PART He-A 304 OPERATIONAL REQUIREMENTS FOR OPIOID DETOXIFICATION AND METHADONE MAINTENANCE, TREATMENT AND REHABILITATION PROGRAMS

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

He-A 304.01 Purpose. 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 provider of an opioid detoxification and methadone maintenance, treatment, and rehabilitation program.

Source. #7496, eff 5-23-01; ss by #9476, eff 5-22-09

He-A 304.02 Definitions. The words and phrases used in these rules shall mean the following:

(a) "Buprenorphine" means a semi-synthetic opiate with partial agonist actions used in the treatment of opiate addiction.

(b) "Bureau" means the New Hampshire bureau of drug and alcohol services.

(c) "Client" means a person who is enrolled in a program and is receiving services from a provider certified by these rules.

(d) "Heroin" means "heroin" as defined in RSA 318-B:10, VII(d)(1), namely, "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."

(e) "Licensed practitioner" means a medical doctor, physician's assistant, advanced registered nurse practitioner, doctor of osteopathy or doctor of naturopathic medicine legally practicing in the State of New Hampshire.

(f) "Methadone" means "methadone" as defined in RSA 318-B:10, VII(d)(2), namely, "a legal drug, methadone hydrochloride, which is a synthetic opioid that has been demonstrated to be an effective treatment agent for heroin abuse and dependence."

(g) "Methadone detoxification treatment" means "methadone detoxification treatment" as defined in RSA 318-B:10, VII(d)(3), namely, "the dispensing of methadone or similar substance in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to the withdrawal from the sustained use of heroin."

(h) "Methadone maintenance program" means "methadone maintenance program" as defined in RSA 318-B:10, VII(d)(4), namely, "a substance abuse treatment program substituting methadone or any of its derivatives, over time, to relieve withdrawal symptoms of heroin dependence, to reduce craving, and to permit normal functioning and engagement in rehabilitative services."

(i) "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.

(j) "Program" means an opioid treatment program which provides opioid detoxification and methadone maintenance, treatment, and rehabilitation services.

(k) "Provider" means any public or private corporation, individual or organization which operates one or more programs for people with alcohol and other drug abuse disorders when such programs are funded in whole or in part by state or federal funds or are operated, monitored or regulated by the bureau.

Source. #7496, eff 5-23-01; ss by #9476, eff 5-22-09

He-A 304.03 Required Approvals. To be certified under He-A 304, an applicant for certification shall:

(a) Be in compliance with He-A 301 through He-A 304;

(b) Have either:

(1) A current accreditation as an opioid treatment program (OTP) from the Commission on Accreditation of Rehabilitation Facilities (CARF) or another Substance Abuse and Mental Health Services Administration (SAMHSA)-approved OTP accrediting body; or

(2) A provisional certification as an OTP from SAMHSA;

(c) Have a current registration with the U.S. Drug Enforcement Administration in accordance with 21 CFR 1301-1307;

(d) Have 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;

(e) Be in compliance with local planning and zoning ordinances;

(f) Have submitted copies of current documentation of required approvals in (b)-(e) above to the bureau; and

(g) Have set hours of operation and procedures for emergency closure and holiday closures that have been filed with the bureau.

Source. #7496, eff 5-23-01; amd by #7599, eff 11-20-01; ss by #9476, eff 5-22-09

He-A 304.04 Client Eligibility. A program shall determine eligibility for admission in accordance with 42 CFR Part 8, Section 8.12 (e).

Source. #7496, eff 5-23-01; ss by #9476, eff 5-22-09

He-A 304.05 Opportunity To Participate in Detoxification Treatment Required.

(a) The medical director shall ensure, and shall document in the client's record, that each client is offered the opportunity to participate in a methadone or buprenorphine detoxification treatment program instead of a maintenance treatment program at the time of admission and at least every 6 months thereafter.

(b) When clinically appropriate, the medical director shall encourage clients to choose a methadone or buprenorphine detoxification treatment program over a maintenance treatment program.

(c) The medical director shall document in the client's record the clinical appropriateness of the form of treatment chosen.

Source. #7496, eff 5-23-01; ss by #9476, eff 5-22-09

He-A 304.06 Required Medical, Treatment and Rehabilitation Services.

(a) The program shall have a designated medical director who shall be responsible for all medical services.

