SUMMARY OF PUBLIC COMMENTS AND DEPARTMENT'S RESPONSE & LIST OF CHANGES MADE TO THE FINAL RULE

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10-144 C.M.R. Ch. 123, BEHAVIORAL HEALTH ORGANIZATIONS LICENSING RULE
14-193 C.M.R. CH. 6, LICENSING MENTAL HEALTH FACILITIES (REPEAL)
14-193 C.M.R. CH. 6A, LICENSING MENTAL HEALTH FACILITIES: PNMI (REPEAL)
14-118 C.M.R. CH. 5, REGULATIONS FOR LICENSING AND CERTIFYING OF SUBSTANCE ABUSE TREATMENT PROGRAMS (REPEAL)

The Department of Health and Human Services, Division of Licensing and Certification (the Department) held a public hearing on September 29, 2023 on a new proposed rule 10-144 C.M.R. Ch. 123, Behavioral Health Organizations Licensing Rule. Written comments were accepted through October 13, 2023. Comments were received from the following people:

TABLE OF COMMENTERS

ID #	First Name	Last Name	Date	Representing	Format
1	Julie	Racine	9/16/23	Not given	Written
2	Cindy	Johnson	9/21/23	Not given	Written
3	Marie	Thomas	9/28/23	Not given	Written
4	Brent	Scobie	9/29/23	Acadia Hospital	Written
5	Kristy	Gelinas	9/29/23	Health Affiliates Maine	Oral
6	Brandi	Farrington	9/29/23	Kennebec Behavioral Health	Oral
7	Claudine	Chaput	9/29/23	Kennebec Behavioral Health	Oral
8	Al	Durgin	10/11/23	Spurwink	Written
9	Robert	White	10/12/23	Sweetser	Written
10	Meisha	Nickerson	10/13/23	Penobscot Community Health Care	Written
11	Dale	Hamilton	10/13/23	Community Health and Counseling Services	Written
12	Claudine	Chaput	10/13/23	Kennebec Behavioral Health	Written
13	Andrea	Conley	10/13/23	Health Affiliates Maine	Written
14	Suzanne	Farley	10/13/23	Wellspring	Written
15	Jonathan	Smith	10/13/23	United Cerebral Palsy of Maine	Written
16	Katie	Fullam Harris	10/13/23	MaineHealth	Written
17	Amber	Kruk	10/13/23	Crisis and Counseling Centers	Written
18	Victor	Dumais	10/13/23	Recovery Connections of Maine	Written
19	James	Cohen	10/13/23	Verrill Dana LLP	Written

Commenters #5 – 7 presented oral testimony, which was transcribed. For many comments, both written and oral, the Department chose to quote the entire comment or a portion of it.

The Department thanks each commenter for their review of the proposed rule and the comments submitted.

The Department's response follows each comment and explains whether any suggestions were followed by the Department. If the Department made no change in response to the comment, then an explanation of the reason(s) why no changes were made also is provided below.

The summary list of changes following these comments identify changes to the proposed rule resulting from either public comment or Assistant Attorney General review of the Rule for form and legality.

Commenter 1:

Comment 1: Are there no longer three categories of residential treatment for SUD? How will this effect reimbursement if these categories no longer exist?

Response: Residential service types are listed in the appendix section of the proposed rule. No changes were made to the adopted rule as a result of this comment.

Comment 2: Do mental health and SUD groups need to be facilitated by in-house employees qualified to do so or may the residential facility contract with an outpatient agency?

Response: The Department has added a definition for "personnel" to the adopted rule that includes independent contractors. The use of independent contractors is described in Section 14 of the adopted rule. The definition of "personnel" reads:

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."

Commenter 2:

Comment 3: Can you elaborate on the "structure of current provider network" and what it has to do with condensing licensing?

Response: This phrase does not appear in rule. No changes were made to the adopted rule as a result of this comment.

Commenter 3:

Comment 4: Section 2 B should be modified to say
(a) Once issued, a license shall not be assignable or transferable, and shall be immediately void if the program ceases to operate, relocates, or its ownership changes.
(b) Once issued, a license shall be granted for a period of one year (12 consecutive months), and shall be eligible for annual renewal on and up to 30 days following the license anniversary date (each renewal shall be dated back to the license anniversary date) upon submission of the appropriate licensing and inspection fees, providing the license has not been suspended or revoked by DHHS, and the program otherwise continues to be in compliance with all local rules, State rules and other requirements.
(c) Once issued, the license shall be conspicuously posted in the facility at all times."

Response: The Department interprets this comment to mean that the commenter is suggesting replacing the language in rule with this wording. The provisions of rule, as drafted, are consistent with standard licensing practice and statutory requirements. No changes were made to the adopted rule as a result of this comment.

Comment 5: Consideration should be given so that the levels of care for substance use are clear and in line with ASAM. By having one set of definitions that relate back to the ASAM levels of care it provides a solid foundation to ensure that all entities are talking about the same service, allows for more efficient services,

assessments, ability for MaineCare to reimburse, ability for OBH to contract and the ability for DLC to ensure compliance. The commenter provided proposed definitions for "halfway house," "long-term residential substance use disorder treatment facility" or "long-term residential facility," non-hospital-based (medical) detoxification/enhanced," "opioid treatment program (OTP)," and "outpatient substance use disorder treatment facility" that included references to ASAM level of care.

Response: Section 23(A)(1) of the adopted rule was amended to read "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, ~~such as~~ ~~those included~~ in accordance with the current edition of The ASAM Criteria: Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions; and

The Department added "3. An organization may develop other admission criteria only with written Department approval." to the adopted rule.

Comment 6: Consideration should be made for the composition of the governing authority that includes qualifications of members and officers, procedures for election or appointments to seats (including mid-term vacancies), terms of service; a written policy preventing nepotism by relatives and family members and preventing paid staff members from serving on the governing body; and a protocol to ensure that references and credentials of all prospective members are checked and verified, including written acceptance/exclusionary criteria to address individuals with past criminal convictions and/or ethical violations;

Response: Most of the proposed additional requirements are consistent with standards for employees, rather than Governing Authority members. There is a requirement for conflict of interest policy in Section 11(G), which the Department rephrased for clarity in response to this comment as follows:

Conflict of interest. The ~~governing authority is subject to~~ organization~~'s~~ must have in place a written conflict of interest policy applicable to the governing authority.

Comment 7: The rule should permit DLC to issue an order curtailing all new admissions and readmissions to a substance use disorder treatment facility including, but not limited to, the following circumstances:

1. Where violations of licensing regulations are found that have been determined to pose an immediate and serious threat of harm to clients of a substance use disorder treatment facility;
2. For the purpose of limiting the census of a facility if clients must be relocated upon closure, when DLC has issued a Notice of Proposed Revocation or Suspension of a substance use disorder treatment facility license;
3. Where the admission or readmission of new clients to a substance use disorder treatment facility would impair the facility's ability to correct serious or widespread violations of licensing regulations related to direct client care and cause a diminution of the quality of care; or
4. For exceeding the licensed or authorized bed or service capacity of a substance use disorder treatment facility, except in those instances where exceeding the licensed or authorized capacity was necessitated by emergency conditions and where immediate and satisfactory notice was provided to OOL.

The order for curtailment may be withdrawn upon finding that the facility has achieved substantial compliance with the applicable licensing regulations or Federal certification requirements and that there is no immediate and serious threat to client safety; or in the case of providers exceeding licensed capacity, has achieved a census equivalent to licensed and approved levels. Such order to lift a curtailment may

reasonably limit the number and priority of clients to be admitted by the facility in order to protect client safety. The facility shall be notified whether the order for curtailment has been withdrawn within 20 working days after the finding.

Response: The Department notes that Section 4(J) of the proposed rule allows the Department to direct an organization to stop all admissions as an intermediate sanction. No changes were made to the adopted rule as a result of this comment.

Commenter 4:

Comment 8: Regarding Sec. 8 Comprehensive Client Assessment item "C" (p. 25): This section appears to expand the previous standard requiring use of the ASAM level of care criteria with clients in substance use programs to now include all clients with a substance use diagnosis even if they are not in a substance use program. Regardless, the requirement is not clear in the second and third sentences (e.g. "all assessments of clients with a sub. use. diagnosis must include ASAM level of care: and "if the assessment is for integrated treatment the assessment must include both a DSM diagnosis and ASAM criteria."). Please clarify do all clients with substance use diagnosis need ASAM level of care criteria or only those in an integrated co-occurring program? Also, please clarify this standard so that we know what it means for an assessment to contain ASAM level of care criteria. Is the intention to identify in the assessment the appropriate ASAM level of care based upon the diagnosis and assessment? If so please be clear about this.

Response: The Department has reviewed this comment and has amended Section 8(C)(4) of the adopted rule to read:

"The comprehensive assessment must be signed, credentialed, and dated by the Clinician conducting the comprehensive assessment. 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 diagnosis(es) and the recommended ASAM level of care criteria."

Commenter 5:

Comment 9: Overall, I appreciate the movement towards one aligned licensing rule, so I want to state thanks and a gratitude for that.

Response: The Department thanks the commenter. No changes were made to the adopted rule as a result of this comment.

Comment 10: Overarchingly, there is a bit more stringent regulations that may align more with a higher level of care. For example, standards for a residential facility are also applied to outpatient therapy services such as the requirement of a nurse consultant, the medical director sign-off, and the 24-hour availability by phone.

Response: The Department has reviewed the comment and has made the following changes to the adopted rule:

Section 13(G) has been amended to read: Nurse consultant. An organization ~~providing, prescribing, or~~ administering medication must have a nurse consultant on staff or under contract.

Section 23(D)(2) was deleted from the proposed rule.

Section 12(I) was added to the proposed rule:

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.

Comment 11: For my organization specifically, we're an independent contractor agency, and so, in an affiliate model, there is a very brief section regarding these licensing rules that are specific to us, but that don't necessarily clarify some other elements in terms of personnel management, supervision, etc. So that makes it a little bit difficult because, in some respects, it forces our hand to treat independent contractors as employees in some ways and then as independent in others. And so that's been a bit of a struggle, and it would continue to be, with this new licensing rule in some respects.

Response: The independent contractor requirements in the proposed rule are designed to ensure that clients receiving services through independent contractors meet the same standards as clients who receive services through agency employees. No changes were made to the adopted rule as a result of this comment.

Comment 12: Please clarify what is required for independent contractor supervision. One section requires supervision depending on if staff have provided 20 hours or more or less than 20 hours of direct service. The independent contractor portion states that they just have to follow their professional licensing board. However, it also states that we have to have some measure of oversight of these providers, and to not provide supervision to them in any way doesn't really give us an opportunity to do that as an agency because someone who's independently licensed requires no supervision at all.

Response: The Department has reviewed the comment and has decided to amend Section 14(D)(6) of the adopted rule to read "A written account of the amount of clinical supervision or consultation ~~required by the independent contractor's professional licensing authority~~ provided by the organization.

Comment 13: It is a tremendous administrative task to maintain a wait list in the Acentra system, and for the hundreds of referrals that we receive on a regular basis for our over 300-plus affiliate population, we simply wouldn't have the personnel, staffing, or resource to be able to accomplish that. Other outpatient facilities will likely struggle with this as well. It is already a struggle to maintain the case management wait lists.

Response: The Department finds that this requirement is necessary for the Department to assess treatment needs and capacity throughout the state. No changes were made to the adopted rule in response to this comment.

Comment 14: There's a mention of private residence not being allowable to provide services. During COVID many providers went to providing telehealth from their home environments, which resulted in a tremendous uptick in affiliates. Not allowing this practice to continue would negatively impact clients. Please consider a revision.

Response: The Department has reviewed this comment and has clarified the definition of "site" at Section 1(A)(89) of the adopted rule to add "A location from which telehealth services are delivered is not a site."

Comment 15: An overarching request is to align the licensing rules with MaineCare regulations. For example, in the current MaineCare regulations, in terms of ISP due dates for mental health services, it's 12 sessions, or annually, and for substance use, it's every 90 days. That makes it a real challenge. So if MaineCare were to do an audit versus licensing, it is difficult for us to indicate to our providers what exactly they would be doing when it comes to, for example, co-occurring services, or even one or the other. Please consider alignment or standardization in the future.

Response: The proposed rule was reviewed by OMS and included their suggestions and input. No changes were made to the adopted rule as a result of this comment.

Comment 16: There's mention of moving towards the severe and persistent mental illness discharge process for all clients. Again, much like the wait list, this would cause a tremendous administrative burden to organizations, and also, to have to ask for permission and await those 30 days presents as a liability to a provider to maintain an open case for someone who's not actively involved in treatment, were they to, for example, complete suicide on their watch.

Response: The Department has reviewed this comment and has decided to delete all of Section 7(F) from the adopted rule.

Comment 17: For the severe and persistent mental illness discharge process, it will be a significant administrative burden for providers to request that through the Acentra portal who could otherwise be providing further care for additional clients.

Response: The Department has reviewed this comment and has decided to delete all of Section 7(F) from the adopted rule, as noted above.

Comment 18: There is a new site fee for each site that's providing service. Obviously, with a situation of having 300 affiliates across the entire state of Maine, that fee would be a bit of a financial burden if it was to be defined as every affiliate location and not simply the organization's originating site or satellite site.

Response: The Department has reviewed this comment and interprets “affiliate sites” to mean either independent contractors or individually licensed practitioners, which do not fall under the definition of site. No changes were made to the adopted rule as a result of this comment.

Comment 19: Further clarification between the intervention plan and crisis plan would be helpful. In addition, defining frequency of visiting the emergency room would help to give structure to when this would need to be implemented for clients on behalf of providers.

Response: The Department has reviewed this comment and had made the following changes to the adopted rule in response:

Section 1 (A)(46), the definition of “intervention plan” has been deleted from the proposed rule.

Section 9(J) has been deleted from the rule.

The following was added to Section 9(I)(6)): "v. A strategy to prevent frequent unnecessary client utilization of emergency services, including emergency room, police, and ambulance services, when such a pattern is known."

Comment 20: The rule indicates that the initial ISP is due after the assessment, but it doesn't quantify that, and then it discusses 90-day reviews thereafter. It would be helpful to have a greater definition for that so that our policies and standards would align.

Response: The Department has reviewed this comment and has revised Section 8(C) of the adopted rule to read: The organization must complete a comprehensive assessment of each client within 30 days of admission to determine the need for treatment and services.

Comment 21: There's a requirement that an agency assess an independent practitioner's financial readiness. Further definition would be helpful. But it feels a little bit like an overreach for an agency to be asking an independent practitioner for their budget or safety net financially. It feels a bit personal and when you're independently practicing, that's up to you and your business to be able to manage and address.

Response: The Department has reviewed this comment and has decided to delete provision 14(B)(1) from the adopted rule.

Comment 22: Requiring the agencies to provide a budget and financial audit feels a little bit more like an overreach in terms of agencies providing that level of information.

Response: The Department has reviewed this comment and has made the following changes to the adopted rule:

Section 2(E)(9) was deleted from the rule: ~~An annual budget showing anticipated expenses and revenues and the source of those revenues;~~

Section 11(F)(4) was deleted from the rule: ~~Reviewing and approving the organization's annual budget;~~

Section 18(C) was deleted from the rule:

~~**C. Budget.** The organization must develop a formal, annualized line-item budget approved by the governing authority, indicating revenues and expenses for the current fiscal year.~~
~~1. Revisions to the budget must be clearly documented; and~~
~~2. The organization must document budget reviews and the date of approval of the budget by the governing authority.~~

Comment 23: The newer critical incident reporting categories seem to present an agency with a potential for a breach of HIPAA. For example, the duty to warn of a death if a client dies of a heart attack. It doesn't seem necessary for the State to have this information. We've actually been in contact with our agency lawyer on this, but have not received a response yet.

Response: The Department has reviewed this comment and finds that the content of critical incident report is beyond the scope of this rule. OBH creates the critical incident report form and is responsible for the content. No changes were made to the adopted rule as a result of this comment.

Comment 24: Discharging a client based on symptoms of a co-occurring condition or disorder is prohibited. But if a client had a provider who could not treat a co-occurring disorder under the provider's scope of practice, it would be appropriate to refer the patient elsewhere. Please clarify under what circumstances this type of referral would be allowable because, if it is out of scope, ethically that provider should provide a referral to an appropriate provider that could provide that service.

Response: The Department has reviewed this comment and has revised Section 10 (C)(1) to read:
1. The organization may not discharge a client solely because of a substance use relapse, or symptoms of a co-occurring condition or disorder <u>unless the program, as fundamentally designed, cannot meet the client's needs.</u>

Comment 25: If a client needs a higher level of care but refuses it and wants to remain with the current provider, this creates an ethical dilemma and a struggle for a clinician who may know their client needs an IOP, for example, or hospital- level care, not being able to indicate to them that this is really the care that they need, providing appropriate referral, and discussing that with the client.

Response: The final rule does not require an organization to discharge a client involuntarily if the client qualifies for higher level of care. The rule permits a provider to make a referral to a higher level of care if the client qualifies for a higher level of care. No changes were made to the adopted rule as a result of this comment.

Comment 26: The access to service portion requires some accommodations for clients, including tactile alarms. Unlike sign language services, tactile alarms don't feel like a reasonable accommodation.

Response: These requirements help ensure access to services in a safe setting for individuals with disabilities. No changes were made to the adopted rule as a result of this comment.

Comment 27: The comprehensive assessment must include "sexual health" but it is unclear whether this refers to reproductive orientation or something else. A further definition would be helpful. .

Response: The Department has amended the adopted rule at Section 8(C)(1)(c) to read: "Medical domain, including but not limited to physical~~/sexual~~ health, current medications, and physical and environmental barriers to treatment"

Comment 28: There is no mention regarding verbal consent, although this has come into play quite a bit, both on a federal and state level, particularly with COVID.

Response: The rule does not prohibit verbal consent. No changes were made to the adopted rule as a result of this comment.

Comment 29: In previous licensing rules, there was a provision identifying the requirements for clinical staff in an SUD program, including 60 hours of alcohol and drug education. The provision was not carried over and it may result in some providers being unable to continue providing services.

Response: The Department has clarified the requirements for clinical staff by inserting the existing requirements from 14-118 CMR Ch. 5 Regulations for Licensing and Certifying of Substance Abuse Treatment Programs as Section 13(J): Staff Credentials, as follows:

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):
   a. Registered Nurse certified as a Psychiatric Nurse,
   b. Advanced Practice Registered Nurse (APRN) with appropriate specialization certification,
   c. Medical Doctor (M.D.),
   d. Doctor of Osteopathy (D.O.),
   e. Licensed Clinical Psychologist,
   f. Licensed Clinical Social Worker (LCSW),
   g. Licensed Clinical Professional Counselor (LCPC), or a
   h. 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.

Comment 30: Clinical staff should include those with a CCS and a mental health license given the experience required by the professional licensing board to hold that license. This also would expand the providers able to offer that treatment.

Response: The Department has reviewed this comment and has added Certified Clinical Supervisor as a qualifying credential as noted in Comment 29 above.

Commenter 6:

Comment 31: Please address how the Department will apply deemed status if the accreditation period is three years but license renewal is every two years.

Response: The term of a licensing cycle is determined by statutes and does not change based on deemed status. No changes were made to the adopted rule as a result of this comment.

Comment 32: How do the assisted housing regulations in chapter 113 impact this rule? Will this rule allow for waiver opportunities for things like the food portion for PNMIs that are supportive apartments as opposed to group home settings, where meals may occur sort of a couple of times a week, but not routinely?

Response: The Department finds that revisions to10-144 CMR Ch. 113 fall outside of the scope of this rulemaking but notes that mental health PNMI settings fall under the scope of this rule and not under chapter 113. The Department also finds that the waiver process is addressed in this rule. No changes were made to the adopted rule as a result of this comment.

Comment 33: Programs such as community rehab services often supervise medication self-administration but do not necessarily have a medical director to make a determination about self-administration.

Response: The Department has reviewed this comment and has decided to revise Section 15(E)(2) to read:

2. ~~If the medical director determines that the client needs supervision in the administration of medication, the medical director must document this finding in the medical orders.~~ 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.

Commenter 7:

Comment 34: The commenter supports adding deemed status to the licensing regulations, stating, "This is something that we . . . have been looking for for some time, so I am definitely in favor of that."

Response: The Department thanks the commenter. No changes were made to the adopted rule as a result of this comment.

Commenter 8:

Comment 35: The commenter commends the Department on the rulemaking and appreciates the inclusion of deemed status. However, the rules seem to have overlooked that many of Maine's children are served by these rules. OBH is mentioned fourteen times in the rule but OCFS and/or CBHS are not mentioned at all, and there is no process for reporting reportable events to OCFS. Please correct this oversight.

Response: The Department reviewed this comment and notes that OCFS reviewed the proposed rule. Applicable OCFS policies will continue to apply to organizations licensed under this rule. The Department addressed the specific requests for inclusion of or reference to OCFS in the comments below.

Comments on Section 1. Definitions

Comment 36: 11. Case management services specified Targeted Case Management Service. It is not clear whether Behavioral Health Homes and/or Opioid Health Homes also fall within the definition of case management services.

Response: Behavioral Health and Opioid Health Homes are MaineCare-specific services and are not terms specifically incorporated in this rule. No changes were made to the adopted rule as a result of this comment.

Comment 37: 26. Critical incident defines such events according to OBS's definition. Does this definition apply to children?

Response: Critical Incidents referenced in this rule relates to adult clients. No changes were made to the adopted rule in response to this comment.

Comment 38: 42. Infectious disease does not make mention of airborne transmission of disease.

Response: This definition was developed in consultation with the Maine Center for Disease Control. No changes were made to the adopted rule in response to this comment.

Comment 39: 46. Intervention plan does not clarify how this plan is different from a crisis plan. This is not clear elsewhere in these rules where this term is mentioned.

Response: The Department has made changes to the adopted rule to address this concern. Please see the response to Comment 19.

Comment 40: 50. Licensed practitioner specifies that the individual be licensed in the state of Maine. In the aftermath of the recent pandemic, efforts are underway to create consent decrees to allow certain professions to practice in states where their license is recognized but not issued. We suggest more open language to accommodate that future. "…currently allowed by license to practice in the State of Maine."

Response: The Department has reviewed this comment and has revised Section 1(A)(50) to read:

Licensed practitioner means a physician, physician's assistant, or nurse practitioner currently allowed by license to practice in the ~~an individual currently licensed in the~~ State of Maine ~~as a physician, physician's assistant, or nurse practitioner~~.

Comment 41: 52. Medical Director is defined as an MD or DO. Unless federal law requires otherwise, we would suggest that a psychiatric nurse practitioner be qualified under these rules to serve as a medical director.

Response: The Department has reviewed this comment and has revised Section 1(A)(52) to read:

Medical director means a licensed practitioner ~~physician (Medical Doctor or Doctor of Osteopathy)~~ 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~~ies~~ out the minimum requirements set forth in this rule.

Comments on Section 2. Licensing and Certification Requirements

Comment 42: A.4. Related to submission of letters of notice. Again, the requirement to submit LONs to OMS and OBH seems inconsistent with the Department's structure if an organization intends to serve children under these rules through school-based outpatient therapy, targeted case management, children's behavioral health day treatment, FFT, MST, med management or other services.

Response: The Department has reviewed this comment and has amended Section 2(E)(13) to read: "A copy of letters of notice from the applicant to the Office of MaineCare Services, ~~and to~~ 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." The Department also added a reference to Section 2(A)(4).

Comment 43: I.3 (also Section 4. I.1) Capacity is an antiquated concept in the world of outpatient and community-based services and should only be required in these rules for services whose "capacity" is limited by seats, offices, or beds. It is not practical or reasonable to set a capacity for outpatient therapy, for example. In a world in which a significant amount of that service is provided by telehealth, it is not possible to estimate the maximum number of individuals to be served. The same is true of targeted case management and behavioral health homes. Setting an artificial capacity cap for these services is a

disservice to individuals waiting for services and organizations prepared to expand services. Requiring an updated licensing action to add a therapist or a med manager or a case manager creates administrative burden and delays in service while serving no beneficial function.

Response: The Department has reviewed this comment and has amended the following sections as shown:

Section 2(I)(3) to read: The organization may not increase ~~client or~~ residential capacity or begin new construction, additions, or alternations to a licensed facility or site without the Department's prior approval in consultation with the State Fire Marshal's Office

Section 4(I)(1) to read: Operation of a residential ~~behavioral health organization or~~ program~~(s)~~ of the organization over the licensed capacity

Section 2(E)(8) to read: A description of the location, capacity, and a sketch of the floor plan with bedroom space identified for each residential program

Comments on Section 4. Enforcement and Inspections

Comment 44: With regard to this section as a whole, there is no provision for licensing action to be applied to a subsection of an organization's services or facilities. I appreciate that the department has issued these rules to cover numerous services and facilities under the same license, and I do not have a specific alternative to propose. However, a number of organizations within the state operate an array of services across facilities and including several residential facilities. It seems that these rules ought to have a mechanism for issuing a temporary or partial license to portions of an organization that are in good standing while deficiencies in another segment of the organization are addressed.

Response: There is flexibility in the enforcement section of rule to address specific sites, services and modules through the use of intermediate sanctions. No changes were made to the adopted rule as a result of this comment.

Comment 45: D. Informal conference. The rules permit a request for a courtesy informal conference but do not provide details of how that request is to be made.

Response: The details in Section 4(D)(1) are clear on how to request a courtesy informal conference. No changes were made to the adopted rule as a result of this comment.

