

CHAPTER 161B

**STANDARDS FOR LICENSURE OF OUTPATIENT
SUBSTANCE ABUSE TREATMENT FACILITIES**

Authority

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

Source and Effective Date

R.2009 d.58, effective June 1, 2009.
See: 40 N.J.R. 535(a), 41 N.J.R. 2268(b).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1b, Chapter 161B, Standards for Licensure of Outpatient Substance Abuse Treatment Facilities, expires on June 1, 2016. See: 43 N.J.R. 1203(a).

Chapter Historical Note

Chapter 161B, Standards for Licensure of Outpatient Substance Abuse Treatment Facilities, was adopted as new rules by R.2009 d.58, effective June 1, 2009. See: Source and Effective Date.

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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 treatment facilities that provide outpatient substance abuse 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 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 treatment facilities by the New Jersey Division of Addiction Services (DAS).

(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 treatment services in a designated outpatient unit or facility or provide any of the modalities of

outpatient substance abuse treatment listed in (a) above. DAS does require a separate license for hospital-based substance abuse treatment programs; hospitals providing services covered by this chapter shall comply with these standards and shall be licensed, monitored and/or reviewed by DAS.

(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 assessment, referral and/or treatment services or provide any of the modalities of outpatient substance abuse treatment listed in (a) above. DAS does require a separate outpatient substance abuse 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.

(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 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 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:

“Accrediting agencies” means those organizations recognized nationally that set standards and review providers based on these standards. These organizations provide their endorsement in the form of accreditation: the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), <http://www.jointcommission.org>; and the Commission on Accreditation of Rehabilitation Facilities (CARF), <http://www.carf.org>.

“Administrator” means an individual appointed by the governing authority to provide administrative oversight for all licensed programs and individual sites within a licensed facility.

“Admitted” means accepted for treatment at an outpatient substance abuse treatment facility.

“Adolescent” means a person between the ages of 11 and up to the age of 18.

“ASAM” means the American Society of Addiction Medicine, 4601 North Park Avenue, Upper Arcade, Suite 101, Chevy Chase, MD 20815, www.asam.org.

“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), 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.research.org/asi.htm.

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

“BOCA” means the model building code of the organization formerly called the Building Officials and Code Administrators International Inc., now called the International Code Council, 4051 W. Flossmoor Road, Country Club Hills, IL 60477-5795, www.iccsafe.org, 1-888-422-7233, which can be obtained from the ICC Store, 1-800-786-4452.

“Buprenorphine” means the Federal Food and Drug Administration approved drug which is used as of the effective date of these rules, in the form of Suboxone and Subutex, for treatment of opiate dependence for medical maintenance and medically supervised withdrawal.

“Bylaws” means a set of rules adopted by the program for governing its operation. A charter, articles of incorporation, or a statement of policies and objectives, is an acceptable equivalent.

“CDC” means the Federal government agency, Centers for Disease Control and Prevention, www.cdc.gov.

“Certificate of Occupancy” means a certificate issued by a local authority indicating that a building meets building code requirements.

“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>, or (973) 504-6582.

“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 only as prescribed by law.

“Client” means any individual receiving treatment services in a licensed treatment facility. In the context of this chapter, client is synonymous with “patient.”

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

“Clinical note” means a written, signed with original signature, and dated notation made by a licensed or credentialed professional, an approved counselor in training (see N.J.A.C. 10:161B-1.9(a)2) or other authorized representative of the program who renders a service to the client or records observations of the client’s progress in treatment.

“Clinical record” means all records in the facility which pertain to the client’s care.

“Commissioner” means the Commissioner of the New Jersey Department of Human Services.

“Communicable disease” means an illness due to a specific infectious agent or its toxic products, which occurs through transmission of that agent or its products from a reservoir to a susceptible host.

“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 in addition to the licensure requirements in this chapter.

“Conspicuously posted” means placed at a location within the facility accessible to and seen by clients and the public.

“Contamination” means the presence of an infectious or toxic agent in the air, on a body surface, or on/in clothes, bedding, instruments or dressings, or other inanimate articles or substances, including water, milk, and food.

“Continuum of Care Plan” means a written plan initiated at the time of the client’s admission, and regularly updated throughout the course of treatment, which addresses the needs of the client after discharge; may be referred to as a Discharge Plan.

“Controlled dangerous substances” or “controlled substances” means drugs defined by and subject to the Federal Controlled Dangerous Substances Act of 1970 (Public Law 91-513; 21 U.S.C. §§801 et seq.) and the New Jersey Controlled Dangerous Substances Act, N.J.S.A. 24:21-1 et seq.

“Co-occurring disorder” means a concurrent substance abuse and mental health disorder as described in the DSM-IV-TR, in which the substance abuse 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 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.

“CSAT” means the Federal Center for Substance Abuse Treatment, within the Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, <http://csat.samhsa.gov>.

“Curtailment” means an order by DAS which requires a licensed substance abuse treatment facility to cease and desist all admissions and readmissions of clients to the facility.

“Daily census” means the number of clients receiving services at the facility on any given day.

“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>.

“DCF” means the New Jersey Department of Children and Families.

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

“Department” means the New Jersey Department of Human Services.

“Dependence” means physical and/or psychological dependence on a substance resulting from the chronic or habitual use of alcohol, tobacco, any kind of controlled substance, narcotic drug, or other prescription or non-prescription drug.

“Designated person” means, in the context of client care, the person chosen by the client to be notified if the client sustains an injury requiring medical care, an accident or incident occurs, there is deterioration in the client’s physical or mental condition, the client is transferred to another facility, or the client is discharged or dies while in treatment.

“Detoxification” means the provision of care, usually short term, prescribed by a physician and conducted under medical supervision, for the purpose of withdrawing a person from a specific psychoactive substance in a safe and effective manner according to established written medical protocols.

“Detoxification treatment short-term” means detoxification treatment for a period not in excess of 30 days.

“Detoxification treatment long-term” means detoxification treatment for a period more than 30 days but not in excess of 180 days.

“DHS” means the New Jersey Department of Human Services.

“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 and treatment related issues.

“Discharge plan” means a written plan initiated at the time of the client’s admission, and regularly updated throughout the course of treatment, which addresses the needs of the client after discharge; also referred to as a Continuum of Care Plan.

“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.

“Dosage” means, in the context of administering medication in prescribed amounts, the quantity of a drug to be taken or applied all at one time or in fractional amounts within a given period of time.

“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; 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 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 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” means the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision, 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 Psy-

chiatric Association, 1000 Wilson Boulevard, Suite 1825, Arlington VA 22209-3901, <http://www.dsmivtr.org>.

“Evidence based practices” means interventions and approaches supported empirically through systematic research and evaluation. These are to be distinguished from best practices, which are interventions and approaches more likely to yield desired results, based on indicative studies or judgment/consensus of experts.

“Facility” means an outpatient substance abuse treatment facility and/or program pursuant to State statute and this chapter.

“Family” means immediate kindred, domestic partner, legal guardian, legally authorized representative, executor, or an individual granted a power of attorney. The term may also be expanded to include those persons having a commitment and/or personal significance to the client.

“Floor stock” means medications from a pharmacist in a labeled container in limited quantities that are not necessarily prescribed for one or more specific individuals.

“Governing authority” means the organization, person, or persons or the board of directors or trustees of a non-profit corporation designated to assume legal responsibility for the management, operation, and financial viability of the facility.

“Handicapped” means disabled as defined in the Federal Americans with Disabilities Act, 1990, 42 U.S.C. §§12101 et seq.

“HIV” means human immunodeficiency virus.

“Immediate and serious threat” means a deficiency or violation that has caused or will imminently cause at any time serious injury, harm, impairment, or even death to clients of the facility.

“Incapacitated” means when a person, as a result of the use of alcohol or other drugs, is unconscious or has his or her judgment so impaired that he or she is incapable of realizing and making a rational decision with respect to his or her need for treatment even though he or she is in need of substantial medical attention.

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

“Interpreter services” means communication services provided to a client and/or family member unable to comprehend and/or communicate without assistance by an interpreter (for example, screened by the NJ Department of Human Services, Division of the Deaf and Hard of Hearing, or similar agency responsible for such screening) due to a language barrier or another disability.

“Intoxicated” means when a person’s mental or physical functioning is substantially impaired as a result of the use of alcoholic beverages or other mood-altering chemicals.

“Job description” means written specifications developed for each position in the facility, containing the qualifications, duties and responsibilities, and accountability required of employees in that position.

“Juvenile” means a person under 18 years of age.

“Legally authorized representative” means an individual or judicial or other body authorized under New Jersey law to consent on behalf of a client subject to the client’s (competent) participation in the procedure.

“License” means a certificate of approval pursuant to N.J.S.A. 26:2G-21 et seq, and/or a license pursuant to N.J.S.A. 26:2B-7 et seq.

“Licensed clinical alcohol and drug counselor (LCADC)” means an individual who holds a current, valid license issued pursuant to N.J.S.A. 45:2D-4 and 45:2D-16 and N.J.A.C. 13:34C-2.2 and 2.1(c).

“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.

“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>.

“Medication administration” means a procedure in which a prescribed medication is given to a client by an authorized person in accordance with all laws and rules governing such procedures. The complete procedure of administration includes removing an individual dose from a previously dispensed, properly labeled container (including a unit dose container), verifying it with the prescriber’s orders, giving the individual dose to the client, seeing that the client takes it (if oral), and documenting the required information, including the method of administration.

“Medication dispensing” means a procedure entailing the interpretation of the original or direct copy of the prescriber’s order for a medication or a biological and, pursuant to that order, the proper selection, measuring, labeling, packaging, and issuance of the drug or biological to a client or a service unit of the facility, conforming with the rules of the New Jersey Board of Pharmacy at N.J.A.C. 13:39.

“Methadone” means a synthetic narcotic (opioid) used in the treatment of opiate addiction by State and Federally approved opioid treatment programs.

“Methadone maintenance” means the dispensing of methadone at relatively stable dosage levels as part of the treatment of an individual for dependence on heroin or other opioids.

“Multidisciplinary team” means those persons, representing different professions, disciplines, and service areas, who work together to provide treatment planning and care to the client.

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

“NIDA” means the National Institute on Drug Abuse within the National Institutes of Health, <http://www.nida.nih.gov>.

“NJ” means New Jersey or the State of New Jersey.

“Nosocomial infection” means an infection acquired by a client while in an outpatient substance abuse treatment facility.

“Opiate” means any preparation or derivative of opium.

“Opioid” means both opiates and synthetic narcotics.

“Opioid treatment program (OTP)” means a program where there is the dispensing of an opioid agonist treatment medication, (that is methadone and other approved medications) along with a comprehensive range of medical and rehabilitative services, when clinically necessary and in compliance with State regulations, to an individual to alleviate the adverse medical, psychological, or physical effects incident to opiate addiction. This term encompasses opioid detoxification treatment, short-term detoxification treatment, long-term detoxification treatment, maintenance treatment, comprehensive maintenance treatment and interim maintenance treatment. Opioid treatment programs providing short-term detoxification (that is less than 30 days) shall comply with the provisions of the detoxification subchapter of this chapter, N.J.A.C. 10:161B-12.

“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.

“Outpatient substance abuse treatment facility” means a facility that is licensed to provide outpatient substance abuse 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 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 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 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 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 Opiate Maintenance Therapy.

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

“Practitioner” means a person licensed to practice medicine or surgery in accordance with N.J.S.A. 45:9-1 et seq. and N.J.A.C. 13:35, or a medical resident or intern, or a podiatrist licensed pursuant to N.J.S.A. 45:5-1 et seq. and N.J.A.C. 13:35.

“Progress note” means a written, signed with original signature, and dated notation by a member of the multidisciplinary team summarizing facts about care and the client’s response to care, during a given period of time.

“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 oversight until it comes into full compliance with this chapter.

“Reasonable efforts” means an inquiry on the employment application, reference checks, and/or criminal background checks where indicated or necessary.

“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>.

“SAMHSA” means the Substance Abuse and Mental Health Services Administration within the Federal Department of Health and Human Services, <http://www.samhsa.gov>.

“Self-administration” means a procedure in which any medication is taken orally, injected, inhaled, inserted, topically, or otherwise administered by a client to himself or herself.

“Signature” means at least the first initial and full surname, title and credential (for example, R.N., L.P.N., M.D., D.O., LCADC, CADC) of a person, legibly written, with his or her own hand. If electronic signatures are used, they shall be used in accordance with this chapter, N.J.A.C. 10:161B-18.4(b)1.

“Staff education plan” means a written plan that describes a coordinated program for staff education, including in-service programs and on the job training.

“Staff orientation plan” means a written plan for each new employee to learn about or get acquainted with the duties and responsibilities of the position as defined in the job description as well as the other policies of the facility and/or program.

“Substance abuse/dependence” 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 defined in the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV-TR) as

amended and supplemented, published by and available from the American Psychiatric Association, 1000 Wilson Boulevard, Suite 1825, Arlington, Va. 22209-3901, <http://dsmivtr.org>, incorporated herein by reference.

“Supervision (direct)” means supervision of clients provided on the premises within view or through the implementation of policies and procedures which may include electronic monitoring, to provide for the safety and the accountability of clients by staff.

“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 and/or its designees to determine compliance or non-compliance with these and other applicable State licensing rules or statutes.

“Tobacco products” means any manufactured nicotine delivery article that contains tobacco or reconstituted tobacco.

“Treatment” means a broad range of primary and supportive services, including identification, brief intervention, assessment, diagnosis, counseling, medical services, psychological services, and follow-up, provided to persons with alcohol, tobacco and other drug problems. The overall goal of treatment is to reduce or eliminate the use of alcohol, tobacco and/or other drugs as a contributing factor to physical, psychological, and social dysfunction and to arrest, retard, or reverse progress of associated problems.

“Treatment plan” means a written plan that has measurable goals, is outcome based, and identifies the coordination of the projected series and sequence of treatment procedures and services based on an individualized evaluation of what is needed to restore or improve the health and function of the client. The treatment plan is developed by the facility’s treatment teams in conjunction with the client where clinically appropriate.

“Unit dose distribution system” means a system in which medications are delivered to client areas in single unit packaging.

“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>, and the National Institute on Alcohol Abuse and Alcoholism, <http://www.niaaa.nih.gov>) for substance abuse treatment.

“Volunteer” means an individual who is neither a client nor a staff member who works at the facility on a non-reimbursed basis and is under the supervision of an appropriately qualified paid staff member.

“Waiver” means a written approval by DAS 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), 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 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.

(b) Although the medical director is not required to be on site on a full-time basis, the medical director is required to be on site as often as necessary in order to perform the responsibilities of the position. The facility shall establish written timeframes in which the medical director is required to be on site and, in the event of emergencies, arrive at the facility. In addition, the facility shall develop written parameters in which the medical director shall be available by telephone. Such parameters shall include the timeframes in which the medical director shall respond to the facility if paged, contacted by cellphone or by other means.

(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. Providing administrative oversight of the facility’s medical services;

2. Assisting the administrator of the program in the development and maintenance of written objectives, policies, a procedure manual, an organization plan, and a quality assurance program for medical services, and review of all medical policies and procedures at least annually;

i. Such documentation shall be shared with the facility’s physician, the director of nursing services and other appropriate medical staff on an ongoing basis or as revisions are made;

3. In conjunction with the administrator and the governing authority of the substance abuse treatment program, planning and budgeting for medical services;

4. Ensuring that medical services are coordinated and integrated with other client care services to ensure continuity of care for each client;

5. Ensuring that the program complies with required medical staffing patterns noted in this chapter;

6. Assisting in the development of written job descriptions for the medical staff, reviewing of credentials, participating in hiring of medical staff, delineating privileges of medical staff, and assigning duties of the medical staff;

7. Participating in staff orientation and staff education activities when applicable;

8. Approving the content and location of emergency kits or carts, medications including controlled substances, equipment and supplies, the expiration dates of medically related time-sensitive items, the frequency with which these items are reviewed for appropriateness and completeness, and assigning qualified staff to perform these reviews;

9. Reviewing any physical examination reports and medical screening results conducted off-site of a client for the preadmissions process or for other medical concerns, in order to ensure that the client's medical needs are considered and addressed in the development of the treatment plan and throughout treatment; and

10. Providing supervision of the facility's physician(s).

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 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 treatment program or facility.

(b) The director of nursing services shall be responsible for the direction, provision and quality of nursing services provided to clients, including the following:

1. Providing administrative oversight of the facility's nursing services, and where appropriate, directly supervising the facility's nursing staff;

2. Assisting the administrator of the facility in the development and maintenance of written objectives, policies and procedures, an organizational plan, and a quality assurance program for nursing services, and reviewing all nursing policies and procedures at least annually;

3. In conjunction with the administrator and the governing authority of the program, planning and budgeting for nursing services;

4. Ensuring the coordination and integration of nursing services with other client care services to ensure continuity of care for each client;

5. Ensuring that the program complies with required nursing staffing patterns;

6. Assisting in the development of written job descriptions for the nursing staff, and assigning duties of the nursing staff;

7. Participating in staff orientation and staff education activities, when applicable; and

8. Participating in team conferences with the multi-disciplinary team, and the client care committee (if the facility chooses to establish a client care committee).

10:161B-1.6 Qualifications of pharmacists

Each opioid treatment program and each outpatient detoxification program dispensing medications on-site shall engage or contract with a pharmacist currently registered with the New Jersey State Board of Pharmacy.

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 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 treatment facility.

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

1. Providing administrative oversight of the facility;

2. Ensuring the development, implementation, and enforcement of all policies and procedures as required under this chapter, including client rights;

3. Planning and administration of all operational functions including managerial, personnel, fiscal, and reporting requirements of the program;

4. Developing an organizational plan, ensuring that programs and services are consistent with the organization's mission, and monitoring their effectiveness;

5. Establishing and implementing a formal quality assurance program that:

i. Is comprehensive and integrated with the facility's programmatic quality assurance plans and programs;

ii. Addresses all levels of treatment programming and client care;

- iii. Ensures that all personnel are assigned duties based upon their education, training, competencies and job description; and
 - iv. Uses written, job-relevant criteria to make evaluation, hiring and promotional decisions;
6. Selection and hiring responsibility for all staff as well as participating in the determination of staffing issues including, but not limited to establishing: hiring policies to ensure references, credentials and criminal history background checks of all prospective staff have been reviewed and verified; written policy regarding employment of family members, past and present governing body members and volunteers; and written policy regarding hiring of staff with past criminal convictions and/or ethical violations which ensures that convictions/violations do not impact staff ability to perform duties and that staff are of good moral character, assessment of staff performance, and employment and termination decisions;
- i. The candidate/staff member shall be notified by the administrator that he or she must disclose to the administrator any disciplinary outcome imposed as a result of an investigation by any State licensing agency, law enforcement agency, or professional disciplinary review board, such as disciplinary probation, suspension of license, revocation of license, or criminal conviction at the time of initial employment, and/or during employment if the action occurs after hire;
7. Ensuring the provision of timely staff orientation, education and supervision;
8. Establishing and maintaining liaison relationships and communication with facility staff, service providers, support service providers, community resources, and clients;
9. Overseeing the development and implementation of policies and procedures, in conjunction with designated staff members, for the various services provided for in this chapter;
- i. Ensuring that appropriate policies and procedures are shared with the governing authority;
10. Ensuring that admission interviews with clients and in the case of juveniles, the client's family, guardian or legally authorized representative, be conducted in accordance with established policies and procedures;
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, and where necessary with the governing authority;
12. Ensuring maintenance of the physical plant as necessary to ensure client and staff safety, and otherwise keeping the facility in compliance with all applicable building, fire and safety codes;
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 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 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 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 to do so;
15. Identifying priority populations (for example, pregnant, IV drug users, women with children, HIV, etc.) for admission and treatment as evidenced by protocol, policies and procedures to provide such treatment services, or where appropriate, referral procedures with interim services available until transfer is completed;
16. Ensuring that DAS plans of correction, licensing deficiencies and complaint reports are addressed as outlined by DAS;
- i. Where necessary, ensure that such reports are shared with the governing authority in a timely manner;
17. Developing and implementing an infection prevention and control program; and
18. Developing, implementing and providing administrative oversight of a volunteer services program, if the facility along with the governing authority elects to utilize such a program.
- 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, is a certified clinical supervisor by The Certification Board, <http://www.certbd.com/pdfs/initial-applications/ccs.pdf>, 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>, 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>, or who is an LCADC;

4. A New Jersey licensed clinical alcohol and drug counselor who, in addition, holds a Master's degree recognized by the New Jersey Board of Marriage and Family Therapy Examiners, Alcohol and Drug Counselor Committee, Division of Consumer Affairs, New Jersey Department of Law and Public Safety as meeting the educational requirements set forth in N.J.A.C. 13:34C-2.2(b)1;

5. A New Jersey licensed physician, certified by the American Society of Addiction Medicine, or a Board-certified psychiatrist; or

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>, or is an LCADC.

(b) Incumbents with a Master's degree in counseling or social work not possessing any of the qualifications specified in (a) above shall obtain LCADC status by June 1, 2012, or another health professional license that includes diagnostic and supervisory authority for work of an alcohol and drug counseling nature.

(c) If the director of substance abuse counseling does not provide direct clinical supervision, the administrator, in conjunction with the director of substance abuse counseling, shall ensure that direct clinical supervision is provided by a staff person who meets the qualifications specified by the regulations of the New Jersey Board of Marriage and Family Counselors, Alcohol and Drug Counselor Committee at N.J.A.C. 13:34C-6.3.

(d) The director of substance abuse counseling services shall be responsible for the direction, provision and quality of substance abuse counseling services, including the following:

1. Developing and maintaining written objectives, policies and procedures, an organizational plan and a quality

assurance program, reviewed by the administrator, for substance abuse counseling services;

2. Ensuring that the behavioral and pharmacologic approaches to treatment are evidence based or based on objective information to provide treatment services consistent with recognized treatment principles and practices for each level of care and type of client served by the program;

3. Providing or ensuring, and documenting, that direct clinical supervision is provided at least one hour per week to all clinical staff, individually or in a group setting, with group supervision not to exceed 50 percent of supervision time;

4. Ensuring that substance abuse counseling services are provided as specified in the client treatment plan, and coordinated with other client care services, if applicable, in order to provide continuity of care;

5. Ensuring that the assessment, diagnosis and treatment of clients with co-occurring disorders is provided by appropriately trained and qualified clinical staff, and that the clinical supervision of such staff is provided;

6. Assisting in developing and maintaining written job descriptions for substance abuse counseling personnel, and assigning duties;

7. Assessing and participating in staff education activities and providing consultation to program personnel;

8. Providing orientation to and evaluation of new counseling staff prior to the assignment of counseling responsibilities;

9. Ensuring that all counseling staff are properly licensed or credentialed in accordance with this chapter;

10. Participating in the identification of quality care indicators and outcome objectives and the collection and review of data to monitor staff and program performance;

11. Participating in planning and budgeting for the provision of substance abuse counseling services; and

12. Ensuring that clinical staff are being supervised by the appropriately credentialed staff.

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

(a) Every facility shall ensure that the ratios of substance abuse counseling staff are maintained so that 50 percent of the staff are LCADC or CADC or other licensed health professionals doing work of an alcohol or drug counseling nature within their scope of practice by June 1, 2012, and at all times thereafter. The remaining 50 percent of substance abuse counseling staff will be considered counselor-interns (formerly referred to as "substance abuse counselors in training") who are actively working toward LCADC or CADC status, or toward another health professional license that includes work

of an alcohol or drug counseling nature within its scope of practice. The director of substance abuse counseling must maintain an active client caseload if the director of substance abuse counseling is to be counted in the above ratios.