(b) The medical director shall ensure that, for every program client:

(1) Treatment plans are prepared and updated pursuant to He-A 302.08 and these rules;

(2) The client's need for methadone 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 alcoholism or psychiatric services, and any such conditions are identified and treated or a referral is made to an appropriate service provider.

Source. #7496, eff 5-23-01; ss by #9476, eff 5-22-09 (from He-A 304.07)

He-A 304.07 Treatment Requirements for Long-Term Detoxification.

(a) For each client participating in long-term detoxification, the program shall administer methadone or buprenorphine in a way designed for a client to reach a drug-free state and to make progress in rehabilitation within a period of between 90 and 180 days, as follows:

(1) The program shall maintain the client with a dose adequate to alleviate all withdrawal symptoms;

(2) The program shall establish client dosing based on individual need, as detailed in the client's treatment plan; and

(3) The program shall provide flexible dosage tapering at the client's request.

(b) All requirements of He-A 304.09 for maintenance treatment shall apply to long-term detoxification treatment with the following exceptions:

(1) Take-home medications shall not be allowed during long-term detoxification except as allowed for state holidays and special circumstances as outlined in He-A 304.10(c) and (d);

(2) A history of one-year physiologic dependence shall not be required for admission to long-term detoxification;

(3) The medical director shall document in the client's record that short-term detoxification is not sufficiently long enough to provide the client with the additional services and supports the physician deems necessary for the client's rehabilitation;

(4) Clients who have been determined by the program physician to be currently physiologically dependent on opioids may be placed, at the physician's discretion, in long-term detoxification treatment regardless of age;

(5) Drug screens shall be performed as follows:

a. An initial drug screen shall be performed for each client; and

b. At least one additional random screen shall be performed monthly on each client during long-term detoxification;

(6) Before the long-term detoxification attempt is repeated, the program physician shall document in the client's record that the client continues to be or is again physiologically dependent on opioids; and

(7) The requirements in (1)-(6) above shall apply to both inpatient and outpatient long-term detoxification treatment.

Source. #7496, eff 5-23-01; ss by #9476, eff 5-22-09 (from He-A 304.12)

He-A 304.08 Treatment Requirements for Short-Term Detoxification.

(a) For each client participating in short-term detoxification, the program shall administer methadone or buprenorphine in a way designed for a client to reach a drug-free state within a period no longer than 90 days, excluding the time needed for the program to maintain the client with a dose adequate to alleviate all withdrawal symptoms, as follows:

(1) The program shall maintain the client with a dose adequate to alleviate all withdrawal symptoms;

(2) The program shall establish client dosing based on individual need, as detailed in the client's treatment plan;

(3) The program shall provide flexible dosage tapering at the client's request; and

(4) The program shall conduct daily observation of the client, monitoring for withdrawal symptoms.

(b) For each client participating in short-term detoxification, the following program requirements shall apply:

(1) Methadone or buprenorphine shall be administered daily;

(2) Take-home medications shall not be allowed during short-term detoxification;

(3) A history of one-year physiologic dependence shall not be required for admission to short-term detoxification;

(4) No urine or blood test or analysis shall be required except for the initial drug screen;

(5) Short-term detoxification shall not be repeated unless the medical director documents in the client's record that the client continues to be or, is again, physiologically dependent on opioids;

(6) Subsequent short-term detoxifications allowed in (5) above shall be limited to one additional short-term detoxification in one 12-month period, in accordance with 42 CFR Part 8; and

(7) Short-term detoxification treatment shall only be used for a pregnant client if maintenance treatment has been determined by the treating physician to be ineffective.

Source. #7496, eff 5-23-01; ss by #9476, eff 5-22-09 (from He-A 304.11)

He-A 304.09 Treatment Requirements for Methadone Maintenance.

(a) Based on the client's treatment plan, methadone maintenance treatment shall include:

(1) Daily methadone doses, either administered on site at a program facility or as unsupervised take-home doses;

(2) Client counseling and rehabilitation;

(3) Urine and/or blood screening; and

(4) Over time, the gradual decrease in the number of required hours of counseling, and an increase in the allowable number of take-home methadone doses per week.

(b) During the first 90 days of treatment, clients shall:

(1) Attend the program 7 days per week for observation and on-site administration of methadone;

(2) Participate in 8 hours of counseling per month; and

(3) Not be provided with any take-home methadone doses, except as detailed in He-A 304.10 below.

