**STATE OF MAINE**

**BEHAVIORAL HEALTH ORGANIZATIONS LICENSING RULE**

**10-144 CODE OF MAINE RULES**

**Chapter 123**



Department of Health and Human Services

Division of Licensing and Certification

11 State House Station

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PURPOSE AND APPLICABILITY

1. Purpose: This rule consolidates requirements for the licensing of mental health and substance use disorder programs and related residential treatment services. Because behavioral health programs often deliver a variety of mental health, substance use disorder, and integrated treatment services provided in diverse settings by an array of qualified professionals, one consolidated licensing rule for behavioral health programs will assist providers who are licensed to provide a variety of services.

This consolidated rule replaces three repealed rules in the Code of Maine Rules (CMR). These three repealed rules were:

1. 14-193 CMR Ch. 6, Licensing of Mental Health Facilities;
2. 14-193 CMR Ch. 6A, Licensing of Mental Health Facilities: PNMI; and
3. 14-118 CMR Ch. 5, Regulations for Licensing and Certifying of Substance Abuse Treatment Programs.

Upon the effective date of this rule, licensees previously regulated under the provisions of one of the above-listed repealed rules are subject to the Behavioral Health Organizations Licensing Rule.

1. **Applicability**:
	1. The Department licenses organizations providing clients with mental health services, substance use disorder treatment services, integrated treatment services, and treatment as defined in 34-B M.R.S. § 6201(3).
	2. Specific organizations requiring licensure as set forth in this rule are more fully set out in Sections 22 and 23, but provide the following services:
		1. Community support and integration mental health services, including but not limited to case management services, community rehabilitation services, Assertive Community Treatment, community integration services, psychosocial clubhouse services, day supports, intensive community integration, skills development, daily living skills, and direct skill teaching;
		2. Community support and integration substance use disorder services, including but not limited to case management services funded under 10-144 CMR Ch. 101, MaineCare Benefits Manual;
		3. Crisis mental health services or crisis substance use disorder services, including but not limited to triage, safety assessments, supportive counseling or crisis/relapse plan development, and follow up;
		4. Outpatient mental health services, including but not limited to psychological assessment, outpatient therapy, outpatient counseling, geriatric psychiatric services, sex offender treatment, trauma recovery services, specialized group services, family psychoeducational treatment, and medication management;
		5. Outpatient substance use disorder services, including but not limited to intensive and structured treatment services; clinical services; educational groups; screening, brief intervention and referral; scheduled or emergency services; counseling; and referral for services;
		6. Residential mental health services for adults, including but not limited to rehabilitative and support interventions with a focus on activities of daily living, medication management, medication self-administration, independent living skills, recovery, community inclusion and supports services, clinical treatment;
		7. Residential substance use disorder services for adults, including but not limited to diagnostic services, educational services, counseling services, provision of medication for opioid use disorders, medically supervised withdrawal programs;
		8. Integrated treatment services, including community support and integration, crisis, outpatient, and residential; and
		9. Rehabilitative and community services for children with cognitive impairments and functional limitations funded under 10-144 CMR Ch. 101, MaineCare Benefits Manual.
	3. This rule does not apply to Children’s Residential Care Facilities licensed under 10-148 CMR Ch. 35, Children's Residential Care Facilities Licensing Rule.

**PART ONE: Core Standards**

# **SECTION 1. DEFINITIONS**

1. Definitions in this rule are in addition to the definitions in applicable statutes. The definitions in statute may not be repeated in this rule. The definitions in this rule and the statutes govern this program.
	1. **Abuse** means the infliction of injury, unreasonable confinement, intimidation, or cruel punishment with resulting physical harm or pain or mental anguish; sexual abuse or exploitation; or the willful deprivation of essential needs.
	2. **Accreditation** means a credentialing process of a licensed behavioral health program by a national organization resulting in the issuance of documented compliance status for a term of years when meeting specific performance requirements and standards.
	3. **Administrator** means an individual, at least 21 years of age, charged with responsibility for the general oversight of an organization. Every individually licensed organization must have an identified administrator.
	4. **Advisory board** means a group created by the organization’s governing body which is charged to review the organization’s operations or practices and submit recommendations for quality improvement.
	5. **Alcohol and drug counselor** means an individual certified or licensed by the Maine State Board of Alcohol and Drug Counselors to provide substance use disorder services in Maine.
	6. **Allied services** means other services eligible for reimbursement that contribute to the functioning of recipients of behavioral health services, including those that allow individuals to access services through assessment of needs and referral to appropriate providers.
	7. **Assertive Community Treatment** **(ACT)** individualized intensive integrated services that are delivered by a multi-disciplinary team of practitioners and are available twenty-four (24) hours a day, every day, three hundred and sixty-five (365) days a year.
	8. **Behavioral health organization** means a licensed provider of mental health treatment, substance use disorder treatment, or integrated mental health and substance use disorder treatment.
	9. **Behavioral support plan** means a written plan that describes all planned interventions which include restrictions of rights or the use of restraint and/or seclusion.
	10. **Biological drug** means a substance made from living organisms, or its products, used in the prevention, diagnosis, or treatment of cancer and other diseases. Biological drugs include vaccines, interleukins, serums, and antigens. Biological drugs may be referred to as biologicals.
	11. **Case management services** means services to identify the medical, social, educational, and other needs (including housing and transportation) of the eligible client, identify the services necessary to meet those needs, and facilitate access to those services. Case management consists of intake/assessment, plan of care development, coordination/advocacy, monitoring, and evaluation. Case management services are also referred to as Targeted Case Management Services and are provided to children and adults.
	12. **Client** means an individual enrolled in services from a licensed behavioral health organization.
	13. **Clinician** means an individual appropriately licensed to provide medical, mental health, or substance use disorder services.
	14. **Clinical staff** means licensed or certified employees that provide direct services within a specified scope of treatment.
	15. **Clinical supervisor** means a substance use disorder certified clinical supervisor (CCS) and other qualified clinical supervisors.
	16. **Cohorting** means the practice of grouping residents infected with the same infectious agent together, to confine their care to one area, and prevent contact with susceptible residents.
	17. **Community integration services** means a biopsychological assessment of the client, an evaluation of community services and natural supports needed by the client, and rapport building through assertive engagement and linking to necessary natural supports and community services while providing ongoing assessment of the efficacy of those services.
	18. **Community rehabilitation services** means services that support the development of the necessary skills for living in the community, and promote recovery, and community inclusion. Services include individualized combinations of services, and are delivered by a team, with primary case management for each client assigned to one team member.
	19. **Community support services** means rehabilitative services, provided pursuant to an individual’s service plan, that promote a client’s recovery and integration into the community and sustain the client in his or her current living situation.
	20. **Complaint investigation** means the Department’s review of information and records and Department-conducted interviews, including of clients and employees, to determine the validity of an allegation of non-compliance with this rule against an organization.
	21. **Comprehensive assessment** means an integrated evaluation of a client’s medical and psychosocial needs, including co-occurring mental health and substance use disorder status, to determine the need for treatment or referral and to establish the appropriate intensity and level of care. Assessment results form the basis for an individual’s service plan.
	22. **Co-occurring behavioral health condition or co-occurring disorder** means a health status that involves a diagnosis of one or more mental health disorders in combination with a diagnosis of one or more substance use disorders identified in the most current edition of the Diagnostic and Statistical Manual of Mental Disorders.
	23. **Counseling professional** means an individual licensed by the Maine Board of Counseling Professionals Licensure, including but not limited to fully or conditionally licensed professional counselors, licensed clinical professional counselors, licensed marriage and family therapists, and licensed pastoral counselors.
	24. **Crisis intervention counselor** means a clinician, mental health rehabilitation technician/crisis service provider (MHRT/CSP), or an individual who has received crisis intervention certification as approved by the Department.
	25. **Crisis services** means immediate intervention services available 24 hours a day, 7 days a week, for the treatment and stabilization of acute emotional disturbances to ensure the safety of a client or others.
	26. **Critical incident** means an occurrence that affects or has the potential to affect the health or safety of the client or others. Level 1 Critical Incidents result in death or serious injury, or significantly jeopardize clients, public safety, or program integrity. Level 2 Critical Incidents include significant errors or undesirable events that compromise quality of care or client safety.
	27. **Daily living support services** means services designed to assist a client to maintain the highest level of independence possible. The services provide personal supervision and therapeutic support to assist clients to develop and maintain the skills of daily living. The services help clients remain oriented, healthy, and safe. Without these supportive services, clients likely would not be able to retain community tenure and would require crisis intervention or hospitalization. These services are provided to clients in or from their homes or temporary living quarters in accordance with an individual support plan. Support methods include modeling, cueing, and coaching.
	28. **Day supports services** (formerly known as “day treatment”) means services focused on training designed to assist the client in the acquisition, retention, or improvement of self-help, socialization, and adaptive skills. These services take place in an agency environment and are offered most often in a group setting.
	29. **Deemed status** means that an accredited organization holding a full license is determined to be in compliance with specific provisions of this rule that are identical, almost identical, or serve an equivalent purpose to standards reviewed, evaluated, and monitored by a Department-approved national accrediting agency.
	30. **Department** means the Maine Department of Health and Human Services, Division of Licensing and Certification (DLC), or its successor organization.
	31. **Direct access** means access to the property, personally identifiable information, financial information, or resources of an individual or physical access to an individual served by an organization subject to this rule.
	32. **Direct access worker** means an individual who by virtue of employment has direct access to an individual served by an organization subject to this rule.
	33. **Direct client contact** means an encounter with a client whether face-to-face, by telephone, or through electronic communication.
	34. **Direct service** means the provision, coordination, or management of preventive, diagnostic, therapeutic, rehabilitative, or supportive service that relates to the physical or mental health or functional status of an individual.
	35. **Directed plan of correction** means a Plan of Correction issued by the Department which directs the organization on how and when to correct cited deficiencies, identifies the responsible party, and gives a deadline by which those actions must be completed.
	36. **Discharge** means cessation of services that occurs when a client has received optimum benefit from treatment, or a transfer to another type of treatment program, or discontinuation of services.
	37. **Emancipated minor** is a person aged 16 or older that has received an order of emancipation under 15 MRS §3506-A (4).
	38. **Exploitation** means the illegal or improper use of an incapacitated or dependent adult or his/her resources for another’s profit or advantage.
	39. **Exposure** means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.
	40. **Facility** means a building, or location within a building, where services are offered.
	41. **Governing body or governing authority** means an individual or association of persons (board of directors) with ultimate managerial control and legal responsibility for the operation of an organization.
	42. **Independent contractor** has the same meaning as set out in 26 MRS §1043 (11)(E) and 39-A MRS §102 (13-A).
	43. **Infectious disease** (also known as “contagious disease” or “communicable disease”) means a disease transmissible by direct contact with an affected individual (e.g., from person-to-person) or the individual's body fluids, or by indirect means (e.g., contaminated object).
	44. **Initiation of services** occurs when the client provides verbal, electronic, or written consent to treatment.
	45. **Integrated treatment service** means the delivery of behavioral health treatment services designed to treat both substance use disorder and mental health conditions in a single setting. Integrated treatment programs provide a set of mental health and substance use disorder services and treatment that offer an appropriate range of psychopharmacologic and addiction pharmacology, psychiatric, crisis, and other services necessary to treat clients with co-occurring behavioral health conditions.
	46. **Interactive telecommunication system** means communication equipment that meets the requirements for telehealth practices under Maine law, for example 32 MRS § 13868 and 24-A MRS §4316. Telephonic telehealth may be used when it is appropriate to the care needs of the client.
	47. **Isolation** means removing an individual from a stimulus by use of involuntary separation and restricted activity. Isolation may mean restriction with adequate supervision in an unlocked room where egress is not denied. Isolation does not mean confinement in a locked room (see “Seclusion”.)
	48. **Legal representative** means a guardian, conservator, medical or financial power of attorney, trustee, or representative payee.
	49. **License** means the whole or any part of any agency permit, certificate, approval, registration, charter, or similar form of permission required by law which represents an exercise of the state's regulatory or police powers.
	50. **Licensed practitioner** means a physician, physician’s assistant, or nurse practitioner currently allowed by license to practice in the State of Maine.
	51. **Licensee** means an organization issued a license by the Department.
	52. **Medical director** means a licensed practitioner with knowledge of substance use disorder, addiction, mental health conditions, and co-occurring disorders relevant to the population(s) served by the organization. For an Opioid Treatment Program, the medical director must be licensed as a physician. In other settings, the medical director may be a licensed practitioner who is qualified under the scope of their license to carry out the minimum requirements set forth in this rule.
	53. **Medication for opioid use disorders** (MOUD) means a treatment method that combines medication approved by the federal Food and Drug Administration for the treatment of substance use disorder with counseling, substance use testing, and behavioral therapy that has proven effective in treating substance use disorder.
	54. **Mental health service** means a service which is provided to a client in the course of their treatment, diagnosis, or coordination of care for their psychological and social well-being.
	55. **Module** means a related group of a specific services within a service type, as defined by this rule, that a licensee may be approved to provide.
	56. **Neglect** means a threat to a client’s health or welfare by physical or mental injury or impairment, deprivation of essential needs or lack of protection from these threats. Neglect may result from action or inaction by the facility, its employees, or its service providers.
	57. **Notifiable disease** means a disease listed in 10-144 CMR Ch. 258, Control of Notifiable Diseases and Conditions Rule.
	58. **Novel virus** means a virus that has not previously been recorded.
	59. **Nurse** means an individual who is currently licensed by the Maine State Board of Nursing as a Registered Nurse (RN) or a Licensed Practical Nurse (LPN).
	60. **Opioid Treatment Program** **(OTP)** means an entity registered by the Attorney General and certified by the federal Substance Abuse and Mental Health Services Administration to dispense opioid agonist treatment medications to individuals for the treatment of opioid use disorder under §303(g)(1) of the Controlled Substances Act. An OTP may also be known as Opioid Supervised Withdrawal and Maintenance Treatment Program.
	61. **Organization** means a licensed entity established to operate, conduct, or maintain one or more behavioral health programs in the State.
	62. **Other Potentially Infectious Material (OPIM)** means the following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.
	63. **Outbreak** means the diagnosis of a notifiable disease in any resident or any employee who has direct care of residents.
	64. **Outpatient services** means treatment conducted in a setting that does not include, require, or provide that someone stay overnight in lodgings provided by the organization.
	65. **Outpatient therapy** means treatment conducted by a licensed or certified individual consisting of counseling and therapeutic services provided to clients to relieve excess stress and promote positive orientation and growth toward more integrated and independent levels of functioning. Services are delivered through planned interaction involving the use of physiological, psychological, and sociological concepts, techniques and processes of evaluation and intervention.
	66. **Personal protective equipment (PPE)** means protective items or garments worn to protect the body or clothing from hazards that can cause injury and to protect residents from cross-transmission.
	67. **Personnel** means all employees of an organization and all independent contractors providing services under contract with that organization. The term “staff” is synonymous with “personnel.”
	68. **Physician** means an individual licensed to practice medicine by the Maine Board of Licensure in Medicine or the Maine Board of Osteopathic Licensure.
	69. **Plan of correction (POC)** means a section of a Statement of Deficiencies completed by the organization and approved by the Department detailing the corrective actions to cited deficiencies, the personnel responsible for implementing the corrective action, and the timeline for completion of those actions that the organization will take to come into compliance with this Rule.
	70. **Prescriber** means a licensed health care provider with authority to prescribe, including a licensed physician, certified nurse practitioner or licensed physician assistant who has training or experience in psychopharmacology.
	71. **Prescription Monitoring Program (PMP)** is a secure, online database that is used across the State of Maine for electronically prescribing opioid medications, in accordance with 22 MRS §7249.
	72. **Program** means a set of coordinated methods undertaken by a licensee to benefit a specific population of need. A licensee may offer different programs to address specific needs of a population within a service type or module.
	73. **Program manager** means the person responsible for assuring compliance with this rule in a specific residential treatment program.
	74. **Psychiatrist** means a physician licensed in the State of Maine who is certified by the American Board of Psychiatry and Neurology to practice psychiatry.
	75. **Psychologist** means an individual licensed by the Maine State Board of Examiners of Psychologists to provide psychological services through recognized psychological techniques.
	76. **Psychosocial clubhouse services** means services delivered through a community-based International Center for Clubhouse Development (ICCD) accredited clubhouse setting in which the client, with staff assistance, engages in operating all aspects of the program. Client choice is a key feature of the model. Through a structured environment that is referred to as the work-ordered day, supports and services related to employment, education, housing, Community Inclusion, wellness, community resources, advocacy, and recovery are provided. Clients participate in the program’s day-to-day decision making and governance.
	77. **Record** means all documentary material, regardless of media or characteristics, including, but not limited to, client records, administrative, financial, health and personnel records made or received and maintained in accordance with law or regulation or in the transaction of business. It also means all electronic records, including, without limitation, electronic health records, email and text messages. “Record” includes admissions and discharges indicating client names and dates of admission and discharge and daily census records.
	78. **Representative** means a person who has been designated in writing by the client or by the client’s guardian to aid the client in upholding his or her rights. The representative may not be a client of, or a staff person currently employed by, the organization that is providing or ensuring the delivery of services to the client.
	79. **Resident** means a client of a behavioral health organization receiving residential services.
	80. **Residential behavioral health facility** means a program that provides accommodations where a rehabilitative mental health treatment program, a substance use disorder treatment program, or an integrated mental health and substance use disorder treatment program is provided to adult clients.
	81. **Residential services** means any behavioral health treatment that requires the client to reside on the premises while receiving treatment.
	82. **Respiratory hygiene/cough etiquette** means measures to contain respiratory secretions that are recommended for all individuals with signs/symptoms of a respiratory infection.
	83. **Restraint** means any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a client to move his or her arms, legs, head or body freely that is not a protective device; or a drug or medication when it is used to manage client behavior or restrict freedom of movement and is not a standard treatment or dosage for the client’s condition.
	84. **Seclusion** means the solitary, involuntary confinement of an individual for any amount of time in a room or a specific area from which egress is denied by a locking mechanism, barrier, or other imposed physical limitation.
	85. **Service** means a specific programmatic intervention to address the needs of clients. For the purposes of this rule, behavioral health service types are mental health services, substance use disorder services, or integrated services. Service modalities may be referred to as “therapy” or “treatment”.
	86. **Service plan** means a written individualized service, treatment, recovery, or other plan of care that specifies the services and supports that are furnished to meet the preferences, choices, abilities, and needs of the individual. A service plan may include a behavioral support plan and/or an intervention plan as components.
	87. **Service location** means a place, other than a site, where services may be delivered. Service locations, including but not limited to schools, jails, and other community settings, are not subject to inspection by the State Fire Marshal’s Office (SFMO) under this rule, but may be inspected by the Department to assure compliance with this rule.
	88. **Shelter** means a service for an adult with substance use disorder that provides food, lodging and supervision to protect and maintain life.
	89. **Site** means the physical location(s) where services are coordinated and managed. A site may consist of one or more facilities. A site is where administrative staff are housed and records are maintained. Services may be delivered at the site. A location from which telehealth services are delivered is not a site.
	90. **Skills development services** mean face-to-face contact with the client, with or without family or non-professional caregivers, that restore and improve the client’s skills and abilities essential to independent living (i.e., self-care and daily life management). Services may be provided to an individual or in a group setting and are targeted to enhance access to community resources, with natural supports, increase independence to promote successful community integration. Skill enhancement is provided through structured interventions for attaining goals identified in the Individual Service Plan.
	91. **Social worker** means a person who is licensed or certified to provide social work services in Maine by the Maine State Board of Social Worker Licensure. “Social worker” may include a Licensed Master Social Worker-Clinical Conditional, Licensed Clinical Social Worker, Licensed Social Worker, or Licensed Social Worker-Conditional.
	92. **Split-dose** means the balance of a dose that is taken by a client off the site of an Opioid Treatment Program, after the initial dose is administered on site.
	93. **Standard Precautions** means infection prevention practices that apply to all residents, regardless of suspected or confirmed diagnosis or presumed infection status, including but not limited to hand hygiene; use of gloves, gown, mask, eye protection, or face shield, depending on the anticipated exposure; safe injection practices; respiratory hygiene/cough etiquette; and the cleaning or disposal of equipment or items in the patient environment likely to have been contaminated with infectious body fluids.
	94. **Statement of deficiencies (SOD)** means a document issued by the Department that describes, with specificity, areas of non-compliance with this rule that require action on the part of the organization to return the organization to compliance with this rule.
	95. **Substance use disorder** means recurrent use of alcohol and/or drugs that causes clinically significant impairment, including health problems, disability, or failure to meet major responsibilities at work, school, or home.
	96. **Substance use disorder qualified staff** means employees or independent contractors who meet the required substance use disorder and behavioral health education and experience set out in statute or rule.
	97. **Substance use disorder treatment services** means interventions designed for the assessment, diagnosis, treatment, or rehabilitation of individuals who are physically, emotionally, or psychologically impacted by the use of alcohol or other drugs.
	98. **Transfer** means a planned transition in care from one organization to another or from one level of care to another within the same organization.
	99. **Transmission-based Precautions** means contact precautions, droplet precautions, and airborne precautions, based on the likely routes of transmission of specific infectious agents, which may be combined for infectious agents that have more than one route of transmission.
	100. **Withdrawal management** means a service that provides immediate diagnosis and treatment, and appropriate referral when required, to clients having acute physical problems related to alcohol or other drug withdrawal.

