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RULE PROPOSALS

**HUMAN SERVICES
DIVISION OF ADDICTION SERVICES**

43 N.J.R. 2218(a)

Proposed New Rules: N.J.A.C. 10:161A

[Click here to view Interested Persons Statement](#)

Licensure of Residential Substance Use Disorders Treatment Facilities

Authorized By: Jennifer Velez, Commissioner, Department of Human Services.

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

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2011-182.

Submit written comments by November 5, 2011 to:

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Division of Addiction Services
New Jersey Department of Human Services
120 South Stockton Street, 3rd Floor
PO Box 362
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The agency proposal follows:

[page=2219] **Summary**

N.J.A.C. 8:42A, Manual of Standards for Licensure of Residential Substance Abuse Treatment Facilities, was adopted as new rules on November 15, 1999 and expired on November, 15 2004. Although the rules expired, the standards and

procedures incorporated in the former rules have continued to be used and constitute the current requirements and standards for licensure of residential substance use disorders treatment facilities in New Jersey.

As a result of Reorganization Plan 002-2004 issued on February 4, 2004 and published in the New Jersey Register at 36 N.J.R. 1149(a), A Plan for the Transfer, Consolidation and Reorganization of the Division of Addiction Services Into the Department of Human Services, the functions, powers and duties of the Division of Addiction Services in the Department of Health and Senior Services, including, but not limited to, the functions, powers and duties under N.J.S.A. 26:2H-1 et seq., and 26:2B-6 et seq., as they apply to residential and ambulatory residential substance use disorders treatment facilities, were transferred, along with necessary personnel, to the Department of Human Services effective April 5, 2004. The Reorganization Plan also provided that "[w]henever in any law, rule, regulation, order, contract, tariff, document, judicial or administrative proceeding or otherwise relating to the Division of Addiction Services reference is made to Department of Health and Senior Services or the Commissioner of Health and Senior Services, the same shall mean the Department of Human Services or the Commissioner of Human Services, respectively."

With the transfer of the Division of Addiction Services ("DAS" or "Division") and its addiction facility licensure authority from the Department of Health and Senior Services (DHSS) to the Department of Human Services (DHS), DAS now proposes to create new N.J.A.C. 10:161A, Licensure of Residential Substance Use Disorders Treatment Facilities, to regulate such programs.

Following transfer of the Division from DHSS to DHS on April 5, 2004, DAS began a process to review and, as necessary, upgrade the licensure standards of residential substance use disorders programs with an overall goal to improve the quality of care for clients. At that time, this process was undertaken in consultation with all affected residential programs and their trade organizations in the State, in particular the New Jersey Association of Treatment Providers and the New Jersey Association of Alcohol and Drug Abuse halfway houses. During this review, DAS held monthly meetings with residential facility staff to examine each chapter of the residential licensure standards under the then current N.J.A.C. 8:42A. Additional review was provided by nurses, physicians, counselors and other professionals practicing in residential facilities. The residential licensure standards at N.J.A.C. 8:42A were also reviewed for content and format consistency with outpatient facility licensure standards then under separate development, and subsequently proposed the separate new rules as N.J.A.C. 10:161B at 40 N.J.R. 535(a) and adopted the new rules at 41 N.J.R. 2268(b), effective June 1, 2009.

Proposed new N.J.A.C. 10:161A includes new standards and requirements that did not exist in former N.J.A.C. 8:42A and builds on earlier draft versions of proposed new N.J.A.C. 10:161A developed during the aforementioned process. In order to provide stakeholders an opportunity to review and provide informal feedback on a more recent draft version of proposed new N.J.A.C. 10:161A, the Division held an informal meeting on March 12, 2009 for residential providers and interested parties. Both verbal and informal written comments were provided to Division staff during this meeting. Additionally, the Division received informal feedback and informal written comments on this draft version of proposed new N.J.A.C. 10:161A from various residential treatment providers and interested parties throughout the summer of 2009. Following this effort, the Division worked closely with the Department's Health Insurance Portability and

Accountability Act (HIPAA) officer who provided technical assistance to ensure that proposed new N.J.A.C. 10:161A was HIPAA compliant.

The following documents are incorporated into the rules by reference, as amended and supplemented:

1. The "ASI," which is the Addiction Severity Index, 5th edition, as developed and available from the Treatment Research Institute, and is first incorporated at N.J.A.C. 10:161A-1.9(d)2. The ASI is an instrument designed to provide important information about aspects of a client's life that may contribute to his or her substance use disorder;

2. The "DSM-IV-TR," which is the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision, and is first incorporated at N.J.A.C. 10:161A-1.9(d)2. The DSM-IV-TR is a document that lists the standard classification of mental disorders in the United States;

3. The "ASAM Patient Placement Criteria" (ASAM PPC-2R), which is the criteria developed by the American Society of Addiction Medicine, contained in "Patient Placement Criteria for the Treatment of Substance Related Disorder," 2d Edition revised (2001) and is first incorporated at N.J.A.C. 10:161A-1.9(d)3. The ASAM PPC-2R determines the appropriate level of care for substance abuse treatment;

4. The "Confidentiality of Alcohol and Drug Abuse Patient Records," 42 CFR Part 2, which is first incorporated at N.J.A.C. 10:161A-3.4. 42 CFR Part 2 is the Federal regulations pertaining to the confidentiality of alcohol and drug abuse patient records;

5. The "Health Insurance Portability and Accountability Act of 1996" (HIPAA) and its implementing regulations at 45 CFR Parts 162 and 164, which are first incorporated at N.J.A.C. 10:161A-3.4. HIPAA is the Federal law that provides for the protection of client identifiable information;

6. The "Tuberculosis Surveillance Procedures for Substance Abuse Treatment Facilities," which are first incorporated at N.J.A.C. 10:161A-3.7 and located at the chapter Appendix A. Chapter Appendix A describes procedures for licensed substance abuse treatment facilities in monitoring and testing for tuberculosis;

7. The "DAS Buprenorphine Guidelines, Administrative Bulletin 4-2007," which are first incorporated at N.J.A.C. 10:161A-7.1 and are the DAS published guidelines for the use and practice of Buprenorphine for the treatment of opiate dependence. This document is not incorporated by reference as amended and supplemented, any changes to the document will be accomplished through a Division rulemaking;

8. The "DAS Vivitrol Injectable Guidelines, Administrative Bulletin" (issued November 30, 2010), which are first incorporated at N.J.A.C. 10:161A-7.1 and are the DAS published guidelines for the use and practice of Vivitrol in Alcohol and Opiate maintenance therapy in conjunction with a full treatment experience, which includes psychological counseling and aftercare programs. This document is not incorporated by reference as amended and supplemented, any changes to the document will be accomplished through a Division rulemaking;

9. The "United States Pharmacopoeia, USP27NF22 (2004)," which is first incorporated at N.J.A.C. 10:161A-14.2(a)6ii and sets the standards for drug products;

10. The "National Fire Protection Association 10" (NFPA 10), 2002 edition, which is first incorporated at N.J.A.C. 10:161A-16.2. The NFPA 10 sets the standards for portable fire extinguishers;

11. The Occupational Safety and Health Administration (OSHA) rules at 29 CFR 1910.1030, "Bloodborne Pathogens," which are first incorporated at N.J.A.C. 10:161A-20.1. Bloodborne Pathogens sets standards for infection control guidelines;

12. The CDC "Guideline for Preventing Healthcare-Associated Pneumonia (2003)," which is first incorporated at N.J.A.C. 10:161A-20.1(c)2. These guidelines are designed to reduce the incidence of healthcare-associated pneumonia and other severe, acute lower respiratory tract infection in facilities where health care is provided;

13. The CDC "Guidelines for Hand Hygiene in Healthcare Settings (2002)," which is first incorporated at N.J.A.C. 10:161-20.1(c)2. These guidelines are designed to improve hand-hygiene practices in healthcare facilities;

14. The 2007 SAMHSA National Outcome Measures, which are first incorporated at N.J.A.C. 10:161A-22.2(c)1. The 2007 SAMHSA National Outcome Measures refers to the data that covers the domains for all discretionary and block/formula grant programs with client-level outcomes;

15. The New Jersey Uniform Construction Code, N.J.A.C. 5:23 (NJ UCC), which is first incorporated at N.J.A.C. 10:161A-24.1(a). The NJ UCC incorporates specific chapters of the International Building Code 2006, New Jersey Edition, appropriate to Use Groups I-1;

16. The "Guidelines for Design Construction of Hospital and Healthcare Facilities 2006," which is first incorporated at N.J.A.C. [page=2220] 10:161-24.1(a). This document provides construction guidelines for the use of physical space for residential programs and hospitals; and

17. The "American National Standard ICC/ANSI A117.1-2003," which is first incorporated at N.J.A.C. 10:161A-24.5 and the "Accessibility Guidelines for Buildings and Facilities (2002)," which is first incorporated at N.J.A.C. 10:161A-24.6. Both of these guidelines are the national standards for building construction, healthcare-related facilities and accessibility for the disabled and handicapped.

Following is a subchapter by subchapter summary of proposed new N.J.A.C. 10:161A:

Subchapter 1, Definitions and Qualifications, outlines the scope and applicability of the proposed new chapter to all health care facilities that provide residential substance use disorders treatment services to adults and adolescents, including designated units of hospitals; describes the overall purpose of the proposed rules; defines all words and terms used in the proposed rules; and describes the qualifications and responsibilities of the medical director, director of nursing services, administrator of the facility, dietitians, food supervisors, director of substance abuse counseling services, pharmacists and substance abuse counseling staff.

Subchapter 2, Licensure Procedures and Enforcement, describes the general application process, fees and requirements; special requirements for newly

constructed or expanded facilities; the review and approval of a license application; facility surveys; conditional licenses; periodic surveys following licensure; deficiency findings; informal dispute resolution; plans of correction; surrender of a license; the possibility of licensure waivers; enforcement remedies; notice of violations; effective date of enforcement actions; enforcement actions; failure to pay a penalty, remedies; curtailment of admissions; provisional license; suspension of a license; revocation of a license; injunction; hearings; and settlement of enforcement actions.

These proposed licensure and enforcement procedures, N.J.A.C. 10:161A-2, follow generally the former licensure standards set forth in N.J.A.C. 8:42A-2, combined with enforcement standards modeled from DHSS as set forth in N.J.A.C. 8:43E. The standard contained in N.J.A.C. 8:42A-2.1(a), which required a certificate of need letter from the Commissioner of Health and Senior Services, is deleted because certificate of need requirements no longer apply to this category of facility, and authority for residential substance use disorders treatment facility licensure has transferred from DHSS to the Department of Human Services, Division of Addiction Services. There are no proposed changes in facility licensure fees and facilities will continue to submit licensure applications to DAS as they have done since the effectuation of Reorganization Plan of 2004 rather than to DHSS. The major difference between the proposed rules and the former standards is that some enforcement authority and remedies have been reduced in the proposed new rules. When drug abuse treatment facilities were regulated under DHSS, statutory authority at N.J.S.A. 26:2H-13 and 14 authorized DHSS to impose civil monetary penalties on a facility of between \$ 250.00 to \$ 2,500 per day, depending on the severity of the licensure violation by the facility. The DHSS statute also authorized that department to close a facility on a cease and desist order issued by the Commissioner of Health and Senior Services. Although the 2004 Reorganization Plan transferring DAS from DHSS to DHS included alcohol and drug abuse treatment facility licensing authority, the Plan did not specifically transfer DHSS statutory authority to DHS to impose these enumerated civil monetary penalties and cease and desist orders. The Department of Human Services and Division of Addiction Services must now, therefore, rely on and propose to use enforcement remedy authority from these separate statutes, N.J.S.A. 26:2BB-5, 26:2B-7 et seq., and 30:1-12 that currently authorize civil monetary penalties of \$ 25.00 to \$ 50.00 per day for unlicensed facility operation, as proposed at N.J.A.C. 10:161A-2.17(a)1.

Subchapter 3, General Requirements, describes the provision of services; compliance with laws and rules; ownership requirements; submission of documents and data; personnel requirements, including minimum client to staff ratios; what must be included in a facility's policy and procedure manual; requirements for employee health; what unusual events must be reported to which agencies or authorities; notices of information that must be posted at the facility; reporting to professional licensing boards; special requirements for the provision of transportation services to clients; and smoke-free requirements on grounds and within the facility.

Subchapter 4, Governing Authority, describes the responsibilities of the facility's governing authority, including oversight of facility operations and the authority's own governing procedures.

Subchapter 5, Administration, describes the appointment of an administrator.

Subchapter 6, Client Care Policies and Services, delineates client care policies, including a client care policy committee; client continuity of care and client safety; standards for preadmission, admission and retention of clients; involuntary discharge; use of restraints; calibration of instruments; and interpretation services.

Subchapter 7, Medical Services, describes the provision of medical services; and medical policies and medical staff bylaws.

Subchapter 8, Nursing Services, describes the provision of nursing services.

Subchapter 9, Client Assessment and Treatment Plan, describes the process of client assessment; and client treatment planning.

Subchapter 10, Substance Abuse Counseling and Supportive Services, delineates the provision of substance abuse counseling, including requirements for structured activities and minimum average counselor to client ratios; appointment of a director of substance abuse counseling services; required supportive services; and co-occurring services.

Subchapter 11, Educational Services, describes the provision of education services to adolescents.

Subchapter 12, Laboratory and Radiological Services, describes minimum laboratory services that must be provided directly or ensured by licensed residential facilities.

Subchapter 13, Recreational Services, delineates the required provision of recreational services.

Subchapter 14, Pharmaceutical Services, describes required provision of pharmaceutical services; standards for drug administration, including self administration; standards for storage of medications; and additional standards for facilities that provide medically monitored detoxification services.

Subchapter 15, Dietary Services, describes the provision of dietary services, the responsibilities of dietary personnel and the requirements for dietary services.

Subchapter 16, Emergency Services and Procedures, delineates the emergency plans and procedures; drills, tests and inspections; and emergency medical services that must be provided or arranged by a licensed facility.

Subchapter 17, Client Rights, describes how each licensed facility must establish policies and procedures to ensure client rights; describes client rights; and describes how complaints may be brought by clients or their families internally with the facility, or externally with outside oversight agencies.

Subchapter 18, Continuum of Care Planning Services, describes required continuum of care planning; continuum of care planning policies and procedures; and client and family education.

Subchapter 19, Clinical Records, describes how licensed facilities must create and maintain a clinical record for each client, including maintenance of clinical records; assignment of responsibility; contents of clinical records; requirements for clinical record entries; access to clinical records; and

preservation, storage and retrieval of clinical records.

Subchapter 20, Infection Prevention and Control, describes the requirements for infection prevention and control and regulated medical waste.

Subchapter 21, Housekeeping, Sanitation and Safety, delineates requirements for the provision of services; housekeeping; the client care environment; waste removal; water supply; and laundry services.

Subchapter 22, Quality Assurance Program, describes facility requirements to create and maintain a quality assurance program; responsibilities for administration of a quality assurance program; and requiring quality assurance programs to be consistent with Federal Substance Abuse and Mental Health Services Administration (SAMHSA) National Outcome Measures and quality assurance activities.

