

APPENDIX E

ELECTRONIC MEDIA CLAIMS (EMC) MANUAL

AGENCY NOTE: The Electronic Media Claims (EMC) Manual is filed as an incorporated Appendix of this chapter/manual, but is not reproduced in the New Jersey Administrative Code. When revisions are made to the EMC Manual, replacement pages will be distributed to providers, placed on the website at www.njmms.com and copies will be filed with the Office of Administrative Law.

For a copy of the EMC Manual, write to:
Molina Medicaid Solutions
PO Box 4801
Trenton, New Jersey 08650-4801

APPENDIX F

MEDICAID REBATE PROGRAM
MANUFACTURERS' LABELER CODE LIST

Appendix F is a list of drug manufacturers, identified by labeler code, whose drug products are covered by the Medicaid and NJ FamilyCare fee-for-service programs. These drug manufacturers have in effect a rebate agreement pursuant to 42 U.S.C. § 1396-r-8(a), (b) and (c). This list is updated periodically by the Centers for Medicare and Medicaid Services subsequent to published listing changes in the Federal Register.

AGENCY NOTE: Appendix F is filed as a part of this chapter/manual but is not reproduced in the New Jersey Administrative Code. When revisions are made to Appendix F, replacement pages will be distributed to providers, placed on the website at www.njmms.com and copies will be filed with the Office of Administrative Law.

For a copy of Appendix F, write to:
Molina Medicaid Solutions
PO Box 4801
Trenton, New Jersey 08650-4801
or contact:
Office of Administrative Law
Quakerbridge Plaza, Building 9
PO Box 049
Trenton, New Jersey 08625-0049

APPENDIX G

STATE OF NEW JERSEY
DEPARTMENT OF HUMAN SERVICES
DIVISION OF MEDICAL ASSISTANCE AND HEALTH SERVICES
NOTIFICATION OF PHARMACEUTICAL SERVICES IN NURSING FACILITIES

(SERVICING PHARMACY)

(PROVIDER NUMBER OF SERVICING PHARMACY)
(IF AVAILABLE)

PROVIDER AGREES:

- 1. To comply with State regulations, in accordance with N.J.A.C. 10:51, Subchapter 2, when providing pharmaceutical services to:
(Nursing Facility)
Nursing Facility Provider Number:
2. In accordance with N.J.A.C. 10:51-2.7(d), the servicing pharmacy shall notify the New Jersey Division of Medical Assistance and Health Services of any change in status regarding the provision of these pharmaceutical services described to avoid improper capitation payments.
3. In accordance with N.J.A.C. 10:51-2.7(d), the pharmacy identified by this agreement shall provide the Division with information requested below:
(i) A copy of a fully executed agreement between the servicing pharmacy provider and the nursing facility.
(ii) The effective date of initiating a new or changed pharmaceutical service to:
(Nursing Facility) is (Date)
(iii) Level of Service to be provided: (Select One)
(01) Twenty-Four (24) Hour Unit Dose Services

- (02) Modified Unit Dose Services (i.e., Bingo, Atromick; 30 day supply)
(03) Traditional Services (i.e., drug vial dispensing)
(04) Twenty-Four (24) Hour Unit Dose Services and ancillary computerized services
(05) Modified Unit Dose Services and ancillary computerized services
(06) Traditional Services and ancillary computerized services

Note: Ancillary computerized services, if provided, shall include, but not be limited to, continuously updated computerized patient profile records medication sheets, treatment sheets and physician order sheets which must be supplied at least monthly.

The completed agreement must be returned by mail to:

Molina Medicaid Solutions
Provider Enrollment Unit
PO Box 4804
Trenton, NJ 08650-4804
PS-I-08(03/94)

(a)

DIVISION OF MENTAL HEALTH AND ADDICTION SERVICES

Licensure of Outpatient Substance Abuse Treatment Facilities

Readoption with Amendments: N.J.A.C. 10:161B

Proposed: July 5, 2016, at 48 N.J.R. 1350(a).

Adopted: October 20, 2016, by Elizabeth Connolly, Acting Commissioner, Department of Human Services.

Filed: November 22, 2016, as R.2016 d.185, with non-substantial changes not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 26:2B-7 et seq., in particular 26:2B-14, 26:2B-5 through 6, 26:2G-1 et seq., and 30:1-12; and Reorganization Plan 002-2004.

Effective Dates: November 22, 2016, Readoption;
December 19, 2016, Amendments.

Expiration Date: November 22, 2023.

Summary of Public Comment and Agency Response:

No comments were received.

Summary of Agency Initiated Changes:

1. Throughout the chapter, the Department is changing "substance abuse" to "substance use disorder" for consistency with the DSM-5, which no longer uses the terms substance abuse; rather, it refers to substance use disorders, which are defined as mild, moderate, or severe to indicate the level of severity, which is determined by the number of diagnostic criteria met by an individual.

2. The Department is changing N.J.A.C. 10:161B-1.14(a) and 11.2(a) to recognize that the American Society of Addiction Medicine (ASAM) no longer offers board certification in addiction medicine; board certification is transitioning to the American Board of Preventive Medicine (ABPM). This is consistent with the Division's communication to licensed substance use disorder treatment providers in July 2016.

3. Due to a Departmental restructure, the Division of Addiction Services (DAS) merged with the Division of Mental Health Services (DMH). The merged division is identified as the Division of Mental Health and Addiction Services (DMHAS). Additionally, the licensing function within the former DAS, was transferred to the Department of Human Services, Office of Licensing (OOL). OOL has the responsibility for all aspects of the licensing process, and will monitor deficiency reports, quality assurance activities, complaints, emergencies, informal dispute resolution, hearings held by the Office of Administrative Law, injunctions, and settlement of enforcement actions. The Division maintains the oversight for program operations, data, and administrative

guidelines. As such, this chapter has been changed to reflect the organizational restructure of DMHAS, DHS, and OOL throughout. N.J.A.C. 10:161B-1.3 has also been changed to include a definition for OOL.

4. Throughout the chapter, the Department is changing “Department of Health and Senior Services” and “DHSS” to “Department of Health” or “DOH,” pursuant to P.L. 2012, c. 17, Section 93; and changing “Division of HIV/AIDS Services” to Division of HIV, STD and TB Services.

5. Throughout the chapter, the Department is changing “Division of Youth and Family Services” and “DYFS” to “Division of Child Protection and Permanency” or “DCPP.”

6. The Department is changing N.J.A.C. 10:161B-3.8 to include a new fax number and an email address for notifying the Division about a reportable event. The previous phone number and fax number no longer exist.

7. The Department is changing N.J.A.C. 10:161B-1.3, 1.4, 1.8, 11.1, 11.11, 12.5, 14.2, 19.1, 21.2, and 23.6 to update hyperlinks and/or phone numbers because the existing links no longer work and/or phone numbers have changed. Additionally, names of publications have been updated to reflect the most recent version.

8. The Department is changing N.J.A.C. 10:161B-21.2(a)1 to correct a typographical error that references a non-existent regulation within N.J.A.C. 10:161B. Specifically, the reference to N.J.A.C. 10:161B-5.2(a)11, which does not exist, is replaced with the proper reference to N.J.A.C. 10:161B-6.2(a)11.

9. The Department is changing Appendix B to reflect the recent change in Federal guidelines (81 FR 44711) permitting qualified physicians to prescribe Buprenorphine from 100 to 275 patients at a time; and, changing “opiate dependence” or “opiate abuse” to “opioid use disorder” for consistency with the DSM-5.

**Federal Standards Statement**

The readopted rules with amendments do not impose standards on outpatient licensed substance use treatment facilities that exceed those contained in any Federal regulation that may be applicable to these facilities. There are no Federal laws that are analogous to these State licensure rules for outpatient addiction treatment facilities.

**Full text** of the readopted rules can be found in the New Jersey Administrative Code at N.J.A.C. 10:161B.

**Full text** of the adopted amendments follows (additions to proposal indicated in boldface with asterisks **\*thus\***; deletions from proposal indicated in brackets with asterisks **\*[thus]\***):

CHAPTER 161B

STANDARDS FOR LICENSURE OF OUTPATIENT SUBSTANCE  
\*[ABUSE]\* **\*USE DISORDER\*** TREATMENT FACILITIES

SUBCHAPTER 1. DEFINITIONS AND STAFF QUALIFICATIONS  
AND RESPONSIBILITIES

10:161B-1.1 Scope and applicability

(a) This chapter applies to all substance (alcohol and drug) **\*[abuse]\* \*use disorder\*** treatment facilities that provide outpatient substance **\*[abuse]\* \*use disorder\*** treatment services to adults and juveniles, including: outpatient, intensive outpatient, partial care, outpatient detoxification and opioid treatment which includes opioid maintenance and opioid detoxification. Outpatient substance **\*[abuse]\* \*use disorder\*** treatment facilities provide diagnostic and treatment services to persons who present at the facility to receive services and depart from the facility on the same day. The rules in this chapter constitute the basis for the inspection of outpatient substance **\*[abuse]\* \*use disorder\*** treatment facilities by the New Jersey **\*[Division of Addiction Services (DAS)]\* \*Department of Human Services (DHS)\***.

(b) This chapter also applies to hospitals licensed by the New Jersey Department of Health **\*[and Senior Services]\***, pursuant to N.J.A.C. 8:43G, which offer hospital-based outpatient substance **\*[abuse]\* \*use disorder\*** treatment services in a designated outpatient unit or facility or provide any of the modalities of outpatient substance **\*[abuse]\* \*use disorder\*** treatment listed in (a) above. **\*[DAS]\* \*DHS\*** does require a separate license for hospital-based substance **\*[abuse]\* \*use disorder\*** treatment programs; hospitals providing services covered by this chapter

shall comply with these standards and shall be licensed, monitored and/or reviewed by **\*[DAS]\* \*DHS\***.

(c) This chapter also applies to primary health care facilities, as defined and licensed by the New Jersey Department of Health **\*[and Senior Services]\***, pursuant to N.J.A.C. 8:43A, which offer outpatient substance **\*[abuse]\* \*use disorder\*** assessment, referral and/or treatment services or provide any of the modalities of outpatient substance **\*[abuse]\* \*use disorder\*** treatment listed in (a) above. **\*[DAS]\* \*OOL\*** does require a separate outpatient substance **\*[abuse]\* \*use disorder\*** treatment facility license for primary health care facilities; primary health care facilities providing services covered by this chapter shall comply with these standards and shall be licensed, monitored and reviewed by **\*[DAS]\* \*DHS\***.

(d) Facilities currently licensed as Ambulatory Care Outpatient Drug Treatment Facilities under N.J.A.C. 8:43A shall comply with this chapter and shall apply for licensure as an outpatient substance **\*[abuse]\* \*use disorder\*** treatment facility upon expiration of existing licenses, in accordance with (a) or (b) above.

10:161B-1.2 Purpose

The purpose of this chapter is to protect the health and safety of clients by establishing minimum rules and standards of care with which an outpatient substance **\*[abuse]\* \*use disorder\*** treatment facility must adhere to be licensed to operate in New Jersey.

10:161B-1.3 Definitions

The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise:

... “Admitted” means accepted for treatment at an outpatient substance **\*[abuse]\* \*use disorder\*** treatment facility.

... “ASAM **\*[Client Placement]\*** Criteria” means the criteria developed by the American Society of Addiction Medicine to place clients in an appropriate level of care, as contained in **\*[“Client Placement Criteria for the Treatment of Substance Related Disorders.” 2nd Edition revised (2001) (ASAM-PPC-2R)]\* \*The ASAM Criteria, Treatment Criteria for Addictive, Substance-Related, and Co-Occurring Conditions, Third Edition, 2013\***, as amended and supplemented, incorporated herein by reference, which can be obtained from the ASAM Publications Center, 1-800-844-8948.

“ASI” means the Addiction Severity Index, 5th Edition, as amended and supplemented, incorporated herein by reference, an instrument designed to provide important information about aspects of a client’s life which may contribute to his or her substance use disorder, as developed by and available from the Treatment Research Institute, 600 Public Ledger Building, Philadelphia, PA 19106, (215) 399-0980, **\*[www.tresearch.org/asi.htm]\* \*http://www.tresearch.org/tools/download-asi-instruments-manuals/\***.

... **\*“Assistant Commissioner” means the individual responsible to oversee the Division of Mental Health and Addiction Services.\***

“Available” means with respect to individuals employed by, or under contract with, an outpatient substance **\*[abuse]\* \*use disorder\*** treatment facility, capable of being reached and able to be present in the facility within 30 minutes.

... “Certified Alcohol and Drug Counselor (CADC)” means an individual who holds a current, valid certificate issued by the New Jersey State Board of Marriage and Family Therapy Examiners, as recommended by the Alcohol and Drug Counselor Committee, pursuant to N.J.S.A. 42:2D-5 and N.J.A.C. 13:34C-2.3; accessible at **\*[http://www.nj.gov/oag/ca/medical/alcdrug.htm, (973-504-6582)]\* \*http://www.njconsumeraffairs.gov/mft/Pages/regulations.aspx, (973) 504-6415\***.

“Child Abuse Record Information” or “CARI” means the information in the child abuse registry as established in N.J.S.A. 9:6-8.11, which may be released to a person or agency outside the Department of Children and Families, Division of **\*[Youth and Family Services]\* \*Child Protection and Permanency\*** only as prescribed by law.

... “Client-centered care” means care including substance **\*[abuse]\* \*use disorder\*** treatment, recovery support, and prevention services which reflect the client’s needs, preferences and values.

“Conditional license” means a license pursuant to N.J.A.C. 10:161B-2.7. A conditional license is not a full license and requires the licensee to comply with all specific conditions imposed by \*[DAS]\* \*OOL\* in addition to the licensure requirements in this chapter.

“Co-occurring disorder” means a concurrent substance \*[abuse]\* \*use disorder\* and mental health disorder as described in the \*[DSM-IV-TR]\* \*DSM-5\*, in which the substance \*[abuse]\* \*use disorder\* and mental health disorders are both primary.

“Counseling” means the utilization of special skills and evidence based practices to assist individuals, families, significant others, and/or groups to identify and change patterns of behavior relating to substance \*[abuse]\* \*use disorders\* which are maladaptive, destructive and/or injurious to health through the provision of individual, group and/or family therapy by licensed or credentialed professionals or approved counselors in training. Counseling does not include self-help support groups such as Alcoholics Anonymous, Narcotics Anonymous, and similar 12-step programs.