# SECTION 2. LICENSING AND CERTIFICATION REQUIREMENTS

A. **Responsibility for compliance.** The applicant/organization must comply with all core standards and the applicable program-specific standards of this rule, excluding provisions formally waived by the Department under § 2(J) of this rule.

1. Licensees must also comply with all other applicable rules, State and federal statutes, and federal regulations.

2. It is the organization’s responsibility to ensure that all staff are trained to act in accordance with the standards contained in this rule.

3. An organization’s failure to develop policies in conformity with this rule is a violation of this rule. In addition, an organization’s failure to adhere to the sections of its policies that are required by this rule is a violation of this rule.

4. Prior to application, organizations intending to provide residential behavioral health services must submit letters of notice to the Office of MaineCare Services and to the Office of Behavioral Health or the Office of Child and Family Services, as applicable, stating the applicant’s intent to be licensed.

1. License is non-transferable. A license is non**-**transferable and non-assignable. Prior to a change in ownership, an organization must apply for and obtain a new license prior to operation.
2. License posted. A copy of the current valid license must be conspicuously posted where it may be seen by the public at each of the locations where services are provided.
3. **Initial or renewal application for a license.** An organization must submit a completed application to the Department prior to securing an initial license and at least 30 days prior to the expiration of a current license.
4. A complete initial or renewal application must include all required information on the Department-approved form, all required documentation, and the appropriate fee.
5. Applications which remain incomplete after 60 calendar days of receipt of the application by Department will become void.
6. The amount of the fee for each initial or renewal application is set out in Section 3 of this rule. Licensing fees are nonrefundable.
7. Whenever an organization has made a timely and complete application for renewal of a license, the existing license will not expire until the status of the application has been finally determined by the Department.
8. Prior to acting on the application for renewal, the Department may:
	* 1. Verify any information in the renewal application and conduct an inspection of the facility, site, or program; and
		2. Issue a Statement of Deficiencies as appropriate. If cited deficiencies are not corrected within the established timeframe, the Department may deny the renewal application, issue a Directed Plan of Correction, and/or impose a Conditional License.
9. A license is non-renewable after the expiration date.
10. An organization with an expired license must submit an application for a new license and is subject to all requirements governing new applications.
11. An organization with an expired license must obtain new licensure prior to resuming operations.
12. **Documents required with initial application.** The following documents must be submitted with the initial application form and application fee:
	1. An organizational chart with an explanation of lines of accountability and authority;
	2. Identification of the individual or board of directors serving as the governing authority, including a list of board or advisory board members, the office held by the member, and members’ addresses and other contact information;
	3. Staff roster;
	4. Sample client file;
	5. A list of all service types and programs the applicant intends to provide, complete with program descriptions;
	6. A list of all sites, service locations, and affiliated independent contractors;
	7. Letter of attestation that the organization has developed all required policies. The Department may require the organization to provide copies of policies to demonstrate compliance with this rule;
	8. A description of the location, capacity, and a sketch of the floor plan with bedroom space identified for each residential program;
	9. A written emergency disaster, hazard, and evacuation plan that is based on a risk assessment and which addresses, at a minimum, the following:
13. Natural disasters and man-made disasters, or other serious events;
14. Security of medication and records;
15. Safety of clients and staff, including an evacuation plan;
16. Notification of closure plan for staff and clients;
17. Responding to a public health emergency; and
18. How medication will be dispensed in the case of an emergency.
19. A written close of business plan governing all organizational components, including record storage and access and evidence of the bond or other financial instrument that covers the costs associated with the close of business, as described in Section 11(I) of this rule;
20. Accredited organizations must submit the required accreditation documents as set out in § 2(M) of this rule;
21. A copy of letters of notice from the applicant to the Office of MaineCare Services, the Office of Behavioral Health and to the Office of Child and Family Services, as appropriate, regarding the applicant’s intent to be licensed as a behavioral health organization; and
22. Documentation from the appropriate municipal official indicating compliance with all local laws or codes for each site relative to the type of services provided and license sought.
23. **Provisional license.** The Department may issue a provisional license for a term of no less than three months and no more than 12 months to an applicant who:
24. Did not previously operate as a behavioral health organization, or is licensed but has not operated during the term of that license;
25. Complies with all applicable laws and rules, except those which can only be complied with once clients are served by the applicant; and
26. Demonstrates the ability to comply with all applicable laws and rules by the end of the provisional license term.
27. **Full license**. A full license may be issued for a term of two years to an applicant that demonstrates compliance with this rule and applicable statutes.
28. **Conditional license**. A conditional license may be issued by the Department when the organization fails to comply with applicable laws and rules, and in the judgment of the Commissioner, the best interest of the public would be served by issuing a conditional license. The conditional license will be issued for a period sufficient to achieve compliance, not to exceed 12 months. The Department will specify when and what corrections must be made during the term of the conditional license. An organization may not add new service types, sites, modules, or programs during the term of a conditional license.
29. **Amended license required when changes occur.** A licensed organization must notify the Department prior to the implementation of any proposed change or modification listed below and request an updated license by filing a change request, with the appropriate fee. Upon completion of its review, the Department may issue an amended letter. The term of the amended license remains the same as the original license but the effective date for the approved change may be different.
30. The organization must notify the Department at least 30 calendar days prior to the addition or deletion of a service type, module, or program, and at least 90 days prior to the addition of a facility, or site. No new service type, module, program, facility, or site may be commenced without Department approval, and the licensee must demonstrate appropriate transfer of care for clients prior to the termination or deletion of a service type, module, program, facility, or site.
31. The organization must notify the Department at least 90 calendar days prior to a change in location or name.
32. The organization may not increase residential capacity or begin new construction, additions, or alterations to a licensed facility or site without the Department’s prior approval in consultation with the State Fire Marshal’s Office.
33. The organization must notify the Department at least 30 calendar days prior to a planned change or within ten calendar days after an unplanned change in the organization’s administrator.
34. Waiver of a licensing rule**.** An organization holding a full license may request, in writing, a waiver of a provision of this rule.
35. The Department may waive or modify a provision of this rule under the following terms and conditions:
36. The organization must provide clear and convincing evidence, including expert opinion at the request of the Department, which demonstrates to the satisfaction of the Department that the organization's alternative method will comply with the intent of the rule provision;
37. The provision is not mandated by State or federal law; and
38. The waiver may not violate the rights of clients receiving services.
39. A waiver granted by the Department is enforceable as rule and a violation is subject to the enforcement procedures in this rule.
40. A waiver, when granted, must be for a specific period, not to exceed the term of the license.
41. A waiver may impact an organization’s ability to receive payment for services. It is the organization’s responsibility to research any potential conflicts before requesting a waiver.
42. An organization may submit a written request for the renewal of the waiver at the time it applies for license renewal.
43. Issued license extends to identified physical sites**.** The license issued by the Department extends to the physical sites identified in a letter from the Department accompanying the license**.**

1. A site must be approved for occupancy by the SFMO.

2. A private residence may not be approved as a site for the delivery of mental health and/or substance use disorder treatment.

3. Opioid treatment programs require a separate license for each site.

1. **Specifications of a license.** The license issued by the Department includes the following information:
2. The legal name of the individual or organization, and the ‘doing business as’ name, as applicable;
3. The service types and modules allowed under the license;
4. The name of the administrator;
5. The location of the physical sites covered under the license; and
6. The effective date and term of the license.
7. **National accreditation and deeming.** To avoid duplicate inspections, accredited organizations that have been issued a full license may be deemed to be in compliance with specific provisions of this rule. Department inspections do not include those specific provisions when the organization is deemed to be in compliance.
8. An accredited organization is deemed to be in compliance with this rule as long as the organization maintains its accreditation status without any limitation or condition placed on it by the accrediting entity.
9. The Department may approve national accrediting organizations with standards that are identical, almost identical, or equivalent in purpose to the licensing provisions set out in this rule and applicable statutes. The following national accrediting organizations are approved by the Department:
	* + 1. The Joint Commission (TJC);
			2. Council on Accreditation (COA);
			3. Commission on Accreditation of Rehabilitation Facilities (CARF International); and
			4. Other Department-approved national accrediting organizations.
10. The organization must provide verification of their accreditation status to the Department.
11. The organization must maintain a physical copy of the accreditation standards on-site for review by the Department, with the standards that are identical, almost identical, or equivalent in purpose to licensing provisions set out in this rule identified.
12. Based on a review of the evidence, the Department may issue a written determination regarding the organization’s request for deemed status.
13. An accredited organization must notify the Department in writing, and submit a copy of the documents issued by the accrediting organization, within 10 business days of any of the following occurrences:
	* + 1. The organization’s accreditation status is modified, discontinued or otherwise changed;
			2. The organization received results of accreditation reviews and similar activity;
			3. The organization was cited for failure to comply with accreditation requirements;
			4. The organization was notified that a response, a corrective action, or an improvement plan is required related to continued compliance with an accreditation standard; or
			5. Any other similar action by the accrediting organization.
14. An accredited organization’s actions may be considered by the Department as evidence of compliance or noncompliance with this rule, upon verification by the Department, and may impact eligibility for deeming.

**N. Approval for occupancy.** Prior to the issuance of a license and prior to re-licensure, each site must be certified by the SFMO to be in compliance with the National Fire Protection Association (NFPA) Life Safety Code and other fire and safety laws and regulations which are applicable to the facility, as follows:

1. Comply with all applicable laws and regulations relating to fire safety, plumbing, water supply, sewage disposal and maintenance of sanitary conditions; and

2. Comply with all other applicable laws and regulations pertaining to licensing.

3. Each site must provide a supply of safe drinking water.

a. Applicants serving drinking water from their own well must demonstrate satisfactory water quality by testing for the following contaminants by a Maine-certified laboratory:

1. Fluoride,
2. Uranium,
3. Arsenic,
4. Lead (first-draw sample),
5. Total coliform bacteria, and
6. Nitrates.

b. Licensees serving water from their own well must test their water annually for coliform bacteria and nitrates. Samples must be analyzed and the results reported by a Maine-certified laboratory. Licensees must maintain water quality reports for Department inspection.

c. In addition to the annual testing required by § 3(b) above, licensees serving water from their own wells must test their water every five years for at least the following contaminants: fluoride, uranium, lead (first-draw, 250 ml. sample) and arsenic.

d. If the licensee chooses to use and serve bottled water for all food preparation and drinking purposes, then the licensee may operate under a written bottled water agreement with the Department. Under this agreement the licensee must:

1. Use bottled water for all consumption and food preparation;
2. Conspicuously post the agreement where it can be seen building occupants; and
3. Continue to conduct annual water testing in accordance with § 2 (N)(3)(b) of this rule.

e. During all hours of operation, drinking water and wastewater disposal must meet the standards of the Department to accommodate the licensed capacity of the licensee.

f. If a facility meets the definition of a public water system in 22 MRS § 2601(8), it must comply with the requirements in 22 MRS Ch. 601 and 10-144 CMR Ch. 231, Rules Relating to Drinking Water.

SECTION 3. FEES

1. **Payable.** Fees are payable to the *Treasurer, State of Maine.*
2. **Nonrefundable.** Fees are nonrefundable.
3. **Type of license and service categories.** The types of license are provisional, full, or conditional.

1. Licenses may be issued for mental health services and/or substance use disorder services.Separate fees are required for each category of service, in accordance with 5 MRS §20024, 34-B MRS §1203-A (4) and 22 MRS §8003.

2. The Department will issue a single license to a provider. The license will indicate if the organization may offer mental health services, substance use disorder services, or integrated treatment services. Providers offering services for co-occurring behavioral health conditions must hold a license for integrated services.

**NOTE:** Specific interventions evolve in response to emerging needs and advances in treatment models and are defined by funding sources and contracting agencies. This rule describes a framework of the types of services available to meet varying needs (See appendix A). The Department will review an applicant’s description of services, treatment, and practices and determine which module(s), as set forth below, are applicable and required for licensure.

3. A mental health license allows an organization to provide one or more of the following modules, as approved:

 a. Community support services, provided in a person’s home or community;

 b. Crisis services, short-term and in response to a specific event;

 c. Outpatient services, provided by a licensed clinician; and/or

 d. Residential services, provided in a designated facility.

4. A substance use disorder license allows an organization to provide one or more of the following modules, as approved:

 a. Community support services, provided in a person’s home or community;

b. Crisis services, short-term and in response to a specific event;

 c. Outpatient services, provided by a licensed clinician;

 d. Residential services, provided in a designated facility.

5. An integrated services license allows an organization to provide from the mental health and substance use disorder modules listed above, as approved by the Department.

1. **Term of license.**

1.The term of a provisional license is three to 12 months.

2. The term of a full license is two years**.**

3.The term of a conditional license may not exceed 12 months.

1. **Fees.**
2. The application fee for a provisional license is $125 for either single service category, or $250 for both service categories or integrated services.
3. The application fee for a full license is $250 for either service category, or $500 for both service categories or integrated services.
4. The fee for the biennial renewal of a full license is $170 for either service category, or $340 for both service categories or integrated services.

|  |  |  |
| --- | --- | --- |
|  |  | Type of License: |
| Services Offered: | Provisional | Full | Renewal |
| Mental Health Only | $125 | $250 | $170 |
| Substance Use Disorder Only | $125 | $250 | $170 |
| Integrated Services  | $250 | $500 | $340 |

1. The processing fee to add a site to an existing license is $50 per added site.
2. The fee to add a module or program to an existing license is $70 per added module or program.
3. The fee to reissue a license when any information is no longer accurate or to make changes to an existing license is $10. The reissued license will have the same expiration date as the original license.
4. The transaction fee to electronically renew a license is $50, in addition to the renewal fee, when electronic renewal is available.

# SECTION 4. **ENFORCEMENT AND INSPECTIONS**

1. Inspections required. The Department may enter the premises of any licensed site, at any reasonable hour, to conduct inspection surveys and complaint investigations.
2. Organizational cooperation. As a condition of receiving and maintaining its license, an organization must cooperate with the Department’s conduct of surveys and investigations. An organization’s failure to cooperate is a separate rule violation. Cooperation includes, but is not limited to, allowing the Department:
3. Immediate access to any documents and records required by this rule to be available on-site, and producing documents and records stored off-site within five business days of the request;
4. Full access to electronic and electronically-stored records, either through a State-owned computer or device, through a computer or device provided by the organization, or with assistance from an organization’s staff member;
5. To copy any documents and records; and
6. To meet or speak in private with any person employed by or receiving services from the organization, except that a person receiving services has the right to refuse to meet or speak to the Department’s authorized representative.
7. Statement of deficiencies. The Department will issue a Statement of Deficiencies (SOD) when it determines that a violation of this rule or applicable statutes has occurred.
8. Informal conference. An organization may request a courtesy informal conference to contest any deficiency cited on an SOD.
9. An organization wishing to dispute the findings of an SOD must submit a written request for a courtesy informal conference to the Department within ten (10) business days of receipt of the SOD.
10. A Plan of Correction (POC) is required to be submitted to the Department within ten (10) business days of the organization’s receipt of an SOD. The organization may not delay submitting a POC within the required timeframe because an informal conference has been requested. Failure to submit a POC within the required timeframe may result in the organization being issued intermediate sanctions.
11. The written request for a courtesy informal conference must specifically identify what deficiencies are being questioned, include a reason for the request, provide evidence sufficient to support the disputation of the deficiency, and explain why this evidence was not presented at the time of the survey or investigation that resulted in the SOD.
12. Informal conferences may not be used to present evidence that was required to be available at the time of a survey or investigation.
13. If the organization meets the requirements of § 4(D)(1)-(4) to the satisfaction of the Department in submitting the request, the Department will schedule an informal conference.
14. Only one informal conference will be permitted regarding an inspection that results in the issuance of a SOD. Failure to appear at the scheduled time of the informal conference or failure to provide at least 24 hours’ notice of the need to reschedule the informal conference will result in forfeiture of the opportunity for an informal conference for that SOD.
15. If an organization chooses to be accompanied by counsel, then the organization must notify the Department of their intent in their request for a courtesy informal conference. The Department reserves the right to cancel a courtesy informal conference when an organization’s counsel arrives without prior notice.
16. Informal conferences will be scheduled upon availability of DLC staff.
17. When an organization is unsuccessful in demonstrating that a deficiency should not have been cited, the Department will notify the provider in writing.
18. When an organization is successful in demonstrating that a deficiency did not occur, the SOD will be revised to accurately reflect the survey outcomes. The Department will reissue a revised SOD to the organization.
19. An informal conference will not delay any subsequent enforcement action against an organization or any other aspect of the inspection and/or licensing process. DLC retains the authority to conduct subsequent inspections that may result in additional actions.
20. The decision to grant or deny a courtesy informal conference is not final agency action and may not be appealed. The outcomes of courtesy informal conferences are not subject to the right of appeal.

13. Nothing in this section prohibits the Department from adding or substituting citations on an SOD based on information presented during an informal conference. In such circumstances, the Department will issue a revised SOD to the organization to accurately reflect the citations supported by the available information.

1. Plan of correction. An organization is required to submit an acceptable Plan of Correction (POC) within ten business days of receipt of a SOD.
2. An acceptable POC must contain the following elements for each and every specific deficiency:
3. How the organization will address processes and systems issues that led to the deficiency;
4. An organization-wide plan to ensure full regulatory compliance throughout the licensed organization;
5. The procedure for implementing the POC, and the date of implementation;
6. The monitoring procedure to ensure that the POC is effective and the specific deficiency cited remains corrected and in compliance with the regulatory requirements, including the timeframe and processes for monitoring to ensure continued compliance after the date of completion; and
7. The title of the person responsible for implementing the acceptable POC.
8. A POC may not contain any client’s name or protected health information.
9. Failure to correct any deficiency(ies), or to file an acceptable timely POC, may lead to the imposition of sanctions or penalties.
10. Refusal to issue a license.

1. The Department may refuse to issue or renew a license when it finds misrepresentation, materially incorrect or insufficient information on the application; when the organization does not meet the requirements for issuing a license; or when the organization fails to comply with this rule and applicable statutes.

2. The Department may, at its discretion, issue a license but decline to include specific sites, modules, or services for which the organization has applied due to non-compliance with the standards set forth in this rule.

1. Revocation or suspension of a license.
2. The Department may revoke, suspend, or refuse to renew a license without a hearing for a period not to exceed 30 days whenever, upon investigation, the Department finds conditions that, in the opinion of the Department, immediately jeopardize the health or physical safety of persons residing in a facility or receiving services, and acting in accordance with the procedure set forth in subchapter 4 or 6 of the Administrative Procedure Act would fail to adequately respond to the known risk, in accordance with 5 MRS §10004 (3).
3. The Department may secure a court order to suspend or revoke a license in accordance with the following provisions:
	1. The Department may file a complaint with the District Court requesting an emergency suspension of the organization’s license whenever, upon investigation, conditions are found that in the opinion of the Department pose an immediate threat to the health, safety, or welfare of persons residing in a facility or receiving services, in accordance with 4 MRS §184 (6).
	2. The Department may seek to suspend or revoke a license for violation of applicable law and rule; or for committing, permitting, aiding or abetting any illegal practices in the operation of the organization; or for conduct or practices detrimental to the welfare of persons residing in the facility or receiving services from the organization, by filing a complaint with the District Court as provided in the Maine Administrative Procedure Act, 5 MRS Chapter 375.
4. Operating without a license: enter and inspect. The Department may enter and inspect an organization that it believes is operating without a license only with the permission of the owner or person in charge, or with an administrative search warrant from the District Court authorizing entry and inspection. The penalties for operating without a license are as set forth in statute. See 5 MRS Ch. 521, 22 MRS Ch. 1667, and 34-B MRS Ch. 1 & 3.
5. Grounds for intermediate sanctions. The following circumstances will be grounds for the imposition of intermediate sanctions:
6. Operation of a residential program of the organization over the licensed capacity;
7. Impeding or interfering with the enforcement of laws or regulations governing the licensing of behavioral health organizations, or giving false information in connection with the enforcement of such laws and regulations;
8. Failure to submit an acceptable POC within 10 working days after receipt of an SOD; and/or
9. Failure to take timely corrective action in accordance with a POC, a Directed POC or Conditional License.
10. Intermediate sanctions. The Department is authorized to impose one or more of the following intermediate sanctions when any of the circumstances listed in Section 4(I) are present and the Department determines that a sanction is necessary and appropriate to ensure compliance with state licensing regulations to protect the organizations clients or clients, or the general public:
11. The organization may be directed to stop all new admissions, regardless of payment source, or to admit only those clients the Department approves until such time as the Department determines that corrective action has been taken; or
12. The Department may issue a directed POC or conditional license.
13. Appeal rights. Any behavioral health organization aggrieved by the Department’s decision to take any of the following actions, or to impose any of the following sanctions, may request an administrative hearing to refute the basis of the Department’s decision, as provided by the Maine Administrative Procedure Act, 5 MRS Chapter 375.
14. Issue a conditional license;
15. Amend or modify a license;
16. Void a conditional license;
17. Refuse to issue or renew a full license;
18. Refuse to issue a provisional license;
19. Stop or limit admissions;
20. Issue a directed POC; or
21. Deny a request for a waiver of a rule.
22. Request for hearing. A request for a hearing must be made in writing to the Director of the Division of Licensing and Certification and must specify the reason for the appeal. Administrative hearings will be held in conformity with 10-144 CMR Ch. 1, Administrative Hearings Regulations.

