control plan using measures to reduce the possibility of diversion of controlled substances that are FDA-approved for the treatment of opioid dependency, which shall include:

- (A) Random callbacks;

164.310: continued

- (B) For patients who test positive for any FDA approved medications for treatment of opioid use disorder at admission, procedures for determining whether patients are enrolled in an opioid treatment program or are prescribed any medications for treatment of opioid use disorder, and documentation of actions taken in patient records;
- (C) Assigning specific responsibility to the Medical Director and administrator for carrying out the diversion control measures and functions described in the plan;
- (D) Random drug screening; and
- (E) Initial and periodic review of patient's prescription history through the MassPAT.

164.311: Involuntary Termination from an Opioid Treatment Program

(A) Emergency Terminations. the Licensed or Approved Provider may terminate a patient immediately prior to a hearing and without provision for medically supervised withdrawal or Referral, under the conditions listed in 105 CMR 164.311(A)(1) through (8):

- (1) when the program director reasonably determines the patient's continuance in the program presents an immediate and substantial threat of physical harm to other patients, program personnel or property; or
- (2) where the program's Medical Director reasonably determines continued treatment of a patient presents a serious documented medical risk; and
- (3) the Licensed or Approved Provider shall document the reason for not providing a Referral in the patient record;
- (4) the Licensed or Approved Provider immediately notifies the patient of the decision and the reasons for the decision to immediately terminate the patient;
- (5) the Licensed or Approved Provider schedules a hearing, to be held on the next business day, on the decision to terminate and provides notice of the hearing to the patient as described in 105 CMR 164.311(B)(1)(a)1. and 3. and (C);
- (6) the hearing is conducted in accordance with procedures specified in 105 CMR 164.311(D) providing that the decision required by 105 CMR 164.311(D)(7) shall be made within one business day;
- (7) the patient is notified of findings of the hearing within one business day of the hearing; and
- (8) Licensed and Approved Providers are not required to provide medically supervised withdrawal services to patients who are discharged on an emergency, involuntary basis.

(B) Nonemergency Termination. In a nonemergency situation, the Licensed or Approved Provider must afford the patient the following procedural rights:

- (1) Prior to initiating medically supervised withdrawal, the Licensed or Approved Provider shall:
 - (a) Provide the patient with prompt written notice which shall contain:
 - 1. a statement of the reasons for the proposed termination, *e.g.*, violations of a specific rule or rules, noncompliance with treatment contract, *etc.*, and the particulars of the infraction including the date, time, and place;
 - 2. notification that the patient has the right, within two business days from the first business day following receipt of written notice, to submit a written request for a hearing as to the proposed termination; and
 - 3. a copy of the Licensed or Approved Provider's hearing procedures.
 - (b) Arrange with the patient or patient's advocate for a mutually convenient date and time for a hearing within ten business days of receipt of the notice. Additional time to secure appropriate representation may be granted to the patient under exceptional circumstances.
- (2) Afford the patient the opportunity of medically supervised withdrawal. If the patient chooses medically supervised withdrawal, the Licensed or Approved Provider shall provide medically supervised withdrawal, or make arrangements for appropriate medically supervised withdrawal in another opioid treatment program. The rate of dosage reduction shall be determined by the Licensed or Approved Provider's Medical Director in accordance with the patient's medical condition and the dosage level at which the patient was medicated before the decision was made to terminate or suspend. In determining an appropriate course of

164.311: continued

withdrawal, the Medical Director shall review the record, consider the patient's physical and mental health status, and, upon request of the patient, may take into account the opinions of the patient's other practitioners and medical providers.

(3) If a patient is terminated for non-payment of fees, medically supervised withdrawal may begin immediately upon providing written notice of termination, and continue concurrent with patient's appeal, if any.

(C) Documentation of Receipt of Notice. The Licensed or Approved Provider shall document provision of notice to the patient by obtaining the signature of the staff person providing notice and by obtaining a signed, dated receipt from the patient. If the patient refuses to sign a receipt, the Licensed or Approved Provider shall document that refusal on its record of notice.

(D) Hearing Procedures. The Licensed or Approved Provider shall ensure that hearings are conducted in accordance with the following procedures:

(1) The hearing shall be presided over by an impartial hearing officer, who may be any staff or other person(s) not directly involved in the facts of the incident giving rise to the disciplinary proceedings or in the decision to commence the proceedings; provided that the persons involved in either the facts of the incident or in the decision to commence the proceedings shall not have authority over the hearing officer(s);

(2) The patient may be represented at the hearing by any responsible adult of the patient's choosing, including legal counsel;

(3) The hearing shall be conducted in accordance with previously established written rules, which need not be the rules of evidence used in judicial proceedings, but which are designed to ensure a fair and impartial proceeding. The program shall prove by a preponderance of the evidence that the patient did commit the alleged violation;

(4) The patient shall be entitled, upon request, to examine any documentary evidence in the possession of the Licensed or Approved Provider that pertains to the subject matter of the hearing;

(5) The patient shall be entitled to call his or her own witnesses and to question any adverse witnesses;

(6) The Licensed or Approved Provider shall make an audio recording of the hearing. The patient may also make an audio recording of the hearing at the patient's expense;

(7) Hearings may be conducted by telephone, or using an audio-visual, real-time, two-way interactive communication system, provided that contemporaneous notes are taken of the hearing, and all other required documentation for the appeal hearing process is in place and documented;

(8) The hearing officer shall make the decision within seven calendar days after the hearing and will base the decision solely upon the information presented at the hearing. The decision shall be based upon the Licensed or Approved Provider's policy and procedures in effect and posted at the time of the violation; and

(9) The hearing officer shall issue the decision in writing, and shall provide the patient (and patient's representative, if requested) with a copy thereof. The decision shall include an explanation of the reasons for the decision, and instructions explaining how to file an appeal of an adverse decision to the Bureau. The instructions shall inform the patient that the patient's written request for an appeal constitutes the patient's consent to release information to the Bureau.

164.312: Bureau Review of Program Decisions to Terminate

(A) The Licensed or Approved Provider shall afford the patient the right to appeal the determination of the hearing officer. The patient must request this appeal in writing to the Bureau within three business days following the receipt of the adverse decision. The scope of the appeal shall be limited to the Bureau's review of whether the Licensed or Approved Provider adhered to the policies and procedures in compliance with 105 CMR 164.075 and 105 CMR 164.311(D). The patient's written appeal shall contain the basis of the appeal. The Bureau will either affirm or reverse the hearing officer's decision, or remand the decision to a new hearing officer for a new hearing. The decision of the Bureau will be made as follows:

164.312: continued

(1) In the case of an emergency termination, the Bureau shall decide within one business day of receipt of the complete hearing record and written materials submitted by both parties; and

(2) In the case of a nonemergency termination, the Bureau shall decide within ten business days of the Bureau's receipt of the complete hearing record and written materials submitted by both parties.

(B) A Licensed or Approved Provider's failure to submit the complete hearing record will result in a finding for the patient. The hearing officer shall deliver a written decision, outlining the reason(s) for the decision, to the patient, his or her advocate, and the program. The decision of the Bureau is final.

(C) In the case of a nonemergency termination, if the patient timely appeals the hearing decision, the Licensed or Approved Provider may not terminate the patient, or begin medically supervised withdrawal, without first receiving, and ensuring the patient also receives, the Bureau's decision on appeal.

164.314: Staffing Pattern

(A) In accordance with federal regulations, the Licensed or Approved Provider shall designate a Medical Director who shall be responsible for administering all medical services provided by the program, and for ensuring the program complies with all applicable federal, state, and local laws and regulations. The Medical Director shall be a physician with documented clinical experience with opioid-dependent, alcohol, and other drug-dependent persons or 40 hours of documented continuing education in treating addicted persons and medications for treatment of addiction, including all FDA-approved medications for treatment of opioid use disorder. The Medical Director shall ensure there are policies and procedures in place for:

(1) Ensuring that a medical evaluation, including a medical history is taken for each patient; and

(2) Ensuring that appropriate laboratory studies are completed and recorded in patient records.

(B) In addition to the staffing requirements of 105 CMR 164.048, the Licensed or Approved Provider shall establish a staffing pattern in sufficient numbers and positions necessary for the service type provided. Such staffing pattern shall include the following positions:

(1) Senior Clinician among direct service staff who shall be responsible for the clinical/educational operation of the substance use disorder service;

(2) Licensed psychiatrist or licensed psychologist on staff or available through a QSOA;

(3) Practitioner, registered nurse, or licensed practical nurse on staff and on-site during hours when medication is dispensed;

(4) If serving pregnant women, an obstetrician/gynecologist available on staff or through a QSOA;

(5) Sufficient staff, including counseling staff, for coverage on all shifts to ensure patient needs are met.

(C) Supervision. In addition to supervision requirements set forth in 105 CMR 164.044, the Licensed or Approved Provider shall ensure supervision of nursing staff is overseen by a practitioner, a registered nurse, or a Licensed Practical Nurse (LPN) or other Qualified Health Care Professional provider defined under 105 CMR 164.005 who possesses the skills and supervision experience as determined by program and/or meets the requirements under professional licensure; provided, however that the supervisor shall be educationally prepared at or above the level of the nursing staff under his or her supervision.

164.315: Hours of Operation

The program shall be open to provide treatment and to administer medications at least six days per week, year round; provided nothing shall limit the Licensed or Approved Provider's ability to dispense medication for take-home use in accordance with federal requirements including on days the program is closed, such as on Sundays and state and federal holidays. Consideration should be given to any identified barriers to receiving and remaining in treatment

164.315: continued

including, but not limited to, patient transportation, childcare, employment, and educational needs. Services must be provided during hours that meet the needs of the overwhelming majority of patients, including hours outside of the traditional 9:00 A.M. to 5:00 P.M., Monday through Friday work schedule.

164.316: Severe Weather Policy

The Licensed or Approved Provider shall comply with federal regulations for ensuring continued dispensing of medications in the event of severe weather conditions such as hurricanes or blizzards, and shall document such compliance in each patient's record.

164.317: Required Agreements

Licensed and Approved Providers providing medically monitored or clinically managed withdrawal services shall have QSOAs for the provision of the following services as needed:

- (A) Psychiatric consultative, diagnostic and evaluative services;
- (B) Acute 24-hour diversionary services medical or psychiatric hospitalization;
- (C) Emergency medical and psychiatric services; and
- (D) Any specialized services a program provides through special arrangement, purchase or contract.

164.400: Residential Rehabilitation

Residential rehabilitation services are organized substance use disorder treatment and education services featuring a planned program of care in a 24-hour residential setting. For purposes of 105 CMR 164.400 this shall not include facilities providing services to individuals committed pursuant to M.G.L. c. 123, § 35. Services are provided in permanent facilities where residents reside on a temporary basis. They are staffed 24 hours a day. Residential rehabilitation services are provided to residents who require safe and stable living environments in order to develop their recovery skills. Types of residential rehabilitation services are those designed for: adult individuals, adults with their families, adolescents, and driving under the influence second offenders.

164.401: Scope

Provisions of 105 CMR 164.402 through 164.409 apply to all residential rehabilitation substance use disorder treatment services. Licensed or Approved Providers shall also comply with all provisions of 105 CMR 164.000: *Part One*.

164.402: Hours of Operation

Residential rehabilitation services shall operate 24 hours per day, seven days per week, 365 per year.

164.404: Physical Plant

- (A) Inspections. The Licensed or Approved Provider shall post in public areas certificates confirming that all local inspections required for operation of the facility are up to date.
- (B) Conformance with 780 CMR: State Board of Building Regulations and Standards. The Licensed or Approved Provider shall comply with the standards specified in 780 CMR, and those standards in 105 CMR 410.000: *Minimum Standards of Fitness for Human Habitation (State Sanitary Code: Chapter II)* regarding heating, electricity, lighting, plumbing and sanitary facilities.

164.404: continued

(C) Location. The Licensed or Approved Provider shall ensure that residential rehabilitation facilities meet the following requirements:

- (1) The Licensed or Approved Provider shall not post signs or notices that would identify the building as a residential rehabilitation facility, except that programs located in large campuses or health care complexes may post signs to provide direction.
- (2) A Licensed or Approved Provider proposing to locate a residential facility within a health care facility shall seek a determination from the Bureau of Health Care Safety and Quality that the residential recovery program in that facility does not jeopardize the status of that facility for purposes of state licensure or federal Medicare or Medicaid certification.

(D) Common Areas. Licensed or Approved Providers shall design and furnish residential facilities in a manner consistent with their use and which provides a homelike setting including:

- (1) space for group counseling area that ensures privacy and that is large enough to accommodate the number of adult residents in the facility;
- (2) space for residents to use for recreation, reading and quiet time;
- (3) laundry facilities;
- (4) closets, cabinets, or other closed spaces for storage of residents' belongings;
- (5) nightlights in corridors and bathrooms;
- (6) in programs where children reside, a separate indoor play area for children, which includes closets or cabinets for storage of play material and an outdoor play area; and
- (7) None of the areas listed in 105 CMR 164.404(D)(1) through (6) may be used as bedrooms.

(E) Bathrooms and Personal Hygiene. The Licensed or Approved Provider shall ensure that:

- (1) Facilities shall be in compliance with 248 CMR 10.00: *Uniform State Plumbing Code*;
- (2) Female and male residents have separate toilet and bathroom facilities;
- (3) All rooms containing toilets, bathtubs and/or showers are equipped with a door, and have ventilation to the outside through a window or extractor vent;
- (4) Rooms containing a toilet or shower shall be separate and allow for privacy;
- (5) Washbasins are located in the same room as or in close proximity to toilets;
- (6) All showers and tubs are equipped with a nonslip surface or mat;
- (7) All toilets have seats;
- (8) Sanitary hand washing requirements and procedures are posted in restrooms and diapering areas, and Licensed or Approved Provider familiarizes staff and families with these procedures;
- (9) Staff and residents use disposable gloves during toileting and diaper changing of children, and dispose of soiled diapers and gloves in a container with a secure lid; and
- (10) Restrooms are maintained in good repair and a sanitary manner, cleaned daily, and supplied with sufficient soap, paper towels and toilet paper at all times.