Comment 46: D.3 and 4. These seem inconsistent and overly rigid. A courtesy informal conference should be an opportunity for inquiry and understanding. Prescribing the evidence allowable and the terms of disputation is for formal hearings, not informal conferences.

Response: The standards are consistent with rule provisions governing informal conferences in other licensed settings and help licensees identify circumstances when an informal conference may be useful. No changes were made to the adopted rule as a result of this comment.

Comment 47: D.12. Again, the section of the rule makes requesting a courtesy informal conference an undesirable action. I don't think that is what the Department intends. If an organization cannot request such a conference and still preserve the right to appeal, then the intermediate step of requesting a conference rather than appealing seems unwise.

Response: Section (D)(12) states that neither a decision to grant or deny an informal conference nor the outcome of the informal conference is subject to appeal. It does not affect rights of appeal otherwise granted by law. No changes were made to the adopted rule as a result of this comment.

Comments on Section 6. Client Rights

Comment 48: C. This paragraph ends with the requirement that, "Any exception, restriction, or limitation of client rights must be documented in the client's record and, *if applicable, signed by the client's physician.* We would request that the department clarify when this is applicable.

Response: The Department has reviewed this comment and has amended Section(6)(C) to remove the following phrase: Any exception, restriction, or limitation of client rights must be documented in the client's record. ~~and, if applicable, signed by the client's physician.~~

Comment 49: F. Of course, we have no objection to the right articulated here. We do note that the prescription for reporting is applicable to service recipients who are adults.

Response: Section 6(F)(2) was amended to read: Critical Incident Reporting forms alleging abuse, neglect, or exploitation of an adult client must be sent to DLC and OBH. The Critical Incident Reporting forms are an OBH document and are not in use by OCFS.

Comment 50: K.1. With regard to reviewing and copying the medical records, is it the Department's intention that this right be actionable by children or only by their parent or guardian?

Response: The Department has reviewed this comment and has amended Section 6(K) to read:

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 legal representative consent pursuant to state and federal law.

Comments on Section 7. Eligibility and Access to Services

Comment 51: F. Notice of denial and referral. The process described here is not consistent with how the Department has managed services for children.

Response: The Department has reviewed this comment and has deleted Section 7(F) from the adopted rule. See Comment 16.

Comments on Section 8. Comprehensive Client Assessment

Comment 52: A. Client Assessment. We suggest adding the modifier "comprehensive" for the sake of clarity.

Response: The Department has reviewed this comment and amended Section 8(A) to read: Comprehensive client assessment.

Comment 53: C.4. As written, this seems to require that a "clinician" complete all comprehensive assessments. For targeted case management and care coordinators under Behavioral Health Homes (and perhaps other coordinating or community-based services) this requirement seems unnecessary. We suggest an exception for case management type services provided under these rules.

Response: The Department has reviewed this comment and has amended Section 8(C)(4) to refer to the "person" signing the comprehensive assessment and to include the sentence: "If the assessment conclusion contains a diagnosis, it must be signed by a clinician."

Comments on Section 9. Client Service Plan

Comment 54: Section 9(C). Service plan team. We suggest clarifying that a representative of the providing organization must be part of the service plan team.

Response: The Department has reviewed this comment and has amended Section 9(C) to read: Service plan team. The service plan team must include the client, the client's guardian or legal representative, clinical consultants, representative(s) of the organization providing services, and other persons chosen by the client, as appropriate.

Comment 55: Section 9(G). Time frame. We request that the Department clarify what it intends by the phrase, "program-specific standards". Do such standards exist for all services delivered under these rules? If not, how is the time frame determined?

Response: The Department has reviewed this comment and find that the rule is clear in describing "program-specific standards" as Chapters 22-24 of the adopted rule. No changes were made in response to this comment.

Comment 56: Section 9(I). Service plan. We would observe that the details required in this service plan significantly exceeds any treatment plan one would get at a Primary Care Provider for episodic or chronic treatment of any condition or illness. Behavioral health conditions should not be subject to disparate treatment plan requirements. Service plans of the complexity prescribed in these rules, with methods and frequencies, multilayered goals and objectives, indicators and timeframes are unnecessary and discriminatory. We encourage the Department to prescribe a significantly simpler structure for the service plan.

Response: The requirements in the proposed rule are a consolidation of what is in existing rules in force. The Department made various changes to the content of the service plan, however, in response to specific comments. See, for example, comments 57, 58, 59, 181, 182, and 187. No further changes were made to the adopted rule as a result of this comment.

Comment 57: I.a. We respectfully note that the findings of the comprehensive assessment should inform the service plan, but there is no reason for the findings of the comprehensive assessment to be included in the service plan.

Response: The Department has reviewed this comment and has deleted Section 9(I)(2)(a) of the proposed rule from the adopted rule and renumbered the remained items accordingly.

Comment 58: I.i. We respectfully suggest that the written crisis plan should be separate from the service plan and its own section in these rules.

Response: The Department has reviewed this comment and has relocated the provisions at Section (9)(I)(2)(i) from the proposed rule to a new Section 9(I). (See also the response to Comment 19.)

Comment 59: I.j. Likewise, we suggest that the behavioral support plan be a separate document and a separate section here.

Response: The Department has reviewed this comment and relocated the requirement for a behavioral support plan from Section (9)(I)(2)(j) to Section 9(I)(5) of the adopted rule.

Comment 60: I.o. These rules should not require a signature as a means of consent or authorization on a treatment plan. The Office of MaineCare Services, following federal initiatives, is permitting verbal consents for services. We believe that the term verbal consent should be specifically used in these rules and should be available unconditionally.

Response: The Department reviewed this and other similar comments and revised what was formerly Section 9(1)(2)(o) (now Section 9(H)(2)(k)) as set forth in the response to Comment 187.

Comment 61: J. Intervention plan. As noted in the definition section above, we do not know what the Department intends an intervention plan to do. Why is it not part of the service plan? Or, the crisis plan? Why is it subject to review every 90 days?

Response: See the response to Comment 19. The Department has deleted this section from the adopted rule.

Comment 62: L.1. Periodic review. Again, we would ask what the Department means by "program-specific standards". For example, how does one determine the frequency of review for medication management.

Response: The Department finds that it has previously addressed this concern in this summary. See Comment 55 above.

Comments on Section 10. Discharge Process

Comment 63: A.4. Discharge policy. We believe that HIPAA and other privacy provisions would permit notification to other parties in this circumstance without consent. This is based on the "coordination of care" principle.

Response: The Department has reviewed this comment and has modified Section 10(A)4) to read:
The requirement to obtain the client's ~~permission~~ 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. The adopted rule requires that the organization have a policy that includes obtaining client consent to notify other parties.

Comment 64: B. Voluntary Discharge. It is unclear how this provision would apply to adolescents and children. We suggest clarification on this point.

Response: The Department has reviewed this comment and has deleted Section 10 (B) from the final rule.

Comment 65: D. This is specific to adults covered under these rules. Is there a provision for children?

Response: The Department has reviewed this comment and has inserted the phrase "or their legal representative" in Sections 10 (C) and (D) of the adopted rule.

Comments on Section 11. Governing Authority

Comment 66: D.3. We believe that this is unnecessarily restrictive. It is certainly appropriate that board members routinely disclose these relationships, but it is not appropriate to prohibit their existence. If an individual at the organization's bank or property management company is interested in the work of the organization, they should be permitted to serve on the board. Organizations are made stronger by recruiting these kinds of experts to their governing boards.

Response: The Department has reviewed this comment and has amended Section 11(D) of the adopted rule to read:

D. 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;
   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 an 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.~~; and~~

~~3. For an advisory board, any individual with a proprietary interest in the organization.~~

Comment 67: F.11. We believe the requirement for notification in two days to be too restrictive. This is insufficient time for the organization to process the situation for itself and determine whether any notification meets these requirements. We suggest 7 days as an alternative.

Response: The Department has reviewed this comment and determined that two days is a reasonable timeframe, given the Department's responsibility to intervene in these types of situations. No changes were made to the adopted rule in response to this comment.

Comment 68: E.3.b. We recommend a change in language (see comment in definitions). "…currently allowed by license to practice in the State of Maine."

Response: The Department has reviewed this comment and has amended Section 12 (E)(3)(b) to read: The organization must confirm that the distant site practitioner is currently allowed by license~~d~~ to practice in Maine, consistent with the appropriate rule of the Department of Professional and Financial Regulation.

Comment 69: F.1.b. It is unclear to us why this provision is in the rules. Generally speaking, criminal behavior, excluding abuse and neglect, is protected under rules of confidentiality for a recipient of behavioral health care.

Response: The Department reviewed this and similar comments, and revised Section 12(F)(1)(b) as described in the response to Comment 106.

Comments on Section 13. Personnel

Comment 70: D. Job descriptions. We find the requirement for an annual review of job descriptions to be overly prescriptive. In our opinion, organizations should determine themselves the frequency of this administrative task. If the Department believes it must prescribe a timeframe, we suggest "every 4 years".

Response: The review of job descriptions is part of the performance evaluation process, which is required annually. No changes were made to the adopted rule as a result of this comment.

Comments on Section 14. Independent Contractors

Comment 71: C.6. Related to records. There is an assumption here and elsewhere in these rules of paper records. This is no longer the norm for organizations operating under these rules. We recommend that the Department assume that electronic health records are the default.

Response: This provision of rule is not specific to paper records. No changes were made to the adopted rule as a result of this comment.

Comment 72: E. Quality Improvement review. We agree that the organization has some responsibility for the quality of work performed by the contractor. However, we believe that contractors assume responsibility for the improvement in the quality of work performed. We suggest "quality review" in place of "quality improvement review".

Response: Services delivered through an organization are the responsibility of the organization. This requirement exists to ensure that services through independent contractors meet the same standards as services delivered by employees. No changes were made to the adopted rule as a result of this comment.

Comments on Section 15. Medication Administration

Comment 73: In general, some clarification on where this section applies would be helpful. For example, an organization may offer medication administration in a specific facility or space under this license, but not in other services. Using the broad term "organization" makes it unclear if providing medication management services in one domain binds the details of this rule to the whole organization.

Response: The Department finds the rule is clear when it states in Section 15 (A) 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 be specific to the setting and/or service in which medications are administered…" No changes were made to the adopted rule as a result of this comment.

Comments on Section 16. Record Management and Retention

Comment 74: There remains an underlying assumption of paper records in this section of rule. We suggest that the Department reconceive this section based on the assumption of electronic records. For example, the rules should require electronic date stamping of all entries in the record (an integrated function in most EHRs) rather than prohibiting back-dating and requiring provisions for late entries. For the benefit of clients, these rules should prescribe some level of security for records maintained in an EHR.

Response: The Department finds that "record" is defined to include written and electronic documentation. Upon review of this comment, the Department has amended Section 16(D)(2) to add e: Organizations utilizing electronic health records must use electronic date stamps for all entries in the record.

Comments on Section 19. Risk Management

Comment 75: D. Quarterly review. We suggest adding confidentiality or privacy breaches to this list.

Response: The Department has reviewed this comment and had amended Section 19(D) to include 7. Any confidentiality or privacy breaches.

Comment 76: D.2. It is not clear why risk management is applied to the seclusion and restraint of adults but not children.

Response: The Department has reviewed the comment and has amended Section 19(D)(2) to read: 2 The use of restrictive behavior management interventions, such as seclusion and restraint ~~as it relates to adult services~~;

Comments on Section 21. Standards for All Residential Programs

Comment 77: We appreciate the incorporation of this set of standards in these rules. One overarching observation is that the terms program and facility recur throughout this section. It is not clear whether the Department has the same entity in view for both terms or whether these are different entities. Some clarification would be helpful.

Response: Both of these terms are defined in the proposed rule. 'Facility' refers to the physical building and 'program' refers to the services provided within that facility. No changes were made to the adopted rule in response to this comment.

Comment 78: H.5.b. IPC training. Is it the Department's intent that every employee be observed using IPC? Who is to observe and under what circumstances?

Response: These provisions were developed in consultation with the Maine CDC and mirror existing provisions for other provider types. No changes were made to the adopted rule in response to this comment.

Comments on Section 22. Mental Health Programs

Comment 79: B. Waiting list. It is not clear why the Department wishes that providers licensed under these rules maintain waiting lists. Under current circumstances, these lists are a significant administrative burden. They are difficult to maintain and are often so long as to be essentially meaningless. Does the Department

compel an organization to maintain a waiting list for a service for which it is not currently accepting referrals?

Response: This requirement is necessary in order for the Department to assess treatment needs and capacity throughout the state. No changes were made to the adopted rule in response to this comment.

Comment 80: E. Crisis services module. Is it the Department's intent to lump programs previously referred to as "emergency services" into this module called "crisis services"? There is no reference to "emergency services" in this rule.

Response: The commenter is correctly identifying that what was termed "emergency services" in the former rule now falls under crisis services. No changes were made to the adopted rule in response to this comment.

Comment 81: E.2.d. We suggest some definition for the term "follow-up".

Response: The Department has reviewed this comment and has amended Section 22(E)(2) to delete provision 22(E)(2)(d) from the adopted rule.

Comment 82: E.4. We find some ambiguity in the description of qualified staff. For example, what does the Department intend by the term "independently licensed". We believe that conditionally licensed social workers or clinical counselors should be qualified to complete crisis assessments. We also believe that registered nurses and nurse practitioners should be qualified to complete crisis assessment though they are not generally considered mental health professionals. We would suggest this rule be clarified and the above be qualified to complete this assessment.

Response: Experience in mental health or crisis services are not prerequisites for licensure as an RN or NP; therefore, these licensees would not necessarily have the expertise to complete crisis assessment. The Department has amended 22(E)(4) to read: Crisis assessments must be completed by appropriately qualified staff, including a mental health rehabilitation technician/crisis service provider (MHRT/CSP), or ~~an independently~~ licensed or certified mental health professional practicing within the scope of his or her license.

Comment 83: E.6. Crisis assessments must be completed with the information immediately available. The degree to which any of the components covered here are subject to that availability. We understand the Department's intent, but as written, this level of detail is often not available or necessary for the purpose of a crisis assessment. We suggest simplification and some allowance in the rules for times when all of these details cannot be ascertained.

Response: The Department has reviewed this comment and has amended Section 22(E)(6) to add i. The written crisis assessment must note when any of the above information is not immediately available.

Comment 84: E.12. We observe that there really is no way to facilitate involuntary hospitalization under present circumstances. This is a rule which cannot be complied with.

Response: The Department has reviewed this comment and has revised Section 22 (E)(12) to read "The organization must have written policies and procedures for ~~facilitating~~ initiating or recommending the involuntary hospitalization process.

Comment 85: F.3.b. We observe that the requirements here are better suited for definition in MaineCare rules than in licensing rules.

Response: Many provisions were included in this rule to apply as minimum standards for clients who are not MaineCare beneficiaries. No changes were made to the adopted rule as a result of this comment.

Comment 86: G.1.c.i. Clinical treatment services. This requirement could be enhanced with more specificity. What does the Department intend these clinical treatment services should entail?

Response: The Department has reviewed this comment and amended Section 22 (G)(1)(c)(i) to read:
i. Services include clinical review and completion of a service plan which includes goals related to support and rehabilitation. ~~treatment services~~.

Comment 87: G.1.c.iii & iv. We suggest changing this time frame to 30 days. With very few exceptions, licensing and MaineCare requirements are for 30 day. The requirement of 20 business days is essentially the same thing, but harder to quantify given weekends and holidays. Pragmatically, it is easy to set workflows in electronic health records for 30 calendar days, but almost impossible to set up for 20 business days.

Response: The Department has reviewed this comment and has revised Sections 22 (G)(1)(c)(iii and iv) in the adopted rule to read:

i. Within 72 hours of admission, the organization must develop an initial service plan and within 30 calendar ~~20 business~~ days of admission, the organization must develop a comprehensive service plan for each client.
ii. Within 30 calendar ~~20 business~~ days of admission, an assessment must be completed to determine the level of care needed by the client.

Comments on Section 23. Substance Use Disorder Treatment Programs

Comment 88: We appreciate the Department's effort to pull rules related to Mental Health and Substance Use Disorders Treatment together. However, additional integration would be helpful. For example, some of the requirements articulated here could be incorporated into general rules related to all residential facilities. Grievance procedures, waiting lists, policies about infection disease control, crisis services are all covered elsewhere in these rules with slightly different frames and details. These should all be aligned into an integrated set of rules. As another example, this section ascribes to the medical director the responsibility for policies about medication and med administration and policies about infectious disease. Elsewhere in the rules these responsibilities are not assigned to a medical director and there doesn't seem to be a good reason to do so here.

Response: The Department has reviewed this comment and determined that some provisions were separated due to statutory or other rule requirements as well as differences in medical focus between Mental Health and Substance Use Disorder treatment. No changes were made to the adopted rule as a result of this comment.

Comment 89: 23.G.5.h. We respectfully suggest that service plans described here do not require approval, by signature or otherwise, of the medical director. We also suggest that verbal consent should be considered as a legitimate alternative to a signature for the client.

Response: The Department has reviewed this comment and notes that the medical director's signature is carried over from the prior rule in force. The Department has also determined Clients are seen in-person and should be available for signature for initial treatment. No changes were made to the adopted rule as a result of this comment.

Comments on Appendix A. Modules and Services

Comment 90: While we appreciate the work that would be involved in aligning the "terms of art" between these rules, the MaineCare Benefit Manual, and the various Offices of the Department, we respectfully ask that the Department undertake this work. In these rules and in the frameworks described in Appendix A, it is not always clear what services should be slotted where. This leaves confusion about what services are covered by these rules and, if they are covered, by what portion of the rules.

Response: Several offices within the Department reviewed this rule and aligned the content with other rules to the extent possible. No changes were made to the adopted rule as a result of this comment.

Commenter #9:

Comment 91: Additional time should be allowed for providers to review and offer comments on the proposed rule. The Division of Licensing and Certification has acknowledged that it required an extended period of time to review the Mental Health, Mental Health PNMI and Substance Abuse agency licensing rules and to draft a proposed consolidated licensing rule. The result is a 79 page, densely written consolidated rule which includes extensive detail on many areas. Providers have many competing priorities and demands on their time and resources, such as quadrennial accreditation renewal reviews with the Council On Accreditation, an immense demand on organizational resources. One month does not suffice thoroughly to review a proposed rule of this length, detail and complexity and to offer thoughtful and complete comments on it.

Response: The Department appreciates the demands on providers time, but did receive extensive and thoughtful comments on the proposed rulemaking during the comment period, which followed the rulemaking procedures outlined in MRS 5 Ch 375, Maine Administrative Procedure Act. No changes were made to the adopted rule as a result of this comment.

Comment 92: A thoroughgoing review and revision of the proposed rule should be undertaken in order to reduce the unnecessary length and excessive details of the rule. Licensing rules should set out a reasonable floor of basic provisions necessary to ensure that agencies provide services in a safe and healthful manner. Beyond that floor, agencies should be allowed flexibility to operate as they may find best suited to provide services and meet needs of their clients. The extent of detailed prescriptiveness in the proposed rule is unnecessary and inappropriate. It is noted, for example, that there are six single-spaced pages of directives set out on medication administration alone and another six pages on crisis services. Sweetser is not aware that any apparent threat to public health or safety has occurred under the licensing rules now in place that would warrant this level of micromanagement. Excessively prescriptive rules require undue expenditure of time and resources by providers as they endeavor to comply, can result in unneeded expenditure of effort on the part of the licensing staff to review compliance with all points of detail and may impede progress as providers are constrained to follow the prescribed operations while accepted health care practices may change. The amount of detail and level of generalization throughout should be much closer to those in the present rules.

Response: The Department has reviewed this comment in the context of its familiarity with patterns of non-compliance, negative outcomes for service recipients, and the role of rule in assuring health and safety for Maine citizens across all licensed entities. No changes were made to the adopted rule as a result of this comment.

Comments on Particular Sections

Comment 93: Rule Section(s): Part I, Section 1.A.29

The applicable Maine statutes mandate that an accredited agency must be deemed to be in compliance with "comparable state licensing rules." There is no requirement of being identical or almost identical and no limitation of the deemed status to specific provisions in the rules. The proposed rule appears intended to limit the scope of deemed status drastically. This is especially so in the context of an excessively lengthy and detailed proposed licensing rule. It is doubtful that any accrediting organization's standards would be identical or even almost identical to most or all of the detailed provisions in the proposed rule. The comparability standard in the Maine statutes must be retained as well as the apparent intent in the statutes that comparability be construed broadly in order to extend meaningful deemed status to licensed agencies.

Response: The Department has reviewed this comment. The commenter has identified the core issue by identifying the word "comparable" in statute. The Department has amended Section 1(29), Section 2(M)(2), and Section 2(M)(4) to include reference to standards serving an "equivalent purpose" to licensing rule provisions. The Department is, however, also responsible for ensuring that a licensee complies with elements of this rule that are not addressed in any accreditation standard (such as use of Maine Background Check Center, for example).

Comment 94: Rule Section(s): Part I, Section 2.A.1

The Division of Licensing and Certification has authority to enforce its licensing rules. It is not a general enforcement body for all state and federal laws, most of which have no relation to proper functioning of a licensed agency. Licensing staff lacks expertise in determining the violation of laws and rules outside the scope of the state licensing rules. This broad statement should be omitted from the rule.

Response: This language is a standard licensing requirement for other provider types. DLC does not enforce federal and state laws or rules but could cite for violation of licensing rule if another authority cited noncompliance with federal/state laws or rules. No changes were made to the adopted rule as a result of this comment.

Comment 95: Rule Section(s): Part I, Section 2.M

These provisions are contrary to the Maine statutes on deemed status. The comment on the definition of deemed status in Part I, Section 1.A.29 applies fully here. Under the statutes, an accredited agency "must" be deemed to be in compliance with "comparable" state licensing rules. The Department's recognition of this is statutorily mandated, not discretionary. Moreover, an accrediting organization's request for information, a response or a corrective or improvement plan is immaterial as long as full accreditation status is not affected. Such actions should engender no reporting requirement and should not affect deemed status in any way, as long as the agency remains fully accredited.

Response: The Department has considered the relevant statutory provisions in Title 5, 22, and 34-B, and modified the rule based on a similar comment. Please see the response to comment 93. The Department further modifies Section 2(M)(7) to delete the reference to "An accreditor" and replace it with "An accredited organization."

Comment 96: Rule Section(s): Part I, Section 4.D

Summary of proposed rule: Procedures are set out for courtesy informal conferences to contest any deficiency cited on an SOD.

The formality and limitations placed on the informal conference process exceed what is needed or appropriate. To encourage and exhibit a collaborative rather than adversarial relationship, informal consultation between licensors and providers ought to be facilitated when there are questions about a deficiency. Discussions should be allowed as may be needed to address questions or issues, without limitation to one conference. Information or evidence related to the finding of a deficiency should be permitted to be provided without restriction. Particularly given that the results of any discussions are not appealable, open discussion ought to be encouraged. While discussions are being held, a provider that questions a deficiency should, on request, be allowed an additional 10 working days to submit the POC. It would appear to serve no purpose to require a POC to be prepared and submitted while the finding on which it is based is still under discussion. Vis-à-vis the eventual submission of an acceptable POC, there does not appear to be a substantive need to have it submitted within 10 rather than 20 working days.

Response: This provision is consistent with the standards for other licensed settings. No changes were made to the adopted rule as a result of this comment.

Comment 97: Rule Section(s): Part I, Section 5.C

Summary of proposed rule: An agency must provide clients with a copy of its grievance procedure and obtain a signed receipt.

Providing a copy of the procedure and obtaining a release burdens the intake process for the client as well as for the provider. Many or most clients would not desire to obtain or sign additional paperwork. Notice of the right to submit a grievance, as is already provided in the summary of client rights given to each client, suffices. A copy of the grievance procedure can be provided to any client who requests it.

Response: The Department has reviewed this comment and has revised Section 5(C)(2) of the adopted rule to read: The ~~organization~~ client record must include documentation that the client was notified of the grievance procedure. ~~a signed client notification of receipt of the procedure in the client's record.~~

Comment 98: As noted with regard to Part I, Section 2.A.1, the Division of Licensing and Certification lacks authority and expertise to enforce all state and federal laws and rules. Its proper investigative authority ought to be limited to items 1 – 4 in Section 5.D.5.

Response: The Department has reviewed this comment and has deleted Section 5(D)(5) from the adopted rule.

Comment 99: Rule Section(s): Part I, Section 5.E and 5.F

Summary of proposed rule: An agency must submit a report to the Division of Licensing and Certification whenever a report of abuse, neglect or exploitation is made to Adult or Child Protective Services.

There is no reason to impose additional reporting burdens on providers. Adult or Child Protective Services can readily refer to DLC any reported matter that could be of potential concern to DLC. If internal communication within DHHS is not occurring, it would be appropriate to address the same within DHHS rather than to impose additional burdens on providers. It is noted as well that most APS and CPS reports involve abuse, neglect or exploitation occurring in the community, unrelated to an agency's license or operations.

Response: The Department has reviewed this comment and has amended Sections 5 (E and F) to read:

E. 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 <u>if the alleged abuse, neglect or exploitation occurred in the context of service provision through the organization</u>.

F. 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 <u>if the alleged abuse, neglect or exploitation occurred in the context of service provision through the organization</u>.