**SECTION 5. COMPLAINT INVESTIGATION**

* 1. **Complaints.** The Department will accept complaints from any person about alleged violations of this rule. The organization must not retaliate against any client or resident or his/her representative for filing a complaint. Any licensing violations noted as a result of a complaint investigation will be provided to the organization in writing, in a SOD.
	2. **Department’s toll-free number posted.** The organization must post the Department’s toll-free telephone number and website URL for electronic complaint reporting in an area visible to clients at each site to enable clients or staff to contact the Department to make a complaint about the organization.
	3. **Organization’s grievance procedure.** The organization must provide their clients the organization’s written grievance procedure.
		1. The written grievance procedure must be consistent with any rules or statutes governing the rights of recipients (see § 6(A) of this rule).
		2. The client record must include documentation that the client was notified of the grievance procedure.
		3. The procedure must be posted in an area visible to clients.
	4. **Department complaint investigation.** On-site Department investigations are unannounced. The Department may investigate, or have investigated on its behalf:
1. Complaints;
2. Incidents of suspected abuse, neglect, exploitation, and inadequate care or supervision;
3. Allegations of the organization’s failure to comply with this rule; or
4. Allegations of rights violations.
	1. **Report adult abuse, neglect, or exploitation.** The organization must immediately report any suspected abuse, neglect, or exploitation of an incapacitated or dependent adult to Adult Protective Services at 1‑800‑624‑8404, available 24 hours a day, 7 days a week. The organization must also immediately call or submit a report to the Division of Licensing and Certification if the alleged abuse, neglect or exploitation occurred in the context of service provision through the organization.
	2. **Report child abuse or neglect.** The organization must immediately report any suspected abuse or neglect of a child to Child Protective Services at 1-800-452-1999, available 24 hours per day/7 days per week. The organization must also immediately call or submit a report to the Division of Licensing and Certification if the alleged abuse, neglect or exploitation occurred in the context of service provision through the organization.

# **SECTION 6. CLIENT RIGHTS**

**A.** **Client rights and rights of recipients of behavioral health services**. Organizations must promote and encourage clients to exercise their rights, and in furtherance thereof, comply with all applicable existing authorities governing client rights, including but not limited to the following.

1. Organizations providing mental health services must, as applicable, comply with 14-193 CMR Chapter 1, Rights of Recipients of Mental Health Services, and 14-472 CMR Chapter 1, Rights of Recipients of Mental Health Services Who Are Children in Need of Treatment.

2. Organizations providing substance use disorder services must comply with client rights set forth in 5 MRS Chapter 521, Subchapter 3.

3. Organizations providing mental health or substance use disorder services to adults with intellectual disabilities, autism, or acquired brain injury must, as applicable, comply with 34-B MRS §5605 and 14-197 CMR Chapter 5, Regulations Governing Behavioral Support, Modification and Management for People with Intellectual Disabilities or Autism in Maine.

1. **Organization policy.** The organization must have a written policy concerning the rights and responsibilities of clients that at a minimum complies with and includes the applicable authorities outlined in § 6(A) of this rule.

1. If providing residential services, the organization must develop policies around visitation, telephone privileges, and client mail.

2. The organization must prepare a document explaining client’s rights, fee schedule, and program rules and regulations.

3. The organization must have specific policies and procedures governing the availability and provision of interpretive services, whether spoken language or sign.

1. **Exceptions, restrictions, and limitations.** An organization may not make an exception to its policy on client rights or impose restrictions or limitations on the exercise of a client’s rights unless the exception, restriction, or limitation is permitted by and made in accordance with the applicable authorities outlined in § 6(A) of this rule. Any exception, restriction, or limitation of client rights must be documented in the client’s record.
2. **Notification of client rights**. The organization must inform each client and their legal representative of these rights prior to or at the time of admission to the organization.
3. The organization must inform each client and legal representative within 30 calendar days of any changes to the organization’s policy and must offer them a copy of the change.

a. A copy must be posted in a prominent place within each organizational site that is accessible to clients.

b. The client record must contain documentation of notification of changes to client rights.

1. The organization must provide accommodation for any communication barriers that exist to ensure that each client is fully informed of his/her rights.

**E. Mandatory report of rights violations**. The organization must have a written policy and procedure to address the reporting of rights violations. The policy may not conflict with 22 MRS §3477 or 22 MRS §4011-A.

1. The policy must require any person or professional who provides services to clients through a licensed organization under this rule who has reasonable cause to suspect that a client’s rights have been violated to immediately report the alleged violation to the Division of Licensing and Certification using the electronic reporting system.

a. If the suspected rights violation pertains to an adult client with intellectual disability, autism, or acquired brain injury and the client’s rights set forth at 34-B M.R.S. § 5605, the person or professional must additionally report the alleged violation to the Department’s reportable events system per 14-197 CMR Ch. 12, Reportable Events System.

b. If the subject of a suspected rights violation is a child, the person or professional must additionally complete a reportable event form within the Department’s electronic reporting system.

2. The failure of a person or professional to report as required by § E(1)(a) may be cited as a violation of this rule by the licensee.

3. In all cases, the organization must maintain documentation that a report(s) of a rights violation was made.

**F. Right to freedom from abuse, neglect and/or exploitation**. Clients must be free from mental, verbal, physical and/or sexual abuse, neglect and exploitation. Reporting suspected abuse, neglect and/or exploitation is mandatory in all cases.

1. As set forth in §5(E) and (F), an organization must immediately report the alleged violation to the Division of Licensing and Certification using the electronic reporting system, and, if applicable, to one or more of the following:

a. Incidents involving adults must also be reported to Adult Protective Services pursuant to 22 MRS §3477; and

b. Incidents involving children must also be reported to Child Protective Services pursuant to 22 MRS §4011-A.

2. Critical Incident Reporting forms alleging abuse, neglect, or exploitation of an adult client must be sent to DLC and OBH.

3. The organization must maintain documentation that all required reports of suspected abuse, neglect, and/or exploitation were made.

**G. An organization’s internal rules and client non-compliance.** Clients have the right to be informed about an organization’s internal program rules and the consequences of non‑compliance. An organization’s internal rules must be confined to those matters that ensure the safety and health of clients and staff, may not violate client rights, and must not be applied arbitrarily. An organization’s internal rules must describe the organization’s expectations regarding client compliance with the organization’s internal rules. The organization must:

1. Prepare a written document explaining the organization’s internal rules and offer it to each client and/or legal representative on admission; and
2. Maintain within the client record documentation that the client and/or legal representative have been offered a copy of the organization’s internal rules.
3. **Right to information regarding licensing deficiencies**. Clients have the right to be fully informed of any non-compliance with this rule identified by licensing survey or complaint investigation.
4. The organization must inform clients and their legal representatives at the time of intake that survey results are public information and are available upon request.
5. Clients and their legal representatives must be notified by the organization, in writing, of any actions proposed or taken against the license of the organization by the Department, including, but not limited to, decisions to issue a Directed Plan of Correction, decisions to issue a conditional license, refusal to renew a license, appointment of a receiver, or decisions to impose fines or other sanctions. This notification must take place within 15 business days from receipt by the organization of notice of action by Department.
6. **Restraints or aversive conditioning.** Restraints or aversive conditioning may only be employed when explicitly permitted by state and federal legal authorities including the authorities set forth in § 6(A) of this rule.
7. **Right to privacy and consideration**. All clients must be treated with respect. Clients in residential services must also be treated with respect and consideration with regard to their individual need for privacy when receiving personal care or treatment, and their preferred mode of language and communication.

**K. Right to confidentiality.** Clients and/or their legal representative have the right to communicate with health care providers in confidence and to have the confidentiality of their individually identifiable health care information protected, as required by state and federal law.

1. Clients and/or their legal representative have the right to review and copy their own medical records and request amendments to their records as permitted by state and federal law.

2. Clients and/or their legal representative have the right to be informed that there may be circumstances where their information may be released without client and/or their legal representative consent pursuant to state and federal law.

**L. Right to freedom from discrimination.** Treatment provided must be fair and impartial regardless of age, race, sex, color, physical or mental impairment, religion or ancestry, familial or marital status, sexual orientation, genetic information, or source of payment. Treatment must be provided in an atmosphere of dignity and trust between program, program staff and client.

1. The organization must make reasonable accommodation in regulations, policies, practices or services, including permitting reasonable supplementary services to be brought into the residential care facility, as required by the Americans with Disabilities Act.

2. The organization is not required to make the accommodation if it imposes an undue financial burden or results in a fundamental change in the program, as set forth in the Americans with Disabilities Act.

**M. Right to communicate grievances and recommend changes**. All clients have the right to a fair and efficient process for resolving differences with providers. The organization must assist and encourage clients to exercise their rights as clients and citizens, in accordance with the authorities set forth in § 6(A) of this rule.

# SECTION 7. ELIGIBILITY AND ACCESS TO SERVICES

Organizations must comply with the following requirements for eligibility and access to services. To the extent an organization is subject to other Department rules (e.g., 10-144 CMR Ch. 101, MaineCare Benefits Manual) and/or existing contracts with the Department, the organization’s compliance with the following requirements must also be in conformance with those other rules and/or contracts.

1. **Access to services.** Organizations must minimize barriers to a client’s ability to access services, including, but not limited to, the following:
2. Communication needs. The organization must accommodate the written and oral communication needs of clients or applicants in accordance with, but not limited, to the following:
3. The organization must provide assistive listening devices, telephone amplification, sign language services, or other communication methods for deaf or hearing-impaired persons;
4. The organization must provide or arrange for communication assistance for clients with special needs who have difficulty making their service needs known, including but not limited to, the following:
5. Providing or arranging for visible or tactile alarms for safety and privacy; and
6. Providing or arranging for communication assistance consistent with the client's literacy level.

2. The organization must ensure that restrictions on access to services and treatment are limited to and based on eligibility or admission requirementsand that no person is denied access to services based solely on a co-occurring condition or on the person’s refusal of any other service.

1. **Eligibility criteria.** The organization must have written policies and procedures regarding eligibility criteria for receiving services.
2. **Intake, screening, referral, and admission policies.** The organization must have written policies and procedures for intake, screening, referral and admission processes.
3. **Screening practices.** Theorganization must screen potential clients to identify the urgency of need.
4. **Waiting list.** The organization must have a written policy for managing waiting lists.

**F. Referral procedure.** The organization must have a written policy for referral to other providers. The policy must describe the actions the organization will take whenever:

* 1. Services are denied;
	2. The organization is unable to meet the client’s assessed needs; and/or

3. The client requests transfer to another organization.

**SECTION 8. COMPREHENSIVE CLIENT ASSESSMENT**

Organizations must comply with the following requirements for comprehensive client assessments. To the extent an organization is subject to other Department rules (e.g., 10-144 CMR Ch. 101, MaineCare Benefits Manual) and/or existing contracts with the Department, the organization’s compliance with the following requirements must also be in conformance with those other rules and/or contracts.

* 1. **Comprehensive client assessment.** Organizations must complete or update existing assessments for each client.
	2. **Assessment policy.** The organization must have a written assessment policy that applies to all clients.
	3. **Comprehensive assessment.** The organization must complete a comprehensive assessmentof each client within 30 days of admission to determine the need for treatment and services.

1. The comprehensive assessment must contain documentation of the client’s current status, history, and strengths and needs and include the following domains:

a. Social domain, including but not limited to personal, family, emotional, and leisure/recreation;

b. Psychological domain, including but not limited to psychiatric, drug and alcohol use (including screening for co-occurring Services), potential need for crisis intervention, emotional abuse, and developmental history;

c. Medical domain, including but not limited to physical health, current medications, and physical and environmental barriers to treatment; and

d. Functional domain, including but not limited to legal, housing, financial, vocational, and educational, and sources of support that may assist the client to sustain treatment outcomes including natural and community resources and state and federal entitlement programs.

2. In a comprehensive assessment for clients with substance use, the documentation must also contain age of onset of alcohol and drug use; duration, patterns and consequences of use; family usage; and types of and response to previous treatment.

3. The comprehensive assessment must be summarized and include a diagnosis in accordance with the current version of the Diagnostic and Statistical Manual of Mental Health Disorders (DSM) or the International Classification of Diseases Revision, Clinical Modification (ICD-10-CM)

or the Diagnostic Classification of Mental Health and Developmental Disorders of Infancy and Early Childhood (DC 0-5), as appropriate.

4. The comprehensive assessment must be signed, credentialed, and dated by the person conducting the comprehensive assessment. If the assessment conclusion contains a diagnosis, it must be signed by a clinician. A comprehensive assessment for a client with a substance use diagnosis must also contain a recommended ASAM level of care criteria. If the comprehensive assessment is for a client receiving integrated treatment for co-occurring disorders, the comprehensive assessment must contain both the DSM or ICD-10-CM diagnosis(es) and the recommended ASAM level of care criteria.

* 1. **Updating assessment.** A client’s comprehensive assessment must be updated at least annually and when there is a change in level of care, a change in status or a major life event occurs.
	2. **Signature.** The dated signature and credentials of the person completing or updating the assessment must be included as part of the assessment documentation.

# SECTION 9. CLIENT SERVICE PLAN

Organizations must comply with the following requirements for client service plans. To the extent an organization is subject to other Department rules (e.g., 10-144 CMR Ch. 101, MaineCare Benefits Manual,) and/or existing contracts with the Department, the organization’s compliance with the following requirements must also be in conformance with those other rules and/or contracts.

* 1. **Service plan.** Organizations must develop and provide ongoing review of each client’s service plan.
	2. **Client participation.** The organization must involve each client to the greatest degree possible, unless contraindicated, in development and ongoing review of the client’s service plan.

* 1. **Service plan team.** The service plan team must include the client, the client’s guardian or legal representative, clinicians, representative(s) of the organization providing services, and other persons chosen by the client, as appropriate.
		1. The organization’s service plan team must provide input and participate in the development and periodic review of the client’s service plan.
		2. When the client does not participate on the service plan team, the organization must document in the organization’s efforts to engage the client and the reason why participation did not occur in the client’s service plan.
	2. **Coordination of services.** The organization must coordinate service planning with the client’s other service providers to minimize duplication and maximize coordination in compliance with applicable confidentiality laws.
	3. **Personal responsibility and self-determination.** The organization must conduct service planning in a manner that supports the client’s personal responsibility and self-determination as much as possible, or as desired by the client. This includes, at minimum, involving the client in setting and prioritizing treatment goals and in deciding how to measure progress toward treatment goals.
	4. **Explanation of service options.** The organization must explain the client’s service options, including, but not limited to, the following:
		1. Available service options;
		2. How the organization provides support for the client to achieve desired outcomes; and
		3. The benefits, alternatives, and risks or consequences of planned services.
	5. **Time frame for completion of service plans.**
		1. The organization must complete service plans consistent with assessed needs and within time frames outlined in the program-specific standards.
		2. When a service plan is not completed in a timely manner, the reason for the delay must be documented in the client’s record.

**H. Service plan.** There must be a written, time-limited, goal-oriented, individualized service plan for each client.

* + 1. The client’s service plan must be based on needs identified during the assessment process and completed within 30 days of admission, unless otherwise specified in program specific standards.
		2. The written service plan must include, but is not limited to, the following:
			1. Identification of the services and treatment to be provided to meet the client’s needs;
			2. The methods and frequency of services and supports to be provided by the organization;
			3. The client’s agreed-upon goals and objectives to reach identified treatment and service outcomes;
			4. A description of the specific indicators and timeframes that will be used to monitor and evaluate the client’s progress in achieving the agreed-upon goals and objectives;
			5. The role of the client’s family and natural support system, as appropriate, in the client’s treatment and recovery;
			6. The client’s agreed-upon plan to address co-occurring conditions, including acute or chronic medical conditions, trauma, or other conditions through identification of area resources or referral;
			7. Referrals for needed services and supports that are not provided directly by the organization or through their independent contractors;
			8. Identification of persons responsible for implementing or coordinating implementation of the client’s service plan, as well as services provided by other service providers, as applicable;
			9. Criteria and a plan for discharge;
			10. A list of needs identified in the assessment process that are notaddressed in the service plan and an explanation why the identified needs are not addressed in the service plan;
			11. The date and documentation of the consent of the client, or the client’s legal representative, as appropriate; and
			12. The dated signatures and credentials of all planning team members participating in the planning process.
		3. Within five working days after the service planning meeting, the organization must

a. Give the client a copy of the written service plan and document that the client was given a copy of the written service plan in the client’s record or,

b. Document an explanation of the reason why the client did not receive a copy of the service plan.

**I. Crisis plan.** When appropriate, the organization must develop a written crisis, relapse or safety plan, which must include the following:

1. The client’s own words to describe the problems and interventions that may alleviate the crisis, whenever the client has the ability to express such concepts verbally;
2. A description of possible crisis needs and concrete steps that may be taken by the client, the community integration worker, crisis service staff, other providers, family members and others, if appropriate and applicable, to prevent or minimize escalation of a crisis or relapse;
3. A list of crisis service providers or hospital emergency departments made available by the organization within the client’s service plan, crisis, or relapse plan; advance directives; the name of the prescriber of psychiatric medication; and contact information, as appropriate; and
4. Procedures for coordinating care during a behavioral health crisis, including procedures for informing other providers, maintaining communication during the crisis evaluation and following through on interventions when the client returns to the program;
5. A behavioral support plan, as appropriate; and
6. A strategy to prevent frequent unnecessary client utilization of emergency services, including emergency room, police, and ambulance services, when such a pattern is known.

**J. Progress notes.** Progress notes must be related to specific problems or goals on the service plan and serve as the basis for evaluating treatment outcomes. Progress notes must include, without limitation:

1. Documentation of implementation of the service plan;
2. Documentation of all treatment rendered to the client;
3. Documentation of progress the client is making toward attaining the goals or outcomes identified in the service plan; and
4. The date, signature and professional qualification of the individual making the entry in the medical record.

**K. Periodic review and update of service plan.** The organization must periodically review and update each client’s service plan.

1. Service plans must be reviewed at least every 90 days, unless otherwise specified in the program-specific standards of this rule.
2. The periodic review process must be consistent with the process used to develop the initial service plan.
3. The organization must assess the appropriateness of continued services for a client during its periodic review of the client’s service plan and as necessary.
4. The organization must conduct an expedited service planning process when an urgent need has been identified, as needed or applicable. Following a crisis episode, a review of the crisis plan and/or service plan is required.

# SECTION 10. DISCHARGE PROCESS

* 1. **Discharge policy.** An organization’s written discharge policy must include, but is not limited to, the following provisions:
		1. A clear, planned, and orderly voluntary discharge process;
		2. Assignment of staff responsibility for the discharge process;
		3. Involvement of the client, the client’s guardian, or legal representative and others as appropriate in the discharge process;
		4. The requirement to obtain the client’s authorization to notify collaborating service providers, the courts, and others as appropriate upon discharge when client authorization is necessary to comply with applicable confidentiality laws;
		5. An involuntary discharge process, specifying the conditions under which services may be discontinued or interrupted;
		6. Emergency discharge procedures; and
		7. Specific procedures when a client leaves the program against clinical recommendations.

**B. Involuntary discharge.** Involuntary discharge of a client may be based upon the organization’s inability to meet the client’s needs or other legal grounds for discharge identified in the involuntary discharge provisions of the program’s discharge policy and supported by statute or rule.

1. The organization may not discharge a client solely because of a substance use relapse, or symptoms of a co-occurring condition or disorder, unless the program, as fundamentally designed, cannot meet the client’s needs.

2. When involuntary discharge is from an OTP, the organization operating the OTP must also comply with applicable program-specific provisions in this rule and applicable statutes.

**C. Notice of involuntary discharge.** The organization’s written notice of involuntary discharge from non-residential services must be provided to the client or their legal representative at least 30 days prior to the effective discharge date, and must:

1. Include the reason(s) for the discharge and the client’s appeal rights;
2. Include information on organizations in the client’s service area where recommended services or supports could be sought; and
3. Become part of the client’s record.

**D.** **Emergency Discharge.** An organization may discharge a client on an emergency basis in accordance with program-specific policies when the client presents a danger to themself or others.In the case of an emergency discharge, the organization must notify the client or their legal representative of emergency discharge as soon as practicable before the discharge.

**E. Self-discharge against clinical recommendations.**

* + 1. When a client self-discharges against clinical recommendations, the organization must prepare a written document describing the client’s self-discharge.
		2. The written document must become part of the client’s record.

**F. Discharge summary.** In all cases, a discharge summary must be completed within 30 days after the date of discharge, and

1. Describe the client’s course of treatment, program completion status, and the client’s clinical status at discharge;

* + 1. Summarize the client’s progress toward meeting planned goals as listed in the client’s service plan;
		2. Include referrals for service to other agencies as needed, including the reason for the referral;
		3. Make recommendations for ongoing services and supports;
		4. Be signed, credentialed, and dated by the individual completing the summary; and
		5. Become part of the client’s record.

# SECTION 11. GOVERNING AUTHORITY

* 1. **Responsibility**. The governing authority has ultimate managerial control and legal responsibility for the organization’s operation.
	2. **Legal authority to operate.** The organization must maintain documentary evidence of its legal authority to operate in the State of Maine, including by-laws, articles of incorporation, charter, partnership agreement, constitution, articles of association or similar documents as applicable. This information must be made available to the Department upon request.
1. An organization operating as a corporation, partnership, or association, whether for-profit or not-for-profit, must maintain records of the names and current addresses of officers and directors.
2. An organization operating as a for-profit entity must maintain a current list of the names and addresses of its principal owners.
	1. **Governance.** The governing authority of an organization may reside in an individual or a board of directors. The composition and structure of the governing authority must be adequate to discharge its responsibilities. All organizations must minimally have either a board of directors or an advisory board.
3. An advisory board must:

a. Have a mechanism for obtaining feedback from clients that includes a procedure for direct input to the advisory board;

b. Include community members and local public officials who reflect diverse perspectives; and

c. Provide advice to the governing authority.