1. Each substance abuse counselor shall be either an LCADC or a CADC or another licensed health professional doing work of an alcohol or drug counseling nature within their scope of practice.

i. A CADC shall work under the supervision of an LCADC, or another health professional licensed to supervise work of an alcohol or drug counseling nature within their scope of practice.

ii. A CADC cannot diagnose substance abuse without the signature approval of an LCADC or other clinical supervisor approved to do so.

2. Substance abuse counseling staff without LCADC or CADC status, or who are not other health professionals licensed to do work of an alcohol or drug counseling nature within their scope of practice, shall function as counselor-interns, and shall:

i. Be enrolled in a course of study leading to CADC or LCADC status, or to another health professional license that includes work of an alcohol and drug counseling nature within its scope of practice, without regard to changes in employment, with progress towards certification or licensing on file, reviewed by the facility at least semiannually and documented; and

ii. Be trained, evaluated and receiving continuing formal clinical supervision by the director of substance abuse counseling or designee, pursuant to the clinical supervision rules of the State health professional licensing board for the course of study in which they are enrolled: the Board of Marriage and Family Therapy Examiners (BMFTE) for licensed marriage and family therapists; the BMFTE's Professional Counselor Examiners Committee for licensed professional counselors; the BMFTE's Alcohol and Drug Counselor Committee for LCADC and CADC; the State Board of Psychological Examiners for licensed psychologists; and the State Board of Social Work Examiners for licensed clinical social workers.

(b) Counseling staff employed in an outpatient treatment facility subsequent to June 1, 2009 shall have three years from the date of employment to obtain LCADC or CADC status or another health professional license that includes work of an alcohol or drug counseling nature within its scope of practice.

(c) Only staff possessing the appropriate clinical background and educational qualifications from the appropriate clinical discipline may provide the diagnosis, assessment and treatment of clients with co-occurring disorders.

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

1. Assessing the counseling needs of the clients;

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

3. Determining the appropriate level of care according to ASAM Patient Placement Criteria (PPC2-R);

4. Obtaining previous records that are relevant to the current treatment episode;

5. Unless clinically contraindicated, collaborating with the client to develop a written treatment plan that includes goals and measurable objectives, and is client centered, recovery oriented;

i. The director of substance abuse counseling shall develop, monitor and provide the client and treatment team a written schedule to update each client treatment plan(s) in order to ensure clients' needs are met;

6. Providing the substance abuse counseling services specified in the client treatment plan;

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

8. Reviewing and, where necessary, revising the client treatment plan to address ongoing problems;

9. Developing a client discharge/transfer plan to ensure movement to the appropriate levels of care;

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

11. Participating as a member of a multidisciplinary team for assigned clients;

12. Providing active case consultation; and

13. Documenting all counseling and education services, assessments, reassessments, referrals and follow-up in the client's clinical record, and providing appropriate signatures and dating of such entries, including those made in electronic records.

10:161B-1.10 Qualifications of dieticians

The facility shall hire at least one dietician registered by the Commission on Dietetic Registration, 120 South Riverside Plaza, Suite 2000, Chicago, IL 60606-6995, www.cdrnet.org, if the facility serves any meals other than snacks to clients in the treatment program.

SUBCHAPTER 2. LICENSURE PROCEDURES AND ENFORCEMENT

10:161B-2.1 Applications for licensure

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

(b) Any person, organization, or corporation planning to operate an outpatient substance abuse 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

(c) DAS 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) Failure to pay the inspection and or licensing fees shall result in non-renewal of the license for existing facilities and the refusal to issue an initial license for new facilities.

(e) An application fee schedule shall be established and maintained by DAS, and will be included with the licensing application provided by DAS. 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 inspection fee as follows:

1. First time applicants of newly created treatment agencies:
 - i. New facility fee (\$1,750);
 - ii. Initial and ongoing biannual DAS inspection fee (\$300.00);
2. Licensed programs maintaining their licensure status:
 - i. License renewal fee (\$750.00);
 - ii. Ongoing biannual DAS inspection fee (\$300.00);
3. Licensed programs modifying the scope and or content of their license:
 - i. License modification to add beds or services (no charge);
 - ii. License modification to relocate or reduce services (\$250.00);
4. Licensed programs transferring ownership interest (\$1,500).

(f) Once licensed, each facility shall be assessed an on-going 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 Fee Schedule:

Type of Facility	New Facility Fee	License Renewal Fee	License Modification to Add Beds or Services	License Modification to Relocate or Reduce Services	Transfer of Ownership Interest	Initial or Biannual DAS Inspection Fee
Outpatient Substance Abuse Treatment Facility	\$1,750	\$750	0	\$250	\$1,500	\$300

(g) The total annual renewal fee shall be calculated by adding together the individual fees, as set forth in (e) above.

(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 shall notify applicants in writing when the application is complete.

(i) The most recent fee schedule will be given to applicants as part of the application forms given to prospective applicants.

(j) None of the following category designations of services shall be provided by an outpatient substance abuse 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 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 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 to provide. Any provision of services not specifically listed on the license shall be con-

sidered unlicensed provision of services, and DAS shall take all appropriate enforcement action.

10:161B-2.2 Licenses

(a) Once issued, a license shall not be assignable or transferable, and shall be immediately void if the program ceases to operate, relocates, or its ownership changes.

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

(c) Once issued, the license shall be conspicuously posted in the facility at all times.

10:161B-2.3 Application requirements

(a) Any person, organization, or corporation applying for a license to operate an outpatient substance abuse 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 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 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) As of June 1, 2009, upon annual renewal of its current license, each program shall specify the types of services to be provided, including if the program wishes to change the specification of services on the license.

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

(f) The applicant shall indicate on its application if a program is new or otherwise innovative, not fitting any of the categories specified in N.J.A.C. 10:161B-2.1(j), and shall

then submit a complete program description with the application, including, at a minimum, the following:

1. The target population, including number of clients to be served;
2. A detailed explanation of the services to be offered;
3. The frequency of counseling sessions;
4. The criteria and/or credentialing for staff;
5. The relationship to existing programs provided by the applicant;
6. The number of clients to be served at each facility and/or, if a new application, a projection of the number of clients to be served at each facility;
7. A proposed treatment category or modality of treatment; and
8. Documentation to demonstrate that the new and or innovative program is effective, safe and provides services that do not violate patient rights.

(g) DAS 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) The applicant shall submit documentation of the ownership or lease agreement of the physical plant and/or property of the facility.

(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. The results of full background checks, any criminal convictions or any sanctions by any State licensing or certification board against any principals, board members, employees or volunteers of the program;
2. Construction and maintenance of the physical plant(s) and equipment;
3. Staffing patterns, criteria and/or credentials thereof, including contract arrangements with outside agencies;
4. Composition and criteria, the code of ethics and conflict of interest standards for any principals, board members and governing bodies;
5. Standards for engaging all principals and management staff;
6. Policies, standard operating procedures and/or institutional rules applicable to the operation of the outpatient substance abuse program(s);
7. State or local rules applicable to the licensing and day-to-day operation of the program(s), when located outside New Jersey; and

8. A record of penalties or fines assessed against the program(s) and its ownership relative to the operation of the program(s) by any national, state, county, or local agency or court of competent jurisdiction, survey results and plans of correction, if any, resulting from accrediting authorities, which may reasonably be considered relevant to the safety of clients of a program and the community in which it is located.

10:161B-2.4 Newly constructed, renovated, expanded or relocated facilities

(a) Applications for licensure of newly constructed or expanded facilities shall include the following:

1. A copy of the written approval of the plans and final construction approval by the Department of Community Affairs or by the facility's municipality; and
2. A proposed plan of operation or set of bylaws for the governing authority of the program.

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

(a) The applicant or DAS 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 shall review it for completeness, and relevant fees in N.J.A.C. 10:161B-2.1. If DAS deems that the application is incomplete, DAS shall notify the applicant in writing of any missing information. Such written notification from DAS 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 within 30 working days. If the application is not deemed complete by DAS in writing to the applicant within six months, it shall be denied as incomplete and the applicant may reapply after 30 days. DAS shall not consider any application until it is deemed complete.

(c) Once the application is deemed complete, DAS 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 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 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.

2. If DAS 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 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 shall notify the applicant in writing of the findings of the survey, including any deficiencies.

ii. If DAS documents deficiencies, DAS shall schedule additional surveys of the outpatient substance abuse treatment program upon notification from the applicant that the documented deficiencies have been corrected. Additional surveys shall be scheduled by DAS within 15 working days after receipt of the applicant's notification that the documented deficiencies have been corrected.

(d) DAS shall approve a complete application for licensure if:

1. DAS 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. Where applicable, the new or otherwise innovative program from N.J.A.C. 10:161B-2.3(f) does not present significant risk of harm to the life, safety, health or well-being of the clients, and the applicant demonstrates that the program is reasonably within the bounds of accepted practice;

2. Surveys of the facility document no deficiencies, or document adequate correction of all previously noted deficiencies;

3. The applicant has provided DAS with written approvals for the facility from the local zoning, fire, health and building authorities. When seeking local approvals, any outpatient substance abuse 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 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 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 license shall be considered unlicensed admissions and DAS 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 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 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.

2. The facility shall notify DAS in writing when the deficiencies have been corrected. Within 30 working days of receiving written notification that the deficiencies have been corrected, DAS 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 with specific conditions and standards defined on such license and/or written in a conditional license letter granted by DAS 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 may issue a conditional license if DAS 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 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, as agreed between DAS and the applicant, with the safety and well being of the clients and staff of the program as the overriding priority.

(d) A conditional license may be issued to a program providing a type or category of service not listed above in N.J.A.C. 10:161B-2.1(j), nor otherwise addressed by this chapter.

(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 receiving written notification from the program that it is fully operational, DAS 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) The conditional license shall be conspicuously posted in the facility at all times.

(g) The conditional license is not assignable or transferable, and it shall be immediately void if the facility ceases to operate, if the facility's ownership changes, or if the facility is relocated to a different site.

10:161B-2.8 Periodic surveys following licensure

(a) Authorized DAS 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 staff for survey purposes.

(b) Survey visits may include, but shall not be limited to:

1. Review of the physical plant and architectural plans;
2. Review of all documents and client records;
3. Conferences or one on one interviews with clients and staff; and
4. Review of compliance with criteria set forth in this chapter.

(c) In addition to periodic surveys, DAS 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 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, 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 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 in the following circumstances during a survey:

1. During the course of a survey to the extent such discussion does not interfere with the surveyor's ability to obtain full and objective information and to complete required survey tasks; or

2. During the exit interview or other summation of survey findings prior to the conclusion of the survey.

(b) Following completion of the survey, a facility may contact the Director of DAS 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. A specific listing of the deficiencies for which informal review is requested; and

2. Documentation supporting any contention that a survey finding was in error.

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

(d) A decision will be issued by DAS 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 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 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 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 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 may request that an amended plan of correction be submitted within 10 business days. In relation to violations of resident or patient rights, DAS 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 with at least 45 days prior notice;

2. The program shall provide each client, prescribing physician(s) and primary substance abuse counselor(s) at least 30 days prior notice. In addition, the program shall arrange for each client to be transferred to a licensed facility or other licensed program capable of providing the appropriate level of care.

3. The program shall provide appropriate notice, in writing, to any program to which it has sent client referrals and from which it has received client referrals in the past three years; and

4. The program shall provide each guarantor of payment at least 30 days prior notice.

(b) When a program is ordered by DAS 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 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 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 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 to be consistent with the general purpose and intent of its enabling statute and these rules; is consistent with prevailing DAS 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. The specific rule(s) for which a waiver(s) is requested;
2. The specific reason(s), justifying the waiver, including a statement of the type and degree of hardship that would result if the waiver were not granted;
3. An alternative proposal to ensure the safety of clients and staff, client families, and the public, as appropriate;
4. Specific documentation to support the waiver request and all assertions made in the request;
5. A statement addressing how the waiver would fulfill the purpose and intent of this chapter; and
6. Such other additional information that DAS 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 shall determine whether the requested timeframes are reasonable.

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

(d) DAS may revoke a waiver at any time if DAS 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 treatment facility for violations of licensure regulations or other statutory requirements:

1. A civil monetary penalty for unlicensed operations;
2. Curtailment of admissions to a licensed substance abuse treatment facility;
3. Reduction of a full license to, or issuance of, a provisional license;
4. Suspension of a license;
5. Revocation of a license;
6. Seek an injunction and/or temporary restraints; and
7. Any other remedies for violations of statutes as provided by State or Federal law, or as authorized by

Federal survey, certification, and enforcement regulations and agreements.

10:161B-2.15 Notice of violations and enforcement actions

The Commissioner or designee shall serve notice to a facility of the proposed assessment of civil monetary penalties, suspension or revocation of a license, or placement on a provisional license, setting forth the specific violations, charges or reasons for the action. Such notice shall be served on a licensee or its registered agent in person or by certified mail.

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 a written answer to the charges and give written notice to the Division 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 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 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 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 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 shall impose penalties consistent with (a)1 above, until the newly constructed or renovated facility is determined by the Division to be in compliance with licensure standards. This determination

shall take into account any waivers granted by the Division; and

5. Operation of a licensed facility following the transfer of ownership of a substance abuse treatment facility without prior approval of the Division, shall be considered operation of an unlicensed facility, and DAS 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 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 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 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 may in its discretion reduce the license to provisional status, or move to suspend or revoke the license, considering the following factors:

- i. The number, frequency and/or severity of the violation(s);
- ii. The location of the facility;
- iii. Any special population served by the facility;
- iv. The facility's utilization of capacity;
- v. The compliance history of the facility;
- vi. The deterrent effect of the penalty;
- vii. Measures taken by the facility to mitigate the effects of the current violation or to prevent future violations; and/or
- viii. Other relevant specific circumstances of the facility or violation.

4. For violations resulting in either actual harm to a client, or in an immediate and serious risk of harm, the Division 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 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 may decrease the penalty assessed in accordance with (a) above, based on the following factors:

1. The number, frequency and/or severity of the violation(s);
2. The location of the facility;
3. Any special population served by the facility;
4. The facility's utilization of capacity;
5. The compliance history of the facility;
6. The deterrent effect of the penalty;
7. Measures taken by the facility to mitigate the effects of the current violation or to prevent future violations; and/or
8. Other relevant specific circumstances of the facility or violation.

(d) In addition to the imposition of penalties in accordance with (a) above, the Division 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 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. 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 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) Failure to pay a penalty within the time frames set forth in (a) or (b) above as applicable may result in one or both of the following actions:

1. Institution of a summary civil proceeding by the State pursuant to the Penalty Enforcement Law (N.J.S.A. 2A:58-10 et seq.); and/or
2. Placing the facility on a provisional license status.

10:161B-2.19 Curtailment of admissions

(a) The Division may issue an order curtailing all new admissions and readmissions to a substance abuse 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 treatment facility;

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

3. Where the admission or readmission of new clients to a substance abuse 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 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.

(b) The order for curtailment may be withdrawn upon a DAS 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 finding.

10:161B-2.20 Provisional license

(a) The Division may place a substance abuse treatment facility on provisional license status as follows:

1. Upon issuance of a Notice for Revocation or Suspension of a License, for a period extending through final adjudication of the action;

2. Upon issuance of an order for curtailment of admission, until the Division 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 treatment facility; and/or

4. Upon a recommendation to the Federal government and/or the New Jersey Division of Medical Assistance and Health Services, for the termination of a provider agreement for failure to meet the Federal certification regulations.

(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 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 shall not authorize or review any application for approval of additional beds or services filed by the facility with the Division;

2. The Division 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 shall notify the same government agencies and third parties; and

3. The facility shall be subject to announced or unannounced monitoring visits and or survey.

(d) While on provisional license status, the Division 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) A facility placed on provisional license status shall post the provisional license in a conspicuous location within the facility at all times.

Administrative correction.
See: 41 N.J.R. 2658(a).

10:161B-2.21 Suspension of a license

(a) The Commissioner or designee may order the suspension of a license of a substance abuse 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 of such correction, or to request a hearing.

(c) If the Division 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 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 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 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 may concurrently or subsequently impose other enforcement actions pursuant to these rules.

(g) The Division 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 treatment facility license may be issued in the following circumstances:

1. The facility has failed to comply with licensing requirements, posing an immediate and serious risk of harm or actual harm to the health, safety, and welfare of clients,

and the facility has not corrected such violations in accordance with an approved plan of correction or subsequent to imposition of other enforcement remedies issued pursuant to this chapter;

2. The facility has exhibited a pattern and practice of violating licensing requirements, posing a serious risk of harm to the health, safety and welfare of clients. A pattern and practice may be demonstrated by more than one finding of violations of the same or similar regulation by any Department and or Division representative or employee and or contracted agent;

3. The facility has failed to correct identified violations which had led to the issuance of an injunction; or

4. When a facility has operated under a provisional license that has not met the stipulated conditions within 12 months or more.

(b) The notice shall be served in accordance with N.J.A.C. 10:161B-2.15, and the facility has a right to request a hearing pursuant to N.J.A.C. 10:161B-2.24.

10:161B-2.23 Injunction

(a) The Commissioner or designee may determine to seek an injunction of the operation of a substance abuse 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 refer the matter to the Office of the Attorney General to file for an injunction and or temporary restraints consistent with the New Jersey Court Rules.

(c) Within five working days, the Division 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 treatment services and effect an orderly transfer of clients to substance abuse treatment facilities or other services approved by the Division and the facility shall document all transfers.

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

(e) The Division 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) Notice of a proposed enforcement action shall be afforded to a facility pursuant to N.J.A.C. 10:161B-2.15.

(b) A facility shall have 30 days following receipt of a notice to request a hearing to appeal the action(s) specified in the notice.

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

(d) Hearings shall be conducted pursuant to the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1.1.

10:161B-2.25 Settlement of enforcement actions

(a) The facility may request that the matter be scheduled for settlement conference prior to transmittal to OAL for an administrative hearing.

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

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

(d) All funds received in payment of penalties shall be deposited in the general state fund.

SUBCHAPTER 3. GENERAL REQUIREMENTS**10:161B-3.1 Provision of services**

(a) An outpatient substance abuse treatment facility shall provide or arrange for the following services:

1. Medical and nursing services (including assessment, diagnostic, treatment);
2. Counseling; and
3. Vocational, educational and other support services.

(b) Written agreements detailing services to be provided shall be made between the outpatient substance abuse treatment facility and any other service provider; such agreements shall specify services rendered and be supported by documentation of services rendered.

1. If the facility contracts with a third party provider, whether for services to be provided within or outside the facility, the written agreement shall specify each party's

responsibilities, including submission of reports and treatment and service recommendations.

- i. Any such services rendered by a third party provider shall comply or be in accordance with the rules in this chapter.

10:161B-3.2 Compliance with laws and rules

(a) The program shall comply with all applicable Federal, State, and local laws, rules, and regulations and with the standards of accrediting organizations as applicable.

(b) If a licensed program provides outpatient substance abuse 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 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. Notice of ownership will be maintained at the facility, or at a separate designated location.

2. The program shall provide DAS 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 facility shall be owned, managed, or operated by any person convicted of a crime relating adversely, either directly or indirectly, to the person's capability of owning, managing or operating the facility.

10:161B-3.4 Submission of documents and data

(a) Upon request, the program shall submit to DAS 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.

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

10:161B-3.5 Personnel

(a) The facility shall maintain personnel records for each employee, including, but not limited to, the employee's name, address, Social Security number, proof of identification, previous employment history (including verification), educational

background, credentials (including progress toward CDA, CADC, or LCADC), professional license number with effective date and date of expiration (if applicable), certification (if applicable), verification of credentials, record of voluntarily disclosed criminal convictions, results of criminal history background checks, records of physical examinations, job descriptions, documentation of staff orientation and staff education received, and evaluations of performance.

1. The facility shall complete performance evaluations on staff a minimum of once per year after initial employment.

2. The program shall initiate State-level criminal history record background checks supported by fingerprints no later than the time of hiring all staff, student interns and volunteers.

3. Programs shall provide each staff member with a photo identification card to include, at a minimum, the staff member's name, job title, degree and/or certification.

4. The facility administrator shall make reasonable efforts to ensure that staff are in good physical and mental health, emotionally stable, of good moral character, concerned for the safety and well-being of clients, and have not been convicted of a crime relating adversely to the person's ability to provide care or interact with clients and families, either directly or indirectly, such as homicide, aggravated assault, kidnapping, sexual offenses, robbery, and crimes against the family, children or incompetents, except where the applicant or employee with a criminal history has demonstrated rehabilitation in order to qualify for employment. Such procedures for hiring employees with past criminal histories, including, but not limited to, those above, shall be clearly written.

i. "Reasonable efforts" shall include, but need not be limited to, an inquiry on the employment application, reference checks, and/or criminal history record background checks where indicated or necessary.

5. Programs shall have a policy governing the review of criminal convictions identified by criminal history background checks or voluntary disclosure by prospective employees that shall include the process and standards by which convictions are reviewed to determine if the nature and severity of the conviction(s) precludes consideration for hiring. Such policy shall not preclude the hiring of persons with criminal convictions, but may reasonably balance the type and severity of the crime, history of rehabilitation, and nature of employment.

6. Programs shall document verification and confirmation of licenses/certifications and educational degrees for all staff in accordance with program policy and requirements established for the position by this chapter to determine that they are both current and not under suspension or other sanction from any licensing or certifying authority, which would preclude employment due to inap-

propriateness (that is, ethical violations) or lack of minimum qualifications/requirements for the position.

(b) The facility administrator shall establish written policies and procedures addressing the period of time during which staff in recovery status are determined to be continuously substance (alcohol and/or other drug) free before being employed in the facility, and which address the consequences of employee use of alcohol, tobacco or illegal drugs during working hours or when representing the treatment program. The program shall establish written policies addressing alcohol and nicotine use during working hours or when reporting to the treatment field.

(c) The facility administrator shall develop written job descriptions for all facility staff including volunteers, and ensure that personnel are assigned duties based upon their education, training and competencies, and in accordance with their job descriptions.

(d) The facility shall employ only those personnel who are currently licensed, currently certified, or authorized under the appropriate laws or rules of the State of New Jersey or under the applicable standards of the appropriate recognized credentialing body to provide client care.

(e) The facility shall ensure that adequate staffing levels are maintained to ensure continuity of care to clients, and shall ensure that substitute staff possess appropriate equivalent qualifications needed to function in that capacity.

(f) The facility shall develop and implement a staff orientation plan and a staff education plan, that includes written plans for each service and designation of person(s) responsible for training as follows:

1. All staff shall receive orientation at the time of employment and at least annual in-service education regarding, at a minimum:

- i. The facility's emergency plans and procedures;
- ii. The infection prevention and control program;
- iii. Universal precautions; and

iv. The policies and procedures concerning conflicts of interest, ethics and confidentiality, client rights, treating individuals with co-occurring disorders, cultural competence, and, where appropriate, identifying and responding to cases of child abuse and elder abuse.

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. The administrator shall ensure that the governing authority shall participate in the review the policy and procedure manual at least annually.

2. This policy and procedure manual shall be signed and dated by the administrator and governing authority presiding officer, attesting that the policy and procedure manual was reviewed.

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 and the public.