(c) Upon a client's compliance with required treatment and counseling and the negative results for all urine and blood screens conducted, the required number of hours of counseling shall be reduced and the allowed number of take-home methadone doses shall be increased, in accordance with Table 304.01.

Table 304.1 Treatment, Counseling, and Take-Home Schedule

Days in Treatment	Required Hours of Counseling per Month	Allowed Doses of Take-Home Methadone 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

(d) No program shall issue more than a 6-day supply of take-home methadone to a client in one week.

(e) Regardless of the time already spent in treatment, a client who has a positive urine and/or blood screen shall be required to comply with the requirements in (b) above.

(f) Required counseling shall include, at a minimum:

(1) Any combination of individual, group, self-help, or family counseling or other mental health services;

(2) Case management services, which may be substituted on an hour-for-hour basis for any required counseling;

(3) Discussion of the following issues in group counseling, individual sessions, or both:

a. Working with family or significant others;

b. Living and coping skills;

c. Medication and drug education;

d. Dealing with a positive drug screen;

e. Education, vocational training, employment, or any combination thereof; and

f. Education about acquired immunodeficiency syndrome (AIDS) and human immunodeficiency virus (HIV); and

(4) Discussion between the treatment and rehabilitation team and the client regarding the commencement of a methadone 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 maintenance between discontinuance attempts.

(g) Documentation of methadone treatment shall be maintained in the client's record.

Source. #7496, eff 5-23-01; ss by #9476, eff 5-22-09 (from He-A 304.08)

He-A 304.10 Unsupervised Take-Home Methadone.

(a) A program's medical and clinical staff shall only give take-home methadone to 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.

(b) Prior to granting take-home privileges, and each time the client's progress is reviewed, the medical director 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.

(c) A client for whom take-home methadone is authorized may be provided with one day of extra medication if the client's regular pickup falls on a state holiday.

(d) For clients who demonstrate a need for a more flexible take-home methadone schedule in order to enhance and extend their rehabilitative and community reintegration progress, a program may request of the state methadone authority, the department, approval to permit a client to follow a temporary take-home medication regimen.

(e) The department shall approve such requests in (d) 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 medical director has found the client to be responsible in using methadone as required in (b) above;

(3) The medical director has determined that a temporarily reduced clinic attendance schedule is appropriate;

(4) The client is not given more than a 2-week supply of methadone at one time;

(5) The reasons for permitting a temporarily reduced clinic attendance schedule have been recorded by program staff in the client's record;

(6) Program staff have evaluated the effectiveness of the temporary take-home regimen; and

(7) The medical director has submitted such exception requests on-line, using the SAMHSA OTP Exception Request Web site at http://www.dpt.samhsa.gov/regulations/exrequests.aspx.

(f) All dispensed medication shall be labeled in accordance with He-A 302.10(b), (q), (r), (s), and (ah), and within the provisions outlined in RSA 318-B:13.

Source. #7496, eff 5-23-01; ss by #9476, eff 5-22-09 (from He-A 304.09)

He-A 304.11 Discontinuance of Methadone.

(a) Methadone shall be discontinued for all clients who request discontinuance.

(b) The determination to voluntarily discontinue methadone shall be left to the judgment of the client, in consultation with the staff of the program.

(c) If the staff of the program do not agree with the client's decision to discontinue methadone, the staff shall document the difference in the client's record.

(d) Reduction of a client's methadone dosage shall:

(1) Be ordered and overseen by medical staff of the program;

(2) Occur gradually in a manner that facilitates the client's withdrawal, as determined by the medical staff; and

(3) Be in accordance with the client's treatment goals.

(e) In situations where medical staff have determined that onsite discontinuance is undesirable, such as due to the client's violent behavior:

(1) Alternative arrangements shall be offered by the program staff; and

(2) If the client refuses all of the arrangements, the refusal shall be documented by program staff in the clinical record.

(f) Programs shall have procedures that permit the timely and orderly re-admission of the client in the event of a relapse.

(g) Continued services and supports necessary to support the client through and after the discontinuance process shall be provided by the program in consultation with the clinical staff.

(h) Programs shall have discharge policies as required by He-A 302.06(b)(15).