“Curtailment” means an order by \*[DAS]\* \*OOL\* which requires a licensed substance \*[abuse]\* \*use disorder\* treatment facility to cease and desist all admissions and readmissions of clients to the facility.

\*[“DAS” means the Division of Addiction Services, the Single State Agency on Substance Abuse for the State of New Jersey, and is a division within the New Jersey Department of Human Services, <http://www.state.nj.us/humanservices/das/index.htm>.]\*

“Deficiency” means a determination by \*[DAS]\* \*OOL\* of one or more instances in which a State licensing regulation has been violated.

\*[“DHSS” means the New Jersey Department of Health and Senior Services.]\*

“Didactic session” means a structured treatment intervention designed to instruct or teach clients about topics related to substance \*[abuse]\* \*use disorders\* and treatment related issues.

\*[“Division Director” means the individual responsible to oversee the Division of Addiction Services as the single state agency on substance abuse for the State of New Jersey.]\*

\*[“DMHAS” means the Division of Mental Health and Addiction Services, a division within the New Jersey Department of Human Services.]\*

\*[“DOH” means the New Jersey Department of Health.]\*

“Drug” means any article recognized in the official United States Pharmacopoeia-National Formulary (USP 31-NF26), accessible at <http://www.usp.org>, 1-800-227-8722, <http://www.usp.org/usp-nf-1-800-227-8772>; or the official Homeopathic Pharmacopoeia of the United States/Revision Service, at <http://www.hpus.com>, as amended and supplemented, incorporated herein by reference, including, but not limited to, a controlled substance, a prescription legend drug, an over the counter preparation, a vitamin or food supplement, transdermal patch or strip, or any compounded combination of any of the above intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or medical condition in humans/animals or intended to affect the structure or function of the human body.

“Drug screening test negative” means a urine or other \*[DAS-approved]\* \*DHS-approved\* specimen from a client that is tested and reports a negative result for drugs of abuse. In an opioid treatment program, the specimen is negative for drugs of abuse but shows the presence of methadone.

“Drug screening test positive” means a urine or other \*[DAS-approved]\* \*DHS-approved\* specimen from a client that is tested and reports positive for drugs of abuse, including, but not limited to, amphetamines, barbiturates, cocaine, opiates, marijuana, benzodiazepine, etc.

\*[“DSM-IV-TR”]\* \*DSM-5\* means the Diagnostic and Statistical Manual of Mental Disorders, \*[4th Edition, Text Revision]\* \*Fifth Edition\*, as amended and supplemented, incorporated herein by

reference, the standard classification of mental disorders in the United States, published by and available from the American Psychiatric Association, 1000 Wilson Boulevard, Suite 1825, Arlington VA 22209-3901, <http://www.dsmivtr.org> \*<http://www.dsm5.org/Pages/Default.aspx>\*.

“Facility” means an outpatient substance \*[abuse]\* \*use disorder\* treatment facility and/or program pursuant to State statute and this chapter.

“Integrated treatment” means the coordination of both substance \*[abuse]\* \*use disorder\* and mental health interventions, preferably by one clinician; integrated services should appear coordinated to the client participating in services.

“Medical maintenance” means the administration and/or dispensing of opioid agonist medications and related medical services to a client who has been referred from an opioid treatment program to a designated physician providing services either in the treatment facility (that is, clinic-based) or in the private office (that is, office-based) of the physician under a formalized agreement approved by the CSAT and \*[DAS]\* \*DMHAS\*.

“Medication” means a drug or medicine as defined by the New Jersey State Board of Pharmacy rules, as set forth in N.J.A.C. 13:39, which is accessible at <http://www.nj.gov/oag/ca/medical/pharmacy.htm> \*<http://www.njconsumeraffairs.gov/regulations/Chapter-39-State-Board-of-Pharmacy.pdf>\*.

“New Jersey Substance Abuse Monitoring System (NJSAMS),” <http://samsdev.rutgers.edu/samstraining/mainhome.htm> \*<https://njsams.rutgers.edu/njsams/>\*, means the client data collection information system required by \*[DAS]\* \*DMHAS\* to be used for all New Jersey substance \*[abuse]\* \*use disorder\* treatment facilities to record and report client data including, but not limited to, admission, status, services, discharge, and such other client information as \*[DAS]\* \*DMHAS\* may require.

“Nosocomial infection” means an infection acquired by a client while in an outpatient substance \*[abuse]\* \*use disorder\* treatment facility.

\*[“Office of Licensing” or “OOL” means the Office of Licensing within the DHS Office of Program Integrity and Accountability.]\*

“Outcomes” means client level of functioning on specific criteria post-treatment as compared with their level of functioning at intake. These criteria include drug and alcohol use, employment, criminal activity, homelessness, and social connectedness, consistent with the SAMHSA National Outcome Measures, accessible at [http://www.nationaloutcomemeasures.samhsa.gov/outcome/index\\_2007.asp](http://www.nationaloutcomemeasures.samhsa.gov/outcome/index_2007.asp) \*<http://integratedrecovery.org/wp-content/uploads/2010/08/SAMHSA-National-Outcome-Measures.pdf>\*.

“Outpatient substance \*[abuse]\* \*use disorder\* treatment facility” means a facility that is licensed to provide outpatient substance \*[abuse]\* \*use disorder\* treatment in one or more of the following categories:

1. Outpatient (OP): A service offered at a licensed, outpatient facility, which provides regularly scheduled individual, group and/or family counseling for less than nine hours per week. This care approximates ASAM [\[PPC-2R\]](#) \*Criteria\* Level I.

2. Intensive outpatient (IOP): A service offered at a licensed outpatient facility that provides a range of treatment sessions. Services include clinical intensive substance abuse counseling and psycho-education (didactic) sessions. Services are provided in a structured environment for a minimum of nine hours of counseling per week for adults and six hours per week for adolescents. This care approximates ASAM [\[PPC-2R\]](#) \*Criteria\* Level II.1;

3. Partial care (PC): A service offered at a licensed outpatient facility that provides a broad range of clinically intensive treatment services in a structured environment for a minimum of 20 hours per week, during day or evening hours. Treatment includes substance abuse counseling, educational and community support services. Programs have ready

access to psychiatric, medical and laboratory services. This care approximates ASAM \*[PPC-2R]\* \*Criteria\* Level II.5;

4. Outpatient detoxification: A service offered at a licensed outpatient facility that provides a range of services including medical and clinical interventions, laboratory testing, the dispensing and/or administration of approved medications provided to treat and monitor clients undergoing withdrawal from drugs, including alcohol. This also includes provision of concurrent assessment, and counseling support services for the purpose of placing these clients in an appropriate treatment setting for continuing care. This care approximates ASAM \*[PPC-2R]\* \*Criteria\* Level I-D or Level II-D; and

5. Opioid treatment: A service offered at a licensed outpatient facility which utilizes methadone, Suboxone or other approved medications to detoxify or maintain substance abusers who are addicted to heroin or other opiate-like drugs. Medication is provided in conjunction with medical monitoring, laboratory testing, clinical assessment, counseling and support services. This care approximates ASAM \*[PPC-2R]\* \*Criteria\* Opiate Maintenance Therapy.

“Plan of correction” means a plan developed by the facility and reviewed and approved by \*[DAS]\* \*OOL\* which describes the actions the facility will take to correct deficiencies and specifies the timeframe in which those deficiencies will be corrected.

... “Provisional license” means a full license that has been reduced because the facility is not in full compliance with all licensing rules in this chapter. A provisional license holder is subject to \*[Division]\* \*OOL\* oversight until it comes into full compliance with this chapter.

... “Release of Information” means a document which allows a program to release client information to designated person(s) with the client’s written consent, in compliance with the Federal Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR Parts 160 and 164, Subparts A and E; and the Federal Confidentiality of Alcohol and Drug Abuse Patient Records regulation at 42 CFR Part 2, both of which are accessible at \*[<http://hipaa.samhsa.gov/privacyrule.htm>]\* \*<http://www.samhsa.gov/laws-regulations-guidelines/medical-records-privacy-confidentiality>\*.

... “Substance \*[abuse/dependence]\* \*use disorder\*” means a maladaptive pattern of substance use manifested by recurrent and significant adverse consequences related to the repeated use of substances. \*[There may be repeated failure to fulfill major role obligations, repeated use in situations in which it is physically hazardous, multiple legal problems, and recurrent social and interpersonal problems.]\* For the purpose of this chapter, substance \*[abuse/dependence also means other substance-use related disorders as]\* \*use disorder is\* defined in the Diagnostic and Statistical Manual of Mental Disorders, \*[4th Edition (DSM-IV-TR)]\* \*Fifth Edition\* as amended and supplemented, published and by and available from the American Psychiatric Association, 1000 Wilson Boulevard, Suite 1825, Arlington, Va. 22209-3901, \*[<http://dsmivtr.org>]\* \*<http://www.dsm5.org/Pages/Default.aspx>\*, incorporated herein by reference.

... “Survey” means the evaluation of the quality of care and/or the fitness of the premises, staff, and services provided by the facility as conducted by \*[DAS]\* \*OOL\* and/or its designees to determine compliance or non-compliance with these and other applicable State licensing rules or statutes.

... “Universally accepted practices” means treatment measures not currently proven through empirical data, but recognized by authorities (for example, SAMHSA, CSAT, the National Institute on Drug Abuse, \*[<http://www.nida.nih.gov>]\* \*<http://www.drugabuse.gov>]\*, and the National Institute on Alcohol Abuse and Alcoholism, \*[<http://www.niaaa.nih.gov>]\* \*<https://niaaa.nih.gov>]\* for substance \*[abuse]\* \*use disorder\* treatment.

... “Waiver” means a written approval by \*[DAS]\* \*OOL\* following a written request from a facility, to allow an alternative to any section(s) in this chapter provided that the alternative(s) proposed would not

endanger the life, safety, or health of clients or the public, as described at N.J.A.C. 10:161B-2.13.

#### 10:161B-1.4 Qualifications and responsibilities of the medical director

(a) Opioid treatment and detoxification facilities are required under N.J.A.C. 10:161B-7 to hire a physician as medical director who is currently licensed in accordance with the laws of this State to perform the scope of services set forth in this chapter. This physician must be certified by the American Society of Addiction Medicine (ASAM), \*or its successor certification board,\* by June 1, 2012.

1. A physician currently licensed to practice in the State of New Jersey, who has not completed ASAM certification by June 1, 2012, must have worked in a substance \*[abuse]\* \*use disorder\* treatment facility a minimum of five years for at least 20 hours per week and have completed the ASAM/American Association for the Treatment of Opioid Dependence (AATOD) clinicians training course, \*[[www.aatod.org/clinician/html](http://www.aatod.org/clinician/html)]\* \*<http://www.aatod.org/resources/additional-education-on-opioid-dependence/providers-clinical-support-system-for-medication-assisted-treatment/>\*.

(b) (No change.)

(c) The medical director shall be responsible for the direction, provision, and quality of medical services provided to clients including, but not limited to, the following:

1.-2. (No change.)

3. In conjunction with the administrator and the governing authority of the substance \*[abuse]\* \*use disorder\* treatment program, planning and budgeting for medical services;

4.-10. (No change.)

#### 10:161B-1.5 Qualifications and responsibilities of the director of nursing services

(a) In addition to the requirement of medical director, opioid treatment programs and facilities providing detoxification services are also required to hire a director of nursing services pursuant to N.J.A.C. 10:161B-8. The program shall hire a registered professional nurse (RN) currently licensed in New Jersey, and who has at least six months of full-time experience, or the full-time equivalent, in nursing supervision or nursing administration in the management of addictions in a licensed substance \*[abuse]\* \*use disorder\* treatment facility. In an opioid treatment program or a facility providing detoxification services, the individual must have one year of supervisory experience or three years of experience in a substance \*[abuse]\* \*use disorder\* treatment program or facility.

(b) (No change.)

#### 10:161B-1.7 Qualifications and responsibilities of the administrator of the facility

(a) The facility shall hire an administrator who has, at a minimum, a Master’s degree and two years of full-time, or full-time equivalent, administrative or supervisory experience in a substance \*[abuse]\* \*use disorder\* treatment facility.

(b) Individuals who do not meet the qualifications in (a) above, shall have a Bachelor’s degree and five years of full-time, or full-time equivalent, administrative or supervisory experience in a substance \*[abuse]\* \*use disorder\* treatment facility.

(c) The administrator’s responsibilities shall include, but need not be limited to, the following:

1.-10. (No change.)

11. Implementing and monitoring the quality of all services provided at the facility, including the review of program outcomes available through NJSAMS;

i. When appropriate share program outcome data with relevant staff, \*[DAS]\* \*DMHAS\*, and where necessary with the governing authority;

12. (No change.)

13. Establishing policies and procedures for provision of emergency services to clients, and policies and procedures for other broader-based emergency situations resulting from either internal or external incidents or natural disasters;

i. Such policies shall include guidelines for the immediate notification to \*[DAS]\* \*DHS\* of such situations, a contingency plan with a minimum of explanation of timeframes for closure and reopening of facility and or service interruption to clients, and procedures governing the dispensing and, where clinically necessary, monitoring of client treatment medications;

14. Establishing written policies and procedures for non-emergency closures (for example, holidays);

i. Such policies shall include the timely notification to \*[DAS]\* \*DHS\* of such closures, the timeframes for closures and re-opening, and procedures governing the dispensing and, where clinically necessary, monitoring of medications administered to clients;

ii. Facilities shall request approval from \*[DAS]\* \*DHS\* in writing at least 48 hours before closing for non-emergency reasons;

iii. Facilities shall not close for non-emergency reasons without written approval from \*[DAS]\* \*DHS\* to do so;

15. (No change.)

16. Ensuring that \*[DAS]\* \*DHS\* plans of correction, licensing deficiencies and complaint reports are addressed as outlined by \*[DAS]\* \*DHS\*;

i. (No change.)

17.-18. (No change.)