2. A board of directors or an advisory board must:

a. Meet, at a minimum, on a quarterly basis;

b. Maintain a current record of its membership including the name, address, contact information, position, and term of office of each member;

c. Maintain a record of meetings that includes the dates, attendance and topics discussed; and

d. Include community members who reflect diverse perspectives.

3. The records of meetings of the board of directors or advisory board must be maintained and made available to the Department upon request.

* 1. **Prohibited.**

1. The following persons are prohibited from serving on the board of directors or advisory board:

a. An employee of the State or federal government that has regulatory oversight of the organization; or

b. For an advisory board, any individual with a proprietary interest in the organization.

2. The organization may allow the following persons to serve on a board of directors or advisory board only when any conflict of interest is disclosed, and must require such persons to recuse themselves from any matters involving a conflict of interest:

a. An employee of the organization, or a member of the immediate family of an employee; and

b. Any employee of an entity holding a contractual relationship with the organization.

* 1. **Valid license.** The governing authority must ensure that the organization has a current valid license.
	2. **Responsibilities.** The governing authority is responsible for, and has authority over, the policies and operations of the organization. The governing authority’s responsibilities include, but are not limited to, the following:
1. Ensuring the organization’s continual compliance and conformity with all relevant laws and regulations, whether federal, State, or local, governing the operation of the organization including, but not limited to, those set out in this rule;
2. Approving written policies and procedures required by this rule and, in consultation with the administrator, developing and implementing a process to review and update the organization’s policies and procedures at least annually;
3. Providing financial oversight of the organization;
4. Reviewing and accepting the organization’s annual audit and annual financial report;
5. Reviewing the organization’s licensing survey results and any associated plan of correction;
6. Providing physical facilities, staff, equipment, supplies and other resources to provide licensed services;
7. Designating a person to act as administrator and delegating to the administrator sufficient authority to fulfill his or her responsibilities;
8. Completing an annual written evaluation of the performance of the administrator;
9. Overseeing the implementation of the organization’s quality improvement program; and
10. Providing written notification to the Department within two (2) business days after the organization receives notice of any legal proceedings related to the provision of services outlined in this rule or the continued operation of the organization, whether brought against the organization or against the organization’s personnel. Legal proceedings include, but are not limited to, bankruptcy, civil rights complaints, professional licensing body adjudications or sanctions, lawsuits, and alleged criminal activities by personnel that have implications for the programmatic or fiscal integrity of the organization or the safety of its clients.
	1. **Conflict of interest.** The organization must have in place a written conflict of interest policy applicable to the governing authority that addresses, at a minimum, the requirements of §11 (D)(2).
	2. **Closure.** The organization must notify the Department, in writing, of its intent to close no later than one business day after the governing body has made the determination to close and provide a copy of all policies and procedures listed in § 11(I) below.
	3. **Closure policy.** The governing authority must develop policies and procedures related to closure of the organization, its programs, or sites. The closure policy must include, at a minimum:
		1. A requirement that the organization must provide clients with a written notice of closure at least 30 calendar days prior to the closure date, unless an emergency situation exists. The written notice of closure must include, at a minimum:
11. The reason for the closure;
12. The effective date of the closure; and
13. The name and address of administrative staff responsible for the oversight of the closure.
	* 1. The roles and responsibilities of the organization’s owners, administrator or temporary management, and staff during the closure process;
		2. The sources of funding that will be required to maintain the organization’s daily operations until all clients are safely transferred or discharged, and funding necessary for record storage after closure;
		3. A process that assures that the organization will identify receiving facilities or programs taking into consideration the need, choice, and best interest of each client in terms of quality, services, and location;
		4. The ongoing assessment and treatment of clients, including provision of medications, if applicable during the closure;
		5. The provision of client information that will be sent to the receiving organization to ensure continuity of care;
		6. A process for disposing of drugs and biologicals, as applicable, in accordance with federal and State laws; and
		7. A specific plan for the secure storage and accessibility of the organization’s records.

**SECTION 12. PROGRAM ADMINISTRATION**

1. **Line of authority.**

1. The organization must have a written, up-to-date organizational chart and policies governing the line of authority, communication, staff responsibility and staff assignment.

2. At all times, an organization remains responsible for the health safety of its clients and for ensuring that the requirements of applicable statutes and rules are met.

1. **Administrator.** The administrator must demonstrate the ability to manage the affairs of theorganization. The administrator’s duties include, but are not limited to, the following:
	* 1. Ensuring immediate notification of any Level 1 critical incident to the Department by telephone within four hours and any Level 1 or Level 2 critical incident by written notification within 24 hours; and
		2. Ensuring written notification to the Department within 24 hours after receiving notice, or learning of, an arrest or indictment of organizational personnel related to criminal activity that is alleged to have occurred on the grounds of the organization or any location where services are provided.
2. **Evidence-based practice.** The organization’s written policies must include its clinical intervention practices for specific populations that are evidence-based practices for that specific client-group.
3. **Food services.** An organization that provides any food services must ensure that food is prepared in in accordance with § 21(D) of this rule.
4. **Teleservices and distant site practitioners.** Consistent with the organization’s written policies, select services or components of services may be provided through an interactive telecommunication system (teleservices) between the originating site (where the client is physically located at the time the service is provided) and the distant site (where the clinician delivering the services is located at the time the service is provided), in compliance with the following standards:
	* 1. Teleservices must be provided in compliance with Maine law, see for example 32 M.R.S. § 13868 and 24-A M.R.S. § 4316. The client must provide verbal, electronic, or written consent for telehealth and telemonitoring services. Teleservices may include, but are not limited to, outpatient services, professional consultation, psychiatric diagnostic interview examinations, individual psychotherapy, counseling, pharmacological management, a neurobehavioral status exam and, for clients who are stable, group and individual outpatient and intensive outpatient services and psycho-educational services. Examinations or evaluations of the client are under the control of the practitioner at the distant site.

3. The distant site practitioner must be qualified to provide the teleservice by education, training, licensure, or the equivalent, consistent with the credentials required for the specific service to be provided.

* + - 1. The delivery of specific services provided by teleservice must be allowed within the scope of practice of the practitioner’s license or credential;
			2. The organization must confirm that the distant site practitioner is currently allowed by license to practice in in Maine, consistent with the appropriate rule of the Department of Professional and Financial Regulation.
			3. When a distant site practitioner is an employee of a licensed entity in another state, the organization must secure a signed and dated Department-approved attestation from the employer of the distant site practitioner. The attestation must state:

i. That the employer has completed a criminal history background check on the distant site practitioner in accordance with local statute or regulation;

ii. That the distant site practitioner has not been found to have any offenses that would be disqualifications for employment under 10-144 CMR Ch. 60, Maine Background Check Center Rule; and

iii. That the distant site practitioner is an employee in good standing of the licensed entity.

* + - 1. A distant site practitioner may be an independent contractor, as defined by §14 of this rule.
			2. The organization must conduct reviews of the distant site practitioner’s performance at least annually.
1. **Reporting adverse events.** The organization must have a policy on reporting adverse events.
	* 1. The organization’s policy on reporting adverse events must include procedures for immediately reporting at least the following events:

a. The organization must notify the Department in the event of fire, structural damage or other catastrophe which renders the facility unsafe, unusable or uninhabitable within a time which is reasonable to permit a determination of whether any change in licensing status is necessary; and

b. Situations in which an employee has a reasonable belief that the client is likely to engage in physical violence that poses a serious risk of harm to the client or to others.

* + 1. The organization’s policy on reporting adverse events must also:

a. Describe in detail how it reports, manages and evaluates adverse or potentially adverse events; and

b. Require notification to the Department of the occurrence of an adverse or potentially adverse event, to include reporting in any electronic system mandated by the Department.

* + 1. The organization must cooperate with any investigation subsequent to the event of a client’s death.
1. **Continuity of operation plan.** The organization must have an appropriate plan for each facility and program for the continuity of operation in the event of an emergency including:
	* 1. Risk assessment of the types of emergencies that the organization may encounter;
		2. Plans for ensuring sufficient personnel and alerting a roster of volunteers to respond in the event of an emergency;
		3. Plans for the management of ensuing medical and psychiatric emergencies;
		4. Plans for the management of medical records and medication;
		5. Options for relocating service recipients, to include transfer and continuity of care agreements; and
		6. Plans for notifying the Department, guardians, placement agencies, and the SFMO.
2. **Annual evaluation**. The organization must adopt a written policy for the annual evaluation of the organization’s operation.

1. The annual evaluation may address the following:

* + 1. General program effectiveness in relation to stated goals and community needs;
		2. General staff effectiveness and staffing patterns;
		3. Staff turnover rate;
		4. Review of grievances and complaints;
		5. Summary of incident reports and adverse events;
		6. Rationale for the grouping of individuals;
		7. Emergency and safety procedures;
		8. Frequency of unplanned discharges of individuals in care;
		9. Assessment and evaluation of treatment services; and
		10. Trauma-informed agency assessment, as applicable.

2. The written annual program evaluation must be available to the Department upon request.

**I. Coordination of care.** The organization must adopt:

1. Policies regarding accessing emergency and non-emergency medical care; and

2. Policies regarding accessing crisis services.

**SECTION 13. PERSONNEL**

1. **Personnel records**. The organization must maintain records for all personnel, except for short-term or episodic volunteers whose job responsibilities do not involve direct client contact.
2. **Background check.** The organization must comply with the requirements of 10-144 CMR Ch. 60, Maine Background Check Center Rule, for conducting background checks for direct access workers. The organization must also secure, document and retain the results of a check of the following, as applicable:
3. The individual’s good standing with the appropriate licensing board, if applicable.
4. The driving record of personnel whose job responsibilities are expected or reasonably anticipated to include the transportation of clients in a motor vehicle and retain that record in each employee’s personnel file. The organization must review the employee’s driving record and assess their ability to safely transport the organization’s clients.
5. Adult Protective Services and Child Protective Services records to review the individual’s history of abuse and/or neglect and evaluate how that history may impact employability.
6. **Qualifications.**
7. The organization’s personnel must be qualified to provide services by education, training, supervisory experience, licensure, or the equivalent, consistent with job descriptions and required qualifications; and
8. The organization is responsible for ensuring its personnel are qualified and must maintain documentation of the references and credentials of prospective personnel, including:

a. Education, training, relevant experience, employment, and professional recommendations; and

b. State registration, licensing, or certification for the respective discipline, if any.

1. **Job descriptions.** Organizations must have written job descriptions for personnel.
2. Job descriptions must state the qualifications, job expectations, essential position functions, responsibilities, and supervisory relationships for each position or group of like positions.
3. Job descriptions must be reviewed and updated at least annually to evaluate the skills, education, and experience relevant to the licensed program, client needs, the specific services provided, and the qualifications or credentials required for personnel.
4. Job description changes and updates in performance expectations must be reviewed with each employee as part of an annual performance evaluation.
5. **Work description: students and volunteers.** Students and volunteers who have direct contact with clients must have a written work description that includes an explanation of their relationship to the organization, minimum qualifications, essential work functions, responsibilities, and supervisory relationships.
6. **Staffing.** The organization must maintain a pattern of staffing that is sufficient to meet the service plan delivery needs for all clients enrolled.
7. The organization’s staffing pattern must comply with licensing, credentialing, and training requirements, including access to supervision and consultation, directly or through independent contractors and across the organization’s sites.
8. The organization must ensure that personnel providing services for a client are acting within the scope of their individual license or certification.
9. **Nurse consultant.** An organization administering medication must have a nurse consultant on staff or under contract.
10. The nurse consultant is responsible for the coordination of medical care in the program, is a liaison with other clinicians, participates in any medically-related quality assurance activities, and reviews and approves the organization’s medical policies.

2. The duties, responsibilities, and availability of the nurse consultant and the terms of agreement must be delineated in writing.

3. The agreement must be signed by the individual serving as nurse consultant and by an authorized representative of the licensed organization.

1. **Clinical supervisor.** The organization must provide clinical oversight of clinical services. The clinical supervisor must be an appropriately-trained and independently-licensed practitioner practicing within the scope of his or her license, consistent with applicable professional licensing requirements.
2. The clinical supervisor is responsible for the delivery of appropriate care by persons supervised by the clinical supervisor.
3. Clinical supervisors must have training in supervision and the credentials to provide supervision consistent with core standards and applicable program-specific requirements as set out in this rule.
4. The clinical supervisor must be personally available or ensure the availability of an appropriate clinician for emergency consultation and intervention.
5. The clinical supervisor is responsible for clinical supervision of clinicians and independent contractors, as applicable, who provide clinical services.
	* + 1. Clinical supervision must focus on the effectiveness of client-specific services, sound clinical practice, evidenced-based practices, and continuity of care. The clinical supervisor must:
6. Review case records and progress notes;
7. Review the adequacy and completeness of screenings, assessments, and referrals;
8. Conduct reviews jointly with the supervisee;
9. Review and sign service plans as the supervisee’s certification or as his/her license requires;
10. Participate in the development of the supervisee’s counseling skills, as applicable; and
11. Provide individual supervision at least one hour each month involving a face-to-face encounter, phone conversation, or video-conference exchange between the supervisor and the supervisee.
12. The clinical supervisor may:
13. Provide education about clinical issues and treatment modalities, review of new policies, and other issues as applicable; and
14. Conduct individual and group supervision for supervisees.
	* + 1. Time recorded as clinical supervision must not be counted as training or administrative supervision.
			2. Documentation of all clinical supervision, including students, must be signed and dated by the clinical supervisor. The record of supervision must include the date of supervision, name of supervisee, and the duration and content of supervision.
15. Regularly scheduled clinical supervision must be provided to staff who are not licensed to practice independently in accordance with the following:
	* + 1. Staff providing 20 hours or more of direct service per week must receive at least four hours of clinical supervision every month;
			2. Staff providing less than 20 hours of direct service per week must receive prorated clinical supervision, scheduled weekly or otherwise, that equals at least one hour of clinical supervision every month; and

c. Students accepted for field placements must be under the direct supervision of a clinical supervisor, or another professional when clinical supervision is not required.

* + - 1. The clinician or other professional supervisor is responsible for supervising the direct services provided by the student.
			2. Student supervision must include the minimum organizational requirements for supervision of students, including minimum hours of supervision within identified time periods, in accordance with the organization’s written policies.
1. An organization remains responsible for the health safety of its clients and for ensuring that the requirements of applicable statutes and rules are met.
2. **Orientation and training.** The organization must ensure that personnel participate in orientation, training, and development programs that provide information necessary to effectively perform their job responsibilities; promote opportunities for learning and skill enhancement; and promote awareness of, and sensitivity to, the cultural backgrounds and needs of the population served.
3. The organization must have a written plan for the orientation and training of personnel that is reviewed and updated annually.
4. The organization must assure that personnel receive, at a minimum, ongoing annual training consistent with the specific services provided, as set out in relevant licensing and certification standards.
5. An organization must include the following program-specific orientation elements for all personnel before they assume their job responsibilities:
6. Orientation to the common life experiences of clients of behavioral health services, conducted by a client of behavioral health services;
7. Orientation to adverse reactions to psychoactive medications, if applicable;
8. Orientation to child development and children’s educational needs, for personnel who work with children or adolescents;
9. Orientation to psycho-geriatrics and communication techniques with elderly clients, for personnel working with individuals over the age of 60; and
10. Orientation to mandated reporting requirements as stated in 22 MRS 22 MRS §3477 and 22 MRS §4011-A.

4. An organization providing children’s behavioral health services must ensure that staff providing these services participate in Trauma-Informed Care training and SAMSHA’s System of Care Principles training within the first 90 days of employment.

**J. Staff Credentials.** Only the following are included in the definition of clinical staff in Substance Use Disorder programs:

1. A Licensed Alcohol and Drug Counselor (LADC) and a Certified Alcohol and Drug Counselor (CADC), or a(n):

1. Registered Nurse certified as a Psychiatric Nurse,
2. Advanced Practice Registered Nurse (APRN) with appropriate specialization certification,
3. Medical Doctor (M.D.),
4. Doctor of Osteopathy (D.O.),
5. Licensed Clinical Psychologist,
6. Licensed Clinical Social Worker (LCSW),
7. Licensed Clinical Professional Counselor (LCPC), or a
8. Licensed Marriage and Family Therapist (LMFT).

2. Any individual with a credential listed in Section J (1)(a-h) above may be employed as clinical staff in a Substance Use Disorder program only when that individual has completed one (1) year clinical experience in substance abuse treatment and a minimum of sixty (60) hours of alcohol and drug education within the last five (5) years.

3. Education accepted by the Department includes, but is not limited to, training and continuing education approved by the Maine State Board of Alcohol and Drug Counselors, 02-384 CMR Chapters 1-9.

4. Any of the credentials listed in Section J (1)(a-h) above may forego additional education hours and experience if they possess a Certified Clinical Supervisor (CCS) credential.

**SECTION 14. INDEPENDENT CONTRACTORS**

1. **Independent contractors.** Organizations must ensure that services provided through an independent contractor comply with this rule and applicable statutes.
2. Written agreement. Organizations must use a written agreement that governs the relationship between the organization and the independent contractor.

1. The prospective independent contractor must be professionally licensed or otherwise legally authorized and credentialed to provide the contracted services, and

2. The organization must have sufficient employees to provide contractual oversight of services delivered by independent contractors.

1. Obligations of the independent contractor. The written agreement includes at least the following independent contractor obligations:
2. The role and responsibility of the independent contractor;
3. Clearly defined services that will be delivered by the independent contractor;
4. A statement attesting to compliance with core standards and applicable program-specific standards outlined in this rule;
5. The requirement to post a sign at the contractor’s place of business in a location visible to clients, identifying the nature of the relationship between the independent contractor and organization;
6. The requirement to display the organization’s license at the independent contractor’s place of business where it is visible to clients and the public;
7. Return of the original client record to the organization by the independent contractor when a client’s case is closed, or when the contract with the independent contractor ends;
8. Records must be made available to the Department, upon request; and
9. The independent contractor agrees to allow the Department’s authorized representative to enter the independent contractor’s premises to inspect for compliance with this rule, or to investigate complaints at any time, consistent with the usual hours of operation.
10. **Obligations of the organization.** The written agreement includes at least the following organization obligations:
11. The role and responsibility of the organization;
12. The title of the position in the organization responsible for oversight of the independent contractor;
13. The requirement to include the independent contractor in the organization’s quality improvement plan;
14. A written record of staff qualification for all contractors providing services under this rule, to include background checks in accordance with this rule;
15. A written record of contractual oversight for each independent contractor, to ensure compliance with the terms of the agreement; and
16. A written account of the amount of clinical supervision or consultation provided by the organization.
17. Quality improvement review**.** Organizations must conduct quality improvement reviews of services provided by independent contractors.
18. The organization’s written quality improvement plan must include provisions for monitoring and evaluating the quality of independent contractor services, including, but not limited to, evaluation of services.
19. The organization, in conjunction with the independent contractor, must develop a written quality improvement plan that includes measurable actions, data collection, and timelines to achieve compliance with the provisions of the independent contract agreement.
20. **Violations.**
	1. The organization’s violation of a provision of the independent contractor agreement may result in a finding of non-compliance with licensing requirements.
	2. An organization is permitted to contract with independent contractors but the organization is responsible for ensuring that the requirements of applicable statutes and rules are met.