Comment 100: It appears appropriate to provide that licensed agencies should adhere to existing statutes and rules on client rights, to have related policies in place without inappropriate restrictions and to notify clients of their rights. It is not appropriate for the Division of Licensing and Certification to create and impose additional rights and reporting requirements. Sections 6.E – 6.M ought to be omitted from the proposed rule. Licensing authority extends to regulating the operations and facilities of licensed agencies to protect safety and health. It does not extend to general recognition of an array of perceived rights of persons served. The Maine legislature has enacted specific rights legislation and rules have been promulgated expressing those rights. Maine DHHS is now undertaking an initiative to review and revise those rules. That initiative is the proper venue for development of further provisions to create, revise or enforce rights, and there is a risk of inconsistency between this rule and future DHHS rules.

Response: The Department has reviewed this comment. The client rights in Section 6(E) –(M) do involve the regulation of licensee operations and facilities to promote client health and safety. Moreover, several of the provisions involve requirements that already are imposed on licensees by other applicable laws, such as those pertaining to restraints and confidentiality. Representatives of other Department divisions who are undertaking rulemaking on client rights were consulted in developing this rule, and future revisions to this section may be considered at a later date. No changes were made to the adopted rule as a result of this comment.

Comment 101: Rule Section(s): Part I, Section 6.D
These requirements would very substantially burden the intake process for the client as well as for the provider. Policies sufficient to address the many rights issues are extensive. Many or most clients would not desire to obtain copies of all of them or to sign additional paperwork. Posting all of them would occupy considerable space at any site. Agencies may have hundreds or even thousands of clients, making the task of

sending copies of all changes extremely difficult and costly. Sweetser is not aware of any indication that the present requirement and practice of providing a notice to clients summarizing their rights has been insufficient. Client rights are protected if they are provided with a clear summary of their rights and are provided, upon request, with a copy of related policies and procedures.

Response: The Department has reviewed this comment and has amended Section 6(D) to read:
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 ~~and must provide a copy of the policy required in § 6(B) of this rule to each client on admission.~~

1. The organization must inform each client and legal representative within 30 calendar days of any changes to the organization's policy and must offer ~~provide~~ them a copy of the change.
    a. A copy must be posted in a prominent place accessible to all clients.
    b. ~~Documentation of receipt by clients must be maintained in each client's record.~~The client record must contain documentation of notification of changes to client rights.

Comment 102:
These introductory requirements in Sections 7, 8, and 9 ought to be removed. It is not the purview of the Division of Licensing and Certification to enforce MaineCare rules, other DHHS rules (apart from the licensing rule) or DHHS contracts. DLC's authority extends to appropriate licensing requirements for protection of public health and safety, not to acting as a general enforcement arm for all DHHS regulatory and contractual matters. MaineCare rules, other DHHS rules and DHHS contracts all have their own compliance, monitoring and enforcement provisions and procedures and have DHHS staff with knowledge and experience in overseeing and applying those provisions and procedures.

Response: The Department finds that this provision is consistent with the requirement of the rule previously in force. The introductory language serves, in part, as a notification that licensing regulations exist in addition to other applicable statutory, regulatory, or contractual obligations, and may help providers remain in compliance with all relevant requirements. No changes were made to the adopted rule as a result of this comment.

Comment 103: Rule Section(s): Part I, Section 7.F.2; Part I, Section 10.D.2
Maine DHHS lacks authority to impose this licensing mandate. A provider's decision to agree to or maintain a provider / client relationship with a person is the provider's right to decide as a private entity. It is unrelated to any health or safety concerns within the purview of the state's licensing authority. The Maine legislature has not enacted any law giving Maine DHHS authority to direct a provider's decision about providing services to a particular client. Notably, MaineCare and DHHS contracts with providers differ from the licensing rule in that they are voluntary engagements. A provider may decline to participate in MaineCare or to agree to a DHHS contract. The voluntary nature of the MaineCare and contract relationships has been relied upon to support the many operational requirements imposed by Maine DHHS in those relationships. The same justification is inapplicable to a licensing mandate. Moreover, in the MaineCare and contract contexts, Maine DHHS extends payment to the provider when the provider is required to accept or to continue serving a person pending OBH consideration of a request to decline or discontinue service provision. If a provider is to be required to serve a person as a licensing matter while OBH approval is pending, a mechanism would need to be included for Maine DHHS to compensate a provider if the person is unable or unwilling to pay for services. The proposed rule contains no such compensation arrangement. As well, with provision of services mandated, provision would need to be included for Maine DHHS to indemnify a provider for adverse consequences if the provider is required to serve a person beyond the provider's ability, scope of practice or caseload capacity. No such indemnity

provision is included in the proposed rule. Accordingly, the mandated provision of services ought to be removed from the proposed rule.

Response: The Department has deleted Section 7(F) from the adopted rule for the reasons cited in this and other comments. Please see comments 16 and 51.

Comment 104: Rule Section(s): Part I, Section 11.D.2, 3
These restrictions on board membership are contrary to current, accepted corporate and business practices. There is no intrinsic reason an employee or family member may not serve on an agency's board. It is not uncommon, for example, for a CEO, who is an agency employee, to serve on the agency's board. With some frequency as well, an officer of a bank in which the agency maintains deposits might serve on the board, or the firm of an architect or other professional on the board might be selected to perform certain contracted work for the agency. Such situations typically are addressed through the conflict of interest policy, which precludes the board member concerned from taking any action related to their own interest in a matter that comes before the board. There is no need to prohibit the person from serving on the board.

Response: The Department has amended Section 11(D) for the reasons cited in this and other comments. Please see comment 66.

Comment 105: Rule Section(s): Part I, Section 12.B.3
This reporting requirement is too broad and vague. It should be removed. Criminal activities could be minor in nature or could involve client actions subject to confidentiality protections if no abuse, neglect or critical incident is involved. Inclusion of service locations could require reporting a theft or property damage, unrelated to services, that an agency learns had occurred at a school or other community location. Section 12.B.2, which requires reporting of arrest or indictment of agency personnel, suffices for reporting of criminal activities that may have licensing implications.

Response: The Department has reviewed this comment and has deleted Section 12(B)(3) from the adopted rule for the reasons cited by the commenter.

Comment 106:
Unless mandated by specific laws, there is no general obligation of any person to report suspected criminal behavior to law enforcement. There is no apparent reason to impose this obligation in Section 12(F)(1)(b) on a licensed agency and to remove its normal discretion to determine what potentially criminal actions warrant being reported to law enforcement. This is particularly the case given that even "suspected" criminal behavior is to be reported. Client behaviors typically would be protected against disclosure in any event unless they involve abuse or neglect. This provision ought to be removed.

Response: The Department has reviewed this comment and has deleted Section 12(F)(1)(b**)** from the adopted rule for the reasons provided by the commenter.

Comment 107: Rule Section(s): Part I, Section 12.F.1 c

The duty to warn is a complicated area of law. It ordinarily applies only to a licensed professional who concludes there is a risk of harm to an identified person, it creates a potential basis for liability if harm results but is not a mandated action in the absence of actual harm and is subject to interpretations and qualifications imposed by the courts. The potential for liability serves as sufficient motivation for agencies to train staff about the duty to warn. It should not be embodied in a licensing rule, which would require

complicated legal analysis whenever it might be asserted to apply to a given situation.

Response: The Department has reviewed this comment and has revised Section 12(F)(1)(c) to read: ~~An employee of an organization has a duty to warn or take reasonable precautions when the employee has a~~ 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. ~~unless that action would endanger the employee or increase the threat of danger to a potential victim.~~

Comment 108: Rule Section(s): Part I, Section 12.F.2

"Adverse or potentially adverse events" is too vague to give providers a reasonably clear indication of what should be reported and hence is too vague to be enforceable. Other reporting requirements in the proposed rule very adequately cover matters which should be reported. This vague catchall provision ought to be removed from the proposed rule.

Response: The Department has reviewed this comment and has deleted Section 12(F)(2)(a) from the proposed rule.

Comment 109: Rule Section(s): Part I, Section 12.H
The identified elements may or may not be relevant to a particular agency. The proposed rule, in Part I, Section 17, requires quality improvement activities to be undertaken pursuant to an operational QI plan. A specified annual evaluation should not be required. Agencies should have flexibility to determine what elements best relate to evaluation of their operations as set out in their QI plans. A specifically defined annual evaluation should not be required.

Response: The Department has reviewed this comment and has amend Section 12 (H) (1) to read:

1. The annual evaluation ~~must~~ may address ~~at least~~ the following:

Comment 110: Rule Section(s): Part I, Section 13.H.4.b.ii

Program or service teams may include more than eight team members. Clinical supervision is most meaningful if provided to the team as a whole, with reference to particular clients under the team's care and to the particular services provided by the team. Group clinical supervision should be allowed in the context of addressing a program or service team, even if more than eight supervisees are participating.

Response: The Department has reviewed this comment and has revised Section 13(H)(4)(b)(ii) to read:

i. Conduct individual and group supervision for ~~eight or fewer~~ supervisees.

Comment 111: Rule Section(s): Part I, Section 21

The Section 21 residential standards, together with programmatic protections elsewhere in the proposed rule, cover essentially all of the standards and requirements of the Letter of Guidance issued by DLC with respect to facilities dually licensed as Mental Health Residential programs and Assisted Housing / Residential Care facilities. Accordingly, there is no need for the burdensome and duplicative process of requiring dual licensure under these separate licensing rules. With the residential and other standards now incorporated into the proposed rule, a provision should be included to clarify that Mental Health Residential

licensure suffices and dual Assisted Housing / Residential Care facility licensure is not required. This clarifying provision may be more appropriately placed in Section 2 rather than section 21 of Part I.

Response: The Department has reviewed this comment. Mental Health residential settings will no longer be required to maintain residential care facility licensure following adoption of this rule, in accordance with PL 2023 Ch 176, which has been codified at 22 M.R.S. § 7852(14). No changes were made to the adopted rule as a result of this comment.

Comment 112: Rule Section(s): Part II, Section 22.E.3; Part II, Section 22.E.c; Part II, Section 23.F.3 and 23.F.3.c
Teleservices should be included as a permitted means of providing crisis services. Teleservices includes telecommunication methods other than just telephone.

Response: The Department has reviewed this comment and has amended the final rule to read as follows:

Section 22(E)(3):
3. Crisis services may be provided by an interactive telecommunication system ~~telephone~~, on a walk-in basis, or through mobile outreach to the individual's home, school, and other community settings.

Section 22(E)(3)(c):
c. 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.

Section 23(F)(3):
3. Crisis services may be provided by an interactive telecommunication system ~~telephone~~, on a walk-in basis, or through mobile outreach to the individual's home, school, and other community settings.

23(F)(3)(c):
c. 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.

Comment 113: Rule Section(s): Part II, Section 22.E.4; Part II, Section 22.E.4.iii
Conditionally licensed clinicians should be included as staff who may complete crisis assessments and who may provide clinical supervision. They are allowed to do so under MaineCare section 65 and the DHHS state crisis contracts. Conditional licensees must receive required supervision but have a scope of practice essentially the same as fully licensed clinicians.

Response: The Department has revised Section 22(E)(4) in the adopted rule. Please see comment 82. Additionally, the Department has revised Section 22(E)(4)(iii) to read: i. 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.

Comment 114: Rule Section(s): Part II, Section 22.E.8

This could be read as meaning the on-call psychiatrist must remediate the medication issues by diagnosis, prescription of medication or the like, which could not be done in a consultation call. Language should be added to the effect that the consultation is to be "for guidance on how to proceed".

Response: The Department has reviewed this comment and has revised Section 22(E)(8) to read:

8. When a crisis assessment reveals medication issues that need to be addressed, the crisis intervention counselor must consult the on-call psychiatrist for guidance on how to proceed.

Comment 115: Rule Section(s): Part II, Section 22.E.17.e; Part II, Section 22.E.17.g
The DHHS state contract for crisis services requires that a comprehensive crisis assessment must be completed within 72 hours after admission unless a comprehensive crisis assessment was completed within 24 hours prior to admission. The unit staff does not need to complete a new assessment if one is available that was done within 24 hours before the admission, as very often is the case. This is a reasonable approach which should be reflected in the licensing rule to provide consistency between the contractual and licensing requirements.

Response: The Department has reviewed this comment and has revised Section 22(E)(17)(g) to read: 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.

Comment 116: Rule Section(s): Part II, Section 22.E.17.h
The term "crisis stabilization plan" could create unintended problems in billing for crisis services. The DHHS state crisis standards, MaineCare rules and requirements of other payers all refer to having a treatment plan in place. The elements listed for a crisis stabilization plan are essentially similar to the elements of a treatment plan. It would be preferable to refer to the plan as a crisis treatment plan that focuses on crisis stabilization needs. It is noted that Section 22.E.17.o refers to a treatment summary describing the course of treatment. This terminology is consistent with having a treatment plan.

Response: The Department has reviewed the comment and has made the following clarifications in the adopted rule:

22(E)(17)(h) was revised to read to read: Within 24 hours of admission, the organization must develop a short-term crisis service ~~stabilization~~ plan. ~~No service plan is required.~~ At a minimum, the written short-term crisis service ~~stabilization~~ plan must include the following:

22(E)(17)(h)(vi) was revised to read: Signatures of all other individuals participating in the development of the short-term crisis ~~stabilization~~ service plan;

22(E)(17)(h)(viii) was revised to read: On the seventh day of service, and every two days thereafter, the short-term crisis service ~~stabilization~~ plan must be reviewed; and

Comment 117:
Crisis intervention counselors, as defined in the proposed rule, must be clinicians or have MHRT/CSP or other DHHS certification for crisis intervention. The MaineCare rules and DHHS state crisis contracts

contemplate unit staff being certified at the MHRT-1 level to provide the services listed in this rule. Section 22(E)(17)(k) should refer to "MHRT-1" or to "appropriately" certified staff instead of referring to crisis intervention counselors.

Response: The Department has reviewed this comment and, for the reasons in the comment, has revised Section 22(E)(17)(k) to read: ~~Crisis intervention counselors~~ 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.

Comment 118: Rule Section(s): Part II, Section 22.E.17.n; Part II, Section 22.E.17.n.i
This provision should be limited to face-to-face contacts with a client by a clinician. Direct care staff of the unit would have numerous face-to-face contacts with all clients but would not be able to address the items listed in clauses i – vi. For clinicians, assessment of ability to make reasoned decisions would be beyond their scope of practice and should be removed. Clinicians could appropriately assess danger to self or others.

Response: The Department has reviewed tis comment and has revised Section 22(E)(17)(n) to read:

i. Each face-to-face contact ~~with~~ between a client in crisis and a clinician must be documented to include the following, as applicable:
   i. 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;
   ii. The sharing of the assessment with the client in crisis and the client's parent, guardian, legal representative or provider when applicable and appropriate;
   iii. The disposition of the episode, including recommendations and referrals to other service providers as appropriate and indicated; and
   ~~iv. Collaboration with the client's other service providers, when appropriate and applicable;~~
   ~~v.~~ The use or non-use of an existing crisis or relapse plan.~~; and~~
   ~~vi. Appropriate follow-up contacts with the client in crisis, as authorized by the client in crisis or otherwise permitted.~~

Commenter #10:

Comment 119: Would request that clarification be given around what is meant by "must have written policies and procedures designed to enhance the dignity of all clients and to protect their civil rights." as this seems too vague to know if we are actually meeting the requirement.

Response: The Department has reviewed this comment and has deleted Section 6(B)(1) of the proposed rule from the adopted rule.

Comment 120: Would request clarification surrounding the idea of "posting" a notice. If we supply the notice (such as internal rules and patient non-compliance) in the intake packet that they signed for and received copies of, could this count as "posting in a common area"?

Response: The Department has reviewed this comment and finds that the requirement for posting in a common area ensures that clients have ongoing access to the document when in the organization's setting(s). The Department clarified Section 6(D)(1)(a) to read: a. A copy must be posted in a prominent place within each organizational site that is accessible to ~~all~~ clients.

Comment 121: The commenter requested clarification of whether the rules require licensees to notify clients of all Plans of Corrections and changes, or only Directed Plans of Correction.

Response: A "Directed Plan of Correction" ("DPOC") is identified as an intermediate sanction in Section 4(J) and is different than a Plan of Correction ("POC"). Section 6(H)(2) of the rule requires that clients are notified of DPOCs, not POCs . No changes were made to the adopted rule as a result of this comment.

Comment 122: Would request clarification surrounding the role of dual-regulations. For example, BHH regulations state that the Care Coordinators (MHRT/C) can complete the comprehensive assessment and plan of care with the patient, and clinical lead must review and sign off. These regulations state that a clinician must conduct the assessment – do BHH regulations supersede these? Can there be a caveat about program specific standards in here?

Response: The Department has reviewed this comment and has made a change to Section 8(C)(4) previously. Please see comment 53.

Comment 123: Would request clarification on what an Expedited Service Plan is – is it an entirely separate process from a standard Treatment Plan, or can it be an addition to the treatment plan if an expedited need arises?

Response: The Department has reviewed this comment and has relocated Section 9(H) of the proposed to rule to Section (9)(K)(4) of the adopted rule to clarify that the expedited service planning process should be used to update a service plan when a crisis or urgent need has been identified.

Comment 124: Would request clarification on what constitutes an Emergency Discharge, and what constitutes AMA in an outpatient setting.

Response: The Department has reviewed this comment. An emergency discharge is one where "the client presents a danger to themselves or others" and the rule permits this to be further clarified through program-specific policies. The emergency discharge criteria are sufficiently clear and the Department declines to elaborate on them further in this rule. The Department has clarified Section 10(E) of the adopted rule to read:

E. Self-discharge against clinical <u>recommendations.</u> ~~advice.~~

1. When a client self-discharges against <u>clinical recommendations</u> ~~medical advice~~, the organization must prepare a written document describing the client's self-discharge~~ against clinical recommendation. medical advice.~~

Comment 125: Would request clarification on what legal proceedings need to be reported – just those impacting the MH license, or any conducted at the Agency?

Response: The Department has reviewed this comment and has amended Section 11(F)(11) to read: 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 <u>outlined in this rule</u> 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.

Comment 126: Would request clarification on what programs constitute "clinical care". Clinical Supervisors per these regs are limited to providing consultation to 8 people at a time – is this also the case if they are providing group supervision for Case Managers, where they are not "clinical" providers. Would Clubhouse and BHH fall under section H4 or H5?

Response: The Department has reviewed this comment and finds no usage of the phrase "clinical care" in the proposed rule. The Department previously amended Section 12(H)(4)(b)(ii). Please see comment 110.

The Department revised Section 13(H)(4) of the adopted rule to read: The clinical supervisor is responsible for clinical supervision of clinicians~~, direct care staff~~ and independent contractors, as applicable, who provide clinical services.

Commenter #11:

Comment 127: Section 6 - CLIENT RIGHTS
D. 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 and must provide a copy of the policy required in § 6(B) of this rule to each client on admission.
• It doesn't state "offer them". It indicates "must provide a copy". Organizations can document attempts to provide but cannot guarantee that the individual will accept the information. "Must" should be changed to offer with supporting documentation.

Response: The Department has reviewed this comment and had amended Section 6(D) of the adopted rule in response to an earlier comment. Please see comment 101.

Comment 128: 1. The organization must inform each client and legal representative within 30 calendar days of any changes to the organization's policy and must provide them with a copy of the change.

b. Documentation of receipt by clients must be maintained in each client's record.

• What is the acceptable form of the documentation? This is not easily tracked as it will likely be inserted into a service note. This creates an enormous administrative burden when it comes time to demonstrating compliance. Does a mailed letter meet the notification requirement even though we cannot be sure that the individual received the letter?

Response: The Department has reviewed this comment and had amended Section 6(D) of the adopted rule in response to an earlier comment. Please see comment 101. The Department declines to add language prescribing how programs provide notice, instead allowing programs to select the approach that works best for the program and its clients.

Comment 129: Section 8 – Comprehensive Assessment
• Add the word 'to' to the second sentence after the word subject.

Response: The Department has reviewed this comment and has made the recommended change in the final rule to the introductory paragraph of Sections 7, 8, and 9, which all contained identical language.

Comment 130: Section 15 – Medication Administration

• This standard is not in line with CRMA training. What is meant by the requirement "the organization may administer a PRN order for antipsychotic-type psychotropic medications only when the organization also has an order prescribing routine scheduled and administered doses of [any?] the antipsychotic-type psychotropic medication for the client?" Does this mean the PRN has to have a scheduled dose of the exact medication? E.g. if there is a PRN of Zyprexa, there must also be a scheduled dose of Zyprexa?

Response: The Department has reviewed this comment and has deleted Section 15(M)(3) from the adopted rule.

Comment 131: Section 13 – Personnel
• G-Nurse Consultant. What is meant by the statement, "The nurse consultant is responsible for the medical direction and coordination of medical care in the program?" The term medical direction should be clarified as prescribing physicians maintain authority for certain aspects of medical direction.
• H-Clinical Supervisor. Can we maintain the four hours per month instead of the 1 hour per week? Items 1-4 need to be defined as to whether they pertain to conditionally licensed employees only.

Response: The Department has reviewed this comment and has revised Section 13(G)(1) to read: The nurse consultant is responsible for the ~~medical direction~~ ~~and~~ 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.

The Department has reviewed this comment and has revised Section 13(H)(5)(a) to read: Staff providing 20 hours or more of direct service per week must receive at least four hours ~~one hour~~ of clinical supervision every month ~~week;~~

Comment 132: Section 21 – Standards for all Residential Programs
B.6. 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.
• There is a concern we may not be able to obtain this information from the client. It is not a realistic requirement. Currently staff always ask the clients where they are going and for contact information, but the clients can refuse to provide the information.

Response: The Department has reviewed this comment and has revised Section 21(B)(6) of the adopted rule to read: 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.

Comment 133: Part Two: Program Specific Standards/ Section 22 – Mental Health Programs

E. Crisis Services Module- have the licensing requirements for crisis providers been aligned with the proposed revisions to the crisis services? Do the requirements of licensing align with the requirements of the new rule?
a. E.3.a. The organization may provide crisis telephone services through a statewide toll-free number.

• Crisis providers do not "provide crisis telephone services through a statewide tol-free number. The state maintains a contract with one vendor to provide this service. This standard implies that a crisis provider would need to maintain a contractual relationship with the statewide vendor. This language should be removed as it is not consistent with the crisis structure.

Response: The Department has reviewed this comment, and in regard to Section 22 (E), notes that the proposed rule was reviewed by OMS and OBH for alignment with the current service system.

In regard to the comment regarding Section 22(E)(3)(a), the Department has revised this provision of the adopted rule to read: a. The organization may provide crisis telephone services referred through a statewide toll-free number.

Comment 134: E.3.b. Crisis walk-in services must provide support to clients in crisis on a walk-in basis.
• This statement needs to be clarified to restrict walk-in services to normal business hours.

Response: The Department has reviewed this comment and has revised Section 22(E)(3)(b) to read: Crisis walk-in services must provide support to clients in crisis on a walk-in basis during normal business hours.

Comment 135: E.8. When a crisis assessment reveals medication issues that need to be addressed, the crisis intervention counselor must consult the on-call psychiatrist.

• This is a very broad statement that leaves crisis providers in a difficult position. What is the definition of medication issues? Does it pertain to all medication or just psychotropic medications? What is the timeframe for reporting issues? Based on the definition you provide for medication issues, how are medication issues identified?

Response: The Department has reviewed this comment and notes that changes to this provision were made in response to comment 114. The Department has further revised Section 22(E)(8) of the adopted rule to read: 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.

Comment 136: E.11. The organization must have written policies and procedures for accessing rescue services that are reviewed and updated no less than annually. The organization must train its personnel on the organization's rescue procedures.

• Please define 'rescue' services and 'rescue' procedures? It is impossible to develop policies and procedures without a clear understanding about the subject requiring such documentation.

Response: The Department has reviewed this comment and has amended Section 22(E)(11) to read: The organization must have written policies and procedures for accessing emergency medical ~~rescue~~ services that are reviewed and updated no less than annually. The organization must train its personnel on the organization's ~~rescue~~ emergency medical services procedures.

Comment 137: E.17.g. The first time a client is admitted to the crisis stabilization unit, the program must conduct a comprehensive crisis assessment of the client.

• Crisis has always been able to reference a comprehensive assessment from a hospital as a stepdown doc and then create our addendum to address follow up and additional needs. This is an example of where the licensing standard conflicts with the crisis structure.

Response: The Department has reviewed this comment and has added Section E(17)(g)(ii)(9) to the adopted rule: 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.

Commenter #12:

Comment 138: Do we still need to retain Assisted Housing licenses for our PNMI programs?

Response: The Department has determined this will no longer be required. Please see the response to comment 111.

Comment 139: How will the department apply deemed status if the accreditation periods are for three years and licensing is two?

Response: The Department has determined that the term of a license is determined by statute and DLC will complete surveys of non-comparable standards in accordance with statute. No changes were made to the adopted rule as a result of this comment.

Comment 140: Section 2 M: 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. – It is not clear to us how this would work or how a determination would be made about what needs to inspected and what does not.

Response: The Department has reviewed this comment. In accordance with Section 2(M)(4) of the proposed rule, the organization must identify the accreditation standards that are comparable to this rule**.** No changes were made to the proposed rule as a result of this comment.

Comment 141: Page 21 E. are we going to need to report to DLS all grievances that we receive as a potential rights violation or only those that are substantiated?

Response: The Department has reviewed this comment and determined that organizations must report all suspected rights violations to DLC in accordance with Section 6(E)(1). No changes were made to the proposed rule as a result of this comment.

