Change the chapter heading for He-A 300, and readopt with amendment He-A 304, effective 5/20/17 (Document #12178, Interim Rule), cited and to read as follows:

CHAPTER He-A 300 CERTIFICATION AND OPERATION OF SUBSTANCE USE DISORDER TREATMENT PROGRAMS

PART He-A 304 CERTIFICATION AND OPERATIONAL REQUIREMENTS FOR OPIOID TREATMENT PROGRAMS

Statutory Authority: RSA 318-B:10, VII(b) and VIII(b)

He-A 304.01 Purpose and Scope.

- (a) The purpose of these rules is to describe the requirements necessary to be certified by the New Hampshire bureau of drug and alcohol services as an approved opioid treatment program.
- (b) These rules shall not apply to licensed practitioners who prescribed buprenorphine to their patients in a setting other than an opioid treatment program certified under these rules.

He-A 304.02 <u>Definitions</u>.

- (a) "Buprenorphine" means a synthetic opiate with partial agonist actions used in the treatment of opioid use disorder.
- (b) "Bureau" means the New Hampshire bureau of drug and alcohol services or successor program area within the department of health and human services.
- (c) "Client" means a person who is enrolled in and receiving services from an opioid treatment program certified under these rules. This term does not include patients who are prescribed buprenorphine by a licensed practitioner practicing within a certified opioid treatment program.
- (d) "Critical incident" means any actual or alleged event or situation that creates a significant risk of substantial or serious harm to physical or mental health, safety, or well being, including but not limited to:

(2)	Neglect;
(3)	Exploitation;
(4)	Rights violation;
(5)	Missing person;
(6)	Medical emergency;
(7)	Restraint; or

(8) Medical error.

(1) Abuse;

- (e) "Heroin" means an illegal semi-synthetic drug produced from the morphine contained in sap of the opium poppy, and known to have the potential for devastating addictive properties in vulnerable individuals.
- (f) "Licensed counselor" means a master licensed alcohol and drug counselor (MLADC), a licensed alcohol and drug counselor (LADC), or a licensed mental health professional who has demonstrated competency in the treatment of substance use disorders.
- (g) "Licensed practitioner" means a medical professional legally practicing within their scope in the State of New Hampshire, is authorized to dispense synthetic opioids for the treatment of substance use disorders, and who is employed by or under contract with the opioid treatment program and practicing under the supervision of the program's medical director.
- (h) "Licensed supervisor" means an MLADC, a LADC who is also a licensed clinical supervisor (LCS), or a licensed mental health professional who has demonstrated competency in the treatment of substance use disorders.
- (i) "Methadone" means a legal drug, methadone hydrochloride, which is a synthetic opioid that has been demonstrated to be an effective treatment agent for opioid use disorders.
- (j) "Methadone/buprenorphine maintenance services" means treatment services which substitute methadone, or any of its derivatives, or buprenorphine, over time, to relieve withdrawal symptoms of opioid use disorder, to reduce craving, and to permit normal functioning and engagement in rehabilitative services.
- (k) "Methadone/buprenorphine withdrawal management" means the dispensing of methadone, buprenorphine, or a similar substance in decreasing doses to a client in order to reduce or eliminate adverse physiological or psychological effects incident to the withdrawal from the sustained use of opioids.
- (l) "Opioid treatment program (OTP)" means a substance use disorder program which dispenses methadone/buprenorphine for the purpose of opioid withdrawal management, maintenance, treatment, and rehabilitation services.
 - (m) "Opioids" means a group of morphine-like substances that are:
 - (1) One of the following:
 - a. Directly derived from the opium poppy, such as morphine and codeine;
 - b. Semi-synthetic substances partially derived from the opium poppy, such as heroin; or
 - c. Purely synthetic substances, such as hydromorphone and meperidine; and
 - (2) Active through specific receptors in the human body.
- (n) "Plan of correction (POC)" means a plan developed and written by the certificate holder, which specifies the actions that will be taken to correct non-compliance with applicable rules or codes identified at the time of an inspection or during the course of a complaint investigation.
 - (o) "Sentinel event" means:
 - (1) An unanticipated death, not including homicide or suicide;

- (2) Permanent loss of function, or risk thereof, not related to the natural course of an individual's illness or underlying condition;
- (3) The person is the victim or alleged perpetrator of a homicide;
- (4) Suicide;
- (5) Suicide attempt;
- (6) Rape or any other sexual assault;
- (7) Serious physical injury, or risk thereof to or by a client that jeopardizes a person's health; or
- (8) Serious psychological injury, or risk thereof, that jeopardizes a person's health that is associated with the planning and delivery of care.
- (p) "Split dose" means the division of the client's daily dose of methadone or buprenorphine into 2 separate doses. This term also includes "split dosing."

He-A 304.03 Application Submission.

- (a) Each applicant for certification as an OTP shall submit the following to the department:
 - (1) A completed application form entitled "Application for Substance Use Disorder Program Certification" (January 2018 edition), signed by the applicant or, if not a sole proprietorship, 2 of the corporate officers and affirming the following:
 - "I swear or affirm that the information provided is accurate to the best of my knowledge and belief. I believe that my facility is in full compliance with RSA 172:8-6 and RSA 318:B and the rules promulgated there under. I understand that providing false information shall be grounds for denial, suspension, or revocation of certification."
 - (2) If applicable, proof of authorization from the New Hampshire secretary of state to do business in the State of New Hampshire in the form of one of the following:
 - a. "Certificate of Authority," if a corporation;
 - b. "Certificate of Formation," if a limited liability corporation; or
 - c. "Certificate of Trade Name," where applicable;
 - (3) Resumes identifying the qualifications of the administrator and medical director;
 - (4) Copies of applicable licenses for the administrator and medical director;
 - (5) Written local approvals as follows:
 - a. For an existing building, the following written local approvals shall be obtained no more than 90 days prior to submission of the application, from the following local officials or, if there is no such official(s), from the board of selectmen or mayor:

- 1. The health officer verifying that the applicant complies with all applicable local health requirements and drinking water and wastewater requirements;
- 2. The building official verifying that the applicant complies with all applicable state building codes and local building ordinances;
- 3. The zoning officer verifying that the applicant complies with all applicable local zoning ordinances; and
- 4. The fire chief verifying that the applicant complies with the state fire code, Saf-C 6000, as adopted by commissioner of the department of safety under RSA 153, and as amended pursuant to RSA 153:5, I, by the state fire marshal with the board of fire control, and local fire ordinances applicable for the facility's type of business; and
- b. For a building under construction, the written approvals required by a. above shall be submitted at the time of the application based on the local official's review of the building plans and upon completion of the construction project;
- (6) A written disclosure from the applicant, certificate holder, and administrator(s), containing a list of any:
 - a. Convictions in this or any other state;
 - b. Permanent restraining or protective orders;
 - c. Findings by the department or any administrative agency in this or any other state for assault, fraud, theft, abuse, neglect, or exploitation; and
 - d. An explanation of the circumstances surrounding disclosure of matters described in a. through c. above; and
- (7) The results of a criminal records check from the NH department of safety for the applicant, certificate holder, and administrator.
- (b) The applicant shall submit the documents in (a) above to:

Department of Health and Human Services Bureau of Drug and Alcohol Services 105 Pleasant Street Concord, NH 03301 Fax: 603-271-6105

Email: BDAS@dhhs.nh.gov

- He-A 304.04 Processing of Initial Applications and Issuance of Certifications.
- (a) An application for an initial certification shall be complete when the department determines that all items required by He-A 304.03(a) have been received.
- (b) If an application does not contain all of the items required by He-A 304.03(a), the department shall notify the applicant in writing of the items required before the application can be processed.

- (c) Unless a waiver has been granted, the department shall deny a certification application in accordance with He-A 304.10(b) after reviewing the information in He-A 304.03(a)(6)-(7) if, after review, it determines that the applicant, certificate holder, or administrator:
 - (1) Has been convicted of any felony in this or any other state;
 - (2) Has been convicted of a sexual assault, other violent crime, assault, fraud, theft, abuse, neglect, or exploitation in this or any other state;
 - (3) Has had a finding by the department or any administrative agency in this or any other state for assault, fraud, theft, abuse, neglect, or exploitation of any person; or
 - (4) Otherwise poses a threat to the health, safety, or well-being of clients.
- (d) All certifications issued in accordance with He-A 304 shall be non-transferable by person or location.
- (e) Following an inspection, a certification shall be issued if the department determines that an applicant requesting an initial certification is in full compliance with He-A 304, including (f) below.
 - (f) To be certified under He-A 304, an applicant shall have:
 - (1) Either:
 - a. Both of the following:
 - 1. A current certification as an OTP from the U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA); and
 - 2. A current accreditation as an OTP from a SAMHSA-approved OTP accrediting body; or
 - b. A provisional certification as an OTP from SAMHSA;
 - (2) A current registration with the U.S. Drug Enforcement Administration in accordance with 21 CFR 1301-1307; and
 - (3) A pharmacy in compliance with RSA 318:51-b and licensed in accordance with Ph 600 as a limited retail drug distributor as defined in RSA 318:1, VII-a.

He-A 304.05 Certification Expirations and Procedures for Renewals.

- (a) When an OTP is not currently certified under He-A 304, certification shall be valid on the date of issuance and expire one year later, on the last day of the month it was issued, unless a completed application for renewal has been received.
- (b) Except as in (a) above, a certification shall be valid on the date of issuance and expire 3 years later, on the last day of the month it was issued, unless a completed application for renewal has been received.

- (c) Each certificate holder shall complete and submit to the department an application pursuant to He-A 304.03(a)(1) at least 120 days prior to the expiration of the current certification.
 - (d) The certificate holder shall submit with the renewal application:
 - (1) A request for renewal of any existing non-permanent waivers previously granted by the department, in accordance with He-A 304.08, if applicable. If such a request is not received, the rule(s) for which the waiver was previously requested shall not continue to be waived beyond the expiration of the current certification;
 - (2) A copy of any non-permanent or new variances applied for and/or granted by the state fire marshal, in accordance with Saf-C 6005.03 6005.04, as adopted by commissioner of the department of safety under RSA 153, and as amended pursuant to RSA 153:5, I, by the state fire marshal with the board of fire control; and
 - (3) A list of any current employees who have a permanent waiver granted in accordance with He-A 304.17(j)(2).
- (e) Following an inspection, a certification shall be renewed if the department determines that the certificate holder:
 - (1) Submitted an application containing all the items required by (d) above, prior to the expiration of the current certification;
 - (2) If deficiencies were cited at the last certification inspection or investigation, has submitted a POC that has been accepted by the department and implemented by the certificate holder; and
 - (3) Is found to be in compliance with He-A 304 at the renewal inspection.
- (f) Any certified OTP that does not submit a complete application for renewal prior to the expiration of an existing certification shall be required to submit an application for initial certification pursuant to He-A 304.03.
- (g) Prior to issuing a certification, the department shall review any of the information submitted in accordance with He-A 304.03(a)(6)-(7) and deny a certification renewal in accordance with He-A 304.10(b).

He-A 304.06 Requirements for Organizational or Program Changes.