# SECTION 15. MEDICATION ADMINISTRATION

1. **Medication policies and procedures**. When the organization offers medication administration services or clients self-administer their medication, the organization must have medication policies and procedures that are based on recognized standards of practice. The policies must include:
2. Ordering, receiving, storing, administering, documenting, transporting, packaging, discontinuing, and destruction or disposal of medications and biologicals;
3. A requirement that all employees must practice proper hand washing and aseptic techniques; and
4. A requirement that a hand-washing sink must be available for staff administering medications.
5. **Use of safe and acceptable procedures.** The organization must ensure that all persons administering medications use safe and acceptable methods and procedures consistent with recognized standards of practice.
6. **Administration of medication.** The organization must ensure that:
7. All persons administering medications are trained and legally authorized to administer medications according to state requirements and must maintain documentation to demonstrate compliance with this provision;
8. Staff responsible for medication administration are oriented to the facility’s procedures and have access to current information regarding medications being used within the facility, including but not limited to side effects of medications, contraindications, and doses; and
9. Each client receives only the medications ordered by the client’s authorized licensed practitioner in the correct dose, at the correct time, and by the correct route of administration, consistent with recognized standards of practice.
10. **Client transfer.** When a client is transferred, the transferring organization or program is responsible for coordinating care with the accepting organization or program to include medication needs and continuity of care.
11. The existing orders at the transferring organization must be transmitted to the accepting organization.
12. Non-expired medication orders that were signed and dated by a licensed practitioner at the transferring organization are acceptable orders during the first 72-hour period at the admitting organization.
13. The accepting organization must ensure that a licensed practitioner has provided new medication orders for the client within 72 hours of admission.
14. The transferring organization must ensure the transferred client’s medications are removed from service and the medications are inventoried, recorded, and disposed of consistent with the organization’s policy.
15. **Self-administered medications**. The organization must, to the extent possible, allow each client the opportunity to personally take medications according to prescription.
16. Upon admission, the organization must assess each client’s ability to self-administer medications, including injectable medications, to determine if the client is safe to self-administer medication, as well as mentally and physically capable, or if the client will require medication administration services.
17. The client or the client’s legal representative, the client’s primary care physician and the organization jointly make a final decision about the client’s ability to self-administer medication.
18. The decision that a client has the ability to self-administer medication(s) must be reevaluated whenever there is a relevant change in the client’s capacity to self-administer medications or other factors that may affect the client’s ability to safely self-administer medications.
19. The client or the client’s legal representative may elect in writing to have the organization administer the client’s medications.
20. **Injectable medications.** Injectable medications must be administered by employees who are legally authorized to administer injectable medications.
21. Epinephrine injections and scheduled insulin for a stable diabetic client may be administered by a direct access worker who has been trained by a registered professional nurse regarding the safe and proper use of an epinephrine injection and insulin.
22. The direct access worker must have current documentation of successful completion of the injectable medication training included in the employee record.
23. **Medication containers.** Medications must be maintained in their original, labeled packaging and containers.
24. Medications must be measured and prepared for administration in accordance with standards of practice for medication administration.
25. Personnel may not reuse disposable medicine containers. Re-useable medication measurement and preparation devices must be cleaned and sanitized consistent with manufacturer’s guidelines and acceptable healthcare standards of practice.
26. **Medications at admission.** The organization must comply with the following provisions when clients are admitted to the program and bring currently prescribed medications with them for existing disorders:
27. The medication and dose must be prescribed by a licensed practitioner;
28. The medication in the container must be confirmed as the prescribed medication by a licensed practitioner or a pharmacist;
29. The medication must be stored in compliance with this rule and applicable statutes: and
30. There must be an order as required by § K(2) of this rule.
31. **Violation of law.** Nothing in this rule may be construed as authorizing or permitting a person to violate applicable federal or State laws.
32. **Lab testing.** Organizations that choose to conduct blood glucose or urine testing as permitted by the Clinical Laboratory Improvement Amendments (CLIA) must have a CLIA waiver and follow CLIA requirements for these tests. The Department may request documentation of the CLIA waiver.
33. Urine testing must not be done in areas where medication or food is stored or prepared.
34. Urine testing chemicals, including tablets or solutions, must be stored in a locked area where no oral medications are stored and where clients will not be able to access them.
35. Each client must have his/her own blood glucose monitoring device that is clearly labeled and is kept calibrated, cleaned, and sanitized consistent with the manufacturer’s guidelines, unless the provisions below are met:
	1. An organization may use a single blood glucose monitoring device for multiple clients, if it is a device designed for use by multiple clients;
	2. The organization must have policies and procedures for cleaning, sanitizing, and disinfecting between each client’s use, as well as calibrating the device; and
	3. There must be documentation to demonstrate the devices are calibrated and maintained consistent with manufacturer guidelines.
36. **Licensed practitioner’s order required.** Organizations must not administer, arrange for self-administration, or discontinue a medication without a written order signed and dated by a practitioner licensed to prescribe medications.
37. An order is required when clients receiving services in a licensed organization are approved by the prescribing provider as safe and responsible for self-administration of a medication. There must be evidence that the physician was advised of the self-administration assessment results.
38. An order is required prior to administration of medications brought into the licensed organization by the client, the client’s family, or friends.
39. **Written orders.** Orders for medications and treatments must be in writing, signed, and dated by a licensed practitioner.
40. Written orders are in effect for the time specified by the licensed practitioner. In no case may the time specified exceed 12 months.
41. A new written order is required to continue medication beyond a 12-month period.
42. Written orders for psychotropic medications must be reissued every three months, unless otherwise indicated by the authorized licensed practitioner.
43. Standing written orders for individual clients are acceptable when signed and dated by the authorized licensed practitioner.
44. A nurse may take a verbal order from a licensed prescriber as long as they later obtain the prescriber’s signature on a written order as transcribed by the nurse.

**M. Pro Re Nata (PRN) orders for psychotropic medications.** The organization is prohibited from administering “as needed” PRN psychotropic medication unless there is an order signed and dated by an authorized licensed practitioner that includes detailed behavior-specific written instructions.

1. Written orders for psychotropic medications must include symptoms that might require use of such medication, exact dosage, exact time frames between dosages, and the maximum dosage to be given in a 24-hour period.

2. The organization must notify the authorized licensed practitioner within 24 hours when a PRN psychotropic medication has been administered, unless otherwise instructed in writing by the licensed practitioner.

3. A person qualified to administer medications must be on-site at the facility when a client is administered psychotropic medications prescribed PRN, if the PRN medication is not self-administered.

**N. Faxed or telephoned orders for medication.** The following provisions apply to faxed or telephoned orders for medication:

1. Only a nurse or a pharmacist may accept a telephone order for medication;
2. The telephone order must be written, dated and signed by the authorized licensed practitioner within 24 hours; and
3. Prescription orders faxed to the organization by the licensed practitioner are acceptable. The fax must be placed in the client’s record.

**O. Medication administration record.** The organization must maintain a written Medication Administration Record (MAR) for each client. The client’s MAR must include, but is not limited to, the following information:

1. The written order for each medication or treatment prescription;
2. The name of the prescribing licensed practitioner;
3. The name of each medication, dosage, route, and time to be given, as well as the clinical indication for the medication;
4. Medications or treatments started, given, refused or discontinued, including those ordered to be administered PRN;
5. Evidence of notification of the physician for refused medications;
6. The type and frequency of monitoring for effects of the medication or treatment;
7. Medications or treatments ordered PRN, including date and time given, medication and dosage, route, reason given, monitored results or response, and initials or signature of administering individual;
8. Any stop order, signed and dated by the authorized licensed practitioner; and
9. At least the following information for each client:
	* + 1. Date and time the medication or treatment is administered;
			2. Type of medication or treatment;
			3. Name of each medication or treatment, dosage, and route;
			4. Frequency of use; and
			5. At the time of administration, the initials of the individual administering the medication or treatment as long as the individual’s full signature is written legibly somewhere on the document.

**P. Medication errors and reactions; incident reports.** Medication errors and adverse reactions must be recorded in an incident report in the client’s record:

1. Medication errors include errors of omission, as well as errors of commission; and
2. Errors in documentation or charting are errors of omission.

**Q. Storage of medication administered by the organization.** The organization must maintain medications in their original containers in a locked storage cabinet.

1. The cabinet must be locked when not in use and:
2. The key to the cabinet must be carried by the person on duty in charge of medication administration; and
3. The cabinet must be equipped with separate cubicles, plainly labeled, or with other physical separation for the storage of each client’s medications.
4. The organization must store sample medications in accordance with the organization’s policies.
5. The organization must keep medications and treatments administered by the organization that are for external use separate from medication taken internally.
6. The organization must keep medications administered by the organization that require refrigeration safely stored in a separate refrigeration unit that is not used to store food.
7. The refrigerator’s temperature must not exceed 41 degrees Fahrenheit;
8. A thermometer must be located in the refrigerator to ensure proper temperature control; and
9. The organization must have a policy and procedure for the monthly monitoring and recording of refrigerator temperatures.
10. Expired and discontinued medication must be taken out of service and locked in a separate cabinet away from other medications until disposed of or destroyed.

**R. Medication labeling requirements.** Organizations that administer the client’s medications must ensure that each prescription dispensed by a pharmacy is clearly labeled in compliance with applicable labeling laws and rules.

1. Organizations that administer the client’s medications must return all pharmaceutical containers having soiled, damaged, incomplete, incorrect, illegible, or makeshift labels to the original dispensing pharmacy for re-labeling within two business days of receipt of the improperly labeled medication or dispose of the medication as allowed by law.
2. The medication label must include at least the information required by 32 M.R.S. § 13794:
	* + 1. Prescription number;
			2. Client’s full name;
			3. Name, strength and amount dispensed of the drug;
			4. Directions for use;
			5. Name of prescribing authorized licensed practitioner;
			6. Name and address of issuing pharmacy; and
			7. Beyond use date.

**S. Schedule II controlled substances**. Organizations that administer the client’s Schedule II controlled substances medication are subject to the following standards:

1. In addition to compliance with federal and State laws, the organization must document and maintain records regarding Schedule II controlled substances in accordance with the following:
	* + 1. The organization must maintain a record of the name of the client, prescription number, the date, drug name, dosage, frequency and method of administration, the signature of the person administering it, and verification of the balance on hand;
			2. The organization must maintain a record and signed count of all Schedule II controlled substances at least once a day, if such substances have been used that day; and
			3. The organization must count all Schedule II and controlled substances on hand at least weekly and keep records of the inventory in a bound book with numbered pages, from which no pages may be removed.
2. The organization must store all Schedule II controlled substances under double lock in a separate locked box or cabinet within the medication cabinet, or in an approved double-locked cabinet attached to the wall.

**T. Disposal and destruction of medications.** Organizations that administer the client’s medications must have written policies regarding the disposal and destruction of discontinued, expired, or unused medications, including non-controlled and controlled substances.

* 1. The organization’s policies must comply with federal and State law, including Drug Enforcement Agency rules and regulations for medications disposal.
	2. The organization may have a written agreement with a dispensing pharmacy that outlines policies, procedures, and responsibilities for both parties regarding the return and disposal of discontinued and unused medication.

**U. Bulk supplies.** Organizations may, but are not required to, stock bulk supplies of those items regularly available without prescription. Bulk supply medications must be dated when opened and discarded consistent with the manufacturer’s guidelines.

**V. Availability of medicine during emergencies.** The organization must have a policy and a written backup plan for ensuring the provision of medications to the clients during an emergency, such as a natural or man-made disaster.

1. There must be a written plan for ensuring the provision of medications to the clients in the event that the organization ceases to exist.

2. These policies and plans must be reviewed and updated annually.

**W. Diversion control plan.** The organization must maintain a current diversion control plan that contains specific measures to reduce the possibility of diversion of controlled substances from legitimate treatment use, and that assigns specific responsibility to the medical director for carrying out the diversion control measures and functions described in the organization’s diversion control plan.

1. Organizations must inform clients and employees that diversion is a criminal offense reportable to law enforcement and would be a criminal offense if substantiated.
2. The organization must indicate how suspicions or evidence of diversion by clients must be handled clinically by the organization.

**SECTION 16. RECORDS MANAGEMENT AND RETENTION**

1. **Record management policy.** The organization must have a written records management policy. The organization’s records management policy must include objective criteria to determine when it would be harmful to allow a client to access his/her record.
2. **Record maintenance.** Organizations must maintain clean, readable records in an orderly, accessible format in a secure and private space and must have a record retention policy that addresses archiving and destruction of records consistent with all applicable State and federal statutes.
3. **Client access to client’s record.** A client or the client’s guardian or legal representative may access the client’s records in accordance with this rule.
4. If serious harm is likely to result from a client’s review of his/her record, the organization may deny or otherwise limit a client's access to part or all of the client’s record.
5. The organization’s decision to deny a client’s access to his/her record must be based on objective criteria.
6. A professional staff person must review the client’s record and may share information with the client only after the qualified professional signs an organization-approved statement that information determined to be harmful will be withheld from the client.
	* + 1. The organization’s administrator or designee must review the findings of a record review and approve or deny a client’s access to his or her record.
			2. The organization must render a written decision, including the findings of fact, to deny a client’s access to part or all of the client’s record. The decision must be included in the client’s record.

1. **Client record.**
2. Client record entries must be made only by authorized personnel and must be:
	* + 1. Specific, factual, relevant, and legible;
			2. Updated from intake through discharge;
			3. Completed, signed with identifying credentials, and dated by the person who provided the service; and
			4. Periodically reviewed by supervisors, in accordance with the organization’s policy and professional licensure requirements.
3. The organization must establish policies that ensure legibility and integrity of entries to records, which, at a minimum, will include the following:
	* + 1. The appropriate manner to make corrections to records and prohibiting the deletion of prior record entries;
			2. The prohibition of back-dating entries;
			3. A provision for making late entries to records, which must include a statement identifying the entry as late;
			4. A requirement for an easily recognizable date for every record entry; and
			5. Organizations utilizing electronic health records must use electronic date stamps for all entries in the record.
4. The organization must maintain documentation in the client’s record in chronological order. The client’s record must minimally include the following information:
	* + 1. Identification data, including name, address, telephone number and date of birth;
			2. All treatment documents (including, but not limited to assessments, service plans, progress notes, incident reports, and discharge summary);
			3. Essential legal information, including the following:
				1. Court records;
				2. Documents of guardianship, legal custody, powers of attorney and similar documents; and
				3. Medical or psychiatric care directives; and
			4. Copies of all completed releases and authorizations, including, but not limited to, the following:
				1. Forms documenting consent to treatment;
				2. Forms authorizing release of the client’s information; and
				3. Forms acknowledging receipt of written notification of client rights and responsibilities; information about fees, if applicable; the organization’s privacy practices; and other notifications required by this rule and applicable law.
			5. Clients may add written statements to their client record.
				1. With the client’s knowledge, organization personnel may add a written follow-up response to the client’s statement in the client’s record; and
				2. The client must be given the opportunity to review and comment on the organization’s follow-up response.
5. The organization must place a written explanation in the client’s record to explain the absence of any required information.

# SECTION 17. QUALITY IMPROVEMENT

1. Policy. The organization must have a quality improvement (QI) policy. The organization must identify any organization-wide issues, implement solutions to improve overall quality, and promote accessible, effective services at all sites. QI must take into account all groups of individuals served by the organization.
2. Operational plan. The organization must have an operational plan that assigns responsibility for coordination and implementation of QI activities and that:
3. Includes stakeholder participation in the QI process. Stakeholders may include, but are not limited to, clients, guardians, employees, volunteers, consultants, citizen review and advisory groups, client advocates, referral sources, contractors, and partners;
4. Includes quality improvement reviews of services provided by independent contractors;
5. Outlines methods and timeframes for monitoring and reporting activities;
6. Describes how opportunities for improvement identified through QI activities will be addressed by the organization; and
7. Provides for an annual assessment of the QI plan that includes stakeholder input and identifies any barriers to, and supports needed for, quality improvement.
8. The organization must develop key outcomes and indicators, and identify sources of reliable data as components of the QI plan.
9. **Focus of data collection.** The organization must focus the collection of service delivery information on the appropriateness, efficacy and effectiveness of services; and dimensions of service quality, including accessibility, availability, efficiency, continuity, safety, and timeliness.
10. **Incident analysis.** At least annually, the organization must review sources of information, as applicable, to identify patterns of reportable incidents and aggregate data regarding treatment outcomes.
11. **Periodic reports to personnel.** The organization must periodically make reports available to stakeholders stating what is learned as a result of its quality measurement and improvement efforts.

# SECTION 18. FINANCIAL MANAGEMENT

1. **Financial accountability and viability.** The organization must apply sound financial management practices and generally accepted accounting principles that are consistent with legal and regulatory requirements.
2. **Management systems.** The organization must maintain a business management system, including written policies and procedures, to assure maintenance of complete and accurate accounts, ledgers, and records.
3. The organization must identify qualified individuals responsible for financial matters, including management of purchasing and inventory, accounts receivable, accounts payable, and setting of fees or charges for services.
4. The governing authority is responsible for assuring the separation of duties in an adequate manner to prevent error and fraud.

**C. Annual financial audit.** The organization must obtain an annual financial audit for the organization.

1. The audit must be conducted by an independent certified public accountant who does not have a conflict of interest with the organization; and
2. Audit reports and financial records are subject to Department review upon request.
3. Organizations with annual revenues under $1,000,000 may provide a statement by an independent certified public accountant attesting that the organization follows Generally Accepted Accounting Principles in lieu of an audit.

**D. Client’s money.** The organization assumes responsibility when handling a client’s money, including a client’s maintenance or allowance funds.

1. The organization may not manage, hold, or deposit the personal funds of a client unless the organization has received written permission to do so from the client or his/her guardian or legal representative.
2. The organization must deposit the personal funds of a client in a financial institution, if the client has a guardian, trustee or conservator who cannot be reached.
3. The organization must maintain a record of each client’s funds.
	1. The records are subject to Department review, upon request; and
	2. The organization must comply with applicable laws and rules governing the handling of client funds.

**E. Fees paid by clients.** Clients may be responsible for identified fees charged by the organization.

1. Prior to service delivery, organizations must inform clients about payment requirements.

2. The information given by the organization to the client upon admission, and as necessary thereafter, must include the following:

1. A written explanation of the current schedule of fees for services and estimated or actual expenses;
2. Notice when fees or co-payments are charged, changed, refunded, waived, or reduced;
3. The amount of the fee charged for a specific service;
4. The manner and timing of payment of the service fee by the client;
5. The consequences of nonpayment of service fees; and
6. A copy of the program’s fee-for-service policy, including the program’s policy for nonpayment.

# SECTION 19. **RISK MANAGEMENT**

1. **Risk prevention and management practices**. The organization must identify individuals who are responsible for risk prevention and management functions.
2. **Annual risk assessment.** At least annually, the organization’s management personnel and governing authority must conduct an internal assessment of overall risk.
3. **Plan of corrective action.** The organization must draft and complete a plan of corrective action to address immediate and ongoing risks.
4. Quarterly review**.** The organization must complete a written quarterly review of immediate and ongoing risks related to the following:
5. Service modalities or other organizational practices that involve risk or limit freedom of choice;
6. The use of restrictive behavior management interventions, such as seclusion and restraint;
7. Cases where it was determined that a client was a danger to himself or herself or others;
8. Physical plants and grounds;
9. Grievances, incidents, or accidents involving clients;
10. Issues related to administering, dispensing, or prescribing medications; and
11. Any confidentiality or privacy breaches

**SECTION 20. NON-RESIDENTIAL BUILDING STANDARDS**

1. Building design. An organization must be housed in a space that allows for record retention and confidential in-person client contact.
2. The building must be operated and maintained in accordance with acceptable standards of practice to ensure the safety and security of clients, visitors, and staff, while still maintaining a clean, sanitary, and therapeutic environment that meets the needs for client treatment and safety.
3. The building must be designed for the service needs of the type(s) of program provided.

1. Local laws and codes**.** The organization must ensure that all building sites are accessible for the clients intended to be served, and in compliance with all applicable State and federal requirements.
2. The organization must obtain documentation from the appropriate municipal official indicating compliance with all local laws or codes whenever a change occurs, which includes, but is not limited to, the following: building renovations, remodeling, repair, or new construction.
3. All construction work must comply with applicable federal, State, and local laws.
4. Plans for construction must be approved in advance by the SFMO, and the site must be approved prior to occupancy in compliance with Life Safety Code and any other fire and safety laws and regulations which are applicable to the facility,
5. Building lease. The lease for any building or buildings not owned by the organization that are used in connection with the provision of client services must clearly define which party to the agreement is responsible for the maintenance and upkeep of the property. The Department must be notified at least 72 hours in advance of any changes in the lease that may impact responsibilities for maintenance and upkeep and compliance with this rule.
6. **Building security.** The organization must have written policies and procedures to protect the safety of its clients, staff, and confidential information for each building and site used in the provision of services under its license.

# SECTION 21. STANDARDS FOR ALL RESIDENTIAL PROGRAMS

1. Program manager. Residential programs must have a qualified, on-site facility and program manager for each residential facility. The program manager’s responsibilities include oversight of the requirements listed in § 21(B) of this rule. Program manager(s) may oversee more than one facility within an organization. An organization remains responsible for the health and safety of its clients and for ensuring that the requirements of applicable statutes and rules are met.
2. General program requirements. A residential program must adhere to the following:

1.Residential facilities are prohibited from having rented apartments, rooms, or space for persons other than clients in the licensed facility.

1. The program’s daily routines must not conflict with implementation of the client’s service plan.
2. Clients must have opportunities to be involved in decision-making about their routines, in accordance with each client’s individual service plan.
3. Living arrangements must address the needs of the clients, including opportunities for privacy and quiet.
4. The program must maintain a relationship with the surrounding community to promote integration in, and support access to, the greater community. The program must develop strategies to optimize the involvement of clients in community activities and optimize the use of community resources.
5. The program must identify its religious orientation, if any, along with particular religious practices that are observed and program restrictions based on religion.
6. When feasible, clients may attend religious activities and services of their choosing in the community and, when necessary, the residential program may arrange transportation.
7. A program must keep a daily census of clients for each residential facility.
8. When a client under legal guardianship makes an overnight visit outside the residential facility, the organization must record the date the client leaves the residence; the client’s location; the duration of the visit; the name, address, phone number, and other contact information of the person responsible for the client while absent from the facility; and the date and time of the client’s return. If the client declines to provide this information, documentation of refusal must be maintained in the client record.
9. Administrative and counseling services in residential settings must occupy space separate and distinct from client living areas and provide for privacy and security of discussions and records.

**C. Disaster, hazard, and evacuation plans.** The organization must have a written disaster, hazard and evacuation plan for each residential location. The disaster, hazard and evacuation plan must be based on a facility’s all-hazards risk and hazard vulnerability assessment, must assign specific tasks and responsibilities to organizational personnel and may be developed with the assistance of qualified fire, health and safety agencies. At a minimum, the plan must address the following:

1. Conspicuously posting emergency numbers in a place visible to persons using the telephone, including telephone numbers for fire, police, physicians, poison control, hospital, and ambulance;
2. Posting evacuation procedures in conspicuous locations throughout buildings;
3. Training personnel and clients to report fires and other emergencies, in accordance with written emergency procedures;
4. Training clients and personnel to evacuate the building, including specialized training for the evacuation of persons with disabilities or other conditions that may impair their ability to evacuate, as necessary, or their ability to understand the nature or purpose of the evacuation;
5. Training personnel on all shifts to perform assigned tasks during emergencies, including the use and location of emergency equipment;
6. Accounting for the whereabouts of clients and personnel;
7. Coordination with emergency responders;
8. Plans for notifying the Department that clients have been evacuated from a residential facility for any reason other than a timed drill, after clients are safely evacuated; and
9. Plans for notifying the SFMO immediately after clients are safely evacuated.