Subchapter 23, Volunteer Services, describes the provision of volunteer services; and volunteer policies and procedures.

[page=2221] Subchapter 24, Physical Plant and Functional Requirements, describes the following requirements and standards: physical plant general compliance for new construction or alteration; physical plant general compliance for construction or alteration completed prior to the effective date of this chapter; plan review and fees; alterations, replacements and damage to existing facilities; provisions for individuals with physical disabilities; restrictions; ventilation; exit access passageway and corridors; automatic fire alarm and detection systems; fire suppression systems; interior finish requirement; attached structures; and multiple occupancy. It also describes citations specific to rehabilitation and barrier free Subchapter of the New Jersey Uniform Construction Code, N.J.A.C. 5:23 and the American National Standard ICC/ANSI A117.1-2003.

Subchapter 25, Physical Environment, describes requirements for resident bedrooms and baths; living and recreation rooms; dining rooms; storage; laundry equipment; kitchens; fire extinguisher specifications; employee rooms, sounding devices; and ceiling height.

Subchapter 26, Existing Facilities, describes physical plant standards for all existing licensed facilities; fire safety requirements for existing facilities; and resident bedrooms.

Subchapter 27, Confidentiality, describes confidentiality requirements for licensed residential substance use disorders treatment facilities.

Chapter 161A Appendix A, Tuberculosis Surveillance Procedures for Substance Abuse Treatment Facilities (SATFs), as prepared by the Department of Health and Senior Services outlines the criteria for testing employees of licensed substance abuse treatment facilities.

Chapter 161A Appendix B, Administrative Bulletin, Division of Addiction Services, Buprenorphine Guidelines, outlines guidelines for the use and practice of Buprenorphine for treatment of opiate dependence.

Chapter 161A Appendix C, Administrative Bulletin, Division of Addiction Services, Vivitrol Injectable Guidelines, outlines guidelines for the use and practice of Vivitrol in Alcohol and Opiate maintenance therapy in conjunction

with a full treatment experience, which includes psychological counseling and aftercare programs.

As the Department has provided a 60-day comment period for this notice of proposal, this notice is excepted from the rulemaking calendar requirements, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The social impact of the proposed new rules is expected to be significant and positive and is expected to have a beneficial impact upon individual clients and their families, providers of treatment services, the health care and social service systems and the public in general. Drug and alcohol abuse and addiction is a major social and health issue nationally and in New Jersey. While addiction to or abuse of substances is difficult to overcome, addiction treatment programs in New Jersey have helped many citizens to be rehabilitated and become productive members of society.

An estimated 13.6 percent or 905,650 of New Jersey's total population are alcohol or drug dependent persons. In State Fiscal Year (SFY) 2010, there were more than 70,000 admissions into all levels of treatment; with 16,300 or 23 percent of all treatment admissions to residential substance use disorders treatment facilities. By subjecting every program and facility providing residential substance use disorders treatment to a stringent licensure process, the proposed new rules provide for continued quality assurance in the delivery of services to these clients.

In addition, consumers using this system will be assured, through the licensure process, of an adequate and consistent level of care and supervision as specified in each rule. Consumers include not only clients directly utilizing the services, but referral services, such as the courts, social service agencies or health insurance and managed care organizations. Further, the newly proposed residential licensure standards are expected to maintain professionalism and provide for client-centered, recovery-oriented care by integrating various services for each type of residential facility and for targeted populations.

While licensure impacts individual programs and facilities differently, it is not expected that residential facilities as a group will be required to significantly upgrade their operations on a variety of levels, including the professional qualifications of counseling staff and facility management, the minimum ratio of counseling staff to clients and the quality of physical facilities. Based on results of an internal Division study of client to counseling staff caseloads of outpatient programs and residential treatment facilities, the Division determined that it was appropriate to ease the client-to-counseling staff requirement from 75 percent of staff certified as Licensed Clinical Alcohol and Drug Counselors or Certified (LCADC) and Drug Counselors Alcohol (from former rule N.J.A.C. 8:42A) to requiring 50 percent of staff be certified as Licensed Clinical Alcohol and Drug Counselors or Certified Alcohol and Drug Counselors (CADC), or other licensed professionals for whom alcohol and drug counseling is within their scope of practice, as is the case with the adopted outpatient licensure rules at N.J.A.C. 10:161B.

There is a general consensus within the addiction treatment community that practices must be standardized and improved and that licensure is the best way to provide for this.

Economic Impact

As of September 2010, there are approximately 62 residential substance use disorders drug abuse treatment facilities in New Jersey licensed under the standards of the former rules at N.J.A.C. 8:42A. An additional 22 facilities have applied for residential licensure under the former standards. As in the former rule, residential treatment facilities applying for licensure will be required to comply with the licensing fees as set forth in Subchapter 2. Licensing fees are also established for new facilities, license renewals, license modifications, transfer of ownership and biennial DAS inspection fees. Additionally, an enforcement provision exists in this chapter that allows the Commissioner or his or her designee to impose monetary penalties should an agency violate licensure rules as set forth in this chapter.

Federal Standards Statement

The proposed new rules do not impose standards on residential addiction treatment facilities in New Jersey that exceed those contained in any Federal regulations that may be applicable to these facilities. Federal laws are included by reference in this chapter, as discussed in the Summary above, however, this chapter does not exceed the standards in these laws or regulations, such as HIPPA or Confidentiality Provisions found at 42 CFR Part 2. There is no Federal law which is analogous to these State licensure rules for residential addiction treatment facilities.

Jobs Impact

Although it is difficult to estimate the aggregate jobs impact of the proposed residential licensure rules, the aggregate impact is not expected to be high because this proposed new rules either carry forward or ease the staffing credentialing requirements of the former rule. To provide additional support in the field, in early 2006, the Division embarked on a Workforce Development Initiative, that offered scholarships for individuals to attend alcohol and drug counseling classes in order to expand the number of LCADCs and CADCs throughout New Jersey. Since its inception, approximately 643 individuals have attended classes while 135 of that number have obtained certification or licensure as alcohol or drug counselors in New Jersey. It is possible that some new or currently unlicensed programs may gain jobs from additional third-party revenue as the result of obtaining a license for the first time.

Agriculture Industry Impact

The proposed new rules contain no provisions that will in any way impact on New Jersey's agriculture industry.

Regulatory Flexibility Analysis

This chapter sets forth a regulatory scheme that will not only impact currently licensed residential alcoholism and drug abuse treatment facilities but will also impact currently non-licensed facilities and programs. The Department has determined that these residential licensure standards are necessary. The Department acknowledges that all facilities required to be licensed under these rules have fewer than 100 full-time employees and are, therefore, categorized as small businesses, as defined in the New Jersey

Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq.

The services provided for clients in various programs and facilities are, or will be, specified by this chapter, regardless of the size of the program or facility. Therefore, the Department has determined that standards apply regardless of program or facility size, and that no differentiation based on size should be provided. The proposed rules have been balanced to minimize adverse economic impact on small businesses while [page=2222] simultaneously assuring quality. The waiver provisions provide the opportunity to modify rules where they would present a clear economic hardship, provided that said waiver does not appreciably detract from program quality and that public health, safety or the general welfare is not jeopardized.

The professional requirements include those for licensed social workers, registered professional nurses, physicians and substance abuse counselors. It is anticipated that facilities whose staffs do not meet the minimum requirement will, over time, assist the staff in reaching the requirements, and this may involve costs to the facility for the provision of training courses or reimbursement to the employees for training. However, costs may be offset by staff taking advantage of the Division's Workforce Development Initiative in which payment for the courses required by the State Board of Marriage and Family Therapy Examiners Alcohol and Drug Counselor Committee for licensure as an LCADC or certification as a CADC is subsidized by the Division. Application fees for certification and licensure that are paid to the State Board of Marriage and Family Therapy Examiners, Alcohol and Drug Counselor Committee for licensure as an LCADC or certification as a CADC are subsidized by the Division. Agencies may provide funding support for licensing fees and test taking fees, as well as providing tuition support for staff that wish to take master's level courses for counseling or social work.

Licensed agencies will be required to comply with all applicable Federal, State and local laws, and rules and accrediting organizations as applicable. This chapter sets forth a new provision for all licensed residential facilities to be Smoke Free in accordance with the New Jersey Smoke Free Air Act, P.L. 2005, c. 383. Agencies will be required to be completely smoke free as of December 12, 2012.

This chapter requires agencies to report client data through NJSAMS, as well as immediately report any event occurring within the facility that jeopardizes the health, safety or welfare of clients or staff. These requirements are consistent with those outlined in N.J.A.C. 10:161B.

The number of programs and facilities expected to be impacted by these specific residential licensure rules is estimated at 90. One agency may provide both residential and outpatient substance use disorders treatment services. An agency that holds or applies for a residential license, under the current standards and under the proposed new rules, will also continue to be required to hold or apply separately for an outpatient facility license separately under adopted outpatient licensure rules at N.J.A.C. 10:161B. The Department will continue to provide technical assistance to facilities in helping them meet and maintain required standards.

Smart Growth Impact

The proposed new rules are not anticipated to have an impact on the

achievement of smart growth and the implementation of the State Development and Redevelopment Plan.

Housing Affordability Impact Analysis

The proposed new rules will have an insignificant impact on affordable housing in New Jersey and there is an extreme unlikelihood that the rules would evoke a change in the average costs associated with housing prices because the rules pertain to licensing of residential substance use disorders treatment facilities.

Smart Growth Development Impact Analysis

The proposed new rules will have an insignificant impact on smart growth and there is an extreme unlikelihood that the rules would evoke a change in house production in Planning Areas 1 or 2, within designated centers, under the State Development and Redevelopment Plan in New Jersey because the rules pertain to the licensing of residential substance use disorders treatment facilities.

Full text of the proposed new rules follows:

CHAPTER 161A

STANDARDS FOR LICENSURE OF RESIDENTIAL SUBSTANCE USE DISORDERS TREATMENT FACILITIES

SUBCHAPTER 1. DEFINITIONS AND QUALIFICATIONS

10:161A-1.1 Scope and applicability

(a) This chapter applies to substance (alcohol and drug) abuse treatment facilities that provide residential substance use disorders treatment to adults and adolescents including, but not limited to, halfway houses, extended care facilities, long-term residential facilities, short-term residential treatment facilities and non-hospital-based (medical) detoxification or any other similar such organization. The rules in this chapter constitute the basis for the licensure and inspection of residential substance use disorders treatment facilities by the New Jersey Department of Human Services, Division of Addiction Services (DAS).

(b) This chapter also applies to hospitals licensed pursuant to N.J.A.C. 8:43G that offer hospital-based medical detoxification services in a designated detoxification unit or facility or provide any of the modalities of residential treatment listed in (a) above. This chapter, while not requiring a separate license for hospital-based substance abuse treatment facilities, sets out standards with which hospitals providing services covered by this chapter must comply.

10:161A-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 to which residential substance use disorders treatment facilities must adhere in order to be licensed to operate in New Jersey.

10:161A-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: Joint Commission, <http://www.jointcommission.org>; 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 facilities and individual sites within a licensed facility.

"Admitted" means accepted for treatment at a residential substance use disorders treatment facility.

"Adolescent" means a person between the ages of 12 up to and including the 18th birthday.

"Adolescent residential substance use disorders treatment facility" means a free-standing residential facility or a distinct part of a facility where care is provided to two or more adolescent clients for the treatment and prevention of substance dependence, under supervision for more than 24 consecutive hours.

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

"ASAM Patient Placement Criteria" means the criteria developed by the American Society of Addiction Medicine, contained in "Patient Placement Criteria for the Treatment of Substance Related Disorder," 2d Edition revised (2001) (ASAM PPC-2R), incorporated herein by reference, as amended and supplemented, which can be obtained from the ASAM Publications Center, 1-800-844-8948.

"ASI" means the Addiction Severity Index, 5th Edition, incorporated herein by reference, as amended and supplemented, which is an instrument designed to provide important information about aspects of a client's life that may contribute to his or her substance use disorder, as developed and available from the Treatment Research Institute, 600 Public Ledger Building, Philadelphia, PA 19106, (215) 399-0980, www.tresearch.org/asi.htm.

"Available" means, for individuals employed by or under contract with a residential substance use disorders treatment facility, capable of being reached and able to be present in the facility within 30 minutes.

[page=2223]"BOCA" means the model building code of the organization formerly called Building Officials and Code Administrators International Inc., now called the International Code Council; which can be obtained at 4051 W. Flossmoor Road, Country Club Hills, IL 60477-5795, <http://www.ICCsafe.org>, 1-888-422-7233, or from the ICC Store, 1-800-786-4482.

"Bylaws" means a set of rules adopted by the facility 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, <http://www.cdc.gov>.

"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://www.samhsa.gov/about/csat.aspx>.

"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 a person 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 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.

"Clear floor area" means room space exclusive of toilet rooms, fixed closets, fixed wardrobes, alcoves or vestibules.

"Client" means any individual who has applied for or been given a diagnosis or treatment for alcohol or drug abuse at a licensed program under this chapter and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program. In the context of this chapter, client is synonymous with patient or resident.

"Clinical note" means a written, signed and dated notation made by a licensed or credentialed professional, an approved counselor-in-training (pursuant to N.J.A.C. 10:161A-1.9(a)2) or other authorized representative of the facility who renders a service to the client or records observations of the client's progress in treatment. The notes shall include medication prescription and monitoring; session start and stop times; modalities and frequencies of treatment; results of clinical tests; summary of any of the following; and diagnosis, functional status, treatment plan, symptoms, prognosis and progress.

"Clinical supervision" means the ongoing process of direct review of a supervisee for the purpose of accountability, teaching, administering or clinical review by a qualified clinical supervisor from the same area of specialized practice providing regular consultation, guidance and instruction to the supervisee.

"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.

"Communication access" means the provision of communication access services or accommodations (either through direct provision or by way of referral) provided to clients with visual impairment or a hearing loss and/or a different linguistic background to fully participate and benefit from substance use disorders treatment services; examples may include assistive listening devices/systems, CART realtime captioning, sign language interpreters.

"Conditional license" means a license pursuant to N.J.A.C. 10:161A-2.7. A conditional license requires the licensee to comply with all specific conditions imposed by DAS in addition to the licensure requirements in this chapter.

"Confidentiality" means the protection of individually identifiable information as required by State and Federal legal requirements as specified in HIPAA.

"Conspicuously posted" means information 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 during the course of treatment that addresses the needs of the client after discharge; may be referred to as a Discharge Plan.

"Controlled dangerous substances or controlled substances" means drugs subject to the Federal Controlled Dangerous Substances Act of 1970 (Title 11, Public Law 91-513, 21 U.S.C. §§ 801 et seq.), the New Jersey Controlled Dangerous Substances Act of 1970, N.J.S.A. 24:21-1 et seq. and the Controlled Dangerous Substances rules, N.J.A.C. 13:45H.