Comment 142: Section 6.H. needs clarification. It is unclear whether the rule means that 1) copies of licensing deficiencies and corrective action plans need to be available for inspection and copying, and 2) whether "in writing" means notice must be mailed.

Response: The Department has reviewed this comment. The language of §6(H)(1) was revised in response to another comment, as described in the response to comment 167, to clarify that statements of deficiency and plans of correction would need to be available to clients and their legal guardians "upon request." The remainder of the section is clear as drafted, and the Department declines to be more prescriptive in defining

the form that written notice must take. No further changes were made to the adopted rule as a result of this comment.

Comment 143: Treatment plan timeframe is 90 days – MaineCare annual or 12 visits for OP services and MC. Do we continue to apply for waivers?

Response: The Department has reviewed this comment and clarified the adopted rule by adding a new provision Section 22(F)(3): Service plans must be completed within thirty (30) days from admission and reviewed every twelve (12) visits or annually, whichever comes first.

Comment 144: The Governing Authority Board restrictions on page 32 D. seem overly restrictive. Immediate family members of employees may not serve on board, BOD members cannot be employees of entities that the agency has a contractual relationship with. In a small community, this may seriously limit the ability to recruit and retain a diverse and engaged Board of Directors.

Response: The Department has reviewed this comment and notes that it has amended this section of the adopted rule in response to comment 66, which raised similar points. No further changes were made to the adopted rule in response to this comment.

Comment 145: Forms acknowledging receipts of client rights, info about fees, privacy practices and other notifications required by law are requiring signatures "signed and dated" ….can these be verbal and documented, particularly in cases where services are provided over telehealth?

Response: The Department has reviewed this comment and has revised Section 16(D)(3)(d) to read: Copies of all ~~signed and dated~~ completed releases and authorizations, including, but not limited to, the following:

Comment 146: Integrated Mental Health and Substance Use Disorder Treatment Programs- it is not clear whether or not our PNMI programs would be considered integrated. Will there be additional guidance as to where our programs fall when it comes to designation?

Response: The Department has reviewed this comment. This rule classifies residential programs as either Mental Health, Substance Use Disorder, or integrated programs, and includes definitions for each of these terms. The rule also explains, in a Note within Section 3, that "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." The PNMI appendix designation by OMS falls outside the scope of this rule. No changes were made to the adopted rule as a result of this comment.

Comment 147: Section 9. J. Intervention Plan- regarding the need to develop an intervention plan, what is the measurable criteria for determining whether or not someone needs one? will/can this be incorporated into the service plan?

Response: The Department has reviewed this comment and has deleted Section 1(A)(46) and 9(J) in response to a previous comment. See comment 19.

Comment 148: Section 15. M.3. The organization may administer a PRN order for antipsychotic-type psychotropic medications only when the organization also has an order prescribing routine scheduled and administered doses of the antipsychotic-type psychotropic medication for the client. Does the PRN antipsychotic medication and scheduled antipsychotic have to be the same medication?

Response: The Department has reviewed this comment and has deleted Section 15(M)(3) in response to a previous comment. See comment 130.

Comment 149: Will waivers still be acceptable for Supported Apartments under the Food service and safety section?

Response: Organizations may apply for waivers in accordance with Section 2(J) of the rule. No changes were made to the adopted rule as a result of this comment.

Commenter #13:

Comment 150: The notice of the proposed rule was not received until September 6, 2023. This provided less than a month of review and preparation of comments in order to be able to participate in the public comment forum on September 29, 2023. It was mentioned at that public forum that DLC sent the notice out in the newspaper. Since DLC has every agency on a listserv, we would request that this be used as the primary method of communicating with the individuals and agencies who will be most impacted by such a major revision of the licensing standards. Publishing in the local newspapers for agencies to be informed is a very outdated means of communicating.

Response: The Department followed the rulemaking procedures outlined in 5 MRS Ch 375, Maine Administrative Procedure Act in adopting this rule, which require 1) publishing notice of rulemaking in the newspaper and 2) that the newspaper publication take place 17 to 24 days before the public hearing. Email notice of rulemaking was sent to the email address on record for every currently licensed mental health agency and substance use disorder provider on September 6, 2023. No changes were made to the adopted rule as a result of this comment.

Comment 151: What efforts were made to ensure agency feedback prior to this rule draft? With the significant revisions to this rule, focus groups and/or survey to agencies prior to the draft would have been beneficial. Agencies have the unique perspective of putting the rules into action and can thus best provide feedback on the application of the rules in actual practice.

Response: The Department followed the rulemaking procedures outlined in 5 MRS Ch 375, Maine Administrative Procedures Act in adopting this rule. In drafting this rule, the Department considered feedback it has received from agencies over the years concerning the prior rules. However, the primary method of receiving input from agencies was through comments on the proposed rule. Email notice of rulemaking was sent to the email address on record for every currently licensed mental health agency and substance use disorder provider on September 6, 2023. No changes were made to the adopted rule as a result of this comment.

Comment 152: As MaineCare no longer differentiates in reimbursement rates for private practitioners and agencies, please provide clarification regarding DLC applying the same measure of oversight for these private practitioners as they do agencies. Will licensing rules and site visits be applied to clinicians in independent practice that are contracted directly with MaineCare?

Response: Part B of Purpose and Applicability section of the rule directly addresses this comment: “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)." No changes were made to the adopted rule as a result of this comment.

Comment 153: Please separate rules that are applicable to only residential services. Throughout the proposal, in the sections applying to all organizations, there are many rules that are clearly focused on when clients are housed by the organization with 24/7 staffing. These rules, identified throughout this response, should not be blanketed to all organizations, and in particular, outpatient and community-based services that regularly use telehealth.

Response: The rule has been separated into core standards that apply to all organizations and sections that apply to different settings/license types. Section 21 of the rule applies to residential programs. No changes were made to the adopted rule as a result of this comment.

Comment 154: Given that agencies have been established for independent contractor relationships for over 20 years, commenter requests licensing give consideration to developing independent contractor licensing regulations as a separate program.

Response: Section 14 of the rule is specific to independent contractors. The federal and Maine Departments of Labor have oversight of the statutes, rules, and regulations governing independent contractors and the scope of this rule is limited to the use of independent contractors within licensed behavioral health settings. No changes were made to the adopted rule as a result of this comment.

Comment 155: It is an administrative burden to review, provide copies of, and post the significant amounts of new documentation added within the core standards sections. There is no additional reimbursement for these steps, and posting is an antiquated method considering many community-based and outpatient services are no longer provided within a "building." The intake process is already laborious for clients. Some of these steps should be eliminated or streamlined.

Response: The Department finds that this comment lacks specificity about which provisions are additional or burdensome. In response to other comments, the Department has revised some notification requirements. See, for example, comments 101, 120, 127, 128, 274, and the responses to those comments. No further changes were made to the adopted rule as a result of this comment.

Comment 156: Commenter requests that the definition of clinical supervisor be clarified to state that clinical supervisors need a CCS ONLY when supervising SU disorder services.

Response: Section 13(H) of the adopted rule contains the following language: *"H. 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."* The definition, therefore, does not need further clarification. No changes were made to the adopted rule as a result of this comment.

Comment 157: Please clarify that the prohibition in Section 2(K)(2) on private residences serving as an approved site does not include independent contractors and services provided via telehealth.

Response: The Department has reviewed this comment and notes that Section 1 (A)(89) was clarified in the adopted rule. Please see comment 14 and the response.

Comment 158: Please clarify that the fee in Section 3(E)(4) to add a site to an existing license does not include independent contractor sites.

Response: The Department has reviewed this comment and finds that the phrase "other community settings" in Section 1 (A)(87) is inclusive of independent contractor's service locations. No changes were made to the adopted rule in response to this comment.

'Comment 159: Please clarify the posting requirements in Section 5(B) for the Department's toll-free number when services are provided via telehealth and clients do not come to a building for services.

Response: The Department has reviewed this comment and has revised Section 5(B) to state: "The organization must post the Department's toll-free telephone number and website URL for electronic complaint reporting in an area visible to ~~all~~ clients at each site to enable clients or staff to contact the Department to make a complaint about the organization."

Comment 160: The grievance procedure is long and clients may not want a copy. Modifying Section 5(C)(2) to provide clients a summary of the grievance procedure and offering a copy should be sufficient and less wasteful. The requirement in Section 5(C)(3) to post the grievance procedure seems excessive and unrealistic for agency space and should be applicable specifically to residential services.

Response: The Department has reviewed this comment and notes that Section 5(C)(2) was revised in response to an earlier comment. See comment 97 and the response. The Department retains the requirement that the grievance procedure be posted in an area visible to clients to promote familiarity with and use of the procedure.

E. Report adult abuse, neglect or exploitation.

Comment 161: Please clarify that Section 5(E) requires reports of abuse, neglect, and exploitation be made to DLC only when it involves a staff member abusing an adult client and Section 5(F) requires reports of abuse, neglect, and exploitation be made to DLC only when it involves a staff member abusing a child client.

Response: The Department has reviewed this comment and notes that Sections 5(E) and (F) were revised in response to an earlier comment. See comment 99.

Comment 162: Current licensing standards apply program rules to SUD services only. Please clarify whether Section 6(B) would require mental health services to provide program rules and whether Section 6(B)(3) requires community support service providers to provide a fee schedule if there are no fees associated.

Response: The Department has reviewed this comment and finds the language of the proposed rule to be clear. All organizations must have a written policy that includes program rules and the fee schedule. When no fees are charged, the fee schedule may reflect that. No changes were made to the adopted rule in response to this comment.

Comment 163: The commenter requests clarification whether the reporting required by Section 6(E)(1) is reporting on the organization with whom the professional is employed or another organization. The

commenter further requests clarification on whether this reporting would be in lieu of offering the client the grievance process.

Response: The Department finds that the rule clearly states that there is a positive obligation to report an alleged rights violation, regardless of whether the alleged violation occurred within the employee's place of employment or at another organization. This requirement for employees to report violations is not in lieu of offering the client the grievance process, which serves a different purpose. No changes were made to the adopted rule as a result of this comment.

Comment 164: Please clarify that organizations must report abuse, neglect, and/or exploitation to DLC in accordance with Section 6(F)(1) when a staff member is abusing a client, whether child or adult.

Response: The Department has reviewed this comment and agrees that reports to the DLC must be made only if the alleged abuse, neglect or exploitation occurred in the context of service provision through the organization. This provision of the final rule has been modified to cross reference Section 5(E) and (F), which contain the limiting language on reporting to DLC.

Comment 165: Reporting to DLC when a provider/employee/staff member is suspected of neglecting and/or abusing a client is appropriate. It is an overreach of confidentiality laws to have MH and SUD providers report all critical incidents regarding alleged abuse and neglect by anyone else to DLC and OBH, which is what Section 6(F)(2) appears to require. The agencies are making legally mandated reports to APS and CPS.

Response: The Department has reviewed this comment and agrees that reports to the DLC must be made only if the alleged abuse, neglect or exploitation occurred in the context of service provision through the organization. Please see the response to comment 164 above.

Comment 166: Requesting the posting of an organization's internal program rules and the consequences of noncompliance, as required by Section 6(G)(3), seems excessive. A copy provided to the client should be sufficient. Many clients do not come to a building for services any longer, so perhaps this should apply specifically to residential services.

Response: The Department has reviewed this comment and has deleted Section 6(G)(3) from the adopted rule for the reasons cited in the comment.

Comment 167: Section 6(H)(1) requires organizations to inform clients and their legal representatives that survey results are available "in a common area of the organization." Aside from residential services, many organizations no longer see clients in a building so a "common area" is no longer applicable.

Response: The Department has reviewed this comment and, for the reasons identified in the comment, has amended Section 6(H)(1) to read: 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 ~~in a common area of the organization~~.

Comment 168: The requirement in Section 6(H)(2) that requires notifying clients and their legal representatives of actions proposed or taken against the organization's license by the Department seems more applicable to a residential setting where clients are more at risk when egregious citations or deficiencies have been determined and have direct relations to their living environment, for example. For

outpatient services, this would seem more appropriate under extreme circumstances that could be further outlined or categorized.

Response: The Department reviewed this comment and finds that this standard regarding notification is consistent with other licensed settings and serves to ensure that clients are aware of substantial non-compliance with minimum standards contained in the rule. No changes were made to the adopted rule in response to this comment.

Comment 169: The provisions laid out in Section 7(A)(1) requiring organizations to provide assistive listening devices and other assistance to minimize barriers to a client's ability to access services "are stricter than ADA language of reasonable." This seems more relevant to a residential setting.

Response: The Department has reviewed this comment and finds these provisions of the proposed rule to be necessary for the needs of the population served. No changes were made to the adopted rule in response to this comment.

Comment 170: Section 7(H)(2) requires organizations to ensure that restrictions on access to services and treatment are limited to and based on eligibility or admission requirements and that no person is denied access to services based solely on a co-occurring condition or the person's refusal of any other service. If a client were to present, at intake, with a co-occurring condition to a clinician that did not have the appropriate training, certification, or licensure, it would be out of the scope of their practice to continue care. For this reason, it would be appropriate for them to refer the client to an alternate provider with the proper licensure and would often be required within the code of ethics for the clinician's individual license. The commenter requests clarification of this provision because, if a "person's refusal of any other service" applies to referrals for a higher level of care, it is not ethical to continue to provide services at a level that is not appropriate to their current clinical need.

Response: The Department finds that this provision is clarified in the provision immediately following, which states "Eligibility criteria. The organization must have written policies and procedures regarding eligibility criteria for receiving services." The scenarios described by this commenter can be addressed in the organization-developed policies and procedures. No changes were made to the adopted rule as a result of this comment.

Comment 171: Through Section 7(F), DLC is proposing to require organizations send a written notice to applicants when the referral is denied, regardless of reason, without any additional funding to support the added staffing time that will be needed to meet the standard.

Response: The Department has deleted Section 7(F) of the proposed rule in response to a previous comment. Please see comment 16.

Comment 172: The commenter requests a description of sexual health (reproductive, sexual activity, orientation, etc.) as used in Section 8(C)(1). To what extent is this applicable to a behavioral health clinician or community support worker with respect to scope?

Response: The Department has amended Section 8(C)(1)(c) of the proposed rule in response to a previous comment. Please see comment 27. No further changes were made to the adopted rule as a result of this comment.

Comment 173: Commenter requests that Section 8(C)(4) be clarified to state that it applies only if a client is being treated for a substance use diagnosis by the organization. It is unclear if ASAM level criteria is required for mental health community support services that are not treating substance use disorder. There is concern that this assessment would become an access barrier. The section on co-occurring is clear that it is someone being treated.

Response: The Department has reviewed this comment and has amended Section 8(C)(4) of the proposed rule in response to a previous comment. Please see comment 8.

Comment 174: Section 9(F)(3) requires documentation of benefits, alternatives, risks, or consequences of planned services in the service plan. This seems unnecessary because this information would, to a great extent, be standardized and applicable to all clients and better promoted within the intake form. Also, this seems to already be established/indicated with informed consent.

Response: The Department has reviewed this comment and finds that explanation of the benefits, alternatives, risks, or consequences of planned services within the service plan is a reasonable expectation for individual receiving services. No changes were made to the adopted rule as a result of this comment.

Comment 175: The program specific standards for outpatient services, per these licensing regulations, do not align with those of the MaineCare benefits manual. Specifically, substance use outpatient service providers must complete a service plan within 3 sessions and review every 90 days. Mental health and co-occurring providers must complete it within 30 days of admission and review every 12 visits or annually, whichever comes first. To ensure that organizations can effectively manage these standards, it would be helpful if they aligned. For example, the assessment is due within 30 days of admission. The ISP due within 30 days. The assessment review due annually and ISP reviews due every 90 days for all outpatient program services.

Response: The Department has reviewed this comment and has amended Section 23(G)(2)(b) to read: "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." In addition, new language was added to Section 22(F)(3) in response to comment 143 to address mental health service plans.

Comment 176: According to Section 9(G)(2), the reasons for failure to complete a service plan in a timely manner must be documented but there is no indication what applicable and appropriate reasons for delay of completion of the ISP are.

Response: The wording of the provision of rule provides latitude for applicable or appropriate reasons for delay of completion of the ISP and requires the organization to document those reasons. The Department has elected not to delineate the reasons as a part of this rulemaking because it would be difficult to create a comprehensive list. No changes were made to the adopted rule as a result of this comment.

Comment 177: Section 9(H) includes an expedited service planning process. A service plan review may not always be applicable in cases of crisis. In addition, the clients are not always mentally prepared to engage in service planning when they are in a state of crisis. The commenter requests the inclusion of language to indicate expedited service planning is "as needed or applicable" and notes that following a crisis episode, "an update to the crisis plan or review would be best practice and appropriate under these circumstances."

Response: The Department has revised Section 9 (K) of the final rule to read:
Periodic review and update of service plan. ~~In accordance with it's written service delivery policy, t~~ The organization must periodically review and update each client's service plan.

The Department has further amended Section 9(K)(4) of the final rule to read:
4. ~~In accordance with its written service delivery policy, t~~ The organization must conduct an expedited service-planning process when an ~~crisis or~~ urgent need has been identified, as needed or applicable. Following a crisis episode, a review of the crisis plan and/or service plan review is required.

Comment 178: Per Section 9(I), there is not a due date indicated for the initial ISP. This would be helpful to ensure compliance.

Response: The Department has reviewed this comment and has amended Section 9(H)(1) of the adopted rule to read: 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.

Comment 179: The commenter requests clarification on how the findings of the comprehensive assessment are to be documented within the service plan as required by Section 9(I)(2)(a), noting that the narrative or summary of the assessment is already located within the chart.

Response: The Department has reviewed this comment and notes that Section 9(H)(2)(a) of the proposed rule was deleted from the adopted rule in response to a similar, earlier comment. Please see comment 57.

Comment 180: Section 9(I)(2)(d) requires the service plan to include short term goals, which are often confused as objectives by providers. A suggestion is to focus on goals with objectives to reach identified treatment outcomes.

Response: The Department agrees with this comment and amended Section 9(H)(2)(c) of the adopted rule to read: The client's agreed-upon ~~long-term~~ goals ~~and specific short-term goals~~ and objectives to reach identified treatment and service outcomes. ~~that will allow completion of the long-term goals~~;

Comment 181: Since it is out of scope for clinicians to be planning for addressing acute or chronic medical conditions, Section 9(I)(2)g) needs further clarification as to how to accomplish this to meet this regulation.

Response: The Department agrees that further clarity is needed and has amended Section 9(H)(2)(f) of the adopted rule to read: 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;

Comment 182: Many survivors will not want any information regarding their sexual assault on their ISP that will regularly be reviewed by themselves and other team members, and potentially social supports. This is not trauma-informed and very specific to one clinical need/area. Other specific needs such as interpersonal violence, physical/emotional abuse or neglect are not asked to be addressed in the same manner. Perhaps a section added to the assessment in the referrals area could be included to have this information required by Section 9(I)(2)(h).

Response: The Department has reviewed this comment and, for the reasons stated by the commenter, has deleted Section 9(I)(2)(h) of the proposed rule from the adopted rule.

Comment 183: The crisis plan is a separate document and can be checked off as completed as part of the ISP process, but to have on the ISP document itself makes it more difficult to access and share relevant crisis plans with parties that would not otherwise have other goal information.

Response: The Department has reviewed this comment and notes that, for the reasons identified by the commenter, Section 9(I)(2)(i) of the proposed rule was relocated to a separate section of the adopted rule (Section 9 (I) of the adopted rule) in response to a previous comment. See comment 58 and the response.

Comment 184: The services that require a behavioral support plan should be specified.

Response: The department has reviewed this comment and notes that Section 9(I)(2)(j) of the proposed rule was relocated to Section 9(I)(5) of the adopted rule, which pertains to the crisis plan, in response to a previous comment. Please see comment 19. The relocation provides sufficient specificity about the services that require a behavioral support plan, and no further changes were made to the adopted rule as a result of this comment.

Comment 185: The commenter requests clarification for how providers will be able to anticipate barriers at the time of discharge while in the process of providing active treatment?

Response: The Department has reviewed this comment and agrees it may not be possible to anticipate discharge barriers. The Department has revised Section 9(H)(2)(i) of the adopted rule to read: Criteria and a plan for discharge~~, and strategies to address anticipated barriers to discharge~~;

Comment 186: Based on the limit of 60 minutes of face-to-face billable time for psychiatric evaluation of an adult, the expectation of comprehensive assessment domains already required in the comprehensive assessment section (several of which are not applicable to psychiatric treatment) and the crisis plan documentation requirements, it is unreasonable to expect that a psychiatric provider will also be able to inquire about, plan, and document to meet the requirements of Section 9(H)(2)(g), (h), (j)-(l), and (n). The only way for psychiatric providers to be able to document all the requirements (as well as a fully developed and documented crisis plan) for each new patient would be to schedule 1 hour initial assessments, then 2- 30 minute follow-up visits weekly over the next 2 weeks. This would meet all the documentation requirements, spending twice as much time as required for commercially insured clients for the same intake, but would also mean that a provider could only intake 50% as many patients in the same month. This would reduce access to MaineCare clients to psychiatric intake by 50%. This seems at odds with the department's stated goals (and focused group efforts) to increase access to psychiatric care. We strongly advocate for Medication Management to have its own requirements for psychiatric service that are aligned with MaineCare and industry standards for psychiatry and not be lumped in with outpatient therapy.

Response: The Department has reviewed this comment and notes that several of the sections identified were removed or modified in response to previous comments. In particular, Section 9(H)(2)(g) of the proposed rule was limited in response to comment 181, Section 9(H)(2)(h) of the proposed rule was deleted in response to comment 182, and Section 9(H)(2)(j) of the proposed rule was relocated to the crisis plan section. These changes limit the required content of the service plan. With regard to Sections 9(H)(2)(k), (l) and (n), the Department finds that this documentation is necessary to the service plan, is commonly documented as part of a service plan, and should be able to be completed without a reduction in client access to psychiatric intake. No further changes were made to the adopted rule as a result of this comment.

Comment 187: Please add verbal consent to Section 9(I)(2)(o) of the proposed rule to align with MaineCare.

Response: The Department has reviewed this comment and has revised Section 9(H)(2)(k) of the adopted rule to read: k. The date and ~~signature~~ documentation of the consent of the client, or the client's legal representative, as appropriate. ~~Where the signature of the client, or the client's legal representative is not obtained, the organization must document the reason why the signature could not be obtained and the client's agreement with the service plan in the client's record; and~~

Comment 188: Can clarification please be provided to differentiate between an intervention plan and a crisis plan? Can "frequency of contacts" be further defined?

Response: The Department has made changes to the adopted rule to address this concern. Please see the response to Comment 19.

Comment 189: If a higher level of care is needed given the co-occurring condition or disorder, would this be applicable under the language in Section 10(C)(1)?

Response: The Department has reviewed this comment and finds that a client requiring a higher level of care would be included in the language: "Involuntary discharge of a client may be based upon the organization's inability to meet the client's needs." Please also see the responses to comments 24 and 25. No changes were made to the adopted rule as a result of this comment.

Comment 190: Section 10(D) indicates that the current process for discharging clients with persistent and severe mental illness would be applicable for all clients. Is this the intention of the regulation? If so, this creates a liability to providers with respect to maintaining open and active cases for clients that are not actively engaged in treatment while awaiting OBH approval. In addition, there is added administrative burden and hardship to agencies in entering this information for approval within the Acentra database.

Response: The Department has reviewed this comment and has deleted Section 10(D)(2) of the proposed rule from the adopted rule and replaced that provision with a new one at Section 10(C)(2) of the final rule: "Include information on organizations in the client's service area where recommended services or supports could be sought;"

Comment 191: Section 10(F)(1) is against the Rights of Recipients. This takes away a client's right for autonomy and informed decision-making. Clients have the right to refuse some or all of the services offered. When a discharge is labeled as involuntary, how does that impact the client in the future? Also, there is no medical reason for needing to remain in outpatient or community support services. It is out of scope for community support workers and clinicians to indicate that a client has discharged against medical advice.

Response: The Department has reviewed this comment and finds that Section 10(F) of the proposed rule does not infringe on client autonomy, ability to make informed decisions, or right to refuse some or all services offered. It requires the organization to prepare documentation. Although the comment questions labeling these self-discharges as involuntary, there is nothing in this provision that labels self-discharge as "involuntary." Self-discharge and involuntary discharge are separate provisions of the rule. The Department has revised the terminology "medical advice" in response to a previous comment. See comment 124. No further changes were made to the adopted rule as a result of this comment.

Comment 192: Please clarify what the expectation is related to the requirement for readmission in Section 10(H) of the proposed rule. How do you envision agencies meeting this rule? For example, would this be a templated letter or would this be documented within a discharge summary. How would the readmission process to the agency be any different than the original admission process for the client when they entered services?

Response: The Department has reviewed this comment and, for the reasons identified in the comment, has deleted Section 10(H) of the proposed rule from the adopted rule.

Comment 193: Please clarify the reasoning for an advisory board, made up of members of the community without education or training in the mental health or substance use field, providing "advice" to a governing authority as required by Section 11(C)(1). How does someone's public official title in the community give them additional knowledge of administering a mental health and substance use agency? If one individual has the capacity to discharge the responsibilities of an agency, requiring a community advisory board is arbitrary and does not provide meaningful information and feedback to the governing authority. It is much more important to that one individual to receive feedback from the clients the agency serves. Having a client advisory board provides specific and targeted information about the organization to the person who governs it.