- (a) The certificate holder shall provide the department with written notice at least 30 days prior to changes in any of the following:
 - (1) Ownership;
 - (2) Physical location; and
 - (3) Name of the place where services authorized by a certification are delivered.
- (b) The certificate holder shall complete and submit a new application and obtain a new or revised certification prior to operating for:
 - (1) A change in ownership; or

- (2) A change in the physical location.
- (c) When there is a change in the name, the OTP shall submit to the department a copy of the certificate of amendment from the New Hampshire secretary of state, if applicable, and the effective date of the name change.
- (d) An inspection by the department shall be conducted prior to operation for changes in the following:
 - (1) Ownership, unless an inspection was conducted within 90 days of the date of the change in ownership and a POC designed to address any areas of non-compliance was submitted and accepted by the department; and
 - (2) The physical location.
- (e) Certifications issued for a change in ownership shall expire on the date the license issued to the previous owner would have expired.
 - (f) When there is a new administrator, the following shall apply:
 - (1) The certificate holder shall provide the department with immediate notice when an administrator position becomes vacant;
 - (2) The certificate holder shall notify the department in writing as soon as possible prior to a change in administrator, and immediately upon the lack of an administrator, and provide the department with the following:
 - a. A resume identifying the name and qualifications of the new administrator;
 - b. Copies of applicable licenses for the new administrator;
 - c. Results of a criminal records check from the NH department of safety; and
 - d. The written disclosure required by in He-A 304.03(a)(7);
 - (3) Upon review of the materials submitted in accordance with (2) above, the department shall make a determination as to whether the new administrator does not have a history of any of the criteria identified in He-A 304.04(c) and meets the qualifications of the position in He-A 304.17(a)-(b); and
 - (4) If the department determines that the new administrator does not meet the requirements in (3) above, it shall notify the OTP in writing so that a waiver can be sought or the OTP can search for a qualified candidate.
- (g) If a certificate holder chooses to cease the operation of a certified OTP, the certificate holder shall submit written notification to the department at least 30 days in advance, including the following:
 - (1) A written closure plan that ensures adequate care of clients until they are transferred or discharged to an appropriate alternate setting; and

(2) A plan for the security and transfer of all client records required by He-A 304.18.

He-A 304.07 <u>Inspections</u>.

- (a) For the purpose of determining compliance with He-A 304, the certificate holder shall admit and allow any representative from the department at any time during regular business hours to inspect the following:
 - (1) The facility premises;
 - (2) All programs and services provided by the certificate holder; and
 - (3) Any records required by He-A 304.
 - (b) The department shall conduct inspections prior to:
 - (1) Issuance of an initial certification;
 - (2) Renewal of a certification;
 - (3) A change of ownership; and
 - (4) A change of physical location.
- (c) In addition to (b) above, an OTP shall be subject to inspection by the department to verify the implementation of any POC accepted or issued by the department.
- (d) A notice of deficiencies shall be issued when, as a result of any inspection, the department determines that the certificate holder is in violation of any of the provisions of He-A 304.
- (e) If the notice identifies deficiencies to be corrected, the applicant shall submit a POC in accordance with He-A 304.09 within 21 days of the date on the letter that transmits the notice of deficiencies.

He-A 304.08 Waivers.

- (a) An applicant or certificate holder may request a waiver of a specific provision of He-A-304, in writing, from the department.
 - (b) A request for a waiver shall include:
 - (1) A specific reference to the rule for which a waiver is being sought;
 - (2) A full description of why a waiver is necessary; and
 - (3) A full explanation of alternatives proposed by the applicant or certificate holder, which shall be equally as protective of clients as the rule from which a waiver is sought or provide a reasonable explanation why the applicable rule should be waived.
 - (c) A waiver shall be permanent unless the department specifically places a time limit on the waiver.
 - (d) No provision or procedure prescribed by statue shall be waived.

- (e) A request for a waiver shall be granted if the department determines that the alternative proposed by the requestor:
 - (1) Meets the objective or intent of the rule;
 - (2) Does not negatively impact the health, safety, or well-being of clients; and
 - (3) Does not negatively affect the quality of OTP services.
- (f) The requestor's subsequent compliance with the alternative provisions or procedures approved in the waiver shall be considered equivalent to complying with the rule for which the waiver was sought.
 - (g) Waivers shall not be transferable.
- (h) When a certificate holder wishes to renew a non-permanent waiver beyond the approved period of time, the certificate holder shall apply for a new waiver with the renewal application or at least 60 days prior to the expiration of the existing waiver, as appropriate, by submitting the information required by (b) above.
 - (i) The request to renew a waiver shall be subject to (b) through (f) above.

He-A 304.09 Administrative Remedies.

- (a) The department shall impose administrative remedies for violations of He-A 304, including:
 - (1) Requiring a certificate holder to submit a POC; and
 - (2) Imposing a directed POC upon a certificate holder.
- (b) When administrative remedies are imposed, the department shall provide a written notice, as applicable, which:
 - (1) Identifies each deficiency; and
 - (2) Identifies the specific remedy(s) that has been proposed.
 - (c) A POC shall be developed and enforced in the following manner:
 - (1) Upon receipt of a notice of deficiencies, the certificate holder shall submit a written POC for each item on the notice describing:
 - a. How the certificate holder intends to correct each deficiency;
 - b. What measures will be put in place, or what system changes will be made to ensure that the deficiency does not recur;
 - c. The date by which each deficiency shall be corrected; and
 - d. The position of the employee responsible for the corrective action;

- (2) The certificate holder shall submit a written POC to the department within 21 days of the date on the letter that transmitted the notice of deficiencies unless the certificate holder requests, either verbally or in writing, and the department agrees, to extend that deadline, based on the following criteria:
 - a. The certificate holder demonstrates that he or she has made a good faith effort to develop and submit the POC within the 21 calendar day period but has been unable to do so; and
 - b. The department determines that the health, safety, or well-being of clients will not be jeopardized as a result of granting the extension;
- (3) The department shall review each POC and accept each plan that:
 - a. Achieves compliance with He-A 304;
 - b. Addresses all deficiencies as cited in the notice of deficiencies;
 - c. Prevents a new violation of He-A 304 as a result of implementation of the POC; and
 - d. Specifies the date upon which the deficiencies will be corrected;
- (4) If the POC is acceptable, the department shall issue a certification or provide written notification of acceptance of the POC, whichever is applicable;
- (5) If the POC is not acceptable:
 - a. The department shall notify the certificate holder in writing of the reason for rejecting the POC;
 - b. The certificate holder shall develop and submit a revised POC within 14 days of the date of the written notification from the department that states the original POC was rejected unless, within the 14 day period, the certificate holder requests an extension, either verbally or in writing, and the department grants the extension, based on the following criteria:
 - 1. The certificate holder demonstrates that he or she has made a good faith effort to develop and submit the POC within the 14 day period but has been unable to do so; and
 - 2. The department determines that the health, safety, or well being of clients will not be jeopardized as a result of granting the extension;
 - c. The revised POC shall comply with (c)(1) above and be reviewed in accordance with (c)(3) above; and
 - d. If the revised POC is not acceptable to the department, or is not submitted within 14 days of the date of the written notification from the department that states the original POC was rejected, unless the department has granted an extension, the certificate holder shall be subject to a directed POC in accordance with (d) below;

- (6) The department shall verify the implementation of any POC that has been submitted and accepted by:
 - a. Reviewing materials submitted by the certificate holder;
 - b. Conducting an on-site follow-up inspection; or
 - c. Reviewing compliance during the next renewal inspection;
- (7) Verification of the implementation of any POC shall only occur after the date of completion specified by the certificate holder in the plan; and
- (8) If the POC or revised POC has not been implemented by the completion date, at the time of the next inspection the certificate holder shall be issued a directed POC in accordance with (d) below.
- (d) The department shall develop and impose a directed POC that specifies corrective actions for the certificate holder to implement when:
 - (1) As a result of an inspection or investigation, deficiencies were identified that require immediate corrective action to protect the health and safety of the clients or personnel;
 - (2) A revised POC is not submitted within 14 days of the written notification from the department or such other date as applicable if an extension was granted by the department; or
 - (3) A revised POC submitted by the certificate holder has not been accepted.
- (e) If at the time of the next inspection the directed POC referenced in (d) above has not been implemented by the completion date stated in the directed POC, the department shall, as appropriate:
 - (1) Deny the application for a renewal of a certification; or
 - (2) Revoke the certification in accordance with He-A 304.10(b).
- (f) The department shall offer an opportunity for informal dispute resolution to any applicant or certificate holder who disagrees with a deficiency cited by the department, provided that the applicant or certificate holder submits a written request for an informal dispute resolution to the department.
- (g) The informal dispute resolution shall be requested in writing by the applicant, certificate holder, or administrator no later than 14 days from the date the notice of deficiencies was issued by the department.
- (h) The department shall change the notice of deficiencies if, based on the evidence presented, the notice of deficiencies is determined to be incorrect. The department shall provide a written notice to the applicant or certificate holder of the determination.
- (i) The deadline to submit a POC in accordance with (c)(2) above shall not apply until the notice of the determination in (h) above has been provided to the applicant or certificate holder.
- (j) An informal dispute resolution shall not be available for any applicant or certificate holder against whom the department has initiated action to suspend, revoke, deny, or refuse to issue or renew a certification.

He-A 304.10 Enforcement Actions and Hearings.

- (a) Prior to taking enforcement action against an applicant or certificate holder, the department shall send to the applicant or certificate holder a written notice that sets forth:
 - (1) The reasons for the proposed action;
 - (2) The action to be taken by the department; and
 - (3) The right of an applicant or certificate holder to a hearing in accordance with RSA 541-A:30, III, or He-C 200, as applicable, before the enforcement action becomes final.
 - (b) The department shall deny an application or revoke a certification if:
 - (1) An applicant or a certificate holder violated He-A 304 in a manner which poses a risk of harm to a client's health, safety, or well-being of a client;
 - (2) After being notified of and given an opportunity to supply missing information, the applicant or certificate holder fails to submit an application that meets the requirements of He-A 304.03(a);
 - (3) Unless a waiver has been granted, the department makes a determination that the applicant, administrator, or certificate holder has been found guilty of or plead guilty to a felony assault, fraud, theft, abuse, neglect, or exploitation of any person, in this or any other state, or had an investigation for abuse, neglect, or exploitation adjudicated and founded by the department or any administrative agency in this or any other state;
 - (4) An applicant, certificate holder, or any representative or employee of the applicant or certificate holder:
 - a. Provides false or misleading information to the department;
 - b. Prevents, interferes, or fails to cooperate with any inspection or investigation conducted by the department; or
 - c. Fails to provide requested files or documents to the department;
 - (5) The certificate holder has submitted a POC that has not been accepted by the department in accordance with He-A 304.09(c)(3) and has not submitted a revised POC as required by He-A 304.09(c)(5);
 - (6) The certificate holder failed to fully implement or continue to implement a POC that has been accepted or directed by the department in accordance with He-A 304.09(c)(3) or (d);
 - (7) The certificate holder is cited a third time under He-A 304 for the same violation within the last 5 years or 3 inspections;
 - (8) A certificate holder, or its corporate officers, has had a certification revoked and submits an application during the 5-year prohibition period specified in (h) below;
 - (9) The applicant or certificate holder fails to employ a qualified administrator;

- (10) The certificate holder fails to pay the certification and administration fee required by He-A 304.11; or
- (11) An applicant or certificate holder had a check returned to the department for insufficient funds and has not re-submitted the outstanding fee in the form of money order or certified check.
- (c) An applicant or certificate holder shall have 30 days after receipt of the notice of enforcement action to request a hearing to contest the action.
- (d) If a written request for a hearing is not made pursuant to (c) above, the action of the department shall become final.
- (e) The department shall order the immediate suspension of a certification, the cessation of services, and the transfer of care of clients when it finds that the health, safety, or well-being of clients is in jeopardy and requires emergency action in accordance with RSA 541-A:30, III.
- (f) If an immediate suspension is upheld, the certificate holder shall not resume operating until the department determines through inspection that compliance with He-A 304 is achieved.
 - (g) Hearings under this section shall be conducted in accordance with RSA 541-A and He-C 200.
- (h) When a certification has been denied or revoked, the applicant, certificate holder, or administrator shall not be eligible to re-apply for a certification or be employed as an administrator for 5 years if the denial or revocation specifically pertained to his or her role in the OTP.
 - (i) The 5 year period referenced in (h) above shall begin on:
 - (1) The date that the department's decision to revoke or deny the certification became effective, if no appeal is filed; or
 - (2) The date a final decision upholding the action of the department is issued, if a request for a hearing was made and a hearing was held.
- (j) Notwithstanding (h) above, the department shall consider an application submitted after the decision to revoke or deny becomes final if the applicant demonstrates that circumstances have changed to the extent that the department now has good cause to believe that the applicant has the requisite degree of knowledge, skills, and resources necessary to maintain compliance with the provisions of He-304.
- (k) No ongoing enforcement action shall preclude the imposition of any remedy available to the department under RSA 541-A or He-A 304.