"Co-occurring disorder" (COD) means the co-occurrence of substance-related and mental disorders as described by the Diagnostic and Statistical Manual of Mental Disorders, DSM-IV-TR, in which the substance abuse and mental health disorders are primary.

"Co-occurring disorder assessment" means an assessment, which includes a full mental status evaluation, a detailed history of psychiatric symptoms, a review of and, if necessary, expansion of, the information collected while completing the ASI and reviewing the previous treatment records.

"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 use disorders that are maladaptive, destructive and/or injurious to health through the provision of individual, group and/or family therapy by licensed or certified professionals or approved counselors-intern. Counseling does not include self-help support groups, such as Alcoholics Anonymous, Narcotics Anonymous or similar 12-step facilities.

"Counselor-intern" shall mean either a "credentialed intern" or an "alcohol and drug counselor intern," as defined at N.J.A.C. 13:34C-6.1.

"Curtailement" means an order by DAS, which requires a licensed substance use disorders treatment facility to cease and desist all admissions and readmissions of clients to the facility or affected service.

"DAS" or "Division" means the Division of Addiction Services, the single State agency for substance abuse issues in the State of New Jersey, and is a division within the New Jersey Department of Human Services,

<http://www.state.nj.us/humanservices/das/home/index.html>.

"DCF" means the New Jersey Department of Children and Families.

"DHSS" means the New Jersey Department of Health and Senior Services.

"DSM-IV-TR" means the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision, incorporated herein by reference, as amended and supplemented, the standard classification of mental disorders in the United States, published by and available from the American Psychiatric Association, 1000 Wilson Boulevard, Arlington VA 22209, <http://psychiatryonline.com/about.aspx>.

"Daily census" means the number of clients residing in the facility on any given day.

"Deficiency" means a determination by DAS of one or more instances in which a State licensing rule or a Federal certification regulation has been violated.

"Department" or "DHS" 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 designated in writing by the client to be notified if the client sustains an injury requiring medical care; if an accident or incident occurs; if there is deterioration in the client's physical or mental condition; if the client is transferred to another facility; or if the client is discharged or dies while in treatment.

"Detoxification" means the provision of care, short-term and/or long-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.

"Didactic session" means a structured treatment intervention designed to instruct or teach clients about topics related to substance use disorders and treatment related issues.

[page=2224]"Disclosure" means the release, transfer, provision of, access to, confirmation of or communication in any manner of information identifying a past or present client or an applicant for services or verifying another person's disclosure, which identifies an individual as a client or the communication of any other information from the record of a client who has been identified. As used in this definition, "applicant for services" shall mean an individual who has applied for diagnosis of treatment at a licensed substance use disorder facility.

"Division Director" means the individual responsible for administratively overseeing substance abuse at the New Jersey Department of Human Services, Division of Addiction Services.

"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-NF 26), accessible at <http://www.usp.org>, or the official Homeopathic Pharmacopoeia of the United States/Revision Service, accessible at <http://www.hpus.com>, both of which are incorporated herein by reference, as amended and supplemented, including, but not limited to, a controlled substance, a prescription legend drug, an over-the-counter preparation, a vitamin or food supplement or any compounded combination of any of the above or transdermal patch or strip, 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 tests negative for drugs of abuse, except that for a client in an opioid treatment facility, the specimen is negative for drugs of abuse and shows the presence of methadone.

"Drug screening test positive" means a urine or other DAS-approved specimen from a client that tests positive for illegal substances or pharmaceuticals other than those prescribed for the client by a licensed practitioner.

"Evidence-based practices" means interventions and approaches supported through empirical or peer-reviewed research and evaluation. Evidence-based practices 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.

"Extended care facility" means a residential substance use disorders treatment facility in which treatment primarily is designed to help clients overcome denial of addiction, enhance treatment acceptance and motivation, prevent relapse, promote reintegration into the community and generally approximates the ASAM PPC-2R, Level III.3 (medium intensity) treatment modality.

"Facility" means a residential substance use disorders treatment facility and/or program licensed to provide treatment services for substance use disorders by the Department pursuant to State statute and this chapter. These facilities include halfway houses, extended care facilities, long-term residential facilities, short-term residential facilities and any similar facility in which care is provided through a structured recovery environment involving professional clinical services and/or specific services for detoxification within hospital-based facilities.

"Family" means 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/trustees in a for-profit or non-profit corporation designated to

assume legal responsibility for the management, operation and financial viability of the facility.

"HIPPA" means the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations at 45 CFR Parts 162 and 164.

"HIV" means Human Immunodeficiency Virus.

"Halfway house" means a residential substance use disorders treatment facility, operating in a physically separate location, in which the halfway house treatment modality is programmatically separate and distinct from short-term substance use disorders residential services or long-term substance use disorders residential services. A halfway house provides substance use disorders treatment designed to assist clients in adjusting to regular patterns of living, engaging in occupational training, obtaining gainful employment and independent self-monitoring and otherwise generally approximates the ASAM PPC-2R, Level III.1 (low intensity) treatment modality.

"Health care" means care, services or supplies related to the health of an individual. Health care includes, but is not limited to, the following; preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of an individual or that affects the structure or function of the body, and sale or dispensing of a drug, device, equipment or other item in accordance with a prescription.

"Health care facility" means a general hospital, comprehensive rehabilitation hospital, nursing home or other health care facility licensed pursuant to P.L. 1971, c. 136 (N.J.S.A. 26:2H-1 et seq.), and a State psychiatric hospital operated by the Department of Human Services and listed in N.J.S.A. 30:1-7.

"Health information" means any information, whether oral or recorded in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university or health care clearinghouse; and relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual.

"Hospital-based (medical) detoxification" means a residential substance abuse treatment facility operated as a distinct part or unit of an acute care hospital (separately and concurrently licensed by DHSS) designed primarily to provide short-term care prescribed by a physician and conducted under medical supervision to treat a client's physical symptoms caused by addictions, according to medical protocols to each type of addiction, and generally approximates ASAM PPC-2R, Level IVD (medically managed intensive inpatient detoxification) treatment modality.

"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 and therefore requires immediate corrective action.

"Incapacitated" means that 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.

"Individual" means the person who is the subject of protected health information.

"Interpreter services" means communication access services provided to or arranged for a client and/or family member unable to comprehend and/or communicate in substance use disorders treatment without the assistance of such services.

"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.

"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 a person 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 2.19(c).

"Long-term residential substance use disorders treatment facility" or "long-term residential facility" means a residential substance use disorders facility in which treatment is primarily designed to foster personal growth and social skills development, with intervention focused on reintegrating the client into the greater community, and where education and vocational development are emphasized and generally approximates ASAM PPC-2R, Level III.5 (high intensity, clinically-managed) treatment modality.

"Medical liaison" means a designated staff member in a residential substance use disorders treatment facility responsible for ensuring that all medical information is entered into the client's clinical records.

[page=2225]"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 www.njconsumeraffairs.gov/pharm/phar_rules.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, observing that the client has taken the medication, orally, by way of injecting, topically or insertion and verifying recording 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, in conformance with the rules of the New Jersey Board of Pharmacy at N.J.A.C. 13:39.

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

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

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

"Non-hospital-based (medical) detoxification" means a residential substance use disorders treatment facility designed primarily to provide short-term care prescribed by a physician and conducted under medical supervision to treat a client's physical symptoms caused by addictions, according to medical protocols appropriate to each type of addiction, and generally approximates ASAM PPC-2R, Level III.7D (medically monitored intensive inpatient detoxification) treatment modality.

"Non-hospital-based (medical) detoxification/enhanced" means an organized service delivered by medical and nursing professionals, which provides 24-hour medically supervised evaluation and withdrawal management in a permanent facility with inpatient beds. Services are delivered under a defined set of physician-approved policies and physician-monitored procedures for clinical protocols. This care approximates ASAM PPC-2R Level III.7D care but enhances that level to include the ability to treat the following:

1. Individuals with co-occurring disorders;
2. Pregnant women;
3. Poly-addicted persons including those addicted to benzodiazepines;
4. Individuals who may or may not be on opiate replacement therapy; and
5. Clients with non-life-threatening medical condition(s) that do not require the services of an acute care hospital.

"Nosocomial infection" means an infection acquired by a client while in the residential substance use disorders treatment facility.

"Opiate" means any preparation or derivative of opium.

"Opioid" means both opiates and synthetic narcotics.

"Outcomes" means the level of functioning of a client on specific criteria post-treatment as compared with their level of functioning at intake. These criteria include drug and alcohol use, employability, criminal activity and homelessness, consistent with the 2007 SAMHSA National Outcome Measures, accessible at <http://www.samhsa.gov/dataOutcomes/>, which are incorporated herein by reference, as amended and supplemented.

"Per diem rate" means the daily charge to the client or other funding source for services rendered by the facility.

"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 or approved staff summarizing facts about care and the client's response to care during a given period of time.

"Protected health information" means individually identifiable health information, except as provided in paragraph (2) of the definition as defined in HIPAA, 42 CFR 160.103(C)(5), that is transmitted by electronic media, maintained in electronic media or transmitted or maintained in any other form or medium, protected health information excludes individually identifiable health information in education records covered by the Family Educational Rights and Privacy Act, as amended, 20 U.S.C. § 1232g; records described at 20 U.S.C. § 1232g(a)(4)(B)(iv); and employment records held by a covered entity in its role as employer.

"Provisional license" means a 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 DAS 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.

"Record" means any item, collection or grouping of information that includes protected health information and is maintained, collected, used or disseminated by or for a covered entity.

"Residential substance use disorders treatment facility or program" means a facility, or a distinct part of a facility that provides care for the treatment of substance use disorders, for 24 or more consecutive hours to two or more clients who are not related to the governing authority or its members by marriage, blood or adoption. The term "residential substance use disorders treatment facility" includes facilities that provide residential substance use disorders treatment services to adolescents, women with dependent children and adult males and/or females. These facilities include halfway houses, extended care facilities, long-term residential facilities and short-term residential facilities; and any similar facility providing substance use disorders treatment services including hospital-based and non-hospital-based detoxification through a structured recovery environment involving professional clinical services, generally approximates ASAM PPC-2R Level III.

"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 medication is taken orally, injected, inserted or topically or otherwise administered by a client to himself or herself. The complete self-administration procedure includes the client removing their own individual dose from a previously dispensed, properly labeled container (including a unit dose container), verifying of the dose with the prescriber's orders, the client taking their own individual dose, staff observing that the client has taken their own medication orally, by way of injection, topically or insertion and staff recording the required information in the client's record and medication administration record. All steps in the self-administration procedure are under the supervision of staff trained and authorized to provide oversight of self-administration.

"Short-term residential substance use disorders treatment facility" or "short-term residential facility" means a substance use disorders treatment facility in which treatment is designed primarily to address specific addiction and living skills problems through a prescribed 24-hour per day activity regimen on a short-term basis, and generally approximates ASAM PPC-2R, Level III.7 (medically monitored intensive inpatient treatment) treatment services.

"Signature" means at least the first initial and full surname and title (for example, RN, LPN, DDS, MD, DO, CADC) of a person, legibly written, with his or her own hand. If electronic signatures are used, they shall be used in accordance with N.J.A.C. 10:161A-19.4(b)1.

"Spiritual assessment" means the process by which a substance abuse provider can identify a client's spiritual needs pertaining to their recovery. The determination of spiritual needs and resources, evaluation of their impact on recovery decisions and discovery of barriers to using spiritual resources are all outcomes of a thorough spiritual assessment.

[page=2226]"Staff education plan" means a written plan, which describes a coordinated program for staff education, including in-service facilities and on-the-job training.

"Staff orientation plan" means a written plan for the orientation of each new employee to the duties and responsibilities of the position as defined in the job description, as well as to other policies of the facility.

"Substance abuse/dependence" means a maladaptive pattern of substance use manifested by recurrent and significant adverse consequences related to the repeated use of substances including alcohol, tobacco and other drugs. 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 and substance dependence also means other substance-use related disorders as defined in the DSM-IV-TR.

"Supervision (direct)" means supervision of clients provided on the premises within view or through the implementation of policies and procedures that 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 a facility as conducted by DAS and/or its designees to determine compliance or non-compliance with this chapter and other applicable State licensing rules or statutes.

"Therapeutic diet" means a diet prescribed by a physician, which may include modifications in nutrient content, caloric value, consistency, methods of food preparation, content of specific foods or a combination of these modifications.

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

"Treatment" means the broad range of primary and supportive services, including identification, 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 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.

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

"Universally accepted practices" means treatment measures not currently proven through empirical data or research but recognized by authorities (that is, 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 use disorders treatment.

"Volunteer" means an individual, who is neither a client or a paid staff member, who works at the facility on a non-reimbursed basis, and is under the supervision of an appropriately licensed, certified or experienced paid staff member.

"Waiver" means a written approval by DAS, following a written request from a facility, to allow an alternative to any rule or regulation in this chapter, provided that the alternative(s) proposed would not endanger the life, safety or health of clients or the public. Any approvals of waivers shall be given by DAS in writing, as described below at N.J.A.C. 10:161A-2.13, and are time limited.

10:161A-1.4 Qualifications and responsibilities of the medical director and physicians

(a) Facilities required under N.J.A.C. 10:161A-7 to hire a medical director shall ensure that the physician 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 ASAM, by (three years of the effective date

of this chapter). This physician shall be a member in good standing in the medical community.

1. A physician currently licensed to practice in the State of New Jersey, who has not completed ASAM certification by (three years of the effective date of this chapter), must have worked in a substance use disorders 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) For those facilities in which 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 minimal timeframes in which the medical director is required to be on-site, as well as time limits in which the medical director shall arrive at the facility should his or her services be needed if the medical director is not on-site. The facility shall establish the parameters in which the medical director is available by cell phone/telephone, pager or 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 facility 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 use disorders treatment facility, 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 facility complies with required medical staffing patterns set forth in this chapter;
6. Assisting in the development of written job descriptions for the medical staff, reviewing of credentials, participating in hiring 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; use of over-the-counter floor stock medications maintained on a list at the facility; and the amounts that may be and are stored

throughout the facility, 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).

(d) Facility physicians who are not the medical director shall meet the following qualifications:

1. Be currently licensed as a physician in New Jersey;
2. Have at least two full years of experience as being employed as a physician; and
3. Be a member in good standing in the medical community.

(e) Facility physician(s) shall not serve as the facility's medical director unless meeting the qualifications set forth in (a) above.

(f) Physicians providing medical care to clients in a residential substance use disorders treatment facility shall be responsible for:

1. Ensuring the provision or documentation of a complete medical examination as required by N.J.A.C. 10:161A-9.1;
2. Ordering, interpreting and documenting medical and drug screening tests as appropriate;

[page=2227] 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 and medications prescribed;

4. Ensuring that all medical interventions are documented in the clinical record; and

5. Ensuring that medical follow-up of all acute or chronic illness and conditions are entered in the client's treatment plan, that referrals for medical services are accomplished during the client's treatment or as part of the client's continuum of care plan, as appropriate.