(F) Sleeping Rooms.

- (1) All sleeping rooms shall be near toilet, lavatory, and bathing facilities.
- (2) Female and male adult residents shall have separate sleeping quarters. Licensed or Approved Providers may permit couples to share sleeping quarters if space permits.
- (3) Sleeping areas shall be designed to promote comfort and provide adequate space and privacy for residents; and shall meet the requirements of 780 CMR: *State Board of Building Regulations and Standards* including, but not limited to:
 - (a) A separate bed for each resident; and
 - (b) A crib for each child two years old or younger;
- (4) The Licensed or Approved Provider shall ensure that pillows are not used in cribs;
- (5) The Licensed or Approved Provider shall provide the following basic equipment and supplies:
 - (a) a twin-size bed with a twin mattress and waterproof mattress cover; cots may not be used;
 - (b) adequate drawer and closet space for storage of personal belongings;
 - (c) an adequate supply of bed linens, pillows, blankets, washcloths and towels in good condition. Linens, blankets, washcloths and towels shall be laundered at least once a week; and
 - (d) a toothbrush, toothpaste and basic hygiene materials.

164.404: continued

- (6) Residents shall be permitted to decorate their sleeping areas with their personal possessions, such as pictures and posters consistent with the rules and philosophy of the program.

164.405: Meals and Food Handling

(A) Food Storage. The Licensed or Approved Provider shall have a written plan for protecting food from contamination and spoilage during its storage, preparation, distribution and service. The plan shall provide for:

- (1) Procuring all food only from sources that ensure that the food is processed under regulated quality and sanitation controls;
- (2) Clearly labeling supplies;
- (3) Storing all nonfood supplies in an area separate from that used for storing food supplies;
- (4) Storing perishable foods in refrigerators at 41 °F or less;
- (5) Ensuring that any walk-in refrigerators or freezers can be opened from the inside even if closed; if the Licensed or Approved Provider padlocks walk-in refrigerators or freezers, the Licensed or Approved Provider shall establish a procedure requiring written documentation that no one is in the refrigerator or freezer prior to securing the lock; and
- (6) Frozen foods remaining frozen.

(B) Food Handling. Persons, whether employees or residents, responsible for food preparation and service shall be free of signs and symptoms of infections, communicable diseases and open skin lesions. The Licensed or Approved Provider shall ensure that there are

- (1) Disposable gloves available and used in handling and preparing food;
- (2) Adequate hand washing and drying facilities located close to the food preparation area; and
- (3) All work surfaces, utensils, equipment and dishes are thoroughly cleaned and sanitized after each use.

(C) Kitchen Facilities. The Licensed or Approved Provider shall ensure that:

- (1) The kitchen is located in a suitable area of the facility and provides adequate work space for the sanitary preparation and serving of all meals.
- (2) Adequate sanitary storage space is provided for the proper storage of all foods, dishes, silverware and cooking equipment.
- (3) If any resident has a food allergy, information concerning the allergy and required responses in the event of an allergic reaction are conspicuously posted in the kitchen and dining areas with permission of the resident or, if a child, of the child's parents or legal guardian. Licensed or Approved Providers shall document refusal to give permission in the resident's record.

(D) Waste Disposal. The Licensed or Approved Provider shall provide for the sanitary disposal of all waste materials in watertight trash bins with tight fitting lids.

(E) Meals. The Licensed or Approved Provider shall ensure sufficient food and beverages are stocked in order to provide a nourishing well-balanced diet to all residents, and shall provide for the following:

- (1) Clean, well-lighted, and ventilated dining areas;
- (2) The dining room shall be large enough so that all residents may take their meals at customary times, but not necessarily simultaneously;
- (3) Three meals each day for residents;
- (4) Beverages and food for snacks;
- (5) Consideration of residents' suggestions for menu planning;
- (6) Menus dated and retained for three months;
- (7) Means to provide for residents with special dietary needs;
- (8) The Licensed or Approved Provider providing Residential Rehabilitation other than Transitional Support Services may assign program residents to prepare and serve meals as part of their household duties under the supervision of a staff member who has documented training in sanitary food handling and preparation. Residents of Transitional Support Service programs may not prepare or serve food; and

164.405: continued

(9) Where applicable, Licensed or Approved Providers shall ensure that food storage and preparation areas meet the standards defined in 105 CMR 590.000: *State Sanitary Code Chapter X – Minimum Sanitation Standards for Food Establishments* and that the food service is inspected and receives a food service permit by the local board of health.

(F) Purchased Food Services. If the Licensed or Approved Provider purchases food and meal services, the Licensed or Approved Provider shall obtain copies of licenses and inspections which document that the food and meal service provider conforms to 105 CMR 590.000: *State Sanitary Code Chapter X – Minimum Sanitation Standards for Food Establishments* or 105 CMR 500.000: *Good Manufacturing Practices for Food*, as applicable.

164.406: Safe Storage and Administration of Medications

Licensed and Approved Providers shall comply with all federal and state laws and regulations relating to the procurement, storage, dispensing, administration, recording and disposal of medications and shall comply with the following:

(A) Written Policy and Procedure. The Licensed or Approved Provider shall establish a written policy and procedure governing the storage and administration of residents' prescription medications.

(B) Storage. All medications shall be maintained in a locked, secure cabinet, accessible only to designated staff positions. The titles of designated positions shall be posted on the cabinet. The Licensed or Approved Provider shall ensure patients do not have direct access to the medication cabinet.

(C) Medications brought by residents to the program shall be stored in a locked, secure cabinet that is separate from the facility's supply, except that residents shall retain medications required to treat acute episodes, such as asthma attacks or allergic reactions.

(1) If injectable drugs are used, Licensed or Approved Providers shall provide containers for safe storage and proper disposal of sharps.

(2) Medications requiring refrigeration shall be kept in a refrigerator in the same area where other medications are stored. Medications shall not be stored in kitchen refrigerators.

(3) The Licensed or Approved Provider shall also establish a record of medications which remain in the possession of residents for treatment of acute episodes.

(D) Prescription medication presented by residents shall bear a pharmacy label, which shows the date of filling, the pharmacy name and address, the filling pharmacist's initials, the serial number of the prescription, the name of the resident, the name of the prescribing practitioner, the name of the prescribed medication, directions for use and cautionary statements, if any, contained in such prescription or required by law, and if tablets or capsules, the number in the container. All over-the-counter medications shall be kept in the original containers containing the original label, which shall include the directions for use.

(E) The Licensed or Approved Provider shall maintain documentation of all medications stored and disposed of.

(F) Upon admission the resident shall count, in the presence of staff, the number of tablets or capsules, or the approximate amount of liquid in each prescribed medication brought by the resident. The count shall be documented.

(G) Self-administration of Medications. Medications shall be self-administered by the resident, unless the Licensed or Approved Provider employs qualified health care professionals authorized to administer medications. Adult residents must be able to administer their own medications, and, unless the Licensed or Approved Provider employs qualified health care professionals for this purpose, staff shall not administer medication to any resident or resident's child. Staff shall observe the resident ingesting the prescribed dose. For children younger than 18 years old residing with their parents or legal guardian, medication shall be administered by the child's resident parent or legal guardian. Medications may not be provided to any resident if other residents are in the storage or office area. The Licensed or Approved Provider may provide a supply of medications for any resident who will be absent from the program when he or she

164.406: continued

would normally take the medication. The Licensed or Approved Provider shall maintain documentation of all administrations of medication, which shall include:

- (1) Name of resident to whom medication was provided;
- (2) Name of staff person observing the resident take the medication, or providing the needed supply;
- (3) Date and time medication was provided; and
- (4) Resident initials confirming that the medication was provided and taken.

(H) Disposing of Medications. Providers shall comply with all federal and state laws and regulations relating to the procurement, storage, dispensing, administration, recording and disposal of medications.

(I) Improper Use. The Licensed or Approved Provider shall establish a policy regarding improper use of medication. Such policies:

- (1) may impose corrective actions on residents who do not take medications in accordance with prescribed dose and frequency; and
- (2) shall impose corrective actions on residents who illegally obtain and use prescription medications.

164.407: Resident Personal Effects and Affairs

(A) Written Policy and Procedure. The Licensed or Approved Provider shall establish a written policy and procedure governing the care of resident personal belongings and support of resident personal affairs.

(B) Safekeeping. The Licensed or Approved Provider may allow residents to bring monies and valuables into the program, if the Licensed or Approved Provider provides for the secure, locked safekeeping of the personal property.

(C) Right to Confiscate. All residents shall be notified that by accepting admission they authorize the Licensed or Approved Provider to:

- (1) confiscate and dispose of any alcohol or drugs (other than those properly provided by prescription) or paraphernalia for the use of illegal drugs found in the possession of the resident; and
- (2) confiscate any weapons or other articles found in the possession of the resident, which may constitute a threat to the life, health, safety, or well-being of the resident, the staff or public, and to turn over any guns to the police.

The Licensed or Approved Provider shall establish a record of any items confiscated or turned over to the police.

164.408: Required Agreements

Each residential program shall have QSOAs for the provision of the following services as needed:

- (A) Psychiatric consultative, diagnostic and evaluative services;
- (B) Acute 24-hour diversionary service medical or psychiatric hospitalization;
- (C) Emergency medical and psychiatric services; and
- (D) Any specialized services that a program provides through special arrangement, purchase or contract.

164.409: Death of a Resident

In addition to the notification requirements of 105 CMR 164.035, the Licensed or Approved Provider shall develop procedures to be followed in the event of the death of a resident. These procedures shall conform with laws governing the report of death to local authorities, and shall include the following:

164.409: continued

- (A) Local emergency services (911) shall be notified immediately.
- (B) The Licensed or Approved Provider shall comply with all laws concerning declaration of death and moving the deceased.
- (C) The Licensed or Approved Provider shall make reasonable efforts to notify the deceased's emergency contact. A written record of these efforts shall be included in the resident's record.

164.420: Residential Rehabilitation for Adults

164.421: Scope

Provisions of 105 CMR 164.422 through 164.424 apply to residential rehabilitation substance use disorder treatment and education services for adults in the early stages of substance use disorder recovery, using the following models: Transitional Support Services, Social Model Recovery Homes, Recovery Homes, Therapeutic Communities, and Co-occurring Enhanced. Licensed and Approved Providers shall also comply with all provisions of 105 CMR 164.400 through 164.409, and 105 CMR 164.000: *Part One*.

164.422: Provision of Services

- (A) Admission. Prior to admission, the Licensed or Approved Provider shall verify the resident is 18 years old or older and that the residential rehabilitation services are appropriate for the resident based upon a determination the resident:
 - (1) has a substance use disorder or a mental or behavioral disorder due to psychoactive substance use and is not intoxicated and is not currently at risk of experiencing withdrawal;
 - (2) is mentally and physically stable and does not pose a risk to self or others;
 - (3) is open to recovery and can understand relapse;
 - (4) requires a 24-hour per day structured and supportive environment in order to maintain gains; and
 - (5) is capable of recognizing physical danger, including when such danger requires immediate egress from the residence, and is able to follow a prescribed procedure for egress, as demonstrated by completion of a self-preservation test.
- (B) Duration of Services. Length of stay may vary depending upon the needs of the resident.
- (C) Assessment. The Licensed or Approved Provider shall ensure that the assessment required by 105 CMR 164.072 shall be completed within the first week of treatment. Pursuant to 105 CMR 164.072(B), the Licensed or Approved Provider may initiate resident treatment prior to completion of the assessment required by 105 CMR 164.072 upon obtaining sufficient information to initiate treatment for the acute problem at the time of presentation and that the assessment is subsequently completed in a reasonable timeframe, provided that a Qualified Healthcare Professional must see such a resident prior to initiating an FDA-approved medication for treatment of addiction. Providers of Residential Rehabilitation for Adults are exempt from the requirement in 105 CMR 164.072(D) that the assessment be completed by a Senior Clinician or Clinician.
- (D) Treatment. The Licensed or Approved Provider shall provide treatment services as required by 105 CMR 164.074, in accordance with program components specified in 105 CMR 164.423.
- (E) Medical Services. Notwithstanding the assessment required by 105 CMR 164.072, the Licensed or Approved Provider shall refer the resident for a complete physical examination within 30 calendar days of admission unless medical reports document a comparable examination within 12 months prior to admission. Referrals shall be documented in the resident's record.
- (F) Licensed or Approved Providers providing services to pregnant and postpartum residents and their infants shall establish QSOAs with early intervention programs to provide developmental assessments and services to infants. Licensed or Approved Providers shall also comply with requirements of 105 CMR 164.082(A) governing services to pregnant patients and residents.