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

1. A written statement describing the program's vision and mission, staffing patterns and the services provided, including the modalities/types and ASAM level of care designation offered;

2. An organizational chart delineating the lines of authority, responsibility, and accountability for the administration and client care services;

3. Policies regarding the program's definition of "business hours," "full-time" and "shift";

4. A description of the facility's quality assurance program, including, but not limited to, client care (including medical and nursing services) and its documentation; and staff performance and supervision, methods for at least annual review of staff performance, staff qualifications and credentials, staff orientation and education, and documentation of these staff functions-related functions;

5. Adherence to privacy and confidentiality policies and procedures ensuring the confidential maintenance of client records while the program is in operation and in the event that it ceases to operate, as required by Federal confidentiality regulations at 42 CFR Part II, and Federal HIPAA requirements at 45 CFR Part 160;

6. A description of the modalities of treatment provided, including a listing of services, procedures, and ASAM level of care designations which may be performed in the facility;

7. A written plan for informing persons in need of substance abuse 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. Policies and procedures for making information about alcohol, tobacco and other drug use prevention and treatment available to the public;

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

i. Include written descriptions of situations that may preclude the use of telephones by clients;

ii. Comply with client care policies and procedures, and not violate client rights, nor be used as a tool to punish or coerce clients; and

iii. Not prevent clients from contacting the local police in the event of an emergency, or from contacting DAS 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, to ensure that clients have access to emergency consultation services on a 24-hour-a-day basis, seven days a week.

11. Policies and procedures to provide for the assessment, diagnosis, identification and treatment of persons with co-occurring mental health disorders, or to coordinate the care and/or referral to appropriate mental health providers, so that services are provided in a coordinated fashion.

i. Clients who have been clinically assessed as being unable to participate in or benefit from the facility's services will be referred to the appropriate treatment provider, and the referral documented in the clinical record;

12. Policies addressing the confiscation and disposition of illicit drugs and weapons within the facility;

i. The policy shall include notification of appropriate parties for clients referred from the criminal justice system;

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) in the clinical record, and serving as a liaison between the facility and DYFS;

ii. If the client is 60 years of age or older, the protocols for notification of any suspected case of client abuse or exploitation to the New Jersey Department of the Public Advocate, Ombudsman for the Institutionalized Elderly, pursuant to N.J.S.A. 52:27G-7.1 et seq.;

iii. The protocols for the identification and treatment of children and elderly and disabled adults who are abused and/or neglected; and

iv. The provision, at least annually, of educational and/or training programs to staff on the identification and reporting of identified and/or suspected cases of child abuse and/or neglect, sexual assault or abuse, domestic violence, abuse of the elderly and/or disabled adults, and related agency policies and procedures; and

14. Policies and procedures governing the delivery of services that include, at a minimum, the following:

i. The frequency of counseling interventions and didactic sessions, including a weekly and monthly posted written schedule of all program activities; and

ii. The content of didactic sessions, including a written description or curriculum of didactic sessions offered in the facility.

Administrative correction.

See: 41 N.J.R. 2658(a).

10:161B-3.7 Employee health

(a) The policy and procedure manual shall include policies and procedures to ensure that physical examinations of staff are performed upon initial employment and at subsequent intervals. Policies and procedures shall specify the circumstances under which other persons providing direct client care services shall receive a physical examination. Policies and procedures shall specify the content and the frequency of the examination.

(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. If an employee can document seropositivity from a previous rubella screening or inoculation with rubella vaccine, the employee shall not be required to submit to any additional rubella screening.

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 as equivalent or better, on a case by case basis.

3. Only employees born in 1957 or later shall be required to submit to a measles screening test.

i. If the employee can document receipt of a live measles vaccine on or after his or her first birthday, physician diagnosed measles, or serologic evidence of immunity to measles, the employee shall not be required to submit to a measles screening test.

ii. If the employee cannot provide the documentation required in (b)3i above, the employee shall submit to a measles hemagglutination inhibition test, or other measles screening test.

4. All employees hired after June 1, 2009 required to submit to screening tests shall do so upon employment.

5. All employees employed as of June 1, 2009 required to submit to screening tests shall do so by July 31, 2009.

(c) The program shall inform each employee of the results of each screening test, record all tests performed and the results thereof in each employee's personnel record, and maintain a list of all employees who are seronegative and unvaccinated.

(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, and incorporated herein by reference as chapter Appendix A.

1. Employees hired after June 1, 2009 shall be required to submit to Mantoux testing upon employment, while employees employed as of June 1, 2009 shall submit to the Mantoux test by July 31, 2009, if the employee has not been tested within the past year.

2. If the Mantoux test result is negative (less than 10 millimeters of induration or less than five millimeters of induration if immunosuppressed), the employee shall submit to a repeat Mantoux skin test within three weeks of the initial test.

3. If either the initial or subsequent test result is positive (10 or more millimeters of induration, or five millimeters if immunosuppressed), the employee shall submit to a chest x-ray and be referred for chemoprophylaxis or treatment for tuberculosis, as appropriate.

4. Employees who can document a negative Mantoux test within the prior 12 months would only need one Mantoux skin test.

5. The following employees shall not be required to submit to a Mantoux test:

i. Employees who can document a positive Mantoux skin test (10 millimeters or more of induration or five millimeters or more of induration if immunosuppressed) regardless of treatment; or

ii. Employees who have received and completed treatment for tuberculosis disease and latent tuberculosis infection.

6. The Mantoux skin test shall be repeated on an annual basis for all employees unless contraindicated.

7. All symptomatic employees shall have a chest x-ray and be medically cleared regardless of the skin test result.

(e) The program shall establish policies and procedures regarding employee safety and shall include procedures for the care of employees who become ill or who are injured at the facility.

(f) The program shall establish policies and procedures that provide for pre-employment drug screening, and shall include the random drug screening of staff including the screening of staff suspected of substance abuse. The policies and procedures shall address the program's response to positive drug screening results.

10:161B-3.8 Reportable events

(a) The facility shall develop policies and procedures governing the reporting and management of reportable events. Such policies shall include, but need not be limited to, the procedures in this section.

(b) The facility shall immediately notify DAS at 609-292-5760, or after hours at 866-666-8108, and immediately fax a report to DAS at 609-292-3816, 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. All fires, floods, disasters, accidents, or other unanticipated events which result in serious injury or death of clients or staff, or evacuation of clients from the facility, or closure of the facility for six or more hours;

2. All deaths of clients under the supervision of the facility or deaths known or suspected of resulting from misuse of medications prescribed or dispensed by the program;

3. All outbreaks of communicable disease or other conditions adversely affecting multiple clients and/or staff. Note: This does not relieve the program from reporting certain communicable diseases to local or State health authorities pursuant to N.J.A.C. 8:57;

4. All alleged or suspected crimes that endanger the life or safety of clients or staff or which jeopardize facility operations or fiscal stability;

- i. Any client or staff member against whom an alleged or suspected crime has been committed shall be advised of his or her right to report the incident to local police;

- ii. Notification or the refusal to notify police authorities shall be documented in writing in the client or staff record, and the administrator shall be notified; and

- iii. The governing body shall be notified of events endangering the life and/or safety of clients and staff, or suspected crimes that jeopardize the facility's operations or fiscal stability;

5. All disciplinary actions of staff, including termination, resulting from inappropriate staff interaction with clients; and

6. All criminal convictions or disciplinary sanctions imposed on staff, board members or representatives of the

governing authority by licensing or credentialing boards since the prior application for licensure.

(c) The facility shall provide DAS 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.

1. The written confirmation shall contain information concerning injuries to clients or staff, disruption of services, and the extent of damages, etc. The written report shall also include identification of the factors that contributed to the occurrence of the event, and corrective actions and timeframes being implemented by the program to minimize the risk of further incidents.

(d) The facility shall notify DAS 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) The facility shall develop procedures, including timeframes, for verbal and written notification to the governing authority of reportable events noted in this section.

Administrative correction.
See: 41 N.J.R. 2658(a).

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;

2. The list of deficiencies from the last annual licensure inspection, and the list of deficiencies from any valid complaint investigation during the past 12 months and the program's plan of correction;

3. A statement of client rights;

4. The names of members of the governing authority of the facility and the facility address to which correspondence may be sent; and

5. The hours of operation and the normal business hours of the facility.

10:161B-3.10 Reporting to professional licensing boards

The facility shall comply with all requirements of professional licensing and credentialing boards for reporting termination, suspension, revocation, or reduction of privileges of any employee licensed or credentialed in the State of New Jersey.

10:161B-3.11 Transportation

(a) The facility shall maintain, or otherwise ensure, that all vehicles used for transportation of clients are in conformity with all motor vehicle and insurance laws and/or rules.

1. The facility shall maintain copies of registration and insurance information on file for all vehicles used to transport clients, including staff's personal vehicles, when applicable.

2. The facility shall keep the name of each driver and a photocopy of his or her current driver's license on file, as well as a driver abstract for all staff members.

3. The facility shall have a policy addressing tobacco use by employees and clients in all vehicles used to transport clients.

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 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. The facility's mission and purpose;

2. Ensuring the facility is operating in accordance with its mission and for the non-profit, the purpose for which it was granted tax-exemption;

3. Providing financial oversight to ensure that proper financial controls are in place;

4. Ensuring adequate financial resources as part of their fiduciary responsibility, which may include such responsibilities as personal contribution, financial planning, fund-raising, grants management, and serving as an advocate;

5. Exercising duty of care (reasonable care while decision making), duty of loyalty (acting in the best interests of the facility without personal gain), and the duty of obedience (being faithful to the facility's mission while managing funds for that purpose);

6. Appointing and supervising an administrator (that is, president, chief executive officer, executive director, etc.) whose references, credentials, professional license, and criminal background are reviewed and verified, and recon-

ciled against the organization's mission and administrator's scope of work;

i. The governing authority shall establish policies for hiring an administrator, including policies for individuals who may have past criminal convictions and/or have been sanctioned for professional ethical violations, which ensure that convictions/violations shall not impact his or her ability to perform duties.

ii. The administrator shall be notified by the governing authority that he or she shall disclose to the governing authority any disciplinary outcome imposed as a result of an investigation by any State licensing agency, law enforcement agency, or professional disciplinary review board, such as disciplinary probation, suspension of license, revocation of license, or criminal conviction at the time of initial employment, and/or during employment if the action occurs after hire;

7. Evaluating, at least annually, the performance of the administrator of the facility, including establishing requirements for the administrator's continuing education credits;

8. Approving, in writing, a person to be designated as the administrator's alternate;

9. Ensuring the administrator has the professional support needed to further the mission and goals of the facility;

10. Ensuring legal and ethical integrity, and maintaining accountability by observing legal standards and ethical norms;

11. Documenting all of its actions and those of its committees by written minutes, and maintaining minutes of meetings, including resolutions and motions pertaining to the fiscal and legal responsibilities of the governing authority;

12. Establishing a grievance mechanism available to both staff and clients;

13. Establishing a notice system accessible to all staff and clients regarding the grievance procedures that shall include the name, address, and telephone number for public access to the facility;

14. Establishing a feedback mechanism in order to receive and respond to staff and client recommendations;

15. Establish client complaint procedures that support client rights, are visibly posted and accessible to clients in client service areas and are understood by clients from point of service intake to leaving the program, as per N.J.A.C. 10:161B-16, Client Rights;

16. Reviewing and approving plans to establish new programs, or to substantially alter or discontinue existing services, substantial changes in levels of service, and/or changes in populations served;

17. Ensuring that the client care policies required in N.J.A.C. 10:161B-6 are developed and maintained;

18. Establishing a pharmacy and therapeutic committee, if so required at N.J.A.C. 10:161B-14;

19. Ensuring that infection control protocols and practices are adhered to;

20. Establishing protocols regarding child abuse and neglect, sexual abuse, elder abuse, and institutional abuse or neglect, including duty to warn and protect;

21. Reviewing and approving the annual audits;

22. Reviewing and approving the facility's compensation plan for staff at least annually;

23. Establishing and approving an annual budget, including any capital projects, for all services to be provided at or through the facility in consultation with the administrator, fiscal officer, and the service directors; and reviewing with the administrator any material changes which may occur during the year with respect to either revenue or expenditures, including the reasons for the changes;

24. Designating a member to certify financial statements by signature, and establishing protocols to periodically review a sliding scale fee for services schedule as well as procedures for assessing income and ability to pay for services;

25. Reviewing any notices issued by DAS 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 of such corrective measures;

26. Establishing policy and procedures to ensure client's confidentiality as required by State and Federal laws (that is, CFR42, Health Insurance Portability Accountability Act (HIPAA), etc.);

27. Developing conflict of interest and disclosure policies for members of the governing authority, and paid and volunteer staff; and

28. If multiple facilities are operated by the governing authority, identifying how the committees and committee functions required by this chapter will be met if organization wide committees are established.

(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 treatment facility, including:

1. The composition of the governing authority, qualifications of members and officers, procedures for election or appointments to seats (including mid-term vacancies), terms of service; a written policy preventing nepotism by relatives and family members and preventing paid staff

members from serving on the governing body; and a protocol to ensure that references and credentials of all prospective members are checked and verified, including written acceptance/exclusionary criteria to address individuals with past criminal convictions and/or ethical violations;

2. Establishment of standing and ad hoc committees, their duties and powers, terms of chairpersons and qualifications for chairpersons and committee members;

3. The methodology by which the governing authority shall approve bylaws, including amendments, policies and procedures required to be maintained by the facility under this chapter and documentation of such approval;

4. Establishment of schedules for review of all policies, procedures and bylaws of the facility;

5. The rules for board meetings, including the frequency and number of members necessary for a quorum;

6. The authority and responsibilities of the administrator and designee as described at N.J.A.C. 10:161B-1.7, including his or her reporting responsibilities to the governing authority;

7. Establishment of the methodology by which financial books and fiscal records shall be maintained, consistent with the standards of this chapter, schedules for regular audits, both internal and independent, and the basis for spot audits by independent sources;

8. Delineation of those services that shall be provided through written agreement; and

9. Delineation of a grievance procedure for staff and clients.

SUBCHAPTER 5. ADMINISTRATION

10:161B-5.1 Appointment of administrator

(a) The governing authority shall appoint an administrator who shall be accountable to the governing authority.

(b) The administrator shall be available in the facility at all times during normal business hours or available by telephone to a designated person in the facility.

(c) Except on a short-term emergency basis not exceeding two weeks, in the event that an alternate or designee is used in the administrator's absence, this individual shall possess the appropriate credentials and qualifications to perform the administrator's role. There shall be written documentation identifying the individual who will act in the absence of the administrator, and this information shall be provided to the facility's staff and approved by the governing authority.

SUBCHAPTER 6. CLIENT CARE POLICIES AND SERVICES**10:161B-6.1 Client care policies**

(a) Every outpatient substance abuse 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. A facility may also choose to establish a client care policy committee which shall, at a minimum, be composed of the administrator, director of substance abuse counseling, director of nursing services, the medical director or the facility's physician, and a client.

i. The facility shall provide written documentation to the governing authority of the mechanisms by which client care policies will be developed, managed and maintained by the facility.

ii. All client care policies related to medical services shall be reviewed and approved by the medical director, and shared with the facility's physician, pharmacist and director of nursing services.

2. Under the direction of the administrator and director of substance abuse counseling, the facility shall ensure that all client care policies and procedures are reviewed at least annually.

3. The facility shall review facility outcome data, available through NJSAMS and/or other means, and consider this data in its review of client care policies.

4. Client care policies shall include specific clinical and administrative guidance addressing incidents occurring or deficiencies found in the facility that impact the adequacy of policies and procedures affecting the health and safety of clients and/or staff. Any incidents or deficiencies shall prompt an immediate policy review, and any resulting policy revisions shall be shared with the facility's governing authority.

(b) The facility shall establish clear mechanisms that verify through written documentation that all client care policies were reviewed by the appropriate parties, including the date the policies were reviewed and the signature of each reviewer.

(c) Should a client care policy committee be established, the facility shall ensure that the committee's meetings, items discussed and actions taken are documented, dated and disseminated.

(d) When developing and reviewing policies and procedures regarding a specific service, the facility shall actively solicit input from facility staff representing that service.

(e) The facility shall ensure that policies and procedures are developed and implemented for the care of the general client population, and address the needs of any special populations that the facility may serve including, but not limited, to pregnant women, women with dependent children, juveniles, homeless and/or indigent, deaf or hard of hearing, blind, or otherwise disabled, those with communication limitations, those who can not speak, read or write the English language, or persons with co-occurring mental health disorders.

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. Admissions and exclusionary criteria that include identification of the conditions or diagnoses eligible and ineligible for admission;

2. Orientation of new clients;

3. Services offered including, but not limited to, screening, assessment, diagnosis, counseling, education, and case management;

4. Client rights, that include the acknowledgement that the client is made aware of, and has approved, receiving counseling services from a substance abuse counselor intern;

5. Staffing patterns;

6. Referral of clients to health care providers outside of the facility, including referrals to other treatment programs along the continuum of care;

7. Emergency care of clients;

8. Care of clients during an episode of communicable disease;

9. Care of clients with tuberculosis, which is not transmissible, or no longer communicable;

10. Informed consent requirements and methodology, including provisions for obtaining informed consent from parents or guardians of juveniles;

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

12. Health education of clients through various mediums, including written, and presented multi-lingually on the basis of client composition of the program;

13. Criteria for discharge, transfer and re-admission of clients from the program;

14. Screening clients for substance use through random urinalysis or other approved methods of drug screening on

grounds that are reasonable and not unfairly discriminatory;

15. Conducting of research activities;

16. Reporting of critical incidents, complaints and threats;

17. Conflict resolution process; and

18. Community relations.

(b) The facility shall establish policies and procedures regarding financial arrangements established between clients and the facility, including:

1. The method and time frames for retention of records of financial arrangements and transactions;

i. The facility shall provide clients with copies of all financial arrangements and transactions relevant to the client;

2. Clients shall be advised in writing at admission of all fees and payments charged by the facility including any services such as physician or nursing visits that are billed separately;

i. Any sliding fee scales or special payment plans, at a minimum, shall provide notice to clients that a description of the sliding fee scales or special payment arrangements, and the circumstances in which they may be appropriate, is available on-site for review upon request;

3. The fee schedule for the provision of services for which the program charges as follows:

i. The facility shall not assess charges, expenses or other financial liabilities in excess of those established in the fee schedule without the written approval of the client, except in the event of an emergency, which requires that the client be provided with special services or supplies; and

ii. The facility shall provide the client written copies of all of his or her approvals of additional expenses, or expenses incurred in rendering services to the client during an emergency;

4. The method for notifying clients regarding the program's agreements with insurance companies, health maintenance organizations (HMOs) and other third-party payers; and

5. The method for notifying clients regarding sources of financial assistance available to clients, and the method for referring clients directly to the source(s) of financial assistance, when appropriate.

(c) If the facility provides medical and/or nursing service, the facility shall establish policies and procedures for the acceptance of verbal and telephone orders from physicians or

other licensed practitioners authorized under New Jersey statute, to include the following:

1. Limitations on verbal and telephone orders to emergency situations; and

2. Written documentation of verbal and telephone orders shall be written into the client's clinical record by the person receiving such orders, and countersigned by the person issuing such orders within 72 hours of the issuance of the verbal or telephone order.

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

(a) Prior to or at the time of admission to the program, the facility shall conduct a preadmissions interview with all clients and, in the case of juveniles, his or her family, guardian or legally authorized representative. A summary of the interview shall be documented in the client clinical record after:

1. The orientation of the client to the facility's policies, business hours, fee schedules, services provided, client rights, criteria for admission, treatment and discharge; and

2. The obtaining of informed consent from the parents or legally authorized representative of a juvenile prior to the juvenile entering treatment, except as provided for by N.J.S.A. 9:17A-4, where a minor voluntarily seeking treatment for substance abuse shall be considered confidential information.

(b) The facility shall not admit a client to a program in the following circumstances:

1. An individual is unconscious at the time of presentation or admission. The facility shall transfer such an individual immediately to a hospital; or

2. An individual manifests such a degree of behavioral disorder that the individual is a danger to himself or herself or others, or whose behavior interferes with the health, safety or welfare of staff or other clients.

i. The facility shall provide assistance in referring such individuals to an appropriate treatment program including a designated mental health screening center.

(c) If admission to the facility is denied, documentation of the reasons for denial and referral of the client to appropriate treatment services shall be entered in the client's record.

(d) Only facilities licensed by DAS 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. Facilities providing detoxification services shall comply with N.J.A.C. 10:161B-12, and all other applicable sections of this chapter.

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

1. Facilities providing opioid treatment and detoxification services shall ensure that each client has received a physical examination in accordance with N.J.A.C. 10:161B-11 and 12;

2. Facilities providing services other than opioid and detoxification shall ensure that each client has completed a comprehensive health history assessment and symptom review and has referred each client for appropriate medical screening and services, as necessary;

3. Facilities that do not require a physical examination shall ensure that clients do not manifest or self-report symptoms of communicable disease such as persistent coughing, fever or other symptoms of illness without receiving medical clearance prior to admission;

4. Clients shall be physically mobile with or without assistive devices; and

5. Clients shall be able to leave the building alone, except in a facility licensed to provide medically monitored detoxification services.

(f) A facility shall not involuntarily admit or retain any client.

(g) A facility shall not retain any client in treatment who is a danger to himself or herself or others, or whose behavior interferes with the health, safety and/or welfare of staff or other clients.

10:161B-6.4 Involuntary discharge

(a) A facility shall have written policies and procedures governing the involuntary discharge of clients. All clients shall be provided with a verbal and written notice of the facility's intent to discharge. If the client is a juvenile, the juvenile's parent(s), guardian or legally authorized representative shall be provided with the time the juvenile will be released to their care, except where the juvenile has voluntarily sought treatment in accordance with N.J.S.A. 9:17A-4.

1. The written notice shall include the specific reason(s) for the discharge, and shall set forth the client's rights and procedures to appeal the discharge decision.

(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 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. A copy of the appeal, and the disposition thereof, shall be entered in the client's clinical record.

(c) A facility may involuntarily discharge a client without prior notice if the client poses a health or safety hazard to himself or herself, other clients, or staff.

1. The facility shall provide assistance in referring such clients to an appropriate client-approved treatment program.

10:161B-6.5 Use of restraints

No facility shall use any physical, chemical, or other types of restraint.

10:161B-6.6 Calibration of instruments

The facility shall ensure that all instruments are calibrated in accordance with manufacturer's instructions, and shall maintain a record of maintenance for all instruments.

10:161B-6.7 Interpretation services

The facility shall provide interpretation services for clients who do not speak English, are deaf or hard of hearing, and when other communication assistance is needed for clients who are blind or otherwise physically impaired; or where and when clinically necessary, the facility shall assist and document the referral of clients requiring such assistance to a program reasonably capable of accommodating their needs. The facility shall develop procedures to ensure that interpretation services are provided in a timely manner for urgent and emergency situations.

SUBCHAPTER 7. MEDICAL SERVICES

10:161B-7.1 Provision of medical services

(a) Medical services shall be provided in outpatient substance abuse treatment programs as follows:

1. Intensive outpatient and outpatient: Medical services are not required to be provided either in the facility or through written agreement;

2. Partial care: Medical services are not required to be provided either in the facility or through written agreement. The program shall have written protocols to ensure ready access to psychiatric and medical services;

3. Outpatient detoxification: Medical services shall be provided in the facility and the facility shall employ a medical director. A physician shall document an initial evaluation of each client and shall prescribe the appropriate course of medical intervention. All medical assessments, evaluations and treatment shall be documented in the client record; and

4. Opioid treatment: The governing authority shall designate a medical director and medical services shall be provided on-site. A physician shall document the provision of an initial evaluation of each client and shall prescribe the appropriate medication dosage. All medical assessments, evaluation and treatment shall be documented in the client record.

10:161B-7.2 Designation of medical director

The governing authority shall designate a physician to serve as medical director for outpatient detoxification and opioid treatment programs, and who meets the qualifications to serve as medical director as noted in this chapter. The medical director shall designate, in writing, a physician to act in the absence of the medical director; information concerning this designation shall be shared with the governing authority. The medical director, or his or her designee, shall be available to the program at all times.