10:161B-1.8 Qualifications and responsibilities of the director of substance abuse counseling services

(a) Every program shall employ at least one individual who meets at least the minimum following qualifications as the director of substance abuse counseling:

1. A New Jersey licensed psychologist who possesses a Certification of Proficiency in the Treatment of Alcohol and other Psychoactive Substance Use Disorders from the American Psychological Association, College of Professional Psychology, \*[[www.apa.org/college](http://www.apa.org/college)], is a certified clinical supervisor by The Certification Board, <http://www.certbd.com/pdfs/initial-applications/ccs.pdf>\* \*<http://www.apa.org/practice/index.aspx>\*, or is an LCADC;

2. A New Jersey licensed clinical social worker, who is a certified clinical supervisor by The Certification Board, \*[<http://www.certbd.com/pdfs/initial-applications/ccs.pdf>]\* \*<http://certbd.org/site/wp-content/uploads/Certified-Clinical-Supervisor-application.pdf>\*], or is an LCADC;

3. A New Jersey licensed professional counselor, or licensed marriage and family therapist, who is a certified clinical supervisor by The Certification Board, \*[<http://www.certbd.com/pdfs/initial-applications/ccs.pdf>]\* \*<http://certbd.org/site/wp-content/uploads/Certified-Clinical-Supervisor-application.pdf>\*], or who is an LCADC;

4.-5. (No change.)

6. A New Jersey licensed advanced practice nurse who is a certified clinical supervisor by the Certification Board, \*[<http://www.certbd.com/pdfs/initial-applications/ccs.pdf>]\* \*<http://certbd.org/site/wp-content/uploads/Certified-Clinical-Supervisor-application.pdf>\*], or is an LCADC.

(b)-(d) (No change.)

10:161B-1.9 Qualifications and responsibilities of the substance abuse counseling staff

(a)-(c) (No change.)

(d) Each substance abuse counselor shall be responsible for the following:

1. (No change.)

2. Assessing clients using the ASI or other standardized clinical interview tool, and diagnosing clients for substance use disorder using the \*[DSM-IV TR]\* \*DSM-5\*;

3. Determining the appropriate level of care according to ASAM \*[Patient Placement]\* Criteria \*[PPC2-R]\*;

4.-6. (No change.)

7. Reviewing clients throughout the treatment episode according to the ASAM \*[PPC2-R]\* \*Criteria\*, to determine the need for continued services, transfer, or discharge/transfer;

8.-9. (No change.)

10. Contact, case consultation if necessary, and coordination with referral sources, (for example, mental health treatment providers, criminal justice agencies, schools, employers, \*[DYFS]\* \*DCPP\*);

11.-13 (No change.)

## SUBCHAPTER 2. LICENSURE PROCEDURES AND ENFORCEMENT

10:161B-2.1 Applications for licensure

(a) All facilities operating as outpatient substance \*[abuse]\* \*use disorder\* treatment facilities shall be licensed by \*[DAS]\* \*OOL\* in accordance with this chapter. No facility shall operate an outpatient substance \*[abuse]\* \*use disorder\* treatment facility until \*[DAS]\* \*OOL\* issues a license to do so.

(b) Any person, organization, or corporation planning to operate an outpatient substance \*[abuse]\* \*use disorder\* treatment facility shall obtain application forms from, and submit completed application forms with the appropriate fees for each site to:

\*[New Jersey Division of Addiction Services

Attention: Licensure Unit

P.O. Box 362

Trenton, NJ 08625-0362]\*

\*New Jersey Department of Human Services

Office of Licensing

PO Box 707

Trenton, NJ 08625-0707\*

(c) \*[DAS]\* \*OOL\* will maintain and update initial license application, renewal application and inspection fees pertinent to newly licensed applicants and or ongoing licensure and will update such fees by amending the fee section of this chapter as needed.

(d) (No change.)

(e) An application fee schedule shall be established and maintained by \*[DAS]\* \*DHS\*, and will be included with the licensing application provided by \*[DAS]\* \*DHS\*. As per the fee schedule, established rates at the time of submission of each application shall apply. All applicants shall submit a non-refundable application fee and a \*[DAS]\* \*DHS\* inspection fee as follows:

1. First time applicants of newly created treatment agencies:

i. (No change.)

ii. Initial and ongoing biannual \*[DAS]\* \*DHS\* inspection fee (\$300.00);

2. Licensed programs maintaining their licensure status:

i. (No change.)

ii. Ongoing biannual \*[DAS]\* \*DHS\* inspection fee (\$300.00);

3.-4. (No change.)

(f) Once licensed, each facility shall be assessed an ongoing bi-annual inspection fee of \$ 300.00. This fee shall commence in the first year the facility is inspected, along with the annual licensure fee for that year. Subsequently, an annual application for license renewal fee and license applications to reflect program changes will be assessed as per the following \*[DAS]\* \*DHS\* Fee Schedule:

<u>Type of Facility</u>	<u>New Facility Fee</u>	<u>License Renewal Fee</u>	<u>License Modification to Add Beds or Services</u>	<u>License Relocate or Reduce Services</u>	<u>Transfer of Ownership Interest</u>	<u>Initial or Biannual * [DAS] * *DHS* Inspection Fee</u>
Outpatient Substance * [Abuse] * *Use Disorder* Treatment Facility	\$1,750	\$750	0	\$250	\$1,500	\$300

(g) (No change.)

(h) An application for licensing shall not be considered complete until the program submits the licensing fee and the initial biannual inspection fee and all other requested information on the licensure application is complete. \* [DAS] \* \*OOL\* shall notify applicants in writing when the application is complete.

(i) (No change.)

(j) None of the following category designations of services shall be provided by an outpatient substance \* [abuse] \* \*use disorder\* treatment facility unless the license application indicates that the service is to be provided by the program: partial care; intensive outpatient; outpatient; outpatient detoxification; or opioid treatment which may include opioid detoxification as well as opioid maintenance.

1. Note: If a program provides primary medical care, in addition to any of the above five categories of outpatient substance \* [abuse] \* \*use disorders\* care, a separate primary care license is required by and must be obtained from the New Jersey Department of Health \* [and Senior Services] \*.

(k) The license issued by \* [DAS] \* \*OOL\* shall specify the services that the program is licensed to provide. The program shall provide only those services in (j) above for which it is licensed or authorized by \* [DAS] \* \*OOL\* to provide. Any provision of services not specifically listed on the license shall be considered unlicensed provision of services, and \* [DAS] \* \*OOL\* shall take all appropriate enforcement action.

10:161B-2.2 Licenses

(a) (No change.)

(b) Once issued, a license shall be granted for a period of one year (12 consecutive months), and shall be eligible for annual renewal on and up to 30 days following the license anniversary date (each renewal shall be dated back to the license anniversary date) upon submission of the appropriate licensing and inspection fees, providing the license has not been suspended or revoked by \* [DAS] \* \*OOL\*, and the program otherwise continues to be in compliance with all local rules, State rules and other requirements.

(c) (No change.)

10:161B-2.3 Application requirements

(a) Any person, organization, or corporation applying for a license to operate an outpatient substance \* [abuse] \* \*use disorder\* treatment facility shall specify the services in N.J.A.C. 10:161B-2.1(j) the facility seeks to provide on the application.

(b) No facility or program shall admit clients until the facility or program has a license by \* [DAS] \* \*OOL\* to operate the specific modality or modalities of treatment as referenced in N.J.A.C. 10:161B-2.1(j).

(c) Survey and other site visits may be made to a facility at any time by authorized \* [DAS] \* \*OOL\* staff. Such visits may include, but not be limited to, the review of all facility documents, client records, and conferences with clients. Such visits may be announced or unannounced.

(d) (No change.)

(e) If a program adds any service listed in N.J.A.C. 10:161B-2.1(j) during the annual licensure period, the program shall submit an application to \* [DAS] \* \*OOL\* for an amended license as well as adhere to all applicable local, State and Federal approvals prior to providing the additional service. An amended license shall be based upon compliance with this chapter, and may be contingent upon an onsite inspection by representatives of \* [DAS] \* \*OOL\*. Opioid

treatment and detoxification services shall not be added during the license period without amending the license application.

(f) (No change.)

(g) \* [DAS] \* \*OOL\* shall determine if the new and or innovative program is effective, safe and does not violate client rights, and if licensure is granted, shall determine whether the licensed program is approved in part or whole.

(h) (No change.)

(i) The applicant shall provide a detailed history of operating any addiction treatment programs in this State or elsewhere, with operational data separated by program, including the following categories:

1.-5. (No change.)

6. Policies, standard operating procedures and/or institutional rules applicable to the operation of the outpatient substance \* [abuse] \* \*use disorder\* program(s);

7.-8. (No change.)

10:161B-2.5 Review and approval of a license application

(a) The applicant or \* [DAS] \* \*OOL\* may request a preliminary review meeting to discuss the applicant's proposed program. Such a functional preapplication review shall provide the applicant with an opportunity for technical assistance regarding the necessity, feasibility, requirements, costs and benefits of applying for a license.

(b) Following receipt of an application, \* [DAS] \* \*OOL\* shall review it for completeness, and relevant fees in N.J.A.C. 10:161B-2.1. If \* [DAS] \* \*OOL\* deems that the application is incomplete, \* [DAS] \* \*OOL\* shall notify the applicant in writing of any missing information. Such written notification from \* [DAS] \* \*OOL\* shall occur within 15 working days upon receipt of said application.

1. The applicant shall be permitted to supply any missing information in the application to \* [DAS] \* \*OOL\* within 30 working days. If the application is not deemed complete by \* [DAS] \* \*OOL\* in writing to the applicant within six months, it shall be denied as incomplete and the applicant may reapply after 30 days. \* [DAS] \* \*OOL\* shall not consider any application until it is deemed complete.

(c) Once the application is deemed complete, \* [DAS] \* \*OOL\* shall review it to determine whether the applicant meets the licensing criteria to operate a program, and whether the facility is safe as demonstrated by the information contained in the application. \* [DAS] \* \*OOL\* may also, at its discretion, consider information obtained from other State agencies and/or agencies in other states, in determining whether to license the program.

1. \* [DAS] \* \*OOL\* shall schedule a meeting to conduct a functional review, as per (a) above, with the applicant to explore and define the program concept, including feasibility and need for proposed services, within 30 days of application receipt by \* [DAS] \* \*OOL\*.

2. If \* [DAS] \* \*OOL\* does not schedule a functional review meeting within the 30 day timeline, the applicant can request one in writing.

3. Within 30 working days after receiving notification from the applicant that the building is ready for occupancy, \* [DAS] \* \*OOL\* shall schedule a survey of the proposed program to determine if the program complies with this chapter.

i. Within 45 days after completion of this survey, \* [DAS] \* \*OOL\* shall notify the applicant in writing of the findings of the survey, including any deficiencies.

ii. If \* [DAS] \* \*OOL\* documents deficiencies, \* [DAS] \* \*OOL\* shall schedule additional surveys of the outpatient substance \* [abuse] \*

**\*use disorder\*** treatment program upon notification from the applicant that the documented deficiencies have been corrected. Additional surveys shall be scheduled by **\*[DAS]\* \*OOL\*** within 15 working days after receipt of the applicant's notification that the documented deficiencies have been corrected.

(d) **\*[DAS]\* \*OOL\*** shall approve a complete application for licensure if:

1. **\*[DAS]\* \*OOL\*** is satisfied that the applicant and its description of the physical plant, finances, hiring practices, management, ownership, operational and treatment procedures, and history of prior operations, if any, are in substantial compliance with this chapter and will adequately provide for the life, safety, health or welfare of the clients, and/or their families;

i. (No change.)

2. (No change.)

3. The applicant has provided **\*[DAS]\* \*OOL\*** with written approvals for the facility from the local zoning, fire, health and building authorities. When seeking local approvals, any outpatient substance **\*[abuse]\* \*use disorder\*** treatment programs providing opioid treatment and opioid detoxification or other detoxification where prescription drugs will be dispensed, shall specifically notify the municipality in which the program is to be located of the full scope of services to be provided. Notification of the municipality shall include notification to appropriate and relevant local authorities and or officials; and

4. The applicant has provided **\*[DAS]\* \*OOL\*** with written approvals for the facility from the local authorities or local official for any water supply and sewage disposal systems not connected to an approved municipal system.

(e) In no instance shall any applicant admit clients to the program until **\*[DAS]\* \*OOL\*** issues a license to the applicant for the program. Any client admissions to the applicant's outpatient treatment program prior to the issuance of a **\*[DAS]\* \*OOL\*** license shall be considered unlicensed admissions and **\*[DAS]\* \*OOL\*** shall take all appropriate enforcement action.

#### 10:161B-2.6 Surveys

(a) When both the written application for licensure is approved and the building is ready for occupancy, **\*[DAS]\* \*OOL\*** representatives shall conduct a survey of the facility within 30 working days to determine if the facility complies with the rules in this chapter.

1. **\*[DAS]\* \*OOL\*** shall notify the facility in writing of the findings of the survey, including any deficiencies found, within 20 working days after completion of the survey by **\*[DAS]\* \*OOL\***.

2. The facility shall notify **\*[DAS]\* \*OOL\*** in writing when the deficiencies have been corrected. Within 30 working days of receiving written notification that the deficiencies have been corrected, **\*[DAS]\* \*OOL\*** will reschedule at least one re-survey of the facility prior to occupancy; additional re-surveys may be scheduled prior to occupancy until all deficiencies are corrected.

#### 10:161B-2.7 Conditional license

(a) A conditional license may be issued by **\*[DAS]\* \*OOL\*** with specific conditions and standards defined on such license and/or written in a conditional license letter granted by **\*[DAS]\* \*OOL\*** when the purposes and intent of the proposed program are outside the scope of a regular license. All standards within this chapter apply unless specifically mentioned in the conditions of said license. Such letter and conditional license must be conspicuously posted by the licensee in accordance with N.J.A.C. 10:161B-2.2(c).

(b) **\*[DAS]\* \*OOL\*** may issue a conditional license if **\*[DAS]\* \*OOL\*** determines that it is in the best interest of the clients benefiting from the treatment program in question and in order to preserve and/or improve the proper functioning of the program.

(c) **\*[DAS]\* \*OOL\*** may issue a conditional license in order to address contingencies and/or special program needs that can be addressed by the applicant and monitored by **\*[DAS]\* \*OOL\***, as agreed between **\*[DAS]\* \*OOL\*** and the applicant, with the safety and well being of the clients and staff of the program as the overriding priority.