Response: The Department has reviewed this comment and finds that the provisions of the proposed rule provide appropriate oversight for behavioral health organizations. The advisory board requires client feedback but also requires community members or local public officials “who reflect diverse perspectives.” No changes were made to the adopted rule as a result of this comment.

Comment 194: If the governing authority and the administrator are the same person, please clarify the expectation regarding Section 11(F)(9).

Response: The Department has reviewed this comment and finds that Section 11(F)(8) of the proposed rule requires that the governing authority designate the administrator; therefore if the governing authority resides in an individual, the same person cannot be the governing authority and the administrator. Additionally, the rule requires “The composition and structure of the governing authority must be adequate to discharge its responsibilities.” It would not be appropriate to have an administrator complete their own annual written performance evaluation. No changes were made to the adopted rule as a result of this comment.

Comment 195: Due to the Cures Act, all agencies must provide clients immediate access to their records through a patient portal. The current rule is that agencies provide clients the ability to obtain their records for a period of time after the closure. Please clarify how Section 11(I)(3) would be enforced to an agency that no longer exists. To expect an agency to continue to have funding after closure to maintain documents is an overreach and does not appear to have purpose as there would be no staffing to release any records. Clients have access to their records continuously while the agency is open and can obtain them in that way.

Response: The Department has reviewed this comment and finds that the provisions of the proposed rule describe policies and procedures that an organization must proactively develop prior to closure. No changes were made to the adopted rule as a result of this comment.

Comment 196: Please add community support services to the list of services that can be provided via teleservices in Section 12(E)(1) to align with MaineCare.

Response: The Department has reviewed this comment and finds that Section 12 (E)(1) includes the permissive language "may include." However, to clarify that this is not an exhaustive list, the Department added "but are not limited to," to this provision.

Comment 197: No appliable confidentiality, HIPAA, 42CFR laws would allow this and having this in regulation would reduce a client's willingness to trust providers with their information pertinent to good care. Duty to warn is covered in the following sentence so this should be excluded. This rule is damaging to our service as written.

Response: The Department has reviewed this comments and notes that Section 12(F)(1)(b) of the proposed rule has been deleted from the adopted rule in response to previous, similar comments. Please see comments 69 and 106.

Comment 198: Section 12(H) is heavily burdensome to complete annually. It is unclear why DLC needs this level of detail on day to day operations.

Response: For the reasons identified in this comment and another, the Department amended Section 12 (H) of the adopted rule to allow greater flexibility in annual evaluations. See comment 109.

Comment 199: For outpatient programs that are not providing or administering medication, a nurse consultant is not required. Medication management programs are often only prescribing medication.

Response: For the reason in this and another comment, the Department amended Section 13 (G) of the proposed rule. See comment 10.

Comment 200: Does any of this section apply to independent contractors? There is another section specific to independent contractors that includes clinical supervision. Please clarify this section in relation to independent contractors.

Response: The Department has reviewed this comment and finds that Section 13(H)(4) of the proposed rule states that clinical supervision applies to independent contractors. Please also see the responses to comments 12 and 203. No change was made to the adopted rule as a result of this comment.

Comment 201: How is "training in supervision and the credentials to provide supervision" defined? Is a clinical supervisor of a community support worker defined the same as one of a clinician?

Response: This phrase is not defined in the rule. The Department refers the commenter to Sections 13(C), (D), (E), and (H)(4) and (5) of the proposed rule and the definition at Section 1(A)(15) for clarification. No change was made to the adopted rule as a result of this comment.

Comment 202: Independent contractors of agencies are providing services under the agency license of an organization. They are not applying for their own license to DLC. Providing financial information to an agency to "qualify" as an independent contractor is an overreach of DLC, and the agency, and could create legal implications with the Department of Labor due to the independent contractor status. Additionally, an agency having financial information of their independent contractors could open agencies up to other regulatory authorities, compliance with financial privacy laws, as well as could potentially be infringing on the rights of independent contractors to their financial privacy under the FTC. What is the purpose for this proposed rule? The agency assumes responsibility for their clients if an independent contractor closes their

practice. The DLC needs to clarify how an agency would determine if an independent contractor has sufficient resources to fulfill the terms of the contract.

Response: The Department has reviewed this comment and, for some of the reasons in this comment and in comment 21, deleted Section 14(B)(1) from the adopted rule. Please see comment 21.

Comment 203: Please clarify what the DLC's intention is in Section 14(D)((5) and (6). The professional licensure boards do not require regular clinical supervision for independently licensed clinicians. Clarification is needed to determine what the expectations of the agency's obligations are of independent contractors related to supervision, training, and contractual oversight.

Response: The Department has reviewed this comment and notes that Section 14(D)(6) was amended in the adopted rule in response to a previous comment. Please see comment 12. The Department has amended Section 14(D)(5) of the adopted rule to read: 5. A written record of ~~regularly scheduled substantive training, and~~ contractual oversight~~, and supervision or consultation sessions~~ for each independent contractor, to ensure compliance with the terms of the agreement; and

Comment 204: Please clarify if Section 16(D)(3)(f) is directed at a client's refusal to complete a form or if a client disengages from services before all the information for assessments, etc. could be obtained.

Response: The Department has reviewed the comment and finds the provision to be clear as written. The provision applies to all clients of the organization and applies when there is an absence of any required information. No changes were made to the adopted rule as a result of this comment.

Comment 205: MaineCare requires a reviewed financial statement. What is the purpose of the DLC requiring an audited financial statement, which is a significant financial burden to the agency compared to reviewed statements. Please clarify.

Response: The Department has reviewed this comment and to lessen the potential for financial burden to organizations has amended Section 18(D)(3) of the proposed rule to read: 3. Organizations with annual revenues under $~~500,000~~ $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.

Comment 206: Please identify what programs this applies to. Community Support Services do not have fees charged to clients.

Response: The Department has reviewed this comment and finds the proposed rule to be clear. There is no requirement to charge fees for community support services, but for those organizations charging fees this provision will apply. No changes were made to the adopted rule in response to this comment.

Comment 207: Agencies may not have "formal" (contractual) linkages with other community partners, however working relationships exist. Please change formal “and” informal to “or”. Additionally, referrals for the listed services are not always applicable. Please add, "as applicable" to the end of the above statement.

Response: The Department has reviewed this comment and, for the reasons identified by the commenter, has amended Section 23(A)(2) to read: 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.

Comment 208: Managing a wait list as described in this regulation would result in an administrative burden to the agency that is not a reimbursable service. For an organization that manages hundreds of referrals at any given time, this creates undue financial hardship and added employee resources.

Response: The Department has reviewed this comment and, for the reasons identified in the response to comment 13, retains the wait list requirement, which was drafted in consultation with OBH. No changes were made to the adopted rule in response to this comment.

Comment 209: Please provide further clarification on Section 23(D)(1)(b). Under what section would this information be found? When is this applicable?

Response: The Department has reviewed this comment. Specific programs/services require medical assessment or screening. Section 23(D)(1)(b) contains the language "when requested" to allow for flexibility, in that some clients may have already had this screening through an outside medical provider, and the clinician may not need to request medical director sign off in these cases. No changes were made to the adopted rule in response to this comment.

Comment 210: What level of care is Section 23(D)(2) for? Please clarify as this level of staffing is not required in outpatient services.

Response: The Department has reviewed this comment and for the reasons in this comment, comment 10, and comment 341, has deleted Section 23 (D)(2) of the proposed rule from the adopted rule. Please see comment 10.

Comment 211: In current regulations, clinicians that have received 60 hours of SUD training within the last 5 years are qualified to provide this service. This change in Section 23(D)(5) would decrease the amount of available providers able to continue to engage in the treatment of current clients or new clients requiring SU services, in particular, during a time of increased client need for this service. In addition, many providers who have a primary mental health licensure also sometimes carry the licensure of certified clinical supervisor. Can this be added as an allowable license to provide this service? In earlier sections it states clients cannot be denied service for co-occurring conditions, however this specific rule would create a huge barrier to access.

Response: The Department has reviewed this comment and, for the reasons identified in this comment and comment 29, has added Section 13(J) to the adopted rule. Please see comment 29. In addition, Section 23(D)(5) is amended to require substance use disorder qualified staff to "meet the requirements of Section 13(J)."

Comment 212: By limiting so significantly the qualified staff who can provide the service in Section 23(D)(5), DLC is reducing agencies' ability to provide integrated care with a "no wrong door" philosophy. On one hand you emphasize co-occurring services should be integrated, and in another section the clinicians qualified to provide the service are significantly reduced. Please clarify why that barrier is being put in place by DLC.

Response: As identified in the responses to comments 29 and 211, the Department has added Section 13(J) to the adopted rule which clarifies who may serve as clinical staff in a Substance Use Disorder program and modified the language in Section 23(D)(5). No further changes were made to the adopted rule as a result of this comment.

Commenter #14:

Comment 213: Section 21 Page 58 E.12.C.iii Will create less beds for long-established SUD halfway houses and create financial deficit. Will old programs be grandfathered in?

Response: The Department has reviewed this comment and for the reasons cited therein has relocated Section 21(E)(12)(C)(iii) of the proposed rule to Section 22(G)(2)(a)(vi) of the adopted rule.

Comment 214: Section 23 C may be difficult to manage in a medically supervised withdrawal management program (Detox). Census can change by hour.

Response: The Department has reviewed this comment and, for the reasons identified in response to comment 13, retains the wait list requirement, which was drafted in consultation with OBH. No changes were made to the adopted rule as a result of this comment.

Comment 215: Section 7 F: Does this apply to medically supervised withdrawal management programs? Also does this apply to Detox screenings or when they have been denied after their in-person intake?

Response: The Department has reviewed this comment and notes that Section 7(F) of the proposed rule was deleted from the adopted rule for the reasons stated in comments 16 and 171. Please see comment 16. No further changes were made to the adopted rule as a result of this comment.

Comment 216: Section 23 2: Does this medical screening fall within the scope of practice of MH and SUD providers? What are the guidelines to determine "the necessity for medical examination and further consultation?"

Response: The Department has reviewed this comment and has clarified Section 23(G)(2) to read: 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. The Department added similar language to Section 23(G)(3)(b)(i).

Comment 217: Section 24: This section does not provide enough guidance and does not identify the multiple levels of treatment. Also no mention of integrated IOP.

Response: The Department has reviewed this comment and finds that Section 24 purposely allows flexibility for organizations to develop integrated programs based on emerging service models and operate the programs in accordance with organization- developed program descriptions and criteria. No changes were made to the adopted rule in response to this comment.

Comment 218: Section 24 D Which regulations should be used when developing policy? SUD and MH have different documentation timelines.

Response: The Department has reviewed this comment and finds that organizations offering integrated services should utilize the higher standard when a client is receiving both mental health and substance use disorder services. Language was added to Section 24(A) of the rule for clarification.

Comment 219: Section 12: need more clarification on how one assesses "general staff effectiveness."

Response: The Department has reviewed this comment and finds that assessment of staff effectiveness is best determined by the employer and is a standard business practice in any industry. No changes were made to the adopted rule as a result of this comment.

Comment 220: Section 13 -c: this is redundant considering that for example: we hire a LCSW which is a masters level degree - why should we have to also verify the masters degree?

Response: The Department has revised Section 13 (C)(2) to read:

2. The organization is responsible for ensuring its personnel are qualified and must maintain ~~verify and~~ documentation of the references and credentials of prospective personnel, including:

Comment 221: Section 13 I: not sure how this would be done on an ongoing basis and also what is the ethics of this? There are more than one set of values and perspectives.

Response: The Department has reviewed this comment and has clarified Section 13(I)(3)(a) to read: a. Orientation to the common life experiences ~~typical perspectives and values~~ of clients of behavioral health services, conducted by a client of behavioral health services;

Commenter # 15:

Comment 222: Do the revisions to Children's and Adult Client Rights align with this proposed rule? Doesn't appear to align with MaineCare in certain ways, so how will possible discrepancies be rectified? Does it align with telehealth rule?

Response: The Department finds that this comment lacks specificity regarding proposed changes or concerns. The proposed rule was reviewed by other offices within the Department for alignment with other rules and policies prior to rule proposal. No changes were made to the adopted rule as a result of this comment.

Comment 223: Will require lots of policy re-writing… Will agencies be supported in reworking reams of policy?

Response: The Department finds that this comment lacks specificity regarding proposed changes or concerns. DLC may provide technical assistance when appropriate, which may include responding to questions regarding interpretation of rule provisions. No changes were made to the adopted rule as a result of this comment.

Comment 224: Section 1(A)(9) We don't plan to use restraints and so they're not standard in our BSPs. Kepro/Acentra is currently holding up approvals when agencies do include them in BSPs/BMPs because it's nonbillable time. As a result, this will pose administrative and authorization barrier if/when these are included in plans.

Response: The Department has reviewed this comment and is unclear how this definition will present a barrier if the use of restraints is not currently included in plans. Despite barriers, however, it is necessary for a behavioral support plan to describe all planned interventions. The Department also notes that Section 6(I) of the proposed rule speaks specifically to the allowable use of restraint techniques. No changes were made to the adopted rule a' a result of this comment.

Comment 225: Section 1(A)(18) Does this imply CRS for Children's as well? Page 62 of the proposed rule seems to lump Children's and Adult services in the Community Support Modules

Response: The Department has reviewed this comment and finds that Community Rehabilitation Services (CRS) is a separate service from rehabilitative and community services for children, as described in the Purpose and Applicability section of the proposed rule. No changes were made to the adopted rule as a result of this comment.

Comment 226: Section 1(A)(36). It might be beneficial to document the full scope of emancipated minors' rights here.

Response: The Department finds this request to be outside the scope of this rule. No changes were made to the adopted rule as a result of this comment.

Comment 227: Section 1(A)(43) Is initiation of services pre-intake or at intake?

Response: The Department has reviewed this comment and finds the definition of initiation of services to be clear. No changes were made to the adopted rule as a result of this comment.

Comment 228: Section 1(A)(76) How far does this requirement go? Does this include all texts, even a text meant simply to confirm an appt? Cataloguing a day's worth of standard back-and-forth communications seems excessive and daunting.

Response: The language at Section 1(A)(76) of the proposed rule is the definition of "Record." The definition includes "all electronic records, including, without limitation. . . text messages" and is sufficiently clear. No changes were made to the adopted rule as a result of this comment.

Comment 229: B.99 Question about Definitions and the proposal in general: Is this an effort to consolidate and reconcile Adult and Children's language and processes? This would be welcome in some ways to provide continuity during transitions, however, some adult processes don't translate well to the Children's world.

Response: The Department has reviewed this comment and notes DLC collaborated with OCFS, OBH and OMS in attempt to consolidate requirements for Adult and Children's Services, when possible. No changes were made to the adopted rule as a result of this comment.

Comment 230: Section 2(E)(4), requiring a sample client file, is new. Noted.

Response: The Department thanks the commenter. No changes were made to the adopted rule as a result of this comment.

Comment 231: Section 2(E)(10) of the prosed rule requires a written emergency disaster, hazard, and evacuation plan based on a risk assessment. Would need developing if this comes to fruition. (Internal note.)

Response: The Department thanks the commenter. No changes were made to the adopted rule as a result of this comment.

Comment 232: Section 2.I. 3 Needs clarifying in that it may be interpreted broadly and limiting of program growth. If it's strictly about building code and physical plants (additions, alterations, etc.) that makes sense.

Response: The Department has reviewed this and comment 43, and for the reasons cited therein, has amended Section 2(I)(3) to read: The organization may not increase ~~client or~~ 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.

Comment 233: Section 2(K). How does this interface with telehealth?

Response: The Department has reviewed this comment and notes that, in response to this and other similar comments, the definition of site was amended. Please see comments 14 and 157 and the responses.

Comment 234: Section 2(M). If obtaining any of these accreditations, does that waive need to pursue and maintain an agency license?

Response: Licensure is a statutory requirement and organizations covered by this rule must maintain a license issued by the Department. No changes were made to the adopted rule as a result of this comment.

Comment 235: Physical posting in office spaces as required by Section 4 will be cluttered, but we do appreciate the clarity in the process this section now offers.

Response: The Department thanks the commenter. No changes were made to the adopted rule as a result of this comment.

Comment 236: All the new postings required by Section 5 may be convoluted. How to achieve this efficiently? Are there alternatives we could create or suggest?

Response: The Department has reviewed this comment and finds suggesting methods to achieve compliance to be outside the scope of this rulemaking. The posting requirements are designed to promote client awareness of and easy access to important information. No changes were made to the adopted rule as a result of this comment.

Comment 237: Section 5(B). How does this apply, or how will it be implemented in HCT, Telehealth, and School-based therapy?

Response: The Department has revised Section 5(B) of the proposed rule in response to a previous similar comment. Please see comment 159.

Comment 238: Section 5(F). May we suggest an edit that provides clarity here in Sections E and F that the self-reports must occur when an agency is being investigated for complaints of abuse, neglect, and exploitation? Otherwise, it might be interpreted to mean agencies must contact DLC after any such report.

Response: The Department has revised Sections 5(E and F) of the proposed rule in response to a previous similar comment. Please see comment 99.

Comment 239: Section 6(G). What exactly does non-compliance mean here? And how extensive does this internal rules document need to be?

Response: The Department has reviewed this comment and finds Section 6(G) of the proposed rule to be clear, and that the Department allowed flexibility for organizations to define non-compliance with their internal rules and the nature of those rules. The Department amended this section in response to a previous comment. See comment 166. No changes were made to the adopted rule as a result of this comment.

Comment 240: Section 7(A). Should this section talk about multilingual needs as well (i.e., translation for clients who don't speak English fluently)?

Response: The Department has reviewed this comment and finds that the rule generally requires organizations to minimize barriers to a client's ability to access services. It is not possible to identify every type of barrier in rule. No changes were made to the adopted rule as a result of this comment.

Comment 241: Section 7(D). "Applicants" is an interesting choice of term because it suggests hiring. Can we say referant or potential clientele?

Response: The Department has reviewed this comment and agrees different terminology would be more appropriate. The Department has amended Section 7(D) to read: Screening practices. The organization must screen potential clients ~~applicants~~ to identify the urgency of need.

Comment 242: Section 7(E). Is this in place now? Can we get clarity around how we can show discretion in waitlist management? Current policy is first-come first-served.

Response: The Department has reviewed this comment and finds that Section 7(E) leaves it to organization to develop this policy. No changes were made to the adopted rule as a result of this comment.

Comment 243: Section 7(G)(2) We believe this should specify when the agency initiates the transition. Otherwise, there should be another item here about client choosing to move on.

Response: The Department has reviewed this comment and has clarified the final rule by adding Section 7(F) (3). The client requests transfer to another organization.

Comment 244: Section 8(C)(1) May we suggest inclusion of standards around gender-affirming language?

Response: The Department has reviewed this comment and finds the suggestion to fall outside of the scope of rulemaking. No changes were made to the adopted rule as a result of this comment.

Comment 245: Section 8(C)(1)(b) Trauma should be listed specifically here as well.

Response: The Department has reviewed this comment and finds the language of the proposed rule to be sufficiently broad to include trauma as applicable. No changes were made to the adopted rule as a result of this comment.

Comment 246: Section 8(C)(4) What about when case managers or RCS Coordinators do their comprehensive assessments? This language specifies clinicians only.

Response: The Department has reviewed this comment and for the reasons in this and other similar comments has amended this section. Please see comments 53 and 121.

Comment 247: Seeing the extensive documentation requirements in Section 9, we remain mindful of our clinical Codes of Ethics that require us to be as unintrusive as possible. We ask what we need to and nothing more. Do these standards require us to operate outside the scope of our Codes of Ethics?

Response: The Department finds that this comment lacks specificity regarding which Code of Ethics is being referred to and which sections of the rule are not needed. Please see responses to previous comments with revisions and/or deletions to Section 9, including 57, 58, 59, 181, 182, and 187. No further changes were made to the adopted rule as a result of this comment.

Comment 248: Section 9(C)(2) Where should this failure to participate on the service plan team be documented? Currently we would do this in the plan of care. Does this new rule require anything different?

Response: The Department has reviewed this comment and has clarified Section 9(C)(2) to read: When the client does not participate on the service plan team, the organization must document ~~in the client's record~~ the organization's efforts to engage the client and the reason why participation did not occur in the client's service plan.

Comment 249: Section 9**(**D). Does this require more collateral contacts for clinical providers than is currently expected? If so, how will this affect time spent in service and reimbursement?

Response: The department has reviewed this comment and finds this question to be outside the scope of this rulemaking. No changes were made to the adopted rule as a result of this comment.

Comment 250: Section 9(E). Could this section include a clause to say we'll engage clients to the greatest degree possible (e.g., a two year old HCT client will have little to say about personal goals)? Additionally, this would be a good place to document the importance of a strengths-based goal focus.

Response: The Department has reviewed this comment and finds that the proposed rule is clear and contains language "as much as possible, or as desired by the client." No changes were made to the adopted rule as a result of this comment.

Comment 251: Section 9(F) For items 1 & 2, we're not clear about where or how this should land in the client's plan of care. Does this differentiate from discussions about treatment modality, course of treatment, length of stay, etc.? Would these items belong more in a service agreement document typically discussed at intake and annually thereafter?

Response: The Department has reviewed this comment and finds Section 9(H)(2) of the final rule to be clear in describing the elements of the written service plan. No changes were made to the adopted rule as a result of this comment.

Comment 252: Section 9(I)(2)(a) We'll gladly do this if required, though we're concerned about this being an unnecessary duplicative task. If documented elsewhere, does it need to be restated in the treatment plan? Just concerned about added administrative burden on providers...

Response: The Department has reviewed this comment and has deleted Section 9(I)(2)(a) of the proposed rule from the adopted rule in response to a previous similar comment. Please see comment 57.

Comment 253: Section 9(I)(2)(f) How thoroughly does this need to be documented in the plan? Again, added layers of details and complexity will increase provider burden, which is directly correlated to issues with provider retention and recruitment.

Response: The Department has reviewed this comment and finds that consideration of the role of family members and natural supports to be a valuable part of service planning. The rule does not address how thoroughly the information must be documented, nor would it be possible to do so. The documentation should be appropriate to the circumstances. No changes were made to the adopted rule as a result of this comment.

Comment 254: Section 9(I)(2)(g) Are these extra provisions unique to substance abuse treatment, or is the expectation these will apply across treatment types?

Response: The Department has reviewed this comment and notes that "co-occurring", in this context, refers broadly to "including acute or chronic medical conditions, trauma, or other conditions" as stated in the proposed rule. This requirements of this provision were clarified in response comment 181. No changes were made to the adopted rule as a result of this comment.

Comment 255: Section 9 I.2.i.iv Are these extra provisions unique to substance abuse treatment, or is the expectation these will apply across treatment types?

Response: The Department has reviewed this comment and has moved these sections of the proposed rule to Section 9(I) of the adopted rule. Please see comment 59. The rule does not limit the provision to substance abuse treatment. No changes were made to the adopted rule as a result of this comment.

Comment 256: Section 9 I.2.j Will this adjust how many hours a provider can bill for assessment and treatment planning? When thinking of some of our clients, we're talking about it already taking multiple sessions to complete one plan of care review and revision. Additional standards will increase plan of care writing time. Who is responsible for writing these behavioral support plans?

Response: The Department has reviewed this comment and finds questions about billing to fall outside the scope of this rulemaking. As a behavioral health service, behavioral support plans may be drafted by clinical staff working within their scope of practice. No changes were made to the adopted rule as a result of this comment.

Comment 257: Section 9 I.2.o. Does this hint at verbal approval as an acceptable means of authorization? If so, that does not align with current MECare rule.

Response: The Department has reviewed this comment and has revised Section 9(H)(2)(k) of the adopted rule in response to a previous comment. Please see comment 187. As is noted in the introductory paragraph to Section 9, organizations that are subject to other Department rules or contracts with the Department are

expected to comply with those requirements. No changes were made to the adopted rule as a result of this comment.

Comment 258: Section 9(J). Independent of the Plan of Care? And what is the threshold for "frequent need for emergency services?" And along these lines, how will an Intervention Plan differentiate from a Crisis Plan?

Response: The Department has reviewed this and other similar comments and deleted Section 9(J) of the proposed rule from the adopted rule due to concerns over the difficulty in distinguishing a crisis plan from an intervention plan. Please see comment 19, 39, 61, 147, and 188. No further changes were made to the adopted rule as a result of this comment.

Comment 259: Section 10 A.7 If a program/agency doesn't have a medical provider giving medical advice, how does/will this apply to those agencies? Is "medical" meant to apply across programs? If so, would "clinical" be a better term here?

Response: The Department has reviewed this comment and for the reasons raised therein and has revised Section 10(A)(7) to read: Specific procedures when a client leaves the program against clinical recommendations ~~medical advice~~.

Comment 260: Section 10 D.5 Is this only for clients with Serious Mental Illness (SMI), or is it being applied across the board?

Response: The Department has reviewed this comment and has determined Section 10(D)(5) of the proposed rule is unnecessary and deleted it from the adopted rule.

Comment 261: Section F.2 Seeing medical and clinical being used interchangeably here. May we request or suggest we use "clinical" if we're looking for a broader application? Or, perhaps another term that can encapsulate other professionals this rule would affect (such as RCS Coordinators or Case Managers)? Additionally, some of the services covered here don't involve a clinician as the advisor (e.g., RCS, BHH/TCM).