10:161B-7.3 Medical policies and medical staff bylaws

(a) The medical director, in conjunction with the medical staff, shall develop, implement and review annually, medical policies, including medical staff bylaws that shall be subject to the review and approval of the governing authority and the administrator, and are consistent with New Jersey laws and rules.

(b) The written medical policies and bylaws shall include, but need not be limited to, the following:

1. A plan for convening medical staff meetings that are documented by minutes;
2. A procedure for reviewing credentials and delinquent qualifications of medical staff, appointments and reappointments, evaluation of medical care, and the granting, denial, curtailment, suspension, or revocation of medical staff privileges;
3. Specifications for verbal orders, including who may give verbal orders and who may receive them;
4. A system for completion of entries in the client clinical records by members of the medical staff, including identification of a time limit for completion of the clinical record, which must not exceed 30 days following a client's last treatment or discharge;
5. For those programs serving pregnant women, and women and children, a plan for ensuring that the medical needs of the fetus, children and mothers are adequately assessed and met during treatment;
6. Identification of the program's quality assurance plan for medical services and how that plan will coordinate with the nursing quality assurance plan; and
7. Medical staffing patterns.

10:161B-7.4 Physician responsibilities

(a) Physicians who provide medical care to clients in an outpatient substance abuse treatment program shall be responsible for:

1. Ensuring the provision or documentation of a complete medical examination as required by N.J.A.C. 10:161B-9.1;
2. Ordering, interpreting and documenting medical screening tests, as appropriate;
3. Documenting all orders for medical services to be provided to the client, including frequency and type of treatment, therapies to be administered or coordinated, medications prescribed, and date of discharge for medical services;
4. Ensuring that all medical interventions are documented in the client's clinical record and also shared with the nursing staff; and
5. Ensuring that medical follow-up of all acute or chronic illnesses and conditions are entered in the client's treatment plan, and that referrals for medical services are completed during the client's treatment, or as part of the client's discharge/continuum of care plan, as appropriate.

(b) In programs that provide medical services on-site, the physician shall ensure that medical staff participate as part of the multidisciplinary treatment team, and shall document medical services provided in client progress notes.

SUBCHAPTER 8. NURSING SERVICES

10:161B-8.1 Provision of nursing services

(a) Nursing services shall be provided in licensed outpatient substance abuse treatment programs as follows:

1. Outpatient, intensive outpatient, and partial care programs are not required to provide nursing services in treatment facilities offering these services. Outpatient, intensive outpatient and partial care programs shall comply with (b) below.
2. Opioid treatment and opioid detoxification programs shall appoint a director of nursing services and shall provide nursing services on site. The director of nursing services or designee shall be on premises during normal business hours and whenever medications are being administered.
 - i. The designee for the director of nursing services shall be a registered professional nurse (RN).

(b) In OP, IOP, or PC facilities, where nursing services are not required and not provided, the substance abuse counselor to whom the client is assigned or another designated staff person identified by the director of substance abuse counsel-

ing services, shall obtain health related information from the client and shall record the information in the client record.

1. Health related information shall include, but not be limited to:

- i. Significant medical history;
- ii. Hospitalizations;
- iii. Treatments;
- iv. History of communicable disease;
- v. Most recent Mantoux test and results;
- vi. Risk of Hepatitis B and HIV exposure;
- vii. Pregnancies and sexually transmitted diseases; and
- viii. Any current symptomatology.

2. If the substance abuse counselor or another designated staff person determines that there is an indication for medical treatment or screening, the substance abuse counselor or another designated staff person shall coordinate referral for medical services as determined by a written protocol using either on-site or affiliated medical services. Resolution of health related problems shall be included as part of the comprehensive treatment plan and all referrals or treatment, and shall be documented in the client chart.

Administrative correction.
See: 41 N.J.R. 2658(a).

10:161B-8.2 Designation of director of nursing services

(a) Programs providing outpatient detoxification and/or opioid treatment shall designate, in writing, a registered professional nurse as the director of nursing services. A registered professional nurse shall be designated, in writing, to act in the absence of the director of nursing services.

(b) Every program that is required to provide nursing services shall designate a director of nursing services who shall be on the premises during normal business hours and whenever medications are being administered during the program's hours of operation.

10:161B-8.3 Responsibilities of licensed nursing personnel

(a) Nursing care needs of clients shall be assessed only by a registered professional nurse.

(b) All nursing services provided shall be documented in the client's clinical record, including, but not limited to:

1. The nursing portion of the client care plan, in accordance with policies and procedures;
2. Clinical notes;
3. Recording of medications administered, including:

- i. The name and strength of the medication;
- ii. The date and time of administration;
- iii. The dosage administered;
- iv. Method of administration;
- v. Adverse reactions and interventions if referred; and
- vi. Signature of the nurse who administered the medication or identification of the nurse by an entry code if a computerized clinical record system is used.

SUBCHAPTER 9. CLIENT ASSESSMENT AND TREATMENT PLANNING

10:161B-9.1 Client assessment

(a) An outpatient substance abuse 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. If the biopsychosocial assessment indicates that the client should be referred to another treatment program or level of care, the program shall coordinate the client's referral to another program. If transfer to another program or level of care is indicated, interim services at the client's current level of care shall be provided until the transfer is effected.

(b) In performing a biopsychosocial assessment, the program shall include the following:

1. The client's medical, alcohol, tobacco, and drug history, and interventions;

2. Clients in outpatient detoxification and opioid treatment programs shall receive a physical exam, in accordance with N.J.A.C. 10:161B-11.6(c);

3. Clients in outpatient, intensive outpatient and partial care facilities shall complete a comprehensive health history and symptom review and be referred as appropriate for primary medical care services including voluntary HIV

testing, hepatitis screening, tuberculosis (TB) testing, and mental health services;

i. No client seeking admission with potential symptoms of communicable diseases such as persistent coughing or fever shall be admitted to treatment without medical clearance;

4. The client's history of psychological and/or psychiatric treatment, which shall include previous admissions to psychiatric facilities, history of suicidal/homicidal ideation and attempts, outpatient psychiatric treatment, psychotropic medications; and assessments by a psychiatrist or other licensed mental health clinician for clients diagnosed with co-occurring mental health disorders;

5. The client's family and relationships, including relationships evidencing co-dependency and the client's current living situation;

6. A social assessment including any legal proceedings involving the client;

7. A recreational assessment that includes the client's interests and physical abilities and limitations; and

8. A vocational and educational assessment of the client's:

i. Current work or vocational skills, employment status and potential for improving those skills or developing new ones;

ii. Educational status and skills;

iii. Aptitudes, interests and motivation;

iv. Physical abilities and any handicaps or disabilities;

v. Relationships with co-workers and supervisors; and

vi. Current and prior work or school related problems, including but not limited to those related to substance abuse.

10:161B-9.2 Client treatment planning

(a) A client treatment plan shall be developed for every client based on the assessment of the client in accordance with N.J.A.C. 10:161B-9.1.

1. The program shall initiate the development of the client's treatment plan upon the client's admission, and shall enter the client's treatment plan in the client record at least after three visits following admission, not to exceed 30 days.

2. The facility shall address each problem, including problems requiring placement at the assessed level of care, and needs and strengths identified in the client assessment, within the client treatment plan through direct provision or

referral to appropriate services, and shall include at least the following:

i. Orders for medication, medical treatment and other services, including the type and frequency of contact, if applicable;

ii. Client substance abuse or dependence and a plan to reduce symptoms, severity and improve treatment outcomes;

iii. Integrated treatment of co-occurring mental health disorders, either on-site or through the coordination of treatment services with an appropriate mental health facility;

iv. The provision of vocational and educational services if needed, either onsite or by referral to community resources;

v. Client participation in self-help group meetings during treatment and after discharge from treatment;

vi. Family and social support services;

vii. The staff responsible for implementation of the treatment plan;

viii. Evidence of client participation in development and implementation of the treatment plan, including, but not limited to, dated signatures of the client as well as signatures of participating multidisciplinary team members;

ix. Long and short term goals with timeframes for achievement;

x. The assessment measures for determining the effectiveness of, and client satisfaction with, treatment or services, including assessments of client adherence to and engagement with treatment and recovery support services;

xi. The time intervals for review of the client's response to treatment or services; and

xii. Discharge/transfer plans.

(b) Practitioners in each of the services providing care to a client shall participate in the development of the client treatment plan.

(c) The client, and his or her family, if indicated and clinically appropriate, shall participate in the development of the client's treatment plan, including the discharge/transfer plan; such participation shall be documented in the client's clinical record.

1. If a physician or other licensed clinician documents in the client's clinical record that the client's participation in the development of the treatment plan is medically contraindicated, a member of the multidisciplinary team providing services to the client shall review the client's treatment plan with the client prior to implementation, and

shall document these activities in the client's clinical record.

2. If the family of a client does not agree to participate in treatment planning, the program shall document the attempt to engage the family as well as their refusal.

(d) The multidisciplinary team shall review the treatment plan and the client's progress at least every 90 days, with such review, and revisions, if any, documented in the client's clinical record in the first year with subsequent treatment plan reviews consistent with program policy.

(e) Results of random drug and alcohol screening shall be incorporated into therapeutic interventions and the treatment planning process.

SUBCHAPTER 10. SUBSTANCE ABUSE COUNSELING AND SUPPORTIVE SERVICES

10:161B-10.1 Provision of substance abuse counseling

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

(b) Programs shall maintain an average ratio of substance abuse counselors to clients on the basis of each program's daily census, as follows:

- 1. Outpatient: 1:35;
- 2. Intensive outpatient: 1:24;
- 3. Partial care: 1:12;
- 4. Outpatient detoxification: 1:24;
- 5. Opioid treatment Phase(s) I through III: 1:50, with no single counselor's caseload exceeding 1:35; and
- 6. Opioid treatment Phase(s) IV through VI: 1:50.

(c) The program shall provide each client education with respect to the disease of addiction; the client's diagnosis; alcohol, tobacco and other drug use; risk of exposure to AIDS and hepatitis; other health consequences of substance abuse; family issues related to substance abuse; and relapse prevention. Psycho-education shall also address the needs of clients with co-occurring disorders and issues such as, but not limited to, domestic violence, parenting and sexual abuse.

(d) Programs providing partial care services shall provide weekly family counseling sessions, and intensive outpatient and outpatient programs shall provide monthly family counseling sessions, unless clinically contraindicated or the client and/or their family members refuse to participate. Opioid treatment programs shall provide family counseling sessions

based upon the clinical determination of the multidisciplinary team.

(e) The program shall provide clients, and their family members, with information regarding the desirability of participating in self-help support groups and recovery support services, and shall provide literature about these resources to clients, and their families, including meeting schedules and locations.

(f) Group counseling sessions shall not exceed an average of 12 clients and shall not exceed 14 clients in any one session. This provision shall not apply to psycho-educational or family counseling sessions.

(g) Programs providing partial care services and intensive outpatient services shall provide clients with at least weekly individual counseling sessions; outpatient programs shall provide at least monthly individual counseling sessions, based upon determination of the multidisciplinary team. Opioid treatment programs shall provide individual sessions based upon, at a minimum, client phase of treatment per N.J.A.C. 10:161B-11.8. In addition to the minimum requirements listed in this subsection, providers should be prepared to increase frequency of individual sessions based upon clinical need.

10:161B-10.2 Director of substance abuse counseling services

Every program shall employ a director of substance abuse counseling services with the qualification and responsibilities specified in N.J.A.C. 10:161B-1.8.

10:161B-10.3 Supportive services

(a) Every program shall provide or coordinate the following services for each client as appropriate to the client's treatment plan:

- 1. Vocational and educational counseling and training;
- 2. Job placement for clients whose plans of care indicate a need for such services; and
- 3. Referral to legal services rendered by an attorney, licensed or otherwise authorized to practice law in New Jersey, when such services are related to the client's treatment.

(b) Every program shall provide support services in accordance with its client care policies governing financial arrangements as specified in N.J.A.C. 10:161B-6.2.

(c) Individuals responsible for providing or coordinating the provision of support services shall document the services provided or coordinated in the client's clinical record.

(d) The program shall maintain a directory of client referral resources, such as housing, child care and social services.

10:161B-10.4 Co-occurring services

(a) Programs providing treatment to clients diagnosed with co-occurring disorders shall have clearly written policies and procedures governing the integrated treatment (assessment, diagnosing and service provision) of individuals diagnosed with co-occurring disorders.

1. Policies and procedures shall include the qualifications of clinical and medical staff responsible for assessing and diagnosing clients with co-occurring disorders and providing treatment and medical services to clients diagnosed with co-occurring disorders.

2. The facility shall ensure that appropriate clinical supervision is provided to staff providing treatment and services to clients diagnosed with co-occurring disorders.

3. The facility shall develop policies and procedures for case consultation, coordination and, where appropriate, referral to mental health treatment services in order to ensure coordinated service provision.

4. The director of substance abuse counseling services and director of nursing services shall ensure that the client treatment plan addresses both the client's substance abuse and mental health disorders.

5. Only counselors possessing the appropriate qualifications may provide assessment and diagnosis of co-occurring addiction and mental illness. All services delivered to co-occurring clients must be supervised by staff whose credentials are equivalent to the director of substance abuse counseling, as noted in N.J.A.C. 10:161B-1.8(a).

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 prior to issuance of a license to operate an opioid treatment program under the outpatient substance abuse 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>. Revocation of certification by SAMHSA shall

constitute the immediate withdrawal of licensure approval to operate an opioid treatment program by DAS;

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>; 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>, as a Narcotic Treatment Program in accordance with N.J.A.C. 8:67, before administering or dispensing opioid agonist treatment medications;

4. Provide services which meet the Federal standards set by accrediting agencies contained in 42 CFR Part 8.12, as well as the more specific State requirements of this chapter;

5. Use only those opioid agonist treatment medications approved by the Food and Drug Administration for use in opioid treatment programs for the treatment of opioid dependence;

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>.

7. Meet all applicable local building, zoning and other codes for the siting of an opioid treatment program;

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

9. Opioid treatment programs providing detoxification shall, in addition, comply with the following:

i. Clients receiving short-term detoxification (that is, less than 30 days) shall receive services in accordance with N.J.A.C. 10:161B-12; and

ii. Clients receiving long-term detoxification (that is, 30 days to 180 days) shall receive all services for Phase I clients required by N.J.A.C. 10:161B-11.8 and 12.

10:161B-11.2 Staffing

(a) All opioid treatment programs shall have a medical director who shall be ASAM certified 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) All opioid treatment programs shall employ a full-time director of substance abuse counseling services who meets the qualifications of N.J.A.C. 10:161B-1.8.

(c) All opioid treatment programs shall employ a director of nursing services who meets the requirements of N.J.A.C. 10:161B-1.5.

(d) All opioid treatment programs shall employ counseling staff who meet the requirements of N.J.A.C. 10:161B-1.9(a)1. An opioid treatment program shall employ an adequate number of counseling staff to provide services in accordance with N.J.A.C. 10:161B-10.1(b), and as necessary to address the individualized needs of each client, including documented responses to changes in client status or failure to achieve treatment goals and outcomes.

(e) Only physicians, registered professional nurses, or licensed practical nurses (working under the on-site supervision of a registered professional nurse), pharmacists or other persons authorized under New Jersey statutes or rules may dispense or administer medications in a facility providing opioid treatment program services.

(f) A registered professional nurse shall be present onsite during every hour in which medication is administered. A registered professional nurse or licensed practical nurse shall be assigned to the medicating area to observe client status prior to medicating.

1. Clients observed or suspected of being under the influence of alcohol or other psychoactive drugs shall be assessed by the registered professional nurse or physician to determine the appropriateness of medicating.

2. If the registered professional nurse is administering medication on the medication line, an additional registered professional nurse is not required.

(g) An opioid treatment program shall employ adequate nursing staff to:

1. Monitor medication stations and client status;
2. Assist the medical director and other program physicians or advanced practice nurses in conducting initial physical examinations, and follow up examinations or nursing assessments;
3. Perform and document related nursing activities; and
4. Provide nursing progress notes in each client record on at least a quarterly basis.

10:161B-11.3 Multidisciplinary team

Clinical decisions regarding phase changes, take home privileges and other treatment issues shall be based on a multidisciplinary team review of each client. Documentation of the multidisciplinary team review with the recommended course of action shall be in the client's chart and include team members' signatures. The multidisciplinary team shall, at a minimum, consist of the medical director or physician, director of substance abuse counseling services, director of nursing services or program nurse, and the client's primary substance abuse counselor.

10:161B-11.4 Policies and procedures

(a) Opioid treatment programs shall develop and implement written policies and procedures to include the following:

1. Medication management, including:

- i. The responsibilities of the medical director, other physicians, and other health care professionals;
- ii. The role of physicians regarding admission, dosage, and discharge;
- iii. Establishing the initial and maintenance dose;
- iv. Unsupervised dosing;
- v. Emergency administration of medications;
- vi. Diversion control plan;
- vii. Medicating traveling clients; and
- viii. Safe storage practices for unsupervised medications to include the use of child-proof or child-resistant containers;

2. Drug-screening procedures including, but not limited to:

- i. Frequency of drug screening;
- ii. Ensuring respect for the clients during drug screening sample collection;
- iii. Testing, at a minimum, for opioids, methadone, amphetamines, cocaine, and benzodiazepines, and as appropriate, testing for drugs of choice as evidenced in evaluation and/or intake assessment;
- iv. Documentation of interpretation of the results, action taken, and treatment planning for positive results;
- v. Minimizing falsification during urine sample collection;
- vi. Medically oriented specimen-handling procedures; and
- vii. A procedure for addressing positive drug screening through the treatment planning process;

3. Other laboratory procedures;

4. Withdrawal procedures which shall address:

- i. Voluntary, medical withdrawal;
- ii. Withdrawal against medical advice;
- iii. Involuntary administrative withdrawal;
- iv. Referral and discharge;

(1) Policies for voluntary and involuntary discharge, which shall address the criteria for discharge, including the provision of assistance in transferring the client to another opioid treatment program or withdrawing the client from methadone or other approved medication prior to discharge;

(A) Program discharge policies shall be shared with the client at admission and shall be part of the client's rights statement provided to and signed by the client at admission;

(2) The discharge policy shall address the discharge of non-compliant clients based on failure to attend counseling sessions, repeated positive urines, missed days or behavior jeopardizing the health, safety or welfare of other clients and/or staff;

(3) Except as provided for by the provisions of Phase I-A (see N.J.A.C. 10:161B-11.8(b)7), the discharge policy shall address the discharge of clients who are not progressing in treatment despite documented efforts by the opioid treatment programs to intensify treatment services and refer the client to supplemental treatment services or other outpatient or residential opioid treatment programs; and

(4) Policies shall provide that no client maintained on methadone or other approved medications shall be discharged from an opioid treatment program without facilitating admission to another opioid treatment program or being withdrawn from the opioid agonist medication prior to discharge;

v. Policies for withdrawal of clients from methadone, which shall include the following:

(1) The dosage of methadone may not be reduced faster than 10 milligrams (mg) every two days, except a client receiving more than 100 mg per day may be reduced up to 20 percent of the starting dose every two days until the client is at 100 mg or less: thereafter, the dosage may be reduced no more than 10 mg every two days.

(2) Pregnant women shall not be voluntarily or involuntarily withdrawn from methadone during the duration of the pregnancy except for medical necessity as determined by the medical director.

(3) If determined to be medically necessary by the medical director or facility's physician, clients con-

tinuing to use illicit drugs may be reduced at a rate faster than described above in (a)4v(1) above.

(4) Clients who must be removed from the program in response to threats or acts of violence against staff or other clients shall be transferred to another opioid treatment program if considered appropriate, or provisions shall be made to withdraw the client from the opioid agonist medication either at the opioid treatment program or at another facility. If the client does not appear at the opioid treatment program or alternate medication site or creates a security disturbance at the opioid treatment program or alternate site, the program shall document the incident in the client's record and the program's responsibility for providing medically supervised withdrawal services shall be considered fulfilled;

5. Emergency medical procedures;
6. Program contingency procedures; and
7. Critical incidents and threats.

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

(a) Opioid treatment programs shall give preference for admission to pregnant women, intravenous (IV) drug users, and individuals who are HIV-positive.

(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. The client record shall document a DSM-IV-TR 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-2R.

10:161B-11.6 Admissions and assessment

(a) In addition to meeting the eligibility criteria for admission, a client admitted to an opioid treatment program shall receive a biopsychosocial assessment in accordance with N.J.A.C. 10:161B-9.1(a).

(b) Drug screening shall be analyzed, at a minimum, for opioids, methadone, cocaine, amphetamines, and benzodiazepines, and, as appropriate, for drugs of choice as evidenced in evaluation and/or intake assessment. Screening for alcohol, marijuana and other drugs shall be conducted based on individual and/or community drug use patterns in accordance with program policy established by the multidisciplinary team. Positive drug screens for other substances shall be documented in the client's case record and an appropriate clinical intervention will occur.

(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. Serological test for syphilis and testing for other sexually transmitted diseases as medically indicated;
 2. Mantoux tuberculin skin test at admission and annually thereafter and chest x-ray if medically indicated. Testing shall be provided in accordance with the Tuberculosis Surveillance Procedures for Substance Abuse Treatment Facilities (SATFs), incorporated herein as chapter Appendix A;
 3. Urine or other approved screening to identify drug use;
 4. Routine and microscopic urinalysis;
 5. Complete Blood Count (CBC);
 6. SMA 12 or comparable screening;
 7. Pregnancy test for women;
 8. Screening for Hepatitis C and Hepatitis B surface antigen and antibody is highly recommended but not required;
 9. All clients shall receive HIV pre-test counseling, and shall be offered HIV testing onsite or at a DHSS/Division of HIV/AIDS 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. Mental health status evaluation to include previous psychiatric admissions, and a history of suicidal ideation, outpatient psychiatric treatment, psychotropic medications and, when clinically indicated, an assessment by a psychiatrist or other licensed clinician of clients diagnosed and identified as having a co-occurring mental health disorder.
- (d) If the client submits documentation of the testing in (c) above performed within 30 days of admission, those tests need not be repeated with the exception of the drug screening and pregnancy testing.
- (e) Clients re-entering an opioid treatment program after discharge shall be examined by the physician, screened for drugs and pregnancy, tested for tuberculosis (if it has been 12 or more months since the previous test), and offered HIV counseling and testing.
- (f) The client assessment shall include information on the client's educational and vocational needs. Unemployed persons and others determined to be in need of educational and/or vocational assistance shall be provided services in the opioid treatment program, or shall be referred to appropriate resources within the community. Such referrals shall be doc-

umented in the client record and addressed in the treatment plan.

(g) Clients shall receive education and counseling regarding the behavioral risk factors for transmission of HIV and hepatitis B and C, screening tests and available treatment.

(h) If the opioid treatment program does not provide primary medical care services to its clients including prenatal care, it shall ensure that appropriate referrals are made for prenatal care, other medical and mental health services. This shall be based on findings of the physical examination or as identified during the course of maintenance treatment. Documentation of referrals, follow up, and coordination of care shall be contained in the client record.

10:161B-11.7 Medical assessments

(a) In all years after the year of admission to an opioid treatment program, a client shall receive either an annual physical examination by a program physician or other licensed independent practitioner under New Jersey statutes, or an annual nursing assessment by a registered professional nurse according to a protocol established by the facility's medical director.

(b) Clients shall be referred to or provided additional medical services, as indicated by the physical examination or nursing assessment. Documentation of physical examinations or nursing assessments, as well as referrals and follow up, shall be included in the client record.