He-A 304.11 Certification and Administration Fee.

- (a) In accordance with RSA 318-B:10, VII(f):
 - (1) Providers of an OTP which had clients in the previous calendar year shall submit to the department a certification and administration fee of \$8 per client served in the previous calendar year; and

- (2) Providers of an OTP which had no clients in the previous calendar year shall submit to the department a certification and administration fee of \$1000.
- (b) The fee in (a) above shall be paid to the department no later than February 15th of each year.
- (c) The number of clients served in a calendar year shall be calculated as follows:
 - (1) The number of unique clients who were enrolled and received treatment in that year, regardless of how long the treatment lasted or the effectiveness of the treatment;
 - (2) A client who has been enrolled and has received treatment more than once in a calendar year shall be counted as a single client for that year;
 - (3) A client who is enrolled and is receiving treatment across a calendar year, as part of a single admission shall be counted in each year; and
 - (4) A client who is admitted only for guest dosing in the year shall not be included in this count.
- (d) Documentation of the number of clients served as described in (c) above shall be submitted with the payment.
- (e) If a provider of more than one OTP submits a single payment for all of its OTPs, the documentation in (d) above shall indicate the client census described in (c) above by OTP location.
- (f) The certification and administration fee shall be paid by check or money order, in the exact amount of the fee, made payable to "Treasurer, State of New Hampshire."
- (g) Any fee submitted to the department in the form of a check or money order and returned to the state for any reason shall be processed in accordance with RSA 6:11-a.

He-A 304.12 Duties and Responsibilities of All Certified OTPs.

- (a) The certificate holder shall comply with all federal, state, and local laws, rules, codes, ordinances, licenses, permits, and approvals, and any rules promulgated thereunder, as applicable.
- (b) The certificate holder shall define, in writing, the scope and type of services to be provided by the OTP.
- (c) The certificate holder shall monitor, assess, and improve, as necessary, the quality of care and services provided to clients on an ongoing basis.
- (d) The certificate holder shall develop and implement written policies and procedures governing its operation and all services provided. Such policies shall be submitted to the bureau upon request.
- (e) If an existing policy fails to support the health, safety, and well-being of clients, staff, and the public, the OTP shall be required to submit a POC in accordance with He-A 304.09.
 - (f) All policies and procedures shall be reviewed annually and revised as needed.
- (g) All staff shall receive a minimum of 8 hours annually of in-service training on OTP policies and procedures.

- (h) The certificate holder shall:
 - (1) Employ an administrator responsible for the day-to-day operation of the OTP; and
 - (2) Establish, in writing, a chain of command that sets forth the line of authority for the operation of the OTP and the staff position(s) to be delegated the authority and responsibility to act on the administrator's behalf when the administrator is absent.
- (i) The certificate holder shall post the following documents in a public area:
 - (1) The current certification issued in accordance with these rules;
 - (2) A copy of the certificate holder's policies and procedures relative to the implementation of client rights and responsibilities, including client confidentiality per 42 CFR Part 2; and
 - (3) The certificate holder's plan for fire safety, evacuation, and emergencies identifying the location of, and access to, all fire exits.
- (j) The certificate holder or any employee shall not falsify any documentation or provide false or misleading information to the department.
- (k) The certificate holder shall comply with all conditions of warnings, administrative remedies, and enforcement actions issued by the department, and all court orders.
- (1) The certificate holder shall admit and allow any department representative to inspect the certified premises and all programs and services that are being provided at any time during regular business hours for the purpose of determining compliance with these rules.
 - (m) Certificate holders shall:
 - (1) Report all critical incidents to the bureau in writing as soon as possible and no more than 24 hours following the incident;
 - (2) Report all contact with law enforcement to the bureau in writing as soon as possible and no more than 24 hours following the incident;
 - (3) Report all media contacts to the bureau in writing as soon as possible and no more than 24 hours following the incident;
 - (4) Report all sentinel events to the department as follows:
 - a. Sentinel events shall be reported when they involve any individual who is receiving services governed by this rule;
 - b. Upon discovering the event, the OTP shall provide immediate verbal notification of the event to the bureau, which shall include:
 - 1. The reporting individual's name, phone number, and agency/organization;
 - 2. Name and date of birth (DOB) of the individual(s) involved in the event;

- 3. Location, date, and time of the event;
- 4. Description of the event, including what, when, where, how the event happened, and other relevant information, as well as the identification of any other individuals involved;
- 5. Whether the police were involved due to a crime or suspected crime; and
- 6. The identification of any media that had reported the event;
- c. Within 72 hours of the sentinel event, the OTP shall submit a completed "Sentinel Event Reporting Form" (February 2017), available at https://www.dhhs.nh.gov/dcbcs/documents/reporting-form.pdf to the bureau;
- d. Additional information on the event that is discovered after filing the form in c. above shall be reported to the bureau, in writing, as it becomes available or upon request of the bureau; and
- e. Reporting in c. and d. above shall be completed through the E-Studio web application, available at https://nh.same-page.com;
- (5) Submit additional information regarding (1) (4) above if required by the department; and
- (6) Report the event in (1) (4) above, as applicable, to other agencies as required by law.
- (n) The certificate holder shall implement policies and procedures for reporting:
 - (1) Suspected child abuse, neglect, or exploitation, in accordance with RSA 169-C:29-30; and
 - (2) Suspected abuse, neglect, or exploitation of adults, in accordance with RSA 149-F:49.
- (o) The certificate holder shall report all positive tuberculosis test results for personnel to the department's bureau of disease control in accordance with RSA 141-C:7, He-P 301.02 and He-P 301.03.
- (p) Certificate holders shall develop policies and procedures to implement state and federal regulations on client confidentiality, including provisions outlined in 42 CFR, Part 2, RSA 172:8-a, and RSA 318-B:12.
- (q) A certificate holder shall, upon request, provide a client or the client's guardian or agent, if any, with a copy of his or her client record.
- (r) All records required for certification shall be legible, current, accurate. and available to the department during an inspection or investigation conducted in accordance with these rules.
- (s) Any certificate holder that maintains electronic records shall develop written policies and procedures designed to protect the privacy of clients and personnel that are consistent with all state and federal regulations and, at a minimum, include:
 - (1) Procedures for backing up files to prevent loss of data;

- (2) Safeguards for maintaining the confidentiality of information pertaining to clients and staff; and
- (3) Systems to prevent tampering with information pertaining to clients and staff.
- (t) The certificate holder's service site(s) shall:
 - (1) Be accessible to a person with a disability using ADA accessibility and barrier free guidelines per 42 U.S.C. 12131 et seq;
 - (2) Have a reception area separate from service areas;
 - (3) Have private space for personal consultation, charting, service delivery, and social activities, as applicable;
 - (4) Have secure storage of active and closed confidential client records; and
 - (5) Have separate and secure storage of toxic substances.
- (u) The certificate holder shall establish and monitor a code of ethics for the OTP and its staff, as well as a mechanism for reporting unethical conduct to the department, appropriate licensing boards, and any other oversight entities.
 - (v) The certificate holder shall maintain specific written policies on the following:
 - (1) Client rights and responsibilities;
 - (2) Grievance policies and procedures for staff and clients including:
 - a. Specific time frames for written responses to the client's written request for consideration or reconsideration of a OTP decision;
 - b. Process for escalating unresolved grievances within the OTP; and
 - c. Information about making complaints to the department;
 - (3) Progressive discipline, leading to administrative discharge, including behaviors that may lead to progressive discipline and/or administrative discharge;
 - (4) Policies on client alcohol and other drug use while receiving OTP services;
 - (5) Policies to create a tobacco-free environment, which, at a minimum, shall:
 - a. Include the smoking of any tobacco product, the use of oral tobacco products or "spit" tobacco, and the use of electronic devices for smoking or vaping;
 - b. Apply to employees, clients, and visitors;
 - c. Prohibit the use of tobacco products within the OTP's facilities at any time;

- d. Include whether or not use of tobacco products is prohibited outside of the facility on the grounds and if use of tobacco products is allowed outside of the facility on the grounds:
 - 1. There shall be a designated smoking area(s) which is located at least 20 feet from the main entrance;
 - 2. All materials used for smoking in this area, including cigarette butts and matches, shall be extinguished and disposed of in appropriate containers; and
 - 3. OTPs shall ensure periodic cleanup of the designated smoking area;
- e. Prohibit the use of tobacco in any OTP owned vehicle;
- f. Prohibit tobacco use in personal vehicles when transporting clients or staff on authorized business;
- h. Post the tobacco free environment policy in the OTP's facilities and vehicles; and
- i. Provide the policy to employees, clients, and visitors at orientation, as applicable;
- (6) Drug-free workplace policy and procedures, including a requirement for the filing of written reports of actions taken in the event of staff misuse of alcohol or other drugs;
- (7) Client and staff exposure to synthetic opioids, including but not limited to fentanyl and carfentanyl;
- (8) Procedures for the prevention, detection, and resolution of controlled substance misuse and diversion, which shall:
 - a. Apply to all personnel;
 - b. Be the responsibility of a designated employee or interdisciplinary team; and
 - c. Include the following:
 - 1. Education;
 - 2. Procedures for monitoring the distribution and storage of controlled substances;
 - 3. Voluntary self-referral by employees who are misusing substances;
 - 4. Co-worker reporting procedures;
 - 5. Drug testing procedures to include at a minimum, testing where reasonable suspicion exists;
 - 6. Employee assistance procedures;
 - 7. Confidentiality;
 - 8. Investigation, reporting, and resolution of controlled drug misuse or diversion; and

- 9. The consequences for violation of the controlled substance misuse and diversion prevention policy;
- (9) A client medication policy;
- (10) Urine specimen collection, as applicable, that:
 - a. Ensures that collection is conducted in a manner that preserves client privacy as much as possible; and
 - b. Minimizes falsification;
- (11) Safety and emergency procedures on the following:
 - a. Medical emergencies;
 - b. Infection control and universal precautions, including the use of protective clothing and devices;
 - c. Reporting employee injuries;
 - d. Fire monitoring, warning, evacuation, and safety drill policy and procedures;
 - e. Emergency closings; and
 - f. Posting of the above safety and emergency procedures;
- (12) Procedures for protection of client records that govern use of records, storage, removal, conditions for release of information, and compliance with the 42 CFR, Part 2 and the Health Insurance Portability and Accountability Act (HIPAA); and
- (13) Procedures related to quality assurance and quality improvement.
- (w) The OTP shall ensure that all staff having direct contact with clients have been trained in the administration of naloxone and that naloxone kits are readily available for staff use at all times.
- (x) The OTP shall ensure that all staff have annual in-service training in the content and implementation of He-A 304.