(d) (No change.)

(e) A conditional license may be issued to a new program that was reviewed before beginning to provide services. Within 30 working days of **\*[DAS]\* \*OOL\*** receiving written notification from the program that it is fully operational, **\*[DAS]\* \*OOL\*** shall schedule a follow up visit to determine whether the program is functioning in accordance with this chapter, and is eligible to receive a regular license.

(f)-(g) (No change.)

#### 10:161B-2.8 Periodic surveys following licensure

(a) Authorized **\*[DAS]\* \*OOL\*** staff may conduct announced or unannounced visits and periodic surveys of licensed programs. The identity of clients will be kept confidential on all data collected by **\*[DAS]\* \*OOL\*** staff for survey purposes.

(b) (No change.)

(c) In addition to periodic surveys, **\*[DAS]\* \*OOL\*** may conduct surveys to investigate complaints of possible licensure violations regarding the program, the facility's physical plant, clients, or staff.

#### 10:161B-2.9 Deficiency findings

(a) A deficiency may be cited by **\*[DAS]\* \*OOL\*** upon any single or multiple determination that the facility does not comply with a licensure regulation. Such findings may be made as the result of either an on-site survey or inspection or as the result of the evaluation of written reports or documentation submitted to **\*[DAS]\* \*OOL\***, or the omission or failure to act in a manner required by regulation.

(b) At the conclusion of a survey or within 20 business days thereafter, **\*[DAS]\* \*OOL\*** shall provide a facility with a written summary of any factual findings used as a basis to determine that a licensure violation has occurred, and a statement of each licensure regulation to which the finding of a deficiency relates.

#### 10:161B-2.10 Informal dispute resolution

(a) A facility may request an opportunity to discuss the accuracy of survey findings with representatives of **\*[DAS]\* \*DHS\*** in the following circumstances during a survey:

1.-2. (No change.)

(b) Following completion of the survey, a facility may contact the Director of **\*[DAS]\* \*OOL\*** to request an informal review of deficiencies cited. The request must be made in writing within 10 business days of the receipt of the written survey findings. The written request must include:

1.-2. (No change.)

(c) The review will be conducted within 20 business days of the request by supervisory staff of **\*[DAS]\* \*DHS\*** who did not directly participate in the survey. The review can be conducted in person at the offices of **\*[DAS]\* \*DHS\*** or, by mutual agreement, solely by review of the documentation as submitted.

(d) A decision will be issued by **\*[DAS]\* \*DHS\*** within 20 business days of the conference or the review, and if the determination is to agree with the facility's contentions, the deficiencies will be removed from the record. If the decision is to disagree with the request to remove deficiencies, a plan of correction is required within 10 business days of receipt of the decision. The facility retains all other rights to appeal deficiencies and enforcement actions taken pursuant to these rules.

#### 10:161B-2.11 Plan of correction

(a) **\*[DAS]\* \*OOL\*** may require that the facility submit a written plan of correction specifying how each deficiency that has been cited will be corrected along with the time frames for completion of each corrective action. A single plan of correction may address all events associated with a given deficiency.

(b) The plan of correction shall be submitted within 10 business days of the facility's receipt of the notice of violations, unless **\*[DAS]\* \*OOL\*** specifically authorizes an extension for cause. Where deficiencies are the subject of informal dispute resolution pursuant to N.J.A.C. 10:161B-2.10, the extension shall pertain only to the plans of correction for the deficiencies under review.

(c) **\*[DAS]\* \*OOL\*** may require that the facility's representatives and/or board of directors appear at an office conference to review findings of serious or repeated licensure deficiencies and to review the causes for such violations and the facility's plan of correction.

(d) The plan of correction shall be reviewed by \*[DAS]\* \*OOL\* and will be approved where the plan demonstrates that compliance will be achieved in a manner and time that assures the health and safety of patients or residents. If the plan is not approved, \*[DAS]\* \*OOL\* may request that an amended plan of correction be submitted within 10 business days. In relation to violations of resident or patient rights, \*[DAS]\* \*OOL\* may direct specific corrective measures that must be implemented by facilities.

#### 10:161B-2.12 Surrender of a license

(a) When a program elects to voluntarily surrender a license, it shall provide written notice of its intention to do so, and the specific date on which it shall surrender its license, to effect an orderly transfer of clients, as follows:

1. The program shall provide \*[DAS]\* \*OOL\* with at least 45 days prior notice;

2.-4. (No change.)

(b) When a program is ordered by \*[DAS]\* \*OOL\* to surrender its license, the facility administrator named in the original license application, the person(s) currently acting in their capacity and/or the facility's appropriate legal representative shall provide written notice of the surrender as required by (a)2, 3 and 4 above, unless the order sets forth other or additional notice requirements.

(c) All notices to \*[DAS]\* \*OOL\* regarding voluntary or ordered surrender of a license, and the physical license, shall be sent to the address set forth at N.J.A.C. 10:161B-2.1(b). All notices and the original license must be sent to \*[DAS]\* \*OOL\* within seven working days of the date that such decision is announced by the agency director, verbally or otherwise, to clients and or program staff and or seven days from the postmarked receipt date of the postmarked \*[DAS]\* \*OOL\* written licensure surrender request.

#### 10:161B-2.13 Waiver

(a) An applicant for licensure or a current licensee may seek a waiver of one or more provisions of this chapter, provided that the applicant or licensee demonstrates that compliance represents an unreasonable hardship for the applicant or licensee, and such a waiver is determined by \*[DAS]\* \*OOL\* to be consistent with the general purpose and intent of its enabling statute and these rules; is consistent with prevailing \*[DAS]\* \*OOL\* public policy; and would not otherwise jeopardize recovery, endanger the life, safety, health or welfare of the client populations to be served, their families, personnel who work or would work at the program, or the public.

(b) An applicant or a current licensee seeking a waiver shall submit the request in writing to the address set forth at N.J.A.C. 10:161B-2.1(b), and shall include the following:

1.-5 (No change.)

6. Such other additional information that \*[DAS]\* \*OOL\* may determine necessary and appropriate for evaluation and review of the waiver request on a case-by-case basis, including timeframes in which the waiver will no longer be needed; \*[DAS]\* \*OOL\* shall determine whether the requested timeframes are reasonable.

(c) \*[DAS]\* \*OOL\*, at its discretion, shall grant a retroactive waiver for a period of up to 21 days.

(d) \*[DAS]\* \*OOL\* may revoke a waiver at any time if \*[DAS]\* \*OOL\* determines that the waiver no longer fulfills the purpose and intent of this chapter, or that continuing the waiver would jeopardize client recovery or endanger the life, safety, health or welfare of the client, personnel, or the public.

#### 10:161B-2.14 Enforcement remedies

(a) The Commissioner or designee may impose the following enforcement remedies against a substance \*[abuse]\* \*use disorder\* treatment facility for violations of licensure regulations or other statutory requirements:

1. (No change.)

2. Curtailment of admissions to a licensed substance \*[abuse]\* \*use disorder\* treatment facility;

3.-7. (No change.)

#### 10:161B-2.16 Effective date of enforcement actions

The assessment of civil monetary penalties, suspension or revocation of a license, or the placement of a license on provisional status shall become effective 30 business days after the date of mailing or the date personally served on a licensee, unless the licensee shall file with \*[the Division]\* \*OOL\* a written answer to the charges and give written notice to \*[the Division]\* \*OOL\* of its desire for a hearing in which case the assessment, suspension, revocation or placement on provisional license status shall be held in abeyance until the administrative hearing has been concluded and a final decision is rendered by the Commissioner or designee. Hearings shall be conducted in accordance with N.J.A.C. 10:161B-2.24.

#### 10:161B-2.17 Enforcement actions

(a) The Commissioner or designee may assess a civil monetary penalty for violation of licensure regulations according to the following standards:

1. For operation of a substance \*[abuse]\* \*use disorder\* treatment facility without a license, or continued operation of a facility after suspension or revocation of a license, \$25.00 per day for a first occurrence, and \$50.00 per day for a subsequent occurrence, from the date of initiation of services;

2. For a violation of an order for curtailment of admissions, \*[DAS]\* \*OOL\* shall construe the order for curtailment of admissions as an order of revocation, and shall impose penalties consistent with (a)1 above;

3. Failure to obtain prior approval from \*[DAS]\* \*OOL\* for occupancy of a new or renovated area, or initiation of a new or enhanced service, shall be considered operation of a facility without a license, and \*[DAS]\* \*OOL\* shall impose penalties consistent with (a)1 above;

4. Construction or renovation of a facility without the New Jersey Department of Community Affairs' approval of construction plans, shall be considered operation of an unlicensed facility, and \*[DAS]\* \*OOL\* shall impose penalties consistent with (a)1 above, until the newly constructed or renovated facility is determined by \*[the Division]\* \*OOL\* to be in compliance with licensure standards. This determination shall take into account any waivers granted by \*[the Division]\* \*OOL\*;

5. Operation of a licensed facility following the transfer of ownership of a substance \*[abuse]\* \*use disorder\* treatment facility without prior approval of \*[the Division]\* \*OOL\*, shall be considered operation of an unlicensed facility, and \*[DAS]\* \*OOL\* shall impose penalties consistent with (a)1 above. Such penalties may be assessed against each of the parties at interest;

(b) The Commissioner or designee may take the following additional enforcement actions:

1. For violations of licensure regulations related to client care or physical plant standards that represent a risk to the health, safety, or welfare of clients of a facility or the general public, \*[the Division]\* \*OOL\* shall reduce the facility's license to provisional status to allow the facility to correct all regulation violations.

2. Where there are multiple deficiencies related to client care or physical plant standards throughout a facility, and/or such violations represent a direct risk that a client's physical or mental health will be compromised, or where an actual violation of a client's rights is found, \*[the Division]\* \*OOL\* shall begin the process to suspend or revoke the license pursuant to N.J.S.A. 26:2G-27 and may seek an injunction pursuant to N.J.S.A. 26:2G-29 and 30:1-12. Any further operation of the facility shall be construed as operation of an unlicensed facility and \*[the Division]\* \*OOL\* shall impose penalties consistent with (a)1 above.

3. For repeated violations of any licensing regulation within a 12-month period or on successive annual inspections, or failure to implement an approved plan of correction, where such violation was not the subject of a licensing action, \*[the Division]\* \*OOL\* may in its discretion reduce the license to provisional status, or move to suspend or revoke the license, considering the following factors:

i.-viii (No change.)

4. For violations resulting in either actual harm to a client, or in an immediate and serious risk of harm, \*[the Division]\* \*OOL\* shall

reduce the license to provisional status, or move to suspend or revoke the license, and may seek an injunction pursuant to N.J.S.A. 26:2G-29 and 30:1-12.

5. For failure to report information to \*[the Division]\* \*OOL\* as required by statute or licensing regulation, after reasonable notice and an opportunity to cure the violation, the facility shall be subject to a fine of not more than \$ 500.00, pursuant to N.J.S.A. 26:2B-14;

(c) Except for violations deemed to be immediate and serious threats, \*[the Division]\* \*OOL\* may decrease the penalty assessed in accordance with (a) above, based on the following factors:

1.-8. (No change.)

(d) In addition to the imposition of penalties in accordance with (a) above, \*[the Division]\* \*OOL\* may also curtail admissions consistent with N.J.A.C. 10:161B-2.19.

10:161B-2.18 Failure to pay a penalty; remedies

(a) Within 30 days after the mailing date of a Notice of Proposed Assessment of a Penalty, a facility that intends to challenge the enforcement action shall notify \*[the Division]\* \*OOL\* of its intent to request a hearing pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq.

(b) The penalty becomes due and owing upon the 30th day from mailing of the Notice of Proposed Assessment of Penalties, if a notice requesting a hearing has not been received by \*[the Division]\* \*OOL\*. If a hearing has been requested, the penalty is due 45 days after the issuance of a Final Agency Decision by the Commissioner or designee, if \*[the Division's]\* \*OOL's\* assessment has not been withdrawn, rescinded, or reversed, and an appeal has not been timely filed with the New Jersey Superior Court, Appellate Division pursuant to New Jersey Court Rule 2:2-3.

(c) (No change.)

10:161B-2.19 Curtailment of admissions

(a) \*[The Division]\* \*OOL\* may issue an order curtailing all new admissions and readmissions to a substance \*[abuse]\* \*use disorder\* treatment facility including, but not limited to, the following circumstances:

1. Where violations of licensing regulations are found that have been determined to pose an immediate and serious threat of harm to clients of a substance \*[abuse]\* \*use disorder\* treatment facility;

2. For the purpose of limiting the census of a facility if clients must be relocated upon closure, when \*[the Division]\* \*OOL\* has issued a Notice of Proposed Revocation or Suspension of a substance \*[abuse]\* \*use disorder\* treatment facility license;

3. Where the admission or readmission of new clients to a substance \*[abuse]\* \*use disorder\* treatment facility would impair the facility's ability to correct serious or widespread violations of licensing regulations related to direct client care and cause a diminution of the quality of care; or

4. For exceeding the licensed or authorized bed or service capacity of a substance \*[abuse]\* \*use disorder\* treatment facility, except in those instances where exceeding the licensed or authorized capacity was necessitated by emergency conditions and where immediate and satisfactory notice was provided to \*[the Division]\* \*OOL\*.

(b) The order for curtailment may be withdrawn upon a \*[DAS]\* \*OOL\* finding that the facility has achieved substantial compliance with the applicable licensing regulations or Federal certification requirements and that there is no immediate and serious threat to client safety; or in the case of providers exceeding licensed capacity, has achieved a census equivalent to licensed and approved levels. Such order to lift a curtailment may reasonably limit the number and priority of clients to be admitted by the facility in order to protect client safety. The facility shall be notified whether the order for curtailment has been withdrawn within 20 working days after the \*[DAS]\* \*OOL\* finding.

10:161B-2.20 Provisional license

(a) \*[The Division]\* \*OOL\* may place a substance \*[abuse]\* \*use disorder\* treatment facility on provisional license status as follows:

1. (No change.)