Response: The Department has reviewed this comment and for the reasons stated in this and other similar comments has amended Section 10(F) of the proposed rule to replace “medical” with “clinical” where appropriate. Please see comment 124.

Comment 262: G. We'll take the 30 days, but does this conflict with a different standard requiring 15 days?

Response: The Department has reviewed this comment and finds it lacks specificity about other standard(s) that may be in conflict, which restricts the Department’s ability to effectively respond. No changes were made to the adopted rule as a result of this comment.

Comment 263: Section 11 D. "The" organization is used everywhere else in this section. It should be used here as well for consistency.

Response: The Department has revised Section 11(D)(2)(a) to read: An employee of ~~an~~ the organization, or a member of the immediate family of an employee; and

Comment 264: *Appendix A*
I. Can this table document corresponding MECare sections for additional clarity?

Response: The Department has reviewed this comment and finds it falls outside the scope of this rulemaking. No changes were made to the adopted rule as a result of this comment.

Commenter #16:

Comment 265: Our chief concern is that the new regulations include a significant increase in administrative burden for behavioral health organizations. This could lead to higher and unsustainable costs to deliver services, which could result in program closures and limited access to care for individuals who desperately need and benefit from MBH's programs. We are also concerned with the financial burden posed by many of the requirements, particularly large-scale notification mailings such as those required in Sections 6 and 7. For organizations such as MBH that are already operating at a deficit, this additional expense will place a significant burden on us. Finally, we are also concerned that many new provisions are considerably more stringent than they were in the previous rules, which may lead to technical violations for issues that do not impact access to care that have not previously been a concern.

Response: The Department has reviewed this comment and finds it is mostly too broad for a response. However, the Department does address these general concerns within the responses to more specific comments submitted by this commenter. The proposed rule does not stipulate mailed notifications and, where notice is required, there are likely other more cost-effective means at the disposal of organizations. No changes were made to the adopted rule as a result of this comment.

Comment 266: We are concerned that, in combining the three existing rules, the proposed rule incorporates and references additional rules and therefore allows the Division of Licensing and Certification (DLC) a way to take licensing action based on violation of rules outside of the proposed rule. For example, Section 2.H says that the Department may issue a conditional license when an organization fails to comply with "applicable laws and rules," which covers more than noncompliance with the proposed rule. As another example, the introductory paragraphs in Sections 7, 8, and 9 say that, to the extent that an organization is subject to other Department rules such as the MaineCare Benefits Manual, it must comply with those rules; those requirements are limited to Department rules but require compliance with more than the proposed rule. We urge the Department to narrow the scope of the potential rule violations to the proposed rule, to confirm that proposed licensing rule addresses licensing issues.

Response: The Department has reviewed this comment and finds that reference to other existing rules and statutes is common within Department rules. The language in Section 2(H) identifying when the Department may issue a conditional license is also found in statute, including 22 M.R.S. § 7802(1)(C) and 34-B M.R.S. § 1203-A(2)(B). However, Section 4(I) lists the grounds for intermediate sanctions, including conditional licensure, and this Section is more limited. It does not include "when an organization fails to comply with applicable laws and rules" as a basis for a conditional license. No changes were made to the adopted rule as a result of this comment.

Comment 267: We are concerned that the program-specific standards are extensive and extremely specific. We are concerned that the Department will find technical violations where a new requirement has changed slightly from an existing requirement and urge the DLC to exercise discretion. We encourage the DLC to allow for a grace period once the proposed rule is implemented in order to allow MBH and other organizations time to bring our policies in line with the new requirements.

Response: The Department thanks the commenter. DLC will provide technical assistance regarding interpretation of this rule, when adopted, and understands that providers will require a transition period in which to achieve compliance. No changes were made to the adopted rule as a result of this comment.

Comment 268: We are concerned that many of the rule's enforcement provisions are more stringent than in the rules that are being repealed, particularly with regards to shorter deadlines for statements of deficiencies and plans of care, and we recommend that the Department bring these provisions into alignment with the previous rules in this area.

Response: The Department has reviewed this comment and finds that the provisions in the proposed rule serve to align the requirements for this group of licensees with the standards in place in other licensed settings. No changes were made to the adopted rule as a result of this comment.

Comment 269: *Section 2: Licensing and Certification Requirements I. Amended license required when changes occur*
We are concerned by the proposed requirement that an organization must notify the Department 90 days prior to the addition of a service, as it reduces flexibility for the organization to better meet the needs of the community. We recommend a 30 day notification period. We are supportive of notifying the Department 90 days ahead of any service deletion.

Response: The Department has reviewed this comment and, for the reasons cited therein, has revised Section 2(I)(1) of the adopted rule to read: The organization must notify the Department at least 30 ~~90~~ 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.

Comment 270: *Section 4. Enforcement and Inspections B. Organizational Cooperation*
We are concerned about the requirement that any records stored off-site must be produced within one business day. This could be challenging for items in deep storage, particularly if they pre-date electronic records. We request a longer timeframe, such as five business days, for producing the records. We are concerned by the provision to allow the Department to copy any documents or records. Per Section 16: Records Management and Retention, Part D: Client Records, client records must include any incident reports; such reports are typically a risk management protected document. Mental health and substance use licensing standards do not generally reference or require that an incident report must be included in the patient record. Currently, only medication errors and reactions are required to be recorded in an incident report in the patient's record (both errors of omission and commission) in residential facilities. If this provision is approved, all internal risk management reports for all mental health, substance use, and residential facilities would be placed specifically into the legal health record; this means that potentially they would become integrated into a client's electronic health record and no longer be protected internally, which could lead to privacy violations. We urge the Department to reconsider this provision.

Response: The Department has amended the final rule as follows:
Section 4(B)(1) of the proposed rule was amended to read:
1. 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 ~~one~~ five business days of the request;

Section 16(D)(3)(b) of the proposed rule was amended to read:

b. All treatment documents (including, but not limited to assessments, service plans, progress notes, incident~~/reportable event~~ report<u>s</u>, and discharge summary);

Comment 271: *Section 4 E. Plan of Correction*
We ask that the submission deadline for submitting an acceptable Plan of Correction be extended from the currently proposed 10 days, as many of the required elements for the plan would be challenging to complete in a satisfactory manner in such a short time frame. For example, an organization-wide plan to ensure full regulatory compliance throughout the licensed organization would take at least five business days to complete thoroughly. We also note that several provisions, for example, Section 2.D.5.b, mention a "Directed Plan of Correction," a term that is not defined. This suggests another enforcement mechanism that has not been previously codified; we ask for clarification about this term.

Response: The Department has reviewed this comment and finds that 10 days is standard timeframe across other licensed settings. When licensees are not in compliance with the rules, the goal is to achieve a plan for compliance quickly for the health and safety of the clients served. The Department has added a definition of Directed Plan of Correction at Section 1(A)(35).

Comment 272: Section 6. *D. Notification of Client Rights*
We are concerned by the new requirement to notify clients within 30 days of any changes to the organization's policy and to provide clients with a copy of the changes. As MBH has over 10,000 clients at any moment in time, this proposed requirement would impose a significant administrative burden on us, as we would be required to mail a notification to every client and to document that the client has received the notification. It is unclear if we would need to send the notification by certified mail in order to document receipt, which would add considerably to the cost. If we could both send the notification and document receipt electronically, that would significantly lessen the burden while ensuring that clients receive the notification. However, as drafted it is not clear that we would be allowed to utilize electronic communications. There would also be a considerable financial burden to this requirement, when the cost of postage, supplies, and staff time is taken into consideration. We urge the Department to remove this requirement or to allow electronic notification to reduce the burden to organizations. We are similarly concerned that the requirement for an organization to provide accommodation for any communication barriers is too broadly worded. We recommend that the Department allow organizations to combine all mandatory documentation and notifications into a single document that can be updated and shared annually in sync with annual paperwork requirements, rather than requiring multiple notifications and updates throughout the year.

Response: The Department has reviewed this comment and finds that the proposed rule does not prohibit electronic notification. The requirement to provide accommodation for any communication barriers is in accordance with the Americans with Disabilities Act and the requirements for translation services necessary for the provision of services. The Department has amended Section 6 (D) of the adopted rule in response to previous comments. Please see comments 101 and 120, which include changes allowing organizations to offer clients a copy of the change but not requiring a copy to be provided. No changes were made to the adopted rule as a result of this comment.

Comment 273: *Section 6 F. Right to freedom from abuse, neglect and/or exploitation*
Critical Incident Reporting is currently reported to the state via Kepro; we would encourage the Division of Licensure and the Office of Behavioral Health to coordinate access to these reports rather than asking provider organizations to duplicate reporting and documentation with new forms.

Response: The Department has reviewed this comment and finds the reporting requirements in the proposed rule to be necessary as the Kepro reporting platform is a proprietary contract with OBH. No changes were made to the adopted rule as a result of this comment.

Comment 274: *Section 6 G. An organization's internal rules and client non-compliance*
Please clarify that an electronic signature would be acceptable to demonstrate that a client and/or their legal representative has received a copy of an organization's internal rules.

Response: The Department has reviewed this comment and for the reasons given by the commenter has revised Sections 6(G)(1 and 2) to read:

1. Prepare a written document explaining the organization's internal rules and offer ~~provide~~ 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 ~~Obtain signed and dated documentation from the client and/or legal representative indicating receipt of the organization's internal rules and maintain this document in the client record; and~~

Comment 275: *Section 6 H. Right to information regarding licensing deficiencies*
We would appreciate clarification whether the requirement to inform clients of any deficiencies at intake is retrospective or only applies to new deficiencies going forward. We would strongly prefer that this provision apply only to new deficiencies going forward.

Response: The Department finds that Statements of Deficiencies are public record and should be made available without limitation. This section was amended in response to a prior comment. Please see comment 167. No changes were made to the adopted rule as a result of this comment.

Comment 276: We are particularly concerned by the requirement that a notification of deficiencies be sent to clients and their legal representatives within 15 days. As we have noted above, MBH has 10,000 clients open at any given point in time and it would represent a significant administrative burden to send out a notification via USPS to each one in such a short period of time. We would also appreciate clarification if "15 days" represents calendar days or business days; we strongly prefer business days.

Response: The 15 day notification requirement applies to Intermediate Sanctions and other actions taken against an organization's license, and not notification regarding deficiencies.

The Department has revised Section 15 (H)(2) of the adopted rule to read: 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.

Comment 277: *Section 7. Eligibility and Access to Services F. Notice of denial and referral*
The new requirement to send written notice of a denial of services would represent a significant burden for our practices as this is currently handled verbally, along with providing additional referral information. We

currently document the reasons for the denial of service in the referral notes; we encourage the Department to allow this to fulfill the requirement. We urge the Department to reconsider.

Response: The Department has reviewed this comment and, for the reasons in this and other comments, has deleted Section 7(F) from the adopted rule. See the response to Comment 16.

Comment 278: We are very concerned by the provision in 7.F.2 that an organization may not deny service to an individual with serious mental illness without prior approval of the Office of Behavioral Health. The proposed rule does not define "serious mental illness," nor does it appear to leave room for denying services if we are unable to meet the assessed needs of a patient with serious mental illness. This could leave MBH open to a licensing violation if we deny services based on inability to provide appropriate care. We note that "severe and persistent mental illness" is defined in statute,[1] but not "serious illness." We urge the Department to clarify this provision, including the definition of serious illness, and to give more leeway for organizations to be able to deny services if they cannot provide appropriate care.
[1] https://legislature.maine.gov/statutes/34-B/title34-Bsec3801.html

Response: The Department removed Section 7(F) of the proposed rule from the adopted rule for the reasons cited in this and other previous, similar comments. Please see comment 16.

Comment 279: *Section 8. Comprehensive Client Assessment D. Other Assessments*
We would like clarification about the types of assessments envisioned under this provision, including whether they are required to be evidence-based, to ensure they are aligned with MBH's assessments.

Response: The Department has reviewed this comment and has determined that the domains listed in Section 8 (D) are included in Section 8 (C) and has deleted Section 8 D from the adopted rule**.**

Comment 280: *Section 9. Client Service Plan*
We request clarification of the time frame for the completion and review of service plans, including whether they are based in the licensing standards or in MaineCare standards. In particular, Section L states that treatment plans must be reviewed every 90 days unless otherwise specified, but MaineCare requirements for outpatient psychiatry services state that treatment plans must be reviewed "every twelve visits or annually, whichever comes first" (10-144 MaineCare Benefits Manual Chapter 2, Section 65.08). We ask the Department to coordinate with MaineCare to ensure that a single standard applies and urge the department to add a specification for OP psychiatry to align the licensing standards with the MaineCare standards (in order to eliminate administrative burden and improve access to care).

Response: The Department has reviewed this comment and notes that service specific standards for Outpatient and other types of services are clarified in Sections 22 and 23 of the adopted rule. The Department has revised Section 22(F) in response to a previous comment that also cited the MaineCare standards. Please see comment 143. No further changes were made to the adopted rule as a result of this comment.

Comment 281: *Section 11. Governing Authority F. Responsibilities*
We are concerned by the proposed requirement for an organization's governing body to approve the policies and procedures required by the rule. MBH's governing body does not currently undertake this level of approval and it could be a significant burden or barrier to updating policies quickly as needed. We recommend that the governing body delegate this authority in writing to the administrator. Our policies are

currently reviewed every three years, not every year as proposed in the rule, and we recommend the longer time frame as annual policy reviews might be burdensome.

Response: The Department has reviewed this comment and notes that rule allows for organizations to apply for waiver of specific rule provisions. The standards in the proposed rule for policy approval by the governing authority and annual policy review are appropriate for many organizations. No changes were made to the adopted rule as a result of this comment.

Comment 282: *Section 12. Program Administration B. Administrator*
This provision requires an administrator to notify the Department within one day of learning of "criminal activities" on the grounds of the organization or at a service location. We are concerned that this requirement is very broad and full compliance would be extremely difficult. While we might be able to report obvious issues, such as drug dealing on our premises, it would be more challenging to report other issues and the justification for why we should do so is unclear. For example, if an employee is committing cybercrimes through their phone while they are at work, should we be required to report it? We are also concerned that there is no definition of what is included under "criminal activities" and would appreciate clarification.

Response: The Department has reviewed this comment and has revised Section 12 (B) of the proposed rule for the reasons identified in a previous comment. Please see comment 105. No further changes were made to the adopted rule as a result of this comment.

Comment 283: *Section 12 F. Reporting adverse events*
We would like a definition of "adverse event" to be included in the rule; we are concerned that without a definition, the DLC might identify violations based on issues that we do not consider to be adverse events. As above, we would like clarification about the level of "suspected criminal behavior" by a client that is required to be reported. For example, if a client were to hypothetically steal a hot meal at a grocery store and MBH staff became aware, would that be reportable? We urge the Department to delete this requirement.

Response: The Department has reviewed this comment and finds that specific adverse events are defined in Section 12(F)(1) of the rule, and that organizations are required to define additional adverse events through development of policy. Section 12(F)(1)(b), which used the term "suspected criminal behavior," was deleted from the final rule in response to comments 69, 106, and 197. No further changes were made to the adopted rule as a result of this comment.

Comment 284: *Section 19. Risk Management D. Quarterly review*
We are concerned that this new requirement would add to the already increased administrative burden under the proposed rule.

Response: The Department has reviewed this comment and declines to make changes to the rule based on the comment. Quarterly review of immediate and ongoing risks is necessary to ensure that pressing concerns are addressed and that clients are receiving safe, effective care in accordance with the rules. The Department has, however, made changes to this section based on other comments (see comments 75 and 76). No changes were made to the adopted rule as a result of this comment.

Comment 285: *Section 21. Standards for All Residential Programs A. Program manager*
We are deeply concerned by the requirement that each residential facility have its own on-site program manager; currently, the regulations for Level IV PNMI homes require the program manager to be "in the

program" a minimum of 20 hours a week, and this has allowed us to have program managers cover two facilities. MBH would need to double our number of program managers to meet this requirement. At a time when we are already struggling to fill our existing positions, adding personnel would be extremely challenging and could potentially result in service reductions.

Response: The Department has reviewed this comment and, for the reasons cited, has clarified Section 21 (A) of the adopted rule to read:

A. 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.

Comment 286: *B. General Program Requirements*
We are concerned that the amount of information required to be collected when a client under legal guardianship makes an overnight visit is burdensome, particularly as the clients themselves may not wish the share this information.

Response: The Department has reviewed this comment. Section 21 (B)(6) of the proposed rule was revised in response to an earlier comment raising similar concerns to those cited by the commenter. Please see comment 132.

Commenter #17:

Comment 287: *Purpose and Applicability*
On page 1, in the Purpose and Applicability section Part A. Purpose, the proposed rule states, "Upon the effective date of this rule, licensees previously regulated under the provisions of one of the above-listed repealed rules are subject to Behavioral Health Organizations Licensing Rule." Does the department anticipate a window of time between enactment of the proposed rule change to allow for provider compliance? If yes, what is the anticipated timeline by which organizations are expected to comply once the rule change takes effect?

Response: The Department has reviewed this comment and finds that guidance about a timeline for enforcement is outside the scope of rulemaking. No changes were made to the adopted rule as a result of this comment.

Comment 288: *Section 1. Definitions*
Page 5, #44, states, "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 system of care." Can the department please define "system of care"?

Response: The Department has reviewed this comment and has revised Section 1(A)(44) for clarity to read: 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 ~~system of care~~. 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.

Comment 289: *Section 2. Licensing and Certification Requirements*
On page 10, part C. For client confidentiality and safety (especially with domestic-related crises), it has been agency policy not to publish publicly the locations of our Crisis Stabilization Units. In the proposed rule, we would be required to post the locations of those units; we respectfully request that crisis stabilization units be exempt from the requirement or that the "department listing licensed sites and service locations of the organization exclude the exact address of crisis stabilization units," to protect client confidentiality and safety.

Response: The Department as reviewed this comment and has revised Section 2(C) of the adopted rule to read: C. License posted. A copy of the current valid license, ~~with the accompanying letter from the Department listing licensed sites and service locations of the organization and the services provided at each location,~~ must be conspicuously posted where it may be seen by the public at each of the locations where services are provided.

Comment 290: On page 12, part K. Issued license extends to identified physical sites; #2 states, "A private residence may not be approved as a site for the delivery of mental health and/or substance use disorder treatment." Does this apply to the delivery of telehealth services by the clinicians/providers from their private residences?

Response: The Department has reviewed this comment and, for the reasons in this and other similar comments, has clarified the definition of "site" at Section 1(A)(89) of the adopted rule to add "A location from which telehealth services are delivered is not a site." Please see response to comment 14.

Comment 291: *Section 5. Complaint Investigation*
On page 20, in part B, can the department please provide the preferred toll-free telephone number and URL it requires to be posted?

Response: The Department has reviewed this comment and finds that including the current telephone number and/or URL in rule would create a need for rulemaking in the event that either changes in the future. This information is readily available on the DLC web page at https://www.maine.gov/dhhs/dlc/. The current telephone numbers are 1-800-383-2441 or 207-287-9308 and the URL for complaint reporting is https://www.maine.gov/dhhs/dlc/safety-reporting/file-a-complaint. No changes were made to the adopted rule as a result of this comment.

Comment 292: *Section 6. Client Rights*
On page 21, section B, Organizational Policy, part 2 states, "If providing residential services, the organization must develop policies around visitation, telephone privileges, and client mail." Does the department anticipate this requirement applying to crisis stabilization units?

Response: The Department finds that the definition of residential services in Section 1(81) of the final rule is sufficiently clear and includes crisis residential services. No changes were made to the adopted rule as a result of this comment.

Comment 293: *Section 7. Eligibility and Access to Services*
On page 24, section F, Notice of denial and referral, states, "The organization must send applicants written notice when an application for services is denied." Can the department define applicants? Additionally, can the department provide parameters or a definition of an "application for services"?

Response: The Department has reviewed this comment and notes that Section 7(F) of the proposed rule was removed from the adopted rule in response to a previous comment. Please see comment 16. No further changes were made to the adopted rule as a result of this comment.

Comment 294: On page 24, section 7.F, Notice of denial and referral, part 2 states, "An organization may not deny service to an individual a serious mental illness, or involuntarily discharge a client with serious mental illness, without the prior approval of OBH."

Response: The Department has reviewed this comment and notes that Section 7(F) of the proposed rule was removed from the adopted rule in response to a previous comment. Please see comment 16. No further changes were made to the adopted rule as a result of this comment.

Comment 295: Can the department define "serious mental illness"? What if the diagnosis/functional level is not known/provided at the time of "application"? Does the department anticipate this requirement applies to crisis services, including crisis stabilization units?

Response: The Department has reviewed this comment and notes that Section 7(F) of the proposed rule was removed from the adopted rule in response to a previous comment. Please see comment 16. No further changes were made to the adopted rule as a result of this comment.

Comment 296: *Section 8. Comprehensive Client Assessment*
On page 25, section C, Comprehensive Assessment, states, "The organization must complete a comprehensive assessment of each client to determine the need for treatment and services." Does the department anticipate this requirement applies to crisis services, including crisis stabilization units?

Response: The Department has reviewed this comment and finds the requirements for the crisis services module in Section 22 (E), including the provisions regarding crisis assessments at Section 22 (E)(4), to be clear. No changes were made to the adopted rule as a result of this comment.

Comment 297: *Section 9. Client Service Plan*
On page 27, the "client service plan" appears to be similar to the "intervention plan" (in definitions on page 5, #46). Is the "client service plan" intended for all services delivered by a licensed organization, or is it specific to one type of service delivery, e.g., crisis services? Further, are the "client service plan," "intervention plan," and "treatment plan" all the same, and if not, what are the differences?

Response: The Department has reviewed this comment and has made multiple revisions to the sections of the proposed rule related to service plans, intervention plans, behavioral support plans, and crisis plans as clarifications. In particular, the Department removed Section 9(J) on intervention plans from the final rule in response to comments 19, 39, 61, 147, 188, and 258. Please see these and other comments and the adopted rule, Section 9. No changes were made to the adopted rule as a result of this comment.

Comment 298: On page 27, section 9.C, Service Plan Team calls for "the service plan team must include the client, the client's guardian or legal representative, clinical consultants, and other persons chosen by the client, as appropriate." Can the department please define clinical consultant? Does the department anticipate this requirement applies to crisis services, including crisis stabilization units?

Response: The Department has reviewed this comment and has replaced the phrase "clinical consultants" with "clinician" in Section 9 (C) of the adopted rule for clarity. Section 9 is part of the core standards of the rule, so this provision applies to all organizations and services.

Comment 299: On page 28, in part I. (Service Plan), section H, the proposed rule states that "the written service plan must include…evidence that services to victims or survivors of rape or incest are either provided directly or through referral." What if the client is not seeking treatment for rape or incest but for something else? Are providers required to provide treatment or referral for treatment regardless of the client's wishes?

Response: The Department has reviewed this comment and, for the reasons cited by this and other commenters, has deleted Section 9 (I)(2)(h) of the proposed rule from the adopted rule. Please see the response to comment 182. No further changes were made to the adopted rule as a result of this comment.

Comment 300: *Section 11. Governing Authority*
On page 32, section D, part 3 indicates that any individual who is an "employee of an entity holding a contract relationship with the organization" is prohibited from serving on the board of directors or advisory board. Can the department please define the parameters of "contract"? Would internship "contracts" with colleges/universities preclude a member of the same university/faculty from sitting on our organization's board of directors or advisory board?

Response: The Department has reviewed this comment and notes that clarifications of Section 11(D) responsive to this comment were made in the adopted rule in response to previous comments. See the response and revision related to comment 65. No further changes were made to the adopted rule as a result of this comment.

Comment 301: *Section 13. Personnel*
On page 37, section A, Personnel records, the proposed rule states, "the organization must maintain records for all personnel, except for short-term or episodic volunteers whose job responsibilities do not involve direct client contact." We appreciate the clarification and flexibility for engaging short-term or episodic volunteers. Can the department define "short-term or episodic"? Additionally, can the department define "all personnel"? Does this rule pertain only to direct care staff or staff with access to clients, or does it include administrative staff?

Response: The Department has reviewed this comment and determined that the rule provision is sufficiently clear and the terms used should be given their common meanings. No changes were made to the adopted rule as a result of this comment.

Comment 302: On page 37, section C, Qualifications, part 2, the proposed rule states, "the organization must verify and document the reference 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." Additional guidance on the expectation for verification by defining "verify" would be helpful to understand how organizations will comply. Are organizations asked to simply collect the documentation for personnel files or verify documentation is accurate? For instance, a person with a Bachelor's degree brings in a copy of their degree. Is that enough, or do we need to verify with the educational institution that they received their bachelors?

Response: The Department has reviewed this comment and finds that clarifications of Section 13 (C)(2) were made in the adopted rule in response to this and previous comments. See the response and revision related to comment 220, which eliminates the word "verify.".

Comment 303: On page 37, section G, Nurse Consultant, the proposed rule states, "An organization providing, prescribing, or administering medication must have a nurse consultant on staff or under contract." Does the department anticipate this requirement applies to crisis services, specifically crisis stabilization units?

Response: The Department has reviewed this comment and notes that, for the reasons in this and other similar comments, clarifications of Section 13 (G) were made in the adopted rule. See the response and revision related to comments 10 and 199. The scope of this requirement is clear and applies to any organization providing medication administration services. No further changes were made to the adopted rule as a result of this comment.