He-A 304.13 Hours of Operation.

- (a) An OTP shall be open 7 days a week except for state and federal holidays and for emergency closures.
- (b) Dispensing hours shall be flexible enough to permit a client who is working or attending school to receive his or her methadone/buprenorphine without jeopardizing such work or school.
- (c) OTPs shall make reasonable accommodations for clients who are unable to utilize standard dispensing hours in (b) above due to work or school, including but not limited to allowing the client to dose outside of standard dispensing hours, but within the OTP's normal business hours.

- (d) An OTP shall maintain hours of operation that:
 - (1) Include day, evening, or both, and weekend hours to accommodate client need;
 - (2) Permit clients to receive medication individually and within 15 minutes of their scheduled dosing appointments; and
 - (3) Are posted at the facility and otherwise made available to clients.
- (e) An OTP shall provide clients with written notice at least 15 days prior to any change of standard hours of operation.
- (f) Pursuant to 42 CFR 8.12, clients shall be permitted to receive a take home dose for a day that the OTP is closed for business due to a state or federal holiday or an emergency closure.
- (g) An OTP shall establish and implement written procedures for emergency closures and holiday closures. Such procedures shall have been filed with the bureau.

He-A 304.14 Community Concerns.

- (a) An OTP shall have and implement policies and procedures that are designed to reduce the risk of its clients causing disruption to the community such as by loitering near the OTP facility premises or acting in a manner that might constitute disorderly conduct or harassment.
- (b) Clients who repeatedly cause disruption to the community or to the OTP shall be evaluated for possible administrative discharge from the OTP pursuant to the OTP's policies.
- (c) Each OTP shall have a specific plan describing its efforts to avoid disruption of the community and actions it will take to respond to community concerns.
- (d) If the OTP's plan in (c) above fails to prevent such disruption, the OTP shall provide the bureau with a written POC in accordance with He-A 304.09.
- (e) The OTP shall take steps to prevent clients from operating a motor vehicle while under the influence of intoxicating liquor or any controlled drug, prescription drug, over-the-counter drug, or any other chemical substance, natural or synthetic, which impairs a person's ability to drive, including but not limited to:
 - (1) Developing, maintaining, and implementing a policy regarding identifying signs of impairment;
 - (2) Assessing the client for impairment from alcohol and/or illicit or prescribed medications at the time of dosing;
 - (3) For those clients that are suspected to be impaired, requiring the client to take an instant oral fluid or urine drug screen prior to dosing;
 - (4) For those clients whose drug screen in (3) above is negative:

- a. Requiring the client to wait 2 hours and take a second instant oral fluid or urine drug screen; or
- b. If a medical professional identifies that impairment is the result of an underlying medical condition that requires immediate medical intervention, providing or procuring such intervention prior to the second screening in a. above;
- (5) If the drug screen in (3) or the second drug screen in (4) above is positive, the client shall only be provided with a dose that day as follows:
 - a. A licensed practitioner determines that it is medically safe for the client to be given a dose; and
 - b. Staff can confirm that the client will be transported by a person who is not impaired;
- (6) If a client appears to be impaired, taking reasonable steps to prevent the client from operating a motor vehicle while impaired; and
- (7) If unable to prevent the client from operating a motor vehicle while impaired, contacting law enforcement to report that the client may be operating a motor vehicle while impaired to the extent allowable under 42 CFR Part 2.

He-A 304.15 Client Fee Schedule.

- (a) The certificate holder shall maintain a current fee schedule for each program, which shall be clearly posted in a public area and a copy shall be available upon request.
- (b) The certificate holder shall maintain procedures regarding collection of fees from clients, private or public insurance, and other payers responsible for the client's finances.
- (c) At the time of screening and admission the certificate holder shall provide the client, and the client's guardian, agent, or personal representative, if any, with a listing of all charges and identify what care and services are included in the charge.

He-A 304.16 Clinical Services.

- (a) Each OTP shall have and adhere to a clinical care manual which includes policies and procedures related to all clinical services provided.
 - (b) All clinical services provided shall:
 - (1) Focus on the client's strengths;
 - (2) Be culturally competent with regard to the clients being served;
 - (3) Be client and family centered;
 - (4) Be evidence based, as demonstrated by meeting one of the following criteria:

- a. The service shall be included as an evidence-based mental health and substance use disorder intervention on the SAMHSA National Registry of Evidence-Based Programs and Practices (NREPP), http://www.nrepp.samhsa.gov/ViewAll.aspx;
- b. The services shall be published in a peer-reviewed journal and found to have positive effects; or
- c. The OTP shall be able to document the services' effectiveness based on the following:
 - 1. The service is based on a theoretical perspective that has validated research; or
 - 2. The service is supported by a documented body of knowledge generated from similar or related services that indicate effectiveness;
- (5) Be trauma informed, which means designed to acknowledge the impact of violence and trauma on people's lives and the importance of addressing trauma in services; and
- (6) Be delivered in accordance with:
 - a. The American Society of Addiction Medicine (ASAM) Criteria: Treatment Criteria for Substance-Related, Addictive, and Co-Occurring Conditions, Third Edition (2013), henceforth referred to as "ASAM Criteria (2013)" available as noted in Appendix A; and
 - b. The Treatment Improvement Protocols (TIPS) and Technical Assistance Publications (TAPS) published by SAMHSA and available at https://store.samhsa.gov/list/series?name=Technical-TIPS-&pageNumber=1 and https://store.samhsa.gov/list/series?name=Technical-Assistance-Publications-TAPs-&pageNumber=1, respectively, and as noted in Appendix A:
 - 1. "TAP 19: Relapse Prevention with Chemically Dependent Criminal Offenders, Counselor's Manual" (1/2006 edition);
 - 2. "TAP 21-A: Competencies for Substance Abuse Treatment Clinical Supervisors" (1/2013 edition);
 - 3. "TAP 21: Addiction Counseling Competencies: The Knowledge, Skills, and Attitudes of Professional Practice" (11/2015 edition);
 - 4. "TAP 34: Disaster Planning Handbook for Behavioral Health Treatment Programs" (5/2012 edition);
 - 5. "TIP 51: Substance Abuse Treatment: Addressing the Specific Needs of Women" (11/2015 edition);
 - 6. "TIP 55: Behavioral Health Services for People Who Are Homeless" (11/2015 edition);
 - 7. "TIP 59: Improving Cultural Competence" (11/2015 edition);
 - 8. "TIP 60: Using Technology-Based Therapeutic Tools in Behavioral Health Services" (11/2015 edition);

- 9. "TIP 41: Substance Abuse Treatment: Group Therapy" (10/2015 edition);
- 10. "TIP 45: Detoxification and Substance Abuse Treatment" (10/2015 edition);
- 11. "TIP 27: Comprehensive Case Management for Substance Abuse Treatment" (10/2015 edition);
- 12. "TIP 39: Substance Abuse Treatment and Family Therapy" (10/2015 edition);
- 13. "TIP 50: Addressing Suicidal Thoughts and Behaviors in Substance Abuse Treatment" (10/2015 edition);
- 14. "TIP 52: Clinical Supervision and Professional Development of the Substance Abuse Counselor" (9/2014 edition);
- 15. "TIP 56: Addressing the Specific Behavioral Health Needs of Men" (5/2014 edition);
- 16. "TIP 57: Trauma-Informed Care in Behavioral Health Services" (3/2014 edition);
- 17. "TIP 58: Addressing Fetal Alcohol Spectrum Disorders (FASD)" (12/2013 edition);
- 18. "TIP 44: Substance Abuse Treatment for Adults in the Criminal Justice System" (9/2013 edition);
- 19. "TIP 42: Substance Abuse Treatment for Persons With Co-Occurring Disorders" (7/2013 edition);
- 20. "TIP 35: Enhancing Motivation for Change in Substance Abuse Treatment" (1/2013 edition);
- 21. "TIP 48: Managing Depressive Symptoms in Substance Abuse Clients During Early Recovery" (1/2013 edition);
- 22. "TIP 46: Substance Abuse: Administrative Issues in Outpatient Treatment" (12/2012 edition);
- 23. "TIP 34: Brief Interventions and Brief Therapies for Substance Abuse" (9/2012 edition);
- 24. "TIP 36: Substance Abuse Treatment for Persons with Child Abuse and Neglect Issues" (7/2012 edition);
- 25. "TIP 29: Substance Use Disorder Treatment for People With Physical and Cognitive Disabilities" (7/2012 edition);
- 26. "TIP 37: Substance Abuse Treatment for Persons With HIV/AIDS" (7/2012 edition);

- 27. "TIP 32: Treatment of Adolescents With Substance Use Disorders" (4/2012 edition);
- 28. "TIP 54: Managing Chronic Pain in Adults With or in Recovery From Substance Use Disorders" (1/2012 edition);
- 29. "TIP 53: Addressing Viral Hepatitis in People With Substance Use Disorders" (12/2011 edition); and
- 30. "TIP 21: Combining Alcohol and Other Drug Abuse Treatment With Diversion for Juveniles in the Justice System" (4/2008 edition).
- (c) All OTPs shall offer the following clinical services:
 - (1) Screening and evaluation services;
 - (2) Treatment services;
 - (3) Recovery support services;
 - (4) Transfer and discharge services; and
 - (5) Client record services.

He-A 304.17 Personnel Requirements.

- (a) The OTP shall employ an administrator responsible for the day to day operations of the OTP.
- (b) Administrators appointed after the 2018 effective date of these rules shall be at least 21 years of age and have a minimum of one of the following combinations of education and experience:
 - (1) A bachelor's degree from an accredited institution and one year of relevant experience working in a substance use disorders treatment related field;
 - (2) An associate's degree from an accredited institution plus 3 years of relevant experience working in a substance use disorders treatment related field; or
 - (3) A New Hampshire license as an RN, MLADC, LADC, or other licensed behavioral health practitioner, with at least one year of relevant experience working in a substance use disorders treatment related field.
 - (c) The OTP shall employ a medical director that meets the requirements of He-A 304.23.
 - (d) The OTP shall meet the minimum staffing requirements:
 - (1) At least one:
 - a. Masters licensed alcohol and drug counselor (MLADC); or
 - b. Licensed alcohol and drug counselor (LADC) who also holds the licensed clinical supervisor (LCS) credential;

- (2) Sufficient staffing levels that are appropriate for the services provided and the number of clients served;
- (3) All unlicensed staff providing treatment, education, and/or recovery support services shall be under the direct supervision of a licensed supervisor;
- (4) No licensed supervisor shall supervise more than 8 unlicensed staff;
- (5) Unlicensed staff shall receive at least one hour of supervision for every 20 hours of direct client contact;
- (6) Supervision shall be provided on an individual or group basis, or both, depending upon the employee's need, experience, and skill level;
- (7) Supervision shall include following techniques:
 - a. Review of case records;
 - b. Observation of interactions with clients;
 - c. Skill development; and
 - d. Review of case management activities; and
- (8) Supervisors shall maintain a log of the supervision date, duration, content, and who was supervised by whom.
- (e) Individuals licensed or certified by the NH board of licensing for alcohol and other drug use professionals or any other NH licensing board shall receive supervision in accordance with the requirements set forth for the license(s) held by the individual.
- (f) The certificate holder shall develop a current job description for all staff, including contracted staff, volunteers, and student interns, which includes:
 - (1) Job title;
 - (2) Physical requirements of the position;
 - (3) Education and experience requirements of the position;
 - (4) Duties of the position;
 - (5) Positions supervised; and
 - (6) Title of immediate supervisor.
- (g) For all applicants for employment, for all contractors, for all volunteers, and for all student interns, the certificate holder shall:

- (1) Require those individuals listed in (d) above to sign a release to allow the OTP to obtain his or her criminal record:
- (2) Obtain and review a criminal records check from the New Hampshire department of safety, except, pursuant to RSA 151:2-d, VI, for those licensed by the New Hampshire board of nursing;
- (3) Review the results of the criminal records check in (2) above in accordance with (h) below; and
- (4) Verify the qualifications of all applicants prior to employment.
- (h) Unless a waiver is granted in accordance with (j)(2) below, the certificate holder shall not offer employment, contract with, or engage a person in (g) above, if the person:
 - (1) Has been convicted of a felony in this or any other state;
 - (2) Has been convicted of a sexual assault, other violent crime, assault, fraud, theft, abuse, neglect, or exploitation in this or any other state;
 - (3) Has had a finding by the department or any administrative agency in this or any other state for assault, fraud, theft, abuse, neglect, or exploitation of any person; or
 - (4) Otherwise poses a threat to the health, safety, or well-being of clients.
- (i) If the information identified in (h) above regarding any person in (g) above is learned after the person is hired, contracted with, or engaged, the certificate holder shall immediately notify the department and either:
 - (1) Cease employing, contracting with, or engaging the person; or
 - (2) Request a waiver of (h) above.
- (j) If a waiver of (h) above is requested, the department shall review the information and the underlying circumstances in (h) above and shall either:
 - (1) Notify the certificate holder that the person cannot or can no longer be employed, contracted with, or engaged by the certificate holder if, after investigation, it determines that the person poses a threat to the health, safety, or well-being of a client; or
 - (2) Grant a waiver of (h) above if, after investigation, it determines that the person does not pose a current threat to the health, safety, or well-being of a client.
- (k) The certificate holder shall check the names of the persons in (g) above against the bureau of elderly and adult services (BEAS) state registry, maintained pursuant to RSA 161-F:49 and He-W 720, prior to employing, contracting with, or engaging them.
- (l) The certificate holder shall not employ, contract with, or engage, any person in (g) above who is listed on the BEAS state registry unless a waiver is granted by BEAS.

- (m) In lieu of (g) and (k) above, the licensee may accept from independent agencies contracted by the certificate holder a signed statement that the agency's employees have complied with (g) and (k) above and do not meet the criteria in (h) and (l) above.
 - (n) All staff, including contracted staff, volunteers, and student interns, shall:
 - (1) Meet the educational, experiential, and physical qualifications of the position as listed in their job description;
 - (2) Be licensed, registered, or certified as required by state statute and as applicable;
 - (3) Receive an orientation within the first 3 days of work or prior to direct contact with clients and annually thereafter, which includes:
 - a. The OTP's code of ethics, including ethical conduct and the reporting of unprofessional conduct;
 - b. The OTP's policies on client rights and responsibilities and complaint procedures;
 - c. Confidentiality requirements as required by He-A 304.12(p);
 - d. Grievance procedures for both clients and staff as required in He-A 304.12(v)(2);
 - e. The duties and responsibilities and the policies, procedures, and guidelines of the position they were hired for;
 - f. Topics covered by both the administrative and personnel manuals;
 - g. The OTP's infection prevention program;
 - h. The OTP's fire, evacuation, and other emergency plans which outline the responsibilities of personnel in an emergency; and
 - i. Mandatory reporting requirements for abuse or neglect such as those found in RSA 161-F and RSA 169-C:29; and
 - (4) Sign and date documentation that they have taken part in an orientation as described in (3) above;
 - (o) Prior to having contact with clients, employees, contractors, volunteers, and student interns shall:
 - (1) Submit to the certificate holder proof of a physical examination or a health screening conducted not more than 12 months prior to employment which shall include at a minimum the following:
 - a. The name of the examinee;
 - b. The date of the examination:
 - c. Whether or not the examinee has a contagious illness or any other illness that would affect the examinee's ability to perform their job duties;

- d. Results of a 2-step tuberculosis (TB) test, Mantoux method, or other method approved by the Centers for Disease Control (CDC); and
- e. The dated signature of the licensed health practitioner;
- (2) Be allowed to work while waiting for the results of the second step of the TB test when the results of the first step are negative for TB; and
- (3) Comply with the requirements of the Centers for Disease Control and Prevention "Guidelines for Preventing the Transmission of *M. tuberculosis* in Health-Care Settings" (2005 edition), available as noted in Appendix A, if the person has either a positive TB test, or has had direct contact or potential for occupational exposure to *M. tuberculosis* through shared air space with persons with infectious tuberculosis.
- (p) Employees, contractors, volunteers, and student interns who have direct contact with clients who have a history of TB or a positive skin test shall have a symptomatology screen of a TB test.
- (q) The certificate holder shall maintain and store in a secure and confidential manner, a current personnel file for each employee, contractor, volunteer, and student intern.
 - (r) A personnel file shall include, at a minimum, the following:
 - (1) A completed application for employment or a resume, including:
 - a. Identification data; and
 - b. The education and work experience of the employee;
 - (2) A copy of the current job description or agreement, signed by the individual, that identifies the:
 - a. Position title;
 - b. Qualifications and experience; and
 - c. Duties required by the position;
 - (3) Written verification that the person meets the OTP's qualifications for the assigned job description, such as school transcripts, certifications, and licenses as applicable;
 - (4) A signed and dated record of the orientation required by (n)(3) above;
 - (5) A copy of each current New Hampshire license, registration, or certification, including CPR certification, as applicable;
 - (6) Records of screening for communicable diseases results required in (o) above;
 - (7) Written performance appraisals for each year of employment or engagement including a description of any corrective actions, supervision, or training determined by the person's supervisor to be necessary;

- (8) Documentation of annual in-service education required in He-A 304.12(x);
- (9) Information as to the general content and length of all continuing education or educational programs attended;
- (10) A signed statement acknowledging the receipt of the OTP's policy setting forth the client's rights and responsibilities, including confidentiality requirements, and acknowledging training and implementation of the policy;
- (11) A statement, which shall be signed at the time the initial offer of employment is made and then annually thereafter, stating that he or she:
 - a. Does not have a felony conviction in this or any other state;
 - b. Has not been convicted of a sexual assault, other violent crime, assault, fraud, theft, abuse, neglect, or exploitation or pose a threat to the health, safety, or well-being of a client; and
 - c. Has not had a finding by the department or any administrative agency in this or any other state for assault, fraud, theft, abuse, neglect, or exploitation of any person;
- (12) Documentation of the criminal records check and any waivers per (g) and (j) above; and
- (13) The results of a check of the BEAS state registry per (k) above.
- (s) An individual need not re-disclose any of the matters in (r)(11) above if the documentation is available and the department has previously reviewed the material and determined that the individual can continue employment, contract, or engagement.
- (t) All OTPs using the services of independent contractors as personnel shall ensure that each personnel file includes a written agreement that describes the services that will be provided.

He-A 304.18 Client Record System.

- (a) Each OTP shall have policies and procedures to implement a comprehensive client record system that complies with this section.
- (b) In addition to (a) above, the OTP shall enter client information into the department's Web Information Technology System (WITS), at https://nh.witsweb.org/, or subsequent web based database, as follows:
 - (1) No later than 3 days following admission to the OTP, the OTP shall complete the following WITS modules:
 - a. Client information (profile), including:
 - 1. Name(s);
 - 2. Gender;

3. Date of birth;
4. Last 4 digits of the client's social security number
5. Ethnicity, if provided by the client;
6. Race, if provided by the client;
7. Special needs, if any;
8. Sexual orientation, if provided by the client;
9. Preferred language;
10. Veteran status;
11. Family member veteran status; and
12. Contact information;
b. Intake transaction, including:
1. Intake facility;
2. Intake staff;
3. Method of initial contact;
4. Town of residence;
5. Referral source;
6. Case status;
7. Initial contact date;
8. Intake date;
9. Pregnancy status, if applicable;
10. HIV testing history, if provided by the client;
11. History of injection drug use;
12. Information on court mandates for treatment;
13. Presenting problem; and
14. Service domain;

c. Admission, including;

1. Admission type;
2. Admission staff;
3. Admission date;
4. Codependent status;
5. Treatment history;
6. Emergency department utilization;
7. Mental health status, if provided by the client;
8. Planned opiate replacement therapy;
9. Education level;
10. Community based support group utilization;
11. Employment status;
12. Income;
13. Payer information;
14. Living situation;
15. Marital status;
16. Number of dependents;
17. Substance use information;
18. Arrest history, if provided by the client; and
19. Diagnostic information; and
d. Program enrollment, including:
1. Program name;
2. Enrolling staff;
3. Program start date;
(2) No later than 3 days following discharge from the OTP, the OTP shall complete the following WITS modules:
a. Program disenrollment, including:

2. Termination reason; and
b. Discharge, including:
1. Discharge date;
2. Date of last contact;
3. Discharge staff;
4. Discharge reason;
5. Community based support group utilization;
6. Arrest history, if provided by the client;
7. Pregnancy status, if applicable;
8. Relationship status;
9. Living arrangement;
10. Employment status;
11. Emergency department utilization;
12. Town of residence;
13. Substance use information; and
14. Diagnosis information; and
(3) No later than 3 days following a change to any of the information in (1) and (2) above, the information shall be updated in WITS.
(c) The client record shall include, but not be limited to:
(1) A record of all client screenings, including, but not limited to:
a. The client name and/or unique client identifier generated by WITS;
b. Client demographic information, including but not limited to:
1. Pregnancy status;

2. Primary, secondary, and tertiary substance, severity frequency and method;

1. Program end date; and

3. Age of first use;

- 4. Intravenous drug use status;
- 5. Presence of a co-occurring mental health disorder;
- 6. Past 30 days arrests, if provided by the client;
- 7. Gender:
- 8. Veteran status;
- 9. Past 14 day administration of Narcan; and
- 10. Involvement with the criminal justice and/or child protection systems;
- c. The client referral source;
- d. The date of initial contact from the client or referring provider;
- e. The date of screening; and
- f. The result of the screening, including the reason for denial of services if applicable;
- (2) Identification data;
- (3) The date of admission;
- (4) If either of these have been appointed for the client, the name and address of the guardian and the representative payee;
- (5) The name, address, and telephone number of the person to contact in the event of an emergency;
- (6) Contact information for the person or entity referring the client for services, as applicable;
- (7) The name, address, and telephone number of the primary health care provider;
- (8) The name, address, and telephone number of the behavioral health care provider, if applicable;
- (9) The name and address of the client's public or private health insurance provider(s), or both, if applicable;
- (10) The client's personal health history;
- (11) The client's mental health history;
- (12) Current medications;
- (13) Signed receipt of notification of client rights;

- (14) Documentation of all elements of the initial screening and evaluation required by He-A 304.21;
- (15) The individual treatment plan, as required by He-A 304.23(e)-(g), updated at designated intervals in accordance with He-A 304.23(h)-(i);
- (16) Documentation that is consistent with SAMHSA's "TAP 21: Addiction Counseling Competencies" (2015 edition), available as noted in Appendix A, of all client services, including, but not limited to:
 - a. Record of all doses provided to the client; and
 - b. Progress notes detailing all services required in:
 - 1. He-A 304.15(c);
 - 2. He-A 304.22(a)-(b);
 - 3. He-A 304.23(c)-(d), (j), and (r);
 - 4. He-A 304.24;
 - 5. He-A 304.25(b); and
 - 6. He-A 304.27(a);
- (17) A narrative discharge summary, as required by He-A 304.28(f);
- (18) Release of information forms compliant with 42 CFR, Part 2;
- (19) Signed informed consent to treatment, including but not limited to an explanation of the department's access to client records;
- (20) Any correspondence pertinent to the client;
- (21) Any other information the OTP deems relevant; and
- (22) For any client who is placed on a waitlist:
 - a. All referrals to and coordination with interim services or reason that such referrals were not made;
 - b. All client contacts between screening and removal from the waitlist; and
 - c. The date the client was removed from the waitlist and the reason for removal.
- (d) All client records maintained by the OTP or its contractors shall be strictly confidential.
- (e) All confidential information shall be maintained in compliance with 42 CFR, Part 2.
- (f) OTPs shall retain client records after the discharge or transfer of the client, as follows:

- (1) For a minimum of 7 years for an adult; and
- (2) For a minimum of 7 years after age of majority for children.
- (g) In the event of an OTP closure, the OTP shall arrange for the continued management of all client records. The closing OTP shall notify the department in writing of the address where records will be stored and specify the person managing the records.
- (h) The closing OTP shall arrange for storage of each record through one or more of the following measures:
 - (1) Continue to manage the records and give written assurance to the department that it will respond to authorized requests for copies of client records within 10 working days;
 - (2) Transfer records of clients who have given written consent to another certified OTP; or
 - (3) Enter into a limited service organization agreement with a certified provider to store and manage records.