(c) When medically indicated, the opioid treatment program shall attempt to obtain written authorization from the client authorizing program medical staff to coordinate medical care with the client's primary care provider, if different than the opioid treatment program. Client refusal shall also be documented in the client's clinical record.

(d) All clients must have access to a program physician or a registered nurse for an appointment or telephone consultation within 72 hours or three business days of making a medically appropriate request. Documentation of the client's request shall be placed in the client's file.

10:161B-11.8 Counseling services

(a) As part of a multidisciplinary team approach, an opioid treatment program shall provide counseling services in accordance with N.J.A.C. 10:161B-10.1.

(b) All opioid treatment programs shall provide counseling services, at a minimum, in accordance with the Phase schedule set forth below. Clients shall be considered for movement from one phase to another when the multidisciplinary team review has determined that the client has progressed in treatment and meets the following criteria:

1. For Phase I: Upon admission.

i. The client shall receive at least one counseling session per week with at least one individual counseling session per month, a total of four counseling sessions per month;

ii. A client shall be considered for Phase II based upon the review, recommendation and documentation of the multidisciplinary team after three consecutive months of negative drug screenings and compliance with other criteria established by the program; and

iii. Minimum duration of Phase I shall be three months if all drug screening results are negative; re-assessment shall take place at this time.

2. For Phase II:

i. The client shall receive at least two counseling sessions per month, including at least one individual counseling session;

ii. A positive drug screening shall result in an immediate clinical intervention, which shall be recorded in the client record;

iii. A second positive drug screening within a 90-day period shall result in a return to weekly counseling until at least one month of negative drug screenings, at which point the multidisciplinary team would determine the frequency of the counseling and the take home schedule based on the stability of the client;

iv. A client shall be considered for Phase III based upon the review, recommendation and documentation of the multidisciplinary team when he/she has had a total of six consecutive months of negative drug screening results in Phase II and is in compliance with other criteria established by the program; and

v. Minimum time in Phase II is six months if all drug screening results are negative.

3. For Phase III:

i. The client shall receive at least one individual counseling session per month;

ii. A positive drug screening shall result in an immediate clinical intervention, which shall be recorded in the client record;

iii. A second positive drug screening within a 90-day period shall result in a return to weekly counseling until at least one month of negative drug screenings, at which point the multidisciplinary team would determine the frequency of the counseling and the take home schedule based on the stability of the client;

iv. A client shall be considered for Phase IV based upon the review, recommendation and documentation of the multidisciplinary team when he/she has had nine consecutive months of negative drug screening results in

Phase III and is in compliance with other criteria established by the program; and

v. Minimum time in Phase III is nine months if all drug screening results are negative.

4. For Phase IV:

i. Based upon the review, recommendation and documentation of the multidisciplinary team, the client shall receive a minimum of one individual counseling session every three months;

ii. A positive drug screening shall result in an immediate clinical intervention, which shall be recorded in the client record;

iii. A second positive drug screening within a 90-day period shall result in a return to weekly counseling until at least one month of negative drug screenings, at which point the multidisciplinary team would determine the frequency of the counseling and the take home schedule based on the stability of the client;

iv. A client shall be considered for Phase V based upon the review and recommendation of the multidisciplinary team when he or she has had six months of negative drug screening results in Phase IV and the multidisciplinary team has determined that the client has progressed in treatment and meets program criteria for promotion; and

v. Minimum time in Phase IV is six months if all drug screening results are negative.

5. For Phase V:

i. Clients who have had 24 consecutive months of negative drug screening results and meet other program criteria for treatment progress shall receive counseling services at a frequency determined by the multidisciplinary team and program policy;

ii. A positive drug screening shall result in an immediate clinical intervention, which shall be recorded in the client record; and

iii. A second positive drug screening within one year shall result in a return to weekly counseling until at least one month of negative drug screenings, at which point the multidisciplinary team would determine the frequency of the counseling based on the take home schedule on the stability of the client.

6. For Phase VI:

i. Clients who have had 36 consecutive months of negative drug screening results and meet other program criteria for treatment progress shall receive counseling services consistent with the clinical needs of the client and the documented recommendation of the multidisciplinary team;

ii. A positive drug screening shall result in an immediate clinical intervention, which shall be recorded in the client record;

iii. A second positive drug screening within one year shall result in a return to weekly counseling until at least one month of negative drug screenings, at which point the multidisciplinary team would determine the frequency of the counseling and the take home schedule based on the stability of the client; and

iv. Clients in this phase may be eligible for clinic based medical maintenance and may be provided up to 30 take home doses of medication based upon the documented recommendation of the multidisciplinary team. Opioid treatment programs electing to provide clinic based medical maintenance shall comply with the provisions of this rule, N.J.A.C. 10:161B-11.15.

7. For Phase I-A:

i. Clients in Phase I, for a period of at least 12 months, who have failed to progress in treatment despite documented efforts by the opioid treatment program to intensify treatment services and where referral to supplemental treatment services or a residential program is not available, may be retained in treatment at a lesser level of service designated as Phase I-A in accordance with the following:

(1) The opioid treatment program can document a multidisciplinary team case conference that determines a substantial identifiable benefit exists to the client and/or the general public that supports retaining the client in treatment despite the client's continued lack of progress in treatment;

(2) An opioid treatment program's decision to retain a client in Phase I-A shall be based on a benefit to the client and/or general public which is documented in the client record and supported in writing by the counselor, director of substance abuse counseling, director of nursing services and medical director; and

(3) Written documentation of alternative treatment (that is, IOP, residential, hospitalization, etc.) options explored by the program shall be included, along with reasons why these options are inappropriate (that is, not available in area, etc.).

ii. Clients designated as Phase I-A shall receive at least two counseling sessions per month, including one individual counseling session, and shall receive at least one monthly drug screening; and

iii. The multidisciplinary team shall review and document the status of clients designated in Phase I-A on a quarterly basis.

10:161B-11.9 Drug screening

(a) Random drug screening shall be conducted on varied days and weeks of the month to detect, at a minimum, the presence of opioids, methadone, cocaine, amphetamines, and benzodiazepenes. Screening for alcohol, marijuana and other drugs shall be conducted based on individual and/or community drug use patterns in accordance with program policy established by the multidisciplinary team.

(b) Random drug screening to identify continued drug abuse shall be conducted every two weeks until the client has maintained drug-free screening results for three consecutive months, after which time random drug screening shall be performed at least monthly. A positive drug screening for drugs other than methadone during any phase of treatment shall require resumption of a sampling schedule as determined by the multi-disciplinary team. The opioid treatment program shall respond to continuing positive drug screening results for drugs other than methadone by documentation in the client's chart of more intensive treatment interventions, or referral to another treatment provider including residential treatment.

(c) Clients in clinic based medical maintenance, Phase VI, shall receive monthly drug screening and an additional two special call backs in the first year with subsequent call backs as delineated by program policy for determining client responsibility in handling extended take-homes and drug screening at the time of the special call backs.

(d) Prescription drug use identified by drug screening shall be considered a positive drug screening result if the client: has not provided documentation from the prescribing physician that the client is under care for a diagnosed medical condition; refuses to sign a release authorizing the opioid treatment program to contact the prescribing physician; or has not documented to the opioid treatment program that the physician is aware that the client is on methadone. Such documentation shall be reviewed and approved in writing by the medical director or opioid treatment program physician.

(e) Client acknowledgement of drug use shall void the necessity of drug testing, shall be considered a positive drug screening, and shall result in appropriate actions as described above.

10:161B-11.10 Eligibility for take-home medication

(a) The multidisciplinary team shall utilize the criteria outlined in the Federal standards set by accrediting agencies at 42 CFR Part 8.12, in determining whether or not a client is eligible to receive take home medication and meets all the eligibility criteria.

1. Any client in an opioid treatment program receiving comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

i. The facility shall make arrangements to provide the clinically appropriate take-home dose should the facility remain closed for business, on a non-emergency basis, for more than one day. This provision shall have been approved by the medical director, reviewed by the treatment team, and supported by documentation in the client record.

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>)) 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-11.12 Take-home medication dosage schedule

(a) An opioid treatment program shall develop and implement written policies and procedures consistent with this chapter and all applicable Federal regulations addressing the following issues:

1. A client meeting the standards set by accrediting agencies for consideration of take-home medication may be permitted take-home medication in accordance with the following schedule based upon the review and documented approval by the multidisciplinary team:

i. For six-day programs, on admission—one daily take-home dose;

ii. For all programs, after three consecutive months of negative drug screens—one to two daily take-home doses;

iii. After an additional three consecutive months, or a total of six consecutive months of negative drug screens—three daily take-home doses;

iv. After an additional three consecutive months or a total of nine consecutive months of negative drug screens—four daily take-home doses;

v. After an additional three consecutive months, or a total of 12 consecutive months of negative drug screens—five daily take-home doses; and

vi. After an additional six consecutive months or a total of 18 consecutive months of negative drug screens—six daily take-home doses.

2. A client determined not to be eligible to receive take-home medication during any phase of treatment shall have take home medication eligibility revoked until such time as the multidisciplinary team determines and documents that take-home medication may be restored in accordance with the provisions of this subchapter.

(b) Positive drug screening results will delay the timeframe for obtaining take-home medications beyond that listed in (a) above. A client must have three consecutive months of negative drug screenings before receiving each additional take-home dose except that six months are required between the fifth and sixth daily take-home doses.

(c) Clients who have had no positive drug screening results within the last 24 consecutive months and meet all other criteria for take-home eligibility, may be eligible for extended take-home medication as set forth in N.J.A.C. 10:161B-11.13.

(d) Clients receiving six or fewer daily take-home doses of medication in accordance with the schedule in (a) above, who have a positive drug screening result, shall receive a documented verbal and written warning that a second positive drug screening within 90 days shall result in the loss of all weekday take-home medications. In addition, counseling contacts and the frequency of urine screening shall be increased in accordance with the provisions of this subchapter and program policy.

(e) Clients receiving six or fewer daily take-homes who have two positive drug screens within any 90-day period shall result in the revocation of all weekday take-home bottles pending review and documentation by the multidisciplinary team and an increase in drug screening frequency to two times per month. Restoration of weekend take-home medication shall be at the documented discretion of the multidisciplinary team. The multidisciplinary team may restore two additional take-home doses for each additional month of negative drug screening results. The multidisciplinary team, with the approval of the medical director, may make exceptions to the 90-day period when clinically indicated and documented.

(f) Loss of take-home medication privilege shall result in a reduction in a phase of treatment according to program policy.

10:161B-11.13 Extended take-home medications

(a) Clients in opioid treatment programs who have 24 and 36 consecutive months of stability in treatment, and who have been determined and documented as eligible by the multidisciplinary team, may be approved for extended take-homes as follows:

1. A Phase V client who has had no positive drug screening results within the last twenty-four consecutive months may be permitted up to a 14-day supply of take-home medication, provided the client meets the criteria for stability and functioning contained in the standards set by accrediting agencies as determined and documented by the multidisciplinary team.

2. A Phase VI client who has no positive drug screening results within the last 36 consecutive months may be permitted up to a 30-day supply of take-home medication, provided the client meets the criteria for stability and functioning contained in the standards set by accrediting agencies as determined and documented by the multidisciplinary team.

3. Clients receiving up to 14 or up to a 30-day supply of daily take-home doses who have a positive drug screen shall be assessed by the multidisciplinary team. This shall be documented and shall include a medication call back, drug screen and appropriate clinical interventions, which shall be documented in the client record. Any client who has been determined to have mishandled take-home medication shall no longer be eligible for take-homes until he or she has again met the initial criteria for take-homes, and been reviewed and approved by the multidisciplinary team.

4. Clients on extended take-homes who have had two positive drug screenings within a 12-month period shall no longer be eligible for extended take-homes. Extended take-homes may be restored when the client has had 12 consecutive months of negative drug screening results and the multidisciplinary team has reviewed his or her progress in treatment and has recommended restoration of extended take-homes. Following restoration of extended take-homes, a positive drug screen shall result in the removal of extended take-homes until the client has had 12 consecutive months of negative drug screening results and been approved by the multidisciplinary team for reinstatement of extended take-homes. If the two positive drug screenings are within 90 days, all weekday take-homes shall be removed in accordance with N.J.A.C. 10:161B-11.12.

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, at 609-292-3816.

10:161B-11.15 Clinic based medical maintenance

(a) An opioid treatment program may elect to provide on-site clinic based medical maintenance services to Phase VI clients under the care of a licensed opioid treatment program physician according to program policy and the provisions of this chapter.

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

1. Submit a written notice to DAS 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. Provide written assurance that counseling services, drug screenings and ancillary services will be provided as needed in accordance with this chapter;

3. Provide written assurance that the opioid treatment program can demonstrate internal protocols for reviewing client eligibility for clinic based medical maintenance utilizing a multidisciplinary team approach to minimally include: the program's medical director, director of substance abuse counseling, director of nursing services and the client's counselor;

4. Have been licensed and approved by all State and Federal authorities to operate an opioid treatment program for at least two years;

5. Be in substantial compliance with all State and Federal rules and regulations governing opioid treatment programs including this chapter and standards set by accrediting agencies;

6. Ensure that all clients in Phase VI designated for clinic based medical maintenance who are receiving monthly take-homes are seen monthly by the designated program physician;

7. Ensure that clients in clinic based medical maintenance receive monthly drug screening and an additional two special call backs in the first year, with subsequent call backs as determined by program policy for determining client responsibility in handling extended take-homes and drug screening at the time of the special call backs; and

8. Ensure that clients in clinic based medical maintenance with a positive urine screening result shall be assessed by the physician, in consultation with the multidisciplinary team, to determine if the client has been responsible in handling take home medication, and can be retained in medical maintenance based on an assessment of

other client factors for stability. The physician shall refer the client for counseling in accordance with the provisions of this subchapter. Clients determined to have not been responsible in handling extended take-home medication shall be removed from clinic based medical maintenance. A second positive urine screening within 12 months shall result in the client being removed from clinic based medical maintenance and returned to the general program.

(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 to cease clinic based medical maintenance services and extended take-homes.

(d) With the approval of the multidisciplinary team, those clients who are in Phase VI and eligible for up to 30 days of take-home medication may participate in a clinic based medical maintenance program, if they have been in compliance for 36 months, with the following provisions:

1. Clients shall be physically and emotionally stable;
2. Clients shall be free of alcohol and drug abuse as verified by monthly drug screening;
3. Clients shall not have been convicted of or known by program staff to be involved in any criminal activity for 36 months;
4. Clients shall be employed, in a similar capacity (that is, student, homemaker), or disabled, as well as living in a stable environment; and
5. Clients shall have demonstrated responsible use of take home medication.

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 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 Buprenorphine Guidelines, Administrative Bulletin 2007-03, incorporated herein as chapter Appendix B.

10:161B-11.17 Emergency phone coverage

An opioid treatment program shall provide emergency telephone coverage by a designated staff member or by other arrangements or agreement 24 hours per day, seven days a week, to respond to clients in crisis, verify client dose levels, etc.

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 treatment programs approved by DAS 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, Level I-D or II-D.

10:161B-12.2 Staff qualifications

(a) Programs providing outpatient detoxification services shall meet the following staffing requirements:

1. Outpatient detoxification services shall be under the direction of a medical director who meets the requirements set forth in N.J.A.C. 10:161B-1.4, and who can demonstrate at least two years of direct experience in the provision of detoxification services.

2. If the program employs physicians under the direction of the medical director, such physicians shall not be required to be ASAM-certified but shall meet the experiential requirements of two years of direct experience providing detoxification services, and shall be supervised by the medical director.

3. If the program elects to employ advanced practice nurses (APNs) or physician assistants (PAs) to supplement the services of the medical director or other physicians, such practitioners shall operate in accordance with all applicable State statutes and rules. APNs and PAs shall be required to have at least two years of direct experience in the treatment of substance abusing and dependent individuals, including the provision of detoxification services.

4. A registered professional nurse shall be on duty at the program during all hours of operation when clients being detoxed are present. The registered professional nurse shall have specific training and experience in substance abuse treatment, including detoxification services. The registered professional nurse shall assess each client daily, seven days a week, including assessment of withdrawal symptoms using established written protocols, vital signs and drug screening in accordance with program policies. If the program administers medication onsite, the registered professional nurse shall reassess vital signs and withdrawal symptoms prior to the client's departure.

5. The program shall employ a director of substance abuse counseling who meets the qualifications set forth in N.J.A.C. 10:161B-1.8.

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. Priority admission for detoxification services shall be given to pregnant women and individuals who are HIV positive.

10:161B-12.4 Required services

(a) All outpatient programs providing detoxification services shall, at a minimum, provide the following services:

1. Biopsychosocial assessment, including physical examination upon admission, meeting the criteria at N.J.A.C. 10:161B-9.1(a) and (b), using a recognized assessment instrument and level of care determination to ensure appropriateness of a client to receive detoxification services in an outpatient setting, including the availability of emotional support, transportation and a supportive home environment. Women of childbearing age shall receive a pregnancy test as part of admission testing;

2. Clients requiring extended on-site monitoring shall participate in the intensive outpatient or partial care programs as soon as medically able. Participation in the intensive outpatient programs or partial care and other appropriate aftercare services shall be included as part of the client treatment agreement for outpatient detoxification services. The program shall make every effort to engage clients in continued services following discharge from, or completion of, detoxification. Such efforts shall be clearly documented in the client's clinical record;

3. Clients receiving outpatient detoxification services without extended on-site monitoring shall participate in a treatment activity such as individual, group or family counseling, educational sessions or self-help meetings during each day of the detoxification. Participation in these services and other appropriate aftercare services shall be included as part of the client treatment agreement for outpatient detoxification services. The program shall make every effort to engage clients in continued treatment services following discharge from or completion of detoxification. Such efforts shall be clearly documented in the client's clinical record;

4. Referral and linkages with other providers and services as indicated;

5. Twenty-four (24) hour access to a nurse on call for clients and family;

6. Treatment services shall be under the direction of a director of substance abuse counseling who meets the requirements of N.J.A.C. 10:161B-1.8;

7. Daily medical supervision of withdrawal, including monitoring of withdrawal symptoms and vital signs, shall be provided by the program nurse, physician, advanced practice nurse or physician assistant;

8. Clients shall receive or be prescribed only a one-day supply of medication for detoxification unless there is a documented medical or other reason why a second day of medication is prescribed or dispensed, except in the case of opiate detoxification using methadone where no take-home medication is permitted;

9. Programs approved to provide outpatient detoxification services should be operational every day of the week during which clients are receiving detoxification services;

10. Programs shall strongly encourage the participation of clients in self-help groups such as Alcoholics Anonymous (AA) and Narcotics Anonymous (NA);

11. The outpatient detoxification program shall be in compliance with all applicable standards in this chapter; and

12. Drug screening shall be conducted at least weekly during the detoxification period in addition to the admission screening.

(b) DAS 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 treatment programs approved by DAS to provide outpatient detoxification shall establish policies and procedures which are consistent with the ASAM Patient Placement Criteria-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>), and acceptable medical treatment practices within the disciplines providing client services for the following:

1. Medical assessment including physical examination;
2. Admission and exclusionary criteria;
3. Client consent/treatment agreement;
4. Drug specific detoxification protocols including, but not limited to, the following:
 - i. Withdrawal assessment instrument(s) used;
 - ii. Medications used to include purpose, frequency of administration and effectiveness; and
 - iii. Frequency of monitoring of vital signs to include pulse, respiration, blood pressure and temperature;
5. Alcohol and drug screening;

6. Staffing;
7. Hours of operation;
8. Emergencies;
9. Discharge criteria; and
10. Measuring treatment outcomes.

(b) The policies and procedures shall address each class of drugs (for example, alcohol, opiates, stimulants, depressants etc.) for which detoxification services are offered, and shall be developed with the involvement of the treatment team, including the medical director, advanced practice nurses or physician assistants if utilized, nursing staff, the facility's director of substance abuse counseling services and counseling staff.

SUBCHAPTER 13. LABORATORY SERVICES

10:161B-13.1 Provision of laboratory services

(a) The outpatient substance abuse 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, 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. The facility shall establish and implement policies and procedures for obtaining, identifying, storing and transporting laboratory specimens.

(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 and incorporated herein as chapter Appendix A.

SUBCHAPTER 14. PHARMACEUTICAL SERVICES

10:161B-14.1 Provision of pharmaceutical services

(a) Any outpatient substance abuse 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. Work with the Pharmacy and Therapeutics Committee or Client Care Policy Committee, if established by the facility, in developing policies and procedures for the delivery of quality pharmaceutical services to clients of the program;

- i. In instances where a client care policy committee is not established, such policies shall be consistent with the client care policies as required at N.J.A.C. 10:161B-6.

2. Bi-annually inspect all areas of the facility where medications are dispensed, administered, or stored according to an inspection policy and procedure, which shall require the pharmacist(s) to maintain a written record of each inspection;

3. Compound medications, if applicable;

4. Be accountable for all medications including verification of medication stock and medication dispensed;

5. Participate in the planning and budgeting for pharmacy services;

6. Coordinate and integrate pharmacy services with other client care services to provide a continuum of care;

7. Assist in the development of job descriptions and assignment of duties to pharmacy personnel, if any; and

8. Maintain all records of all pharmaceutical services transactions, including a record system for requisition and distribution of pharmaceutical supplies.

(b) Any program that administers or dispenses medication to clients shall establish a process for providing staff responsible for the administration of the medications with cautionary instructions and additional information as applicable to the medications to be administered or dispensed.

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. Methods for procuring medications on a routine basis, in emergencies and in the event of disaster;

2. Acceptable methods for ordering medications, consistent with the following:

- i. Orders shall be in writing, and shall specify the name and strength of the medication, dose, frequency and route of administration;

- ii. Orders shall be signed and dated by the prescriber;

- iii. Verbal orders shall be written on the chart when given and countersigned within 72 hours of the original order and provide the information required in (a)2i and ii above; and
 - iv. Special requirements for prescribing or dispensing controlled drugs shall be noted on the prescription and in the client's clinical record;
3. Administration of medication, including establishment of the times for administration of medication prescribed;
 4. If the program permits it, self-administration of medication, including:
 - i. A prohibition on self-administration of medication except upon a written order of the prescriber;
 - ii. Storage and labeling of medications including directions for use and appropriate cautionary and/or warning messages;
 - iii. Methods for documenting self-administration of medication in the client's clinical record;
 - iv. Training and education of clients in self-administration and the safe use of medications; and
 - v. Establishment of precautions against clients sharing their medications with one another;
 5. Procedures for documenting and reporting adverse medication reactions, medication errors, and medication defects, subject to the following:
 - i. Allergies shall be documented in the client's clinical record and on its outside front cover; and
 - 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>, incorporated herein by reference, as amended and supplemented;
 6. If the program permits it, use of over the counter floor stock medications approved as set forth on a list maintained at the facility, and the amounts that may be stocked throughout the facility;
 7. Discontinuation of medication orders, including:
 - i. The length of time medication orders may be in effect, for medications that are not specifically limited as to duration of use or number of doses when ordered, including intravenous infusion solutions; and
 - ii. A process for notifying the prescriber prior to the expiration of a medication order in accordance with the written policy of the program, to ensure that the medication for the specific client is discontinued if no specific renewal is ordered.
 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>, and N.J.S.A. 24:21-1 et seq.;
 9. Standards for the procurement, storage, use and disposal of needles and syringes in accordance with the State laws, and a system of accountability which shall not require counting of individual needles and syringes after they are placed in a container for disposal;
 10. Standards for the control of medications subject to N.J.S.A. 24:21-1 et seq., consistent with N.J.A.C. 13:39 and other applicable Federal and State laws, including:
 - i. Provisions for a verifiable record system for controlled medication;
 - ii. Procedures to be followed when inventories of controlled medications cannot be verified and medications are lost, contaminated, and/or unintentionally wasted or destroyed, which shall include a written report of the incident signed by the individuals involved and any witnesses; and
 - iii. Procedures for the intentional wasting of controlled medications, including the disposal of partial doses, which shall include written documentation of the event signed by the individual responsible and the individual assigned to witness the event;
 11. Maintenance of a record of each prescriber's Federal Drug Enforcement Administration (DEA) number and New Jersey Controlled Dangerous Substance (CDS) number;
 12. Data to be maintained within each program, including:
 - i. A list of abbreviations, metric conversion charts and chemical symbols, subject to approval by the medication staff;
 - ii. A current Physician's Desk Reference (PDR), or other current medical reference materials that contains specific information on medications and other drugs, including indications, contraindications, actions, reactions, interactions, cautions, precautions that should be taken, toxicity, and dosages; and
 - iii. Antidote information and the telephone number of the New Jersey Poison Information and Education System at 1-800-POISON-1;
 13. The program shall have access to all current applicable Federal and State laws, regulations and information concerning all medications used in the facility; and
 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>.