Comment 304: On page 38, section G, Nurse Consultant, part 2, the proposed rule states, "The nurse consultant may be a registered nurse." Can the department provide a complete listing of qualifying license types to fulfill this role? Further, if an organization has a medical director on staff, can the MD perform the duties and functions of a Nurse Consultant?

Response: The Department has reviewed this comment and has deleted Section 13 (G)(2) of the proposed rule from the adopted rule. A licensed physician may perform the functions of other staff in the health care field with lower levels of education and training.

Comment 305: On page 39, section I, Orientation and training, part 2, the proposed rule states, "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." What does "relevant licensing and certification standards" mean? Is this language limited to personnel with a professional license (i.e., LCSW) or credential (i.e., MHRT I or C) to follow those guidelines for continuing education?

Response: The Department has reviewed this comment and finds that training requirements within the rule are clear and contained in multiple sections throughout the rule, including but not limited to Sections 15, 21, 22 and 23. No changes were made to the adopted rule as a result of this comment.

Comment 306: On page 39, section I, Orientation and training, part 4, can the department clarify if the expectation is that all organization staff receive Trauma Informed Care and SAMHSA's System of Care Principals training within 90 days or if the requirement is for program-specific staff?

Response: The Department has reviewed this comment and has revised Section 13(I)(4) of the adopted rule to read: An organization providing children's behavioral health services must ensure that staff <u>providing these services</u> participate in Trauma-Informed Care training and SAMSHA's System of Care Principles training within the first 90 days of employment.

Comment 307: *Section 14. Independent Contractors*
On page 40, section C, Obligations of the independent contractor, parts 4 and 5, if the independent contractor provides client services to an organization's clients from the organization's place of business, is the independent contractor expected to put a notice up at their other places of business, where they do not see the organization's clients, to demonstrate that they have a relationship with the contracting organization?

Response: The Department has reviewed this comment and finds the elements of the written contract between an organization and an independent contractor in the proposed rule to the clear as written as it pertains to an organization's "clients" as defined in the rule. No changes were made to the adopted rule as a result of this comment.

Comment 308: *Section 15. Medication Administration*
On page 42, section D, Client transfers, does the department anticipate this requirement applying to crisis stabilization units?

Response: The Department has reviewed this comment and determined that the rule is sufficiently clear that this provision applies to organizations that offer medication administration services and that are transferring clients to a different organization. No changes were made to the adopted rule as a result of this comment.

Comment 309: On page 42, section E, Self-administered medications, part 2, the proposed rule reads, "If the medical director determines that the client needs supervision in the administration of medication, the medical director must document this finding in the medical orders." Does this rule apply to crisis residential/crisis stabilization units? By nature of crisis services, all clients are determined to need the administration of meds and supervision of self-administered injectable meds, and a medical director is not involved in that decision. If yes, we request that the department reconsider its position.

It will be challenging to comply with this section of the rule, specifically given the short-term nature of client stays (1-7 days). Clients are admitted to a crisis residential level of care seven days per week, 365 days per year. Medication administration management is coordinated at the time of admission; the cost associated with having a medical director available to make these determinations for clients who require self-administered meds (e.g., insulin) would be prohibitively high. As a result of those costs and the workforce availability of a medical director seven days per week, 365 days per year, client admissions will likely be delayed until a medical director can clear them for admission. All fully trained crisis residential staff are CRMA certified and can pass meds compliant with prescribers' orders to limit the need to self-administer medications. Currently, in instances where self-administration is required in crisis stabilization units, staff observe self-administration of medications.

CRMA does not provide documented training on injectables. However, it is an add-on for EpiPen usage and Insulin, but those regs say it must be CLIENT-SPECIFIC training. Meaning every time a new client with diabetes is admitted, staff would need to be trained on insulin use for THAT particular client. That would not be possible in a crisis stabilization unit where clients rotate in for short-term stays but do not reside (live) in the home.

Response: The Department has reviewed this comment and notes that, for the reasons in this and other comments, Section 15(E)(2) of the adopted has been clarified to remove the reference to medical directors. Please see comment 33. No changes were made to the adopted rule as a result of this comment.

Comment 310: On page 44, section K, Licensed practitioner's order required. Does the department anticipate this requirement applying to crisis stabilization units?

Response: The Department has reviewed this comment and determined that the proposed rule is clear that this provision applies to organizations that administer medications. The Department notes that

organizations may apply for waivers of provisions with an alternate method that meets intent of rule. No changes were made to the adopted rule as a result of this comment.

Comment 311: Section 21. Standards for all Residential Programs
Does the department consider Crisis Stabilization Units "residential programs"?

Response: The Department has reviewed this comment and determined that the definition of "residential program" is sufficiently clear in Section 1 of the proposed rule. No changes were made to the adopted rule as a result of this comment.

Comment 312: *Section 22. Mental Health Programs*

On page 63, section E, Crisis services module, part 2c., can the department define supportive counseling?

Response: The Department has reviewed this comment and determined that supportive counseling is a phrase in common usage and does not require definition in this rule. No changes were made to the adopted rule as a result of this comment.

Comment 313: On page 63, section E, Crisis services module, part 2c., can the department define supportive counseling?

Response: The Department has reviewed this comment and determined that supportive counseling is a phrase in common usage and does not require definition in this rule. No changes were made to the adopted rule as a result of this comment.

Comment 314: On page 63, section E, Crisis services module, part 4a., the proposed rule indicates that the program must have access to a psychiatric consultant. Can the department define psychiatric consultant, including the required qualifications?

Response: The Department has reviewed this comment and has broadened Section 22(E)(4)(a) of the proposed rule to read:

a. ~~The crisis services program must have access to a psychiatric consultant who is~~ 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.

Comment 315: On page 63, section E, Crisis services module, part 4b. iii. the proposed rule states, "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." Can the department provide a comprehensive list of licensures or credentials that satisfy the definition of "appropriately qualified professionals"?

Response: The Department has reviewed this comment and notes that Section 22(E)(4)(b)(iii) of the adopted rule was clarified in response to an earlier comment. Please see comment 113. Although the Department has not created a comprehensive list, the examples of appropriately qualified professionals suggests that other similar professionals could also be qualified. No changes were made to the adopted rule as a result of this comment.

Comment 316: On page 65, section E, Crisis services module, part 11, can the department define "rescue services" and "rescue procedures"?

Response: The Department has reviewed this comment and finds that Section 22(E)(11) of the adopted rule was clarified in response to an earlier, similar comment. Please see comment 136. No further changes were made to the adopted rule as a result of this comment.

Comment 317: On page 65, section E, Crisis services module, part 17e.i., can the department define "crisis counselor"?

Response: The Department has revised Section 22 (E)(17)(e)(i) of the proposed rule to read:
i. 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.

Comment 318: *Section 23. Substance Use Disorder Treatment Programs*
On page 73, #2, and #3B, the terms "medical screening" and "medical assessment" will be required as part of the clinical record. Can the department clarify expectations regarding what should be included in these medical screenings and assessments?

Response: The Department has reviewed this comment and determined that the rule is sufficiently clear that medical screening is completed to determine if medical care is needed. Additional language was added to Section 23(G)(2) to help clarify how the need for further medical testing or examination may be indicated. See comment 216. No further changes were made to the adopted rule as a result of this comment.

Comment 319: *Appendix A. Modules and Services*
Does the department anticipate that an organization with a substance use-only license will be licensed to provide crisis services?

Response: The Department has reviewed this comment and determined that crisis services are a module under Substance Use Disorder licensure. No changes were made to the adopted rule as a result of this comment.

Commenter #18:

Comment 320: Our first comment is that we appreciate the new format and find this much easier to navigate than the previous system of multiple rules. Great idea, thanks!

Response: The Department has reviewed this comment and thanks the commenter.

Comment 321: Page 31: C.3.: We would advocate for inclusion of the ICD-10-CM (and subsequent editions) as an acceptable alternative to the DSM for diagnosis. The ICD 10 CM was developed by the US Dept. of Health and Human Services and aligns closely with other relevant diagnostic tools, including ASAM.

Response: The Department reviewed this comment and has further revised Sections 8(C)(3 and 4) of the adopted rule to read:

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-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 clinician 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 c~~C~~riteria.

Comment 322: Page 31: E.: We would advocate for removal or revision of this proposed requirement. Movement between levels of care is often fluid, and completing a new comprehensive assessment may slow down the process of moving clients into the level of care that is required, in addition to tying up additional clinical staff time. This is even more significant if programs are required to renew comprehensive assessments every time a client experiences "a major life event." This is open to a wide variety of interpretation.

Response: The Department was reviewed the comment and finds the provisions Section 8(E) of the proposed rule to be broadly phrased to allow for clinical judgment. Updating the comprehensive assessment as described in the rule is not meant to require completing a new assessment, and assessment updates may be addressed in the organization's assessment policy. No changes were made to the adopted rule as a result of this comment.

Comment 323: Page 33: C: As written, this will require the client, client's guardian or lawyer, "clinical consultants (we're not sure what this means), and others chosen by the client when creating or updating a service plan. We would advocate for inclusion of "and/or," or similar language, as gathering all of these parties for every treatment plan review is not a realistic requirement.

Response: The Department has reviewed the comment and finds Section 9 (C) of the proposed rule has been revised in response to an earlier comment to remove the term "clinical consultants" and provide clearer language. Please see the response to comment 298. The Department declines to make inclusion of the identified service plan team members optional by using "and/or" to describe who must be included on the team. If the client has these relationships (e.g., a guardian), the individual must be included in the service plan team. The Department also notes that although the commenter equates "legal representative" with "lawyer," the term "legal representative" in this context takes the meaning given in the rule's definitions. No further changes were made to the adopted rule as a result of this comment.

Comment 324: Page 36: D: Provision of 30 days' notice of involuntary discharge is not realistic in many cases – for example if a client is involved in a violent conflict on agency grounds or requires immediate detox prior to returning to services. In addition, agencies are frequently unable to contact clients prior to discharge (or following discharge) when individuals leave services without notice and are currently homeless and/or without access to a personal phone or computer. To require this of all involuntary discharges is not feasible.

Response: The Department has reviewed the comment and notes Section 10 (D) of the proposed rule has been revised in response to an earlier comment. Please see the response to comments 189 and 190. The rule

retains the requirement for at least 30 days' notice of involuntary, discharge, however, unless the circumstances are appropriate for emergency discharge as set forth in Section 10(E) of the proposed rule. A client who was involved in a violent conflict or who requires immediate detox may be appropriate for emergency discharge, depending on the totality of the circumstances. Finally, there is a separate rule provision for self-discharge, which is found in Section 10(F) of the proposed rule, which may be considered for those clients who self-discharge against clinical recommendations. No changes were made to the adopted rule as a result of this comment.

Comment 325: Page 40: C.: This requires "evidence based practices for that specific client-group." There are not evidence-based practices available for all specific client groups. In addition, this language limits the use of promising practices that may be effective.

Response: The Department has reviewed this comment and Section 12(C), and determined that evidence-based practices are the most appropriate standard to promote health and safety of clients. No changes were made to the adopted rule as a result of this comment.

Comment 326: Page 43: B.3.: At present, Child Protective Services records are not necessary for employing professionals who do not work with children. We would advocate for continuation of the current requirement for APS for individuals who work with adults and CPS for individuals who work with children, as adding additional unrelated checks creates additional unnecessary expense.

Response: The Department has reviewed this comment and Section 13(B)(3) and determined that the abuse/neglect history of employees is relevant regardless of the age group of the victim. No changes were made to the adopted rule as a result of this comment.

Comment 327: Page 43: D.2.: The requirement to review job descriptions annually presents additional administrative expense and is not necessary in most cases.

Response: The Department finds that the review of job descriptions is part of the performance evaluation process, which is required annually. Please see the response to comment 70. No changes were made to the adopted rule as a result of this comment.

Comment 328: Page 43.G.: The addition of a "Nurse consultant" presents an outrageous challenge to providers. This position is unnecessary for most practices. There is a national shortage of nurses, so filling this required position poses a significant challenge. In addition, nurse salaries are very expensive relative to other clinical staff. The addition of this position is completely unworkable and should be removed.

Response: The Department has reviewed the comment and notes Section 13(G) of the proposed rule has been revised for reasons provided in this and other comments. Please see the responses to comments 10, 199, 303, and 304.

Comment 329: Page 57: D.: We appreciate the modification of requirements for annual audits, as the GAAP audit has been challenging for our organization to complete.

Response: The Department has reviewed this comment and thanks the commenter.

Comment 330: Page 59: All: This new section is unnecessary and poses an additional administrative burden. The administrative requirements within this field are already considerable, and more quarterly reviews will result in additional work for agencies with no benefit to clients.

Response: The Department has reviewed this comment and it is not clear which section of rule the commenter feels is unnecessary. Throughout this set of comments, the page numbers cited do not match the pagination of the proposed rule. This appears, however, to be a reference to Section 19. The risk management practices required by the rule were carefully considered and, in the Department's view, provide necessary and useful tools for organizations. Please also see the response to comment 284. No changes were made to the adopted rule as a result of this comment.

Comment 331: Page 61: C: "…must be developed with the assistance of qualified fire, health and safety agencies." This requirement is vague and difficult to complete – we are not aware of agencies available to consult in completion of this. All plans that have previously been approved by the Department should be sufficient rather than requiring additional cost of contracting with additional agencies – this creates additional administrative and cost burden without benefit to clients.

Response: The Department has reviewed the comment and finds that the assistance of such professionals may be extremely helpful, but recognized the commentor's intent. The Department has amended Section 21(C) of the proposed rule to allow for more permissive language, to read: Revise 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 ~~must~~ may be developed with the assistance of qualified fire, health and safety agencies.-At a minimum, the plan must address the following:

Comment 332: Page 62: D.1.b and D.1.c.: Requirement of "therapeutic diet" is vague, and inclusion of dietician for all client diets, if that is the intention of this rule, is an unusual, unnecessary additional expense. We would advocate that these requirements are removed or revised.

Response: The Department has reviewed the comment and finds that the language in Sections 21(D)(1)(a) and (b) of the proposed rule provides a description of therapeutic diets and that Section 21(D)(1)(c) requires that the program have a current therapeutic diet manual, but a dietician is not required. No changes were made to the adopted rule as a result of this comment.

Comment 333: Page 62: E.3.: Requirement of a central heating system is an enormous expense that will create a significant new barrier to existing programs as well as new programs seeking to increase access to care for residential services. This is practically impossible for small businesses and would create an environment in which only major existing health systems would be able to create residential services due to significant up-front costs. We advocate for removal of this requirement.

Response: The Department has reviewed this comment and determined that in common usage, 'central heating plant' means a system such as a furnace or boiler that heats a building. No changes were made to the adopted rule as a result of this comment.

Comment 334: Page 64: 12.c.i. and 12.c.iii.: We would advocate that existing programs with floor plans that do not meet these two requirements but are licensed and active in the state be "grandfathered," rather

than required to renovate existing buildings and reducing currently approved treatment beds – failure to do this will reduce available beds for a service that is already too limited to meet demand.

Response: The Department has reviewed this comment and has relocated Section 21(E)(12)(C)(iii) of the proposed rule to Section 22G)(2)(a)(vi) of the adopted rule for the reasons cited in this and a similar comment. Please see the response to comment 213.

Comment 335: Page 64: 12.e.: In many cases client-provided decorations are unfit for a group setting (e.g. images with nudity, violence, drug use, etc); and client-provided furnishings may not be fit for size of available rooms, doorways, etc. We would advocate for softening of the language of this requirement to allow agency discretion for what can be brought into facilities.

Response: The Department has reviewed this comment and finds that there is adequate flexibility in the language of Section 21(E)(12)(e) of the proposed rule: e. 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. Either the program rules (See Section 6(B)(3) or the client's service plan would allow addressing objectionable materials. No changes were made to the adopted rule as a result of this comment.

Comment 336: Page 65. G.: Diabetes management training from a registered nurse to all direct access workers presents an additional administrative and cost burden. This need can be aptly met with far less administrative oversight and we would advocate for removal of this requirement as it is largely redundant with the requirements on food services listed previously in this section.

Response: The Department has reviewed this comment and has revised Section 21(G) of the adopted rule to read: A direct access worker providing ~~care~~ 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:

Comment 337: Page 66: H.1.: Requirement that the facility employ or contract with a person with certification or training in IPC is an unnecessary expense. H.e. requires that plans reflect Maine CDC standards, which provide guidance obviating the need for an additional contractor.

Response: The Department has reviewed this comment and finds that online training in Infection Prevention and Control is available at no cost through federal Centers for Disease Control. An employee of the organization could complete this training and satisfy the requirements of Section 21(H)(1), and this requirement may not incur expense for the organization. No changes were made to the adopted rule as a result of this comment.

Comment 338: Page 66. H.2.b.: The Maine CDC updates guidance frequently and does not provide notice to all licensed providers. Requiring agencies to monitor for all Maine CDC updates to guidance for all conditions presents a significant administrative burden without benefit to clients.

Response: The Department has reviewed this comment and finds that this rule was developed in consultation with MeCDC and is based on their recommendations for minimum standards. No changes were made to the adopted rule as a result of this comment.

Comment 339: Page 67.4.a-d.: Requirement that the facility implement ALL recommendations of the Maine CDC is not realistic or necessarily beneficial for reasons listed in 19. CDC recommendations are often irrelevant to client population, and sometimes change daily or multiple times a day – requiring update to policy documents for every change is not realistic.

Response: The Department has reviewed this comment and finds that this rule was developed in consultation with MeCDC and is based on their recommendations for minimum standards. No changes were made to the adopted rule as a result of this comment.

Comment 340: Page 77: C: Requiring use of a DHHS-provided waitlist system creates an unnecessary administrative burden. DHHS-provided systems (e.g. MainePAS) are typically unwieldy and onerous. Maintaining a waitlist can be accomplished very efficiently with a simple spreadsheet, freeing administrative staff to complete other tasks rather than navigating yet another department portal.

Response: The Department has reviewed this comment and determined that the rule was developed in consultation with the Office of Behavioral Health and this provision is necessary to determine system need and capacity. No changes were made to the adopted rule as a result of this comment.

Comment 341: Page 77: D. 2.: Requirement of a 24-hour on-call medical professional is an unreasonable additional expense for most types of facilities. Furthermore, this does not stand to benefit clients, as emergency services will be recommended and utilized in the vast majority of after-hours issues.

Response : The Department has reviewed this comment and, for the reasons cited in this and other similar comments, has deleted Section 23(D)(2) of the proposed rule from the adopted rule. Please see the response to comment 10.

Comment 342: Page 78: D.3.: Requirement of a nurse or LPN is unnecessary, unrealistic, and expensive, for reasons stated above (including the national shortage of nurses – this will be an extremely difficult position to fill and is not a reasonable requirement).

Response: The Department has reviewed this comment and has deleted Section 23 (D)(3) of the proposed rule from the adopted rule, and notes that RN consultant continues to be a requirement if the program is administering medications in Section 13 of the adopted rule.

Comment 343: Page 79: 4.b.: MOUD service plans are unlikely to include all services provided by an agency that provides more than one type of care: many MOUD clients will not require mental health medication management, for example, and none will be eligible to engage in residential, IOP, and outpatient services at the same time.

Response: The Department has reviewed this comment and has revised Section 23 (G)(4)(b) of the proposed rule to read: MOUD service plans must include all <u>relevant</u> SUD services provided by organization.

Comment 344: Page 82: H.2.: Meaningful access to OTPs (methadone) is not a realistic requirement, as Mainecare considers OTPs non-concurrent with all other substance use service types. Additionally, waitlists for OTPs are typically several months long, and as such we are typically unable to provide 'meaningful' access to methadone.

Response: The Department has reviewed this comment and, for the reasons stated by the commenter, has revised Section 23(H)(2) to read: 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 ~~provide meaningful~~ 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.

Comment 345: Page 82. H.3.f.: Requiring a Licensed Practitioner (what does this mean) to be on-call is not helpful to clients who are experiencing medical emergencies – any client contacting any medical provider will be immediately referred to emergency services and as such it would be safer and better for client health that they reach directly out to emergency services. This is an unnecessary expense that may actually harm clients who are experiencing medical emergencies.

Response: The Department has reviewed this comment and, for the reasons cited by the commenter, has revised Section 23(H)(3)(f) of the proposed rule to read: ~~Physician Licensed practitioner back-up and~~ ~~o~~On-call staff must be provided to deal with ~~medical~~ emergencies; Section 23(H)(3)(k), containing similar language, was deleted from the rule.

Comment 346: Page 82. H. i. and H.j.: These are unnecessary and irrelevant in almost all cases. Emergency services do not require any contract to provide emergency services; regardless of location if called they will provide medical care if requested. This doesn't make any sense and constitutes an additional unnecessary administrative burden.

Response: The Department has reviewed this comment and, for the reasons cited by the commenter, has revised Sections 23(H)(3)(i) and (j) of the adopted rule to read:

(i) There must be a written ~~agreement~~ plan for transportation between the program and emergency care facilities;

(j) The program must ~~have a written agreement with an ambulance service to assure~~ 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;

Commenter #19:

Comment 347: Background on OTPs and how they operate. By way of background, opioid treatment programs ("OTPs") are outpatient programs that provide comprehensive treatment services for opioid use disorder and are among the most heavily regulated forms of health care. OTPs are extensively regulated at the federal level by the Substance Abuse and Mental Health Services Administration (SAMHSA) and the Drug Enforcement Administration (DEA). Part of the benefit of OTPs is the flexibility that they provide as the programs can be hospital-based, standalone, or part of a larger program.

Response: The Department thanks the commenter for background information and has identified no changes to the rule in response to this comment.

Comment 348: As part of their comprehensive treatment services, OTPs utilize medication-assisted treatment ("MAT"), which includes several different modalities of which MAT utilizing methadone is one. Methadone treatment has been in widespread use in this country for nearly six decades and is one of the most studied modalities of healthcare. Study after study demonstrates that methadone treatment works and is the gold standard of care for opioid use disorder. The benefits of the OTP setting are evidenced by the fact that available data indicates that OTPs are unlikely to be the source of methadone in methadone-related

deaths. In short, OTP clinics provide a safe and effective setting for methadone treatment to be administered.

Response: The Department thanks the commenter for background information and has identified no changes to the rule in response to this comment.

Comment 349: Our Coalition supports several proposed amendments to the licensure rule. The Maine DHHS maintains detailed licensing requirements for providers of substance use disorder treatment. These requirements are currently set forth in Chapter 5 of the rules of Maine's Office of Substance Abuse and Mental Health Services within DHHS. ME C.M.R. 14-118, Chapter 5. In the case of OTPs, addressed in Section 19 of those rules, there are dozens of requirements that have been in place for decades that exceed federal standards on OTPs. Many of these standards reflect a bygone era when MAT was not as well-accepted. Fortunately, MAT has become widely accepted within the health care and law enforcement communities, as well as more generally in society. Many proposed modifications to the DHHS licensure rule will create more flexibility for clinics to meet the individual treatment needs of patients, reduce the cost of treatment, create more flexibility for OTPs to hire qualified personnel, and improve working conditions for OTP staff. As a result, our Coalition supports several specific modifications to the Department's proposed behavioral health organizations licensure rule, including the following:

Response: The Department thanks the commenter and has identified no changes to the rule in response to this comment.

Comment 350: Elimination of OTP maximum patient caps (§ 19.8.4.3). Licensure rule Section 19.8.4.3 currently limits OTP sites to a 500-client maximum. To our knowledge, there is no medical basis for this cap, and most other jurisdictions do not utilize them. In fact, larger clinics would enable greater economies of scale, similar to what large hospitals are able to leverage. In the recent past, DHHS has granted waivers to raise, but not eliminate, this cap in the case of individual clinics, but only up to a set amount such as 800 patients. Moreover, the licensure rules only allow for a waiver of this cap when the OTP satisfies certain requirements under Section 19.8.3.1 such as the ability to hire and retain adequate number of staff. There is simply not a justification for clinic caps of any level as long as a clinic otherwise meets standards related to staffing, safety, and operations. Removing patient caps for OTP clinics, as proposed in this rulemaking, will allow OTPs to treat more patients and save more lives. Accordingly, our Coalition supports the Department's proposed elimination of this patient cap.

Response: The Department thanks the commenter for background information and has identified no changes to the rule in response to this comment.

Comment 351: Elimination of prohibition on take-home medication during the first 90 days of treatment (§ 19.8.10.3). Current licensure rules prohibit any take-home medication for clients during the first 90 days of continuous treatment. Although in-person treatment is valuable for patients, it should also be acknowledged that a rigid rule around take-home doses creates a barrier for some new patients who are unable or unwilling to come physically to a clinic every day without exception. As a result, some patients don't start treatment, or leave treatment early. Importantly, this prohibition on take-home medication contrasts with the requirements surrounding buprenorphine treatment, which allows for take-home medication up to two weeks for all patients, including patients who are just starting treatment. Allowing greater access to take-home medication to more patients would allow OTPs to care for more patients. Accordingly, our Coalition supports the Department's proposal to remove the prohibition on take-home medication for patients during the first 90 days of treatment. This will allow Maine to align with federal standards, which allow up to one

take-home dose per week during the first 90 days of treatment, two take-home doses during the second 90 days of treatment, and three take-home doses during the third 90 days of treatment. 42 C.F.R. § 8.12.

Response: The Department thanks the commenter for background information and has identified no changes to the rule in response to this comment.