Source. #7496, eff 5-23-01; amd by #7599, eff 11-20-01; ss by #9476, eff 5-22-09 (from He-A 304.13)

He-A 304.12 Urine and Blood Screens.

(a) In addition to the requirements of He-A 302.06(b)(8), a program shall perform, or have performed, tests of clients as described in (b)-(f) below.

(b) All new clients shall have a minimum of a urine or blood screen upon admission and randomly every week thereafter for the first 3 months of treatment.

(c) A minimum of monthly random urine or blood screens shall be collected from each client while in treatment.

(d) All required urine or blood screens shall include, at a minimum, the following substances, unless otherwise documented in the client record by staff:

(1) Opiates;

(2) Methadone;

(3) Amphetamines;

(4) Cocaine;

(5) Benzodiazepines;

(6) Barbiturates; and

(7) Cannabis.

(e) A program shall test monthly for pregnancy any female client of childbearing age who is using buprenorphine.

(f) For all other females of childbearing age, a program shall:

(1) Evaluate, by counselor interview, the risk of pregnancy;

(2) If risk is found to be positive, order a pregnancy confirmation test; and

(3) If pregnancy is confirmed:

a. Refer the client for health care for her pregnancy; and

b. Coordinate her treatment with her health care provider.

(g) If a pregnant client refuses to obtain primary care for her pregnancy, program staff shall ask the client to sign a statement indicating she has refused such care.

Source. #7496, eff 5-23-01; amd by #7599, eff 11-20-01; ss by #9476, eff 5-22-09 (from He-A 304.10)

He-A 304.13 Administrative Discharge.

(a) A program may administratively discharge a client from a treatment program only if:

(1) The client's behavior on program premises is abusive, violent, or illegal;

(2) The client fails to pay fees after being been informed in writing and counseled regarding financial responsibility and possible sanctions including discharge;

(3) The client misses 3 consecutive medication days, and the medical director, after a reevaluation of the client, has determined that administrative discharge is warranted; or

(4) Clinical staff documents therapeutic reasons for discharge, which may include the client's continued use of illicit drugs or an unwillingness to follow appropriate clinical interventions.

(b) If a client is administratively discharged due to financial reasons in (a)(2) above, the program shall provide medically supervised withdrawal in accordance with (c) below, regardless of the client's ability to pay.

(c) For each client participating in medically supervised withdrawal, the program shall administer methadone or buprenorphine for a period no longer than 21 days, excluding the time needed for the program to maintain the client with a dose adequate to alleviate all withdrawal symptoms, as follows:

(1) The program shall maintain the client with a dose adequate to alleviate all withdrawal symptoms;

(2) The program shall establish client dosing based on individual need, as detailed in the client's treatment plan;

(3) The program shall provide flexible dosage tapering at the client's request;

(4) The program shall develop a detoxification schedule of not more than 21 days long with daily dosage reductions of not more than 10 percent of the original dose;

(5) The program shall conduct daily observation of the client, monitoring for withdrawal symptoms;

(6) Methadone or buprenorphine shall be administered daily; and

(7) Take-home medications shall not be allowed during medically supervised withdrawal.

Source. #7496, eff 5-23-01; ss by #9476, eff 5-22-09

He-A 304.14 Client Transfer between Programs.

(a) When a client transferring to a program has received a medical and laboratory examination within 3 months prior to admission, the program shall not conduct a repeat physical and laboratory examination unless requested by the medical director.

(b) The program to which a client transfers shall include copies of the previous examination and laboratory studies in the client's record within 30 days of admission.

(c) Upon receipt of an appropriately executed release of information, a program shall provide to the receiving program 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.

(d) Clients who are in good standing at their previous methadone or buprenorhpine opiate treatment program may be accepted as a transfer client and 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 program has verified the client's compliance in their previous program.

Source. #7496, eff 5-23-01; ss by #9476, eff 5-22-09

He-A 304.15 Security of Drugs. In addition to being compliant with DEA regulations 21 CFR 1301-1307 and He-A 302.10, a program shall:

(a) Limit access to secure areas where methadone is stored and dispensed to staff licensed, registered, or certified to order, prepare, dispense, or administer methadone;

(b) Arrange that the area where methadone is stored and dispensed is securely and physically separate from the client and visitor areas;

(c) Select and install alarm systems in such a way so that codes and locks can be changed following the termination of an employee authorized under (a) above;

(d) Notify the bureau in writing of any theft, attempted theft, loss, or spillage of any methadone and send copies of DEA reporting forms to the bureau; and

(e) Handle containers as follows:

(1) Immediately after administration, containers shall be purged by rinsing, inversion, or by an alternative method that prevents the accumulation of residual methadone;

(2) Used containers shall be destroyed, including those containers used in the program as well as all take-home bottles dispensed to clients in maintenance-type programs; and

(3) Maintenance clients shall return take-home bottles before receiving further take-home medication.