164.423: Program Components

- (A) Residential rehabilitation programs for adults, regardless of program model, shall:
- (1) provide daily clinical services to improve residents' ability to structure and organize the tasks of daily living and recovery;
 - (2) advocacy and ombudsman services to support residents in obtaining needed resources and services and actively promote residents' interests; and
 - (3) directly connect the resident to substance use disorder treatment or community support services upon discharge.
- (B) Transitional Support Services. Residential rehabilitation programs based on a Transitional Support model shall provide:
- (1) at a minimum, four hours of nursing services available each day;
 - (2) case management services;
 - (3) a dedicated staff member to provide transportation services available at least 12 hours per day, seven days per week; and
 - (4) health monitoring, education and crisis services.
- (C) Social Model Recovery Homes. Residential rehabilitation programs based on a Social Model shall provide:
- (1) individual treatment plans developed by residents with assistance within the first 30 calendar days of residence;
 - (2) planned program activities to stabilize and maintain the stability of the resident's substance dependence symptoms and to help the resident develop and apply recovery skills; and
 - (3) case management and support to promote successful involvement in regular, productive daily activity, such as work or school, and, as indicated, successful reintegration into family and community living.
- (D) Recovery Homes. Residential rehabilitation services based on a Recovery Home model shall provide:
- (1) planned daily clinical program activities to stabilize the resident's substance dependence symptoms and to help the resident develop and apply recovery skills;
 - (2) counseling and clinical monitoring by qualified staff to promote successful involvement in regular, productive daily activity, such as work or school, and, as indicated, successful reintegration into community living;
 - (3) a range of cognitive and motivational therapies on a group and individual basis; and
 - (4) a daily schedule of services designed to develop and apply recovery skills.
- (E) Therapeutic Communities. Residential rehabilitation services based on a Therapeutic Community model shall provide:
- (1) daily clinical services to promote the residents' ability to develop and practice pro-social behaviors;
 - (2) planned daily clinical program activities to stabilize and maintain stabilization of the resident's substance dependence symptoms and to help the resident develop and apply recovery skills;
 - (3) counseling and clinical monitoring by qualified staff to promote successful involvement in regular, productive daily activity, such as work or school, and, as indicated, successful reintegration into family and community living;
 - (4) a range of cognitive and motivational therapies on a group and individual basis;
 - (5) motivational enhancement and engagement strategies appropriate to the resident's stage of readiness to change; and
 - (6) planned community reinforcement designed to foster pro-social values and group living skills.
- (F) Co-occurring Enhanced Residential Services. Residential rehabilitation services based on a Co-occurring Enhanced Services model shall be delivered by appropriately credential medical staff who are available to assess and treat co-occurring disorders and to monitor the patients' administration of medication in accordance with a physician's prescription, as well as provide:

164.423: continued

- (1) staffing patterns that include appropriately credentialed mental health professionals, who are able to assess and treat co-occurring disorders with the capacity to involve addiction trained psychiatrists or in coordination with community physicians for review of treatment as needed;
- (2) planned daily clinical program activities constituting at least five hours a week of professionally directed treatment designed to stabilize and maintain the resident's substance dependence symptoms and to help the resident develop and apply recovery skills;
- (3) counseling and clinical monitoring by qualified staff to promote successful involvement in regular, productive daily activity, successful reintegration into community living;
- (4) a range of cognitive and motivational therapies on a group and individual basis, where the goals of such therapies pertain to both the substance use disorder and any mental health disorder;
- (5) a daily schedule of self-help, health education, relapse and overdose prevention and recovery maintenance education as well individual and group services designed to develop and apply recovery skills;
- (6) trauma-informed care, with an emphasis on individual choice and decision making, including trauma screening in all assessments and access to trauma specific services;
- (7) specific medication education and management services; and
- (8) Recovery Support services, referral, and engagement.

(G) Programs may provide services through telemedicine where appropriate and at the discretion of the program director, based on federal guidance.

164.424: Staffing Pattern

Residential Rehabilitation programs for adults are exempt from the requirements set forth in 105 CMR 164.048(A)(2). Staffing pattern shall include the following positions:

(A) Direct Care Staff. Job descriptions shall specify that direct care staff have knowledge of and ability to promote recovery. Each program must, at a minimum, include the following direct care staff: clinical supervisor, counselor/case manager, and a recovery specialist or case aide.

(B) Coverage. At minimum, the staffing pattern must include a full time Clinical Supervisor meeting the definition of a Senior Clinician present to provide oversight of clinical services and at least two FTE direct care staff present on each shift as outlined below, seven days per week, 24 hours per day, which shall be adjusted upward to address resident acuity and programmatic need. No staff on any shift shall be permitted to sleep during the shift. Any program which serves persons who identify as male or female must have a plan in place for ensuring at least one direct care staff person on-site who identifies as female, and one direct care staff person who identifies as male on each shift.

- (1) At minimum, there shall be at least one recovery specialist or case aide and at least one full-time counselor or case manager present on each day and evening shift.
- (2) At minimum, there shall be at least two recovery specialists or case aides present for each overnight shift.
- (3) Where the resident census exceeds 100 residents, the Licensed or Approved Provider shall ensure four direct care staff are present on all shifts.

(C) Licensed or Approved Providers providing Transitional Support Services shall ensure a registered nurse, advanced practice registered nurse, physician assistant, or licensed practical nurse is available on-site at least four hours each day and shall ensure that supervision of nursing staff is overseen by either a registered nurse, or a Licensed Practical Nurse (LPN) or other Qualified Health Care Professional provider defined under 105 CMR 164.005 who possesses the skills and supervision experience as determined by program and/or meets the requirements under professional licensure; provided, however that the supervisor shall be educationally prepared at or above the level of the nursing staff under his or her supervision.

(D) Administrative Staff. Each residential rehabilitation program shall have a full-time manager who is responsible for the administration and operation of the residential rehabilitation program. A full-time administrative staff, or designee on duty on the premises, shall be available to respond to emergencies at all times.

164.430: Residential Rehabilitation for Adults with Their Families

164.431: Scope

Provisions of 105 CMR 164.432 and 164.433 apply to residential rehabilitation substance use disorder treatment services for individuals with their families. The Licensed or Approved Provider shall also comply with all provisions of 105 CMR 164.400 through 164.409, and with provisions of 105 CMR 164.000: *Part One*.

164.432: Provision of Services

(A) At the time of admission, the Licensed or Approved Provider shall determine that Family Residential Substance Use Disorder Treatment Services are appropriate based upon the following criteria:

- (1) The parent or legal guardian:
 - (a) is 18 years old or older;
 - (b) has a substance use disorder or a mental or behavioral disorder due to psychoactive substance use and is not intoxicated and is not currently at risk of experiencing withdrawal symptoms requiring medical monitoring;
 - (c) is not currently experiencing acute symptoms of physical illness or mental health conditions, and does not pose a risk to self or others;
 - (d) is open to recovery and can understand relapse;
 - (e) requires a 24-hour per day structured and supportive environment in order to maintain gains;
 - (f) has custody of at least one child or reunification with at least one child is planned within 30 calendar days of admission, or is pregnant; and
 - (g) is capable of recognizing physical danger, including when such danger requires immediate egress from the residence, and is able to follow a prescribed procedure for egress, as demonstrated by completion of a self-preservation test.
- (2) The determination may consider whether the family is homeless and is eligible for Emergency Assistance (EA) through the Department of Housing and Community Development as determined by the DHCD pursuant to the standards of 760 CMR 67.00: *Eligibility for Emergency Assistance (EA)*; or the family has housing resources located in a community or social environment that is unsupportive of recovery or constitutes a risk to maintenance of abstinence.

(B) Assessment. Licensed or Approved Provider may initiate patient treatment prior to completion of the assessment required by 105 CMR 164.072, provided sufficient information to initiate treatment for the presenting complaint or problem on that day of services is obtained and that the assessment is completed in a reasonable timeframe. The Licensed or Approved Provider shall complete the following in a reasonable timeframe:

- (1) an assessment as required in 105 CMR 164.072 for each adult family member in the program;
- (2) assessments of the physical and mental health needs of all family members in the program; and
- (3) evaluations, physical examinations, immunizations, and/or consultations by qualified professionals, as indicated by the assessments required under 105 CMR 164.432(B)(1) and (2).

(C) Treatment Plan. The Licensed or Approved Provider shall develop an Individual Treatment Plan as required by 105 CMR 164.073 for each family member residing in the program. In addition to substance use disorders, the treatment plan shall address mental health disorders, trauma, domestic violence, child welfare, parent- or legal guardian-child relationships and family life.

(D) Substance Use Disorder Treatment Services. In addition to the Minimum Treatment Services Requirements specified in 105 CMR 164.074, the Licensed or Approved Provider shall provide the following services for adults and adolescents:

- (1) Monthly case review or consultation meetings between the Licensed or Approved Provider's staff and any Qualified Service Organizations providing services for a family under a QSOA;
- (2) 24-hour per day crisis intervention services;

164.432: continued

(3) Engage in the Plan of Safe Care (POSC) process with all pregnant residents, and work collaboratively with other involved providers provided appropriate releases of information are in place;

(4) Offer group and individual education and counseling specific to pregnancy and parenting for all pregnant, postpartum, and parenting residents whether or not they currently have custody; and

(5) Help pregnant and postpartum residents prepare for and navigate any Department of Children and Families (DCF) involvement, and assist them in the DCF process, including collaborating with DCF and other involved providers, with the resident's written consent and participation whenever feasible.

(E) Mental Health Services. The Licensed or Approved Provider shall establish QSOAs with licensed Mental Health Providers in order to provide the following for adults and children:

(1) A mental health assessment that includes a history of mental health concerns or disorders and treatment, psychosocial, family and medical history, and a psychopharmacological assessment; and

(2) Individual and/or group counseling for mental health issues such as childhood or adult sexual abuse, depression, domestic violence and traumatic stress symptoms.

(F) Parenting and Life Skills Education. The Licensed or Approved Provider shall provide, either directly or through a QSOA, the following adult services:

(1) Weekly, on-site parenting education and parenting skill building; and

(2) Counseling and clinical monitoring to promote successful involvement in regular, productive daily activity, such as work or school, and, as indicated, successful reintegration into family and community living.

(G) Transitional Assistance and Employment. The Licensed or Approved Provider shall provide advocacy services to assist the family in applying for transitional assistance through the DTA.

(H) Services for Children Residing in the Program. The Licensed or Approved Provider shall:

(1) Obtain parent(s)' or legal guardian(s)' consent prior to referring a child for services or consulting with service providers:

(a) Refer children from birth to age three for a Developmental Assessment through an Early Intervention Program (EIP) certified by the Department;

(b) Consult with other service providers or institutions providing services to children, *e.g.*, courts, schools, Early Intervention Program, Department of Youth Services, Department of Social Services, *etc.*;

(c) Ensure that children receive medical examinations in accordance with recommended schedules of pediatric care; and

(d) Ensure that children's immunizations are up to date in accordance with the recommendations of the Department, unless the child's parent or legal guardian has stated in writing that vaccinations or immunizations conflict with his or her sincere religious beliefs or if the child's practitioner has stated in writing that the vaccination or immunization is medically contraindicated.

(2) Assist parent(s) or legal guardian(s) in obtaining child care services, including after school child care for school-age children;

(3) Assist parents or legal guardian in ensuring school age children are registered in and attending school; and

(4) Provide on-site services and activities for children who are not in community-based child care programs or in school. Such services shall be designed to promote the child's development and shall be available for children of all ages, including adolescents.

(I) Aftercare. In addition to requirements in 105 CMR 164.076 and 164.077, the Licensed or Approved Provider shall provide the following aftercare services:

(1) Assistance to obtain housing, child-care, employment, continued health care and other social services that the family has received while in the program.

(2) Follow-up services for up to three months following the family's discharge; and

(3) Directly connect the family to another family residential program through policy established by the Department if the family is discharged before completion of treatment.

164.433: Staffing Pattern

(A) In addition to the staffing requirements of 105 CMR 164.424 and 105 CMR 164.048, excluding 105 CMR 164.048(A)(2), the Licensed or Approved Provider shall establish a staffing pattern that, at a minimum, includes the following:

- (1) a Clinical Supervisor who also meets the definition of a Senior Clinician;
- (2) a Family Therapist who also meets the definition of a Senior Clinician with experience working with families experiencing substance use disorders;
- (3) children's services staff including, but not limited to, a Children's Services Coordinator and a Children's Services Assistant;
- (4) counselors to serve as Recovery Specialists;
- (5) a minimum of one FTE staff member on-site at all times; and
- (6) no on-duty staff shall be permitted to sleep during their shift.

(B) The Licensed or Approved Provider shall establish policies requiring parents or legal guardian to ensure that children are supervised by an adult at all times.

(C) In addition to meeting staff training and supervision requirements contained in 105 CMR 164.044 Training and Supervision, the Licensed or Approved Provider shall ensure that all staff are trained to recognize child abuse and neglect and to report incidents of child abuse and neglect to the Department of Children and Families under M.G.L. c. 119, § 51A.

164.440: Residential Rehabilitation for Adolescents and Transition Age Youth

164.441: Scope

Provisions of 105 CMR 164.442 through 164.444 apply to residential rehabilitation substance use disorder treatment services for adolescents and transition age youth. The Licensed or Approved Provider shall also comply with all provisions of 105 CMR 164.400 through 164.409, and with 105 CMR 164.000: *Part One*.

164.442: Provision of Services

(A) Admission. Prior to admission, the Licensed or Approved Provider shall determine that adolescent and transition age youth residential rehabilitation services are appropriate based upon the following criteria:

- (1) the resident is younger than 26 years old; and:
 - (a) has a substance use disorder or a mental or behavioral disorder due to psychoactive substance use and is not intoxicated and is not currently at risk of experiencing withdrawal symptoms;
 - (b) is not currently experiencing acute symptoms of physical illness or mental health conditions, and does not pose a risk to self or others;
 - (c) meets patient placement criteria defined by the American Society of Addiction Medicine for Clinically Managed Residential Treatment for adolescents;
 - (d) does not require intensive therapeutic intervention for a serious mental health condition as a primary diagnosis or severe emotional disturbance and/or aggressive behavior; and
 - (e) does not require 24-hour per day nursing care.
- (2) residents 18 years old or older consent to treatment;
- (3) residents 12 through 17 years old consent to treatment by either:
 - (a) the consent of the parent or legal guardian; or
 - (b) without the consent of a parent or legal guardian upon a finding of two or more physicians that the minor is drug dependent.

(B) Developmentally Appropriate Services. The Licensed or Approved Provider shall ensure treatment plans, facility programs and materials are tailored to adolescents and transition age youth. Program services shall address adolescent and transition age youth concerns, including education, community, juvenile justice, mental and physical health. The licensee shall ensure treatment plans, facility programs and materials recognize this unique stage of brain development, physical, social and psychological growth, and the complexity of substance use and

164.442: continued

co-occurring mental health disorders during this developmental stage. Program services shall address concerns of substance use and misuse, and their negative consequences on school performance, socialization in the community, family interaction and overall physical and mental health.

(C) Assessment. Pursuant to 105 CMR 164.072(B), the Licensed or Approved Provider may initiate resident treatment prior to completion of the assessment required by 105 CMR 164.072 upon obtaining sufficient information to initiate treatment for the acute problem at the time of presentation and that the assessment is subsequently completed in a reasonable timeframe, provided that a Qualified Healthcare Professional must see such a resident prior to initiating an FDA-approved medication for treatment of addiction. In addition, the Licensed or Approved Provider shall assess the following:

- (1) the resident's educational status and remedial educational needs; and
- (2) the resident's mental health status to determine whether a co-occurring mental health disorder is present.