He-A 304.19 Quality Management.

- (a) On a quarterly basis, OTPs shall conduct a client record review of a minimum of 10% of the open client records, in order to evaluate the delivery of services identified in the treatment plan and to ensure that clients' needs are being met.
- (b) OTPs shall document the results of the review in (a) above in a quarterly quality management report, including:
 - (1) The number of records reviewed;
 - (2) A summary of the review results;
 - (3) A description of any deficiencies identified;
 - (4) The corrective action taken and/or planned to address the deficiencies identified in (3) above including the dates action was taken or will be taken;
 - (5) An evaluation of the effectiveness of the corrective action taken; and
 - (6) A summary of unmet service needs.
- (c) OTPs shall plan and take any remedial action necessary to address deficiencies in service delivery identified in the quarterly quality management report in (b) above.
- (d) OTPs shall retain the quarterly quality management report in (b) above for 2 years and make them available to the department upon request.

He-A 304.20 Client Eligibility, Admission, and Denial of Services.

- (a) An OTP shall determine eligibility for admission in accordance with 42 CFR 8.12 (e) and ASAM Criteria (2013), available as noted in Appendix A.
- (b) When an OTP's service capacity has been reached, the OTP shall maintain a waiting list of clients screened but not offered services.
- (c) Regardless of service capacity, an OTP shall admit pregnant women for treatment within 2 business days of initial contact, and if the OTP is unable to admit within 2 business days, such a client shall be referred to the department for assistance.
 - (d) Clients shall be admitted for services from a waiting list in the following order of priority:
 - (e) OTPs shall admit clients for services according to the order of priority described below:
 - (1) Pregnant women shall be admitted for treatment within 2 business days of initial contact, and if the OTP is unable to admit within 2 business days, such a client shall be referred to the department for assistance;
 - (2) Individuals who have been administered Narcan to reverse the effects of an opioid overdose either in the 14 days prior to screening or in the period between screening and admission to the OTP:
 - (3) Individuals with a history of injection drug use;
 - (4) Individuals with substance use and co-occurring mental health disorders;
 - (5) Veterans with substance use disorders; and
 - (6) Individuals with substance use disorders who are involved with the criminal justice system or child protection system.
 - (f) For any client who is denied services, the OTP shall:
 - (1) Inform the client of the reason for denial;
 - (2) Assist the client in identifying and accessing appropriate available services.
- (g) The OTP shall not deny services to a client solely because the client evidences one or more of the following:
 - (1) Previously left services against the advice of staff;
 - (2) Relapsed from an earlier service episode;
 - (3) Is on any class of medications, including but not limited to opiates or benzodiazepines, unless treatment with methadone/buprenorphine is contraindicated; or
 - (4) Has been diagnosed with a mental health disorder.
 - (h) A client who meets the criteria in (a) shall only be denied services if:

- (1) The client was previously administratively discharged from services for abusive, violent, or illegal behavior; or
- (2) The client is unable to demonstrate an ability to pay for services.
- (i) The OTP shall report on (c) (e) above at the request of the department.

He-A 304.21 Screening and Evaluation Requirements.

- (a) A screening interview shall be conducted by a licensed counselor, unlicensed counselor under supervision of a licensed supervisor, or CRSW in accordance with SAMHSA's "TAP 21: Addiction Counseling Competencies" (2015 edition), available as noted in Appendix A.
 - (b) The information gathered during the interview in (a) above shall be used to determine:
 - (1) The likelihood that the client meets criteria for an opioid use disorder as described in the American Psychiatric Association's "Diagnostic and Statistical Manual of Mental Disorders (DSM-5)," Fifth Edition (2013), available as noted in Appendix A;
 - (2) An estimate of the appropriate initial level of care for the client based on ASAM Criteria (2013), available as noted in Appendix A; and
 - (3) Whether or not the client fits into a priority population as established in He-A 304.20(b).
- (c) For clients who require treatment services as determined by the screening interview in (a) above, a clinical evaluation interview shall be conducted and documented:
 - (1) By a licensed counselor or unlicensed counselor under supervision of a licensed supervisor;
 - (2) In accordance with SAMHSA's "TAP 21: Addiction Counseling Competencies" (2015 edition), available as noted in Appendix A;
 - (3) Utilizing an evidence-based evaluation tool;
 - (4) Addressing all ASAM Criteria (2013), available as noted in Appendix A, domains; and
 - (5) Including an HIV/AIDS screening, to include:
 - a. The provision of information;
 - b. Risk assessment;
 - c. Intervention and risk reduction education, and
 - d. Referral for testing, if appropriate, within 7 days of admission.
 - (d) The information gathered during the interview in (a) above shall be used to:
 - (1) Determine if a client meets DSM-5 criteria for a opioid use disorder and to document the appropriate DSM-5 diagnosis(es);

- (2) Determine the appropriate initial level of care for the client based on ASAM Criteria (2013), available as noted in Appendix A; and
- (3) Develop the client's treatment plan in accordance with He-A 304.23.
- (e) Each client shall have a medical examination conducted in accordance with 42 CFR Part 1, 8.12(f)(2).

He-A 304.22 Opportunity To Participate in Withdrawal Management Required.

- (a) A licensed practitioner shall ensure, and shall document in the client's record, that each client is offered the opportunity to participate in a methadone/buprenorphine withdrawal management program instead of a maintenance treatment program at the time of admission, at least every 6 months thereafter, and upon client request.
- (b) When clinically appropriate based on ASAM Criteria (2013), available as noted in Appendix A, the licensed practitioner shall encourage clients to choose a methadone/buprenorphine withdrawal management program instead of a maintenance treatment program. Such encouragement shall not be considered a requirement to participate in a withdrawal management program.
- (c) The licensed practitioner shall document in the client's record the clinical appropriateness of the form of treatment chosen.

He-A 304.23 Required Medical and Clinical Services.

- (a) The OTP shall have a designated medical director who shall be responsible for all medical services.
 - (b) The medical director shall ensure that, for every client:
 - (1) Treatment plans are prepared and updated pursuant to (f)-(i) below;
 - (2) The client's need for methadone/buprenorphine maintenance is evaluated at least every 6 months;
 - (3) Any controlled substances prescribed for a client are clinically justified and documented in accordance with all applicable regulations, statutes, and rules; and
 - (4) A determination is made regarding the client's need for any other specialized services, such as treatment for other substance use disorders, medical services, or psychiatric services, and any such conditions are identified and treated or a referral is made to an appropriate service provider.
- (c) Upon a client's admission, the OTP shall conduct a client orientation, either individually or by group, to include the following:
 - (1) Rules, policies, and procedures of the OTP and facility;
 - (2) Obtaining consent, which is compliant with 42 CFR Part 2, relative to the OTP reporting to law enforcement that a client may be operating a motor vehicle while impaired in as described in He-A 304.14(e);

- (3) Requirements for successfully completing the program;
- (4) The administrative discharge policy and the grounds for administrative discharge;
- (5) All applicable laws regarding confidentiality, including the limits of confidentiality and mandatory reporting requirements; and
- (6) Requiring the client to sign a receipt that the orientation was conducted.
- (d) Pregnancy testing shall be conducted as follows:
 - (1) Unless contraindicated by sexual orientation or physiological factors, a OTP shall test monthly for pregnancy any female client of childbearing age who is using methadone/buprenorphine;
 - (2) If pregnancy is confirmed, the OTP shall:
 - a. Refer the client for health care for her pregnancy; and
 - b. Coordinate her treatment with all health care providers involved in her prenatal care; and
 - (3) If a pregnant client refuses to obtain primary care for her pregnancy, staff shall ask the client to sign a statement indicating she has refused such care, or shall document the client's refusal of care and refusal to sign.
- (e) A licensed counselor or unlicensed counselor under the supervision of a licensed supervisor shall develop and maintain a written treatment plan for each client in accordance with SAMHSA's "TAP 21: Addiction Counseling Competencies" (2015 edition), available as noted in Appendix A, which addresses all ASAM Criteria (2013), available as noted in Appendix A, domains.
 - (f) Treatment plans shall be developed in the first session following the evaluation.
 - (g) Individual treatment plans shall contain, at a minimum, the following elements:
 - (1) Goals, objectives, and interventions written in terms that are specific, measurable, attainable, realistic, and timely.
 - (2) Identifies the recipient's clinical needs, treatment goals, and objectives;
 - (3) Identifies the client's strengths and resources for achieving goals and objectives in (1) and (2) above;
 - (4) Defines the strategy for providing services to meet those needs, goals, and objectives;
 - (5) Identifies referral to outside providers for the purpose of achieving a specific goal or objective when the service cannot be delivered by the OTP;
 - (6) Provides the criteria for terminating specific interventions; and

- (7) Includes specification and description of the indicators to be used to assess the individual's progress.
- (8) Documentation of participation by the client in the treatment planning process or the reason why the client did not participate; and
- (9) Signatures of the client and the counselor agreeing to the treatment plan, or if applicable, documentation of the client's refusal to sign the treatment plan.
- (h) Treatment plans shall be reviewed no less frequently than every 4 sessions or every 4 weeks, whichever is less frequent and updated based on any changes in any of the ASAM Criteria (2013) domains, available as noted in Appendix A.
 - (i) Treatment plan updates shall include:
 - (1) Documentation of the degree to which the client is meeting treatment plan goals and objectives;
 - (2) Modification of existing goals or addition of new goals based on changes in the client's functioning relative to ASAM Criteria (2013), available as noted in Appendix A, domains and treatment goals and objectives;
 - (3) Documentation that the ASAM Criteria (2013), available as noted in Appendix A, transfer, discharge, and continuing care criteria were reviewed with the client in each of the ASAM Criteria (2013), available as noted in Appendix A, domains and that the client, counselor and licensed practitioner have jointly concluded that:
 - a. The client requires continued treatment at the current level of care; or
 - b. The client requires treatment at a higher or lower level of care and the updated treatment plan reflects transition to that level of care; and
 - (4) The signature of the client and the counselor agreeing to the updated treatment plan, or if applicable, documentation of the client's refusal to sign the treatment plan.
- (j) In addition to the individualized treatment planning in (d) above, all OTPs shall provide client education on:
 - (1) Substance use disorders;
 - (2) Relapse prevention;
 - (3) Infectious diseases associated with injection drug use, including but not limited to, HIV, hepatitis, and TB;
 - (4) Sexually transmitted diseases;
 - (5) Emotional, physical, and sexual abuse;
 - (6) Nicotine use disorder and cessation options;