D. Food service and safety. Residential programs must ensure that food is prepared in a safe manner and in accordance with applicable standards.

1. Residential programs must offer a nourishing, well-balanced diet that meets the daily nutritional and special dietary needs of each client.
2. Therapeutic diets are medically prescribed treatment and must be ordered in writing by an authorized licensed practitioner acting within the scope of his or her license.
3. Menus for medically prescribed therapeutic diets must be planned in writing and approved by a qualified consultant dietitian.
4. Residential programs must have a current therapeutic diet manual (published within five years of the current date) that is recommended or approved by a qualified consultant dietitian. The organization may reference an electronic resource to meet this requirement.
5. Residential programs must have a 30-day menu plan that varies the food served daily, in accordance with client needs and preferences. The 30-day menu must be made available to the Department, upon request. The menu must offer a variety of foods, including fresh fruits and vegetables.
6. Residential programs must offer clients at least three meals in a 24-hour period. Additional food and beverages must be available 24 hours per day. Clients may choose whether to eat the offered meals, unless otherwise directed by a physician.
7. Residential programs must comply with the organization’s written policies governing the safety and storage of client-owned food.
8. Nothing in this rule prohibits a client from accepting and consuming gifts of home canned goods and other foods from family members or others. The organization must ensure that these items are appropriately labeled and dated.
9. Poultry, poultry stuffing, stuffed meats, and stuffing containing meat, must be cooked to heat all parts of the food to at least 165° Fahrenheit, with no interruption of the cooking process. Pork and any food containing pork must be cooked to heat all parts of the food to at least 150° Fahrenheit. Rare roast beef and beefsteak must be cooked to an internal temperature of at least 130° Fahrenheit, unless otherwise ordered by the client. Fin fish must be cooked to at least 145° Fahrenheit.
10. Only pasteurized milk and milk products may be used. No reconstituted powdered milk or evaporated milk may be served to drink. Powdered milk or evaporated milk may be used for cooking. Milk served for drinking must be served in the original container or poured directly from the original container into the client's glass at mealtime. Approved bulk dispensers may be used.
11. Perishable food must be stored at temperatures that protect against spoilage.
12. Residential programs must provide and clients must receive food that accommodates resident allergies.
13. Physical plant. The residential program’s physical plant must be operated and maintained in accordance with acceptable standards of practice for cleanliness and sanitation, while still ensuring the safety and security of clients and staff.
14. The organization must conduct a risk assessment of its physical plants and grounds as part of the organization’s overall risk management plan and must ensure that it takes appropriate measures to mitigate those risks that have been identified as posing a serious risk to staff or client safety. The risk assessment and plan of corrective actions will be reviewed and updated annually, or more often if necessary to ensure the safety of staff and clients. The organization may include this as part of their Quality Improvement program.
15. Roads and driveways must be regularly maintained and passable at all times of the year.
16. Residential facilities must have a central heating plant that can maintain a safe and comfortable ambient temperature between 65 - 75° F.
17. UL (Underwriters Laboratories Inc.) listed heating appliances properly installed by an appropriately licensed professional are acceptable as an alternate heating system, or a supplement to a central heating system, conditional upon SFMO approval.
18. Heating systems other than electric heating systems must be inspected annually by a qualified technician who is certified to work on the system. The organization must have written evidence that the heating system passed the inspection.
19. Portable space heating devices are prohibited, unless authorized for usage by the SFMO.

4. Residential facilities must have an adequate, safe and sanitary water supply.

* + 1. In order to hold a license, the organization must provide a supply of water safe for cooking and drinking.
		2. Each residential site must comply with the requirement of § 2 (N) of this rule regarding testing or the provision of bottled water.

5. The organization must ensure that all plumbing and sewage disposal is compliant with all local, State, and federal codes and requirements.

1. Exterior areas must have sufficient lighting to ensure the safety of clients and staff. Rooms, corridors and stairways within the residential facility must be sufficiently illuminated.
2. Corridors and stairways within a residential facility must be illuminated during the night or when activated by a motion detector.
3. Open flame lighting is prohibited.
4. There must be an effective pest control program, so that the facility is free of pests and rodents.
5. Residential facilities must store poisonous, toxic, flammable, and other dangerous materials in locked compartments used for no other purpose when not in use. Such materials:
6. Must not be stored with household cleaning solutions or other non-food supplies; and
7. Must be stored in a location that is separate from food storage and preparation areas, cleaning equipment, utensil storage rooms, and medication storage areas.
8. If an on-site laundry room is utilized, it must be maintained in a sanitary manner and kept in good repair.
9. The organization must ensure that linen and clothing are regularly laundered and are handled using proper sanitary techniques.
10. The laundry room must not be in an area used to prepare or serve food.
11. Soiled laundry must not be carried through food preparation areas, unless enclosed in containers.
12. Clothes dryers must be vented to the exterior of the building, unless designed by the manufacturer to operate without ventilation and approved for use in this type of facility by the SFMO.
13. Residential facilities that employ a laundry service for client linens or clothing must collect, transport, and store soiled and clean laundry separately.
14. Organizations must have written policies that govern all aspects of laundry service, whether the laundry service is provided by program staff, through a contracted service, or made available to clients on a self-serve or personnel-supervised basis.
15. Power-driven equipment must be maintained in safe and good repair.
16. Safety features must not be disabled, disconnected, or removed.
17. Safety features must be used during operation.
18. Use of power-driven equipment by clients, when appropriate, must be monitored by staff.
19. Residential facilities must comply with all applicable life safety codes and safety requirements, including fire drills and the use of smoke and carbon monoxide detectors.
20. Prior to initial licensure and prior to re-licensure thereafter, residential facilities must secure written documentation of compliance with the life safety code after an inspection by the SFMO or designee.
21. The residential facility must conduct timed evacuation drills in accordance with SFMO requirements.
22. No extension cords may be used, unless UL approved for use.
23. Client living areas must be cleaned regularly, well maintained and kept in good repair.
24. Residential facilities must have doors on all closets, bedrooms, and bathrooms that can be readily opened from both sides. Doors on closets may be removed for programmatic reasons.
25. Windows and window-covers must be kept clean and in good repair and must ensure the safety of clients.
26. Each client bedroom must have at least one exterior wall and be of sufficient design to allow for adequate natural light while still ensuring the safety and privacy of the clients residing there.
	* + 1. Each client bedroom must have direct access to a corridor without passing through a bathroom or another client's bedroom. No client room may be used for access to other rooms or corridors.
			2. No new license may be granted for a residential facility unless client bedrooms have 100 square feet of usable floor space per client in a single occupancy bedroom or 80 square feet of usable floor space per client in multiple occupancy bedrooms. Only floor space that has a ceiling height of at least six feet may be included in the calculation of usable floor space.

iii. The organization must make reasonable accommodations to the client rooms, in accordance with the Americans with Disabilities Act (ADA).

1. Organizations must provide each client a bed and mattress that is solidly constructed and in good repair. Rollaway beds, metal cots, inflatable mattresses, or folding beds are not acceptable.
	* + 1. Beds must be easily accessible in the bedroom and must not be in a location that is subjected to extremes of heat or cold. No bed may be placed within three feet of a heating unit unless the unit is properly protected.
			2. Beds provided for adults must be at least 36 inches wide.
2. The organization must permit and encourage clients to use their own furnishings and decorations in accordance with each client’s service plan and available space, to the extent that it does not prohibit the organization’s ability to comply with this rule.
3. Residential facilities must have adequate towel, linen, and bedding supplies. A complete linen change must be available at all times. Residential facilities may only use water resistant bedding when necessary.
4. Firearms, other weapons, and ammunition are prohibited on the grounds or within the building of any structure under the organization’s control that is used for the delivery of services. Law enforcement personnel entering the premises in an official capacity may carry weapons, in accordance with applicable regulations. The organization must adopt and adhere to a policy to carry out this provision. In drafting the policy, the organization shall take into consideration other applicable laws, including but not limited to 26 MRS § 600.

13. A swimming pool that is maintained by the organization or its landlord and made available for client use must be free from contamination and maintained in accordance with manufacturer guidelines and applicable laws and rules governing swimming pools.

* + - 1. Access to the pool must be secured to ensure client safety and prevent unsupervised use.
			2. When clients have access to a swimming pool and the pool has a water depth of greater than 24 inches, the residential facility must have an individual on duty that has a current water safety instructor certificate or senior lifesaving certificate from the Red Cross or similar organization approved by the Department.

14. Facilities must have bathrooms equipped with toilets and hand-washing facilities at a ratio of at least one flush toilet per each six users, and:

a. Water temperatures in client areas must not exceed 120° Fahrenheit;

b. There must be an adequate supply of hot water to meet the needs of the residential facility;

* + - 1. Knock-lights and visual alarms must be installed in bathrooms when there is a deaf or hard-of-hearing client or staff member;
			2. Residential facilities must have at least one bathroom that includes, at a minimum, a toilet and hand-washing sink on each floor having a client bedroom;
			3. There must be an adequate supply of hand-cleansing soap and paper towels, or an approved hand-drying device, conveniently located in each bathroom;
			4. Common towels and drinking cups are prohibited, except in a private bathroom in a client’s bedroom;
			5. Residential facilities must have at least one bathtub and one shower, that may be one combined unit;
			6. Bathing facilities must provide privacy and safety;
			7. Bathtubs and showers must contain slip-proof surfaces;
			8. Bathing facilities must be maintained in a sanitary condition; and
			9. Bathing facilities must be equipped with grab bars that meet the ADA standards.

15. The organization must maintain documented proof of rabies vaccinations for pets and service animals.

1. Pets, except fish in aquariums, are not permitted in common dining areas during meals.
2. No animals are permitted in common food preparation areas.
3. Pets may not present a danger to clients or guests.
4. Residential facilities must be free of pet odors and must dispose of pet waste regularly.
5. Use of service animals, including guide dogs, is governed by 5 MRS §4553, 17 MRS §1314-A, and 17 MRS §1312.
6. **Policies for residential programs.** An organization operating a residential program must maintain current written policies consistent with this rule and applicable statutes. Residential programs must have at least the following policies:
7. Programs must have a policy regarding smoking on-site. Programs may prohibit smoking on the premises or have a designated smoking area on the premises, in accordance with 10-144 C.M.R. Ch. 250, Rules Relating to Smoking in the Workplace.
	* 1. The organization must have a policy governing the provision of emergency healthcare to clients receiving services. The policy must address at least the following:
			1. Ensuring accessibility of emergency medical and mental health or psychiatric services 24 hours a day;
			2. Having trained program staff administer first aid and cardiopulmonary resuscitation (CPR) and ensuring at least one CPR-trained staff is on site 24 hours a day; and
			3. Maintaining first aid supplies adequate to meet situations reasonably anticipated.
8. **Diabetes management training**. A direct access worker providing assistance with activities of daily living for a client with diabetes must receive in-service diabetes management training from a registered professional nurse, and documentation of successful completion of the diabetes management training must be included in the direct access worker’s record. Diabetes management training must include at least the following topics:
9. Dietary requirements;
10. Diabetic oral medications, adverse reactions, including hyperglycemic and hypoglycemic reactions, and appropriate interventions;
11. Insulin storage;
12. Injection techniques and site rotation;
13. Foot care;
14. Laboratory testing, including urine testing and blood glucose monitoring; and
15. Standard precautions.

**H. Infection Prevention and Control.** The facility must establish, implement, and maintain an Infection Prevention and Control Plan (IPCP) to control the transmission of infectious diseases amongst residents, staff, visitors, and other individuals providing services under a contractual arrangement.

1. The facility must employ or contract with a person with certification or training in IPC to oversee the development and implementation of the IPCP. The certification or training must include the following content areas, at a minimum:

 a. Standard precautions;

 b. Transmission-based precautions;

 c. Respiratory protection; and

 d. Use of PPE and source control measures.

2. The facility must develop a written IPCP. The development process must include:

a. A risk assessment and overall program review. The risk assessment and program review must include:

i. Identification of resources necessary to care for residents during day-to-day operations and emergencies;

ii. Identification of any policies/protocols that need to be developed; and

iii. Review of current Maine Center for Disease Control and Prevention (MeCDC) standards and federal Center for Disease Control (CDC) guidelines. The facility should keep a log noting specifically what guidelines were utilized, and identification of any changes needed to meet those standards.

b. The facility must review and update the plan and all related policies/protocols annually, and whenever there is any change or plan for change that would require a substantial modification to any part of the current IPCP.

c. The plan must be updated as needed to reflect current Maine Center for Disease Control and Prevention (MeCDC) standards and federal Center for Disease Control (CDC) guidelines. The facility should keep a log noting specifically what guidelines were utilized and identifying any changes needed to meet those standards.

3. The IPCP must include policies and procedures for the prevention of the spread of any infectious disease, including:

1. Requirements for staff to perform hand hygiene before and after each direct and indirect resident contact for which handwashing is indicated by nationally recognized professional practice;
2. Use of PPE and source control measures;
3. A respiratory protection program;
4. Identification of the adequate amount of PPE to have on hand at all times, and measures to take when PPE is not readily available;
5. The conduct of environmental cleaning and disinfection, specifying the cleaning agents and processes to be used;
6. Documentation of random visual observations of staff use of PPE throughout an outbreak of an infectious disease;
7. Notification of the MeCDC, all other residents and their primary family contact, staff, and the DLC in the event of an outbreak of a notifiable disease;
8. Transmission-based precautions and isolation of the resident, when the MeCDC determines that a resident needs isolation to prevent the spread of infection;
9. Work-exclusion processes and steps to be taken in the event of a staff or resident exposure, when the type of infectious disease requires instituting specific work restrictions;
10. An exposure control plan to address potential hazards posed by blood and body fluids and other potentially infectious material (OPIM) or infectious diseases;
11. A crisis staffing plan;
12. A process for reporting notifiable diseases to the MeCDC; and
13. A policy requiring consultation with the MeCDC in the management of any outbreak of a reportable infectious disease or novel virus.

4. The facility must implement any recommendations of the MeCDC, including but not limited to:

a. Universal testing and resident cohorting, when applicable;

b. Practices for safe visitation or alternatives to in-person visits, and practices to assure resident safety during departures from the facility;

c. Reasonable methods and processes to allow residents to communicate with family and friends in ways that maintain resident safety; and

d. Conditions and protocols for screening all full and part-time staff, all essential healthcare individuals who enter the facility (such as hospice staff, physicians, etc.), and any other individual entering the facility.

5. The facility must provide education on IPC to all staff at hire.

a. The training must include:

i. Standard Precautions, including:

1. Hand hygiene, which must include procedures to be followed by staff involved in direct patient care or food preparation;

2. Bloodborne pathogens;

3. The proper selection and use of Personal Protective Equipment (PPE); to include putting on (donning) and taking off (doffing); and

4. Respiratory hygiene/cough etiquette;

ii. Environmental cleaning and disinfection;

iii. Transmission-based precautions; and

iv. Sharps/injection safety, including immediate actions to take when exposure to blood or other potentially infectious material (OPIM) occurs.

b. Documentation of staff training and observed competency in Infection Prevention and Control must be maintained in each employee’s personnel file.

c. In the event of an outbreak of an infectious disease, the facility must provide a refresher training to all employees.

d. The facility must maintain a copy of the IPC training curriculum utilized to provide education to staff.

# PART TWO: Program-Specific Standards

# **SECTION 22. MENTAL HEALTH PROGRAMS**

1. **Admission criteria.** The organization must have written admission criteria for all levels of care that is consistent with all applicable rules pertaining to client eligibility for services.
2. **Waiting lists and capacity management.** The organization must maintain a current wait list of individuals who are awaiting admission into the program. Organizations that are required to maintain “hold for service” lists pursuant to other Department rules may meet this requirement through the maintenance of that list.
3. **Personnel.** In addition to the core personnel requirements, mental health treatment programs must provide additional qualified staff as needed to ensure each client’s safe and effective treatment and to implement any restrictive behavior management plan.
4. **Community support services module.** Community support and integration services include, but are not limited to, case management services, Assertive Community Treatment (ACT), community integration services, intensive community integration, Rehabilitative and Community Support Services for Children with Cognitive Impairments and Functional Limitations, day supports services, psychosocial clubhouse services, skills development services, direct skill teaching, and daily living support services.

1. Case management consists of intake/assessment, plan of care development, coordination, referral and related activities, advocacy, monitoring and follow-up, and evaluation.

2. Rehabilitative and Community Support Services for Children with Cognitive Impairments and Functional Limitations are medically necessary treatment services for clients under the age of twenty-one (21).

* + - * 1. Treatment services are designed to retain or improve functional abilities which have been negatively impacted by the effects of cognitive or functional impairment and are focused on behavior modification and management, social development, and acquisition and retention of developmentally appropriate skills.
				2. Services may be evidence based under the supervision of a Board Certified Behavior Analyst.

3. An organization providing ACT must have a multi-disciplinary assertive community treatment team that complies with the requirements of 34-B MRS §3801(11).

a. If an organization provides ACT, the service must be available 24 hours per day, 7 days per week.