(D) Medical Examination. Notwithstanding the assessment required by 105 CMR 164.072, a medical and health history and physical examination shall be conducted by the program or upon referral within two weeks of admission, unless documentation of a physical examination, conducted within one year prior to admission, is provided. With resident's consent, the medical examination shall include laboratory tests for sexually transmitted diseases and, for females, pregnancy. Refusal to consent to medical examinations shall be documented, and shall not be grounds for discharge.

(E) Treatment Plan. In addition to the requirements of 105 CMR 164.073, the Licensed or Approved Provider shall ensure that the treatment plan is reviewed at least every 30 calendar days, and includes:

- (1) a statement of the resident's educational needs and opportunities to attain them;
- (2) educational services to be provided;
- (3) projected length of stay;
- (4) employment readiness and skill building;
- (5) family reconciliation or reunification, if appropriate; and
- (6) skills for identifying and building healthy relationships.

(F) Family Involvement in Treatment. The Licensed or Approved Provider shall ensure that services, including family therapy, are offered to parents or legal guardian and family members. The Licensed or Approved Provider shall inform parents or legal guardian of program policies and procedures, including:

- (1) names and telephone numbers of staff whom parents or legal guardian may contact;
- (2) resident manual provided pursuant to 105 CMR 164.081; and
- (3) criteria for discharge.

(G) Treatment Services.

(1) In addition to the requirements of 105 CMR 164.074, the Licensed or Approved Provider shall provide the following:

- (a) individual and group psychotherapeutic counseling that addresses substance use and misuse, including safety and opioid overdose prevention;
- (b) educational services designed to assist the resident in maintaining or achieving participation in a developmentally appropriate school program;
- (c) mental health services to address co-occurring mental health disorders;
- (d) group programming for families of residents;
- (e) recreational programming;
- (f) exposure to support and self-help groups for adolescents;
- (g) opportunities for residents to participate in planning, organizing or managing non-clinical programming;
- (h) clinical, educational and support services designed specifically for females, separate from males, and for males, separate from females;
- (i) clinical and educational programming designed to address racial inequities and health disparities and meet the needs of culturally and ethnically diverse residents; and

164.442: continued

- (j) a dedicated staff member to support provision of transportation services to ensure residents can obtain needed off-site services, such as medical, psychiatric and recreational services, and to support parent or legal guardian and family participation in program services and activities.
- (2) In addition to the requirements of 105 CMR 164.442(G)(1), the Licensed or Approved Provider shall provide the following services for Transition Age Youth:
 - (a) assist the resident maintain or obtain participation in a developmentally appropriate school or vocational program;
 - (b) support and self-help groups for young people;
 - (c) skills for independent living and functioning;
 - (d) vocational skills development; and
 - (e) assist the resident develop and strengthen peer, family and community recovery supports.
- (H) Length of Stay. If the resident's length of stay exceeds 90 calendar days, the Licensed or Approved Provider shall document reasons for this extension in the resident's record.
- (I) Aftercare Services. The Licensed or Approved Provider shall ensure the aftercare service plan provides for continued educational services, and continued family and social support services including, but not limited to,:
 - (1) directly connecting the resident to outpatient substance use disorder treatment services;
 - (2) identifying self-help resources such as Alcoholics Anonymous (AA), Narcotics Anonymous (NA), Al-Anon, and Alateen.

164.444: Staffing Pattern

In addition to the requirements of 105 CMR 164.424, 105 CMR 164.048 excluding 105 CMR 164.048(A)(2), and 105 CMR 164.082(B), the Licensed or Approved Provider shall require that all staff are knowledgeable about adolescent development and adolescent substance use disorder as well as co-occurring mental disorders. The Licensed or Approved Provider shall establish a staffing pattern in sufficient numbers and positions necessary for the service type provided. No on-duty staff shall be permitted to sleep during their shift. Staffing pattern shall include the following positions, which shall be adjusted upward to address patient acuity and programmatic need:

- (A) a Clinical Supervisor who meets the definition of a Senior Clinician responsible for reviewing and approving mental health assessments conducted by Clinicians;
- (B) at least one full-time counselor or case manager; and
- (C) at least two direct care staff or recovery specialists on each shift.

164.450: Residential Programs for Operating under the Influence Second Offenders164.451: Scope

Provisions of 105 CMR 164.452 through 164.454 apply to Licensed or Approved Providers providing Residential Programs for Operating under the Influence Second Offenders. The Licensed or Approved Provider shall also comply with all provisions of 105 CMR 164.400 through 164.409, and with provisions of 105 CMR 164.000: *Part One*.

164.452: Provision of Services

- (A) Admission. The Licensed or Approved Provider shall admit residents who are referred by a Massachusetts court pursuant to the provisions of M.G.L. c. 90, § 24.
 - (1) At admission, the Licensed or Approved Provider shall determine that residential second offender services are appropriate based upon the court referral and the resident's absence of withdrawal symptoms.

164.452: continued

(2) Denial of Admission. The Licensed or Approved Provider shall not admit an intoxicated individual. In the event of denial of admission due to intoxication, the Licensed or Approved Provider shall notify the referring court of the denial within one business day. The Licensed or Approved Provider shall provide a copy of the written notice to the individual who was denied admission.

(3) Medical Assessment. Prior to admitting an individual, the Licensed or Approved Provider shall ensure that a medical evaluation is conducted by a qualified health care professional to establish whether the individual's health status is appropriate for the service type provided by the program. The medical report shall determine:

- (a) whether the individual suffers from acute or chronic medical conditions requiring immediate medical care;
- (b) whether the individual has any physical limitation which would limit participation in any program component, such as physical exercise. If such a condition exists, the Licensed or Approved Provider shall make, and document, efforts to adapt the physical requirements of the program to meet the individual's physical abilities; and
- (c) If, as a result of the individual's medical or physical condition, the Licensed or Approved Provider is unable to provide adequate care, the Licensed or Approved Provider shall notify the referring court.

(B) Program Structure. The Licensed or Approved Provider shall establish a program structure that includes:

- (1) At least 14 consecutive calendar days of residential programming;
- (2) Policy and procedures governing telephone, mail and visitation privileges;
- (3) A daily schedule of resident activities and rules governing resident participation in these activities;
- (4) Provisions for security that include:
 - (a) Measures to ensure that residents do not leave the facility without notifying a member of the administrative or counseling staff;
 - (b) A sign-in and sign-out system for all visitors, staff and residents; and
 - (c) A census count to be taken once during each eight-hour shift.

(C) Services. The Licensed or Approved Provider shall provide the following:

- (1) Three individual counseling sessions for each resident during the 14-day stay, including an initial evaluation session, a termination session, and one intermediate session.
- (2) Educational and motivational groups, as follows:
 - (a) Two 1.5 hour groups each day. Over any two-week period, at least 14 of such groups shall be educational and at least ten shall be motivational.
 - (b) A written educational curriculum, approved by the Department, which:
 - 1. addresses the physiological, psychological and social consequences of substance use disorder;
 - 2. assists residents to identify their substance use disorder behavior, recovery methods and treatment options; and
 - 3. teaches techniques for changing problematic behavior resulting from or contributing to substance use disorder.
 - (c) Community or self-help group meetings shall not be substituted for required educational and motivational groups.
- (3) A physical education program consisting of planned, regularly scheduled activities, monitored by a staff member who is certified in CPR.

(D) Discharge. The Licensed or Approved Provider shall discharge residents upon completion of their sentence and shall refer residents who continue on probation for additional substance use disorder treatment. With the resident's written consent, the Licensed or Approved Provider shall provide the outpatient provider with a summary of the resident's completed assessment and diagnosis.

(E) Aftercare. If a resident completes the probation period at the same time as the residential program, the Licensed or Approved Provider shall directly connect the resident to an appropriate provider to ensure a continuum of care for the resident, including direct referrals for further substance use disorder treatment, the provision of post discharge counseling and other supportive services.

164.453: Notice to the Court

The Licensed or Approved Provider shall establish procedures for notifying court personnel when the program is operating at capacity and cannot accept additional referrals, and when it is available for additional referrals.

164.454: Staffing Pattern

In addition to the staffing requirements of 105 CMR 164.424 and 105 CMR 164.048, excluding 105 CMR 164.048(A)(2), the Licensed or Approved Provider shall establish a staffing pattern with sufficient personnel to oversee daily activities and to ensure safe operation of the program, which shall include:

- (A) A Senior Clinician or Clinician to provide individual counseling, and group counseling/ education services.
- (B) Staff qualified by education or experience responsible for the structure and delivery of physical education and recreation activities.
- (C) Qualified health care personnel to conduct initial medical assessments. Health care staff may be employees of the Licensed or Approved Provider, or may be employees of an entity with whom the Licensed or Approved Provider has a QSOA for provision of health care services.
- (D) No on-duty staff on any shifts shall be permitted to sleep during the shift.

PART THREE: DEPARTMENT OF MENTAL HEALTH LICENSEES, BUREAU OF HEALTH CARE SAFETY AND QUALITY LICENSEES, AND AGENCIES OF THE COMMONWEALTH

164.500: Licensure Requirements for Providers Licensed by the Department of Mental Health or the Bureau of Health Care Safety and Quality, or Operated by an Agency of the Commonwealth

164.505: Scope

The provisions of 105 CMR 164.505 through 105 CMR 164.587 shall apply to any substance use disorder treatment program operated by a facility licensed by the Department of Mental Health or the Department of Public Health's Bureau of Health Care Safety and Quality, operated by the Department of Mental Health, or Agencies of the Commonwealth. In addition to the standards contained within 105 CMR 164.505 through 105 CMR 164.587, each Licensed or Approved Provider shall comply with the applicable level or levels of service provided pursuant to 105 CMR 164.100 through 164.400: *Part Two*.

164.507: Application Requirements for Licensure or Approval

A substance use disorder treatment program must have a License or Approval from the Department.

- (A) Applications for licensure or approval shall be made in a form prescribed by the Department and include all supporting documents required by the applicable level or levels of service provided pursuant to 105 CMR 164.100 through 164.400: *Part Two*.
- (B) An application for an original license, or the transferee's application in the case of a transfer of ownership, shall not be approved until the applicant has been deemed suitable by the Department.
- (C) Except for an Agency of the Commonwealth accepting civil commitments pursuant to M.G.L. c. 123, § 35, an application for a license or approval renewal, shall include a sworn statement of the names and addresses of any person with an ownership or control interest in the facility or in the real property upon which the facility is located. For the purposes of 105 CMR 164.507, "person with an ownership or control interest" shall mean a person who:

164.507: continued

- (1) has a direct or indirect ownership interest of 5% or more in the facility or the organization that holds the license;
- (2) is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the facility or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5% of the total property and assets of the facility or organization that holds the license;
- (3) is an officer or director of a corporate licensee;
- (4) is a partner of a licensee organized as a partnership; or
- (5) is the Trustee of a Trust.

164.508: Application Submission

(A) Applications for licensure or approval shall be made in a format prescribed by the Department, together with the required fee and any other documents and materials required by the applicable level or levels of service provided pursuant to 105 CMR 164.100 through 164.400: *Part Two* or that the Department deems appropriate.

(B) Applicants for licensure or approval who choose to use a vendor to provide the identified substance use disorder treatment being applied for shall only use a vendor licensed or eligible for licensure under 105 CMR 164.000.

(C) Applicants for renewal must submit to the Department completed forms and fees required by the Department at least 60 calendar days prior to the expiration of the current License or Approval. An application for renewal, if timely filed with the required fee (as applicable pursuant to 105 CMR 164.008), shall have the effect of a License or Approval from the date of License or Approval expiration until such time as the Department takes action on the application. If a renewal application is not timely filed, such an application will not have such effect and the License or Approval shall lapse.

164.509: Evaluation of Application and Suitability of Applicant or Licensed or Approved Provider

(A) The Department shall evaluate the suitability of the applicant or Licensed or Approved Provider including, but not limited to, the following factors. A negative determination with respect to any one of the factors constitutes an adequate ground for deeming an applicant or Licensed or Approved Provider unsuitable to establish or maintain a substance use disorder treatment program and upon which the Department may deny an initial or renewal application for a License or Approval.

(1) Past performance as a provider of substance use disorder treatment services, based upon documentation of applicant's or Licensed or Approved Provider's:

- (a) history of compliance with applicable provision of 105 CMR 164.100 through 164.500;
- (b) history of providing substance use disorder treatment services or other health care services, including provision of services in other states;
- (c) ability to provide substance use disorder treatment services;
- (d) history of response to correction orders issued under 105 CMR 164.516;
- (e) history of failure to provide services to any individual when licensed or approved to provide such services; and
- (f) history of patient or resident abuse, mistreatment or neglect in any licensed health care program or facility.

(2) Except for facilities accepting civil commitments pursuant to M.G.L. c. 123, § 35, whether the applicant is able to provide services to residents of the Commonwealth with public health insurance on a nondiscriminatory basis and able to report the facility's payer mix to the Department on a quarterly basis.

(3) Except for facilities accepting civil commitments pursuant to M.G.L. c. 123, § 35, whether the applicant can demonstrate need for the services in accordance with 105 CMR 164.511(A).

(4) Such other information as the Department may require.

(B) The application shall also include an attestation from the applicant confirming that any substance use disorder treatment program subject to licensure or approval under 105 CMR 164.000 operated by said applicant will:

164.509: continued

- (1) Provide services on a nondiscriminatory basis to residents of the Commonwealth with public health insurance and report the substance use disorder treatment program's payer mix to the Department in a format prescribed by the Department on a quarterly basis, as required by M.G.L. c. 111E, § 7. 105 CMR 164.509 shall not apply to facilities accepting civil commitments pursuant to M.G.L. c. 123, § 35;
- (2) Provide medications for treatment of addiction, including all FDA-approved medications for addiction treatment, directly or through a QSOA;
- (3) Provide overdose prevention education as part of evidence-based practices; and
- (4) Provide data and other information as requested by the Department pursuant to 105 CMR 164.522.