- (7) The impact of drug and alcohol use during pregnancy, risks to the fetus, and the importance of informing medical practitioners of drug and alcohol use during pregnancy;
- (8) Education around neonatal abstinence syndrome (NAS) for pregnant women to include significant others and/or care givers as appropriate.
- (9) Working with family or significant others;
- (10) Living and coping skills;
- (11) Medication and drug education;
- (12) Dealing with a positive drug screen;
- (13) Education, vocational training, employment, or any combination thereof; and
- (14) Education about acquired immunodeficiency syndrome (AIDS) and human immunodeficiency virus (HIV).
- (k) Based on the client's treatment plan, methadone/buprenorphine maintenance treatment shall include medication and clinical services as detailed in Table 304.01.
 - (1) The OTP shall maintain the client with a dose adequate to alleviate all withdrawal symptoms;
- (m) The OTP shall establish client dosing based on individual need, as detailed in the client's treatment plan; and
 - (n) The OTP shall provide flexible dosage tapering at the client's request.
- (o) Upon a client's compliance with required treatment and counseling and the negative results for all drug screens conducted, the required number of hours of counseling shall be reduced and the allowed number of take-home doses shall be increased, in accordance with Table 304.01 below:

Table 304.1 Treatment, Counseling, and Take-Home Schedule

Consecutive Days in Compliance	Required Hours of	Allowed days supply of Take-
with He-A 304.24(o)	Counseling per Month	Home Doses per Week
1-90	8	0
91-180	8	1
181-364	6	2
365-540	4	3
541-730	4	4
731-909	2	5
910+	1	6

- (p) For clients who are required to engage in 8 hours of counseling per month, the OTP may reduce the number of hours by up to 4 hours if clinical staff determine that such a reduction will not result in an increased risk assessment in any of the ASAM Criteria (2013), available as noted in Appendix A, dimensions.
 - (q) An OTP shall not issue more than a 6-day supply of take-home doses to a client in one week.

- (r) Required substance use disorder counseling shall be based on the client's individualized treatment plan and be consistent with ASAM Criteria (2013), available as noted in Appendix A, and SAMHSA's TIPS and TAPS standards, as applicable, and include, at a minimum:
 - (1) Any combination of individual, group, or family substance use disorder treatment services;
 - (2) Case management services, which may be substituted on an hour-for-hour basis for up to 25% of the required counseling hours; and
 - (3) Discussion between clinical staff and the client regarding the commencement of a methadone/buprenorphine discontinuance plan, with projected target dates for implementation, which may:
 - a. Be short-term or long-term in nature based on the client's need and preference; and
 - b. Include intermittent periods of methadone/buprenorphine maintenance between discontinuance attempts.
- (s) If the licensed practitioner determines that split dosing is medically necessary, the OTP shall request a split-dose exception on-line, using the SAMHSA OTP Exception Request website at https://otpextranet.samhsa.gov/login.aspx?ReturnUrl=%2f.
- - (t) Such requests shall include, as appropriate: (1) OTP identification number;
 - (3) OTP name;
 - (4) OTP contact information;

(2) Patient identification number;

- (5) Requestor information;
- (6) Patient admission date;
- (7) Patient's current dosage;
- (8) Medication type;
- (9) Patient's attendance schedule;
- (10) Employment status;
- (11) Nature of the change request;
- (12) Start date of the requested change;
- (13) End date of the requested change;
- (14) Number of doses to be dispensed during the exception period;

- (15) Justification for the change request;
- (16) Regulatory compliance information; and
- (17) Submitting physician information and dated signature.
- (u) The OTP shall provide group education and counseling as follows:
 - (1) The OTP shall maintain an outline of each educational and group therapy session provided; and
 - (2) All group counseling sessions shall be limited to 12 clients or fewer per counselor.
- (v) All client activities and services shall be documented in accordance with SAMHSA's "TAP 21: Addiction Counseling Competencies" (2015 edition), available as noted in Appendix A, and He-A 304.18.

He-A 304.24 <u>Drug Screens</u>.

- (a) An OTP shall perform, or have performed, drug screens of clients as described in this section.
- (b) All new clients shall have a minimum of a drug screen upon admission and randomly every week thereafter for the first 3 months of treatment.
- (c) After the first 3 months of treatment, all clients shall have a minimum of one drug screen performed randomly every month.
- (d) All required drug screens shall include, at a minimum, the following substances or their metabolites:
 - (1) Opiates;
 - (2) Methadone;
 - (3) Buprenorphine;
 - (4) Amphetamines;
 - (5) Cocaine;
 - (6) Benzodiazepines;
 - (7) Cannabis; and
 - (8) Methamphetamine.
- (e) A drug screen shall be considered positive for illicit substances only if the substance identified is not being used under the supervision of and as directed by a licensed practitioner.

(f) When a client disputes the results of a positive drug screen, the screen shall only be considered positive after confirmatory testing by a Clinical Laboratory Improvement Amendments (CLIA) certified laboratory.

He-A 304.25 Take-Home Medications

- (a) An OTP's staff shall approve take-home methadone/buprenorphine only for a client who meets the take-home criteria in accordance with 42 CFR Part 8.12(h)(4)(i)(2).
- (b) In addition to the criteria in (a) above, a client shall complete individual or group counseling specific to the safe transport and storage of take-home medication to prevent diversion, theft, or use by another person, each time the client is eligible for consideration of an additional unsupervised take-home dose.
- (c) Prior to granting take-home privileges, and each time the client's progress is reviewed, the licensed practitioner shall document in the client's record that the criteria in (a) above have been met and that, in his or her judgment, the potential risk of diversion or misuse is outweighed by the rehabilitative benefits to be derived from decreasing the frequency of clinic attendance and the client's demonstrated overall responsibility in the handling of methadone/buprenorphine.
- (d) A client for whom take-home methadone/buprenorphine is authorized may be provided with one day of extra medication if the client's regular pickup falls on a state holiday.
- (e) For clients who demonstrate a need for a more flexible take-home methadone/buprenorphine schedule in order to enhance and extend their rehabilitative and community reintegration progress, an OTP may request of the department, approval to permit a client to follow a temporary take-home medication regimen.
 - (f) The department shall approve such requests in (e) above if it determines that:
 - (1) The client is unable to comply with the required treatment, counseling, and/or take-home schedule because of exceptional circumstances such as:
 - a. Illness;
 - b. Personal or family crisis;
 - c. Travel difficulties, such as bad weather; or
 - d. Other hardship that would similarly prevent the client's compliance;
 - (2) The licensed practitioner has found the client to be responsible in using methadone/buprenorphine as required in (c) above;
 - (3) The licensed practitioner has determined that a temporary reduction in clinic attendance is appropriate;
 - (4) The client is not given more than a 2-week supply of methadone/buprenorphine at one time;
 - (5) The reasons for permitting a temporary reduction in clinic attendance have been recorded by in the client's record;

- (6) Staff have determined that the rehabilitative benefit the patient derived from decreasing the frequency of clinic attendance outweighs the potential risks of diversion; and
- (7) The licensed practitioner has submitted such requests on-line, using the SAMHSA OTP Exception Request Website at https://otp-extranet.samhsa.gov/login.aspx?ReturnUrl=%2f, including:
 - a. OTP identification number:
 - b. Patient identification number;
 - c. OTP name;
 - d. OTP contact information;
 - e. Requestor information;
 - f. Patient admission date:
 - g. Patient's current dosage;
 - h. Medication type;
 - i. Patient's attendance schedule:
 - j. Employment status;
 - k. Nature of the change request;
 - 1. Start date of the requested change;
 - m. End date of the requested change;
 - n. Number of doses to be dispensed during the exception period;
 - o. Justification for the change request;
 - p. Regulatory compliance information; and
 - q. Submitting physician information and dated signature.

He-A 304.26 Treatment Requirements for Withdrawal Management.

- (a) For each client participating in withdrawal management, the OTP shall administer methadone/buprenorphine in a way designed for the client to reach an opioid-free state and to make progress in the ASAM Criteria (2013), available as noted in Appendix A, domains within a period of up to 180 days.
- (b) All requirements of He-A 304.23 through He-A 304.25 for treatment shall apply to withdrawal management.

- (c) Before a withdrawal management program is repeated, the licensed practitioner shall document in the client's record that the client continues to be or is again physiologically dependent on opioids.
- (d) Withdrawal management shall not be repeated unless a licensed practitioner documents in the client's record that the client continues to be or is again physiologically dependent on opioids; and
- (e) Repetition of withdrawal management episodes shall be determined in accordance with 42 CFR Part 8.

He-A 304.27 <u>Discontinuance of Methadone/Buprenorphine</u>.

- (a) At the time of admission and every 6 months thereafter, the OTP shall provide each client with a written protocol to request discontinuance of methadone/buprenorphine treatment, including but not limited to:
 - (1) The client's right to request discontinuance of treatment at any time;
 - (2) The process to be followed in making this request; and
 - (3) The procedure for filing any grievances related to this process.
- (b) An individual methadone/buprenorphine discontinuance plan shall be developed and implemented for all clients who request discontinuance.
- (c) The determination to voluntarily discontinue methadone/buprenorphine shall be left to the judgment of the client, in consultation with staff.
- (d) If staff do not agree with the client's decision to discontinue methadone/buprenorphine, the staff shall document such disagreement in the client's record.
 - (e) Reduction of a client's methadone/buprenorphine dosage shall:
 - (1) Be ordered and overseen by medical staff;
 - (2) Occur gradually in a manner that facilitates the client's discontinuance, as determined by the medical staff; and
 - (3) Be in accordance with the client's treatment goals.
- (f) In situations where staff have determined that onsite discontinuance is undesirable, such as due to the client's aggressive behavior:
 - (1) Alternative arrangements shall be offered by the staff; and
 - (2) If the client refuses all of the arrangements, the refusal shall be documented by staff in the client's record.
- (g) OTPs shall have procedures to modify a client's discontinuance protocol or to engage the client in withdrawal management or maintenance services in the event that a client relapses during discontinuance.

- (h) Continued services and supports necessary to support the client through and for up to 90 days after the discontinuance process shall be provided by the OTP in consultation with the clinical staff.
 - (i) OTPs shall have discharge policies as required by He-A 304.28.

He-A 304.28 Client Discharge and Transfer.

- (a) A client shall be discharged from an OTP for the following reasons:
 - (1) Program completion or transfer based on changes in the client's functioning relative to ASAM Criteria (2013), available as noted in Appendix A; or
 - (2) Program termination, including:
 - a. Administrative discharge;
 - b. The client left the program before completion against advice of treatment staff; and
 - c. The client is inaccessible, such as the client has been jailed or hospitalized.
- (b) An OTP may administratively discharge a client from a treatment program only if:
 - (1) The client's behavior on OTP premises is abusive, violent, or illegal;
 - (2) The client repeatedly causes disruption to the community or to the OTP and fails to change their behavior subsequent to written notice of the required behavior change;
 - (3) The client fails to pay fees within 5 business days after being informed in writing and counseled regarding financial responsibility and possible sanctions including discharge;
 - (4) The client has had unexcused absences on 3 consecutive medication days, and the medical director, after a reevaluation of the client, has determined that administrative discharge is warranted:
 - (5) Clinical staff documents therapeutic reasons for discharge, including but not limited to:
 - a. The client becoming unwilling to participate in achieving their treatment goals; or
 - b. The client continuing to use alcohol or other drugs in a manner that poses a risk to either the client's physical well-being or public safety;
 - (6) The client is non-compliant with prescription medications; or
 - (7) The client violates OTP rules in a manner that is consistent with the OTP's progressive discipline policy.
- (c) If a client is administratively discharged due to financial reasons in (b)(2) above, the OTP shall provide medically supervised withdrawal in accordance with (d) below, regardless of the client's ability to pay.