(g) In facilities that provide medical services on-site, the physician shall ensure that the appropriate medical staff participate as part of the multidisciplinary treatment team, with such participation documented in client progress notes.

(h) A facility is not required to hire psychiatrists, but if a facility does elect to hire a psychiatrist, the facility shall engage psychiatrists who are certified or eligible for certification by the American Board of Psychiatry and

Neurology, Inc., or the American Osteopathic Board of Neurology and Psychiatry.

10:161A-1.5 Qualifications and responsibilities of the director of nursing services and licensed nursing personnel

(a) Every facility required to provide nursing services shall designate a director of nursing who shall, at a minimum, meet the following qualifications:

1. Be a registered professional nurse pursuant to N.J.S.A. 45:11-26 et seq. with at least one year in nursing supervision or nursing administration; and
2. One year full-time experience with the management of addictions in a licensed substance use disorders treatment facility.

(b) For a facility providing detoxification services, the individual shall have one year of supervisory experience or three years of experience in an opioid treatment facility or detoxification facility.

(c) Every facility that is required to provide nursing services shall designate a director of nursing, or designee who meets the criteria of director of nursing (pursuant to (a) above), who shall be on the premises or available on-site, or respond within 30 minutes during the facility's hours of operation.

(d) 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 developing and maintaining written objectives, policies and procedures related to nursing services, developing an organization plan, and developing a quality assurance program for nursing services, and reviewing all nursing policies and procedures, minimally, on an annual basis;
3. In conjunction with the administrator and the governing authority of the facility, 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 facility 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 multidisciplinary team and the client care committee (if the facility chooses to establish a client care committee).

(e) All nursing personnel shall possess the appropriate current nursing license

necessary to provide the services set forth in this subchapter. All nursing personnel shall be a member in good standing.

(f) Licensed nursing personnel shall, at a minimum, be responsible for the following:

1. Participating in the development of client treatment plans;
2. Providing face-to-face health care monitoring for the facility's clients;
3. Where medically and clinically appropriate, participating on the multidisciplinary treatment team; and
4. Providing required documentation in the client records.

(g) Only a registered professional nurse shall assess the nursing care needs of clients.

(h) All nursing services provided shall be documented in the nursing portion of the client care plan and shall comport with the facility's policies and procedures governing client documentation and with this subchapter. Such documentation shall include, but need not be limited to, the following:

1. Clinical notes;
2. A record of medications administered including, but not limited to:
 - i. The date the medication is ordered by the physician and the date the medication is to be discontinued;
 - ii. The name and strength of the medication;
 - iii. The date and time of the administration of the medication;
 - iv. Effects of medication (if indicated);
 - v. The dosage administered;
 - vi. Method of administration;
 - vii. The 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. If initials are used, a section shall be included identifying the respective signature and title for all initials; and
 - viii. The reason the client refused to receive the medication or why the client did not receive the medication at the designated time, if applicable; and
3. A record of medication self-administered by clients shall be maintained in the nursing portion of the client care plan and the medication administration record. Such documentation shall include:
 - i. Whether medication was taken orally, injected, inserted, topically or otherwise administered by a client to himself or herself;

- ii. Verification of the dose with the prescriber's orders;
- iii. Verification that the client took his or her own individual dose;
- iv. If self-administration is observed, a recording of the observation that the client has taken his or her own medication orally, by way of injection, topically or insertion in nursing portion of the client care plan and medication administration record; and
- v. Signature of the nurse who observed the client's self-administration of medication or identification of the nurse by an entry code if a computerized clinical record system is used.

10:161A-1.6 Qualifications of pharmacists

Each pharmacist shall be currently licensed by the New Jersey State Board of Pharmacy and shall be a member in good standing.

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

(a) Each 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 licensed substance use disorders treatment facility.

(b) Individuals who do not meet the qualifications in (a) above must have a Bachelor's degree and five years of full-time, or full-time equivalent, administrative or supervisory experience in a licensed substance use disorders 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 facility;
4. Developing an organizational plan and ensuring that facilities and services are consistent with the organization's mission, while monitoring their effectiveness;
5. Establishing and implementing a formal quality assurance program that is comprehensive and integrated with the facility's programmatic quality assurance plans and programs; address all levels of treatment programming and client care; ensure that all personnel are assigned duties based upon their education, training, competencies and job description; while utilizing written, job-relevant criteria to make evaluation, hiring and promotional decisions;

[page=2228] 6. Selecting and hiring responsibility for all staff, as well as participating in the determination of staffing issues including, but not limited to, establishing and maintaining policies ensuring references, credentials and

criminal history background checks of all prospective staff and making certain that they have been reviewed and verified; developing written policies regarding the employment of family members, past and present governing body members and volunteers; developing written policies regarding hiring staff with past criminal convictions and/or ethical violations that ensure that the convictions/violations do not impact staff ability to perform duties; and developing policies for assessing staff performance, determining employment and termination decisions;

i. The administrator shall advise candidates and staff members that candidates and staff members 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 developed and implemented under this paragraph are shared with the governing authority;

10. Ensuring that admission interviews with clients are conducted in accordance with the facility's policies and procedures.

i. Admissions interviews with adolescent clients shall include the client's family, guardian or legally authorized representative;

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 facility 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, including policies and procedures for broader-based emergency situations resulting from either internal incidents, 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 service interruption to clients, closure and reopening of a

facility and procedures governing the dispensing and, where necessary, monitoring of client treatment medications;

14. Establishing written policies and procedures for non-emergency closures.

i. Policies established under this paragraph shall include the timely notification to DAS of such closures, the timeframes for service interruption, closures and reopening and procedures governing the dispensing and, where clinically necessary, monitoring of medications administered to clients.

ii. Facilities shall submit a written request to DAS at least 48 hours before closing for non-emergency reasons.

iii. Facilities shall not close for non-emergency reasons without receiving 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 protocols, 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 specified by DAS.

i. Ensure that such reports are shared with the governing authority in a timely manner;

17. Developing and implementing an infection prevention and control program;

18. Developing and implementing client safety policies and procedures that include, but are not limited to, forbidding staff to engage in client coercion, sexual harassment and sexual relationships with clients; and

19. 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.

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

(a) Every facility shall ensure that there is at least one individual qualified to function as the director of substance abuse counseling services and that the clinical supervision requirements in this chapter are met. The director of substance abuse counseling shall meet at least one of the following qualifications:

1. Be a New Jersey licensed psychologist with at least five years of experience in addiction services, two of those years in a supervisory capacity, 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/, or is a Certified Clinical Supervisor by the Addictions Professionals Certification Board of New Jersey (APCBNJ), <http://www.certbd.com/pdfs/initial-applications/ccs.pdf>;

2. Be a New Jersey licensed clinical social worker with at least five years of experience in addiction services, two of those years in a supervisory capacity, who is a certified clinical supervisor by the APCBNJ, <http://www.certbd.com/pdfs/initial-applications/ccs.pdf>;
3. Be a New Jersey licensed professional counselor with at least five years of experience in addiction services, two of those years in a supervisory capacity, who is a certified clinical supervisor by the APCBNJ, <http://www.certbd.com/pdfs/initial-applications/ccs.pdf>;
4. Be a New Jersey LCADC with at least five years of experience in addiction services, two of those years in a supervisory capacity, who, in addition, holds a clinical Master's degree recognized by the State Board of Marriage and Family Therapy Examiners, Alcohol and Drug Committee, Division of Consumer Affairs, New Jersey Department of Law and Public Safety;
5. Be a New Jersey licensed physician who is certified by the American Society of Addiction Medicine, or is a Board-certified psychiatrist, and has at least two years of supervisory experience in addiction services;
6. Be a New Jersey licensed advanced practice nurse with at least five years of experience in addiction services, two of those years in a supervisory capacity, who is a clinical supervisor certified by the APCBNJ, <http://www.certbd.com/pdfs/initial-applications/ccs.pdf>; or
7. Have a doctoral degree in human services, mental health or social work with at least two years of supervisory experience.

(b) Incumbents with a Master's degree in counseling or social work not possessing any of the qualifications set forth in (a)1 through 6 above, shall obtain LCADC status or another health professional license that includes diagnostic and supervisory authority for work of an alcohol and drug counseling nature by (three years of the effective date of this chapter).

(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, must ensure that direct clinical supervision is provided by a staff person who meets the qualifications specified by and recognized as direct clinical supervision pursuant to the rules of the State Board of Marriage and Family Therapy Examiners, Alcohol and Drug Counselor Committee, New Jersey Department of Law and Public Safety 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 for [page=2229] substance abuse counseling services that are reviewed by the administrator;
2. Ensuring that the behavioral and pharmacologic approaches to treatment are evidence-based or based on universally accepted information to provide treatment services consistent with recognized treatment principles and practices for each level of care and type of client served by the facility;

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 facility personnel;
8. Providing orientation to and evaluation of new counseling staff prior to assigning them 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 a counseling services; and
12. Ensuring that clinical staff (LCADCs, CADCs and counselor-interns) are supervised by the appropriately credentialed staff as per N.J.A.C. 13:34C and this chapter.
 - i. The director of substance abuse counseling is responsible for verifying that clinical supervision is provided as per N.J.A.C. 13:34C and this chapter and maintaining documentation of the provision of such clinical supervision.

10:161A-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 clinical professionals doing work of an alcohol and drug counseling nature within their scope of practice by (three years of the effective date of this chapter) and at all times thereafter. The remaining 50 percent of substance abuse counseling staff shall be designated as alcohol and drug counseling-interns or credentialed-interns (formerly referred to as "substance abuse counselors in training") who are actively working toward their LCADC or CADC status, or toward another New Jersey clinical license that includes work of an alcohol and drug counseling nature within its scope of practice. Counselor-interns may be actively working toward their LCADC or CADC status for

no more than three years. 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 CADC or another licensed health professional doing work of an alcohol and drug counseling nature within their scope of practice.

i. A CADC must work under the supervision of an LCADC or another New Jersey licensed clinical professional designated as a qualified clinical supervisor per N.J.A.C. 13:34C-6.2.

ii. A CADC cannot diagnose substance abuse.

2. Substance abuse counseling staff without an LCADC or CADC status or who do not possess another New Jersey clinical professional license that includes work of an alcohol or drug counseling nature within their scope of practice shall function as alcohol and drug counselor-interns or credential-interns and shall:

i. Be enrolled in a course of study leading to a CADC or LCADC, or another New Jersey clinical 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 semi-annually and documented; and

ii. Be trained, evaluated and receive 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:

(1) The State Board of Marriage and Family Therapy Examiners for licensed marriage and family therapists;

(2) The State Board of Marriage and Family Therapy Examiners Professional Counselor Examiners Committee for licensed professional counselors;

(3) The State Board of Marriage and Family Therapy Examiners Alcohol and Drug Counselor Committee for LCADCs and CADCs;

(4) The State Board of Psychological Examiners for licensed psychologists; and

(5) The State Board of Social Work Examiners for licensed clinical social workers.

(b) Counseling staff employed in a residential substance use disorders treatment facility subsequent to (the effective date of this chapter) shall have three years from the date of employment to become certified as an LCADC or CADC, or another clinical licensed professional that includes the work of an alcohol and 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 using other standardized assessment tool and for adolescents using the CASI or using other evidence-based validated assessment tool and diagnosing clients for substance disorders using the DSM-IV-TR;
3. Determining the appropriate level of care based on ASAM PPC-2R;
4. Obtaining previous records that are relevant to the current treatment episode;
5. Collaborating with the client in order to develop a written treatment plan that is client-centered and recovery oriented and includes goals and measurable objectives.
 - i. The director of substance abuse counseling shall develop, monitor and provide clients and the treatment team with written schedules that will be used to update each client treatment plan(s) in order to ensure that each client's treatment needs are addressed;
6. Providing the substance abuse counseling services specified in the client treatment plan;
7. Reviewing clients throughout the treatment episode according to ASAM PPC-2R, to determine the need for continued services or discharge/transfer;
8. Reviewing and, where necessary, revising the substance abuse counseling portion of the client treatment plan to address emerging problems;
9. Developing the client discharge/transfer plans to ensure movement to the appropriate levels of care;
10. Contacting referral sources, providing case consultation and coordination with referral sources (for example: mental health treatment providers, criminal justice agencies, schools, employers, the Division of Youth and Family Services);
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, providing appropriate signatures and dating of such entries, including those made in electronic records.

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Qualifications of dietitians and food

service supervisors

(a) The facility shall engage at least one dietitian registered by the Commission on Dietetic Registration, 120 South Riverside Plaza, Suite 2000, Chicago, Illinois 60606-6995, <http://www.cdrnet.org/>.

(b) The facility shall engage food service supervisors who, if not dietitians, are:

1. Graduates of a dietetic technician or dietetic assistant training facility approved by the American Dietetic Association's Commission on Dietetic Registration, 120 South Riverside Plaza, Suite 2000, Chicago, Illinois, 60606-6995, www.cdrnet.org; or
2. Graduates of a course providing 90 or more hours of classroom instruction in food service supervision approved by the New Jersey Department of Education, and have one year of full-time experience, or the full-time equivalent, as a food service supervisor in a health care facility in consultation with a dietitians; or trained and experienced in food service supervision and management through military service programs equivalent to this subsection.

(c) Halfway houses may employ as a food service supervisor an individual possessing 18 hours or more of approved classroom instruction in food service supervision in a health care facility; or certification by ServSafe, www.servsafe.com, or an equivalent food protection program certified by the American National Standards Institute, <https://www.ansica.org/wwwversion2/outside/Default.asp> under standards set by the Conference for Food Protection, www.foodprotect.org, 1302 Silver Spur Circle, Lincoln, CA 95648. The food service supervisor shall be on site a minimum of five days per week and is responsible for ensuring that protocols for meal preparation and food storage are performed seven days a week even in his or her absence.

SUBCHAPTER 2. LICENSURE PROCEDURES AND ENFORCEMENT

10:161A-2.1 Applications for licensure

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

(b) Any person, organization or corporation planning to operate a residential substance use disorders treatment facility shall obtain application forms from, and submit completed application forms with the appropriate fees for each site to:

New Jersey Department of Human Services
Office of Program Integrity and Accountability
Attention: Office of Licensing
PO Box 700
Trenton, NJ 08625-0700

(c) DAS will maintain and update the 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 subsection of this section 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 this fee schedule, established rates at the time of submission of each application will 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 (\$ 500.00 + \$ 3.00 per Bed); and
 - ii. Initial and ongoing biennial DAS inspection fee (\$ 500.00);
2. Licensed facilities maintaining their licensure status:
 - i. License renewal fee (\$ 500.00 + \$ 3.00 per Bed); and
 - ii. Ongoing biennial DAS inspection fee (\$ 500.00);
3. Licensed facilities modifying the scope and/or content of their license:
 - i. License modification to add beds or services (\$ 500.00); and
 - ii. License modification to relocate or reduce services (\$ 250.00); and
4. Licensed facilities transferring ownership interest (\$ 1,500).