164.510: Inspections

- (A) The Department or its agents may visit at any time without prior notice and inspect the facility, its staff, activities, and records to determine compliance with the applicable level or levels of service provided pursuant to 105 CMR 164.100 through 164.500 and applicable state and federal laws.
- (B) Applicants and Licensed or Approved Providers shall provide Department inspectors with access to:
 - (1) The entire physical plant, including those portions open to patients or residents and staff and those open only to staff;
 - (2) All information including, but not limited to, records, and documentation related to the provision of substance use disorder treatment services, and to the operation of the program, including personnel records and documents relating to the licensed legal entity. All such records and documentation shall be in English, legible, and current to within five business days of the most recent provision of service.
- (C) Refusal to allow entry to Department inspectors shall constitute grounds to seek a warrant in district or superior court to authorize entry.

164.511: Issuance of Licenses and Approvals

Upon the approval of the application for a License or Approval, the Department shall issue a License or Approval to the applicant. Every License and Approval shall state the name and address of the program if either differs from that of the Licensed or Approved Provider or approved entity; the period of Licensure or Approval; the specific service(s) the program is Licensed or Approved to deliver; and the name and address of any satellite location(s).

- (A) In accordance with M.G.L. c. 111E, § 7, the Department shall not approve an application for an original license, unless the applicant can demonstrate need for the substance use disorder treatment program based upon the following factors:
 - (1) The health needs of drug dependent persons and persons with alcohol use disorder, as defined in M.G.L. c. 111B, § 3, in the Commonwealth, including underserved populations and persons with co-occurring mental health conditions and substance use disorder; and
 - (2) The demonstrated ability and history of a prospective Licensed or Approved Provider to meet the needs of such persons.
- (B) The Department must determine the applicant suitable to establish or maintain the service in accordance with 105 CMR 164.009 prior to issuing a License or Approval. Any Agent of the Commonwealth shall be deemed to have satisfied the requirements.
- (C) Upon satisfactory submission of an application and completion of an inspection(s), the Department may grant a license, approval, or renewal for a term of six months or two years.
- (D) Provisional Licenses and Approvals.
 - (1) When the Department finds an applicant for an initial or renewal License or Approval has not complied with all applicable regulations, but is in substantial compliance and has submitted, within 90 days of notice of noncompliance from the Department, an acceptable

164.511: continued

plan for bringing the facility into full compliance with specific dates included, the Department may issue a Provisional License or Approval, provided that:

- (a) The applicant demonstrates to the Department's satisfaction a good faith intent to meet all the requirements;
 - (b) The Department finds the service offered protects or will protect the health, safety, and well-being of the facility's patients or residents; and
 - (c) The Department finds the applicant evidences the potential for full compliance within a reasonable period of time, not to exceed six months.
- (2) A Provisional License or Approval is valid for a period not to exceed six months and may be renewed once for no more than six months.

164.512: Posting of a License or Approval

Each Licensed or Approved Provider shall post the current License or Approval issued by the Department in a conspicuous public place at each service location.

164.513: Transfer of Ownership

(A) Circumvention. A transfer of ownership shall not be recognized and the new owner shall not be considered suitable for licensure when the Transfer of Ownership is proposed or made to circumvent the effect and purpose of 105 CMR 164.500. The Department shall consider the following factors in determining whether a Transfer of Ownership has been proposed or made to circumvent 105 CMR 164.500:

- (1) The transferor's record of compliance with Department licensure laws and regulations;
- (2) The transferor's current licensure status;
- (3) The transferor's familial, business or financial relation to the transferee; and
- (4) The terms of the transfer.

(B) Suitability. At least 90 calendar days in advance of any transfer of ownership, any applicant who intends to acquire a substance use disorder treatment program shall submit a Notice of Intent to the Department on a form supplied by it. The Department shall notify each applicant in writing of the date on which the form is deemed completed. Within 90 calendar days of such date, the Department shall complete its suitability review for licensure pursuant to the standards of 105 CMR 164.509. With the consent of the applicant, the Department may extend the 90-day suitability determination period for a maximum of 30 calendar days.

(C) Application for Licensure. Upon a finding by the Department of suitability in accordance with 105 CMR 164.513(B), an applicant for licensure or approval as a result of any Transfer of Ownership shall file an application for licensure within two business days of the Transfer of Ownership, unless an extension of the two business day period is granted by the Commissioner.

- (1) A License or Approval application filed as a result of a Transfer of Ownership, if timely filed, shall have the effect of a License or Approval from the date of transfer until such time as the Department takes action on the application. If not timely filed, an application will not have such effect and the License or Approval shall lapse.
- (2) Any notice of hearing, order, or decision, which the Department or Commissioner issues to a facility prior to a transfer of ownership, shall be effective against the former owner prior to transfer and, where appropriate, the new owner following the transfer, unless the notice, order, or decision is modified or dismissed by the Department or the Commissioner.

164.514: Change of Location

(A) A Licensed or Approved Provider may not move the delivery of any services licensed pursuant to 105 CMR 164.511 to another location without receiving express prior approval by the Department for each proposed site.

(B) An application submitted by a Licensed or Approved Provider for a change in location must be filed with the Department at least 90 calendar days in advance in a manner prescribed by the Department and shall be subject to all requirements of initial licensure.

164.515: Change of Program Name

- (A) A Licensed or Approved Provider may not change the name of any program licensed pursuant to 105 CMR 164.000 without receiving express prior approval by the Department.
- (B) An application submitted by a Licensed or Approved Provider for a change in name must be filed with the Department at least 90 calendar days in advance in a manner prescribed by the Department.

164.516: Correction Orders

The Department shall prepare a written deficiency correction order for each violation of the applicable provisions of 105 CMR 164.100 through 164.500, M.G.L. c. 111E and M.G.L. c. 111B and send the deficiency correction order to the Licensed or Approved Provider of record. The deficiency correction order shall include a statement of the deficiencies found, the period within which the deficiency must be corrected, which shall not exceed 60 calendar days, except as provided for in 105 CMR 164.517(C), and the provision(s) of law and/or regulation relied upon

164.517: Plan of Correction

(A) The Licensed or Approved Provider shall submit a plan of correction to address each deficiency within 14 calendar days, unless otherwise specified by the Department and, as provided in 105 CMR 164.517(B), shall remedy or correct each deficiency cited within 60 calendar days of receipt of the deficiency correction order.

(B) The plan of correction shall set forth, with respect to each deficiency, the specific corrective step(s) to be taken, a timetable for each step, and the date by which full compliance will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible. The plan of correction shall be signed by either the Licensed or Approved Provider or his or her designee.

(C) Where, in the opinion of the Department, the deficiency is not capable of correction within 60 calendar days, the Licensed or Approved provider shall submit a written plan for correction of the deficiency in a reasonable manner within 14 calendar days of such determination by the Department. The plan of correction shall comply with 105 CMR 164.517(B).

(D) The Department may modify the plan of correction by providing notice to the Licensed or Approved Provider. The Licensed or Approved Provider may submit a written request for administrative reconsideration of the modified plan of correction, or any portion thereof, within seven calendar days of receipt of notice.

(E) If a Licensed or Approved Provider fails to remedy or correct a cited deficiency by the date specified in the deficiency correction order or fails to remedy or correct a cited deficiency by the date specified in a plan of correction as accepted or modified by the Department, the Department may:

- (1) Suspend, limit, restrict or revoke the Licensed or Approved Provider's License or Approval;
- (2) Impose a civil fine upon the Licensed or Approved Provider not to exceed \$1,000 per deficiency for each day the deficiency continues to exist beyond the date prescribed for correction (except for Agencies of the Commonwealth);
- (3) Pursue any other sanction as the Department may impose administratively upon the Licensed or Approved Provider; or
- (4) Impose any combination of the penalties set forth in 105 CMR 164.517(E)(1) through (3).

(F) Administrative Reconsideration of Civil Fines.

(1) Request for Administrative Review. The Licensed or Approved Provider may submit a written request for administrative reconsideration within seven calendar days of receipt of notice of the fine on forms approved by the Department. The request for review must fully state and support the reasons why a waiver or reduction of a fine is warranted, including specific reference to all relevant factors under the applicable level or levels of service provided pursuant to 105 CMR 164.100 through 164.500 and any and all supporting documentation.

164.517: continued

(2) The Department shall conduct an administrative review, based solely on the evidence presented within the written request and Department records, and shall issue a written decision. This decision shall constitute a final agency decision in an adjudicatory proceeding subject to judicial review pursuant to M.G.L. c. 30A, § 14.

(3) The failure to file an appeal requesting administrative review within seven calendar days of receipt of the notice constitutes a waiver of the right to request reconsideration and all fines set forth in the notice shall be imposed. The payment of a fine constitutes a waiver of the right to appeal.

164.518: Administrative Penalties

(A) Summary Suspension. The Department may summarily suspend a License or Approval prior to a hearing if:

(1) In the opinion of the Department, the violation of rules, regulation, deficiency correction orders, or plans of correction jeopardizes the health, safety, or well-being of patients or the public or seriously limits the capacity of a facility to provide adequate care; or

(2) Where the violation of such rules, regulation, deficiency correction orders, or plans of correction is the second or subsequent such violation occurring during a period of 12 months.

(B) The suspension shall remain in effect until the Department rescinds or amends such requirements or until such time as the Department takes final action on any related pending complaint and issues a final decision.

164.519: Grounds for Denial, Refusal to Renew, Restriction, Limitation, or Revocation of License or Approval

In addition to 105 CMR 164.019(A) through (J), each of the following, separately, shall constitute full and adequate grounds to deny, revoke, limit, restrict, or refuse renewal of a License or Approval:

(A) Failure to meet the applicable requirements for licensure or approval as specified in the applicable level or levels of service provided pursuant to 105 CMR 164.100 through 164.400: *Part Two*.

(B) Failure to meet the requirements of applicable federal or state law or regulations.

(C) Violating of any applicable requirement of 105 CMR 164.100 through 164.500.

(D) Failure to give proper care to patients or residents.

(E) Denying entry to agents of the Department or attempt to impede the work of a duly authorized representative of the Department.

(F) Knowingly making an omission of material information or providing false or misleading statements orally or in writing to the Department.

(G) Operating the facility without a required License or Approval or after the expiration of a License or Approval if the applicant or Licensed or Approved Provider has not timely submitted an application for renewal.

(H) There is a reasonable basis for the Department to conclude there is a discrepancy between the facility's representations as to the treatment services to be afforded patients and the treatment services actually rendered or to be rendered.

(I) Conviction of an applicant or Licensed or Approved Provider or a person with ownership or control interest in the program of Medicare or Medicaid fraud or other criminal offense related to operating the program.

(J) Conviction of an applicant or Licensed or Approved Provider or a person with ownership or control interest in the program of a violent crime against a person, which indicates that operation of the program may endanger the public health or safety.

164.520: Hearings

(A) If the Department refuses to renew, suspends, restricts, limits, or revoke licensure or approval pursuant to 105 CMR 164.019, the Department shall notify the applicant in writing of the following:

- (1) the intended action;
- (2) the reason(s) and ground(s) for the action; and
- (3) the Licensed or Approved Provider's right to file a written request for an adjudicatory hearing in accordance with M.G.L. c. 30A, and 801 CMR 1.01: *Formal Rules*.

(B) The Licensed or Approved Provider's may request a hearing on the Department's decision. A written request for a hearing shall be submitted within 14 calendar days of receipt of the notice. Upon receipt of a Licensed or Approved Provider's request for a hearing, the Department shall provide an opportunity for a hearing in accordance with M.G.L. c. 30A, and 801 CMR 1.01: *Formal Rules*.

164.521: Commissioner and Judicial Review

(A) The Commissioner shall review the recommended decision of the hearing officer in any adjudicatory proceeding conducted pursuant to 801 CMR 1.01: *Formal Rules*. The decision of the Commissioner shall constitute a final agency decision in an adjudicatory proceeding, and is subject to judicial review pursuant to M.G.L. c. 30A, § 14.

(B) A Licensed or Approved Provider or applicant that fails to exercise the right to an adjudicatory proceeding pursuant to 105 CMR 164.020 waives both the right to administrative review by the Commissioner and the right to judicial review pursuant to M.G.L. c. 30A, § 14.

164.522: Providing Information to the Department

(A) Each Licensed or Approved Provider shall timely submit management information data in a manner prescribed by the Department including, but not limited to, admissions, discharges, patient or resident characteristics, services and outcomes, and staff patterns and characteristics. It shall also submit to the Department such data, statistics, schedules, or information as the Department may require for the purposes of licensing and/or monitoring and evaluating a service as well as data required to meet federal reporting requirements including, but not limited to, outcome data.

(B) Each Licensed or Approved Provider is responsible for requesting patient or resident authorizations to ensure the timely submission of data to the Department.

(C) All information submitted pursuant to the applicable requirements of 105 CMR 164.100 through 164.500 or otherwise required by the Department shall be kept current by each Licensed or Approved Provider.

164.523: Waivers

(A) The Department may, in its discretion, waive the applicability of one or more of the requirements of 105 CMR 164.100 through 164.500 as requested by a Licensed or Approved Provider, upon a written finding that:

- (1) compliance would cause undue hardship to the provider, as documented by the Licensed or Approved Provider in a manner defined by the Department;
- (2) the provider is in substantial compliance with the spirit of the requirement and has instituted compensating features that are acceptable to the Department;
- (3) the provider's non-compliance does not jeopardize the health, safety, or well-being of its patients and does not limit the provider's capacity to provide the service; and
- (4) the provider provides to the Department written documentation supporting its request for a waiver.

(B) The Department may, in its discretion, rescind or impose a time limit on any waiver it grants.

164.534: Qualified Service Organization Agreements

Each Licensed or Approved Provider must establish written agreements with any qualified service organization providing services, programs, agencies, or facilities to the Licensed or Approved Provider. The qualified service organization agreements (QSOAs) shall:

- (A) be signed by both parties;
- (B) be renewed at a minimum of every five years;
- (C) require the qualified service organization to agree to be bound by requirements of 42 CFR Part 2;
- (D) specify the services, programs, agencies or facilities to be provided; and
- (E) if the qualified service organization provides services to the Licensed or Approved Provider's patients or residents, specify the method of referral and review of treatment plans.