10:161B-14.3 Standards for storage of medications

(a) The program shall keep all medications and intravenous solutions in locked storage areas, stored in accordance with manufacturer's instructions at or near the nursing unit(s).

1. The program shall store all medications that require refrigeration in a locked box within a refrigerator, in the locked medication room, at temperatures that conform to United States Pharmacopoeia requirements of 36 to 46 degrees Fahrenheit.

2. The program shall store all scheduled medications separate from non-scheduled medications unless unit dose.

3. The program shall keep all medications for external use separate from medications for internal use.

(b) The program shall keep all medication storage and preparation areas locked when not in use, and comply with applicable State and Federal storage procedures for storing, preparing and subsequent distribution or destruction of such medications.

SUBCHAPTER 15. EMERGENCY SERVICES AND PROCEDURES

10:161B-15.1 Emergency plans and procedures

(a) The outpatient substance abuse 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;

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

2. Locations of emergency equipment and alarm signals;

3. Evacuation routes;

4. Client evacuation protocols;

5. Identification of one or more facilities to which clients would be referred in the event of extended closure of the facility, including mental health and medical services in clinically indicated;

6. Protocol for reentry after evacuation;

7. Tasks and responsibilities assigned to all personnel and identification of the person in the facility designated to coordinate emergency activities;

8. Protocols for removal, storage and return of records, medications, supplies and equipment after evacuation; and

9. Alternative plans if clients cannot be returned to the facility.

(c) The facility shall conspicuously post throughout the facility a written evacuation diagram that includes evacuation procedures as well as location of fire exits, alarm boxes, and fire extinguishers.

(d) The facility shall provide training for all employees in emergency procedures to be followed in the event of a fire, and other emergencies other than fire, including use of fire-fighting equipment and client evacuation, as part of initial orientation and at least annually thereafter.

10:161B-15.2 Drills, tests and inspections

(a) The facility shall conduct and document drills of emergency plans annually and as follows:

1. On an annual basis, fire emergency drills shall be conducted at least quarterly during each of two shifts (eight drills per annum);

2. On an annual basis, emergency disaster drills other than fire, that is, hurricane, natural disasters, bomb threat, loss of water, loss of power, radiological, biological or chemical incidents, shall be conducted at least quarterly (four drills per annum); and

3. The facility shall maintain documentation of all drills, including the date, hour, description of the drill, participating staff, and signature of the person in charge of the drill.

(b) The facility shall perform quarterly tests of the building's manual pull alarm system and shall maintain documentation of test dates, locations of manual pull alarms tested, individuals testing the alarms, and results of the tests.

(c) The facility shall annually examine its fire extinguishers and maintain or replace them in accordance with manufacturer's requirements, National Fire Protection Association (NFPA) 10, 2002 edition, as amended and supplemented, incorporated herein by reference; N.J.S.A. 52:27D-198, the Uniform Fire Safety Act; and N.J.A.C. 5:70, the New Jersey Uniform Fire Code. NFPA publications are available from the NFPA, One Battery March Park, P.O. Box 9101,

Quincy, MA 02269-9101, 1-800-344-3555, <http://www.nfpa.org>.

(d) The facility shall conduct the following inspections:

1. Monthly testing of emergency lighting;
2. Semi-annual inspection of the fire detection system;
3. Semi-annual inspection of the automatic sprinkler system, if applicable;
4. Annual fire inspection by the local fire code authority;
5. Annual elevator inspection in accord with N.J.A.C. 5:23-12.3, Elevator safety subcode, Reference Standard ASME A17.1-96; and
6. Annual inspection of the heating and ventilation system.

(e) The facility shall document the results of all inspections, including:

1. Documentation of the test date;
2. The location of the system or requirement tested;
3. The name and title of the individual conducting test; and
4. The result of the test.

10:161B-15.3 Emergency medical services

(a) The facility shall establish written policies and procedures that are reviewed annually and revised as needed, for the provision of emergency services based on the types of clients typically treated at the program, including policies and procedures regarding emergency kits and emergency carts, if applicable.

1. The facility shall be able to respond to medical emergencies occurring on-site during its hours of operation.
2. The facility shall make provision for emergency transportation to, and emergency medical services at, a nearby hospital.
3. The facility shall specify the locations, contents, frequency of review, expiration date, and staff assigned to review emergency kits and emergency carts, as applicable, and shall ensure that emergency kits are kept secure, but not under lock and key.
4. The facility shall require that at least one person, trained in the use of the emergency equipment maintained on-site, is available whenever there is a client on-site.

(b) The program shall post the numbers of emergency transportation along with police, fire, ambulance, and the State poison control center in each area in which clients may receive services including all counseling and group rooms.

(c) At least one person who is certified in basic cardiac life support by the American Heart Association, the American Red Cross, the National Safety Council, or certified as an emergency medical technician (EMT) shall be in the facility at all times during its hours of operation.

SUBCHAPTER 16. CLIENT RIGHTS

10:161B-16.1 Establishment of policies and procedures

(a) The outpatient substance abuse 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) The program shall provide annual in-service education to its staff concerning the implementation of policies and procedures regarding client rights, and as part of new employee orientation.

(c) The program shall comply with all applicable Federal and State statutes and rules concerning client rights.

10:161B-16.2 Rights of each client

(a) Each client receiving services shall have:

1. The right to be informed of these rights, as evidenced by the client's written acknowledgment or by documentation by staff in the clinical record that the client was offered a written copy of these rights and given a written or verbal explanation of these rights in terms the client could understand;
2. The right to be notified of any rules and policies the program has established governing client conduct in the facility;
3. The right to be informed of services available in the program, the names and professional status of the staff providing and/or responsible for the client's care, and fees and related charges, including the payment, fee, deposit, and refund policy of the program and any charges for services not covered by sources of third-party payment or the program's basic rate;
4. The right to be informed if the program has authorized other health care and educational institutions to participate in his or her treatment, the identity and function of these institutions, and to refuse to allow their participation in his or her treatment;
5. The right to receive from his or her physicians or clinical practitioner(s) an explanation of his or her complete medical/health condition or diagnosis, recommended treatment, treatment options, including the option of no treatment, risks(s) of treatment, and expected result(s), in terms that he or she understands;

- i. If, in the opinion of the medical director or director of substance abuse counseling, this information would be detrimental to the client's health, or if the client is not capable of understanding the information, the explanation shall be provided to a family member, legal guardian or significant other, as available;
 - ii. Release of information to a family member, legal guardian or significant other, along with the reason for not informing the client directly, shall be documented in the client's clinical record; and
 - iii. All consents to release information shall be signed by client or their parent, guardian or legally authorized representative;
6. The right to participate in the planning of his or her care and treatment, and to refuse medication and treatment;
- i. A client's refusal of medication or treatment shall be documented in the client's clinical record;
7. The right to participate in experimental research only when the client gives informed, written consent to such participation, or when a guardian or legally authorized representative gives such consent for an incompetent client in accordance with law, rule and regulation;
8. The right to voice grievances or recommend changes in policies and services to program staff, the governing authority, and/or outside representatives of his or her choice either individually or as group, free from restraint, interference, coercion, discrimination, or reprisal;
9. The right to be free from mental and physical abuse, exploitation, and from use of restraints;
- i. A client's ordered medications shall not be withheld for failure to comply with facility rules or procedures, unless the decision is made to terminate the client in accordance with this chapter; medications may only be withheld when the facility medical staff determines that such action is medically indicated;
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 for statutorily authorized purposes; and
 - ii. The program may release data about the client for studies containing aggregated statistics only when the client's identity is protected and masked;
11. The right to be treated with courtesy, consideration, respect, and with recognition of his or her dignity, individuality, and right to privacy, including, but not limited to, auditory and visual privacy;
- i. The client's privacy also shall be respected when program staff are discussing the client with others;
12. The right to exercise civil and religious liberties, including the right to independent personal decisions;
- i. No religious beliefs or practices, or any attendance at religious services, shall be imposed upon any client;
13. The right to not be discriminated against because of age, race, religion, sex, nationality, sexual orientation, disability (including, but not limited to, blind, deaf, hard of hearing), or ability to pay; or to be deprived of any constitutional, civil, and/or legal rights.
- i. Programs shall not discriminate against clients taking medications as prescribed;
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. Transfers and discharges, and the reasons therefore, shall be documented in the client's clinical record; and
 - ii. If a transfer or discharge on a non-emergency basis is planned by the outpatient substance abuse 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. The right to be notified in writing, and to have the opportunity to appeal, an involuntary discharge; and
16. The right to have access to and obtain a copy of his or her clinical record, in accordance with the program's policies and procedures and applicable Federal and State laws and rules.

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

(b) The administrator shall provide all clients and their families, upon request, the names, address, and telephone numbers of offices where information concerning Medicaid coverage may be obtained.

(c) The program shall develop a policy and procedure in which clients are able to voice grievances or recommend changes of policies and services to agency personnel and the governing authority without fear of reprisal.

(d) The administrator shall also conspicuously post the DAS 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 treatment program shall initiate discharge/continuum of care planning for each client upon admission.

1. Goals for discharge shall be incorporated in the client's treatment plan at admission and shall address problems identified at admission and during treatment.

i. Such goals shall be shared with the substance abuse counselor staff and supervisor, and routinely reviewed and assessed with the client and the client's treatment team.

2. The client and his or her family or legally authorized representative, unless family participation is refused or contraindicated, shall participate in developing the discharge/continuum of care plan. Such participation shall be documented in the client's clinical record.

(b) The program shall establish and implement staff educational services regarding discharge/continuum of care planning.

10:161B-17.2 Discharge/continuum of care planning policies and procedures

(a) The program shall establish and implement written policies and procedures for discharge/continuum of care planning services, which shall address at least the following:

1. The staff responsible for planning, providing, and/or coordinating discharge/continuum of care planning services, including:

i. Making referrals to community agencies (for example, mental health agencies) and resources for clinically appropriate services in the continuum of care; and

ii. Promoting and facilitating the continuing involvement of clients with support groups, such as Alcoholics Anonymous (AA) and Narcotics Anonymous (NA), following discharge;

2. Documentation of discharge/continuum of care planning in the treatment plan, and including accompanying supervision;

3. Use of the multidisciplinary team in discharge/continuum of care planning;

4. The criteria for client discharge;

5. Description of the methods of client, and family involvement, where clinically appropriate, in developing the discharge/continuum of care plan; and

6. Written criteria for the discharge of juvenile clients only to parent(s) or legal guardian except as provided for by N.J.S.A. 9:17A-4.

10:161B-17.3 Client and family education

(a) The program shall include education of the client and his or her family, if applicable, or legally authorized representative as part of its discharge/continuum of care planning service and shall provide information regarding the following:

1. Community agencies and resources available for support services, health care facilities, including but not limited to, the identification of resources for prenatal care, services for the treatment of HIV infection, vocational rehabilitation centers, Women, Infants and Children (WIC) Program, and legal and social service agencies; and

2. The availability of support groups and referrals, when appropriate, to programs including but not limited to Narcotics Anonymous (NA), Nar-Anon, Alcoholics Anonymous (AA), Al-Anon, and Alateen.

SUBCHAPTER 18. CLINICAL RECORDS

10:161B-18.1 Maintenance of clinical records

(a) The outpatient substance abuse 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. The facility shall establish a clinical record for each client;

2. The facility shall require that documentation of all services provided and transactions regarding the client are entered in his or her clinical record in a uniform manner;

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

i. The clinical record is removed in accordance with a court order;

ii. The clinical record is removed due to a physical plant emergency or natural disaster; or

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

4. The facility shall preserve the confidentiality of information contained in the clinical record 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.

(b) The facility shall establish a record system so that each client's complete clinical record is filed as one unit within 30 days of discharge, with access to and identification of all client clinical records maintained.

(c) The facility shall establish policies and procedures to protect clinical records against loss, tampering, alteration, destruction, unauthorized use or other release of information without the client's consent.

(d) The facility's policies and procedures shall specify the period of time, not to exceed 30 days, within which the clinical record shall be completed following client treatment or discharge.

(e) The facility shall establish policies and procedures regarding the transfer of the client's clinical record information to another health care or treatment facility.

(f) The facility shall establish policies and procedures to provide copies of a client's clinical record to the client, his or her legally authorized representative or a third-party payer where permitted by law or otherwise authorized in writing by the client, consistent with N.J.A.C. 10:161B-18.5.

10:161B-18.2 Assignment of responsibility

(a) The administrator and director of substance abuse counseling services shall ensure that clinical records are maintained.

(b) The facility shall designate a staff member to act as the coordinator of clinical record services and one or more staff to act in his or her absence to ensure staff access to clinical

records at all times, if such an individual is needed to comply with (a) above.

10:161B-18.3 Contents of clinical records

(a) The facility shall require the following, at a minimum, to be included in the clinical record:

1. Client identification data, including name, date of admission, address, date of birth, race, religion (optional), gender, and the name, address, and telephone number of the person(s) to be notified in an emergency;

2. Admission, discharge and other reports required by this chapter as part of the substance abuse client management information system, as well as previous treatment records and correspondence;

3. The client's signed acknowledgment that he or she has been informed of and received a copy of client rights;

4. A summary of the admission interview, and a copy of the biopsychosocial assessment;

5. Documentation of the medical history and physical examination signed and dated by the physician for opioid treatment and detoxification clients, or the comprehensive health history for clients receiving other outpatient services;

6. A client treatment plan signed and dated by medical and clinical personnel as required by this chapter;

7. In programs providing IOP and PC services, clinical notes, including progress notes for individual, group, and family counseling sessions as well as psycho-educational groups, shall be documented in each client's record no less than weekly by a summary note for each individual and group session listing the date and topic of all treatment sessions attended, and a narrative of his or her participation and treatment progress. Weekly summary notes shall be based on the compilation of the session notes of all clinicians providing services to the client;

8. In programs providing OP services, clinical notes, including progress notes for individual, group, and family counseling sessions as well as psycho-educational groups, shall be documented in each client's record by contact listing the date and topic of all treatment sessions attended, and a narrative of his or her participation and treatment progress;

9. In programs providing OTP services, clinical notes, including progress notes for individual, group, and family counseling sessions as well as psycho-educational groups, shall be documented in each client's record by contact listing the date and topic of all treatment sessions attended, and a narrative of his or her participation and treatment progress. Medication dispensing requires documentation per contact but does not require a narrative or summary;

10. Medical notes for services provided by physicians, nurses and other licensed medical practitioners shall be entered in the client record on the day of service;

11. Documentation of the client's participation in the development of his or her treatment plan, or documentation by a physician or licensed clinician that the client's participation is medically contraindicated;

12. A record of medications administered, including the name and strength of the drug, date and time of administration, the dosage administered, method of administration, a description of reactions if observed, and signature of the person who administered the drug;

13. A record of self-administered medications, in accordance with the program's policies and procedures;

14. A record of medications dispensed or prescribed for home use;

15. Documentation of the client's allergies in the clinical record and on the outside front cover of the client record;

16. The results of laboratory, radiological, diagnostic, and/or screening tests performed;

17. Reports of accidents;

18. A record of referrals to other health care and social service providers;

19. Summaries of consultations;

20. Any signed, written informed consent forms or an explanation of why an informed consent was not obtained;

21. A record of any treatment, drug, or service offered by appropriate program staff and refused by the client;

22. Instructions given to the client and/or the client's family for care following discharge;

23. The discharge/continuum of care plan; and

24. The discharge/continuum of care summary, in accordance with N.J.S.A. 26:8-5.

10:161B-18.4 Requirements for clinical record entries

(a) The facility shall require that all orders for client care be prescribed in writing, signed and dated by the prescriber(s), in accordance with State law.

1. All medical orders, including verbal orders, shall be verified or countersigned in writing within 72 hours and in accordance with State law.

(b) The facility shall require that all entries in the clinical record be typewritten or written legibly in black or blue ink, dated and signed by the person entering them, or authenticated if a computerized clinical records system is used.

1. If computer-generated orders with a physician's electronic signature are used, the program shall develop a

procedure to ensure the confidentiality of each electronic signature and to prohibit the improper or unauthorized use of any computer-generated signature.

2. If a facsimile communications system (FAX) is used, entries into the clinical record shall be in accordance with the following procedures:

i. The physician shall sign the original order, and include the history and/or examination if conducted at an off-site location;

ii. The original order shall be transmitted by FAX system to the program for inclusion in the clinical record;

iii. The physician shall submit the original for inclusion in the clinical record within seven days, unless a plain paper laser facsimile process was used; and

iv. The copy transmitted by FAX system shall be replaced by the original, unless a plain paper laser facsimile process was used.

(c) The clinical record shall be completed within the time frame specified in the clinical records policies and procedures, which shall be no longer than 30 days from the last treatment or discharge.

(d) The clinical record shall be available to the client's substance abuse practitioner or clinician involved in the client's care at all times during the hours of operation.

10:161B-18.5 Access to clinical records

(a) The facility shall furnish a legible, written copy of the clinical record, or portion of the clinical record, as appropriate, for a fee based on actual costs to a client, his or her legally authorized representative, or a third party payer, upon written request and receipt of a properly executed release of information form within 30 days of receipt of the written request, in accordance with the following:

1. The fee for copying shall not exceed \$1.00 per page for the first 100 pages, and \$.25 per page thereafter, not to exceed \$200.00 for the entire record.

2. In addition to per page costs, the following charges are permitted:

i. A search fee of no more than \$10.00 per request; and

ii. A postage charge of actual costs for mailing, not to exceed \$5.00.

3. No charges shall be assessed other than those permitted in (a)1 and 2 above.

(b) The facility shall establish a policy assuring access to copies of clinical records for clients who do not have the ability to pay notwithstanding (a) above.

(c) The facility shall establish a fee policy providing an incentive for use of abstracts or summaries of clinical records but shall not impede a client or his or her legally authorized representative's ability to receive a full or certified copy of the clinical record.

(d) The facility shall establish a policy and procedure that shall govern those instances in which access to a client's clinical record is subject to denial under the Health Insurance Portability and Accountability Act (HIPAA) 42 U.S.C. §§1320d et seq., and 45 CFR Parts 160 and 164, and such policy and procedure shall comply with HIPAA.

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

(a) The facility shall preserve all clinical records in accordance with N.J.S.A. 26:8-5 for a period of 10 years following the most recent discharge of the client, or until he or she reaches 23 years, whichever is longer. In addition, a discharge/continuum of care summary sheet shall be retained by such custodian of records for a period of 20 years following the most recent discharge of the client. The discharge summary sheet shall contain the client's name, address, date(s) of admission and discharge and a summary of the treatment and medication rendered during the client's stay.

(b) If the facility plans to cease operation, it shall notify DAS 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.

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

i. Retrieval and delivery of clinical records within one business day following request, seven days per week, 24 hours per day; and

ii. Immediate availability of clinical record information through telephone and facsimile communications systems.

SUBCHAPTER 19. INFECTION PREVENTION AND CONTROL SERVICES

10:161B-19.1 Infection prevention and control

(a) The administrator shall ensure the development, implementation and up-to-date maintenance of an infection prevention and control program.

(b) The outpatient substance abuse treatment program shall establish an infection control committee, or designate an

individual responsible for ensuring that the rules in this subchapter are followed.

1. If an infection control committee is established, it shall include a representative of administration, a person designated by the administrator to be responsible for implementing the policies and procedures regarding infection prevention and control in the facility, and, when applicable, the medical director or consultant physician, and a representative from nursing services.

(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. The process within the facility for investigating, reporting, and evaluating the occurrence of all infections or diseases which are reportable in accordance with N.J.A.C. 8:57, Communicable Diseases, or are conditions that may be related to activities and procedures of the facility;

2. The process within the facility for identifying and monitoring nosocomial infections in accordance with the latest guidelines available from the Centers for Disease Control and Prevention (CDC), National Center for Infectious Diseases, Division of Healthcare Quality Promotion (DHQP), 1600 Clifton Road, Atlanta GA, 30333, on the DHQP Infection Control Guidelines website at <http://www.cdc.gov/ncidod/dhqp/guidelines.html>, or tollfree 1-800-311-3435; in particular, the "Guideline for Preventing Healthcare-Associated Pneumonia (2004)", accessible at http://www.cdc.gov/ncidod/dhqp/gl_hcpneumonia.html, and the "Guideline for Hand Hygiene in Healthcare Settings" (2002), accessible at <http://www.cdc.gov/handhygiene>, incorporated herein by reference;

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 websites, http://www.osha.gov/SLTC/bloodborne pathogens/bloodborne_faq.html; and http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051; or from the Government Printing Office, Order #S/N 869-044-00105-5; (202) 512-1800, <http://bookstore.gpo.gov>;

4. The control measures or studies to be initiated by the facility following identification of an infection control problem;

5. The facility's aseptic techniques, and procedures to ensure employee health in accordance with N.J.A.C. 10:161B-3.7, and staff training;

6. Care of clients with communicable diseases;

7. Exclusion of staff with communicable diseases from work, and authorization to return to work;

8. The facility's surveillance techniques to minimize sources and transmission of infection;

9. The facility's sterilization, disinfection and cleaning practices and techniques; and

10. The facility's practices regarding collection, handling, storage, decontamination, disinfection, sterilization and disposal of regulated medical waste and all other solid and liquid waste.

SUBCHAPTER 20. HOUSEKEEPING, SANITATION AND SAFETY

10:161B-20.1 Provision of services

(a) The outpatient substance abuse treatment facility shall provide and maintain a sanitary and safe environment for clients and staff.

(b) The facility shall provide housekeeping and pest control services; as well as laundry services if needed.

(c) The facility shall develop and implement written objectives, policies, a procedure manual, an organizational plan, and a quality assurance program for housekeeping, sanitation and safety services.

10:161B-20.2 Housekeeping

(a) The facility shall establish and implement a written work plan for housekeeping operations with categorization of cleaning assignments as daily, weekly, monthly, or annually within each area of the facility.

(b) The facility shall ensure that all housekeeping personnel are trained in cleaning procedures, including the use, cleaning, and care of equipment.