2. Upon issuance of an order for curtailment of admission, until \*[the Division]\* \*OOL\* finds the facility has achieved substantial compliance with all applicable licensing regulations;

3. For violations of licensing regulations that have been determined to pose a threat to the safety of clients of a substance \*[abuse]\* \*use disorder\* treatment facility; and/or

4. (No change.)

(b) A facility placed on provisional license status shall be provided notice of same, in accordance with the notice requirements set forth in N.J.A.C. 10:161B-2.15. Provisional license status is effective upon receipt of the notice, although the facility may request a hearing to contest provisional license status in accordance with the requirements set forth in N.J.A.C. 10:161B-2.22. Where a facility chooses to contest provisional license status by requesting a hearing in accordance with the provisions set forth in this section and in N.J.A.C. 10:161B-2.24, provisional license status remains effective at least until the final decision or adjudication (as applicable) of the matter, or beyond in instances where \*[the Division's]\* \*OOL's\* action is upheld, in accordance with these rules. In addition, provisional license status remains effective in cases where the underlying violations which caused the issuance of provisional licensure status are the subject of appeal and/or litigation, as applicable, in accordance with these rules.

(c) While a facility is on provisional license status, the following shall occur:

1. \*[The Division]\* \*OOL\* shall not authorize or review any application for approval of additional beds or services filed by the facility with \*[the Division]\* \*OOL\*;

2. \*[The Division]\* \*OOL\* shall notify any government agency that provides funding or third party reimbursement to the facility or that has statutory responsibility for monitoring the quality of care rendered to clients that the facility's license has been deemed provisional and the reasons therefor. Upon resolution favorable to the facility, \*[the Division]\* \*DHS\* shall notify the same government agencies and third parties; and

3. (No change.)

(d) While on provisional license status, \*[the Division]\* \*DHS\* may place specific conditions on the facility's continued operation, including that the facility seek qualified professional and/or clinical assistance to bring itself into compliance with this chapter.

(e) (No change.)

10:161B-2.21 Suspension of a license

(a) The Commissioner or designee may order the suspension of a license of a substance \*[abuse]\* \*use disorder\* treatment facility or a component or distinct part of the facility upon a finding that violations pertaining to the care of clients or to the hazardous or unsafe conditions of the physical structure pose an immediate threat to the health, safety, and welfare of the public or the clients of the facility.

(b) Upon a finding described in (a) above, the Commissioner or the Commissioner's authorized representative shall serve notice in person or by certified mail to the facility or its registered agent of the nature of the findings and violations and the proposed order of suspension. Such notice shall be served within five days of the finding. The notice shall provide the facility with a 30-day period from receipt to correct the violations and provide proof to \*[the Division]\* \*OOL\* of such correction, or to request a hearing.

(c) If \*[the Division]\* \*OOL\* determines the violations have not been corrected, and the facility has not filed notice within 30 days of receipt of the Commissioner's notice pursuant to (e) below requesting a hearing to contest the notice of suspension, then the license shall be deemed suspended. Upon the effective date of the suspension, the facility shall cease and desist the provision of substance \*[abuse]\* \*use disorder\* treatment services and effect an orderly transfer of clients to licensed facilities or other approved services and shall document all transfers.

(d) Within five working days after suspension becomes effective, \*[the Division]\* \*OOL\* shall approve and coordinate the process to be followed during an evacuation of the facility or cessation of services pursuant to an order for suspension or revocation.

(e) If the facility requests a hearing within 30 days of receipt of the Notice of Proposed Suspension of License, \*[the Division]\* \*DHS\* shall arrange for an immediate hearing to be conducted by the Office of Administrative Law (OAL), and a final agency decision shall be issued by the Commissioner or designee as soon as possible, adopting, modifying or rejecting the initial decision by the OAL. If the Commissioner affirms the proposed suspension of the license, the order shall become final.

(f) Notwithstanding the issuance of an order for proposed suspension of a license, \*[the Division]\* \*DHS\* may concurrently or subsequently impose other enforcement actions pursuant to these rules.

(g) \*[The Division]\* \*DHS\* may rescind the order for suspension upon a finding that the facility has corrected the conditions which were the basis for the action.

#### 10:161B-2.22 Revocation of a license

(a) A Notice of the Proposed Revocation of a substance \*[abuse]\* \*use disorder\* treatment facility license may be issued in the following circumstances:

1.-4. (No change.)

(b) (No change.)

#### 10:161B-2.23 Injunction

(a) The Commissioner or designee may determine to seek an injunction of the operation of a substance \*[abuse]\* \*use disorder\* treatment facility or a component or distinct part of the facility upon a finding that violations pertaining to the care of clients or to the hazardous or unsafe conditions of the physical structure pose an immediate threat to the health, safety, and welfare of the public or the clients of the facility.

(b) (No change.)

(c) Within five working days, \*[the Division]\* \*DHS\* shall approve and coordinate the process to transfer/relocate all of the facility's current clients. Upon the Court issuing an injunction or temporary restraint, the facility shall cease and desist the provision of substance \*[abuse]\* \*use disorder\* treatment services and effect an orderly transfer of clients to substance \*[abuse]\* \*use disorder\* treatment facilities or other services approved by \*[the Division]\* \*DHS\* and the facility shall document all transfers.

(d) Notwithstanding the issuance of an injunction and or temporary restraint \*[the Division]\* \*DHS\* may concurrently or subsequently impose other enforcement actions pursuant to this chapter.

(e) \*[The Division]\* \*DHS\* shall seek to lift the injunction and or temporary restraint upon its determination that the facility has corrected the conditions which were the basis for the action.

#### 10:161B-2.24 Hearings

(a)-(b) (No change.)

(c) \*[The Division]\* \*DHS\* shall transmit the hearing request to the New Jersey Office of Administrative Law (OAL) within seven working days of receipt.

(d) (No change.)

#### 10:161B-2.25 Settlement of enforcement actions

(a) (No change.)

(b) \*[The Division]\* \*DHS\* shall schedule a settlement conference within 30 days but \*[the Division]\* \*DHS\* and the party may extend that time if they both agree.

(c) \*[The Division]\* \*DHS\* has the discretion to settle the matter as it sees fit. Settlement terms may include \*[the Division's]\* \*DHS's\* agreement to accept payment of penalties over a schedule not exceeding 18 months where a facility demonstrates financial hardship.

(d) (No change.)

### SUBCHAPTER 3. GENERAL REQUIREMENTS

#### 10:161B-3.1 Provision of services

(a) An outpatient substance \*[abuse]\* \*use disorder\* treatment facility shall provide or arrange for the following services:

1.-3. (No change.)

(b) Written agreements detailing services to be provided shall be made between the outpatient substance \*[abuse]\* \*use disorder\*

treatment facility and any other service provider; such agreements shall specify services rendered and be supported by documentation of services rendered.

1. (No change.)

#### 10:161B-3.2 Compliance with laws and rules

(a) (No change.)

(b) If a licensed program provides outpatient substance \*[abuse]\* \*use disorder\* treatment services in addition to other health care services, the licensee shall comply with the rules in this chapter and all other applicable rules.

#### 10:161B-3.3 Ownership

(a) \*[DAS]\* \*OOL\* shall hold the licensee for a facility responsible for ensuring that the facility is and remains in compliance with all applicable statutes and rules related to the construction and maintenance of the physical plant, regardless of whether the licensee owns the physical plant.

(b) Programs in which ownership of the physical plant, and/or the property on which it is located is by an entity other than the licensee for the facility, shall provide notice of the current ownership of the property(ies), upon request.

1. (No change.)

2. The program shall provide \*[DAS]\* \*OOL\* written notice of any change in ownership of the physical plant or land on which it is located at least 30 days prior to such change, at the address set forth at N.J.A.C. 10:161B-2.1(b).

(c) (No change.)

#### 10:161B-3.4 Submission of documents and data

(a) Upon request, the program shall submit to \*[DAS]\* \*DMHAS\* any documents required to be maintained by the program in accordance with this chapter. Information identifying clients shall be kept confidential at all times by \*[DAS]\* \*DMHAS\*.

(b) The facility shall report monthly to \*[DAS]\* \*DMHAS\* all client admissions to and discharges from the facility, and such additional client and service data as \*[DAS]\* \*DMHAS\* may require, on the NJSAMS or other \*[DAS-designated]\* \*DMHAS-designated\* reporting system.

#### 10:161B-3.6 Policy and procedure manual

(a) The administrator shall develop, implement and ensure the review, at least annually, of a policy and procedure manual(s) about the organization and operation of the facility.

1.-2. (No change.)

3. This policy and procedure manual shall be maintained on-site at the facility and available for review at all times by clients, staff, \*[DAS]\* \*DHS\* and the public.

(b) The facility shall ensure that, at a minimum, the following is contained in the policy and procedure manual(s):

1.-6. (No change.)

7. A written plan for informing persons in need of substance \*[abuse]\* \*use disorder\* treatment services, their friends and family members, the public, and health care providers of the availability of the facility's services, all program fees and available financial arrangements, including a description of referral mechanisms and linkages with consultants, other health care facilities, law enforcement, social and community agencies that will provide continuity of care including designation of staff responsible for implementation of the plan;

8. (No change.)

9. Policies and procedures that ensure the accessibility of and use of telephone(s) by clients. Such policies and procedures shall:

i.-ii. (No change.)

iii. Not prevent clients from contacting the local police in the event of an emergency, or from contacting \*[DAS]\* \*DHS\* to issue a complaint regarding the facility;

10. Policies and procedures for answering and responding to incoming telephone calls for clients at times other than designated business hours;

i. The program must use either an answering service, a designated on call staff or an alternative method approved by \*[DAS]\* \*OOL\*, to ensure that clients have access to emergency consultation services on a 24-hour-a-day basis, seven days a week.

11.-12. (No change.)

13. Policies and procedures for complying with applicable statutes and rules to report child abuse and/or neglect, abuse or mistreatment of elderly clients and disabled adults, sexual abuse, sexual assault, specified communicable diseases, including HIV infection, poisonings, and unattended or suspicious deaths. Such policies and procedures shall include the following:

i. The designation of a staff member(s) responsible for coordinating the reporting of identified and/or suspected cases of child abuse and/or neglect in compliance with N.J.S.A. 9:6-1 et seq., recording the notification to the Division of \*Youth and Family Services (DYFS)\* \*Child Protection and Permanency (DCPP)\* and in the clinical record, and serving as a liaison between the facility and \*DYFS\* \*DCPP\*;

ii.-iv. (No change.)

14. (No change.)

#### 10:161B-3.7 Employee health

(a) (No change.)

(b) The program shall require all staff employed as of June 1, 2009, and all staff hired thereafter, to submit to screening tests for rubella and measles, subject to the following:

1. (No change.)

2. If an employee cannot provide documentation required by (b)1 above, the employee shall be given a rubella hemagglutination inhibition test or other rubella-screening test approved by \*DAS\* \*DOH\* as equivalent or better, on a case by case basis.

3.-5. (No change.)

(c) (No change.)

(d) The program shall require all employees, including medical staff members, to submit to tuberculosis testing using a two-step Mantoux in accordance with the Tuberculosis Surveillance Procedures for Substance Abuse Treatment Facilities, published by \*DAS\* \*DMHAS\*, and incorporated herein by reference as chapter Appendix A.

1.-7. (No change.)

(e)-(f) (No change.)

#### 10:161B-3.8 Reportable events

(a) (No change.)

(b) The facility shall immediately \*notify DAS at 609-292-5760, or after hours at 866-666-8108\* \*e-mail [dmhas.incidentrept@dhs.state.nj.us](mailto:dmhas.incidentrept@dhs.state.nj.us), and immediately fax a report to \*DAS at 609-292-3816\* \*DMHAS at 609-341-2324\*, regarding any event occurring which jeopardizes the health, safety, or welfare of clients or staff as noted in this subchapter, including, but not limited to, the following:

1.-6. (No change.)

(c) The facility shall provide \*DAS\* \*DHS\* with a written report no later than five business days after the event or circumstances listed in (b)1 through 6 above. This written report does not replace the required immediate telephone contact and faxed report to \*DAS\* \*DHS\*.

1. (No change.)

(d) The facility shall notify \*DAS\* \*OOL\* in writing of the resignation or termination of employment of the administrator, medical director, director of nursing, or the director of substance abuse counseling services and the name and qualifications of the replacement or acting replacement, no later than seven days following the date of resignation or termination.

(e) (No change.)

#### 10:161B-3.9 Notices

(a) The facility shall conspicuously post a notice that the following information is available in the facility during its normal business hours for clients and the public:

1. All waivers granted by \*DAS\* \*OOL\*;

2.-5. (No change.)

#### 10:161B-3.12 Tobacco products

The smoking of tobacco products and the use of spit or any form of tobacco is prohibited within all outpatient substance \*abuse\* \*use disorder\* treatment facilities.

### SUBCHAPTER 4. GOVERNING AUTHORITY

#### 10:161B-4.1 Responsibility of the profit and/or non-profit governing authority

(a) Every facility shall have a governing authority, which shall assume legal responsibility for the management, operation, and financial viability of the facility. The governing authority shall have written policies and protocols for the following:

1.-24. (No change.)

25. Reviewing any notices issued by \*DAS\* \*OOL\* regarding non-compliance with any requirements of this chapter or any violations of law by the facility, staff, volunteers or consultants, ensuring corrective measures have been taken, and where appropriate, advising \*DAS\* \*OOL\* of such corrective measures;

26.-28. (No change.)

(b) The governing authority shall act in accordance with a plan of operation or bylaws that shall set forth policies and procedures for its conduct and oversight of the operation of the outpatient substance \*abuse\* \*use disorder\* treatment facility, including:

1.-9. (No change.)

### SUBCHAPTER 6. CLIENT CARE POLICIES AND SERVICES

#### 10:161B-6.1 Client care policies

(a) Every outpatient substance \*abuse\* \*use disorder\* treatment facility shall develop, establish and ensure the implementation and maintenance of client care policies and procedures consistent with the requirements of this chapter. At a minimum, the administrator, director of substance abuse counseling, director of nursing services, and medical director or physician shall provide direct input and review of all client care policies.

1.-4. (No change.)

(b)-(e) (No change.)

#### 10:161B-6.2 Client care policies and procedures

(a) Client care policies shall facilitate continuity of care and client safety, and shall include, but need not be limited to, the following:

1.-10. (No change.)