Comment 352: Elimination of requirement that OTPs are open 7 days per week (§ 19.8.4.2). In 2017, the Maine Legislature modified state law to allow OTPs to be open 6 days per week, which is consistent with federal law. Previously, Maine law required clinics to be open seven days per week. Based on this change in law, Section 65.06-11 of the MaineCare Benefits Manual was modified several years ago to reflect current state and federal requirements and allow OTPs to be open 6 days a week. Allowing clinics to close one day a week helps save money, and reduce burdens on staff. However, despite the change in Maine law allowing clinics to be open only 6 days a week, the DHHS licensure rules have not been conformed and continue to require OTPs to be open 7 days a week, including holidays. Our Coalition supports the Department's proposed elimination of such requirement to match State law.

Response: The Department thanks the commenter for background information and has identified no changes to the rule in response to this comment.

Comment 353: While our Coalition supports many of the proposed changes to the Department's licensure rules, there are several amendments we believe should be included with the proposed licensure rules to ensure cost-effective and expanded access to needed OTP treatment in Maine:

Increase patient-staff ratios for counselors (§§ 19.8.8.6.3 and 19.8.8.6.4). Full time counselors are currently limited to caseloads of 50 clients under current Section 19.8.8.6.3. Additionally, under Section 19.8.8.6.4, caseloads are limited to 35 clients for full time counselors who have not yet completed 2000 hours of substance abuse practice. Proposed Chapter 123 keeps such patient-staff ratios in place. Caseload caps prevent OTPs from providing individuals with the lifesaving intervention they require, and our Coalition recommends that the proposed licensure rule be amended to increase patient-staff ratios for counselors so that OTPs can treat more patients with the staff they currently have on hand. In practical terms, expanded patient-staff ratios have been the norm for years as many OTPs in Maine have routinely requested and received waivers of the 50:1 ratio in order to provide a 75:1 ratio. This expanded ratio is more cost-effective, and to our knowledge, this higher ratio has not interfered with the quality of patient care. For this reason, we would encourage the Department to further modify the draft rule to allow for a 75:1 patient-staff ratio for counseling.

Response: The Department has reviewed this comment and finds that the 50:1 client to staff ratio aligns with required counseling requirements and seeks to ensure that counselor caseloads are manageable and ensure health and safety of clients. Organizations may continue to apply for waivers in accordance with the adopted rule. No changes were made to the adopted rule as a result of this comment.

Comment 354: Eliminate specific credentialing requirements for counselors (§ 9.2.2). Current DHHS licensure rules contain rigid staff credentialling requirements OTP staff credentials, including that counseling be undertaken by certified alcohol and drug counselors (CADC) and licensed alcohol and drug counselors (LADC). The draft rule seems to keep such credentialing requirements in place. By contrast, federal regulations governing OTPs are more broadly worded and require that "each person engaged in the treatment of opioid use disorder must have sufficient education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions." 42 CFR § 8.12. Federal

regulations do not have strict credentialing requirements and allow for more flexibility for hiring staff. Accordingly, our Coalition would encourage the Department to further modify the draft rule to adopt a more flexible standard regarding credentialing requirements for counseling that better align state standards with federal regulations.

Response: The Department has reviewed this comment and finds that credentials for counselors align with scope of practice for individual licensure in Maine. No changes were made to the adopted rule as a result of this comment.

SUMMARY OF CHANGES RESULTING FROM COMMENTS & AAG REVIEW:

SECTION 1. DEFINITIONS

Section 1(A)(29) was revised to read: 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, ~~or~~ almost identical, or serve an equivalent purpose to standards reviewed, evaluated, and monitored by a Department-approved national accrediting agency.

Section 1(A)(35) was added, and the following definitions were renumbered sequentially: 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.

Section 1(A)(45) of the adopted rule was revised to read:
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 ~~system of care~~. 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.

Section 1 (A)(47), the definition of "intervention plan", has been deleted from the adopted rule.

Section 1(A)(50) was amended to read: Licensed practitioner means a physician, physician's assistant, or nurse practitioner currently allowed by license to practice ~~an individual currently licensed~~ in the State of Maine ~~as a physician, physician's assistant, or nurse practitioner~~.

Section 1(A)(52) was amended to read: **Medical director** means a licensed practitioner ~~physician (Medical Doctor or Doctor of Osteopathy)~~ 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~~ies~~ out the minimum requirements set forth in this rule.

Section 1(A)(67) was added, and the following definitions were renumbered sequentially: "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.""

Section 1(A)(89) was amended to include: "A location from which telehealth services are delivered is not a site."

SECTION 2. LICENSING AND CERTIFICATION REQUIREMENTS

Section 2(A)(4) was revised to read: 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.

Section 2(C) of the adopted rule was revised to read: C. **License posted**. A copy of the current valid license, ~~with the accompanying letter from the Department listing licensed sites and service locations of the organization and the services provided at each location,~~ must be conspicuously posted where it may be seen by the public at each of the locations where services are provided.

Section 2(E)(8) was amended to read: A description of the location, capacity, and a sketch of the floor plan with bedroom space identified for each residential program

Section 2(E)(9) was deleted from the rule: ~~An annual budget showing anticipated expenses and revenues and the source of those revenues;~~

Section 2(E)(13) was amended to read: 2(E)(12) "A copy of letters of notice from the applicant to the Office of MaineCare Services, ~~and to~~ 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"

Section 2(I)(1) of the adopted rule was revised to read: The organization must notify the Department at least 30 ~~90~~ 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.

Section 2(I)(3) was amended to read: The organization may not increase ~~client or~~ 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.

Section 2(K) was amended to read: 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.

Section 2(M)(2) was amended to read: The Department may approve national accrediting organizations with standards that are identical, ~~or~~ 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:

Section 2(M)(4) was amended to read: The organization must maintain a physical copy of the accreditation standards on-site for review by the Department, with the standards that are identical, ~~or~~ almost identical, or equivalent in purpose to licensing provisions set out in this rule identified.

Section 2(M)(7) was amended to read An ~~accreditor's~~ 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.

SECTION 4. ENFORCEMENT AND INSPECTIONS

Section 4(B)(1) of the adopted rule was amended to read: 1. 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 ~~one~~ five business days of the request;

Section 4(F)(1) was amended to read: 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 ~~is unable~~ to comply with this rule and applicable statutes.

Section 4(I)(1) was amended to read: Operation of a residential ~~behavioral health organization or~~ program~~(s)~~ of the organization over the licensed capacity.

SECTION 5. COMPLAINT INVESTIGATION

Section 5(B) was revised to read: 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 ~~all~~ clients at each site to enable clients or staff to contact the Department to make a complaint about the organization.

Section 5(C)(2) of the adopted rule was revised to read: The ~~organization~~ client record must include documentation that the client was notified of the grievance procedure. ~~a signed client notification of receipt of the procedure in the client's record.~~

Section 5(D)(5) was deleted from the adopted rule.

Sections 5(E and F) of the proposed rule were amended to read:

E. 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.

F. 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

Section 6(B)(1) has been deleted from the adopted rule.

Section(6)(C) was amended to remove the following phrase: Any exception, restriction, or limitation of client rights must be documented in the client's record. ~~and, if applicable, signed by the client's physician.~~

Section 6(D) of the adopted rule was amended to read:

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 ~~and must provide a copy of the policy required in § 6(B) of this rule to each client on admission.~~

1. The organization must inform each client and legal representative within 30 calendar days of any changes to the organization's policy and must offer ~~provide~~ them a copy of the change.
    a. A copy must be posted in a prominent place accessible to all clients.
    b. ~~Documentation of receipt by clients must be maintained in each client's record.~~ The client record must contain documentation of notification of changes to client rights.

Section 6(D)(1)(a) of the proposed rule was clarified to read: a. A copy must be posted in a prominent place within each organizational site that is accessible to ~~all~~ clients.

Section 6(D)(1)(b) of the proposed rule was amended to read: ~~Documentation of receipt by clients must be maintained in each client's record.~~ The client record must contain documentation of notification of changes to client rights.

Section 6(F)(2) was amended to read: Critical Incident Reporting forms alleging abuse, neglect, or exploitation of an adult client must be sent to DLC and OBH.

Sections 6(G)(1 and 2) were revised to read:

3. Prepare a written document explaining the organization's internal rules and offer ~~provide~~ it to each client and/or legal representative on admission; and
4. Maintain within the client record documentation that the client and/or legal representative have been offered a copy of the organization's internal rules ~~Obtain signed and dated documentation from the client and/or legal representative indicating receipt of the organization's internal rules and maintain this document in the client record; and~~

Section 6(G)(3) was deleted from the adopted rule.

Section 6(H)(1) of the adopted rule was amended to read: 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 ~~in a common area of the organization~~.

Section 6 (H)(2) of the adopted rule was revised to read: 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.

Section 6(K) of the adopted rule was amended to read:

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 legal representative consent pursuant to state and federal law.

SECTION 7. ELIGIBILITY AND ACCESS TO SERVICES

Section 7 introductory paragraph was amended to read: 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.

Section 7(D) was amended to read: Screening practices. The organization must screen potential clients ~~applicants~~ to identify the urgency of need.

Section 7(F) of the adopted rule was clarified by adding 3. The client requests transfer to another organization.

Section 7(F) of the proposed rule was deleted.

SECTION 8. COMPREHENSIVE CLIENT ASSESSMENT

Section 8 introductory paragraph was amended to read: 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.

Section 8(A) was amended to read: Comprehensive client assessment.

Section 8(C) of the proposed rule was amended to read: The organization must complete a comprehensive assessment of each client within 30 days of admission to determine the need for treatment and services.

Section 8(C)(1)(c) of the proposed rule was amended to read: "Medical domain, including but not limited to physical~~/sexual~~ health, current medications, and physical and environmental barriers to treatment"

Sections 8(C)(3 and 4) of the adopted rule were amended to read:
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-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 ~~clinician~~ 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 c~~C~~riteria.

Section 8 (D) was deleted from the proposed rule.

SECTION 9. CLIENT SERVICE PLAN

Section 9 introductory paragraph was amended to read: 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.

Section 9(C) was amended to read: Service plan team. The service plan team must include the client, the client's guardian or legal representative, clinician ~~clinical consultants~~, representative(s) of the organization providing services, and other persons chosen by the client, as appropriate.

Section 9(C)(2) was clarified to read: When the client does not participate on the service plan team, the organization must document ~~in the client's record~~ the organization's efforts to engage the client and the reason why participation did not occur in the client's service plan.

Section 9(H) of the proposed rule was relocated to Section (9)(K)(4) of the adopted rule.

Section (9)(I)(2)(i) was relocated to a new Section 9(I)(6).

Section 9(I)(2)(h) of the proposed rule was deleted from the adopted rule.

Section (9)(I)(2)(j) was relocated to Section 9(I(5) of the adopted rule.

Section 9(H)(1) of the adopted rule was amended to read: 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.

Section 9(H)(2)(c) of the adopted rule was amended to read: The client's agreed-upon ~~long-term~~ goals and ~~specific short-term goals and~~ objectives to reach identified treatment and service outcomes~~. that will allow completion of the long-term goals~~;

Section 9(H)(2)(f) of the adopted rule was amended to read: 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;

Section 9(H)(2)(i) of the adopted rule was revised to read: Criteria and a plan for discharge~~, and strategies to address anticipated barriers to discharge~~;

Section 9(H)(2)(k) of the adopted rule was revised to read: m. The date and ~~signature~~ documentation of the consent of the client, or the client's legal representative, as appropriate. ~~Where the signature of the client, or the client's legal representative is not obtained, the organization must document the reason why the signature could not be obtained and the client's agreement with the service plan in the client's record; and~~

The following was added to Section 9(I) of the adopted rule: 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.

Section 9(J) has been deleted from the rule.

Section 9 (K) of the adopted rule was revised to read:
Periodic review and update of service plan. ~~In accordance with it's written service delivery policy, t~~ The organization must periodically review and update each client's service plan.

Section 9(K)(4) was revised to read:
4. The organization must conduct an expedited service-planning process when an ~~crisis or~~ urgent need has been identified, as needed or applicable. Following a crisis episode, an update to the crisis plan and/or service plan review is required.

SECTION 10. DISCHARGE PROCESS

Section 10(A)(4) was revised to read: The requirement to obtain the client's ~~permission~~ 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.

Section 10(A)(7) was revised to read: Specific procedures when a client leaves the program against clinical recommendations ~~medical advice~~.

Section 10 (B) was deleted from the rule.

Sections 10 (C) and (D) of the adopted rule: inserted the phrase "or their legal representative."

Section 10 (B)(1) of the adopted rule was revised to read: 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.

Section 10(C)(4) was deleted from the rule.

Section 10(D)(2) of the proposed rule was deleted from the adopted rule and replaced with a new Section 10(C)(2): "Include information on organizations in the client's service area where recommended services or supports could be sought;"

Section 10(D)(5) of the proposed rule was deleted from the adopted rule.

Section 10(E) of the adopted rule was amended to read:
E. Self-discharge against clinical recommendations. ~~advice.~~

1. When a client self-discharges against clinical recommendations ~~medical advice~~, the organization must prepare a written document describing the client's self-discharge ~~against clinical recommendation. medical advice.~~

Section 10(H) of the proposed rule was deleted from the adopted rule.

SECTION 11. GOVERNING AUTHORITY

Section 11(D) of the adopted rule was amended to read:

D. 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;
      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 an 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.~~; and~~
      ~~c. For an advisory board, any individual with a proprietary interest in the organization.~~

Section 11(D)(2)(a) was revised to read: An employee of ~~an~~ the organization, or a member of the immediate family of an employee; and

Section 11(F)(4) was deleted from the rule: ~~Reviewing and approving the organization's annual budget;~~

Section 11(F)(11) of the proposed rule was renumbered 11(F)(10) and was amended to read: 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.

Section 11(G) was amended to read: The ~~governing authority is subject to the~~ organization~~'s~~ must have in place a written conflict of interest policy applicable to the governing authority that addresses, at a minimum, the requirements of §(D)(2).

SECTION 12. PROGRAM ADMINISTRATION

Section 12(B)(3) was deleted from the adopted rule.

Section 12 (E)(1) was revised to read:

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.

Section 12 (E)(3)(b) was revised to read: The organization must confirm that the distant site practitioner is currently allowed by license~~d~~ ~~to practice in~~ in Maine, consistent with the appropriate rule of the Department of Professional and Financial Regulation.

Section 12(F)(1)(b) was deleted from the adopted rule.

Section 12(F)(1)(c) was revised to read: ~~An employee of an organization has a duty to warn or take reasonable precautions when the employee has a~~ 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. ~~unless that action would endanger the employee or increase the threat of danger to a potential victim.~~

Section 12(F)(2)(a) was deleted from the proposed rule.

Section 12 (H)(1) of the proposed rule was amended to read: 1. The annual evaluation ~~must~~ may address ~~at least~~ the following:

SECTION 13. PERSONNEL

Section 13 (C)(2) was revised to read:

2. The organization is responsible for ensuring its personnel are qualified and must maintain ~~verify and~~ documentation of the references and credentials of prospective personnel, including:

Section 13(H)(4) of the adopted rule was revised to read: The clinical supervisor is responsible for clinical supervision of clinicians~~, direct care staff~~ and independent contractors, as applicable, who provide clinical services.

Section 13(H)(4)(b)(ii) was revised to read: i. Conduct individual and group supervision for ~~eight or fewer~~ supervisees.

Section 13(G) was amended to read: "Nurse consultant. An organization ~~providing, prescribing, or~~ administering medication must have a nurse consultant on staff or under contract.

Section 13(G)(1) was revised to read: The nurse consultant is responsible for the ~~medical direction and~~ 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.

Section 13 (G)(2) of the proposed rule was deleted from the adopted rule.

Section 13(H)(5)(a) was revised to read: Staff providing 20 hours or more of direct service per week must receive at least four hours ~~one hour~~ of clinical supervision every month ~~week;~~

Section 13(I)(3)(a) was clarified to read: a. Orientation to the typical life experiences ~~perspectives and values~~ of clients of behavioral health services, conducted by a client of behavioral health services;

Section 13(I)(4) of the adopted rule was revised to read: 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.

Section 13(J), Staff Credentials, was added:

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):
      a. Registered Nurse certified as a Psychiatric Nurse,
      b. Advanced Practice Registered Nurse (APRN) with appropriate specialization certification,
      c. Medical Doctor (M.D.),
      d. Doctor of Osteopathy (D.O.),
      e. Licensed Clinical Psychologist,
      f. Licensed Clinical Social Worker (LCSW),
      g. Licensed Clinical Professional Counselor (LCPC), or a
      h. 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

Section 14(B)(1) was deleted from the proposed rule: ~~1. Prior to implementation of the written agreement, the organization must have documentation to show that it reviewed and determined that the prospective independent contractor has sufficient human and financial resources to fulfill the terms of the contract.~~

Section 14(D)(5) of the adopted rule was amended to read: 5. A written record of ~~regularly scheduled substantive training,~~ contractual oversight~~, and supervision or consultation sessions~~ for each independent contractor, to ensure compliance with the terms of the agreement; and

Section 14(D)(6) was amended to read "A written account of the amount of clinical supervision or consultation ~~required by the independent contractor's professional licensing authority~~ provided by the organization."

SECTION 15. MEDICATION ADMINISTRATION

Section 15(C) was amended to read: The organization must ~~assure~~ ensure that:

Section 15(E)(2) was amended to read:

2. ~~If the medical director determines that the client needs supervision in the administration of medication, the medical director must document this finding in the medical orders.~~ 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.

Section 15(M)(3) was deleted from the adopted rule.

Section 15 (R) (i-l) was revised to read:

i. Name and address of issuing pharmacy; and
~~j. Date of filling;~~
~~k.~~ Beyond use date. ~~; and~~
~~l. Appropriate accessory and cautionary instructions.~~

SECTION 16. RECORDS MANAGEMENT AND RETENTION

Section 16(D)(2)(e) was amended to add e: Organizations utilizing electronic health records must use electronic date stamps for all entries in the record.

Section 16(D)(3)(b) of the proposed rule was amended to read:

b. All treatment documents (including, but not limited to assessments, service plans, progress notes, incident~~/reportable event~~ report<u>s</u>, and discharge summary);

Section 16(D)(3)(d) was revised to read: d. Copies of all ~~signed and dated~~ completed releases and authorizations, including, but not limited to, the following:

SECTION 17: QUALITY IMPROVEMENT

Section 17(B)(1) was amended to read …contractors, and partners

SECTION 18. FINANCIAL MANAGEMENT

Section 18(C) was deleted from the rule:

~~**C. Budget.** The organization must develop a formal, annualized line-item budget approved by the governing authority, indicating revenues and expenses for the current fiscal year.~~
~~3. Revisions to the budget must be clearly documented; and~~
~~4. The organization must document budget reviews and the date of approval of the budget by the governing authority.~~

Section 18(D)(3) of the proposed rule was amended to read: 3. Organizations with annual revenues under ~~$500,000~~ $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.

SECTION 19. RISK MANAGEMENT

Section 19(D) was amended to include 7. Any confidentiality or privacy breaches.

Section 19(D)(2) was amended to read: 2 The use of restrictive behavior management interventions, such as seclusion and restraint ~~as it relates to adult services~~;

SECTION 21. STANDARDS FOR ALL RESIDENTIAL PROGRAMS

Section 21(B)(6) of the adopted rule was revised to read: 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.

Section 21(E)(12)(C)(iii) of the proposed rule was relocated to Section 22G)(2)(a)(vi) of the adopted rule.

Section 21 (A) of the adopted rule was clarified to read:

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.

Section 21(B)(6) of the adopted rule was revised to read: 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.

Section 21(C) proposed rule was amended the to read: Revise 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 ~~must~~ may be developed with the assistance of qualified fire, health and safety agencies. At a minimum, the plan must address the following:

Section 21(G) of the adopted rule was revised to read: A direct access worker providing ~~care~~ 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:

SECTION 22. MENTAL HEALTH PROGRAMS

Section 22(E)(2) was amended to delete provision 22(E)(2)(d) from the adopted rule.

Section 22(E)(3) was amended to read:

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

Section 22(E)(3)(a) was revised to read: a. The organization may provide crisis telephone services referred through a statewide toll-free number.

Section 22(E)(3)(b) was revised to read: Crisis walk-in services must provide support to clients in crisis on a walk-in basis during normal business hours.

Section 22(E)(3)(c) was revised to read:
c. 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.

Section 22(E)(4) was amended to read: Crisis assessments must be completed by appropriately qualified staff, including a mental health rehabilitation technician/crisis service provider (MHRT/CSP), or a~~n independently~~ licensed or certified mental health professional practicing within the scope of his or her license.

Section 22(E)(4)(a) of the proposed rule was broadened to read:

a. ~~The crisis services program must have access to a psychiatric consultant who is~~ 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.

Section 22(E)(4)(iii) was amended to read:

iii. 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.

Section 22(E)(6) was amended to add i. The written crisis assessment must note when any of the above information is not immediately available.

Section 22(E)(8) was revised to read: 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.

Section 22(E)(11) was amended to read: The organization must have written policies and procedures for accessing emergency medical ~~rescue~~ services that are reviewed and updated no less than annually. The organization must train its personnel on the organization's ~~rescue~~ emergency medical services procedures.

Section 22 (E)(12) was amended to read: The organization must have written policies and procedures for ~~facilitating~~ initiating or recommending the involuntary hospitalization process.

Section 22(E)(17)(e)(i) was revised to read:
i. 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.

Section 22(E)(17)(g) was revised to read: 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.

Section 22(E)(17)(g)(ii)(9) was added to the adopted rule: 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.

Section 22 (E)(17)(h) was revised to read: Within 24 hours of admission, the organization must develop a short-term crisis service ~~stabilization~~ plan. ~~No service plan is required.~~ At a minimum, the written short-term crisis service ~~stabilization~~ plan must include the following:

Section 22(E)(17)(h)(vi) was revised to read: Signatures of all other individuals participating in the development of the short-term crisis ~~stabilization~~ service plan;

Section 22(E)(17)(h)(viii) was revised to read: On the seventh day of service, and every two days thereafter, the short-term crisis service ~~stabilization~~ plan must be reviewed; and

Section 22(E)(17)(k) was revised to read: ~~Crisis intervention counselors~~ 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.

Section 22(E)(17)(n) was revised to read:

j. Each face-to-face contact ~~with~~ between a client in crisis and a clinician must be documented to include the following, as applicable:
   vii. 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;
   viii. The sharing of the assessment with the client in crisis and the client's parent, guardian, legal representative or provider when applicable and appropriate;
   ix. The disposition of the episode, including recommendations and referrals to other service providers as appropriate and indicated; and
   ~~x. Collaboration with the client's other service providers, when appropriate and applicable;~~
   ~~xi.~~ The use or non-use of an existing crisis or relapse plan.~~; and~~
   ~~xii. Appropriate follow-up contacts with the client in crisis, as authorized by the client in crisis or otherwise permitted.~~

Section 22(F)(3) was added to the adopted rule: Service plans must be completed within thirty (30) days from admission and reviewed every twelve (12) visits or annually, whichever comes first.

Section 22 (G)(1)(c)(i) was amended to read:

i. Services include clinical review and completion of a service plan which includes goals related to support and rehabilitation. ~~treatment services~~.

Sections 22 (G)(1)(c)(iii and iv) in the adopted rule were revised to read:

i. Within 72 hours of admission, the organization must develop an initial service plan and within 30 calendar ~~20 business~~ days of admission, the organization must develop a comprehensive service plan for each client.
ii. Within 30 calendar ~~20 business~~ days of admission, an assessment must be completed to determine the level of care needed by the client.

SECTION 23. SUBSTANCE USE DISORDER TREATMENT PROGRAMS

Section 23(A)(1) of the proposed rule was amended to read: "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

Section 23(A)(2) was amended to read: 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.

Section 23(A)(3) was added to the rule: "An organization may develop other admission criteria only with written Department approval."

Section 23(D)(2) of the proposed rule deleted from the adopted rule.

Section 23(D)(3) of the proposed rule deleted from the adopted rule.

Section 23(D)(5) was amended to require substance use disorder qualified staff to "meet the requirements of Section 13(J)."

Section 23(F)(3) was revised to read:
3. Crisis services may be provided by an interactive telecommunication system ~~telephone~~, on a walk-in basis, or through mobile outreach to the individual's home, school, and other community settings.

23(F)(3)(c) was revised to read:
c. 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.

Section 23(G)(2) was clarified to read: 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 indicated by observation or report of physical symptoms of infectious disease or illness.

Section 23(G)(2)(b) of the prosed rule was amended to read: 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.

Section 23 (G)(4)(b) of the proposed rule was revised to read: MOUD service plans must include all relevant SUD services provided by organization.

Section 23(H)(2) of the proposed rule was revised to read: 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 ~~provide meaningful~~ 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.

Section 23(H)(3)(f) of the proposed rule was revised to read: ~~Physician back-up and o~~ On-call staff must be provided to deal with ~~medical~~ emergencies;

Section 23(H)(3)(k) was deleted from the rule.

Sections 23(H)(3)(i) and (j) of the adopted rule were revised to read:

(i) There must be a written ~~agreement~~ plan for transportation between the program and emergency care facilities;

(j) The program must ~~have a written agreement with an ambulance service to assure~~ 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;

SECTION 24. INTEGRATED MENTAL HEALTH AND SUBSTANCE USE DISORDER TREATMENT PROGRAMS (CO-OCCURRING BEHAVIORAL HEALTH CONDITIONS)

Section 24 (A) was clarified to read:

A. 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.