164.535: Required Notifications to the Department

(A) Legal Proceedings. The Licensed or Approved Provider shall report to the Department in a manner prescribed by the Department any civil action or criminal charge initiated against the Licensed or Approved Provider or any person employed or contracted by the Licensed or Approved Provider that relates to the delivery of the service or may affect the continued operation of the program. The report shall be provided no later than one calendar day after the initiation of any legal action.

(B) Closure. When a Licensed or Approved Provider plans to cease operation said Provider shall notify the Department, patients, and residents pursuant to 105 CMR 164.587.

(C) Interruption or Suspension of Service. If a Licensed or Approved Provider determines the health, safety or well-being of patients or residents is in imminent danger as a result of conditions existing within the program, the Licensed or Approved Provider shall notify the Department immediately upon becoming aware of the danger to patients or residents and comply with 105 CMR 164.586.

(D) Change of Program or Service Provision. A Licensed or Approved Provider shall notify the Department in a manner prescribed by the Department at least 30 calendar days before any change in program or service provision. The Department shall determine whether such change requires re-licensure.

(E) Change of Administrator, Executive or Program Director. A Licensed or Approved Provider shall notify the Department at least 14 calendar days before a planned change of Administrator, Executive or Program Director. In the event of an unplanned departure of a director, the Licensed or Approved Provider shall notify the Department upon the next business day of the change of director in a manner prescribed by the Department.

(F) Death, Serious Incident, Accident or Fire.

(1) The Licensed or Approved Provider shall notify the Department immediately upon any of the following occurring at the program:

- (a) learning of the death of any person currently admitted to the program, regardless of where the death occurs;
- (b) full or partial evacuation of the facility for any reason;
- (c) fire;
- (d) suicide;
- (e) criminal acts alleged to have been committed by patients, residents, contractors, or staff members;
- (f) pending or actual strike action by its employees, and contingency plans for operation of the program;
- (g) alleged abuse or neglect, or physical or sexual assault, or prohibited interaction which occurs between or among patients and/or residents currently or previously treated by the program, or which occurs between or among such patients or residents and current

164.535: continued

or former staff regardless of location, including any incident which is reported to another agency or law enforcement;

(h) alleged abuse or neglect at the program which includes the following:

1. any reports of child abuse or neglect made under M.G.L. c. 119, § 51A;
2. any reports of elder abuse or neglect made under M.G.L. c. 19A, § 15; and
3. any reports of abuse of a disabled person made under M.G.L. c. 19C;

(i) any condition at the program which poses a threat to the health, safety or well-being of patients, residents, or staff;

(j) confirmed cases among staff or patients and residents of communicable diseases which are reportable under 105 CMR 300.000: *Reportable Diseases*; or

(k) any other serious incident or accident as specified in guidelines of the Department.

(2) The program shall report to the Department any other serious incident occurring on premises covered by the License or Approval that seriously affects the health, safety, or well-being of a patient(s) or that causes serious physical injury to a patient(s) within five business days of the date of occurrence of the event.

164.536: Marketing of Services

A Licensed or Approved Provider may not engage in advertising which:

- (1) is false, deceptive or misleading;
- (2) has the effect of intimidating or exerting undue pressure;
- (3) guarantees a cure; and/or
- (4) makes claims of professional superiority which a Licensed or Approved Provider cannot substantiate.

164.539: Nondiscrimination and Accommodation

(A) No Licensed or Approved Provider shall discriminate in the provision of service against any person on the basis of race, color, ethnicity, religious creed, national origin, sex, sexual orientation, gender identity, age, disability, genetic information, ancestry or status as a veteran.

(B) No Licensed or Approved Provider shall discriminate in the provision of service against any Medicaid recipient.

(C) Program space, including satellites and medication units, used for patients or residents shall be accessible to individuals with disabilities and shall comply with all federal, state and local requirements for accessibility.

164.540: Written Policies

(A) Licensed or Approved Providers that directly provide services shall have written policies and procedures consistent with and implemented in accordance with the applicable requirements established in 105 CMR 164.100 through 164.500, Department administrative guidelines, accepted standards of care for substance use disorder treatment services and applicable laws. All policies required under 105 CMR 164.000 shall be in writing, and available to staff, patients, residents and Department inspectors, and shall at a minimum address the following areas:

- (1) program rules;
- (2) confidentiality in accordance with 105 CMR 164.584;
- (3) security of and access to patient and resident records, and patient and resident information;
- (4) personnel policies, including:
 - (a) prohibition of sexual harassment and procedures for handling and investigating sexual harassment complaints;
 - (b) prohibited interactions between staff and patients or residents, and between or among patients and/or residents; and
 - (c) requirements of 42 CFR Part 2 (federal confidentiality regulations) and 45 CFR Parts 160, 162 and 164 (Health Insurance Portability and Accountability Act, HIPAA), where applicable.

164.540: continued

- (5) ensuring patient safety, including adequate patient and resident oversight and periodic patient and resident safety checks;
- (6) responses to and reports of death, accident, injury, fire and alleged assault, and responses to and reports of safety and health conditions at the program;
- (7) all-hazard and emergency planning and procedures;
- (8) orientation and supervision of staff from contract or temporary agencies; and
- (9) care and treatment protocols developed in accordance with all applicable federal regulations.

(B) Standards for the content of required policies may be set by administrative requirements issued from time to time by the Department.

164.544: Training and Supervision

Licensed or Approved Providers that directly provide services shall:

(A) Provide ongoing staff training and supervision to all staff, including clinical staff, qualified health care professionals, relief staff, interns, volunteers, contractors and others, in accordance with 105 CMR 164.544(B). The Licensed or Approved Provider shall have a written plan for supervision sufficient to meet the needs of staff, patients and residents. The written supervision plan shall specify the frequency and goals of supervision for all staff, and shall provide that all direct care staff requiring clinical supervision receive clinical supervision from appropriately licensed staff qualified to deliver supervision, and that supervision must be documented.

(B) Have a written plan for ongoing in-service training of all personnel. The plan shall include the following:

- (1) orientation and ongoing supervision of employees regarding policies and procedures of the program including, at a minimum, program operations; state and federal confidentiality laws; professional ethics, including staff-patient and staff-resident boundaries; behavioral management; record keeping; internal incident reporting and investigation; and the reporting of abuse and neglect of children, the elderly and disabled persons; and
- (2) over the course of a year, monthly scheduled in-service training sessions in accordance with Department guidance including, but not limited to, the following topics:
 - (a) HIV/AIDS, sexually transmitted diseases (STDs) and Viral Hepatitis;
 - (b) substance use disorders, clinical assessment and diagnosis; treatment planning; relapse prevention and aftercare planning; and overdose prevention and risk assessment;
 - (c) co-occurring disorders, including mental health disorders, gambling and other addictive behaviors, and mechanisms for ensuring coordination of care related to all co-occurring disorders, including risk assessments and creation of safety plans;
 - (d) other topics specific to the requirements of the service type and/or the population served;
 - (e) effects of substance use disorders on the family and related topics such as the role of the family in treatment and recovery;
 - (f) the benefits and risks of all clinically appropriate medication for addiction treatment options, as well as the risks and benefits of not receiving treatment;
 - (g) abuse and neglect reporting requirements; and
 - (h) professional ethics, including staff-patient and staff-resident boundaries.

(C) The Licensed or Approved Provider shall maintain a record of all in-service training sessions provided, including topic, date, duration and attendance.

164.548: Staffing Pattern

Licensed or Approved Providers that directly provide services shall:

(A) Provide an adequate number of qualified personnel to fulfill the service objectives and needs of each patient based on acuity, patient assessments, treatment plans, and other relevant factors as determined by the Licensed or Approved Provider. At a minimum, such staffing shall include:

164.548: continued

(1) A program director who shall administer the day-to-day operations of the facility and who shall be on the premises during regular business hours. In his or her absence a professional staff person shall be designated to act in his/her place. The Licensed or Approved Provider shall provide the designee with contact information for the administration in the event of an emergency.

(2) A multidisciplinary team that includes professionals sufficient to meet the needs of each patient or resident served with recognized expertise in a variety of areas of substance use disorder treatment. The team may include, as necessary to care for patients and residents served, Licensed or Approved Provider's staff as well as other treatment professionals through QSOAs. The team may include physicians, psychiatrists, psychologists, acupuncturists, advanced practice registered nurses, physician assistants, registered nurses, licensed practical nurses, social workers, psychiatric nurses, substance use disorder counselors with master's or bachelor's degrees in a related field and certified or licensed substance use disorder counselors.

(a) The multidisciplinary team shall review assessments, treatment plans and other patient and resident-specific issues to ensure quality of services and to provide education and training to staff.

(b) The Licensed or Approved Provider shall ensure the multidisciplinary team is incorporated into the staffing plan.

(B) Establish a staffing pattern sufficient to meet the program's patient or resident acuity, which includes paid staff in numbers, qualifications and shift coverage to ensure:

(1) required services are provided;

(2) safety of patients or residents and staff; and

(3) the program operates in accordance with 105 CMR 164.000.

164.570: Referrals and Admissions

Except for Agencies of the Commonwealth facilities accepting civil commitments pursuant to M.G.L. c. 123, § 35, the Licensed or Approved Provider must comply with the following:

(A) Admission and Eligibility Criteria.

(1) The Licensed or Approved Provider shall establish written admission eligibility criteria and procedures, provided such criteria and procedures do not impose any restrictions that would be reasonably conceived as a barrier to treatment access, including discrimination against patients and residents with public health insurance.

(2) Such criteria and procedures shall describe the Licensed or Approved Provider's method of determining which service type and program are suitable for the prospective patient or resident.

(3) Such eligibility criteria shall not establish a category of automatic exclusion that is defined by a history of criminal conviction or type of primary substance used, or mental health diagnosis, or prescribed medication including FDA-approved medications for the treatment of addiction.

(4) The Licensed or Approved Provider shall make the criteria and procedures available to prospective patients or residents upon the patient's or resident's application for admission.

(5) Admission eligibility criteria shall be posted in a conspicuous public area.

(B) The Licensed or Approved Provider shall comply with all applicable state and federal antidiscrimination laws such that the Provider evaluates all potential admissions regardless of the source of payment, and may not deny admission on the basis of race, color, ethnicity, religious creed, national origin, sex, sexual orientation, gender identity, age, disability, genetic information, ancestry or status as a veteran, except that Licensed or Approved Providers providing a service designed for a specific population, *e.g.*, civil commitments, women or adolescents, may limit admissions to members of that population.

(C) Where consistent with the program of services, admission eligibility criteria shall specifically address priority populations defined by the Department including, but not limited to, Medicaid patients or residents.

164.570: continued

(D) Licensed and Approved Providers shall directly connect individuals who do not meet eligibility requirements or who are inappropriate for the Licensed or Approved Provider's services to the appropriate level of care. The Licensed or Approved Provider shall collaborate, as appropriate, with care managers, case managers, health plans, and any others necessary to obtain an appropriate placement for the patient. Additionally, the Licensed or Approved provider must maintain a log of applications denied, reasons for denial and direct referrals made, and shall make this documentation available to the Department for inspection.

(E) The Licensed or Approved Provider may not deny admission to an individual solely because the individual uses medication prescribed by a practitioner outside the Licensed or Approved Provider's service or facility, including any FDA-approved medication for addiction treatment or medications used to treat mental health disorders.

(1) Programs may not require a designated amount of medication for admission.

(a) Programs must accept prospective patients or residents who arrive with medication(s) remaining on current prescription(s), and facilitate the ability to refill such prescription(s).

(b) Programs cannot deny admission to prospective patients or residents who lack current prescription refills and must work with such patients or residents to coordinate medication refills.

(c) Programs cannot deny admission based upon the types of medication a patient or resident is prescribed.

(2) Programs may not deny admission to or exclude prospective patients or residents who lack an official state identification card.

(F) Licensed or Approved Providers may deny admission to individuals who refuse to provide information necessary to complete an assessment and treatment plan, provided the Licensed or Approved Provider shall maintain a log of applications denied, reasons for denial and referrals made, and shall make this documentation available to the Department for inspection.

(G) The Licensed or Approved Provider may not deny readmission to any person solely because that person

(1) withdrew from treatment against clinical advice on a prior occasion;

(2) relapsed from earlier treatment; or

(3) filed a grievance regarding an action or decision of the Licensed or Approved Provider.

164.572: Assessment

(A) Licensed or Approved Providers that directly provide services shall complete an assessment for each patient and resident that includes the following elements, as well as applicable elements prescribed for each applicable level or levels of service provided pursuant to 105 CMR 164.100 through 164.400: *Part Two*:

(1) A history of the use of alcohol, tobacco and other drugs, including age of onset, duration, patterns and consequences of use; history of overdose, including witnessing an overdose; use of alcohol, tobacco and other drugs by family members; and types of and responses to previous treatment.

(2) An assessment of the patient's or resident's psychological, social, health, economic, educational/ vocational status; co-occurring mental health and/or physical health conditions; trauma history; and history of compulsive behaviors such as gambling. The assessment must be completed before a comprehensive service plan is developed for the patient.

(B) Patient or resident treatment may begin prior to completing the assessment, provided that sufficient information to initiate treatment for the presenting complaint or problem on that day of services is obtained and that the assessment is completed in a reasonable timeframe.

(C) When the assessments indicates a need for further evaluation, the program shall conduct necessary testing, physical examination and/or consultation by qualified professionals, or make appropriate referrals for such testing, physical examination and/or consultation by qualified professionals, provided the program continues to provide treatment to the patient or resident in the interim.

164.572: continued

(D) The assessment shall be reviewed and signed by a Senior Clinician, Clinician, or Practitioner. If conducted by a Clinician, it must be approved in writing by a Senior Clinician or Practitioner.