1. Crisis services module. A crisis services program must provide immediate short-term interventions designed to de-escalate and stabilize the crisis, to ensure the safety of the client and others and to provide referral and follow-up services, including but not limited to triage, safety assessments, supportive counseling or crisis/relapse plan development.
2. Crisis services must be provided in the least restrictive setting and least disruptive manner possible that meets the needs of the client in crisis.
3. A crisis services program must provide the following services, available 24 hours a day, seven days a week:
4. Triage;
5. Safety assessments; and
6. Supportive counseling, or crisis/relapse plan development, based on the assessment of the client’s immediate safety and support needs.
7. Crisis services may be provided by an interactive telecommunication system, on a walk-in basis, or through mobile outreach to the individual’s home, school, and other community settings.
8. The organization may provide crisis telephone services referred through a statewide toll-free number.
	1. Crisis telephone services must promote stabilization, evaluate the need for additional services, provide triage to additional services needed, include supportive interventions and problem solving, serve as ongoing support and backup to the program’s mobile outreach services, and provide information and referrals to other services and resources.
	2. When calls are from clients in crisis, the crisis services program must initiate the assessment, intervention, and triage process.
	3. When calls are from clients not in crisis, the crisis services program must refer the caller to help lines, peer support services, or other service providers.
	4. The crisis services program must maintain a written log of all contacts with the crisis telephone service, including the name of the caller when available, the crisis telephone worker, and the time and duration of the call.
	5. The crisis services program must document the presenting problem, an assessment of risk factors, the intervention, the evaluation of the intervention, and the plan for the management and resolution of the crisis.
9. Crisis walk-in services must provide support to clients in crisis on a walk-in basis during normal business hours.
10. Mobile outreach services must provide support to clients in crisis and their families, including triage, an interactive telecommunication system telephone and face-to-face assessments, supportive counseling, crisis/relapse plan development based on the assessment of the client’s immediate safety and support needs, and follow up.
11. Crisis assessments must be completed by appropriately qualified staff, including a mental health rehabilitation technician/crisis service provider (MHRT/CSP), or a licensed or certified mental health professional practicing within the scope of his or her license.
	1. The licensed or certified mental health professional must be available to provide consultation and advice to the crisis team, community hospital emergency department physicians and others on issues relating to medical evaluation and medication treatment, diagnosis and the overall service plan.
	2. The crisis services program must have a crisis team. The crisis team includes, at a minimum, a consulting psychiatrist and an independently licensed clinical supervisor.
		* 1. The crisis team may include other crisis services staff, including crisis intervention counselors, crisis clinicians, nurses, or other mental health providers.
			2. The crisis team must be sufficiently staffed to ensure compliance with OBH contract standards regarding the elapsed time between the time that the crisis services program is notified, or the time the client is available to be seen, until the time of the initial crisis intervention.
			3. Clinical supervision for crisis services must be provided by a psychiatrist, psychologist, licensed clinical professional counselor (LCPC), licensed clinical social worker (LCSW), a licensed marriage and family therapist (LMFT), or another appropriately qualified professional. Conditional licensure as an LCPC, LCSW, or LMFT is considered appropriately qualified.
12. Appropriately qualified staff must perform a crisis assessment in each situation in which there is face-to-face contact with a client in crisis.
	* + 1. The organization must conduct a full assessment for each client being seen by the crisis services program for the first time.
			2. Subsequent assessments for the same client must focus on the presenting issue and changes that may have occurred in the client’s situation and functioning since the prior presentation.
			3. Others designated by the client in crisis may be involved in the assessment.
			4. When the client has a service plan, a crisis/relapse plan, or intervention plan, the crisis intervention counselor, whenever possible, and with the client’s consent, must contact the client’s other providers to gather information to use in formulating the crisis intervention counselor’s recommendations.
13. The organization must draft a written comprehensive crisis assessment for each client that addresses the following components:
	* + 1. Demographic and diagnostic information;
			2. Risk of harm to self and others including, but not limited to, the following factors: current and past suicidal or homicidal impulses, thoughts and behaviors; trauma history; risk of victimization, abuse, or neglect; physically or sexually aggressive impulses or behaviors; ability for self-care; and use of environment for safety;
			3. Functional status including, but not limited to, the following factors: self-care and hygiene; ability to maintain social and interpersonal relationships; changes or disturbances in biologic functioning, such as sleeping, eating, or activity level; and school or work performance;
			4. Evidence of co-occurring conditions that may have a potential impact on the course or treatment of the presenting conditions;
			5. Environmental stressors including, but not limited to, the following factors: transitions and losses, current living situation or home environment, serious illness or injury of client in crisis or relative, exposure to substance use disorder and its effects, and danger or threat in home or community;
			6. Environmental supports including, but not limited to, the ability to take advantage of community and professional resources and social and emotional support from friends or relatives;
			7. Current and past experiences with treatment and services including, but not limited to, the following: response to treatment, ability to manage recovery, ability to engage in the treatment process, history of psychiatric hospitalization, history of involvement with crisis services, and resiliency following setbacks; and
			8. Pertinent medical history, medication history, and current use of medications.
			9. The written crisis assessment must note when any of the above information is not immediately available.
14. Following each face-to face contact with a client in crisis, the organization must document the following:
	* + 1. The presenting problem;
			2. The client’s history and factors precipitating the crisis;
			3. An assessment of the client’s capacity to make reasoned decisions, the client’s danger to self or others, and the client’s ability to care for him or herself;
			4. The sharing of the assessment with the client in crisis and the client’s parent, guardian, legal representative, or provider when applicable and appropriate;
			5. The disposition of the episode, including recommendations and referrals to other services as appropriate and indicated;
			6. Collaboration with the client’s other providers, including, but not limited to, the client’s community integration worker, when appropriate and applicable;
			7. The use or non-use of an existing crisis/relapse plan during the contact; and
			8. Appropriate follow-up contacts with the client, as authorized by the client or otherwise permitted.
15. When a crisis assessment reveals medication issues that may be related to the crisis episode that need to be addressed, the crisis intervention counselor must consult the on-call psychiatrist for guidance on how to proceed.
16. Based on the client’s treatment and support needs, the organization must offer the client written recommendations.
17. A crisis plan must be written for a client in crisis who contacts the crisis services program. An individualized service plan is not required.
	* + 1. A crisis program must obtain a copy of a client’s crisis/relapse plan to include in the client’s record.
			2. When a client does not have an existing crisis/relapse plan, the crisis program must collaborate with the client and the client’s community integration worker or other mental health provider to develop a crisis/relapse plan in accordance with this rule.
			3. Under no circumstances may a client be denied access to crisis services because that client failed to comply with his or her crisis/relapse plan.
			4. A client’s crisis/relapse plan may not be used to restrict that client’s access to crisis services.
18. The organization must have written policies and procedures for accessing emergency medical services that are reviewed and updated no less than annually. The organization must train its personnel on the organization’s emergency medical services procedures.
19. The organization must have written policies and procedures for initiating or recommending involuntary hospitalizations.
20. The organization must establish written policies and procedures regarding standards for the timely delivery of crisis services.
21. The organization must monitor compliance with its standards for timely delivery of services by documenting the date and time that a request for crisis services is made and the date and time when services are delivered in the client’s record.
22. The organization must have written policies and procedures regarding criteria for making follow-up contact with a client in crisis.
	1. Follow-up contacts must be documented in the client’s record.
	2. The organization must comply with confidentiality protections and informed consent protections.
23. The organization must maintain contact notes in each client’s record, including documentation of follow-up evaluations regarding service recommendations and referrals.
24. Crisis stabilization unit services are provided to adults when services cannot be safely provided in a non-residential community setting.
25. The organization must involve the client in crisis stabilization admission, service planning, intervention, and discharge.
26. The organization must encourage the involvement of family members and others, as appropriate.
27. Subject to the client’s consent, the organization must coordinate assessment and crisis services with services the client is receiving from other providers.
28. Crisis stabilization services provided must include assessment, treatment, stabilization, and preparation of the client for return to a home environment.
29. A crisis assessment of the client must be completed within 24 hours of each admission to the crisis stabilization unit.
	1. A crisis intervention counselor must complete a face-to-face crisis assessment with the client in crisis and a written crisis assessment for each admission.
	2. The client in crisis may designate a person to participate in the crisis assessment.
30. When a crisis assessment identifies medication needs, the crisis intervention counselor must consult the on-call psychiatrist.
31. The first time a client is admitted to the crisis stabilization unit, the program must conduct a comprehensive crisis assessment of the client within 72 hours after admission, unless a comprehensive crisis assessment was completed within 24 hours prior to admission.
	* + 1. When the program has conducted a comprehensive assessment of a client, the crisis stabilization unit must ensure that subsequent assessments focus on the initial presenting issue and any changes that have occurred in the client’s situation and functioning.
			2. The program must develop a standardized comprehensive assessment that includes at least the following components:
				1. Demographic and diagnostic information;
				2. Evidence of co-occurring conditions;
				3. Risk of harm to self and others, including but not limited to, the following factors: current and past suicidal or homicidal impulses, thoughts and behaviors; trauma history; risk of victimization, abuse, or neglect; physically or sexually aggressive impulses or behaviors; and ability for self-care and use of environment for safety;
				4. Functional status, including at least the following factors: self-care and hygiene; ability to maintain social and interpersonal relationships; changes or disturbances in biologic functioning, such as sleeping, eating, or activity level; and, school or work performance;
				5. Environmental stressors, including at least the following factors: transitions and losses, current living situation or home environment, serious illness or injury of client in crisis or relative, exposure to substance use disorder and its effects, and danger or threat in home or community;
				6. Environmental supports, including at least the following: ability to take advantage of community and professional resources and social and emotional support from friends or relatives;
				7. Current and past experiences with treatment and services, including at least the following: response to treatment; ability to manage recovery, ability to engage in the treatment process, history of psychiatric hospitalization, history of involvement with crisis services, and resiliency following setbacks; and
				8. Pertinent medical history, medication history, and current use of medications.
				9. When an organization is utilizing an assessment that was conducted by another provider, the organization may supplement that assessment with an addendum that documents any required components not found in the initial assessment.

h. Within 24 hours of admission, the organization must develop a short-term crisis service plan. At a minimum, the written short-term crisis service plan must include the following:

* + - * 1. A problem statement;
				2. Goals consistent with the client’s needs and projected length of stay;
				3. Objectives that build on the client’s strengths and stated in terms that allow measurement of progress;
				4. Specification of treatment responsibilities and methods;
				5. Documented evidence of input by the client in crisis, including his or her signature;
				6. Signatures of all other individuals participating in the development of the short-term crisis service plan;
				7. A description of any physical disability and any accommodations necessary to provide the same or equal services and benefits, as those afforded individuals without disabilities;
				8. On the seventh day of service, and every two days thereafter, the short-term crisis service plan must be reviewed; and
				9. With the consent of the client in crisis, the residential crisis stabilization program coordinates the development of the client’s service plan with existing active service plans that the client in crisis has with other providers.
1. When the client already has a crisis stabilization service plan, a crisis or relapse plan, or other established service plan with another provider, the residential crisis stabilization program’s crisis intervention counselor must contact those providers whenever possible.
2. Services provided by the crisis stabilization unit must be consistent with the targets and objectives of existing service plans that the client in crisis has with other providers.
3. Appropriately certified staff must be available 24-hours a day to assist clients with at least the following: daily living skills; monitoring medication administration; behavioral management; supportive interventions; and discharge planning.
4. Clinical supervision must be provided to all staff by qualified clinicians.
5. Prior to direct contact with clients, staff providing crisis stabilization services must complete at least the following staff training: orientation and training in the core standards and program-specific standards set out in this rule and applicable statutes; accompany an experienced staff member (also known as “shadowing”) for an appropriate period, as set out in the organization’s written policy; training in managing aggressive behaviors (e.g. MANDT, NAPPI); crisis stabilization training; and training in milieu management.
6. Each face-to-face contact between a client in crisis and a clinician must be documented to include the following, as applicable:
7. An assessment of the client’s danger to self or others, and the client’s ability to care for him or herself;
8. The sharing of the assessment with the client in crisis and the client’s parent, guardian, legal representative or provider when applicable and appropriate;
9. The disposition of the episode, including recommendations and referrals to other service providers as appropriate and indicated; and
10. The use or non-use of an existing crisis or relapse plan.
11. The crisis stabilization unit must have a written treatment summary that describes the client’s course of treatment and ongoing needs at transition.
12. The organization must provide a copy of the treatment summary to the client and share it with the client’s other service providers, if applicable, and as authorized by, the client.
13. Within 24 hours of discharge, the organization must enter the written treatment summary in the client’s record and include documentation of the client’s course of treatment and ongoing needs at discharge.
14. At a minimum, each written treatment summary must include the following:
	* + - 1. The assessment of the individual in crisis with challenges and strengths;
				2. The evolution of the mental status to inform ongoing placement and support decisions;
				3. Treatment interventions;
				4. The final assessment, including general observations and significant findings of the client’s condition initially, while services were being provided, and at discharge;
				5. The course and progress of the client, with regard to each identified problem;
				6. Recommendations and arrangements for services needed by the client after discharge;
				7. The reasons for termination of services; and
				8. The crisis or relapse plan.

**F. Outpatient services module.** Outpatient services include, but are not limited to, psychological assessment, outpatient therapy, outpatient counseling, geriatric psychiatric services, sex offender treatment, trauma recovery services, specialized group services, family psychoeducational treatment, or medication management.

1. Comprehensive assessment must be conducted by a qualified mental health professional to determine service needs, including those activities that focus on diagnosis and the identification of the need for any medical, educational, social or other services. Assessment must be conducted through contact with the client and, where appropriate, consultation with other providers and with the member's family.

2. Outpatient therapy may include:

* 1. Intervention services by psychological examiners;
	2. Individual, group, and family therapy;
	3. Specialized treatment for sexual abuse victims or offenders;
	4. Medication review;
	5. Geriatric psychiatric services;
	6. Trauma recovery services; and
	7. Similar professional therapeutic services.

3. Service plans must be completed within thirty (30) days from admission and reviewed every twelve (12) visits or annually, whichever comes first.

4. Intensive Outpatient Programs (IOP) must provide an intensive and structured program assessment and group treatment services in a setting which may not include an overnight stay.

1. IOPs must include a structured sequence of multi-hour clinical and educational sessions scheduled for a minimum of 3 days per week/3 hours per day per client.
2. Services provided include:
	* 1. Care coordination;
		2. Comprehensive assessments;
		3. Clinical services, to include daily didactic and counseling groups;
		4. Involvement of affected others; and
		5. Planning for and referral to further treatment, as needed.

**G. Mental health residential services module.** Residential mental health services for adults include but not limited to rehabilitative and support interventions with a focus on activities of daily living, medication management, medication self-administration, independent living skills, recovery, community inclusion and supports services, clinical treatment; In addition to meeting the standards for all residential programs stated in the core standards of this rule, residential programs for the treatment of mental health diagnoses must meet the specific program standards below.

1. Adult residential treatment facilities provide services to adults with severe and persistent mental illness who need the level of service offered in an adult residential treatment facility.

1. Residential treatment services may be provided to emancipated minors with severe and persistent mental illness who need the level of service offered in an adult residential treatment facility.
2. An organization licensed for integrated services may provide mental health and substance use disorder treatment services in a licensed adult residential treatment facility, as applicable.
3. Services include rehabilitative and support interventions with a focus on activities of daily living, medication management, medication self-administration, independent living skills, recovery, and community inclusion and supports services, as applicable.
	* + 1. Services include clinical review and completion of a service plan which includes goals related to support and rehabilitation.
			2. Service coordination includes facilitating access to medical services; participation in hospital discharge meetings; and participation in crisis intervention and resolution.
			3. Within 72 hours of admission, the organization must develop an initial service plan and within 30 calendar days of admission, the organization must develop a comprehensive service plan for each client.
			4. Within 30 calendar days of admission, an assessment must be completed to determine the level of care needed by the client.
			5. Mental health and substance use disorder treatment services must be provided by licensed professionals practicing within the scope of their license.
4. Residential programs may be conducted in an adult group setting or an apartment setting.
	* 1. When an organization provides a group living model residential program, the following program-specific standards apply:
5. The facility must have separate living and dining room areas that include comfortable furnishings appropriate to the use of the room. The use of folding chairs or patio furniture to furnish these rooms is prohibited.
6. The living and dining rooms must be well lit and free of hazards.
7. Living rooms must include a space for informal use by clients that is constructed and equipped in a manner consistent with the programmatic goals.
8. Dining rooms must be large enough to accommodate clients, personnel and guests eating together.
9. The program must permit and encourage client participation in food preparation and food service in accordance with food preparation and sanitation standards and provide skill development when it is part of the client’s service plan.
10. The organization must limit the number of clients per bedroom to no more than two adults.

b. When an organization provides private apartments for its clients, the following standards apply:

* + 1. Clients’ service plans allow them to live in private apartments.
		2. No more than two clients may share an apartment. Clients may share an apartment if both clients agree to share the apartment, and only after the treatment team for each client has determined that neither client’s recovery will be adversely affected by sharing an apartment with the other client.
		3. Apartment furniture provided by the organization must be safe, in good repair, clean and sanitary.
		4. Each apartment must have a solid door that can be locked.
		5. Program personnel may have a key to the apartment when the treatment team determines that staff access is necessary to protect the health and safety of the client.
		6. The treatment team ensures that the client’s service plan includes, as appropriate, training to develop the independent living skills necessary to keep the apartment clean and well maintained. Clients must demonstrate basic safety regarding the use and storage of poisonous, toxic, flammable, or other dangerous materials.
		7. Each apartment must have an area for food storage and preparation.
		8. Program personnel must assess resident food preparation and food safety skills, and provide support as needed to meet food preparation and sanitation standards.
		9. The food preparation area includes, at a minimum, six square feet of clear countertop, a small refrigerator, bar-type sink, a cabinet for food storage and either a two-burner stovetop or a microwave oven.
		10. Each apartment must have a bathroom that is equipped with at least one flush toilet, a hand-washing facility, and at least one bathtub or shower.
		11. A visual alerting system, such as a knock-light or exterior light switch, must be installed at the bedroom door for any client who is deaf or hard of hearing.
		12. The client must have control of the temperature in his/her apartment.

3. A residential facility for adults may be designated as a secure capacity facility if it provides an ongoing mental health program to adults who do not meet clinical criteria for acute inpatient hospitalization and whose diagnostic assessment and ongoing treatment needs indicate that the persistent pattern of the adult’s mental health presents a likely threat of harm to self or others and requires treatment in a locked setting that prevents the adult from leaving the program.

1. The secure capacity facility’s annual evaluation must include the frequency of use of restraints and seclusion, as well as client elopements.
2. The facility must retain a sufficient number of qualified employees, in order to maintain a safe and therapeutic environment at all times. There must be sufficient staff to meet the needs of the clients residing within the facility, based on the clients’ service plans and the facility policies and procedures.
3. Completed training must be documented in staff personnel records. Training records must be available for review by the Department upon request. The facility’s staff training policy must include the following training for all new staff and annual retraining for all staff:
4. Specialized training of staff regarding management of aggressive behaviors and client de-escalation techniques; and
5. Training regarding the secure character of the facility, including emergency evacuation plans.
6. A secure capacity residential behavioral health facility must employ a sufficient number of full-time registered nurses to meet the needs of the clients residing within the facility, based on their comprehensive assessment and service/care plans, 24 hours per day, seven days per week.
7. A secure capacity residential behavioral health facility must make available a psychiatrist who is on call 24 hours each day, seven days per week.
8. The psychiatrist must be on-site for consultations at least one day per month.
9. The psychiatrist must complete a psychiatric evaluation for each client within one week of the client’s admission.
10. The facility must ensure that medications are administered by those who are appropriately trained and qualified to administer medications.
11. Upon admission, the facility must develop an admission service plan based on anticipated client needs.
12. Within 72 hours of the client’s admission, the facility must complete an initial service plan.
13. The facility must require at least one progress note per day in each client’s record, written and signed by a staff member that includes the client’s progress toward service plan goals.
14. Within 30 days of admission, the facility must complete a comprehensive service plan.
15. Every 90 days thereafter, the service plan must be reviewed and updated by the service plan team. The review must include an evaluation of the client’s progress and an updated written plan submitted by each professional team member.
16. The service plan team must meet and revise the service plan consistent with the facility policy on service plans, but not later than two days after a significant change in the client’s condition warranting a change in the service plan has been identified.
17. The facility must be constructed to provide maximum security and safety for clients and staff members. Prior to initial operation and prior to licensure renewal thereafter, the facility must receive written approval from the SFMO for all required safety and security devices, including, but not limited to, sprinkler systems.

4. Clients who self-administer medications and who handle their own medication regimen may keep medications in their own room or apartment when properly secured. There must be documentation which denotes who will be responsible for the storage and safety of the client’s medications, the documentation of administration, and approved/agreed upon locations where the client may self-administer medication safely.

# SECTION 23. SUBSTANCE USE DISORDER TREATMENT PROGRAMS

1. **Admission criteria.** The organization must have written admission criteria which include:
2. Evidence-based, substance use disorder-specific patient placement criteria for clients with substance use and co-occurring behavioral health conditions at all levels of care offered by the organization, in accordance with the current edition of The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions; and
3. Formal and/or informal linkages with community providers, in order to facilitate referrals to human immunodeficiency virus (HIV) prevention services, medical care, sexually transmitted diseases (STD) screening and treatment, hepatitis B and C screening, hepatitis A and B vaccination and hepatitis treatment, as applicable.
4. An organization may develop other admission criteria only with written Department approval.

**B. Grievance procedures.**

1. Substance use disorder programs must develop grievance procedures that specify the process for dispute resolution, and display or otherwise make them available to clients. The following elements must be assured:

a. Clients may express verbally or in writing their dissatisfaction or complaints;

b. Clients may initiate grievance procedures and pursue those procedures;

c. The review of the complaint or grievance by a party other than staff member(s) involved in the dispute;

d. The receipt of a decision in writing, with the reasoning articulated, and time frames and deadlines that are reasonable and fair, and that apply to both the client and the provider.

e. Minimally, responses should occur within ten working days at each step of the process, unless time extensions are agreed upon by all parties. The time frame will apply to both client and the provider and must be included in the written explanation of rights.

2. All grievances must be documented.

1. **Waiting lists and capacity management.** The organization must maintain a current wait list of individuals who are awaiting admission into the program through an electronic treatment data system of the Department of Health and Human Services, Office of Behavioral Health (OBH) or its contractor.
2. **Personnel.** In addition to the core personnel requirements, substance use disorder treatment programs must have sufficient numbers of qualified staff to ensure each client’s safe and effective treatment, to include, but not be limited to, the following:
3. Substance use disorder treatment programs, with the exception of organizations that provide only services in the Community Supports Module, must have a medical director with responsibilities that minimally include, but are not limited to, the following:
	* + 1. Developing or approving the forms used for medical assessment;
			2. Reviewing and signing off on medical portions of client records when requested;
			3. Developing or approving written policies regarding medications and supervising the administration of medications;
			4. Reviewing and approving the program’s written policies and procedures for screening for infectious diseases, including human immunodeficiency virus (HIV) disease, tuberculosis and hepatitis B and C; and
			5. Demonstrating training, competency, or experience and, if applicable, access to psychiatric consultation, commensurate with the volume and characteristics of the population of individuals with co-occurring disorders routinely served by the organization, if licensed to provide integrated services.

2. Licensed substance use disorder treatment programs must employ or contract with certified clinical supervisors (CCS) licensed in accordance with 32 MRS § 6214-E and 02-384 CMR Ch. 6, Standards for Certification of Clinical Supervisors.

* 1. A CCS must provide supervision and oversight of alcohol and drug counseling services.
	2. In addition to licensure as a CCS, at least one or more CCS must also be qualified by training, competency or experience to provide supervision to all staff in the provision of co-occurring disorder services. If applicable, the CCS must have access to mental health consultants.

3. Substance use disorder qualified staff must meet the requirements of Section 13(J) to provide substance use disorder treatment.

1. **Community support module.** Case management services are service provided by a social services or health professional, or other qualified staff, to identify the medical, social, educational, or other needs (including housing and transportation) of a client, identify the services necessary to meet those needs, and facilitate access to those services.
2. Case management consists of intake/assessment, service plan development, referral, and related activities, monitoring and follow-up, coordination, advocacy, monitoring and evaluation.
3. Anorganization that intends to provide mobile substance use disorder services must have prior approval from OBH.
4. Crisis services module. A crisis services program must provide immediate short-term interventions designed to de-escalate and stabilize the crisis, to ensure the safety of the client and others and to provide referral and follow-up services. Substance use disorder crisis services include but not are limited to triage, safety assessments, supportive counseling, or crisis/relapse plan development, and follow up.

1. Crisis services must be provided in the least restrictive setting and least disruptive manner possible that meets the needs of the client in crisis.

2. A crisis services program must provide the following services, available 24 hours a day, seven days a week:

1. Triage;
2. Safety assessments;
3. Supportive counseling, or crisis/relapse plan development, based on the assessment of the client’s immediate safety and support needs; and
4. Follow-up.

3. Crisis services may be provided by an interactive telecommunication system, on a walk-in basis, or through mobile outreach to the individual’s home, school, and other community settings.

1. The organization may provide crisis telephone services through a statewide toll-free number.
2. Crisis walk-in services must provide support to clients in crisis on a walk-in basis.
3. Mobile outreach services must provide support to clients in crisis and their families, including triage, an interactive telecommunication system, and face-to-face assessments, supportive counseling, crisis/relapse plan development, based on the assessment of the client’s immediate safety and support needs, and follow up.

4. The organization must draft a written comprehensive crisis assessment for each client.

5. A crisis plan must be written for a client in crisis who contacts the crisis services program. An individualized service plan is not required.