10:161B-20.3 Client care environment

(a) The facility shall meet the following housekeeping and sanitation conditions:

1. The facility and its contents shall be clean to sight and touch and free of dirt and debris;

2. All rooms shall be free of condensation, mold growth, and noxious odors;

3. All equipment and materials necessary for cleaning, disinfecting, and sterilizing (if applicable), shall be available in the facility at all times;

4. Thermometers, which are accurate to within three degrees Fahrenheit, shall be kept in a visible location in refrigerators, freezers, and storerooms used for perishable and other items subject to deterioration;

5. Articles in storage shall be elevated from the floor and away from walls, ceilings, and air vents;

6. Aisles in storage areas shall be unobstructed;

7. Controls safe for clients and staff shall be used to minimize and eliminate the presence of rodents, flies, roaches, fleas and other vermin in the facility, and to prevent the breeding, harborage, or feeding of vermin;

i. All openings to the outer air shall be effectively protected against the entrance of insects;

8. Toilet tissue, soap, and disposable towels or air driers shall be provided in each bathroom at all times;

9. Draperies, upholstery, and other fabrics or decorations shall be fire-resistant and flameproof;

10. The temperature within client areas of the facility shall be maintained within a minimum of 68 to 72 degrees Fahrenheit.

i. The facility shall maintain adequate ventilation in all areas used by clients; and

11. Facilities which provide areas for children on the premises shall ensure that children are not exposed to lead based paint hazards in accordance with the provisions of N.J.A.C. 8:51, Childhood Lead Poisoning. Facilities constructed prior to 1978 shall be considered to contain lead based paint unless an inspection and testing by an individual with a New Jersey Lead Inspector/Risk Assessor permit has determined that the paint does not contain lead.

(b) The facility shall meet the following safety conditions:

1. Nonskid wax shall be used on all waxed floors.

2. Throw rugs or scatter rugs shall not be used.

3. All equipment shall have unobstructed space provided for operation.

4. Pesticides shall be applied in accordance with State Pesticide Control Code, N.J.A.C. 7:30.

5. All household and cleaning products in the facility shall be identified, labeled, and securely stored in a cabinet, closet, or room, which is inaccessible to clients.

6. Combustible materials shall not be stored in heater rooms or within 18 feet of any heater located in an open basement.

7. Minimum supplies of paints, varnishes, lacquers, thinners, and other flammable materials shall be stored in a locked storage room or in closets, locked metal cabinets or containers in a non-client area of the facility.

8. All furnishings shall be clean and in good repair, and mechanical equipment shall be in good working order.

i. Equipment shall be kept covered to protect from contamination and accessible for cleaning and inspection.

ii. Broken or worn items shall be repaired, replaced, or removed promptly.

9. In facilities that provide areas for children, all areas accessible to the children shall be maintained in a safe and sanitary manner by ensuring that:

- i. There are no poisonous plants;
- ii. Toxic chemicals including cleaning agents are stored in locked cabinets or enclosed in areas not accessible to the children;
- iii. All electrical outlets have protective covers;
- iv. Any and all water coolers in areas that may at any time occupy children do not dispense hot water and outlets to the water cooler are not accessible to children;
- v. All fluorescent tubes and incandescent light bulbs have protective covers or shields;
- vi. All windows and other glass surfaces that are not made of safety glass shall have protective guards;
- vii. Materials and furniture for indoor and outdoor use are of sturdy and safe construction, easy to clean, and free of hazards;
- viii. Poisons, insect traps, and rodent traps are kept out of reach of children;
- ix. All indoor and outdoor areas are maintained in a safe and sanitary manner; and
- x. Children do not have access to medications administered by the facility.

10:161B-20.4 Waste removal and regulated medical waste

(a) The facility shall collect, store and dispose of all solid or liquid waste (which is not regulated medical waste), garbage, and trash in accordance with all applicable State and local laws and shall:

1. Store solid waste in insect proof, rodent proof, fireproof, non-absorbent and watertight containers with tight fitting covers;
2. Collect solid waste from storage areas regularly to prevent nuisances such as odors; and
3. Provide for regular, scheduled cleaning of storage areas and containers for all waste in accordance with N.J.A.C. 8:24.

(b) If garbage compactors are used, the facility shall install and use them in compliance with all State and local codes.

(c) The facility shall comply with N.J.S.A. 13:1E-48.1 et seq., the Comprehensive Regulated Waste Management Act, and the rules promulgated pursuant thereto, N.J.A.C. 7:26-3A, that apply to the collection, storage, handling and disposal of regulated medical waste.

10:161B-20.5 Water supply

(a) The facility shall use a water supply for drinking or culinary purposes that is adequate in quantity, of a safe and sanitary quality, and from a water system constructed, protected, operated, and maintained in conformance with the New Jersey Safe Drinking Water Act, N.J.S.A. 58:12A-1 et seq., N.J.A.C. 7:10, and local laws, ordinances, and regulations, with no back siphonage conditions present.

(b) The facility shall maintain the temperature of the hot water used for hand washing between 95 degrees and 120 degrees Fahrenheit or 35 to 49 degrees Celsius.

(c) The facility shall use a sewage disposal system maintained in good repair and operated in compliance with State and local laws, ordinances, rules and regulations.

SUBCHAPTER 21. QUALITY ASSURANCE PROGRAM

10:161B-21.1 Quality assurance program

(a) The outpatient substance abuse 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. The quality assurance program shall specify a timetable for implementation, provision for ongoing monitoring of staff and client care services, including the development of the facility's quality plans.

2. The quality assurance program shall incorporate all of the facility's quality assurance plans and discipline specific (medical, nursing, client care) quality assurance programs as identified in this subchapter.

3. The facility shall establish a mechanism to include participation of all disciplines in the identification of areas for quality assurance review that effect client care throughout the facility.

4. The administrator shall identify one staff person who will be responsible for administering the facility's quality assurance program and complying with the requirements of this subchapter.

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;

2. Review of policies, procedures, and practices relating to the provision of clinical supervision of staff, including the methods and frequency by which staff receive clinical supervision;

3. Evaluation of client care shall be criteria-based, and trigger certain review actions when specific, quantified, predetermined levels of outcomes or potential problems are identified;

4. Periodic reviews of client clinical records;

5. Evaluation by clients of care and services provided by the program;

6. If the families of clients are routinely involved in the care and services provided by the facility, the quality assurance plan shall include a means for obtaining their input; and

7. The quality assurance plan shall include at a minimum an annual review of staff qualifications and credentials, and staff orientation and education.

(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.

2. Deficiencies jeopardizing client or staff safety shall be verbally reported to the governing authority and to DAS immediately, with written correspondence provided to the governing authority and DAS 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/> 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.

(d) The program shall submit results of the quality assurance program to its governing authority at least annually, including reporting of deficiencies found and recommendations for corrections or improvements.

SUBCHAPTER 22. VOLUNTEER SERVICES

10:161B-22.1 Provision of volunteer services

(a) The outpatient substance abuse treatment facility may provide volunteer services as an integral part of its services.

1. Volunteers shall not provide direct client care or treatment services in lieu of staff as required by this chapter.

2. Volunteers shall not administer medications.

3. Volunteers shall not be used to restrain clients.

(b) The facility shall provide initial orientation and continuing in-service education for volunteers regarding the following topics, at a minimum:

1. Emergency plans and procedures;

2. Client confidentiality;

3. The infection prevention and control program; and

4. Program policies and procedures relating to the tasks or duties the volunteers will perform.

(c) The facility shall ensure that client confidentiality is maintained when volunteers have access to client clinical records or other identifying information, in accordance with its policies and all applicable laws.

(d) Volunteers shall not receive gifts or gratuities from clients.

(e) Volunteers who function as counselor interns will perform their duties in accordance with established professional training, clinical care and supervision requirements.

10:161B-22.2 Volunteer policies and procedures

(a) If the program provides volunteer services, it shall establish and implement written policies and procedures that shall include, but not be limited to, the following:

1. Criteria for individuals to participate in, or be excluded from, volunteer service, including, but not be limited to, the following criteria:

i. Minimum age and physical examination requirements for volunteers; and

ii. The minimum period of time during which individuals with a prior history of substance abuse (alcohol, tobacco and other drugs) shall be continuously substance free before being accepted as volunteers;

2. Methods for obtaining information regarding each volunteer, including at least their education, credentials, employment experience, driver abstracts, sanctions by licensing boards, and arrests or convictions, if any;

3. Photo identification cards, which shall include the volunteer's name, and their volunteer status;

4. Assignment of volunteers to clients, including criteria for assignment, and description of responsibilities;
5. Functions which volunteers may perform; and
6. Background checks.

(b) The facility shall provide for volunteer services under the supervision of appropriately trained and qualified staff, in accordance with client treatment plans and the rules of this chapter.

1. The client clinical record shall provide written documentation that the client agrees to work with the volunteer.
2. Clients maintain the right not to work with a volunteer.

(c) Volunteers shall be considered as staff with regard to meeting the requirements for background checks, physical examination and testing, verification of credentials, photo identification cards, and program policies and procedures relating to staff behavior.

(d) The facility's volunteer program shall be approved by the governing authority.

Administrative correction.
See: 41 N.J.R. 2658(a).

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 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 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-23.2 Physical plant general compliance for construction or alteration completed prior to June 1, 2009

Facilities constructed or altered prior to June 1, 2009, shall conform with Federal, State, and local standards in effect at the time of construction, alteration, or approval of plans for construction or alteration by the Department of Community Affairs.

10:161B-23.3 Plan review

(a) Prior to any construction, all plans for construction, alterations or renovations shall be submitted for review and approval to the local Office of the Building Code Official of the municipality in which the project is located, or the municipality having jurisdiction.

(b) Review fees shall be paid pursuant to N.J.A.C. 8:31-1.1.

(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, for a cursory review and inclusion in DAS 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

10:161B-23.4 Alterations, replacements and damage to existing facilities

(a) Existing structures, when repaired, renovated, altered or reconstructed, shall conform to the requirements of N.J.A.C. 5:23-6, Rehabilitation Subcode.

(b) If an existing structure is damaged by fire or any other cause, the requirements of N.J.A.C. 5:23-6, Rehabilitation Subcode, shall apply to the restoration of such building or structure.

(c) Any work which is mandated by any housing, property or fire safety maintenance code, standard or regulation or other State or local law requiring improvements to buildings or structures, shall be made to conform only to the requirements of that code, standard, law or regulation and shall not

be required to conform to the subcodes adopted pursuant to this chapter unless the code requiring the alterations so provides.

10:161B-23.5 Provision for the handicapped

All facilities shall be made available and accessible to the physically handicapped pursuant to the New Jersey Uniform Construction Code, N.J.A.C. 5:23-6, Rehabilitation Subcode, and 5:23-7, Barrier Free Subcode.

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>, or from the Superintendent of Documents, Government Printing Office, Washington, DC, 20402.

10:161B-23.7 Ventilation

Ventilation shall be provided in accordance with the International Mechanical Code 2003, as incorporated in N.J.A.C. 5:23.

10:161B-23.8 Exit access passageway and corridors

The width of passageways including doors, aisles and corridors in a facility shall not be less than 36 inches.

10:161B-23.9 Fire alarm and detection systems

The facility shall have a fire alarm and smoke detection system throughout the physical plant, which shall be in accordance with all applicable rules of the New Jersey Department of Community Affairs at N.J.A.C. 5:23 and 5:70.

10:161B-23.10 Interior finish requirement

Interior wall and ceiling finishes shall be installed in accordance with all applicable rules of the New Jersey Department of Community Affairs at N.J.A.C. 5:23 and 5:70.

10:161B-23.11 Attached structures

(a) Attached structures such as storage sheds or private garages located beneath the buildings shall have fire separation assemblies at the walls, floors, and ceilings separating the space from the adjacent interior enclosed space constructed of not less than one-hour fire resistance rating.

(b) Attached private garages shall be completely separated from the adjacent interior enclosed spaces and the attic area by means of one-hour fire rated separation assembly applied to the garage side.

(c) The sills of all door openings in the garage between garage and building shall be raised not less than four inches above the garage floor and openings shall be protected in accordance with the rules of the Department of Community Affairs at N.J.A.C. 5:23 and 5:70.

SUBCHAPTER 24. PHYSICAL ENVIRONMENT

10:161B-24.1 Kitchens

The facility shall keep all kitchen exhaust fans and metal ducts free of grease and dirt, and metal ducts shall comply with the rules of the New Jersey Department of Community Affairs at N.J.A.C. 5:23.

10:161B-24.2 Fire extinguisher specifications

(a) The facility shall keep a minimum of two fire extinguishers in the basement or in a place that will ensure a fire extinguisher within 50 feet of any oil or gas used as a fuel source. There should be at least one fire extinguisher on each floor or as many as necessary to ensure that no one must travel more than 75 feet (excluding the kitchen), and as many as may be necessary in or near the kitchen to ensure that a fire extinguisher is within 50 feet of any ranges and stoves. All of the extinguishers shall bear the seal of the Underwriters Laboratory.

1. Fire extinguishers in all kitchen areas shall be Class B dry chemical type 2-B and a minimum of five pounds.

2. Fire extinguishers in the basement shall comply with (a) above if oil or gas is used as a fuel source.

3. In all other instances, fire extinguishers may be Class A air pressurized 2.5 gallon water type 2-A.

10:161B-24.3 Ceiling heights

The facilities shall have ceiling heights in corridors, storage rooms, client rooms, bathrooms and lavatories in accordance with the rules of the New Jersey Department of Community Affairs at N.J.A.C. 5:23. Ceilings in other spaces not normally occupied may be reduced to seven feet in height.

SUBCHAPTER 25. EXISTING FACILITIES

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

Existing licensed outpatient substance abuse 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.

10:161B-25.2 Fire safety

Smoke detectors, fire suppression systems, and building separations shall be in compliance with the Uniform Fire

Code of the State of New Jersey, N.J.A.C. 5:70-3 and 4, as applicable.

APPENDIX A

TUBERCULOSIS SURVEILLANCE PROCEDURES
SUBSTANCE ABUSE TREATMENT FACILITIES (SATFs)

INTRODUCTION

TB Problem among Substance Abusers

- From 1992 to 2001 newly reported TB cases in New Jersey declined by 46.1 percent (984 to 530 cases annually). New Jersey reported 530 TB cases for the second consecutive year in 2002, ending nine consecutive years of declining morbidity. In 2003, TB disease resumed its downward trend dropping 6.6 percent to 495 cases for a case rate of 5.7 per 100,000 of population. The number of new TB cases has dropped by an average 4.5 percent and the case rate by 5.0 percent annually since the peak in 1992.
- During 2003, 495 cases of TB were reported in New Jersey and of these 58 TB Cases or 11.7 percent gave a history of substance abuse within the last year. This is equivalent to 11.7 percent of 530 cases in 2002 and less than 13.8 percent in 2001. Substance abuse was reported by TB cases in 12 of 21 counties statewide in 2003.
- With the sustained decline of TB in the U.S. over the past decade, TB has been retreating into well-defined risk groups. Every effort should be made to test only those persons at highest risk for latent TB infection, interpret tuberculin skin reactions accurately, and ensure appropriate treatment and completion of the recommended regimen. Screening persons other than members of high-risk groups is not recommended.
- Without treatment, approximately 20 percent of persons with latent TB infection (LTBI), formerly called preventive therapy and a history of injection drug use could be expected to develop active TB over the next 20 years. Over the same time period, approximately 70 percent of persons with HIV infection could be expected to develop active TB. HIV infection contributes most to an increased risk for progression of LTBI to active TB.

Opportunity for Preventing TB Among Injecting Drug Users

- Injection drug users have an increased risk for progressing to active TB (10 cases per 1000 person-years), and this risk is even greater for injection drug users co-infected with HIV and TB (76 cases per 1000 person-years). These higher rates may reflect increased transmission, more recent infection in this population, and the increased risk associated with injection drug use and HIV infection.
- Most health department jurisdictions have been successful in achieving the highest priority TB objectives of identifying and ensuring completion of therapy among active cases and ensuring complete follow up and treatment of TB contacts. While maintaining these efforts, accelerated progress towards TB elimination will occur through testing and treatment of latent TB infection among groups at the highest risk of developing active TB.
- Fortunately, latent TB infection, if discovered, is at a stage where progression to infectious TB disease is almost entirely preventable. Prevention requires identification of the infected individual and treatment for the latent infection with Isoniazid for 9 months. Studies have shown that persons who complete a full course of treatment for latent TB infection have more than a 90% reduction in the risk of developing active TB compared with persons who are not treated.
- Adherence to latent TB infection is greatly enhanced by the implementation of a directly observed therapy (DOT) program. Tuberculin skin testing should not be undertaken by a SATF unless DOT is provided by the facility staff.
- As indicated in the table below, treatment for LTBI among injection drug users, with or without HIV infection, is a relatively efficient way to prevent active, infectious TB. Therefore, SATFs provide a unique setting in which to cost-effectively prevent TB in an otherwise difficult to reach high risk population.

TB Risk	Annual Risk of TB - Without TX	# Completing TX to Prevent 1 Case of TB Over a 20 - Year Period
IDU & HIV Positive	.0760	1
HIV Positive	.0450	2
IDU & HIV Neg or Unk	.0100	6
No Risk	.0007	77

Objectives

For Clients

1. All clients will receive TB counseling and education before admission to a SATF.
2. All clients will receive a symptom assessment for pulmonary tuberculosis before admission to a SATF. Past history of treatment for TB disease, tuberculin skin tests (TST) or adequate treatment for latent TB infection (LTBI) will be obtained. An efficient and feasible screening tool to identify those persons in need of evaluation for active tuberculosis disease attending SATFs is the implementation of a Pulmonary Tuberculosis Symptom Assessment.
(See Attachment 2)
3. All clients with symptoms consistent with pulmonary tuberculosis will promptly be referred for a chest X-ray and medical evaluation for active tuberculosis.

4. Using the 2-step method, the Mantoux TST status will be known on those clients with a history of intravenous drug use and/or clients with a history of HIV who are in treatment plans consisting of 9 months or longer that are enrolled in long term care-residential SATFs or methadone maintenance—opioid pharmacotherapy facilities within 30 days of admission.
5. Clients with newly identified positive TSTs will receive a chest X-ray and be evaluated for active TB within 10 days of the TST.
6. At least 90% of clients with a positive TST will be started on treatment for LTBI, unless medically contraindicated, within 10 days of the evaluation for TB.
7. Directly observed therapy (DOT) will be provided by the SATF for clients receiving treatment for latent TB infection or TB disease.
8. At least 85% of clients placed on treatment will complete the recommended regimen within 12 months.

For Employees

1. All employees will receive TB counseling and education at time of employment.
2. All employees will receive a symptom assessment for pulmonary TB at the time of employment. (See Attachment 2) Past history of previous treatment for TB disease, tuberculin skin tests (TST), or adequate treatment for latent TB infection (LTBI) will be documented.
3. All employees with symptoms consistent with tuberculosis will promptly be referred for a chest X-ray and medical evaluation for active tuberculosis.
4. Using the two-step method, the Mantoux TST status will be known on all employees within 30 days of employment at the SATF.
5. All employees with a newly identified positive TST will receive a chest X-ray and be evaluated for active TB within 10 days of the TST.
6. At least 90% of employees with a positive TST will be started on treatment for LTBI, unless medically contraindicated, within 10 days of the evaluation for TB.
7. At least 85% of employees placed on treatment will complete the recommended regimen within 12 months.

Federal and State Requirements for TB Testing

The Substance Abuse and Mental Health Services Administration (SAMHSA), through its Center for Substance Abuse Treatment (CSAT), stipulates that facilities receiving Block Grant funds provide, or arrange for, TB services for each individual receiving substance abuse services. TB services may include:

- Counseling the individual with respect to TB, testing to determine whether the individual has been infected with mycobacterium tuberculosis to determine the appropriate form of treatment for the individual, and
- Providing for or referring the individuals infected by mycobacterium tuberculosis for appropriate medical evaluation and treatment.

Source: Public Law 102-321 45 CFR 96 – Rules and Regulations; Section 96.121 – Definitions and Section 96.127 – Requirements Regarding Tuberculosis

State: The *Standards for Licensure* include requirements for TB testing and follow up (if indicated). The *TB Surveillance Procedures* provide more specific guidance in carrying out the requirements and are based on recent scientific findings and on newly published recommendations. Therefore, SATFs should be guided by the *TB Surveillance Procedures* in developing and updating their TB-related policies and procedures.

Purpose of Tuberculosis Surveillance Procedures

Each year, over 50,000 substance abusers are admitted to SATFs in New Jersey. In 2003, there were 54,543 individuals admitted to substance abuse centers and 10,827 were injecting drug users. Since injection, drug users and/or clients with a history of HIV are at high risk for progressing to active infectious TB once infected and since TB is feasibly preventable among these individuals with LTBI, the purpose of the *Tuberculosis Surveillance Procedures* is to:

- Identify and treat persons with active, infectious TB and
- Identify and treat, with the initiation of DOT, high risk persons with LTBI to prevent the development of active, infectious TB

These *Procedures* will cover the following:

- Initial examination, follow up, and treatment procedures for both clients and employees.
- Annual examination requirements for employees.
- Procedures following exposure to infectious TB.
- Documentation of results and reporting requirements.

At the end of this document is a list of resources to assist SATFs in implementing these *Procedures*.

I. CLIENTS

A. INITIAL EXAMINATION

1. Counseling and Evaluation for Signs and Symptoms of TB

All newly admitted clients to a SATF will be counseled about tuberculosis infection and disease. All clients will also be evaluated for signs and symptoms of tuberculosis. The symptoms of pulmonary tuberculosis may include productive, prolonged cough, chest pain, and/or hemoptysis. Systemic symptoms of tuberculosis may include fever, unexplained appetite loss, unexplained weight loss (10 pounds or greater), night sweats (regardless of room temperature), chills and/or persistent fatigue. If the client is determined to have symptoms and/or clinical evidence suggest of active TB (regardless of the results of the TST), the SATF will immediately isolate the client in a separate area of the facility away from other clients, until the need for hospitalization has been determined. Local hospitals can be used for inpatient care when necessary. The SATF should contact the NJDHSS, TB Program at (609)-588-7522 for consultation and referral.

2. Mantoux Tuberculin Skin Test (TST)

- **Purpose:** The purpose of the TST is to identify clients who have been infected with TB so that these persons can be (a) evaluated for active, infectious TB and (b) if active TB is ruled out, placed on treatment to prevent the future development of active TB.
- **Who Will Be Tested**

Clients with a history of intravenous injection drug use and/or clients with a history of HIV infection who are in treatment plans consisting of 9 months or longer that are enrolled in long term care-residential SATFs or methadone maintenance – opioid pharmacotherapy facilities, where DOT is feasible. The provision of a DOT program by SATF staff is an essential component of the tuberculin testing procedure.

Exceptions: Clients presenting *written* documentation of a (a) prior positive Mantoux TST reaction, (b) prior or present TB disease, or (c) adequate treatment for latent TB infection (LTBI).

Note: A *verbal history* from the client of prior testing or treatment results is *not sufficient to exclude testing*. Unless written documentation can be provided, the TST must be performed.

Note: Tuberculin *testing is not contraindicated for persons* who have been vaccinated with *BCG*. These persons should receive a TST and be managed without regard to the history of BCG.

- **Administration of the Mantoux TST**

The Mantoux TST is performed by the intradermal injection of 0.1 ml of Purified Protein Derivative (PPD) tuberculin containing 5 TU (tuberculin units) into either the volar or dorsal surface of the forearm. The injection should be made with a disposable safety tuberculin syringe with a short (one-quarter to one-half inch), bluntly beveled, platinum (26-gauge) or steel (27-gauge) needle. The injection will be made just beneath the surface of the skin, with the needle bevel facing upward to produce a discrete, pale elevation of the skin (a wheal) 6 mm to 10 mm in diameter.

To prevent needle stick injuries, needles will not be recapped, purposely bent or broken, removed from disposable syringes, or otherwise manipulated by hand. After use, syringes and needles will be placed in puncture-resistant containers for disposal. Institutional guidelines regarding universal precautions for infection control will be followed.