(f) Once licensed, each facility shall be assessed an ongoing biennial inspection fee of \$ 500.00. 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 facility 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 Biennial DAS Inspection Fee
Residential Substance Abuse Treatment Facility	\$500 + \$3/Bed	\$500 + \$3/Bed	\$500	\$250	\$1,500	\$500

(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 facility submits the licensing fee and the initial biennial 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 included and distributed 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 a residential substance use disorders treatment facility unless the license application indicates that the service is to be provided by the facility: nonhospital-based detoxification facility; long-term residential treatment facility; short-term residential treatment facility; halfway house; or extended care facility.

1. If a facility provides primary medical care, in addition to any of the five categories of residential substance use disorders care listed in this subsection, a separate primary care license is required by and must be obtained from the New Jersey Department of Health and Senior Services.

(k) In addition to (j) above, any person, organization or corporation applying for a license to operate a residential substance use disorders treatment facility shall specify on the application whether the client population to be served by the facility will be adult-only; adolescent-only; or both adult and adolescent; and whether the client population to be served by the facility will be males and females; males only; or females only. Applicants proposing to provide multiple levels of care within a facility shall designate the number of beds for each level of care and shall document that the facility meets the appropriate staffing and other requirements applicable to each level of care provided.

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

10:161A-2.2 Licenses

(a) Once issued, a license shall not be assignable or transferable and shall be immediately void if the facility 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 must be [page=2231] 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 facility otherwise continues to be in compliance with all local rules, regulations and other requirements.

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

10:161A-2.3 Application requirements

(a) Any person, organization or corporation applying for a license to operate a residential substance use disorders treatment facility shall specify the services in N.J.A.C. 10:161A-2.1(j) the facility seeks to provide on the application.

(b) No facility shall admit clients until the facility has been licensed by DAS to operate the specific modality or modalities of treatment as referenced in N.J.A.C. 10:161A-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 shall not be limited to, the review of all program documents, client records and conferences with clients. Such visits may be announced or unannounced.

(d) As of (the effective date of this chapter), upon annual renewal of its current license, each facility shall specify the types of services to be provided therein, including if the facility wishes to change the specification of services on the license.

(e) If a facility adds any service listed in N.J.A.C. 10:161A-2.1(j) during the annual licensure period, the facility 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 on-site inspection by representatives of DAS.

(f) The applicant shall indicate on its application if a facility is new or otherwise innovative, not fitting into any of the categories specified in N.J.A.C. 10:161A-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 facilities 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 facility is effective, safe and provides services that do not violate client rights or compromise client health and safety.

(g) DAS shall determine if the new and/or innovative facility is effective, safe and does not violate client rights or compromise client health and safety, and if licensure is granted, shall determine whether the licensed facility 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 facility in this State or elsewhere, with operational data separated by program, including the following categories:

1. The results of State-level 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 facility;
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 residential substance use disorders facility(s);
7. State or local rules applicable to the licensing and day-to-day operation of the facility(s), when located outside New Jersey; and
8. A record of penalties or fines assessed against the facility(s) and its ownership relative to the operation of the facility(s) by any national, state, county or local agency or court of competent jurisdiction; and 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 facility and the community in which it is located.

10:161A-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 New Jersey Department of Community Affairs; and
2. A proposed plan of operation or set of bylaws for the governing authority of the facility.

10:161A-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 facility. 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 receipt of relevant fees as set forth in N.J.A.C. 10:161A-2.1. If DAS deems that the application is incomplete, DAS shall notify the applicant in writing of any missing information.

1. The applicant shall be permitted to supply any missing information in the application to DAS within 30 working days of notification. 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 as complete by DAS.

(c) Once the application is deemed complete, DAS shall review it to determine whether the applicant meets the licensing criteria to operate a facility 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 facility.

1. DAS shall schedule a meeting to conduct a functional review, as per (a) above, with the applicant to explore and define the facility 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 30 days, 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 facility to determine if the facility complies with this chapter.

i. Within 45 days after completion of the survey required in this paragraph, 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 residential substance use disorders treatment facility 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 facility from N.J.A.C. 10:161A-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 facility is reasonably within the bounds of accepted practice;

[page=2232] 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 residential substance use disorders treatment facility providing opioid treatment and opioid detoxification or other detoxification where

prescription drugs will be dispensed, shall specifically notify the municipality in which the facility is to be located of the full scope of services to be provided therein. Notification to 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 facility until DAS issues a license to the applicant for the facility. Any client admissions to the applicant's residential treatment facility prior to the issuance of a DAS license shall be considered unlicensed admissions and DAS shall take all appropriate enforcement actions in response thereto.

10:161A-2.6 Surveys

(a) When both the written application for licensure is approved and the building is ready for occupancy, DAS licensure staff 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 resurvey of the facility prior to occupancy; additional resurveys may be scheduled prior to occupancy until all deficiencies are corrected.

10:161A-2.7 Conditional license

(a) A conditional license may be issued by DAS with specific conditions and standards defined on such license granted by DAS when the purposes and intent of the proposed facility are outside the scope of a regular license. All standards within this chapter apply unless specifically mentioned in the conditions of said license.

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

(c) DAS may issue a conditional license in order to address contingencies and/or special facility 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 facility as the overriding priority.

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

(e) A conditional license may be issued to a new facility that was reviewed before it begins to provide services. Within 30 working days of DAS receiving

written notification from the facility that it is fully operational, DAS shall schedule a follow-up visit to determine whether the facility 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 in accordance with N.J.A.C. 10:161A-2.2(c).

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

10:161A-2.8 Periodic surveys following licensure

(a) Authorized DAS staff may conduct announced or unannounced visits and periodic surveys of licensed facilities. The identity of clients shall 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 facility, the facility's physical plant, clients or staff. The identity of a complainant shall be kept confidential and shall not be considered public information.

10:161A-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 rule. 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 rule.

(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 rule to which the finding of a deficiency relates.

10:161A-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 this chapter.

10:161A-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 timeframes 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. 10:161A-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 [page=2233] repeated licensure deficiencies and to review the causes for such violations and the facility's plan of correction.

1. Each facility shall provide DAS with the current mailing addresses for all members of the board of directors.

(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 ensures the health and safety of clients 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 clients rights, DAS may direct specific corrective measures that must be implemented by facilities.

10:161A-2.12 Surrender of a license

(a) When a facility 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, as follows:

1. The facility shall provide DAS with at least 45 days notice prior to the license surrender date;
2. The facility shall provide each client, prescribing physician(s) and primary substance abuse counselor(s) with at least 30 days prior notice of its intention to surrender its license. In consultation with DAS, the facility shall arrange for each client to be transferred to a licensed facility or other licensed program capable of providing the appropriate level of client care;
3. The facility shall provide appropriate notice, in writing, to any facility to which it has sent client referrals and from which it has received client referrals in the past year; and
4. The facility shall provide each guarantor of payment at least 30 days prior notice.

(b) When a facility 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. 10:161A-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 facility staff and/or seven days from the postmarked receipt date of the DAS written licensure surrender request.

10:161A-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 this chapter; is consistent with prevailing DAS policy and procedure; 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 facility 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. 10:161A-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 is not granted;

3. An alternative proposal that 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 facility or the public;
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 within which the waiver will no longer be needed; DAS shall determine whether the requested timeframes are reasonable.

(c) 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.

10:161A-2.14 Enforcement remedies

(a) The Commissioner, or designee thereof, may impose the following enforcement remedies against a residential substance use disorders treatment facility for violations of licensure rules or other statutory requirements, as set forth in this chapter:

1. Civil monetary penalty for unlicensed operation;
2. Curtailment of admissions to a licensed substance use disorders treatment facility;
3. Reduction of a license 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 or rules as provided by State or Federal law, or as authorized by Federal survey, certification and enforcement regulations and agreements.

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

The Commissioner, or designee thereof, 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.

10:161A-2.16 Effective date of enforcement actions

The assessment of civil monetary penalties, 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 thereof. Hearings shall be conducted in accordance with N.J.A.C. 10:161A-2.24.

10:161A-2.17 Enforcement actions

(a) The Commissioner, or designee thereof, may assess a penalty for violation of licensure rules according to the following standards:

1. For operation of a substance use disorders 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 for any 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 use disorders 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 thereof, may take the following additional enforcement actions:

[page=2234] 1. For violations of licensure rules 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 pursuant to N.J.A.C. 10:161A-2.20(a) to allow the facility to correct all rule 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 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 fines consistent with (a)1 above;

3. For repeated violations of any licensing rule 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 previous penalty assessment, the Division may, at its discretion, reduce the license to provisional status, or move to suspend or revoke the license. In doing so, the following factors will be considered:

- 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; and

5. For failure to report information to the Division as required by statute or licensing rule, 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)1 above, based on the following factors:

1. The number, frequency and/or severity of violations by the facility;
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)1 above, the Division may also curtail admissions consistent with N.J.A.C. 10:161A-2.19.

10:161A-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 thereof, 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 timeframes set forth in (a) or (b) above as applicable may result in one or more 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.

10:161A-2.19 Curtailment of admissions

(a) The Division may issue an order curtailing all new admissions and readmissions to a substance use disorders treatment facility including, but not limited to, the following circumstances:

1. Where violations of licensing rules are found, that have been determined to pose an immediate and serious threat of harm to clients of a substance use disorders 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 use disorders treatment facility license;

3. Where the admission or readmission of new clients to a substance use disorders treatment facility would impair the facility's ability to correct serious or widespread violations of licensing rules related to direct client care and cause a diminution of the quality of care; or

4. For exceeding the licensed or authorized bed or service capacity of a substance use disorders 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 rules 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 that the order for curtailment has been withdrawn within 20 working days after the DAS finding.

10:161A-2.20 Provisional license

(a) The Division may place a substance use disorders treatment facility on provisional license status when the following circumstances apply:

1. Upon issuance of a Notice of Revocation of a License or a Notice of Suspension of a License, pursuant to N.J.A.C. 10:161A-2.18 or 2.19, for a period extending through final adjudication of the action;
2. Upon issuance of an order for curtailment of admissions pursuant to N.J.A.C. 10:161A-2.16, until the Division finds the facility has achieved substantial compliance with all applicable licensing rules;
3. For violations of licensing rules that have been determined to pose a threat to the safety of clients of a substance use disorders treatment facility; 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 rules.

(b) A facility placed on provisional license status shall be provided notice of same, in accordance with the notice requirements set forth at N.J.A.C. 10:161A-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. 10:161A-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. 10:161A-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 this section. In addition, provisional license status remains effective in cases where the underlying violations that caused the issuance of provisional licensure status are the subject of an appeal and/or litigation, as applicable, in accordance with this section.

(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;

[page=2235] 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 at all times post the provisional license in a conspicuous location within the facility.

10:161A-2.21 Suspension of a license

(a) The Commissioner may order the suspension of a license of a residential substance use disorders 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 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 that 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 from the provision of substance use disorders 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, 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 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 this chapter.

(g) The Division may rescind the order for suspension upon a finding that the facility has corrected the conditions that were the basis for the action.

10:161A-2.22 Revocation of a license

(a) A Notice of the Proposed Revocation of a residential substance use disorders treatment facility license may be issued in the following circumstances, when:

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 rule by any Department and/or Division representative or employee and/or contracted agent;
3. The facility has failed to correct identified violations that had led to the issuance of an order for suspension of a license or issuance of an injunction;
or
4. 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. 10:161A-2.12 and the facility has a right to request a hearing pursuant to N.J.A.C. 10:161A-2.24.

10:161A-2.23 Injunction

(a) The Commissioner, or designee thereof, may determine to seek an injunction of the operation of a substance use disorders 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 designee thereof, 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 Rules of Court.

(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 use disorders treatment services and effect an orderly transfer of clients to substance use disorders 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 that were the basis for the action.

10:161A-2.24 Hearings

(a) Notice of a proposed enforcement action shall be afforded to a facility pursuant to N.J.A.C. 10:161A-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 the receipt thereof by DAS.

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

10:161A-2.25 Settlement of enforcement actions

(a) The facility may request that the matter be scheduled for settlement conference prior to transmittal to the Office of Administrative Law (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 both parties agree.

(c) The Division has the discretion to settle the matter as it deems appropriate. 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 State's General Fund.

SUBCHAPTER 3. GENERAL REQUIREMENTS

10:161A-3.1 Provision of services

(a) A residential substance use disorders treatment facility shall provide or arrange for the following services: medical and nursing services (including assessment, diagnostic, treatment), counseling, vocational, educational, case management and other supportive services. Written agreements detailing services to be provided shall be made between the residential substance use disorders 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 of the facility, the written [page=2236] agreement shall specify each party's responsibilities, including submission of reports and treatment and service recommendations.

i. Such services shall comply or be in accordance with the requirements and rules set forth in this chapter.

10:161A-3.2 Compliance with laws and rules

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

(b) If a licensed facility provides residential substance use disorders treatment services in addition to other health care services, the licensee shall comply with the rules in this chapter and all other applicable rules and regulations.

10:161A-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, rules and regulations related to the construction and maintenance of the physical plant, regardless of whether the licensee owns the physical plant.

(b) Facilities 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.

2. The facility 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. 10:161A-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.

10:161A-3.4 Submission of documents and data

(a) Upon request, the facility shall submit to DAS any documents required to be maintained by the facility in accordance with this chapter. Information identifying clients shall be kept confidential at all times by DAS as required by Federal confidentiality regulations at 42 CFR Part 2 and Federal HIPAA requirements at 45 CFR Part 160.

(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 systems.

10:161A-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 acquiring the 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 facility shall initiate State-level criminal history background checks supported by fingerprints not later than the time of hiring all staff, including student interns and volunteers.
3. Facilities shall provide each staff member with a photo identification card to include, at a minimum, the staff member's first name and last initial, job title, degree and/or certification.
4. The facility administrator shall make reasonable efforts to adhere to facility policies regarding the hiring of staff to ensure that staff are in good physical and mental health, emotionally stable, 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, but not limited to, drug-related offenses, 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 include, but are not limited to, this paragraph, 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. Facilities 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 thereof 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 duties.
6. Facilities shall document verification and confirmation of licenses/certifications and educational degrees for all staff in accordance with facility 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 inappropriateness (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 are determined to be continuously substance-free (alcohol and/or other drug) before being employed in the facility, and which address the consequences of employee use of alcohol, tobacco or illegal substances during working hours or when representing the treatment facility. The facility shall establish written policies precluding illegal substance, alcohol use and tobacco use, or showing evidence of use (for example, paraphernalia, cigarette packs or other tobacco products) within the facility, on the grounds of the facility or when representing the facility.

1. Use of alcohol, tobacco, tobacco products or illegal substances within the facility, on the grounds of the facility, within facility vehicles or when representing the facility is prohibited.

2. Facilities shall immediately comply with the New Jersey Smoke-Free Air Act, P.L. 2005, c. 383, in which the smoking of tobacco products and the use of spit tobacco is prohibited within all buildings.

i. Compliance with the requirements in this chapter governing the prohibition of tobacco products and the use of spit tobacco on the grounds of the facility and in facility vehicles shall begin on December 12, 2012.

(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 and/or treatment.