11. Initiation, implementation, review, and revision of a written treatment plan of care to include \*DSM IV-TR\* \*DSM-5\* diagnosis, ASAM level of care assessment, measurable goals, objectives and treatment outcomes;

12.-18. (No change.)

(b)-(c) (No change.)

#### 10:161B-6.3 Standards for preadmission, admission and retention of clients

(a)-(c) (No change.)

(d) Only facilities licensed by \*DAS\* \*OOL\* to provide medically monitored detoxification services or hospitals providing medical detoxification services in a designated detoxification unit or facility shall admit clients requiring medically monitored detoxification.

1. (No change.)

(e) Upon admission to an outpatient substance \*abuse\* \*use disorder\* treatment facility, the following shall apply:

1.-5. (No change.)

(f)-(g) (No change.)

#### 10:161B-6.4 Involuntary discharge

(a) (No change.)

(b) Clients shall have the right to appeal an involuntary discharge in accordance with procedures established by the facility. The actual discharge from the facility shall not be initiated until the appeal process is complete. If the client is a juvenile, the parent(s), guardian or legally authorized representative must file an appeal.

1. The outpatient substance \*abuse\* \*use disorder\* treatment facility shall require the appeal to be initiated by the client verbally or in writing. If initiated verbally, a written appeal shall follow, provided by the client or an individual chosen by the client to act on behalf of the client.

2. (No change.)

(c) (No change.)

## SUBCHAPTER 7. MEDICAL SERVICES

## 10:161B-7.1 Provision of medical services

(a) Medical services shall be provided in outpatient substance **[abuse]\* \*use disorder\*** treatment programs as follows:

1.-4. (No change.)

## 10:161B-7.4 Physician responsibilities

(a) Physicians who provide medical care to clients in an outpatient substance **[abuse]\* \*use disorder\*** treatment program shall be responsible for:

1.-5. (No change.)

(b) (No change.)

## SUBCHAPTER 8. NURSING SERVICES

## 10:161B-8.1 Provision of nursing services

(a) Nursing services shall be provided in licensed outpatient substance **[abuse]\* \*use disorder\*** treatment programs as follows:

1.-2. (No change.)

(b) (No change.)

## SUBCHAPTER 9. CLIENT ASSESSMENT AND TREATMENT PLANNING

## 10:161B-9.1 Client assessment

(a) An outpatient substance **[abuse]\* \*use disorder\*** treatment facility shall complete, within three visits of admission, a drug screen, and a comprehensive biopsychosocial assessment of all clients using an assessment instrument which assesses medical status, vocational/employment and support, alcohol, tobacco and other drug use, legal status, family/social status, psychiatric status, as well as behavioral risk factors for HIV and hepatitis. The client shall be placed in a treatment facility, the modality and underlying philosophy of which is consistent with the client's preferences and values and which is also consistent with the client's needs based on criteria defined in the ASAM **[Patient Placement]\* Criteria [2-R]\*** (see N.J.A.C. 10:161B-1.3.).

1. All client assessments shall result in a DSM diagnosis for alcohol, tobacco and other substance use, shall include screening for other identified co-occurring disorders, and shall document level of care determination using ASAM **[Patient Placement]\* Criteria [2-R]\***.

2. (No change.)

(b) (No change.)

## SUBCHAPTER 10. SUBSTANCE ABUSE COUNSELING AND SUPPORTIVE SERVICES

## 10:161B-10.1 Provision of substance abuse counseling

(a) Every outpatient substance **[abuse]\* \*use disorder\*** treatment facility shall provide substance abuse counseling on-site, and shall assign every client to a primary substance abuse counselor at admission.

(b)-(g) (No change.)

## SUBCHAPTER 11. OPIOID TREATMENT SERVICES

## 10:161B-11.1 Authority

(a) A program applying for licensure to operate an opioid treatment program under these standards shall:

1. Provide written documentation that the applicant for licensure of the opioid treatment program has notified the governing authority of the municipality of the full scope of services, including opioid treatment, to be provided at the facility. Notification shall be subject to verification by **[DAS]\* \*DHS\*** prior to issuance of a license to operate an opioid treatment program under the outpatient substance **[abuse]\* \*use disorder\*** treatment license;

2. Be certified as an opioid treatment program by the Substance Abuse and Mental Health Services Administration (SAMHSA) and accredited by an accreditation body approved by SAMHSA in accordance with 42 CFR Part 8, available at **[http://dpt.samhsa.gov/regulations/regindex.aspx]\* \*http://www.samhsa.gov/laws-regulations-guidelines/substance-use-regulations-mandates#opioid\***. Revocation of certification by SAMHSA shall constitute the immediate

withdrawal of licensure approval to operate an opioid treatment program by **[DAS]\* \*OOL\***;

3. Comply with all regulations enforced by the Drug Enforcement Administration (DEA) under 21 CFR Chapter II and be registered by the DEA, at 1-800-882-9539, or online at **[http://www.deadiversion.usdoj.gov]\* \*http://www.deadiversion.usdoj.gov/index.html\***; and State of New Jersey Department of Law and Public Safety, Drug Control Unit, (973) 504-6351, **[http://www.nj.gov/oag/ca/drug/dchome.htm]\* \*http://www.njconsumeraffairs.gov/dcu/Pages/default.aspx\***, as a Narcotic Treatment Program in accordance with N.J.A.C. 8:67, before administering or dispensing opioid agonist treatment medications;

4.-5. (No change.)

6. Comply with the publication "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs," issued by the Center for Substance Abuse Treatment (CSAT) as part of the Treatment Improvement Protocol Series, TIP 43 (2005), incorporated herein by reference as amended and supplemented; copies are available from the National Clearinghouse for Alcohol and Drug Information, P.O. Box 2345, Rockville, MD 20847-6686, 1-800-729-6686, **[http://ncadi.samhsa.gov; or for online download at http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.82676]\* \*http://www.cocommunity.net/agency/national-clearinghouse-alcohol-and-drug-information.html or for online download at http://store.samhsa.gov/product/TIP-43-Medication-Assisted-Treatment-for-Opioid-Addiction-in-Opioid-Treatment-Programs/SMA12-4214\***.

7. (No change.)

8. Each opioid treatment program shall participate in a registry or other data management system implemented by **[DAS]\* \*DMHAS\***, submitting information in the format prescribed by **[DAS]\* \*DMHAS\***, for the purpose of preventing the enrollment of clients in more than one program and facilitating client relocation; and

9. (No change.)

## 10:161B-11.2 Staffing

(a) All opioid treatment programs shall have a medical director who shall be ASAM certified\*, or certified by its successor board,\* by June 1, 2012 in accordance with N.J.A.C. 10:161B-1.4. The medical director or other designated program physician shall be available on site or by telephone during all operating hours of the opioid treatment program. A physician, licensed to practice in the State of New Jersey, who worked a minimum of five years at least 20 hours per week and has completed the ASAM/AATOD clinician's training course, may be considered for a waiver of the above provision.

(b)-(g) (No change.)

## 10:161B-11.5 Minimum standards for admission to an opioid treatment program

(a) (No change.)

(b) All persons admitted to an opioid treatment program shall meet the admission criteria outlined in the Federal standards set by accrediting agencies contained in 42 CFR Part 8.12. Program criteria for admission shall be based on the definition of opioid dependence in **[DSM-IV-TR]\* \*DSM-5\***. The client record shall document a **[DSM-IV-TR]\* \*DSM-5\*** diagnosis by a qualified clinician and/or a determination that opioid maintenance therapy on an outpatient basis is appropriate according to ASAM **[Client Placement]\* Criteria [2-R]\***.

## 10:161B-11.6 Admissions and assessment

(a)-(b) (No change.)

(c) An opioid treatment program shall conduct a complete physical examination, a medical history including drug use and current medications, treatment history and personal history before dispensing or administering medication. A program physician or other licensed independent practitioner authorized under New Jersey statutes shall conduct a complete physical examination at admission and shall include testing for the following:

1.-8. (No change.)

9. All clients shall receive HIV pre-test counseling, and shall be offered HIV testing onsite or at a **[DHSS Division of HIV/AIDS]\* \*DOH/HIV, STD, and TB\*** Services approved rapid HIV testing clinic, with referral documented in the client file; however, a client has the right

to refuse HIV testing. Documentation of refusal must be contained in the client file; and

10. (No change.)  
(d)-(h) (No change.)

#### 10:161B-11.11 Labeling of take-home medication

(a) Take-home medication provided to eligible clients shall be provided in a child-proof container in accordance with the Poison Prevention Packaging Act (PL 91-601, 15 U.S.C. §1471, Federal Consumer Product Safety Commission, [\\*\(http://www.cpsc.gov/BUSINFO/Pppa.pdf\)\\*](http://www.cpsc.gov/BUSINFO/Pppa.pdf) [\\*http://www.cpsc.gov/Global/PDF/Statures/pppa.pdf\\*](http://www.cpsc.gov/Global/PDF/Statures/pppa.pdf) and shall be labeled as follows:

Name, address, and telephone number of the opioid treatment program

- Date of issue  
Client's full name  
Name and strength of drug  
Number of doses, if multiple dose  
Directions for use  
Name of prescribing Physician or advanced practice nurse  
Warning/caution statement

#### 10:161B-11.14 Take-home exceptions

(a) An opioid treatment program may request an exception of the take-home requirements contained in the standards set by accrediting agencies for a client deemed responsible in handling take-home medication who is unable to be medicated at the program due to illness, family emergency, job training, travel, etc. A request for exception is only necessary if the program physician makes a treatment decision that differs from the Federal regulatory requirements at 42 CFR Part 8. A client's request for an exception of the take-home requirements contained in standards set by accrediting agencies shall be reviewed and approved by the multidisciplinary team, signed by a program physician and submitted by fax to the CSAT at 240-276-1630, or online per instructions at <http://dpt.samhsa.gov/webintro.htm>. A copy of the exemption request shall be concurrently submitted by fax to [\\*\[DAS\]\\*@DMHAS](mailto:[DAS]*@DMHAS), at 609-292-3816.

#### 10:161B-11.15 Clinic based medical maintenance

- (a) (No change.)

(b) Prior to initiating clinic based medical maintenance, an opioid treatment program shall:

1. Submit a written notice to [\\*\[DAS\]\\*@DMHAS](mailto:[DAS]*@DMHAS) of its intent to initiate clinic based medical maintenance to Phase VI clients who meet the criteria in (c) below. The opioid treatment program shall identify the physician who will direct the clinic based medical maintenance program and submit documentation of the physician's qualifications to oversee the program;

- 2.-8. (No change.)

(c) Opioid treatment programs electing to provide clinic based medical maintenance will be subject to a comprehensive licensure survey to determine compliance with standards set by accrediting agencies and this chapter. Programs determined to not be operating in accordance with these standards may be directed by [\\*\[DAS\]\\*@OOL](mailto:[DAS]*@OOL) to cease clinic based medical maintenance services and extended take-homes.

- (d) (No change.)

#### 10:161B-11.16 Office based opioid treatment

An opioid treatment program seeking to affiliate with an office based private physician for the provision of opioid treatment in the physician's office shall request an exemption from the CSAT in accordance with 42 CFR Part 8. The opioid treatment program shall also file for a waiver in accordance with N.J.A.C. 10:161B-2.13, and shall be subject to conditions imposed by [\\*\[DAS\]\\*@OOL](mailto:[DAS]*@OOL) if the waiver is approved. Opioid treatment programs utilizing Suboxone shall comply with all mandates from CSAT governing the administration of Suboxone. All facilities shall comply with the [\\*\[DAS\]\\*@DMHAS](mailto:[DAS]*@DMHAS) Buprenorphine Guidelines, Administrative Bulletin 2007-03, incorporated herein as chapter Appendix B.

## SUBCHAPTER 12. DETOXIFICATION SERVICES

### 10:161B-12.1 Provision of outpatient detoxification services

(a) The standards in this subchapter shall apply to all outpatient substance [\\*\[abuse\]\\*@use\\_disorder](mailto:[abuse]*@use_disorder) treatment programs approved by [\\*\[DAS\]\\*@OOL](mailto:[DAS]*@OOL) to provide outpatient detoxification services, including opioid treatment programs providing short-term (that is, less than 30 days) opiate detoxification using methadone and/or other approved medications.

(b) The program shall accept and provide detoxification services only to clients meeting the ASAM [\\*\[Client Placement\]\\*@Criteria](mailto:[Client Placement]*@Criteria), Level I-D or II-D.

### 10:161B-12.3 Client eligibility for outpatient detoxification

Clients admitted to outpatient detoxification shall meet the admission criteria for either ASAM Level I-D (outpatient detoxification without extended on-site monitoring) or Level II-D (outpatient detoxification with extended on-site monitoring) of the ASAM [\\*\[-PPC-2R\]\\*@Criteria](mailto:[-PPC-2R]*@Criteria). Priority admission for detoxification services shall be given to pregnant women and individuals who are HIV positive.

### 10:161B-12.4 Required services

- (a) (No change.)

(b) [\\*\[DAS\]\\*@DHS](mailto:[DAS]*@DHS) does not sanction or condone the use of ultra rapid opioid detoxification and rapid opioid detoxification as a means for detoxification from opioids or other substances.

### 10:161B-12.5 Policies and procedures

(a) Outpatient substance [\\*\[abuse\]\\*@use\\_disorder](mailto:[abuse]*@use_disorder) treatment programs approved by [\\*\[DAS\]\\*@OOL](mailto:[DAS]*@OOL) to provide outpatient detoxification shall establish policies and procedures which are consistent with the ASAM [\\*\[Patient Placement\]\\*@Criteria](mailto:[Patient Placement]*@Criteria) [\\*\[-2R\]\\*](mailto:[-2R]*), the CSAT Treatment Improvement Protocol (TIP 19, 1995) publication "Detoxification From Alcohol and Other Drugs," incorporated herein by reference (accessible to download from [\\*http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.39784\\*](http://www.ncbi.nlm.nih.gov/books/bv.fcgi?rid=hstat5.chapter.39784) [\\*http://www.taadas.org/publications/prodimages/TIP%2019.pdf\\*](http://www.taadas.org/publications/prodimages/TIP%2019.pdf)), and acceptable medical treatment practices within the disciplines providing client services for the following:

- 1.-10 (No change.)  
(b) (No change.)