Source. #7496, eff 5-23-01; ss by #9476, eff 5-22-09 (from He-A 304.14)

He-A 304.16 Hours of Operation.

(a) A program shall be open 7 days a week.

(b) Dispensing hours shall be flexible enough to permit a client who is working or attending school to receive his or her methadone without jeopardizing such work or school.

(c) A program shall maintain hours of operation that:

(1) Include day, evening, or both, and weekend hours to accommodate client need; and

(2) Permit clients to receive medication individually and within 15 minutes of their scheduled dosing appointments.

(d) A program shall not close for holidays except for state holidays.

Source. #7496, eff 5-23-01; ss by #9476, eff 5-22-09 (from He-A 304.15)

He-A 304.17 Community Concerns.

(a) A program shall ensure that its clients do not cause unnecessary disruption to the community by loitering near the program or acting in a manner that would constitute disorderly conduct or harassment.

(b) Clients who consistently cause disruption to the community or to the program shall be evaluated for possible discharge from the program pursuant to the program's policies.

(c) Each program shall provide to the bureau 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 bureau determines that the program's plan is not sufficient to avoid disruption to the community, the program shall provide the bureau with a written corrective action plan, within 10 days, including time lines for implementation.

Source. #7496, eff 5-23-01; ss by #9476, eff 5-22-09 (from He-A 304.16)

He-A 304.18 Client Grievances. The program shall have a written policy for handling client grievances, including specific time frames for written responses to the client's written request for consideration or reconsideration of a program decision.

Source. #9476, eff 5-22-09

He-A 304.19 Waivers.

(a) A program may request a waiver of a specific provision or procedure of He-A 304, in writing, from the department.

(b) A request for a waiver shall include:

(1) A specific reference to the section of 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 alternative provisions or procedures proposed by the applicant.

(c) No provision or procedure prescribed by statue shall be waived.

(d) A request for a waiver shall be granted after the commissioner or his or her designee determines that the alternative proposed by the applicant:

(1) Meets the objective or intent of the rule;

(2) Does not negatively impact the health or safety of clients; and

(2) Does not affect the quality of provider services.

(e) Upon receipt of approval of a waiver request, the applicant's subsequent compliance with the alternative provisions or procedures approved in the waiver shall be considered compliance with the rule for which the waiver was sought.

(f) Waivers shall not be transferable.

(g) Waivers shall be granted in writing for a specific duration which shall not exceed 3 years or until the end of the current certification period.

(h) The applicant may request a renewal of the waiver from the department. Such request shall be made at least 90 days prior to the expiration of the current waiver.

Source. #9476, eff 5-22-09 (from He-A 304.17)

APPENDIX

Rule Number	**RSA/Federal Citation**
He-A 301, 302, 303 (all sections) Specific provisions implementing specific statutes are listed below.	
He-A 301	RSA 172:8-b, III; RSA 172:10
He-A 302.04(d)(8)-(9)	RSA 172:14
He-A 302.05	RSA 318-B: 10, VII(b)(3)
He-A 302.04(e)(4) He-A 302.05(a)(10)c He-A 302.05(c)(7) He-A 302.09(e)(1)	He-A 302.04(e)(4) He-A 302.05(a)(10)c He-A 302.05(c)(7) He-A 302.09(e)(1)
He-A 302.06 He-A 302.07 He-A 302.08 He-A 302.10	RSA 318-B: 10, VII(b)(4)
He-A 302.09	RSA 318-B: 10, VII(b)(5)
He-A 302.11(b)	RSA 172:2-a
He-A 303.04(b)(1)	RSA 172:2-a
He-A 303.06	RSA 318-B:10, VII(b)(7)
He-A 303.08(a)(5)	RSA 172:14
He-A 304 (all sections)	RSA 172:2-a; RSA 318-B:10, VII(b)