(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) Facilities shall maintain a staff-to-client ratio as follows:

1. Notwithstanding the counselor-to-client ratios specified in N.J.A.C. 10:161A-10.1, facilities serving adults shall have at least one staff member responsible for the supervision of each 24 adult clients during waking hours, and at least one staff member responsible for each 30 adult clients during sleeping hours, except that during waking or sleeping hours no less than two staff shall be present and awake at all times.

i. Halfway houses with 24 or fewer beds shall have at least one overnight staff on duty and awake to whom residents have immediate access in case of emergency;

2. Facilities serving adolescents shall have at least one staff member responsible for the supervision of each 10 adolescent clients during waking hours and at least one staff member responsible for the supervision of each 20 adolescent clients during sleeping hours, except [page=2237] that during waking or sleeping hours not less than two staff members shall be present at all times;

3. Facilities serving women and children shall meet the staff-to-client ratios

specified in (f)1 above for adults for the women. The following ratio of staff-to-children shall apply when the children are not under the direct care of their mothers who are identified as providing care as primary activity, and the mothers are not engaged in any treatment or other facility-based activity:

- i. At least one staff member for every five children under 2 1/2 years of age, and one staff for every 10 children ages 2 1/2 to six during waking hours;
- ii. At least one staff member for every 10 children under 2 1/2 years of age and one staff for every 20 children ages 2 1/2 to six during rest or sleeping hours; and
- iii. When children of mixed age groups, requiring different staff-to-child ratios are in one room or an area within a large divided room, the facility shall compute the staff-to-child ratios applicable for each group separately to the nearest 10th decimal. If the resulting cumulative figure for both age groups is any fraction above a whole number, an additional staff member shall be required; and

4. Non-counseling staff responsible for supervision during day or evening hours shall, at a minimum:

- i. Be 18 years of age;
- ii. Possess a high school or high school equivalency diploma.

(g) 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, the facility's emergency plans and procedures, the infection prevention and control program, universal precautions, 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.

(h) At least one staff person who is currently certified in basic cardiac life support by the American Heart Association and the American Red Cross shall be present in the facility at all times during the facility's hours of operation.

10:161A-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 of the facility's policy and procedure manual at least annually.
2. The 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. The 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 facility's vision and mission, staffing patterns and the services provided by the facility;
2. An organizational chart delineating the lines of authority, responsibility and accountability for the administration and client care services;
3. Policies regarding the facility'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; staff performance and supervision, at least annual review of staff performance, staff qualifications and credentials, staff orientation and education and documentation of these staff-related functions;
5. Adherence to privacy and confidentiality policies and procedures ensuring the confidential maintenance of client records while the facility is in operation and in the event that it ceases to operate, as required by Federal confidentiality regulations at 42 CFR Part 2 and Federal HIPAA requirements at 45 CFR Part 160;
6. A description of the modalities of treatment provided, including a listing of services and procedures, which must be performed and ASAM (ASAM PPC 2R) designations that may be offered in the facility;
7. A written plan for informing persons in need of substance use disorders treatment services, their friends and family members, the public and health care providers of the availability of the facility's services, all facility 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.
 - i. Such policies and procedures shall include written descriptions of situations that may preclude the use of telephones by clients.
 - ii. Such policies and procedures shall comply with the facility's client care policies and procedures and shall not violate client rights, nor be used as a tool to punish or coerce clients.
 - iii. Such policies and procedures shall 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 the facility's designated business hours.

i. The facility must use either an answering service, or assign a designated on-call staff or provide an alternative method approved by DAS, to ensure that clients have access to emergency incoming telephone calls on a 24-hour-a-day basis, seven days a week.

11. Policies and procedures addressing the use of sanctions in the facility.

i. The following practices are expressly forbidden in facilities serving adolescents:

(1) Corporal punishment;

(2) Use of restraints of any sort;

(3) Use of a behavior management room, unless such a room is permitted and regulated under the auspices of the Department of Children and Families, Division of Youth and Family Services (DYFS), or DAS; and

(4) Sanctions that include verbal, mental or physical abuse;

12. Policies and procedures to provide for the assessment, diagnosis, identification and treatment of persons with co-occurring substance abuse mental health disorders; or to coordinate the care and/or referral to appropriate mental health providers, so that services are provided in a integrated 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 an appropriate treatment provider, and the referral documented in the clinical record;

13. Policies addressing the confiscation and disposition of illicit substances, alcohol, weapons and other prohibited items or materials within the facility.

i. Procedures governing client search and seizure that ensures protection of staff and clients, do not violate client rights and preserve the dignity of clients.

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

14. 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 [page=2238] neglect in compliance with N.J.S.A. 9:6-8.11 et seq., documenting the notification to the Department of Children and Families, 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 Office of the Ombudsman for the Institutionalized Elderly, which is in, but not of, the Department of the Treasury, 1-877-582-6995, 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 facilities 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;

15. 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; and

16. Policies and procedures pertaining to P.L 100-336, the Americans with Disabilities Act (ADA) that include at a minimum:

i. Assessing and referring clients with disabilities; and

ii. Staff training for ADA compliance.

10:161A-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, including follow-up examinations where medically warranted.

(b) The facility shall require all staff employed as of (the effective date of this chapter), and all staff hired thereafter, to submit to screening tests for rubella and measles.

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 screenings.

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 DHSS 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 (the effective date of this chapter), that are required to submit to screening tests shall do so upon employment; and

5. All employees employed as of (the effective date of this chapter), that are required to submit to screening tests shall do so within 60 days.

(c) The facility 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 facility 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 N.J.A.C. 10:161A Appendix A.

1. Employees hired after (the effective date of this chapter), shall be required to submit to Mantoux testing upon employment, while employees employed as of (the effective date of this chapter), shall submit to the Mantoux test within 60 days, if the employee has not been tested within the past year.

2. If the initial 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 need only one Mantoux skin test.

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

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

ii. Employees who can document having 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 whose previous skin test results were negative, unless contraindicated.

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

(e) The facility 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 facility 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 agency's policies and procedures shall address the facility's response to positive drug screening results.

10:161A-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, as well as immediately fax a report to DAS at 609-292-3816, regarding any event occurring within the facility that jeopardizes the health, safety or welfare of clients or staff as set forth in this subchapter, including, but not limited to, the following:

1. All fires, floods, disasters, accidents or other unanticipated events that result in serious injury or death of clients or staff, evacuation of clients from the facility or closure of the facility;
2. All deaths of clients under the supervision of the facility, including deaths known or suspected of resulting from misuse of medications prescribed or dispensed by the facility;
3. All outbreaks of communicable disease or other conditions adversely effecting multiple clients and/or staff. This does not relieve the facility 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 that 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.
 - 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.

[page=2239] (c) The facility shall provide DAS with a written report no later than five business days after the event or circumstances listed in (b) 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 facility 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(s) and qualifications of the replacement(s) or acting replacement(s) no later than seven days following the date of resignation(s) or termination(s).

(e) The facility shall develop procedures, including timeframes, for verbal and written notification to the governing authority of reportable events set forth in this section.

10:161A-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 facility's plan of correction;
3. A statement of client rights;
4. The names of members of the governing authority of the facility and current addresses to which correspondence may be sent;
5. The hours of operation and the normal business hours of the facility;
6. DAS complaint telephone number; and
7. Emergency telephone numbers.

10:161A-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.

10:161A-3.11 Transportation

(a) The facility shall develop and implement a method of client transportation for services provided outside of the facility, which shall include plans for security and accountability for the client and his or her personal possessions, as well as transfer of client information to and from the provider of the services.

(b) 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 current registration and current insurance information for all vehicles used to transport clients.

2. The facility shall keep on file the name of each driver responsible for transporting clients, a photocopy of each driver's current driver's license and the driver's abstract of all staff who may transport clients.

i. The use of tobacco products, spit tobacco, alcohol or illegal substances is prohibited by employees and clients in facility vehicles.

ii. Facilities shall have policies and procedures ensuring that additional staff coverage for clients is provided in facility vehicle(s) when needed.

10:161A-3.12 Tobacco products

(a) Facilities shall immediately comply with the New Jersey Smoke-Free Air Act, P.L. 2005, c. 383, in which the smoking of tobacco products and the use of spit tobacco is prohibited within all buildings.

(b) The smoking of tobacco products and the use of spit tobacco is prohibited within the facility, on the grounds of the facility, within facility vehicles or when representing the facility.

1. Compliance with the requirements in this section, governing the prohibition of tobacco products and the use of spit tobacco on the grounds of the facility and in facility vehicles shall begin on December 12, 2012.

SUBCHAPTER 4. GOVERNING AUTHORITY

10:161A-4.1 Responsibility of the 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 organization's mission and purpose;

2. Ensuring that the organization is operating in accordance with its mission and, for non-profits, 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, fundraising, 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 organization without personal gain) and the duty of obedience (being faithful to the organization's mission while managing funds for that purpose);
6. Appointing and supervising an administrator (that is, president, CEO, executive director, etc.) whose references, credentials, professional license and criminal background are reviewed and verified, and reconciled with 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 governing authority must advise the administrator that he or she must 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 and professional development;
8. Approving, in writing, a person to be designated as the administrator's alternate;
9. Ensuring that the administrator has the professional support needed to further the mission and goals of the organization;
10. Ensuring legal and ethical integrity and maintaining accountability by observing legal standards and ethical norms;
11. Documenting all of the governing authority's 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 written 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 agency;

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

15. Establishing client complaint procedures that support client rights, that are conspicuously posted and accessible to clients in client service areas and are understood by clients from point of service admission to discharge, as per N.J.A.C. 10:161A-6;

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. 10:161A-6 are developed and maintained;

18. Establishing a pharmacy and therapeutic committee, if so required at N.J.A.C. 10:161A-14.1(b);

[page=2240] 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 review with the administrator any material changes that may occur during the year with respect to either revenue or expenditures, including the reasons for the change;

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 (such as 42 CFR Part 2, HIPAA, etc.);

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

28. If multiple facilities are operated by the governing authority, identifying

how the committees and/or 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 residential substance use disorders 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. 10:161A-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;
9. Delineation of a grievance procedure for staff and clients; and
10. Reviewing plans of correction and deficiency reports.

SUBCHAPTER 5. ADMINISTRATION

10:161A-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 designated staff responsible

for contacting the administrator when the administrator is not in the facility.

(c) In the event that an alternate or designee is used in the administrator's absence (except on a short-term emergency basis not to exceed two weeks), 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 the length of time this individual shall serve in this capacity. This information shall be provided to the facility's staff and approved by the governing authority.

SUBCHAPTER 6. CLIENT CARE POLICIES AND SERVICES

10:161A-6.1 Client care policies and procedures

(a) Every residential substance use disorders 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 the medical director or facility's physician shall provide direct input and review of all client care policies.

1. A facility shall 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 deficiencies or incidents shall prompt an immediate policy review, and any resulting policy revisions shall be shared with the agency'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) The facility shall ensure that during client care policy committee meetings, items are discussed, actions are taken and documented in minutes, dated and disseminated to appropriate parties.

(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 that the policies and procedures address the needs of any special populations that the facility may serve including, but not limited, to pregnant women, women with dependent children, adolescents, homeless and/or indigent, individuals with physical disabilities, individuals with communication limitations requiring communication services or persons with co-occurring mental health disorders.

(f) In addition to addressing specific client care policies and procedures, the facility shall address plans and policies for separate housing of adult and adolescent clients and male and female clients.

[page=2241] 1. Adult and adolescent clients shall be physically separated by floor, wing or other physical barriers. Excluding hospital medical units, male and female sleeping quarters shall be physically separated by floor, wing or other adequate physical barriers, ensuring the clients' rights to privacy and dignity in treatment.

(g) All client care policies and procedures shall be sensitive to cultural, religious, ethnic, age and gender issues.

10:161A-6.2 Client continuity of care and client safety

(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 process for 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 facilities along the continuum of care;
7. Procedures governing client search and seizure that ensures protection of staff and clients, doesn't violate client rights and preserves the dignity of clients;

8. Emergency care of clients;
9. Care of clients during an episode of communicable disease;
10. Care of clients with tuberculosis that is no longer communicable or is not transmissible;
11. Informed consent requirements and methodology, including provisions for obtaining informed consent from parents or guardians of adolescents and the identification of staff designated to obtain informed consent from clients, or in the case of an adolescent, the parents or guardians of the adolescent;
12. 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;
13. Health education of clients through various media, including written materials that are presented multi-lingually on the basis of client composition of the facility;
14. Criteria for discharge, transfer and re-admission of clients from the facility;
15. Screening clients for substance use through random urinalysis or other approved methods of drug screening on grounds that are reasonable and not unfairly discriminatory;
16. Criteria and procedures for conducting of research activities;
17. Reporting of critical incidents, complaints and threats;
18. Conflict resolution process;
19. Responsibility of the facility with respect to client care and supervision off-site, including staff who may accompany clients and the identification of destinations for clients or classes of clients;
20. The facility shall develop policies and procedures governing the permitting of pets at the facility;
21. When clothing for clients is provided by the facility, such clothing shall be suitable for the season, client size and compatible with the clothes worn by the client's peers;
22. Policies governing which on-site activities, work and/or vocational activities are to be performed by the client.
 - i. Such activities, that are appropriate to the facility include, but are not limited to, clerical functions, housekeeping and light manual labor.
 - ii. The therapeutic benefit, along with the client's voluntary written consent to participate in such activities, shall be documented in the client's treatment plan.
 - iii. The client shall sign a client consent form verifying their voluntary

participation in the activities described in this paragraph; and

23. Care and documentation of deceased clients, including notification of local law enforcement and DAS, pronouncement of death, recording of death in the client's clinical record, immediate notification of the deceased client's family, guardian or legal representative, if not present at the time of death, and person responsible for the deceased client until released.

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

1. The method and timeframes 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. Descriptions of any sliding fee scales or special payment plans shall be provided to clients;

3. 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.

i. 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 facility'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 regarding verbal and telephone orders from physicians or other licensed practitioners authorized under New Jersey statute, to include the following:

1. Specifications of the circumstances under which verbal and telephone orders may be given and received;

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

3. Written documentation of verbal and telephone orders shall be entered into the client's clinical record by medical staff authorized medical to receive such orders, and countersigned within 72 hours of the original order by the physician or medical staff issuing the verbal or telephone order.

(d) The facility shall establish policies and procedures for providing documented written notifications to families of clients including, but not limited to, the following situations:

1. Client injury requiring medical care;
2. Accidents or incidents involving the client;
3. Client transfer; and
4. Client death.

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

(a) Prior to or at the time of admission to the facility, the facility staff shall conduct a preadmission interview with all clients and, in the case of an adolescent, 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;
2. The obtaining of informed consent from the parents or legally authorized representative of an adolescent prior to the adolescent 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; and
3. If admission to the facility is denied, the documentation of the reasons for denial and referral of the client to appropriate treatment services.

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

1. An individual is unconscious at the time of presentation or admission.

[page=2242] i. The facility shall transfer such an individual immediately to a hospital emergency room; or

2. An individual manifests such a degree of behavioral or psychiatric 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 facility including a designated mental health screening center.