## SUBCHAPTER 13. LABORATORY SERVICES

### 10:161B-13.1 Provision of laboratory services

(a) The outpatient substance [\\*\[abuse\]\\*@use\\_disorder](mailto:[abuse]*@use_disorder) treatment program shall provide laboratory services directly in the program or shall ensure the availability of services through written affiliation agreements.

1. The program shall only contract with laboratories that are licensed or approved by the New Jersey Department of Health [\\*\[and Senior Services\]\\*](mailto:[and Senior Services]*), in accordance with N.J.A.C. 8:44 and 8:45, for the provision of drug screening and other diagnostic and screening tests if required by this chapter or otherwise provided by the program.

2. (No change.)

(b) The program shall have a policy for assuring that employees and clients with a positive Mantoux test are referred and obtain an X-ray in accordance with the Tuberculosis Surveillance Procedures for Substance Abuse Treatment Facilities, available from [\\*\[DAS\]\\*@DMHAS](mailto:[DAS]*@DMHAS) and incorporated herein as chapter Appendix A.

## SUBCHAPTER 14. PHARMACEUTICAL SERVICES

### 10:161B-14.1 Provision of pharmaceutical services

(a) Any outpatient substance [\\*\[abuse\]\\*@use\\_disorder](mailto:[abuse]*@use_disorder) treatment program that administers or dispenses medication to clients shall either appoint a pharmacist as the director of pharmaceutical services, or engage a consultant pharmacist, to direct, provide, and monitor the quality of pharmaceutical services in accordance with this chapter, and who shall:

- 1.-8. (No change.)  
(b) (No change.)

## 10:161B-14.2 Standards for drug administration

(a) The facility's policies and procedures shall ensure that medications, in the correct strengths and dosages and at the ordered correct time intervals, are administered to each client through the prescribed route of administration. The facility's policies and procedures shall ensure a method of tracking the line of possession of the medications while in the facility and shall describe the program's plan to ensure the adequate maintenance of supplies, including the following:

1.-4. (No change.)

5. Procedures for documenting and reporting adverse medication reactions, medication errors, and medication defects, subject to the following:

i. (No change.)

ii. Medication product defects shall be reported in accordance with the United States Pharmacopeia - National Formulary (2007 version USP30-NF 25) published by the US Pharmacopeia Convention, 12601 Twinbrook Parkway, Rockville, MD 20852, [\\*http://usp.org\\*](http://usp.org) [\\*http://www.usp.org\\*](http://www.usp.org), incorporated herein by reference, as amended and supplemented;

6.-7. (No change.)

8. Standards for the purchase, storage, safeguarding, accountability, use and disposal of medications consistent with New Jersey Board of Pharmacy rules, N.J.A.C. 13:39, accessible at [\\*http://www.nj.gov/oag/ca/medical/pharmacy.htm\\*](http://www.nj.gov/oag/ca/medical/pharmacy.htm) [\\*http://www.njconsumeraffairs.gov/phar/Pages/regulations.aspx\\*](http://www.njconsumeraffairs.gov/phar/Pages/regulations.aspx), and N.J.S.A. 24:21-1 et seq.;

9.-13. (No change.)

14. In no instance shall the program permit drug or medication samples to be accepted, stocked, distributed or otherwise used for any client or staff unless specifically approved by the Pharmacy and Therapeutics Committee in writing.

i. If the program utilizes drugs marked "samples," the Pharmacy and Therapeutics Committee shall develop a mechanism for the control and limitations of these drugs in accordance with New Jersey State Board of Medical Examiners rule N.J.A.C. 13:35-6.6, accessible at [\\*http://www.state.nj.us/lps/ca/bme/bmelaws.pdf\\*](http://www.state.nj.us/lps/ca/bme/bmelaws.pdf) [\\*http://www.njconsumeraffairs.gov/bme/Pages/regulations.aspx\\*](http://www.njconsumeraffairs.gov/bme/Pages/regulations.aspx).

## SUBCHAPTER 15. EMERGENCY SERVICES AND PROCEDURES

## 10:161B-15.1 Emergency plans and procedures

(a) The outpatient substance **\*[abuse]\* \*use disorder\*** treatment facility shall maintain written emergency plans, policies, and procedures to be followed in case of hazards that necessitate an evacuation, ensuring that clients receive necessary services during the evacuation or other emergency, including internal and external disasters such as fire, natural disaster, environmental threats, bomb threats, or industrial or radiological accidents.

(b) Procedures for emergencies shall include:

1. Protocols for notification of emergency service providers, officials and **\*[DAS]\* \*DHS\***;

i. **\*[DAS]\* \*DHS\*** emergency notification shall follow at least the non-emergency notification requirements of N.J.A.C. 10:161B-1.7(c)14;

2.-9. (No change.)

(c)-(d) (No change.)

## SUBCHAPTER 16. CLIENT RIGHTS

## 10:161B-16.1 Establishment of policies and procedures

(a) The outpatient substance **\*[abuse]\* \*use disorder\*** treatment program shall establish, implement and conspicuously post written policies and procedures regarding the rights of clients, including appeals procedures for involuntary discharge, which shall be available to clients, staff, and the public.

(b)-(c) (No change.)

## 10:161B-16.2 Rights of each client

(a) Each client receiving services shall have:

1.-9. (No change.)

10. The right to confidential treatment of information about the client;

i. Information in the client's clinical record shall not be released to anyone outside the program without the client's written approval to

release the information in accordance with Federal statutes and rules for the Confidentiality of Alcohol and Drug Abuse Client Records at 42 U.S.C. §§290dd-2, and 290ee-2, and 42 CFR Part 2 §§2.1 et seq., and the provisions of the Health Insurance Portability and Accountability Act (HIPAA) at 45 CFR Parts 160 and 164, unless the release of the information is required and permitted by law, a third-party payment contract, a peer review, or the information is needed by **\*[DAS]\* \*DHS\*** for statutorily authorized purposes; and

ii. (No change.)

11.-13. (No change.)

14. The right to be transferred or discharged only for medical reasons, for the client's welfare, that of other clients or staff upon the written order of a physician or other licensed clinician, or for failure to pay required fees as agreed at time of admission (except as prohibited by sources of third-party payment);

i. (No change.)

ii. If a transfer or discharge on a non-emergency basis is planned by the outpatient substance **\*[abuse]\* \*use disorder\*** treatment program, the client and his or her family shall be given at least 10 days advance notice of such transfer or discharge, except as otherwise provided for in N.J.A.C. 10:161B-6.4(c);

15.-16. (No change.)

## 10:161B-16.3 Complaints

(a) The administrator shall provide all clients and their families, upon request, the name, address, and telephone number of the following State office where clients and their families may submit complaints:

**\*[New Jersey State Department of Human Services**

**Division of Addiction Services**

**P.O. Box 362**

**Trenton, New Jersey 08625-0362**

**Telephone: tollfree 1-877-712-1868]\***

**\*New Jersey State Department of Human Services**

**Division of Mental Health and Addiction Services**

**PO Box 700**

**Trenton, New Jersey 08625-0700**

**Telephone: toll-free 1-877-712-1868\***

(b)-(c) (No change.)

(d) The administrator shall also conspicuously post the **\*[DAS]\* \*DHS\*** address and telephone number in (a) above, and Medicaid coverage contact information, in the admissions waiting area or room, in the client service area of the business office, and in other public areas throughout the facility.

## SUBCHAPTER 17. DISCHARGE PLANNING SERVICES

## 10:161B-17.1 Discharge/continuum of care planning

(a) The outpatient substance **\*[abuse]\* \*use disorder\*** treatment program shall initiate discharge/continuum of care planning for each client upon admission.

1.-2. (No change.)

(b) (No change.)

## SUBCHAPTER 18. CLINICAL RECORDS

## 10:161B-18.1 Maintenance of clinical records

(a) The outpatient substance **\*[abuse]\* \*use disorder\*** treatment program shall establish and implement policies and procedures for production, maintenance, retention and destruction of clinical records, which shall be reviewed at least annually by the administrator. The policy and procedure manual shall address the written objectives, organizational plan and quality assurance program for all clinical records, subject to the following:

1.-2. (No change.)

3. The facility shall maintain all clinical records and components thereof on-site at all times unless:

i.-ii. (No change.)

iii. Off-site storage of clinical records is approved by **\*[DAS]\* \*OOL\*** pursuant to N.J.A.C. 10:161B-18.6; and

4. (No change.)

(b)-(f) (No change.)

## 10:161B-18.6 Preservation, storage, and retrieval of clinical records

(a) (No change.)

(b) If the facility plans to cease operation, it shall notify \*[DAS]\* \*OOL\* in writing, at least 14 days before cessation of operation, of the location where clinical records shall be stored and of methods for their retrieval.

1. The facility shall store all clinical records on-site unless off-site storage is approved by \*[DAS]\* \*OOL\*.

2. \*[DAS]\* \*OOL\* shall approve off-site storage if the notice from the facility requesting approval ensures that off-site storage shall maintain:

i.-ii. (No change.)

## SUBCHAPTER 19. INFECTION PREVENTION AND CONTROL SERVICES

## 10:161B-19.1 Infection prevention and control

(a) (No change.)

(b) The outpatient substance \*[abuse]\* \*use disorder\* treatment program shall establish an infection control committee, or designate an individual responsible for ensuring that the rules in this subchapter are followed.

1. (No change.)

(c) The infection control committee or responsible individual, in consultation with each service in the facility, shall develop, implement, and annually review and revise as necessary written policies and procedures regarding infection prevention and control, addressing at least the following:

1.-2. (No change.)

3. Infection control practices shall also be in compliance with the Federal Occupational Safety and Health Administration rules at 29 CFR 1910.1030, Occupational Exposure to Blood Borne Pathogens, incorporated herein by reference; accessible at the OSHA website \*[s, [http://www.osha.gov/SLTC/bloodborne/pathogens/bloodborne\\_fa.html](http://www.osha.gov/SLTC/bloodborne/pathogens/bloodborne_fa.html)]; and [http://www.osha.gov/pls/oshaweb/owadisp.show\\_document?p\\_table=STANDARDS&p\\_id=10051](http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051)]\* \*<https://www.osha.gov/law-regs.html>]\*; or from the Government Printing Office, Order #S/N 869-044-00105-5; (202) 512-1800, <http://bookstore.gpo.gov> ;

4.-10. (No change.)

## SUBCHAPTER 20. HOUSEKEEPING, SANITATION AND SAFETY

## 10:161B-20.1 Provision of services

(a) The outpatient substance \*[abuse]\* \*use disorder\* treatment facility shall provide and maintain a sanitary and safe environment for clients and staff.

(b)-(c) (No change.)

## SUBCHAPTER 21. QUALITY ASSURANCE PROGRAM

## 10:161B-21.1 Quality assurance program

(a) The outpatient substance \*[abuse]\* \*use disorder\* treatment facility shall establish and implement an integrated comprehensive quality assurance program for client care; review the program at least annually; and revise as necessary.

1.-4. (No change.)

## 10:161B-21.2 Quality assurance activities

(a) The facility's quality assurance program shall provide for an ongoing process for monitoring and evaluating client care services, staffing, infection prevention and control, housekeeping, sanitation, safety, maintenance of physical plant and equipment, client care statistics, discharge planning services, volunteer services and shall include, but not be limited to:

1. Evaluation of the behavioral and pharmacological approaches to treatment to ensure that treatment practices are evidence-based or based on best objective information to provide treatment services consistent with recognized treatment principles and practices for each level of care and type of client served, as defined at N.J.A.C. 10:161B-\*[5.2(a)11]\*6.2(a)11\*;

2.-7. (No change.)

(b) The administrator shall follow-up on the findings of the quality assurance program to ensure that effective corrective actions have been taken, or that additional corrective actions are no longer indicated or needed. The following shall apply:

1. The administrator shall follow-up on all recommendations resulting from findings of the quality assurance program or \*[DAS]\* \*OOL\*.

2. Deficiencies jeopardizing client or staff safety shall be verbally reported to the governing authority and to \*[DAS]\* \*DMHAS\* immediately, with written correspondence provided to the governing authority and \*[DAS]\* \*DMHAS\* within five working days.

(c) The facility shall identify and establish indicators of quality care and outcome objectives specific to the program.

1. The indicators shall be consistent with the Federal SAMHSA National Outcome Measures (NOMs), as defined and accessible at \*[<http://www.nationaloutcomemeasures.samhsa.gov/>]\* \*<http://integratedrecovery.org/wp-content/uploads/2010/08/SAMHSA-National-Outcome-Measures.pdf>]\* incorporated herein by reference.

2. The facility shall monitor and evaluate each of the specific indicators at least annually, and develop reports as required by the facility, governing authority and \*[DAS]\* \*DHS\*.

(d) (No change.)

## SUBCHAPTER 22. VOLUNTEER SERVICES

## 10:161B-22.1 Provision of volunteer services

(a) The outpatient substance \*[abuse]\* \*use disorder\* treatment facility may provide volunteer services as an integral part of its services.

1.-3. (No change.)

(b)-(e) (No change.)

## SUBCHAPTER 23. PHYSICAL PLANT AND FUNCTIONAL REQUIREMENTS

## 10:161B-23.1 Physical plant general compliance for new construction or alteration

(a) New buildings and alterations and additions to existing buildings for freestanding outpatient substance \*[abuse]\* \*use disorder\* treatment facilities shall conform with the New Jersey Uniform Construction Code, N.J.A.C. 5:23-3.2, incorporating specified subchapters of the model code of the International Building Code 2000 (IBC 2000), New Jersey Edition, published by the International Code Council, Inc. (formerly BOCA), 4051 W. Flossmoor Road, County Club Hills, IL 60478-5795, appropriate to Use Group B, as amended and supplemented; and the 2006 edition of the Guidelines for Design and Construction of Hospitals and Health Care Facilities, published by the American Institute of Architects Press, 1735 New York Avenue, NW, Washington, DC 20006, telephone 202-626-7475, as amended and supplemented, incorporated herein by reference.