(E) The assessment shall conclude with:

- (1) a diagnosis of the status and nature of the patient's or resident's substance use disorder, using standardized definitions established by the American Psychiatric Association, or a mental or behavioral disorder due to use of psychoactive substances, as defined by the World Health Organization; and
- (2) an offer to the patient or resident to initiate any FDA-approved medication for addiction treatment.

164.573: Individual Treatment Plan

Licensed or Approved Providers that directly provide services shall complete an individual treatment plan based on the patient's or resident's treatment, medical, psychiatric and social histories, which includes the following elements, as well as applicable elements prescribed for each level or levels of service provided pursuant to 105 CMR 164.100 through 164.400: *Part Two*.

(A) The treatment plan and all subsequent updates shall, at a minimum, include documentation of the following information:

- (1) A statement of the patient's or resident's strengths, needs, abilities and preferences in relation to his or her substance use disorder treatment, described in behavioral terms;
- (2) Evidence of the patient's or resident's involvement in formulation of the treatment plan, in the form of the patient's or resident's signature attesting agreement to the plan;
- (3) Service to be provided;
- (4) Service goals, described in measurable, behavioral terms, with time lines;
- (5) Description of discharge plans and aftercare service needs;
- (6) Aftercare goals;
- (7) Plan for initiating, coordinating, managing, and referring to:
 - (a) concurrent additional substance use disorder treatment that may require the use of medication, such as medication for addiction treatment when a patient or resident is enrolled in outpatient counseling or residential rehabilitation;
 - (b) treatment of co-occurring disorders;
 - (c) primary medical care; and
 - (d) recovery supports and resources.

(B) Such plan shall identify providers of care and responsibilities of each, specifying method(s) for coordination and communication, and method(s) for ensuring that sharing of information is consistent with the requirements of 105 CMR 164.548. With patient consent, treatment plans may be submitted from the discharging provider to the admitting provider during the referral process.

164.574: Minimum Treatment Service Requirements

The Licensed or Approved Provider shall provide directly or through QSOA with Qualified Service Organizations, the following services, as applicable in 105 CMR 164.100 through 164.400: *Part Two*.

- (A) Medications for treatment of addiction, including all FDA-approved medications for addiction treatment;
- (B) Overdose prevention education as part of evidence-based practices;
- (C) Substance use disorder therapies;
- (D) Counseling and education as clinically indicated which conform to accepted standards of care, uses evidence-based practices, and monitors progress and outcomes;
- (E) HIV education and counseling;

164.574: continued

- (F) TB screening, education and treatment;
- (G) Tobacco education and counseling;
- (H) Case management including:
 - (1) directly connecting patients and residents to appropriate providers based on continuum of care, and patient and resident educational, vocational, financial, legal and housing needs;
 - (2) updating the patient or resident's primary care provider on treatment and progress, such as by providing the patient's or resident's record to the primary care provider upon the patient's or resident's documented authorization;
 - (3) documentation of patient or resident consent to provide treatment information to the patient or resident's primary care provider or release information to the receiving provider prior to or upon patient transfer. In the event the patient or resident refuses such consent, the Licensed or Approved Provider shall document such refusal in the patient or resident's record.
- (I) Mental health services, including screening, crisis intervention, and psychopharmacological services, for individuals with co-occurring disorders;
- (J) Health services, including primary care, oral health, and family planning services requested by the patient or resident;
- (K) Services for individuals with compulsive behaviors such as compulsive gambling;
- (L) Relapse prevention and recovery maintenance counseling and education and shall:
 - (1) include monitoring of the patient's or resident's behavior;
 - (2) address risks specific to the patient or resident, including, where applicable, risk of overdose; and
 - (3) include services intended to maintain the patient or resident in treatment and support recovery;
- (M) Planning for patient's or resident's completion of treatment, and identification of transitional, discharge and aftercare supports the patient or resident may require; and
- (N) Family support services, including family therapy, or social or education services.

164.575: Termination and Discharge

- (A) Licensed or Approved Provider shall establish written termination and discharge policies and procedures and shall make these available to prospective patients or residents at the time of admission. These policies shall include:
 - (1) Written criteria defining:
 - (a) Successful completion of treatment;
 - (b) Voluntary termination prior to program completion, except in the case of an individual committed to treatment under M.G.L. c. 123, § 35;
 - (c) Involuntary termination, including:
 - 1. emergency termination when the program director or Practitioner reasonably determines the patient's or resident's continued presence in the program presents an immediate and substantial threat of physical harm to other patients or residents, program personnel, or property; and
 - 2. nonemergency termination, including notice to the patient or resident of the reasons for termination and the right to grieve the decision as required by 105 CMR 164.080 prior to termination; and
 - (d) Procedures for determining, in consultation with the patient or resident, referrals needed to ensure a continuum of care, reduction of risk of relapse, and reduction of risks to patient's or resident's well-being, provided the patient or resident is directly connected to such services prior to or within a reasonable time following discharge. Such referrals may include, but are not limited to:
 - 1. certified alcohol and drug-free housing;

164.575: continued

2. additional substance use disorder treatment;
 3. treatment of co-occurring disorders;
 4. continued care coordination and management with the patient's or resident's medical and psychiatric care providers;
 5. community based overdose prevention programs;
 6. employment resource; and
 7. community and social supports, including family support services.
- (2) Procedures for planning the discharge in consultation with the patient or resident when one of the following conditions are met and discharge will not create an immediate safety risk for the patient:
- (a) Patient or resident has received optimum benefit from treatment and further progress requires either the patient's or resident's return to the community or the patient's or resident's referral to another type of treatment program;
 - (b) Patient or resident is ready to transition to different service type, which may be more or less intensive than the current program;
 - (c) Except in the case of an individual committed to treatment under M.G.L. c. 123, § 35, patient or resident voluntarily requests discharge from treatment, in which case procedures shall include review of risks and benefits of terminating treatment; or
 - (d) Patient or resident is involuntarily terminated on a nonemergency basis.
- (3) A written discharge summary including:
- (a) Description of services provided, patient's or resident's response to such services, and progress in attaining treatment plan goals;
 - (b) Patient's or resident's substance use at discharge, including risk of overdose and recommendations for follow-up services;
 - (c) Patient's or resident's current vocational, educational and financial status;
 - (d) Reason for termination;
 - (e) Direct referrals provided; and
 - (f) Supports and services available to the patient or resident after discharge, provided by the Licensed or Approved Provider or by others;
- (B) Licensed or Approved Providers that directly provide services may discharge patients or residents who refuse to provide information required for necessary coordination of treatment, provided the Licensed or Approved Provider shall maintain a log of involuntary discharges, reasons for involuntary discharge and referrals made, and shall make this documentation available to the Department for inspection.

164.576: Aftercare

Licensed or Approved Providers that directly provide services shall establish written policies and procedures for provision of aftercare patients or residents who are discharged, which shall include provisions for patient and resident participation in developing the aftercare plan, a method for contacting the patient or resident, and ensuring the patient's or resident's ability to continue any prescribed medications. Aftercare services shall include:

- (A) Directly connecting the patient or resident to an appropriate provider to ensure a continuum of care for the patient or resident, including arrangements for further substance use disorder treatment and post-discharge counseling and other supportive services;
- (B) Providing information concerning available community-based service agencies and programs, which shall include a description of services, addresses, phone numbers and the names of contact persons;
- (C) Referrals, the aftercare plan and information provided to the patient or resident shall be documented in the patient's or resident's record; and
- (D) If a patient or resident refuses aftercare services, the Licensed or Approved Provider shall document the refusal in the patient's or resident's record.

164.579: Patients' and Residents' Rights

Licensed or Approved Providers that directly provide services shall:

(A) Safeguard the legal and civil rights of each patient and resident at all times during treatment and throughout the discharge process. Each Licensed or Approved Provider shall adopt and maintain an updated set of rules, which set forth the responsibilities and the rights of patients and residents regarding treatment and discharge.

(B) Guarantee the patient or resident, at a minimum, the following rights:

- (1) freedom from physical and psychological abuse;
- (2) freedom from strip searches and body cavity searches;
- (3) control over his or her bodily appearance; provided, however, on program premises, the Licensed or Approved Provider may prohibit attire and personal decoration which interfere with treatment;
- (4) access to his or her patient or resident record in the presence of the administrator or designee unless there is a determination that access to parts of the record could cause harm to the patient or resident;
- (5) the right to challenge information in his or her patient or resident record by inserting a statement of clarification or letter of correction signed by both the clinician and the patient or resident;
- (6) the right to obtain a copy of the patient's or resident's records as specified in 105 CMR 164.083;
- (7) the right to have the confidentiality of his or her records secured as required by 105 CMR 164.084;
- (8) the right to terminate treatment at any time, except in the case of an individual committed to treatment under M.G.L. c. 123, § 35;
- (9) freedom from coercion;
- (10) treatment without regard to race, ethnicity, creed, national origin, religion, sex, sexual orientation, gender identity, ability to speak English, age, or disability;
- (11) treatment in a manner sensitive to individual needs and which promotes dignity and self-respect;
- (12) full disclosure regarding fee charged and, in residential rehabilitation programs, any patient or resident benefits to be contributed;
- (13) the right to grieve actions or decisions of the Licensed or Approved Provider regarding the patient's or resident's treatment;
- (14) freedom to practice his or her religious faith;
- (15) the right to request referral to a facility which provides treatment in a manner to which the patient or resident has no religious objection;
- (16) drug screens conducted in a manner which preserves the patient's or resident's dignity and, when the drug screen is by urine sample, accommodates any medically confirmed inability to give urine by providing for an alternate effective means of screening such as oral swab; and
- (17) the right to contact the Department.

(C) Provide for translations of rights, rules and manuals for patients and residents who do not read English.

164.580: Grievances

Licensed or Approved Providers that directly provide services shall establish written policy and procedures for the resolution of patients' or residents' disagreement(s) or dispute(s) arising in relation to treatment or program requirements. The policy and procedures shall specify:

- (1) Patients' and residents' right to grieve actions and/or decisions of the Licensed or Approved Provider regarding the patient or resident's treatment;
- (2) Steps to be taken to resolve the matter; and
- (3) Provisions for a hearing on the matter presided over by an impartial grievance officer who may be any staff or other person(s) not directly involved in the facts of the incident giving rise to the action grieved or in the decision to commence the action; provided that the persons involved in either the facts of the incident or in the decision to commence the proceedings shall not have authority over the hearing officer(s). Grievance officers shall be selected based upon their expertise in issues being grieved (*e.g.*, medical officer/medical grievance, administrative officer/administrative grievance). All hearings may be conducted by telephone or using an audio-visual, real-time, two-way interactive communication system.

164.582: Special Populations

Licensed and Approved Providers directly providing services to special populations listed in 105 CMR 164.582(A) through (E) shall make additional provisions as specified:

- (A) Pregnant Women. Licensed and Approved Providers serving pregnant women shall:
- (1) establish in writing clinically appropriate medical protocols for pregnant women;
 - (2) designate a hospital for emergency obstetrical and medical back-up; however, patients or residents may elect to choose their own medical providers;
 - (3) coordinate care with obstetrical or other maternity care providers as appropriate;
 - (4) provide for appropriate parent or legal guardian-child services directly or through a QSOA; and
 - (5) be available to serve women in all three trimesters of pregnancy.
- (B) Adolescents and Transition Age Youth. Licensed and Approved Providers serving Adolescents and/or Transition Age Youth shall:
- (1) ensure assessments, as required in 105 CMR 164.072, include an evaluation of:
 - (a) developmentally age-appropriate behaviors;
 - (b) cognitive functioning;
 - (c) physical maturation;
 - (d) existing peer and family supports, peer group and family functioning;
 - (e) experience of trauma;
 - (f) history of mental health diagnoses;
 - (g) availability and access to recovery supports;
 - (h) social maturity; and
 - (i) educational needs.
 - (2) determine the person's custody status if younger than 18 years old;
 - (3) ensure the staff providing services for children and adolescents have specific training in child and teen development, including a minimum of five college credit hours in courses related to the topic;
 - (4) ensure services for adolescents are supervised by a Senior Clinician with at least two years post-master's experience working with adolescents with substance use disorders;
 - (5) ensure available parent or care-giver support and education services;
 - (6) ensure adolescents are served in programs which are separate from programs serving adult populations; and
 - (7) prior to providing any services to persons younger than 18 years old, inform the Department of the nature and scope of any services provided to adults in the same facility as those intended for services for adolescents. The Department shall determine whether such proximity of adult services constitutes a risk to adolescents.
- (C) Persons with Co-occurring Disorders. Licensed and Approved Providers serving persons with co-occurring disorders shall:
- (1) establish policies and procedures for referrals for specialized psychiatric/psychological care; and
 - (2) if the Licensed or Approved Provider is not also licensed or approved to provide mental health services, establish QSOAs providing for mental health interventions and coordinated care.
- (D) Elders. Licensed and Approved Providers serving persons 60 years old or older shall establish QSOAs with local organizations providing services for the elderly.
- (E) Persons with Disabilities. Licensed and Approved Providers serving persons with disabilities shall document the patient's or resident's current functioning, ability to perform activities of daily living, and ability to comprehend program policies and procedures.

164.583: Patient and Resident Records

The Licensed or Approved Provider shall maintain separate records for each patient and resident in a secure and confidential manner consistent with state and federal law, including 42 CFR Part 2. Records shall be legible and up to date no later than five business days from the date of last patient or resident contact, and shall include a record of patient care coordination, including relevant releases of information.

164.584: Confidentiality

Patient- and resident-specific information shall be privileged and confidential and shall be made available only in conformity with all applicable state and federal laws and regulations regarding the confidentiality of patient and resident records including, but not limited to, 42 CFR Part 2, and 45 CFR Parts 160 and 164 (HIPAA Privacy and Security Rules) if applicable.

164.586: Interruption or Suspension of Service

(A) If the Department determines there is a need to interrupt or suspend a service or program because the health, safety, or well-being of patients or residents is in imminent danger as a result of conditions existing within the service, program, or facility, the Licensed or Approved Provider shall:

- (1) notify patients and residents of the interruption or suspension;
- (2) provide for continuity of care for patients and residents during the period of interruption or suspension; and
- (3) provide for the secure storage or safe transfer of patient or resident records, with patient or resident authorization.