(c) A facility licensed to provide services to adolescents shall admit adolescents only to areas within the facility approved for adolescent occupancy by the Department, as part of the licensure process.

1. Areas for adolescents shall be physically separated from and have restricted

access to any part of a facility occupied by or accessible to adult clients.

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

(e) A facility shall adhere to N.J.A.C. 10:161A-24.5 and comply with the Federal ADA requirements governing the provision of reasonable accommodations for persons with physical disabilities.

(f) Upon admission, the facility shall ensure that each client has received a physical examination, according to the medical standards at N.J.A.C. 10:161A-7.1 and 9.1(b). In addition, a physician shall certify that the client is:

1. Free of communicable disease or, if a client had a communicable disease, that the client is treated, or, if the disease is not curable, that the client is managed to prevent transmission to other clients;
2. Physically mobile with or without assistive devices; and
3. Able to leave the building unaccompanied, except in a facility licensed to provide medically monitored detoxification services.

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

(h) 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.

10:161A-6.4 Involuntary discharge

(a) A facility shall have written policies and procedures governing the involuntary discharge of clients, a copy of which shall be given to and signed by the client at intake. All clients shall be provided with a verbal and written notice of the facility's intent to discharge. If the client is an adolescent, the adolescent's parent(s), guardian or legally authorized representative shall be provided with the time the adolescent will be released to their care, except for those circumstances in which the adolescent 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. If the client is an adolescent, the parent(s), guardian or legally authorized representative must file an appeal in accordance to procedure.

1. Clients may initiate an appeal of an involuntary discharge either verbally or in writing.

2. In instances where client does not pose a health or safety hazard to themselves, other clients or staff, the client shall not be discharged from the

facility until the appeal process is complete.

3. In instances where the client poses a health or safety hazard to themselves, other clients or staff, as documented by facility staff (such as a substance abuse counselor, director of nursing services), the client may be discharged from the facility prior to completion of the appeal process.

4. Clients may initiate an appeal of an involuntary discharge immediately and up to 30 calendar days after the involuntary discharge.

5. 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, or otherwise violates facility policies that were presented to the client at the time of admission.

1. If a client is discharged involuntarily, the facility shall provide assistance in referring the client to secure shelter or making a referral to a client-approved treatment facility.

10:161A-6.5 Use of restraints

(a) Pharmacological restraints shall only be used in a facility licensed by DAS that provides medical detoxification services. No other types of restraints (for example, physical or medical devices) are permitted in DAS licensed substance use disorders treatment facilities.

1. The facility shall develop and implement written policies and procedures regarding pharmacological restraint use including, but not limited to:

i. Use on clients posing a threat or harm to self or others, and after other less restrictive methods have been utilized and documented in the client record and medical record as such;

ii. Specification of the circumstances in which pharmacological restraints are permitted;

iii. Specification of the frequency with which a client shall be monitored by licensed medical or nursing personnel (for example, licensed practical nurse, registered nurse, physician's assistant, physician);

iv. Specification of the documentation required in the client record and medical record describing client's reaction and behavior while on pharmacological restraint;

v. Protocols for notifying the facility's medical director or facility's physician when a pharmacological restraint is not effective and must be re-administered;

vi. A requirement that specifies a pharmacological restraint be administered only when authorized in writing by the facility's medical director or designee; and

vii. Requirement that medical and nursing staff responsible for administering pharmacological restraints have been trained and are competent to administer pharmacological restraints.

(b) The results achieved through administering a pharmacological restraint shall be documented in the client's clinical record and medical record by the facility's medical director and director of nursing and reviewed by the treatment team.

(c) Any serious incident (for example, client or staff injury or death) occurring as a result of administering a pharmacological restraint shall be reported immediately to the medical director, the administrator, the governing authority, DAS and the police.

10:161A-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.

10:161A-6.7 Interpretation services

The facility shall either provide or make an appropriate referral for a reasonable accommodation for communication access services for clients with hearing impairments or hearing loss; or clients unable to comprehend and/or communicate due to a language barrier, that without such assistance clients would be unable to participate in the substance use disorder treatment process.

SUBCHAPTER 7. MEDICAL SERVICES

10:161A-7.1 Provision of medical services

(a) Every residential substance use disorders facility shall provide for the rendering of medical services to clients. All residential substance use disorders treatment facilities governed by this chapter shall comply with all guidelines issued from CSAT that mandate any Federal Food and Drug Administration-approved medications for detoxification and maintenance. All facilities shall also comply with the DAS Buprenorphine Guidelines, Administrative Bulletin 4-2007, incorporated herein by reference as chapter Appendix B and with the DAS Vivitrol Injectable Guidelines, Administrative Bulletin (issued November 30, 2010), incorporated herein by reference, as chapter Appendix C.

1. Hospital-based (medical) detoxification facilities, non-hospital-based (medical) detoxification facilities, short-term residential facilities [page=2243] and long-term residential facilities shall designate a medical director who shall supervise the medical services provided, or supervise the coordination of the medical services provided.

i. Hospital-based (medical) detoxification facilities, non-hospital-based (medical) detoxification facilities and short-term residential facilities shall provide for the rendering of medical services on site.

ii. Long-term residential facilities may provide for the rendering of medical services on site or through written agreements with one or more physicians who

provide services outside of the facility.

2. Extended care facilities and halfway houses are not required to designate a medical director, but shall incorporate information regarding medical services rendered to a client in the client's treatment plan.

i. Extended care facilities and halfway houses shall establish agreements/contracts with licensed physicians to provide medical services on site or outside the facility.

ii. Extended care facilities and halfway houses shall designate qualified facility staff as identified by a licensed physician to serve as the facility medical liaison. Such an individual shall possess at least a B.A. with at least five years of experience in a substance abuse treatment facility.

iii. The medical liaison shall be responsible for:

(1) Incorporating medical information in client treatment plans;

(2) Documenting all medical contacts in the clinical record;

(3) Coordinating all medical and dental appointments and arranging transportation as necessary;

(4) Monitoring compliance with self-administrated medications and treatments;
and

(5) Participating as a full member of the multi-disciplinary treatment team representing medical issues.

iv. Extended care facilities and halfway houses shall obtain written consent from each client for the release of information from the physician to the medical liaison. Such written consents shall comply with the 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 and the provisions of HIPAA.

(b) Prior to a client's admission, facilities shall perform or have performed:

1. A physical examination of the client upon admission that meets the standards of N.J.A.C. 10:161A-9.1(b).

i. The physical examination requirements for a client at admission may be waived if the facility verifies and documents that a physical examination meeting those requirements in N.J.A.C. 10:161A-9.1(b) were performed within 30 days prior to admission;

2. A physical examination within 72 hours of admission to the facility, provided that the client has been assessed by a registered professional nurse for symptoms of communicable disease. The physical examination requirements may be waived when there is written documentation verifying that such an examination and/or laboratory tests were performed within 30 days prior to the date or anticipated date of admission of the client in the facility; and

3. An assessment of the client for communicable disease prior to the admission of the client to the facility.

i. A client suspected of having a communicable disease shall not be admitted to the facility until the client is determined to be free of communicable disease as based upon a complete physical examination of the client.

(c) The physical exam may be waived by the receiving facility if a client in treatment at another residential treatment facility is transferred directly to a direct treatment facility, had a physical examination within 12 months and is medically stable. This information shall be verified by the facility and such verification documented in the client's record.

(d) Along with providing the medical services in accordance with (a) above, the facility may refer clients to licensed physicians outside of the facility for additional medical services as necessary to provide a continuum of care for the client.

1. Facilities with adolescent clients shall provide notice to and obtain the written consent for the rendering of medical services from the adolescent's parent, guardian or legally authorized representative as the services require.

(e) Facilities not required to designate a medical director shall have a written policy and procedure regarding the provision or coordination of medical services, including detailed descriptions of how the facility shall ensure performance of the responsibilities set forth in (a) above.

(f) Facilities serving women and dependent children shall ensure and document that the children are immunized at admission, show no signs of illness and have been receiving regular primary medical care prior to admission and continue to receive primary medical care as needed during their stay at the facility.

10:161A-7.2 Medical policies and medical staff bylaws

(a) The medical director, in conjunction with the medical staff, shall develop, implement and review annually written medical policies. This shall include medical staff bylaws that shall be subject to the review and approval of the governing authority and 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 medical staff meetings that are documented by minutes;

2. A procedure for reviewing credentials and delineating 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 and telephone orders, including the identification of the licensed medical staff authorized to give and receive verbal and telephone orders;

4. A system for completion of entries in client clinical records by members of the medical staff, including specification of a time limit for completion of the clinical record, which must not exceed 30 days following a client's last treatment or discharge; and

5. For those facilities serving women and dependent children, a plan for ensuring that the needs of the children, as well as the mothers, are adequately assessed and met during treatment.

SUBCHAPTER 8. NURSING SERVICES

10:161A-8.1 Provision of nursing services

(a) Every hospital-based (medical) detoxification facility, non-hospital-based (medical) detoxification facility, short-term residential facility, long-term residential facility and extended care facility shall provide nursing services, as follows:

1. Hospital-based (medical) detoxification facilities and non-hospital-based (medical) detoxification facilities shall dedicate at least one registered professional nurse on each of its detoxification nursing units 24 hours a day, seven days a week;
2. Short-term residential facilities shall staff at least one registered professional nurse on duty eight hours a day Monday through Friday, a minimum of five days a week and shall have a registered professional nurse available at all other times on an on-call basis;
3. Long-term residential facilities shall staff at least one registered professional nurse on duty eight hours a day, Monday through Friday, a minimum of five days a week and shall have a registered professional nurse available at all other times on an on-call basis;
4. Extended care facilities shall have nursing services on-site a minimum of two hours daily.
 - i. Extended care facilities shall comply with N.J.A.C. 10:161A-1.5(f).
 - ii. Extended care facilities that do not have nurses on staff shall provide nursing services through written contract; and
5. Halfway houses are not required to have on-site nursing services but shall have a medical liaison who is responsible for ensuring that clients receive appropriate medical follow up as indicated in the pre-admission physical examination. In addition, there shall be follow up for any additional medical problems that occur during the stay within the facility.

(b) Hospital-based (medical) detoxification facilities, non-hospital-based (medical) detoxification facilities, short-term residential facilities and long-term residential facilities shall provide additional licensed nursing personnel and ancillary nursing personnel in accordance with each facility's client care policies and procedures for determining staffing levels.

[page=2244] SUBCHAPTER 9. CLIENT ASSESSMENTS AND TREATMENT PLAN

10:161A-9.1 Client assessment

(a) A residential substance use disorders treatment facility shall provide within 72 hours of admission, a comprehensive biopsychosocial assessment of all

clients using the Addiction Severity Index or a similar standardized validated assessment instrument that assesses medical status, employment and support, tobacco, drug and alcohol use, legal status, family status/social status, psychiatric status, including diagnosis, as well as behavioral risk factors for HIV and Hepatitis. In order to ensure that the client is placed in the appropriate treatment facility, the client must be assessed for level of care determination based upon the ASAM PPC-2R.

1. All client assessments shall document the result in a DSM diagnosis for alcohol, tobacco and other drug use, screening for other co-occurring disorders and ASAM level of care determination. Such documentation shall be included in the client record.
2. At the time of assessment, all clients must be screened for co-occurring disorders and, as appropriate, provided with or referred for full diagnosis and treatment planning. Such provision to a facility in which treatment staff are appropriately licensed to provide a full diagnosis of or referral for treatment planning shall be documented in the client's file.
3. If the biopsychosocial assessment indicates that the client should be referred to another treatment program or level of care, the facility shall coordinate the client's referral to another program. If transfer to another facility or level of care is indicated, interim services that are responsive at the client's current level of care shall be provided until the transfer is made.
4. If the physical examination and clearance is not conducted prior to admission, the client shall be assessed at admission by a registered professional nurse, licensed physician or other licensed medical practitioner to ensure that the client does not exhibit potential symptoms of communicable disease, such as persistent coughing, fever, etc. The full physical examination shall be completed within 72 hours of admission, except as otherwise required for clients receiving detoxification services, or if conducted within 30 days pre-admission and waived per N.J.A.C. 10:161A-7.1(b)1.

(b) In performing a bio-psychosocial assessment, the facility shall assess the following:

1. The client's medical, alcohol, tobacco, and drug history, and interventions, if any;
2. The results of the client's physical examination, which shall include a certification by the examining physician that the level of medical care needed by the client is available through the facility and the following laboratory tests and evaluations, subject to client's written consent:
 - i. Blood work for chronic, incurable and/or communicable diseases or conditions as indicated by the client's medical history and the physician's evaluation;
 - ii. Serologic tests for syphilis, smears and cultures for gonorrhea and other sexually transmitted diseases, as medically indicated;
 - iii. Routine and microscopic urinalysis, including pregnancy testing for females;
 - iv. Human immunodeficiency virus antibody testing, as medically indicated, for

which the facility shall obtain a separate written consent. All clients shall receive HIV pre-test counseling and post-test counseling if the client elects to be tested. If HIV testing is performed onsite, the facility is required to report positive results according to N.J.A.C. 8:57-2 and maintain client confidentiality according to N.J.S.A. 26:5C-7 et seq.;

v. All pregnant women shall be provided information on HIV and AIDS and offered testing for HIV infection. This information may be provided by the administrator or delegated to another healthcare professional, but such delegation of duties shall not relieve the administrator from the ultimate responsibility to see that this information is provided in accordance with N.J.A.C. 8:61-3.1;

vi. Hepatitis B and Hepatitis C, as medically indicated; and

vii. A Mantoux tuberculin skin test and tuberculosis screening and treatment in accordance with the Tuberculosis Surveillance Procedures for Substance Abuse Treatment Facilities, incorporated herein by reference as chapter Appendix A;

3. The client's history of psychological problems or psychiatric disorders and treatment received, including previous psychiatric admissions, history of suicidal or homicidal ideation and attempts, outpatient psychiatric treatment and psychotropic medications;

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

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

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

7. 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, impairments 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 problems related to substance abuse;

8. Readiness to change;

9. Spiritual assessment; and

10. Assessment of housing needs.

10:161A-9.2 Client treatment planning

(a) The facility shall establish a client treatment plan that is specific, measurable and outcomes-focused for every client, which shall be developed based on the assessments made of the client in accordance with N.J.A.C. 10:161A-9.1.

1. The facility shall initiate development of a measurable client treatment plan upon the client's admission, and shall enter the client's treatment plan into the client record within 72 hours following the client's admission.

i. The client treatment plan, shall be revised and/or updated as assessments are completed and/or new client information is obtained or on an as-needed basis.

ii. Clients shall be continually assessed, using the ASAM PPC-2R, to assess level of care and needs.

2. Problems, strengths and needs identified in the placement, assessment and treatment planning process shall be addressed directly by the facility or by way of referral to appropriate services. Such service provision shall include, but not limited to:

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 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 on-site or by referral to community resources;

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

vi. Family, recovery supports, spiritual, housing and social support services;

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

viii. Evidence of client participation in the 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 relative to the services the practitioner shall provide.