- **Reading the Mantoux TST**

The Mantoux test is read between 48 to 72 hours after administration by a trained health care provider. Positive reactions (see **Interpretation of TST Results** section for definition of *positive*) tend to persist for several days and can be read up to 7 days from the date of testing. However, if an individual who fails to return within 48 to 72 hours has a negative test, the TST must be repeated.

If the result of the initial test is negative, administer a second test one to three weeks later. If the second test is positive, the person is classified as infected; if the second test is negative, the person is classified as uninfected. If the new client has documentation of having received a single negative TST within the past year, only a one-step Mantoux test is required upon employment.

Readings should be made in good light, with the forearm slightly flexed at the elbow. The basis of the reading is the presence or absence of induration, which may be determined by inspection (from a side view against the light as well as direct light) and by palpation. The diameter of induration (raised, hardened area) should be measured using a tuberculin ruler. Erythema (redness) or bruise without induration should not be measured. The reaction is measured transversely to the long axis of the forearm and recorded in millimeters of induration. If no induration is found 0 mm will be recorded.

Documentation in the medical record should include date of administration, date of the reading, measurement in millimeters of induration, name of administrator and/or reader, site of placement, brand name of the PPD solution, lot# and expiration date of PPD solution.

- **Interpretation of TST Results**

A **Positive** TST indicates the probable presence of TB organisms in the body. Persons with a positive TST must receive follow up evaluation (including a chest X-ray) to rule out active TB and will be considered for treatment of LTBI if active TB is ruled out.

A **Negative** TST indicates the probable absence of TB organisms in the body. Persons with a negative TST do not require further evaluation unless symptoms compatible with active TB are present (see Section I.A.1.)

Depending on the HIV status, the TST reaction size should be interpreted as follows:

HIV Status	TST Reaction	Interpretation
Positive or Unknown	0 - 4 mm	Negative
	5+ mm	Positive
Negative	0 - 9 mm	Negative
	10+ mm	Positive

- **Anergy Testing**

Because results of anergy testing in HIV infected populations in the US do not seem useful to clinicians making decisions about treatment for latent TB infection, **anergy testing is no longer recommended as a routine component of TB screening among HIV-infected persons**. However, some experts support the use of anergy testing to help guide individual decisions regarding treatment for latent TB infection, and some recommend that a tuberculin skin test be performed on patients previously classified as anergic if evidence indicates that these individuals' immune systems have responded to therapy with antiretroviral drugs. Experts in TB/HIV illness should be consulted about anergy testing and specific treatment recommendations. Referral for consultation is available by contacting the NJDHSS, TB Program at (609)-588-7522.

B. FOLLOW UP EVALUATION OF CLIENTS WITH A POSITIVE TST

Any individual whose TST is positive shall promptly be referred for a chest X-ray in order to rule out the presence of active TB.

A posterior-anterior chest X-ray is the standard view used for the detection and description of chest abnormalities. In some instances, other views or additional studies may be necessary.

Abnormalities on chest X-rays may be suggestive of, but are never diagnostic of, TB. However, chest X-rays may be used to rule out the possibility of pulmonary TB in an individual who has a positive reaction to the tuberculin skin test and no symptoms of disease. *Note:* In HIV- infected individuals, pulmonary TB may present atypically on chest X-ray.

Further diagnostic evaluation and/or treatment will depend on the results of the chest X-ray:

- X-ray Abnormal - Compatible with Tuberculosis.

These individuals will be considered TB suspects and will be immediately referred to a local chest clinic or regional chest clinic that has the capability of collecting sputum and performing a clinical evaluation to confirm or rule out the presence of active TB. Referral for consultation is available by contacting the NJDHSS, TB Program at (609)-588-7522.

- X-ray Normal or X-Ray Abnormal - Not Compatible with Tuberculosis.

These individuals can be evaluated by the local chest clinic, regional chest clinic or private medical doctor, and considered for treatment of LTBI. Referral for consultation is available by contacting the NJDHSS, TB Program at (609)-588-7522.

C. TREATMENT FOR LATENT TB INFECTION (LTBI)

- **Rationale:** Unless treated, persons with LTBI who have a history of injection drug use and/or HIV infection are at an increased risk for progressing to clinically active TB disease and infecting staff members and other clients. Treatment of LTBI substantially reduces the risk of developing clinically active tuberculosis in infected persons. Therefore, all clients with a positive TST in whom active TB has been ruled out should be placed on treatment for LTBI unless medically contraindicated. SATFs provide a unique setting in which to efficiently use DOT to reach high risk population and ensure completion of treatment for LTBI.

- **Treatment Regimens for LTBI**

The recommended treatment regimen for LTBI in adults is isoniazid 5 mg/kg (maximum 300 mg) given daily in a single dose for 9 months (total of 270 doses). Completion of therapy is based on total number of doses administered not on duration of therapy alone. Allowing for minor interruptions in therapy, the regimen is considered complete when the client has taken all 270 doses within a 9 to 12 month period. For persons who complete this regimen, the risk of developing active TB is reduced by over 90 percent. This regimen can be given twice weekly by increasing the dosage to 15 mg/kg (maximum 900 mg).

A 6 month regimen of INH is also acceptable, but not as effective as the 9-month regimen. The six-month regimen of INH should consist of at least 180 doses administered within 9 months. Completion of a 6-month regimen of INH reduces the risk of developing active TB by approximately 65 percent.

Twice-weekly INH regimens should consist of at least 76 doses administered within 12 months for the 9-month regimen and 52 doses within 9 months for the 6-month regimen. **Directly observed therapy (DOT) must always be used with twice-weekly dosing.**

Recommendations for HIV-infected adults largely parallel those for HIV-uninfected adults. However, when INH is chosen for treatment of LTBI in persons with HIV infection, 9-month regimens rather than 6-month regimens are recommended.

Other alternative treatment regimens for LTBI are available for individuals who cannot tolerate INH or who may have been exposed to INH-resistant TB. Referral for consultation is available by contacting the NJDHSS, TB Program at (609)-588-7522.

- **Adherence To Treatment for LTBI**

For maximum benefit, every effort should be made to ensure adherence to treatment for LTBI until the client completes the regimen. Since clients will likely have difficulty adhering to the regimen on a self-administered basis, SATFs should not initiate a tuberculin testing program unless the medication can be administered by directly observed therapy (DOT) in the SATF. DOT is defined as "observation of the patient by a health care provider or other responsible person as the patient ingests TB medication." All clients on the twice-weekly regimen must receive each dose on a DOT basis. Referral for consultation on this matter is available by contacting the NJDHSS, TB Program at (609)-588-7522.

- **Site for Providing INH Medication**

Treatment for LTBI can be administered at any of the SATFs, provided that they have a nurse and/or physician on staff who can monitor the patients adherence with medication, observe side effects, administer the medications, and counsel/educate the patients. On-site provision of treatment helps foster continuity of care and is more convenient for the client than referring the client to another site. For clients who routinely return to the SATF at least twice weekly, e.g., to receive methadone, the SATF provides a unique setting in which to efficiently ensure completion of treatment for LTBI through DOT. Referral for consultation regarding the provision and monitoring of INH is available by contacting the NJDHSS, TB Program at (609)-588-7522.

If the SATF is unable to carry out the functions noted above, a tuberculin skin testing program should not be initiated.

For clients with dual tuberculosis and HIV infection (without disease), treatment may be provided at a state or federally funded HIV Early Intervention Program, where both conditions can be treated simultaneously.

- **Monitoring Patients On Treatment for LTBI**

Baseline Evaluation

Baseline laboratory testing is not routinely indicated for all persons at the start of treatment for LTBI, even in older persons. Persons with the following high-risk conditions should have baseline laboratory testing:

- HIV infection.
- History of, or at risk for, chronic liver disease (e.g., hepatitis B or C, alcoholic hepatitis, or cirrhosis).
- Pregnancy and immediate postpartum period (within 3 months of delivery).
- Alcohol abuse.

In these persons taking Isoniazid, baseline hepatic measurements of serum AST (SGOT) or ALT (SGPT) and bilirubin are indicated.

Evaluation During Treatment

- **Clinical Evaluation:** Clients receiving treatment for LTBI should be questioned carefully, at least monthly, for signs and symptoms consistent with liver damage or other adverse effects. These include any of the following: unexplained anorexia, nausea, vomiting, dark urine, jaundice, rash and/or itching, persistent parenthesis of the hands and feet, persistent fatigue, weakness or fever of greater than 3 days duration, and/or abdominal tenderness (especially right upper quadrant discomfort), easy bruising or bleeding, and arthralgia. Clients should be instructed that if any of these or other signs occur during treatment for LTBI, they should report immediately to the treating physician for evaluation, including biochemical tests for hepatitis.
- **Laboratory Monitoring:** Routine laboratory monitoring during treatment of LTBI is indicated for persons whose baseline liver function tests are abnormal and for other persons at risk for hepatic disease (e.g., HIV infection, pregnancy or immediate postpartum, chronic liver disease, or regular alcohol use). Laboratory testing should be used to evaluate possible adverse effects that occur during the course of treatment.

Medication should be withheld if the patient's transaminase level exceeds 3 times the upper limit of normal in the presence of symptoms and 5 times the upper limit of normal if the patient is asymptomatic.

D. TREATMENT OF TUBERCULOSIS DISEASE

Persons with suspected or confirmed TB disease should be started on a drug regimen recommended by CDC/ATS (see reference Treatment of Tuberculosis, MMWR, June 20, 2003, (99-7490)).

However, it is strongly recommended that clients with suspected or confirmed active TB disease be referred to the local chest clinic or the regional chest clinic for treatment and management of their disease, since:

- TB treatment is complex and requires experience and expertise to manage effectively.
- TB Clinics have access to TB experts and other resources to deal with the major problems associated with curing TB patients, such as non-adherent to treatment regimens, drug resistance, adverse reactions to medication, and HIV infection.
- TB Clinics are ultimately responsible for ensuring that persons with TB in the community are promptly started on and complete an appropriate drug regimen and for conducting a thorough contact investigation.

SATFs wishing to provide medical management of clients with active TB should do so in close collaboration with their local or regional chest clinic. Referral for consultation is available by contacting the NJDHSS, TB Program at (609) 588-7522.

Asymptomatic patients with active pulmonary TB disease can resume receiving services at the SATF as soon as they are determined to be non-infectious. Patients are considered non-infectious when they are on effective therapy, are improving clinically, and they have had three consecutive negative sputum AFB smears collected on different days.

E. ANNUAL TESTING

Clients with an Initially Negative TST:

- Annual tuberculin skin testing is not required.

Clients with an Initially Positive TST:

- For clients in whom active TB has been ruled out (e.g., no TB symptoms and a negative X-ray) following an initially positive TST, repeat skin tests and chest X-rays are *not* recommended, even in clients who did not complete treatment for LTBI. These persons should be instructed to seek medical attention, including a chest X-ray, as soon as they experience signs and symptoms suggestive of active TB disease.

Note: Periodic monitoring for symptoms may be considered for clients with a positive TST who are at increased risk for developing TB (e.g., clients with HIV-infection, clients who are otherwise severely immunocomprised or clients whose TST has converted from negative to positive within the last 2 years.)

II. EMPLOYEES

A. INITIAL EXAMINATION

Basis for Testing: These guidelines are based Public Employees Occupational Safety and Health Program (PEOSH) standards and/or recommendations and are recommended by the Centers for Disease Control and Prevention (CDC).

Testing Requirement: All employees will receive a two-step base-line Mantoux tuberculin skin test upon employment. If the result of the initial test is negative, administer a second test one to three weeks later. If the second test is positive, the person is classified as infected; if the second test is negative, the person is classified as uninfected. If a new employee has documentation of having received a single negative TST within the past year, only a one-step Mantoux test is required upon employment. **NOTE:** See protocol under *CLIENTS* for information about administering, reading and interpreting the Mantoux tuberculin skin test.

Exception from Testing: Employees shall be exempt from any testing if they present *written* documentation of:

- A prior positive Mantoux TST
- Prior or present TB disease
- Prior adequate treatment of LTBI
- A negative two-step Mantoux TST within the last year.

Note: A verbal history from the employee of prior testing or treatment results is *not sufficient to exclude testing*. Unless written documentation can be provided, the tuberculin skin test must be performed.

Note: Tuberculin skin testing is *not contraindicated* for persons who have been vaccinated with *BCG*, and, if positive, should be considered to have TB infection. Thus, the skin-test results of such persons should be used to support or exclude the diagnosis of latent TB infection.

B. FOLLOW UP EVALUATION AND TREATMENT

See protocol under *CLIENTS* for the required follow up medical evaluations, treatment, and monitoring of persons identified as having TB infection or disease.

C. ANNUAL TESTING

At minimum, an annual routine one-step Mantoux tuberculin skin test shall be required for all employees with an initially negative TST. For persons with a positive TST in whom active TB disease was initially ruled out, routine follow-up skin tests and chest radiographs are unnecessary. These persons should be instructed to seek medical attention if they experience signs and symptoms suggestive of active TB disease.

In addition, a Tuberculosis Control Program that includes an annual risk assessment of the SATF should be implemented. The frequency of follow-up Mantoux tuberculin skin tests will be based on this risk assessment.

III. POST-EXPOSURE

Employees or clients who were exposed to an individual with suspected or confirmed active infectious TB shall be managed according to CDC recommendations. The SATF should immediately report the possible TB exposure to the local chest clinic/regional chest clinic, which will provide consultation and assistance.

IV. REGIONAL CHEST CLINIC/LOCAL CHEST CLINICS ASSISTANCE WITH NON-ADHERENT CLIENTS

SATF clients with TB disease who are overdue for a medical evaluation or who are non-adherent with prescribed TB therapy should be referred to the local chest clinic/regional chest clinic where the patient resides. Action will be taken based upon the priority of the referral and the availability of resources.

V. DOCUMENTATION

A. IN MEDICAL CHARTS

The New Jersey Department of Health and Senior Services Symptom Assessment Form for Pulmonary Tuberculosis and the Mantoux Skin Test Documentation Sheet (when appropriate) are to be completed for client/employee and placed in the individual's medical record. (See attachment I & II).

B. PERIODIC REPORTING TO THE STATE TB PROGRAM

1. Results of Follow-up as a Result of Post-Exposure to Active TB Case

The Record of Contact Interview form (TB-41) must be completed for a post-exposure episode to an infectious tuberculosis case by a representative of the NJDHSS or local chest clinic/regional chest clinic (with input from appropriate SATF staff). Information about the clients and employees, as well as their initial screening, follow-up medical information, including therapy prescribed (as applicable) should be forwarded to the appropriate State local chest clinic or regional chest clinic, within three weeks after the interview is completed.

These forms may be obtained from the NJDHSS, TB Program (609) 588-7522.

2. Case and Status Reporting of Cases and Suspects

The Tuberculosis Case, Suspect and Status Report (TB-70) form is to be used to report individuals with suspected or confirmed tuberculosis disease. It is also used to report, at minimum, the current status of a person with tuberculosis disease on a quarterly basis. Changes in medication, laboratory results, changes in status, or termination from follow up are to be reported as they occur.

These forms may be obtained from the NJDHSS, TB Program (609) 588-7522.

Attachment I

MANTOUX SKIN TESTING DOCUMENTATION SHEET
SUBSTANCE ABUSE TREATMENT FACILITY

FACILITY: _____ PERIOD: _____

NAME OF CLIENT: _____

MANTOUX SKIN TEST: DATE IMPLANTED _____ TIME: _____
LOCATION: _____

MANUFACTURER OF PPD.: _____ EXPIRATION DATE: _____
LOT NUMBER: _____

NURSE/MD SIGNATURE: _____

RESULTS: DATE READ: _____ TIME: _____
INDURATION/SIZE IN MM: _____

NURSE/MD SIGNATURE: _____

POSITIVE MANTOUX TEST, REFERRED FOR CHEST X-RAY

DATE OF CHEST X-RAY (MOBILE CHEST X-RAY UNIT): _____
RESULTS: _____

INTERVENTIONS TAKEN: _____

SUBMITTED BY: _____ PHONE: _____

Attachment II

NEW JERSEY DEPARTMENT OF HEALTH AND SENIOR SERVICES
SYMPTOM ASSESSMENT FORM FOR PULMONARY TUBERCULOSIS (TB)

Name (Last, First, MI): _____

Birth date (mm/dd/yyyy): _____

Street Address: _____ Phone: (____) _____

City: _____ State: _____ Zip: _____

Date of Symptom Assessment (mm/dd/yyyy): _____

Check all TB-like symptoms that apply:

- Productive Cough of Undiagnosed Cause (more than 3 weeks in duration)
- Coughing Up Blood (Hemoptysis)

These are the primary symptoms of pulmonary TB. If either of the above symptoms is reported, a chest radiograph is warranted regardless of the results of a Mantoux tuberculin skin test.

- Unexplained Weight Loss (10 pounds or greater without dieting)
- Night Sweats (regardless of room temperature)
- Unexplained Loss of Appetite
- Very Easily Tired (Fatigability)
- Fever
- Chills
- Chest Pain

Above are secondary symptoms and if present, without prolonged productive cough or hemoptysis, warrant a Mantoux tuberculin skin test with further evaluation if a significant reaction (10mm or greater) is measured or the patient's medical history indicates a significant risk for active disease (previous exposure to infectious TB, etc.).

- No TB-Like Symptoms Reported or Observed

Next Symptom Assessment Due (mm/dd/yyyy) _____

Person Completing Assessment (Print): _____ Date: _____

REFERENCES

1. CDC. Targeted Tuberculin Testing and Treatment of Latent Tuberculosis Infection, 2000 MMWR Vol.49 (No. RR-6)
2. Model Tuberculosis Infection-Control Program, New Jersey Department of Health and Senior Services, Public Employees Occupational Safety and Health Program, February 1998
3. American Thoracic Society, CDC, Disease Society of America, Treatment of Tuberculosis, 2003, MMWR Vol.52 (No. RR-11)
4. CDC, 1998. Prevention and treatment of tuberculosis among patients infected with human immunodeficiency virus: principles of therapy and revised recommendations. MMWR 47(No. RR-11):36-42.
5. CDC. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care facilities, 1994 MMWR Vol.43 (No. RR-13).

RESOURCES

- **New Jersey Department of Health and Senior Services, Division of Addiction Services**
 - Questions about federal and state requirements for TB testing in SATFs
- **New Jersey Department of Health and Senior Services, Tuberculosis Program 609-588-7522**
 - Questions on the content of the *TB Surveillance Procedures*.
 - Contact and referral information (local or regional chest clinics).
 - Reporting of persons with suspected or confirmed TB.
 - Mantoux TST testing material and Isoniazid to treat LTBI.
 - NJDHSS, TB forms.
- **New Jersey Medical School National Tuberculosis Center**
 - Call the TB Hotline 800-482-3627 for consultation on the clinical management (diagnosis, treatment, infection control) of persons with TB infection or disease.
 - Additional TB information available at the Center's website: <http://www.umdnj.edu/ntbcweb/tbsplash.html>
- **Local Chest Clinic or Regional Chest Clinic List** available from the State Tuberculosis Program.
 - Reporting of persons with suspected or confirmed TB.
 - Arranging for isolation of persons with suspected or confirmed TB.
 - Referral of persons with LTBI for a chest x-ray and evaluation for active TB.
 - Consultation on providing treatment for LTBI at the SATF, including directly observed therapy.
- **Centers for Disease Control and Prevention (CDC), Division of Tuberculosis Elimination (DTBE)** The CDC/DTBE website (<http://www.cdc.gov/nchstp/tb/default.htm>) contains a wealth of information on the prevention and control of TB. The website includes an on-line ordering system (https://www2.cdc.gov/nchstp_od/PIWeb/TBorderform.asp) from which users can view, order, and download *free of charge* a variety of educational materials and current guidelines. Materials can also be ordered from a touch tone phone by calling (888) 232-3228, then press options 2, 5, 1, 2 (Note: You may select these options at any time without listening to the complete message). SATFs may find the following items especially useful:
 - **Health Care Provider Educational Materials**
 - **Interactive Core Curriculum on Tuberculosis, 4th Edition(CD ROM) – 2004 (Order # 99-8049)** training guide on clinical & public health aspects of TB control
 - **TB Information CD ROM – Version 4.1, 12/04 (99-6879)**
 - TB materials, major TB guidelines, MMWRs, surveillance reports, and slide set
 - **TB Facts for Health Care Workers – 1997 (99-5497)**
14-page booklet for clinicians on diagnosis, treatment, and prevention of TB
 - **Think TB!**
Wall poster listing the symptoms of active TB.
 - In English – 1992 (00-6186)
 - In Spanish – 1993 (00-6406)
 - **Mantoux Tuberculin Skin Testing**
Visual aids and tools pertaining to the Mantoux test
 - **Ruler – 2002 (99-7047)**
 - **Wall Chart – 2004 (New) (005564)**
 - **Videotape Training Kit – 2003 (00-5457)**
 - **Health Care Provider Guidelines**
 - **Targeted Tuberculin Testing and Treatment of Latent TB Infection. MMWR, April 2000 (99-6422)**
 - **Treatment of Tuberculosis, MMWR, June 20, 2003, (99-7490)**
 - **Prevention and Treatment of Tuberculosis Among Patients Infected with Human Immunodeficiency Virus: Principles of Therapy and Revised Recommendations. MMWR, October 30, 1998. (99-5879)**
 - **Guidelines for Preventing the Transmission of Mycobacterium tuberculosis in Health Care Facilities. MMWR, 1994. (00-5856)**
 - **Patient Education Materials**
 - **Tuberculosis - Get the Facts! – 1990:** One-page pamphlet on basic facts about TB transmission, infection, and the tuberculin skin test
 - In English (00-5743)
 - In Spanish (00-5772)

- **Tuberculosis - The Connection Between TB and HIV (the AIDS Virus)-1990** One-page pamphlet on the risk of HIV-related TB, tuberculin skin testing, and preventive therapy (treatment of LTBI)
 - In English (00-5738)
 - In Spanish (00-5745)
- **Tuberculosis Fact Sheets (tear-off pads, 40 tear-off sheets per pad) - 1997**
 - TB Facts - You Can Prevent TB (00-5981)
 - TB Facts - TB and HIV (The AIDS Virus) (00-5982)
 - TB Facts - Exposure to TB (00-5983)
 - TB Facts - The TB Skin Test (00-5984)
 - TB Facts - TB Can Be Cured (00-5985)
 - Stop TB! - 1994
 - Wall poster describing the transmission and pathogenesis of TB (00- 6474)
 - Pad of 50 tear-off sheets duplicating the Stop TB! wall poster (00- 6475)
- **Treatment of Latent Tuberculosis Infection (LTBI) Card and Poster** Provides summary information on drug regimens, monitoring, and candidates for treatment of LTBI. Available in two formats:
 - Pocket Reference Card (5.5" X 4.25")
 - Clinic Poster (13" X 19.5")

These can be ordered free of charge from the Charles P. Felton National TB Center at Harlem Hospital website (<http://www.harlemtbcenter.org/prods.htm>) or by fax (212-939-8259)

Administrative correction.
See: 41 N.J.R. 2658(a).

APPENDIX B

Administrative Bulletin
Division of 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 opiate 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 to 100 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 Addiction Services (DAS) 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 opiate dependence only in the formulation as Suboxone or Subutex. **Injectable Buprenorphine is not approved for the treatment of opiate dependence.**

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 a DAS licensed substance abuse 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 abuse 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 abuse 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 DMS-IV-TR criteria for opiate dependence or opiate abuse.**

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 opiate dependence 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 Patient Placement Criteria-2). **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

Opiate 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 abuse treatment providers or medical practitioners using Buprenorphine, in the form of Suboxone and Subutex, for the treatment of opiate dependence for medical maintenance and medically supervised withdrawal.