(B) Within five calendar days of the interruption or suspension of services or program, the Licensed or Approved Provider shall notify the Department in writing of its plans to resume service, or for transfer of services to another program or facility.

164.587: Closure

(A) Except as provided by 105 CMR 164.087(D), the Licensed or Approved Provider shall ensure that the Department, each patient and resident, each staff member of the program, and each labor organization that represents the facility's workforce is notified at the time of notice orally and in writing at least 90 calendar days prior to the termination of the program that the program will close, and document the notification in each patient's or resident's record. Notification shall specify the date of closure.

(B) Licensed or Approved Providers that directly provide services shall develop a written referral plan in collaboration with each patient and resident that includes a plan for continuing the patient's or resident's substance use disorder treatment, including directly connecting patients and residents to an appropriate provider for continued treatment. If insufficient time remains to ensure an appropriate referral plan with respect to an involuntary closure, the Licensed or Approved Provider shall cooperate with the Department and the patient or resident to ensure an appropriate referral, if required.

(C) The Commissioner may waive the 90-day time frame for initial notification of closure in circumstances where the Commissioner has determined that such a waiver is necessary to protect the health, safety, and well-being of the patients and residents served by the program.

(D) The Department may grant permission for the temporary closure of the program provided that:

- (1) the Licensed or Approved Provider has submitted a plan for continued substance use disorder treatment for all patients and residents during the temporary closure; and
- (2) the Licensed or Approved Provider may only close after approval from the Department.

164.600: Approval Requirements for Substance Use Disorder Treatment Programs Operated by Penal Facilities

164.605: Scope

The provisions of 105 CMR 164.607 through 105 CMR 164.626, as well as any standards set forth by the Department shall apply to any program operated by a penal facility.

164.607: Application Submission for Approval and Provisional Approval

No penal facility shall hold itself out as operating a substance use disorder treatment program without an Approval from the Department.

164.607: continued

- (A) In order to operate a substance use disorder treatment program, a penal facility must:
- (1) submit a complete application package in a manner prescribed by the Department; and
 - (2) meet the requirements contained within 105 CMR 164.612 through 105 CMR 164.630.
- (B) Provisional Approval.
- (1) When the Department finds a first time applicant for Approval, or an applicant for renewal of Approval, has not complied with all applicable requirements and regulations, but is in substantial compliance and has submitted an acceptable plan of correction for bringing the penal facility into full compliance, the Department may issue a provisional approval provided that:
 - (a) The applicant demonstrates to the Department's satisfaction a good faith intent to meet all applicable requirements and regulations;
 - (b) The Department finds the service offered protects the health, safety, and well-being of the penal facility's patients; and
 - (c) The Department finds the applicant evidences the potential for full compliance within a reasonable period of time, not to exceed six months.
 - (2) A provisional approval is valid for a period not to exceed six months and may be renewed once for no more than six months. The Department may issue a provisional approval only when an applicant submits a written plan for full compliance. This written plan shall include specific target dates for achieving full compliance.

164.608: Renewal of Approval

- (A) Applicants seeking renewal for an Approval shall meet all requirements for approval specified in 105 CMR 164.607.
- (B) Applicants for renewal must submit to the Department completed applications required by the Department prior to the expiration of the Approval.
- (1) If the complete renewal application is timely filed with the Department, the Approval shall not expire until the Department makes a determination on the renewal application.
 - (2) If an application is not submitted timely, the service may not continue to operate after the expiration of its Approval without the written permission of the Department.

164.609: Administrative Action on the Approval

- (A) Summary Suspension. The Commissioner may summarily suspend an Approval if the continued operation of the program or service poses an immediate threat to the health, safety, or well-being of its patients. The Approved Provider may not operate during the period of suspension of its license, after notification of the suspension.
- (B) Grounds for Denial, Refusal to Renew, Restriction, Limitation, or Revocation of License. Each of the following, separately, shall constitute full and adequate grounds to deny, revoke, limit, restrict, or refuse renewal of an Approval:
- (1) Failure to satisfy the Department as to any of the application requirements under 105 CMR 164.607;
 - (2) Failure to meet the requirements of applicable federal or state law or regulations;
 - (3) Violation of any applicable requirement of 105 CMR 164.000;
 - (4) Failure to give proper care to patients;
 - (5) Failure to remedy or correct a cited violation;
 - (6) Denial of entry to agents of the Department or attempt to impede the work of a duly authorized representative of the Department;
 - (7) Knowingly making an omission of material information or providing false or misleading statements orally or in writing to the Department; and
 - (8) Operation of the Program without a required Approval or after the expiration of an Approval.
- (C) Appeals.
- (1) The Department shall provide written notice to the penal facility stating the grounds for the suspension, revocation, restriction, limitation, or refusal to renew an Approval. Such action shall take effect immediately upon issuance of the notice.

164.609: continued

(2) The penal facility may, within 14 days of receipt of the written notice, file a written request for an adjudicatory hearing in accordance with M.G.L. c. 30A, and 801 CMR 1.01: *Formal Rules*.

(3) Upon receipt of a timely filed request, the Department shall refer the matter to the DALA for hearing.

(4) The Commissioner shall review the recommended decision of DALA pursuant to 801 CMR 1.01: *Formal Rules*. The decision of the Commissioner shall constitute a final agency decision in an adjudicatory proceeding, and is subject to judicial review pursuant to M.G.L. c. 30A, § 14.

164.612: Minimum Treatment Service Requirements

The Approved Provider shall provide directly or through QSOAs the following services:

(A) Medications for treatment of addiction, including all FDA-approved medications for addiction treatment;

(B) Overdose prevention education as part of evidence-based practices;

(C) Substance use disorder therapies;

(D) Counseling and education as clinically indicated which conform to accepted standards of care, uses evidence-based practices, and monitors progress and outcomes;

(E) Case management including:

(1) directly connecting patients and residents to appropriate providers based on continuum of care and patient and resident educational, vocational, financial, legal and housing, and

(2) updating the patient or resident's primary care provider on treatment and progress, such as by providing the patient's or resident's record to the primary care provider upon the patient's or resident's documented authorization.

(3) documentation of patient or resident consent to provide treatment information to the patient or resident's primary care provider or release information to the receiving provider prior to or upon patient transfer. In the event the patient or resident refuses such consent, the Licensed or Approved Provider shall document such refusal in the patient or resident's record.

(F) Relapse prevention and recovery maintenance counseling and education and shall:

(1) include monitoring of the patient's or resident's behavior;

(2) address risks specific to the patient or resident, including, where applicable, risk of overdose; and

(3) include services intended to maintain the patient or resident in treatment and support recovery; and

(G) Planning for patient's or resident's completion of treatment, and identification of transitional, discharge and aftercare supports the patient or resident may require.

164.614: Inspections

(A) The Department or its agents may visit at any time without prior notice and inspect the portion of the facility approved for substance use disorder treatment, its staff, activities, and records to determine compliance with 105 CMR 164.000 and applicable state and federal laws.

(B) Applicants and Approved Providers shall provide Department inspectors with access to:

(1) The entire physical plant, including those portions open to patients and staff and those open only to staff; and

(2) All information including, but not limited to: records, and documentation related to the provision of substance use disorder treatment services, and to the operation of the program, including personnel records and documents relating to the licensed legal entity. All such records and documentation shall be in English, legible, and current to within five business days of the most recent provision of service.

164.614: continued

(C) Refusal to allow entry to Department inspectors shall constitute grounds to seek a warrant in district or superior court to authorize entry.

164.616: Correction Orders

The Department shall prepare a written deficiency correction order for each violation of 105 CMR 164.000, M.G.L. c. 111E and M.G.L. c. 111B and send the deficiency correction order to the Approved Provider of record. The deficiency correction order shall include, a statement of the deficiencies found, the period within which the deficiency must be corrected, which shall not exceed 60 calendar days, except as provided for in 105 CMR 164.618(C), and the provision(s) of law and/or regulation relied upon.

164.618: Plan of Correction

(A) The Approved Provider shall submit a plan of correction to address each deficiency within 14 calendar days, unless otherwise specified by the Department and, as provided in 105 CMR 164.618(B), shall remedy or correct each deficiency cited within 60 calendar days of receipt of the deficiency correction order. The Department may modify the plan of correction by providing notice to the Approved Provider. The Approved Provider may submit a written request for administrative reconsideration of the modified plan of correction, or any portion thereof, within seven calendar days of receipt of notice.

(B) The plan of correction shall set forth, with respect to each deficiency, the specific corrective step(s) to be taken, a timetable for each step, and the date by which full compliance will be achieved. The timetable and the compliance dates shall be consistent with achievement of compliance in the most expeditious manner possible. The plan of correction shall be signed by either the Approved Provider or his or her designee.

(C) Where, in the opinion of the Department, the deficiency is not capable of correction within 60 calendar days, the Approved provider shall submit a written plan for correction of the deficiency in a reasonable manner within 14 calendar days of such determination by the Department. The plan of correction shall comply with 105 CMR 164.616.

(D) The Department may modify the plan of correction by providing notice to the Approved Provider. The Approved Provider may submit a written request for administrative reconsideration of the modified plan of correction, or any portion thereof, within seven calendar days of receipt of notice.

164.620: Required Notifications to the Department

(A) Legal Proceedings. The Approved Provider shall report to the Department in a manner prescribed by the Department any civil action or criminal charge initiated against the Approved Provider or any person employed or contracted by the Approved Provider that relates to the delivery of the service or may affect the continued operation of the facility. The report shall be provided no later than one calendar day after the initiation of any legal action.

(B) Closure. When an Approved Provider plans to cease operation said Provider shall notify the Department, patients, and residents.

(C) The Department may grant permission for the temporary closure of the service or program provided that:

- (1) the Licensed or Approved Provider has submitted a plan for continued substance use disorder treatment for all patients during the temporary closure; and
- (2) the Licensed or Approved Provider may only close after approval from the Department.

(D) Interruption or Suspension of Service. If an Approved Provider determines that the health, safety or well-being of patients or residents is in imminent danger as a result of conditions existing within the program, the Approved Provider shall notify the Department immediately upon becoming aware of the danger to patients and comply with 105 CMR 164.086.

164.620: continued

(E) Change of Program or Service Provision. An Approved Provider shall notify the Department in a manner prescribed by the Department at least 30 calendar days before any change in program or service provision. The Department shall determine whether such change requires re-licensure.

(F) Change of Administrator, Executive or Program Director. An Approved Provider shall notify the Department at least 14 calendar days before a planned change of Administrator, Executive or Program Director. In the event of an unplanned departure of a director, the Approved Provider shall notify the Department upon the next business day of the change of director in a manner prescribed by the Department.

(G) Death, Serious Incident, Accident or Fire.

(1) The Approved Providers that directly provide services shall notify the Department immediately upon the occurrence of any of the following at the program:

- (a) learning of the death of any person currently admitted to the program, regardless of where the death occurs;
- (b) full or partial evacuation of the facility for any reason;
- (c) fire;
- (d) suicide;
- (e) criminal acts alleged to have been committed by patients, contractors, or staff members;
- (f) pending or actual strike action by its employees, and contingency plans for operation of the program;
- (g) alleged abuse or neglect, or physical or sexual assault, or prohibited interaction which occurs between or among patients currently or previously treated by the program, or which occurs between or among such and current or former staff regardless of location, including any incident which is reported to another agency or law enforcement;
- (h) alleged abuse or neglect at the program which includes the following:
 1. any reports of child abuse or neglect made under M.G.L. c. 119, § 51A;
 2. any reports of elder abuse or neglect made under M.G.L. c. 19A, § 15; and
 3. any reports of abuse of a disabled person made under M.G.L. c. 19C;
- (i) any condition at the program which poses a threat to the health, safety, or well-being of patients or staff;
- (j) confirmed cases among staff or patients and residents of communicable diseases which are reportable under 105 CMR 300.000: *Reportable Diseases, Surveillance, and Isolation and Quarantine Requirements*; or
- (k) any other serious incident or accident as specified in guidelines of the Department.

(2) Approved Providers that directly provide services shall report to the Department any other serious incident occurring under the auspices of the Approved services that seriously affects the health, safety, or well-being of a patient(s) or that causes serious physical injury to a patient(s) within five business days of the date of occurrence of the event.

164.623: Waiver

(A) The Department may, in its discretion, waive the applicability of one or more of the requirements of 105 CMR 164.600 as requested by an Approved Provider, upon a written finding that:

- (1) Compliance would cause undue hardship to the provider, as documented by the Licensed or Approved Provider in a manner defined by the Department;
- (2) the provider is in substantial compliance with the spirit of the requirement and has instituted compensating features that are acceptable to the Department;
- (3) the provider's non-compliance does not jeopardize the health, safety, or well-being of its patients or residents and does not limit the provider's capacity to provide the service; and
- (4) the provider provides to the Department written documentation supporting its request for a waiver.

(B) The Department may, in its discretion, rescind or impose a time limit on any waiver it grants.

164.624: Patient Records

The Approved Provider shall maintain separate records for each patient in a secure and confidential manner consistent with state and federal law, including 42 CFR Part 2. Records shall be legible and up to date no later than five business days from the date of last patient contact.

164.626: Confidentiality

Patient-specific information shall be privileged and confidential and shall be made available only in conformity with all applicable state and federal laws and regulations regarding the confidentiality of patient records including, but not limited to, 42 CFR Part 2, and 45 CFR Parts 160 and 164 (HIPAA Privacy and Security Rules) if applicable.

164.700: Severability

Any section, subsection, paragraph, sentence, clause, phrase, or word of 105 CMR 164.000 declared to be invalid for any reason shall be severed and shall not affect any other portion of 105 CMR 164.000, which shall remain in full force and effect.

REGULATORY AUTHORITY

105 CMR 164.000: M.G.L. c. 17, § 19, c. 90, § 24 and 24D, c. 94C, § 6A, c. 111, § 3, c. 111B, § 6, and c. 111E, § 7.