(b) New buildings and alterations and additions to existing buildings for outpatient substance \*[abuse]\* \*use disorder\* treatment facilities which are part of an acute care hospital shall conform with the New Jersey Uniform Construction Code, N.J.A.C. 5:23-3.2, incorporating specified subchapters of the model code of the International Building Code 2000 (IBC 2000), New Jersey Edition, published by the International Code Council, Inc. (formerly BOCA), 4051 W. Flossmoor Road, County Club Hills, IL 60478-5795, appropriate to Use Group B or Multiple Use Occupancy, Use Group B within an I-2 Use Group, as amended and supplemented; and the 2006 edition of the Guidelines for Design and Construction of Hospitals and Health Care Facilities, published by the American Institute of Architects Press, 1735 New York Avenue, NW, Washington, DC 20006, telephone 202-626-7475, as amended and supplemented, incorporated herein by reference.

## 10:161B-23.3 Plan review

(a)-(b) (No change.)

(c) Simultaneously with any plan(s) submission to the local Building Code Official, each agency shall submit one set of floor and furniture plans to \*[DAS]\* \*OOL\*, for a cursory review and inclusion in \*[DAS]\* \*OOL\* facility files. Submit floor and furniture plans to:

\*[Director of Licensing and Construction  
Division of Addiction Services

Department of Human Services  
P.O. Box 362  
Trenton, NJ 08625-0362]\*

\*New Jersey Department of Human Services  
Office of Licensing  
PO Box 707  
Trenton, NJ 08625-0707\*

#### 10:161B-23.6 Restrictions

Mixed use occupancy shall not be permitted in buildings classified as High Hazard (H), Factory (F) or Assembly (A-2) Use Groups, in accordance with N.J.A.C. 5:23 and P.L. 100-336, the Americans with Disabilities Act, as amended and supplemented, and the Accessibility Guidelines for Buildings and Facilities (2002), as amended and supplemented, incorporated herein by reference. The Accessibility Guidelines are available at the United States Access Board website, \*[<http://www.access-board.gov/adaag/html/adaag.htm>]\* \*<https://www.access-board.gov/guidelines-and-standards/buildings-and-sites/about-the-ada-standards>\*, or from the Superintendent of Documents, Government Printing Office, Washington, DC, 20402.

#### SUBCHAPTER 25. EXISTING FACILITIES

##### 10:161B-25.1 Physical plant standards for all existing licensed facilities

Existing licensed outpatient substance \*[abuse]\* **\*use disorder\*** treatment facilities shall comply with, and shall continue to be inspected according to, those codes and standards which were in effect at the time of their initial licensure, with the exception that safety standards must be upgraded to meet current regulations.

(Agency Note: The text of N.J.A.C. 10:161B Appendix B follows without boldface and asterisks or brackets and asterisks symbolizing changes upon adoption; those portions of the appendix appearing in boldface are intended to be so permanently.)

#### APPENDIX B

##### Administrative Bulletin

##### Division of Mental Health and Addiction Services

4-2007

#### Subject: BUPRENORPHINE GUIDELINES

##### I. Background

The FDA approved the use of Buprenorphine, in the form of **Suboxone and Subutex**, for the treatment of opioid dependence on October 8, 2002 for **medical maintenance and medically supervised withdrawal**. Buprenorphine is a partial agonist that is available for use solely by certified physicians in addiction medicine and those who have satisfied qualifications set-forth by and under the provisions of the Drug Addiction Treatment Act of 2000 (DATA 2000). **Qualified physicians may prescribe up to 275 patients at one time.**

While there are some current federal guidelines for use and the practice of opiate treatment, the State of New Jersey's Division of Mental Health and Addiction Services (DMHAS) seeks to provide modified details and guidelines for the use and practice in New Jersey. These guidelines are meant to enhance the existing federal guidelines.

##### A. Rationale for Buprenorphine Treatment

Patients are reporting for opiate treatment at increasingly higher rates than ever before. The opiate drugs are heroin, illegal methadone, hydrocodone, and oxycodone. The rates of addiction to prescription medication are also increasing at an alarming rate from both licit and illicit use. Recent data has shown that two or more narcotic pain medications, oxycodone, hydrocodone, and codeine were ranked among the 10 most common drugs involved in drug abuse deaths (SAMHSA 2002). The prevalence of heroin addiction has also been on the rise and is the highest since the 1970s. The need for effective opiate treatment is unquestionable.

It has been long noted that opiate addicted patients who present for treatment often find it difficult to remain engaged in treatment, detoxification and primary counseling, because the withdrawal is very

uncomfortable and the craving and compulsion to use is too great to overcome. In those situations where patients are able to make a reasonable start in their recoveries, they often relapse before they can become fully engaged in continuing and aftercare therapy. Use of Buprenorphine can significantly address both issues. The detoxification, when indicated, can be performed much smoother. The issue of craving can also be managed for longer periods of time until the patient can get his or her recovery network and program stabilized. Lastly, for those individual patients who require long opiate medication therapy, Suboxone or Subutex can be safely utilized. Buprenorphine is approved by use for the treatment of opioid use disorder only in the formulation as Suboxone or Subutex. **Injectable Buprenorphine is not approved for the treatment of opioid use disorder.**

##### II. Services To Be Provided Post Detoxification

**Buprenorphine therapy is an adjunct to the full treatment experience; not in lieu of a full treatment experience** which includes stabilization (detoxification or maintenance), rehabilitation (counseling and education) and then follow-up (aftercare counseling and support groups). **All patients accepted into buprenorphine therapy must be referred to an OOL licensed substance use disorders treatment facility or individual therapists who are certified and/or licensed to provide substance abuse counseling. Such licensure and certification shall be current and not revoked or suspended.**

##### A. Primary and Aftercare Counseling

**The primary counseling providers would need to accept buprenorphine therapy as an adjunct to addiction treatment, and not "contrary" to the previous concepts of total abstinence.** Treatment professionals will need **initial and ongoing education** to effect this significant change in treatment philosophy. Those patients who are receiving therapy *should not be in segregated groups*. Currently those individuals in treatment with co-occurring disorders are not routinely segregated for primary and continuing care therapy, and those patients receiving Buprenorphine should not be segregated either. **Patients on Suboxone or Subutex should be permitted to participate in primary and aftercare substance abuse counseling.**

##### B. Patient Assessments/Screening Tools

All patients in all medical encounters should be screened for substance use disorders. Those patients who are presenting for substance use disorders treatment need to undergo a screening process to determine diagnosis, severity of illness, and the selection of an appropriate level of care for rehabilitation counseling. Providers should select a screening tool to utilize for each and every patient routinely (e.g. CAGE; COWS; CAGE-AID; and Narcotic Withdrawal Scale).

##### C. Complete History and Physical Examination

Each patient should undergo a complete history and physical examination. The history should include drug and alcohol use, psychiatric, past legal, medical, surgical, and family issues, and previous substance use disorders treatment. The physical examination should be complete and be specific for signs of addiction. Patient should also undergo a neurological and mental status examination. **All patients treated with Suboxone or Subutex should meet DSM-5 criteria for opioid use disorder.**

##### D. Comprehensive Patient Management and Referrals

**All patients should be referred for follow-up of other primary medical conditions** not being addressed in opiate outpatient therapy by the provider. Additionally, all patients with **psychiatric diagnoses** should be under the care of a psychiatrist who is expert in managing patients with addictive disorders. Patients need appropriate referral for specialized care of non-addiction medical issues.

##### E. Detoxification

**Subutex** is the *formulation of choice for detoxification in the inpatient setting*. Subutex is Buprenorphine without Naloxone and is therefore less likely to induce a withdrawal syndrome in patients that are still under the influence of some opiate. **Suboxone** is the *formulation of choice for use in outpatient detoxification settings*. Suboxone is the Buprenorphine formulated with Naloxone which provides added protection and deterrence from using unauthorized opiates which is assumed to be a greater risk in the outpatient settings. Buprenorphine, when prescribed appropriately, is very effective in stabilizing opiate

withdrawal symptoms without initiating or worsening withdrawal symptomatology in appropriately prepared patients.

Many patients who enter into treatment for opioid use disorder are fearful that they will not receive the appropriate care and will be left to suffer moderate to severe withdrawal. Therefore, many patients who arrive have used an opiate just prior to their arrival. Use of Buprenorphine prematurely can induce withdrawal as it is also a partial agonist. **It is important to instruct the patients that they do not use any opiates at least twelve hours before they arrive.**

**Detoxification is a two-step process; stabilization** (the amelioration of signs and symptoms of withdrawal) followed by a **tapering** of the medication to zero. Patient selection for rapid detoxification is crucial. Some patients may require a slower detoxification occurring over a number of weeks and other patients may require maintenance therapy with Buprenorphine. *For those patients who cannot be stabilized and withdrawn from Buprenorphine on an inpatient basis, they can be managed by qualified providers, Addiction Medicine Physicians or Primary Care Physicians with the Buprenorphine Waivers.*

Once the patient has begun or completed detoxification, he or she is ready for primary substance abuse counseling.

#### F. Buprenorphine Maintenance

##### 1. Adjunctive Therapy

Once detoxification or stabilization through the adjunctive use of Buprenorphine has occurred, **primary opiate addiction counseling** can commence without the distraction of opiate craving and withdrawal. The primary counseling should begin at the appropriate level of care as indicated by the use of some standardized criteria (**ASAM Criteria**). **Primary counseling** can occur as **residential, intensive outpatient, traditional weekly individual or group therapy**. While the patient is engaged in primary substance abuse counseling treatment, his or her Buprenorphine can be managed by a certified physician provider. **Upon completion of primary treatment (counseling) and aftercare, the patient can continue under the care of a prescribing physician for continued use of the Buprenorphine, if indicated.**

If patients are stabilized with Subutex they should be switched over to Suboxone, which has less of an abuse potential and provides the added benefit of being a deterrent to illicit opiate use, during the time of primary treatment.

##### G. After Primary and Aftercare Treatment and Discharge Care

After patients have completed their primary and aftercare counseling, some patients will have been effectively withdrawn from their Buprenorphine therapy while others may be continuing on a maintenance regime. These patients will need to follow-up with a provider, their primary care physician, another provider with a waiver, or an Addiction Medicine Specialist, to prescribe the Buprenorphine. **These arrangements should be made prior to discharge from the counseling phase of treatment** so as not to interrupt the maintenance pharmacotherapy.

### III. Treatment Protocols

All physicians are referred to the federal guidelines established through the Center for Substance Abuse Treatment (CSAT) for the minimum requirements. The New Jersey Guidelines are meant to enhance the guidelines put forth by CSAT.

#### A. 24-Hour Medical Care Availability

During the induction and stabilization phase of Buprenorphine therapy, medical care and consultation shall be available on a 24-hour basis. This care should be supervised by the waived physician performing the induction.

### IV. Special Populations

#### A. Buprenorphine and Pregnancy

Currently, *Methadone is still the pharmacotherapy of choice* for the treatment of opiate dependent pregnant patients. Patients should be offered referral to a Methadone provider for care. If the patient, however, refuses or has misgivings about Methadone, Buprenorphine has been used successfully. The FDA classifies Buprenorphine as a Category C drug. The risks of Category C drugs must be explained to the patient and thereafter can be used with **informed consent**. Buprenorphine use in pregnancy needs to be further evaluated by controlled studies. To date, the safety has been determined by case series

reports. **The discussion and informed consent should be clearly documented in the patient's chart. Subutex is the formulation of choice.**

#### B. Buprenorphine Maintenance and Pain Management

##### 1. Acute Pain

Patients who are on Buprenorphine maintenance and who are experiencing *acute pain* should attempt to manage the pain with *non-narcotic medications* in combination with their prescribed Buprenorphine. Buprenorphine has analgesic properties and can be an effective analgesic. The dose of Buprenorphine can be increased to try to improve the analgesia, in conjunction with non-narcotic analgesics. **Patients for whom the pain is not relieved should undergo aggressive treatment with narcotic analgesics.** The Buprenorphine should be discontinued while the appropriate opiate analgesic is employed to address the acute pain. Once the acute pain has been successfully managed, the Buprenorphine should be restarted.

##### 2. Chronic Pain

Opioid dependent patients with *chronic pain* are usually not good candidates for Buprenorphine therapy because of the analgesic "ceiling effect". These patients fair better with long acting narcotic analgesics. Methadone has proven to be an effective choice.

### V. Clinical Guidelines References

For DETOXIFICATION see Clinical Guidelines CSAT TIP #40.

For INDUCTION see Clinical Guidelines CSAT TIP #40.

For MAINTENANCE THERAPY see Clinical Guidelines CSAT TIP #40.

For BUPRENORPHINE DISCONTINUATION see Clinical Guidelines CSAT TIP #40.

### VI. Scope

Substance use disorders treatment providers or medical practitioners using Buprenorphine, in the form of Suboxone and Subutex, for the treatment of opioid use disorder for medical maintenance and medically supervised withdrawal.

(a)

## DIVISION OF FAMILY DEVELOPMENT

### Notice of Readoption

#### Child Care Services

#### Readoption with Technical Changes: N.J.A.C. 10:15

Authorized By: Elizabeth Connolly, Acting Commissioner,

Department of Human Services.

Authority: N.J.S.A. 30:1-12.

Effective Date: September 28, 2016.

New Expiration Date: September 28, 2023.

**Take notice** that, in accordance with N.J.S.A. 52:14B-5.1, N.J.A.C. 10:15 was scheduled to expire on November 2, 2016. The Division of Family Development (DFD) has reviewed the rules and will readopt this chapter with technical amendments. In accordance with N.J.S.A. 52:14B-5.1.c, the new expiration date for N.J.A.C. 10:15 is September 28, 2023.

**Take further notice** that effective June 29, 2012, P.L. 2012, c. 16, § 20, renamed the Division of Youth and Family Services as the Division of Child Protection and Permanency. Technical changes are made throughout N.J.A.C. 10:15 to reflect the renaming of this division and its acronym.

**Take further notice** that effective June 29, 2012, P.L. 2012, c. 17, § 93, renamed the Department of Health and Senior Services as the Department of Health. Technical changes are made throughout N.J.A.C. 10:15 to reflect the Department's renaming.

The purpose of N.J.A.C. 10:15 is to set forth the policies for a unified child care service delivery system inclusive of all child care programs, including voucher child care programs and contracted child care programs for which identified funding is received by the Department of Human Services (DHS) and administered through the DFD.