- (d) If a client is being administratively discharged for any reason, they shall have the opportunity to participate in medically supervised withdrawal as follows:
 - (1) The OTP shall maintain the client with a dose adequate to alleviate all withdrawal symptoms;
 - (2) The OTP shall establish client dosing based on individual need, as detailed in the client's treatment plan;
 - (3) The OTP shall provide flexible dosage tapering at the client's request;
 - (4) The OTP shall develop a detoxification schedule with daily dosage reductions of not more than 10 percent of the original dose;
 - (5) The OTP shall conduct daily observation of the client, monitoring for withdrawal symptoms;
 - (6) Methadone/buprenorphine shall be administered daily; and
 - (7) Take-home medications shall not be allowed during medically supervised withdrawal.
 - (e) Clients may transfer between OTPs subject to the following:
 - (1) When a client transferring to a program has received a medical examination within 3 months prior to admission, the OTP shall not conduct a new medical examination unless requested by the licensed practitioner;
 - (2) The OTP to which a client transfers shall include copies of the previous medical examination in the client's record within 30 days of admission;
 - (3) Upon receipt of an appropriately executed release of information, an OTP shall provide to the receiving OTP the client's clinical record, including attendance, dosage, previous 3 drug screens, and all pertinent medical information, even if the client still has an outstanding financial balance;
 - (4) Clients who have qualified for unsupervised take home doses at their previous methadone/buprenorphine opiate treatment program shall continue to receive unsupervised take home doses at the same level, not to exceed 6 take home doses per week, as long as the receiving OTP has verified the client's compliance in his or her previous program;
 - (5) When transferring a client, the counselor shall:
 - a. Complete a progress note on the client's treatment and progress towards treatment goals, to be included in the client's record; and
 - b. Update the client evaluation and treatment plan; and
 - (6) When transferring a client to another treatment program, the current OTP shall forward copies of the following information to the receiving OTP, only after a release of confidential information is signed by the client:
 - a. The discharge summary in (f) below;

- b. Client demographic information, including the client's name, date of birth, address, telephone number, and the last 4 digits of his or her Social Security number; and
- c. A diagnostic assessment statement and other assessment information, including:
 - 1. TB test results;
 - 2. A record of the client's treatment history; and
 - 3. Documentation of any court-mandated or OTP-recommended follow-up treatment.
- (f) In all cases of client discharge or transfer, the counselor shall complete a narrative discharge summary, including, at a minimum:
 - (1) The dates of admission and discharge or transfer;
 - (2) The client's psychosocial substance use history and legal history;
 - (3) A summary of the client's progress toward treatment goals in all ASAM Criteria (2013), available as noted in Appendix A, domains;
 - (4) The reason for discharge or transfer;
 - (5) The client's DSM-5 diagnosis and summary, to include other assessment testing completed during treatment;
 - (6) A summary of the client's physical condition at the time of discharge or transfer;
 - (7) A continuing care plan, as applicable, including all ASAM Criteria (2013), available as noted in Appendix A, domains; and
 - (8) The dated signature of the counselor completing the summary.
- (g) The discharge summary shall be completed no later than 7 days following a client's discharge or transfer from the OTP.
- (h) The counselor shall meet with the client at the time of discharge or transfer to establish a continuing care plan that:
 - (1) Includes recommendations for continuing care in all ASAM Criteria (2013), available as noted in Appendix A, domains;
 - (2) Addresses the use of community based support groups; and
 - (3) Assists the client in making contact with other agencies or services.
- (i) The counselor shall document in the client record if and why the meeting in (h) could not take place.

Appendix A: Incorporation by Reference Information

Rule	Title	Obtain at:
He-A 304.16(b)(6)a.;	ASAM Criteria:	Publisher: American Society of Addiction Medicine (ASAM).
.20(a); .21(b)(2),	Treatment Criteria for	The ASAM Criteria (2013) can be purchased online through the
(c)(4), (d)(2); .22(b);	Substance-Related,	ASAM website at: http://www.asamcriteria.org/.
.23(e), (h), (i)(2),	Addictive, and Co-	Cost = \$95 (non-members) or \$85 (members). Discounts are available
(i)(3), (p), (r); .27(a);	Occurring	for large purchases.
.28(a)(1), (f)(3),	Conditions, Third	Tot imige purvisases
(f)(7), (h)(1)	Edition (2013)	
He-A	1. "TAP 19:	Publisher: U.S. Department of Health and Human Services, Substance
304.16(b)(6)b.14.	Relapse Prevention	Abuse and Mental Health Services Administration (SAMHSA), Center
	with Chemically	for Substance Abuse Treatment, www.samhsa.gov.
	Dependent Criminal	
	Offenders,	The Technical Assistance Publications (TAPS) are available at:
	Counselor's Manual"	https://store.samhsa.gov/list/series?name=Technical-Assistance-
	(1/2006 edition);	Publications-TAPs-&pageNumber=1
	2. "TAP 21-A:	
	Competencies for	
	Substance Abuse	
	Treatment Clinical	
	Supervisors"	
	(1/2013 edition);	
	3. "TAP 21:	
	Addiction	
	Counseling	
	Competencies: The	
	Knowledge, Skills, and Attitudes of	
	Professional	
	Practice" (11/2015	
	edition);	
	4. "TAP 34:	
	Disaster Planning	
	Handbook for	
	Behavioral Health	
	Treatment	
	Programs" (5/2012	
	edition)	
He-A	5. "TIP 51:	Publisher: U.S. Department of Health and Human Services, Substance
304.16(b)(6)b.530.	Substance Abuse	Abuse and Mental Health Services Administration (SAMHSA), Center
23.110(0)(0)0.3.30.	Treatment:	for Substance Abuse Treatment, www.samhsa.gov.
	Addressing the	
	Specific Needs of	The Treatment Improvement Protocols (TIPS) are available free of
	Women" (11/2015	charge at:
	edition);	· · · · · · · · · · · · · · · · · · ·
	6. "TIP 55:	https://store.samhsa.gov/list/series?name=TIP-Series-Treatment-
	Behavioral Health	Improvement-Protocols-TIPS-&pageNumber=1
	Services for People	
	Who Are Homeless"	

Rule	Title	Obtain at:
	(11/2015 edition);	
	7. "TIP 59:	
	Improving Cultural	
	Competence"	
	(11/2015 edition);	
	8. "TIP 60: Using	
	Technology-Based	
	Therapeutic Tools in	
	Behavioral Health	
	Services" (11/2015	
	edition);	
	9. "TIP 41:	
	Substance Abuse	
	Treatment: Group	
	Therapy" (10/2015	
	edition);	
	10. "TIP 45:	
	Detoxification and	
	Substance Abuse	
	Treatment" (10/2015	
	edition);	
	11. "TIP 27:	
	Comprehensive	
	Case Management	
	for Substance Abuse	
	Treatment" (10/2015	
	edition);	
	12. "TIP 39:	
	Substance Abuse	
	Treatment and	
	Family Therapy"	
	(10/2015 edition);	
	13. "TIP 50:	
	Addressing Suicidal	
	Thoughts and Behaviors in	
	Substance Abuse	
	Treatment" (10/2015	
	edition);	
	14. "TIP 52:	
	Clinical Supervision	
	and Professional	
	Development of the	
	Substance Abuse	
	Counselor" (9/2014	
	edition);	
	15. "TIP 56:	
	Addressing the	
	Specific Behavioral	
	Health Needs of	
	11041411110045 01	

Rule	Title	Obtain at:
	Men" (5/2014	
	edition);	
	16. "TIP 57:	
	Trauma-Informed	
	Care in Behavioral	
	Health Services"	
	(3/2014 edition);	
	17. "TIP 58:	
	Addressing Fetal	
	Alcohol Spectrum	
	Disorders (FASD)"	
	(12/2013 edition);	
	18. "TIP 44:	
	Substance Abuse	
	Treatment for Adults	
	in the Criminal	
	Justice System"	
	(9/2013 edition);	
	19. "TIP 42:	
	Substance Abuse	
	Treatment for	
	Persons With Co-	
	Occurring	
	Disorders" (7/2013	
	edition);	
	20. "TIP 35:	
	Enhancing	
	Motivation for	
	Change in Substance	
	Abuse Treatment"	
	(1/2013 edition);	
	21. "TIP 48:	
	Managing	
	Depressive	
	Symptoms in	
	Substance Abuse	
	Clients During Early	
	Recovery" (1/2013	
	edition);	
	22. "TIP 46:	
	Substance Abuse:	
	Administrative	
	Issues in Outpatient	
	Treatment" (12/2012	
	edition);	
	23. "TIP 34: Brief	
	Interventions and	
	Brief Therapies for	
	Substance Abuse"	
	(9/2012 edition);	

Rule	Title	Obtain at:
	24. "TIP 36:	
	Substance Abuse	
	Treatment for	
	Persons with Child	
	Abuse and Neglect	
	Issues" (7/2012	
	edition);	
	25. "TIP 29:	
	Substance Use	
	Disorder Treatment	
	for People With	
	Physical and	
	Cognitive	
	Disabilities" (7/2012	
	edition);	
	26. "TIP 37:	
	Substance Abuse	
	Treatment for	
	Persons With	
	HIV/AIDS" (7/2012	
	edition);	
	27. "TIP 32:	
	Treatment of	
	Adolescents With	
	Substance Use	
	Disorders" (4/2012	
	edition);	
	28. "TIP 54:	
	Managing Chronic	
	Pain in Adults With	
	or in Recovery From	
	Substance Use	
	Disorders" (1/2012	
	edition);	
	29. "TIP 53:	
	Addressing Viral	
	Hepatitis in People	
	With Substance Use	
	Disorders" (12/2011	
	edition); and	
	30. "TIP 21:	
	Combining Alcohol	
	and Other Drug	
	Abuse Treatment	
	With Diversion for	
	Juveniles in the	
	Justice System"	
**	(4/2008 edition).	
He-A 304.17(o)(3)	Guidelines for	Publisher: U.S. Department of Health and Human Services, Centers for

Rule	Title	Obtain at:
	Preventing the	Disease Control and Prevention
	Transmission of <i>M.</i> tuberculosis in Health-Care Settings, 2005 edition	Available free of charge from the CDC website at www.cdc.gov .
He-A 304.18(c)(16)c.; 304.21(a); 304.21(c)(2); 304.23(e); and 304.23(u)	TAP 21: Addiction Counseling Competencies, 2015 edition	Publisher: U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment, www.samhsa.gov Available free of charge at: http://store.samhsa.gov/shin/content//SMA12-4171/SMA12-4171.pdf
He-A 304.21(b)(1)	Diagnostic and Statistical Manual of Mental Disorders (DSM-5), Fifth Edition (2013)	Publisher: The American Psychiatric Association (APA). The DSM-5 can be purchased on line at: https://www.appi.org/Course/Book/Subscription/JournalSubscription/id-3322/Diagnostic_and_Statistical_Manual_of_Mental_Disorders_(DSM-5®) The publication is available at a variety of formats and price points from \$96 to \$210.

APPENDIX B

Rule Number	RSA/Federal Citation
He-A 304	RSA 172:2-a; RSA 172:8-b, II; RSA 318-B:10, VII & VIII