**G. Outpatient services module.**

1. Outpatient substance use disorder services may include but are not limited to intensive and structured treatment services, clinical services, educational groups, screening, brief intervention and referral, scheduled or emergency services, counseling. and referral for services. Outpatient programs may offer the following services:

* + - 1. An intensive and structured program of treatment services, including a structured sequence of multi-hour clinical and educational sessions;
			2. Clinical services, including daily didactic and counseling groups;
			3. Educational groups on chemical dependency, including education about tuberculosis, HIV, and hepatitis C;
			4. Planning and referral for further treatment, as needed;
			5. Screening, brief intervention and referral of clients at risk, but not in need of outpatient level of treatment;
			6. Services provided on a scheduled or emergency basis, in accordance with client needs;
			7. Individual, group, and family counseling;
			8. Referral for services based on the client’s need including, but not limited to, the following:
			9. Mental health consultation;
			10. Medication management;
			11. Medical care; and
			12. Planning and referral for further treatment.

2. All outpatient programs must provide a comprehensive assessment within 30 days of the date that services begin, including a medical screening to determine the need for further medical testing or a physical exam conducted by qualified personnel. The need for further medical testing or examination may be indicated by observation or report of physical symptoms of infectious disease or illness.

* 1. A program may utilize a comprehensive assessment completed not more than 30 days prior to the start of services to fulfill this requirement, provided the assessment was conducted by qualified personnel and appropriately updated within five days of the start of services.
	2. A service plan must be developed upon completion of the comprehensive assessment and/or within 3 sessions, and it must be reviewed at least every 90 days.
	3. This service plan must be updated, as needed, based on changes to the client’s condition and/or identified needs.

3. Intensive Outpatient Programs (IOP) must provide an intensive and structured program of alcohol and other drug assessment and group treatment services in a setting which may not include an overnight stay.

1. IOPs must include a structured sequence of multi-hour clinical and educational sessions scheduled for a minimum of 3 days per week/3 hours per day per client.
2. Services provided include:
3. Procedures to determine the client’s medical needs. The program must determine the necessity for medical examination and further consultation. The medical assessment must be part of the client record;
4. Comprehensive assessments;
5. Clinical services, to include daily didactic and counseling groups;
6. Educational chemical dependency groups;
7. Involvement of affected others; and
8. Planning for and referral to further treatment, as needed.

4. Medication for Opioid Use Disorder (MOUD) may be provided in an opioid treatment program, an opioid treatment medication unit (pharmacy, physician’s office) or a physician’s office or other healthcare setting, with the exception of methadone, which must be administered in an opioid treatment program (OTP).

a. MOUD service plans must be multi-disciplinary.

b. MOUD service plans must include all relevant SUD services provided by organization.

5. Opioid treatment programs must comply with the federal opioid treatment standards as set forth in 42 CFR §§8.11 through 8.12.

a. Any violation of any of the federal standards and certification requirements at 42 C.F.R. §§8.11 through 8.12 or the Federal Guidelines for Opioid Treatment Programs constitutes a violation of this rule.

1. OTPs must comply with Maine Criminal Code and Maine State Pharmacy Rules.
2. OTPs must comply with the requirements of the State of Maine’s Prescription Monitoring Program.
3. OTPs must invite the public and municipal officials, including without limitation, elected officials, public health, and public safety officials to an annual meeting with clinic management and OBH staff to discuss the clinic’s impact on the municipality.
4. An organization may not operate more than one OTP under one license. Each OTP site must be individually licensed.
	1. The OTP site must limit OTP counselors to a case load of 50 clients or less except OTP counselors who have not completed 2,000 hours of substance use disorder practice under clinical supervision must be limited to 35 clients or less.
	2. Any request for a waiver of these size limitations must be accompanied by a written recommendation for approval of the waiver by OBH.
5. OTP staff must receive at least the following training:
	* + 1. An intensive program of training specific to opioids and opioid agonist issues, pursuant to a written training plan developed by the OTP.
			2. The training plan and documentation of attendance must be maintained in personnel files.
			3. All personnel must receive basic training on methadone and crisis intervention, as well as:
6. Training specific to staff duties at the OTP;
7. Annual training updates specific to opioids and opioid agonist issues;
8. HIV infection and the treatment of clients with HIV;
9. Hepatitis B and C, including the treatment and prevention of hepatitis; and
10. Treatment improvement protocol.
11. Service plans must be developed to describe the most appropriate combination of services and treatment.
	1. The initial service plan must be in writing and completed within seven days of admission.
	2. The initial service plan must be developed and signed by the client, the primary counselor and the medical director.
	3. Service plans must include the rationale for use of the dosage plan. The rationale must be documented by a physician, physician assistant or nurse practitioner.
	4. Results of substance use tests must be documented in the client record and there must be a clear indication in client records that the results of substance use testing have been reviewed and considered as part of the service planning process and decision for take-home dosing.
	5. The medical director must review and sign service plans on an annual basis.
12. The OTP must develop and follow written policies and procedures that are adequate to ensure that treatment medication used by the program is administered and dispensed in accordance with approved product labeling, the dosage form and initial dosing requirements. The written policies and procedures must include, but are not limited to:

i. Administration of additional dose of medication to a client (“re-dosing”);

ii. Courtesy dosing, to ensure a client’s ability to secure medication when traveling, or when otherwise unable to secure medication at their OTP. The written policies must address, but are not limited to, the following:

1) The OTP must identify situations when it is appropriate for the OTP to request or provide courtesy dosing for a client;

2) Documentation must include the factors supporting the decision to request or provide courtesy dosing;

3) The OTP must submit a request for courtesy dosing to another approved OTP or medication assisted treatment facility (MAT); and

4) The OTP must maintain documentation which includes contact information for the OTP or MAT providing the courtesy dosing.

iii. Emergency exceptions to the take-home schedule consistent with this rule; and

iv. Communication of medication information when there is a client transfer. When a client transfers from one OTP to another, medication information must be communicated by medical personnel at the transferring program to medical personnel at the receiving program, as permitted by applicable law and rule.

j. An OTP must comply with the medication administration requirements set out in federal regulations, this rule, and applicable statutes.

* + - 1. The OTP must ensure that client identity, and the correct medication and dose, are verified prior to medication administration and appropriately documented when administered.
			2. The medication must be administered in liquid form only, using a dispensing pump. The client’s ingestion and swallowing of the medication must be observed by the OTP staff person who administers the medication. Administration of the medication must be documented in the client’s record.
			3. At the time of administration, there must be a face-to-face evaluation by qualified staff to determine if the client is under the influence or at immediate risk for complications if the dose is administered. When the need for further evaluation is indicated to make that determination, or if a need for an intervention is identified, it must be documented in the client record.
			4. All female clients of childbearing potential must be tested for pregnancy upon admission to the OTP and when requested or indicated during the course of treatment. Pregnant clients must be referred for prenatal care.
			5. Medication may be withheld when the OTP physician determines that administration of the medication would not be medically or clinically appropriate.
			6. The factors that support withholding of medication must be documented in the record and signed by the medical director.
			7. The appropriateness of the decision to withhold medication may be reassessed later during the same day the decision is made.
			8. Client take-home medication supplies must not exceed the limits allowed by 42 CFR § 8.12(i)(3)(v) & (vi).
			9. Exceptions to the take-home schedule must be submitted on-line through the federal SAMHSA/Center for Substance Abuse Treatment OTP extranet.
			10. SAMHSA and OBH approve or deny an OTP’s written request for an exception to the take-home schedule.
			11. No exception to the take-home schedule may be implemented prior to receiving approval for the exception.
			12. Documentation of the OTP’s request for an exception and the response received from OBH, SAMHSA, or both, as applicable, must be placed in the client’s record.
1. The OTP must maintain documentation of all attempts to contact OBH for approval of the exception. There must be documentation in the client’s record that the nature of the emergency was verified by the OTP, as well as the OTP director and the medical director decision and rationale for their decision. All required documentation must be submitted to OBH by the OTP director within one business day of the emergency take home exception occurrence.
2. An OTP’s written request for a split-dose exception must be submitted to both SAMHSA and OBH. No split-dose may be dispensed to a client prior to the OTP’s receipt of written approval for the split-dose exception. Split-dosing may only be authorized if medically necessary. Documentation of the OTP’s request for a split-dose exception and the response received from SAMHSA and OBH must be placed in the client’s record.
3. Rehabilitation counseling services must be provided by OTP staff and must be consistent with the client’s service plans.
4. The client record must include documentation of the provision of counseling and the results of counseling.
5. This counseling must be in addition to the face-to-face evaluation done at the time of dosing.
6. Counseling must include group counseling and individual counseling in accordance with the client’s service plan.

**H. Substance use disorder residential services module.** Residential substance use disorder treatment programs provide services in a full-time (24 hours a day) residential setting. Residential substance use disorder services for adults may include but not limited to diagnostic services, educational services, counseling services, provision of medication for opioid use disorders, and medically supervised withdrawal programs.

1. The program must provide a scheduled treatment regimen which consists of diagnostic, educational, and counseling services and must refer clients to support services as needed.
2. In addition to meeting the standards for all residential programs stated in the core standards of this rule, residential programs for the treatment of substance use disorder must promote access to all forms of MOUD onsite or by direct coordination with outpatient providers and/or referral and meet the specific program standards below.
3. Services provided either on site or through referral must include:
4. Evaluation of the client’s medical and psychosocial needs;
5. A medical examination by a licensed practitioner within 5 days of admission unless a prior examination was conducted not more than 30 days prior to admission;
6. Individual and group counseling must be provided at a minimum of 14 hours per week or 2 hours per day for each client;
7. The treatment mode may vary with the member’s needs and may be in the form of individual, group or family counseling;
8. There must be group/individual/family treatment sessions appropriate to the phase of treatment;
9. Group counseling may include didactic/educational presentations;
10. Provisions for family involvement must be made;
11. Qualified staff must teach attitudes, skills, and habits conducive to good health and the maintenance of a substance free lifestyle;
12. Programs must have staff coverage 24 hours per day, including weekend coverage.
13. On-call staff must be provided to deal with emergencies;
14. Vocational assessment and preparation must be provided;
15. Transportation must be available 24 hours/day;
16. There must be a written plan for transportation between the program and emergency care facilities;
17. The program must be able to provide 24-hour access to transportation to emergency medical care facilities for clients requiring such transport when there is no local access to emergency services;
18. Extended care services must provide a scheduled therapeutic plan consisting of treatment services designed to enable the client to sustain a substance-free lifestyle within a supportive environment;
19. Opportunities for learning basic living skills, such as personal hygiene skills, knowledge of proper diet and meal preparation, constructive use of leisure time, money management, and interpersonal relationship skills, which may include supervised housekeeping responsibilities;
20. Educational services, vocational placement and training, and recreational opportunities as appropriate to the client group to be served; and
21. The program must make agreements with community resources to provide client services through referrals when the program is unable to provide them.
	* 1. Organizations may provide residential medically supervised withdrawal programs in a residential facility with appropriate medical monitoring and management of withdrawal symptoms. The facility may be secured, based on client-safety needs and facility risk assessment. Services include, but are not limited to, the following, as applicable:
		2. A physical examination by a physician, nurse practitioner, or physician assistant performed within 24 hours of admission, accompanied by appropriate laboratory and substance use tests. In lieu of a physical exam, a review of the record of a physical examination administered by a physician, nurse practitioner, or physician assistant within the seven calendar days prior to admission would fulfill this requirement;

b. Continued medical management, including integrated bio-psychosocial evaluation, medical observation, monitoring, treatment, counseling, and follow-up referral services;

c. In addition to the assessments completed by all residential programs, an initial assessment completed by qualified personnel, including an addiction-focused history that is reviewed by the physician during the admission process;

d. A service plan developed upon completion of the comprehensive assessment, which must be reviewed at least every 30 days and there must be evidence to demonstrate that it was reviewed at least every 30 days and updated as needed;

e. Daily medical monitoring and management of acute withdrawal symptoms including:

i. Assessment of clients’ medical and behavioral symptoms;

i. Monitoring by a nurse, based on assessment of the clients’ needs;

f. The residential medically supervised withdrawal program must comply with the following program staffing requirements:

* + - 1. A physician, nurse practitioner, or physician assistant is available 24 hours a day by telephone;
			2. Nurse practitioners are available to conduct a nursing assessment on admission;
			3. A nurse is on-site at all times when clients’ assessments determine nursing care is needed. The nurse is responsible for overseeing the monitoring of the client’s progress and medication administration on an hourly basis, as needed;
			4. Appropriately licensed and credentialed personnel available to administer medications in accordance with physician orders;
			5. Appropriately credentialed alcohol and drug counselors are available to provide evaluation and treatment services for clients and family support as needed;
			6. Personnel in direct contact with clients must have training in recognizing impending alcohol, drug or other medical emergencies, and must ensure clients exhibiting signs or symptoms of an impending medical emergency receive appropriate care or are transferred to an appropriate emergency facility;
			7. Transportation support must be available 24 hours a day; and
			8. The program must have a written agreement for transfer with an emergency healthcare facility.

g. Individual and group counseling to include:

i. Withdrawal support, or provision of such counseling through other resources;

ii. Opportunities for family involvement and referral of family to counseling, when appropriate;

iii. Motivational counseling to seek further treatment;

iv. A range of cognitive, behavioral, medical, mental health, and other therapies, designed to enhance the client’s understanding of addiction, the completion of the medically supervised withdrawal process, and referral for continuing treatment and support;

v. Meaningful access to all forms of MOUD onsite or by direct coordination with outpatient providers; and

vi. Health education services;

h. Written referral arrangements, as applicable, with clinicians and facilities for specialized services beyond the capability of the withdrawal management program, including, but not limited to:

i. Full medical acute care services;

ii. Intensive care;

iii. Nutritional services, including special diets, as needed; and

iv. Specialized clinical consultation and supervision for biomedical, emotional, and behavioral and cognitive problems;

i. Program records must include written documentation of the following:

* + - 1. Progress notes entered by clinical personnel and nurses daily, or, at each client encounter;
			2. Withdrawal management rating scale tables and flow sheets, as needed;
			3. A record of discharge or transfer planning that begins at admission; and
			4. Planning for, and referral to, further substance use disorder treatment, mental health treatment, or medical consultation.

5. Residential rehabilitation programs for clients residing with their children are designed to treat clients who have significant social and psychological problems and are provided in a residential setting for clients and their children. Services include, but are not limited to, the following:

* + - 1. Group, individual, and family counseling;
			2. Planned clinical program activities to stabilize and maintain stabilization of the client’s substance dependence symptoms and to help the client develop and apply recovery skills;
			3. Relapse prevention skills to improve interpersonal choices and a development of a social network supportive of recovery;
			4. Daily didactic, educational presentations;
			5. Parenting and caretaking skill building; and
			6. Child care and educational services for the children in the facility.

SECTION 24. INTEGRATED MENTAL HEALTH AND SUBSTANCE USE DISORDER TREATMENT PROGRAMS (Co-Occurring Behavioral Health Conditions)

1. **Licensed integrated mental health and substance use disorder treatment programs**. Organizations offering an integrated mental health and substance use disorder treatment program must comply with all of the standards in this rule, as applicable based on program setting. When the standards for mental health and substance use disorder treatment in this rule differ, the organization offering an integrated mental health and substance use disorder treatment program must comply with the higher standard.

1. **Population.** Integrated treatment programs are designed to identify and treat individuals with co-occurring behavioral health conditions who have moderate-to-high symptom acuity.
2. **Cross-trained clinician or team.** Organizations must provide integrated mental health and substance use disorder treatment services delivered by a clinician or team cross-trained to provide both mental health and substance use disorder treatment concurrently.
3. **Services.** The organization must have written policies and procedures regarding its services, including but not limited to, screening, assessment, program content, service planning, discharge planning, interagency relationships and staff competencies designed to routinely provide integrated services to individuals with co-occurring behavioral health conditions.
4. **Interventions.** Organizations must provide a broad range of appropriate interventions, including motivational treatment, skill building, and relapse prevention strategies for clients with mental health and substance use disorders. Organizations may offer services from community support and integration, crisis, outpatient, and residential modules.
5. **Program self-assessment.** Organizations must have and follow written policies and procedures that require written documentation of completed self-assessments of the organization’s capacity for providing integrated services to clients with co-occurring behavioral health conditions.

**G. Integrated residential model.** An integrated residential treatment program provides co-occurring treatment for clients with mental health and substance use disorder needs in a full-time (24 hours a day) residential setting.

1. The program must provide a scheduled treatment regimen which consists of diagnostic, educational, and counseling services to address co-occurring conditions and must refer clients to support services as needed.

2. In addition to meeting the standards for all residential programs stated in the core standards of this rule, integrated residential programs must meet the specific program standards below.

a. Integrated residential programs must develop a written program description that contains eligibility criteria, program goals and objectives, treatment modalities, treatment schedule and program length. Services include but are not limited to the following:

i. Evaluation of the client’s medical needs;

ii. Group, individual, and family counseling to address both mental health and substance use disorder needs as clinically recommended; and

iii. Daily didactic, educational presentations.

3. Integrated residential programs must ensure that staff providing care and treatment receive training in the interaction of co-occurring conditions.

**STATUTORY AUTHORITY AND HISTORY**

1. **STATUTORY AUTHORITY**

5 MRS §§20001-20007(A) and 20024

22 MRS §42 (1), (1-A)

22 MRS §§1501-1507

22 MRS §§7801-7807

22 MRS §§8001-8005

22-A MRS §205 (2)

34-B MRS §1203-A

34-B MRS § 3603

1. **History**
2. New Rule:

10-144 CMR Ch. 123, Rule for the Licensing of Behavioral Health Programs

(date)\_\_- filing 2022 - \_\_\_\_

1. Repeals and replaces:

14-118 CMR Ch. 5, Regulations for Licensing and Certifying of Substance Abuse Treatment Programs

February 29, 2008 - filing 2008-76

14-193 CMR Ch. 6, Mental Health Licensing Regulations

October 20, 1993 - filing ?

14-193 CMR Ch. 6-A, Mental Health Licensing Regulations – Private Non-Medical Institutions (PNMI)

June 201 [sic], 2005 – filing 2004-225

**APPENDIX A. MODULES AND SERVICES**

The Department, in drafting this rule, is aware that the language and terminology used to describe services for the treatment of mental health and substance use disorder varies between systems and is in a constant state of development as new treatment modalities emerge and are supported by evidence. The intent of this rule is to create standards that apply to current and potentially emerging services, within a flexible format that recognizes the variance in current practice.

The modules described in this rule reflect the current language and terminology used by the Division of Licensing and Certification. These services may be known by different but equivalent ‘terms of art’ in the Office of Behavioral Health, the Office of Aging and Developmental Services, and the MaineCare Benefits Manual. The Department reserves the right to categorize the services provided by applicants within the following framework:

**I. Mental Health:**

|  |  |  |
| --- | --- | --- |
| **Module:** | **Services** | **May also be known as:** |
| Community Support Services | Case managementCommunity rehabilitation servicesAssertive community treatmentRehabilitative and community support services for children with cognitive impairments and functional limitationsPsychosocial clubhouse servicesSkills development | Community integration services, day supports, intensive community integration, skills development, daily living skills, direct skill teaching, Section 28, day supports, or intensive community integration. |
| Crisis Services | Crisis intervention servicesCrisis telephone servicesMobile outreach  | Supportive counselingMobile crisis servicesCrisis walk-in services |
| Outpatient Services | Psychological assessment Outpatient therapyIntensive Outpatient ProgramFamily psychoeducational treatment | Outpatient counseling, geriatric psychiatric services, sex offender treatment, trauma recovery services, specialized group services, or medication management |
| Residential Services | Residential Treatment Facility: Group living residential facility Apartment model residential living facilityResidential treatment facility with secure capacityCrisis stabilization residential program | Private non-medical institution (PNMI), community residence for persons with mental illness, supportive housing, intensive in-home supports, supportive living, stabilization facility, crisis residential services, activities of daily living, medication management, medication self-administration, independent living skills, recovery, community inclusion and supports services, clinical treatment. |

**II. Substance Use Disorder:**

|  |  |  |
| --- | --- | --- |
| **Module:** | **Services** | **May also be known as:** |
| Community Support Services | Case managementIntensive case management | Community services |
| Outpatient Services | Outpatient Treatment Intensive outpatient program MOUD Opioid treatment program Withdrawal management program | Non-residential rehabilitation, intensive outpatient services, outpatient counseling, opioid supervised withdrawal and maintenance, Medication Assisted Treatment |
| Crisis Services | Intensive and structured treatment servicesClinical servicesEducational groupsScreeningBrief intervention and referral Scheduled or emergency servicesCounselingReferral for services | Crisis intervention services, crisis telephone services, crisis walk-in services, mobile outreach |
| Residential Services | Residential Treatment programDiagnostic servicesEducational servicesCounseling servicesProvision of medication for opioid use disordersMedically supervised withdrawal programs  | Residential rehabilitation facility, private non-medical institution (PNMI), drug and alcohol withdrawal management, social setting withdrawal management , drug and alcohol shelter, freestanding residential withdrawal management programs, substance use disorder treatment facility, residential rehabilitation type I or type II Detoxification programsResidential withdrawal management programResidential rehabilitation program for clients with their children  Category I (extended shelter or  residential rehabilitation) Category II (halfway house) Category III adolescent long-term rehabilitation or extended care program) |

**III. Integrated Services**

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| --- | --- | --- |
| Outpatient Services | Integrated Residential model  | Dual diagnosis residential |