[page=2245] (c) The client and the client's family, if indicated and where considered appropriate, shall participate in the development of the client treatment plan, including the continuum of care plan, which 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 client 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. The client's family or legal guardian shall be informed of the treatment plan, and such information shall be documented in the client's clinical record.

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

(d) The multidisciplinary team shall review the client treatment plan and client treatment progress at least every 30 days, with such review and revisions, if any, documented in the client's clinical record.

1. The multidisciplinary team shall revise the client treatment plan based upon the client's response to the care provided, the client's abilities and disabilities and each team member's continuing reassessment of services rendered.

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

(f) Self-help group meetings shall be held on-site or transportation provided to off-site meetings throughout the treatment stay in order to facilitate client involvement in such groups upon discharge from the facility.

SUBCHAPTER 10. SUBSTANCE ABUSE COUNSELING AND SUPPORTIVE SERVICES

10:161A-10.1 Provision of substance abuse counseling

(a) Every residential substance use disorder facility shall provide substance abuse counseling on-site, and shall assign every client to a substance abuse counselor at admission.

(b) A facility shall maintain a ratio of substance-abuse-counselors-to-clients on the basis of each facility's daily census, with substance abuse counseling required as follows:

1. For hospital-based (medical) detoxification, non-hospital-based (medical) detoxification facilities, substance abuse counselors shall be provided at the same ratio as that required for non-detoxification beds. Clients shall participate in required treatment services as soon as medically able, as ordered by the medical director/physician or the detoxification facility's supervisor in the client's medical record;

2. For short-term residential facilities, one substance abuse counselor for every eight clients, with each client receiving at least 12 hours of counseling per week, on at least six separate occasions and shall include a minimum of one hour of individual client counseling and 10 hours of group counseling;

3. For long-term residential facilities, one substance abuse counselor for every 12 clients, with each client receiving at least eight hours of counseling per week on at least five separate occasions and shall include a minimum of one hour of individual client counseling and seven hours of group counseling;

4. For extended care facilities, one substance abuse counselor for every 15 clients, with each client receiving six hours of counseling per week, on at least three separate occasions per client, with at least one hour of individual client counseling and five hours of group counseling;

5. For halfway houses, one substance abuse counselor for every 20 clients, with each client receiving at least three hours of counseling per week, with at least one hour of individual client counseling and two hours of group counseling; and

6. Group counseling sessions, which shall not apply to educational or family counseling sessions, shall be as follows:

i. Short-term residential facilities shall have, at a minimum, one counselor for eight or fewer clients;

ii. Long-term residential facilities and extended care facilities shall have at a minimum one counselor for 12 or fewer clients; and

iii. Halfway houses shall have at a minimum, one counselor for 15 or fewer clients.

(c) The facility shall provide each client education with respect to the client's drug, alcohol and tobacco use, risk of exposure to AIDS and Hepatitis, other health consequences of substance abuse and dependence, relapse prevention, needs of clients with co-occurring disorders and gender-specific issues such as domestic violence, parenting and sexual abuse, for at least the number of hours per week, specified as follows:

1. For hospital-based (medical) detoxification and non-hospital-based (medical) detoxification facilities, clients shall participate in required educational sessions as soon as they are medically able to do so;

2. For short-term residential facilities, at least eight hours per week;

3. For long-term residential facilities and extended care facilities, at least three hours per week; and

4. For halfway houses, at least two hours per week.

(d) Each facility shall provide family counseling as clinically indicated.

(e) Each facility shall provide clients and their family members information regarding the desirability of participating in self-help and support groups, shall make literature and representatives of such groups available to clients

and their families, and enable clients and their families to attend support group meetings either onsite or by client transportation to offsite meetings.

(f) Each facility shall design programs to ensure that clients spend at least seven hours each day in structured activities to include individual and/or group counseling, psychoeducation, life skills training, vocational training/activity, education, recreation and self help meetings.

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

Every facility shall appoint a director of substance abuse counseling services with the qualifications and responsibilities specified in N.J.A.C. 10:161A-1.8.

10:161A-10.3 Supportive services

(a) Every facility 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. Legal services rendered by an attorney, licensed or otherwise authorized to practice law in this State, when such services are related to the client's treatment;
3. Job placement for clients whose plans of care indicate a need for such services;
4. Housing resources;
5. Name, address and telephone numbers of offices where information concerning Medicaid coverage may be obtained; and
6. DAS address and telephone number in the admissions waiting area or room, in the client service area of the business office and in other public areas shall be conspicuously posted throughout the facility.

(b) Every facility shall provide support services in accordance with its client care policies governing financial arrangements established pursuant to N.J.A.C. 10:161A-6.2.

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

(d) The facility shall maintain a directory of client referral resources, such as housing, child care and social services, to be made available for use by staff and, where appropriate, by clients.

10:161A-10.4 Co-occurring services

(a) All agencies shall screen for co-occurring disorders and either treat or refer those clients in need of co-occurring services.

(b) Facilities providing substance use disorders treatment to clients diagnosed with co-occurring disorders shall have clearly written policies and procedures

governing the integrated treatment of substance abuse and mental health treatment (screening, assessment, diagnosis and service provision including referrals to mental health agencies and integrated treatment plans) or individuals diagnosed with co-occurring disorders.

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

[page=2246] i. Only licensed individuals whose licensure scope of practice allows them to render a DSM diagnosis for both mental health and substance abuse may assess and diagnosis clients with co-occurring disorders.

2. The facility shall ensure that clinical supervision is provided by staff possessing clinical credentials necessary to provide clinical supervision to staff rendering treatment and services to clients diagnosed with co-occurring disorders.

3. The facility shall develop policies and procedures for developing and maintaining affiliation agreements, case consultation, coordination and referral mechanism to mental health treatment services in order to facilitate the provision of integrated treatment service.

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 co-occurring disorders.

SUBCHAPTER 11. EDUCATIONAL SERVICES

10:161A-11.1 Provision of education services for adolescents

(a) Every residential substance use disorders treatment facility shall provide, or coordinate the provision of educational services for clients, as specified in the client's treatment record and in accordance with New Jersey Department of Education rules.

1. Educational services may be provided in a public or private educational institution in the community, in an approved on-site school operated by the facility, or on-site pursuant to an agreement with and under the direction of the staff of a nearby school district based on a home-instruction model.

2. Regardless of the method by which the educational services are delivered to clients, substance abuse counselors shall confer with teachers and/or their principals on the progress of each client.

3. Whenever appropriate, staff shall encourage clients to become active in extracurricular school activities and shall make arrangements necessary to enable the client to participate.

(b) The facility shall ensure that any adolescent who legally is not attending school participates in a training program that provides necessary life skills, vocational training and teaches methods of job acquisition.

(c) The substance use disorders facility shall provide community vocational

education services that are appropriate to the age, skill level, interest and abilities of those adolescent clients for whom such services are required on-site.

(d) Facilities providing services to women and dependent children shall develop and implement policies and procedures to ensure that mothers engage in at least 45 minutes each day of age appropriate activities with their children. These activities should be age and developmentally appropriate and include, but need not be limited to:

1. Language activities;
2. Sensory activities;
3. Manipulative activities;
4. Building activities;
5. Large muscle activities; and
6. Activities involving music, arts, science and mathematics.

SUBCHAPTER 12. LABORATORY AND RADIOLOGICAL SERVICES

10:161A-12.1 Provision of laboratory and radiological services

(a) All residential substance use disorders treatment facilities, except halfway houses, shall provide laboratory and radiological services directly in the facility or shall ensure the availability of services through written affiliation agreements.

1. The facility shall contract only with laboratories that are licensed by DHSS in accordance with N.J.A.C. 8:44 and 8:45.
2. The facility shall contract only with radiological services that are registered by the New Jersey Department of Environmental Protection, Bureau of Radiological Health, in accordance with N.J.A.C. 7:28.

(b) The facility shall establish and implement policies and procedures for obtaining, identifying, storing and transporting laboratory specimens.

SUBCHAPTER 13. RECREATIONAL SERVICES

10:161A-13.1 Provision of recreational services

(a) Every residential substance use disorders treatment facility shall provide a planned, diversified program of indoor and outdoor recreational activities that allow clients to participate on an individual or group basis in physical, social, intellectual, religious and cultural activities.

(b) The facility administrator shall be responsible for the direction, provision and quality of the recreational service, including the following:

1. Developing and implementing written objectives, policies and procedures, an organizational plan and a quality assurance program for the recreational

service;

2. Ensuring that recreational services are provided for each client as specified in the client treatment plan and coordinated with other client care services to provide a continuum of care for the client, with documentation of services provided in the client's clinical record;
3. Assisting in the development of written job descriptions for recreational service personnel and assigning duties to such personnel;
4. Posting a current weekly recreational activities schedule in a location where it can be read by clients and staff; and
5. In facilities serving women and dependent children, the provision of age appropriate recreational activities for the children while the mothers are participating in treatment services, as well as the provision of recreational activities for mothers and their children.

SUBCHAPTER 14. PHARMACEUTICAL SERVICES

10:161A-14.1 Provision of pharmaceutical services

(a) Residential substance use disorders treatment facilities shall make pharmaceutical services available to clients 24 hours a day, seven days a week, directly or through written affiliation agreements.

1. If the facility has an institutional pharmacy, the pharmacy shall comply with all laws applicable to any pharmacy operated in this State, including N.J.A.C. 13:39, State Board of Pharmacy Rules, and current registration with the Federal Drug Enforcement Administration and the DAS in accordance with N.J.S.A. 24:21-1 et seq. (New Jersey Controlled Dangerous Substance Act).

(b) If the facility has an institutional pharmacy, it shall establish a multidisciplinary Pharmacy and Therapeutics Committee. The responsibilities of the Pharmacy and Therapeutics Committee shall include, but need not be limited to, the following:

1. Developing written policies and procedures regarding evaluation, selection, obtaining, dispensing, storage, distribution, administration, use, control, accountability and safe handling practices pertaining to all medications used in the treatment of clients. Such policies and procedures shall be reviewed by the facility's governing committee on an annual basis;
2. Developing a formulary, and review thereof on at least an annual basis; and
3. Reviewing medication errors and adverse medication or treatment reactions and the provision of recommendations for corrective action, as appropriate, as part of the facility's quality assurance program.

(c) If the facility coordinates pharmaceutical services through a written affiliation agreement, the duties of the Pharmacy and Therapeutics Committee shall be assumed by the client care policy committee, provided that the assumption of those responsibilities set forth in this subchapter are clearly delineated to the client care committee and documented in the plan of operation and the bylaws of the facility.

(d) The facility's policies and procedures manual shall include the qualifications and responsibilities of the pharmacist, including individuals who serve as a pharmacist on a consultant basis. Such procedures shall be included in a written affiliation agreement between the facility and the pharmacist, including the consulting pharmacist's availability for a general review on a quarterly basis.

1. Halfway houses shall conduct a general pharmacy review at least twice per year, which review may be conducted by a consultant pharmacist or a consultant registered professional nurse (RN).

2. The pharmacy consultant services should include, but not be limited to:

i. Inspecting all areas of the facility where medications are dispensed, administered or stored; and

[page=2247] ii. Educating and training of clients and staff concerning medications including self-administration.

3. There shall be a written record of each inspection, including the date of the inspection and the name and signature of the individual pharmacist(s) responsible for the inspection.

10:161A-14.2 Standards for drug administration

(a) The facility's policies and procedures shall ensure that medication(s), in the correct strength and dosage and at the correct time intervals, are administered to the correct 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 facility's plan to ensure the adequate maintenance of supplies, including at least the following:

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

2. Stocking and maintenance of emergency kits and carts, including:

i. Assuring the contents thereof are appropriate for the type of clients served in the facility;

ii. Verification and approval by the medical director of the contents of emergency kits and carts, and review thereof by the director of nursing;

iii. The location and contents of emergency kits and carts;

iv. Frequency of reviewing contents and expiration dates of medications;

v. Assignment of responsibility for reviewing contents; and

vi. Emergency kits should have a breakable seal to indicate use of the kit, since they are not to be kept under lock and key;

3. Acceptable methods for ordering medications shall be 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 and telephone orders shall be written and countersigned by authorized medical personnel issuing the verbal order or telephone within 72 hours of the original order and provide the information required in (a)3i 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;

4. Administration of medication, including establishment of the times for administration of medication prescribed;

5. When self-administration is permitted at the facility, the self-administration process shall include:

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 and medication administration record along with signature and date of staff observing self-administration;

iv. Individualized client medication administration record;

v. Training and education of clients and staff in self-administration and the safe use of medications including procedures for self-administration off-site (examples include field trips, outings away from the facility, etc.);

vi. Identification of staff trained and authorized to observe self-administration; and

vii. Establishment of precautions against clients sharing their medications with one another;

6. 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 and medical record and on their outside front covers; and

ii. Medication product defects shall be reported in accordance with the United States Pharmacopoeia, USP27NF22 (2004), incorporated herein by reference, as amended and supplemented, published by the US Pharmacopoeia Convention, 12601 Twinbrook Parkway, Rockville, MD 20852;

7. Procedures for ensuring the immediate delivery of emergency (STAT) doses from

the pharmacy even during off hours;

8. If permitted at the facility, over-the-counter floor stock medications approved as set forth on a list maintained at the facility and the amounts that may be and are stored throughout the facility.

i. A limited quantity of prescription (legend) medications that are approved by the medical director, properly labeled according to the manufacturer and State law, may be stocked for STAT doses. The number of doses stocked for each medication shall be that number that would last one client approximately three days;

9. 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;

ii. A process for notifying the prescriber prior to the expiration of a medication order in accordance with the written policy of the facility, to ensure that the medication for the specific client is discontinued if no specific renewal is ordered; and

iii. Removal of discontinued medications within 30 days of the discharge of the client;

10. Standards for the purchase, storage, safeguarding, accountability, use and disposal of medications consistent with N.J.A.C. 13:39 and N.J.S.A. 24:21-1 et seq.;

11. Standards for the procurement, storage, use and disposal of needles and syringes in accordance with State laws and a system of accountability therefor, which shall not require counting of individual needles and syringes after they are placed in a container for disposal;

12. 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, medications are lost, contaminated, unintentionally wasted or destroyed, which procedures shall include a written report of the incident signed and dated 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 for the intentional wasting of the medication and an individual assigned to witness the event;

13. Maintenance of a record of each onsite prescriber's Federal Drug Enforcement Administration numbers and State CDS numbers;

14. Data to be maintained on each medical unit, including:

i. A list of abbreviations, metric conversion charts and chemical symbols, subject to approval by the medication staff;

ii. Specific information on medications and other drugs, including indications, contraindications, actions, reactions, interactions, cautions, precautions that should be taken, toxicity and dosages that is, Physician's Desk Reference (PDR), United States Pharmacopeia (USP); and

iii. Antidote information and the telephone number of the State Poison Information and Education System Center 1-800-POISON-1;

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

i. If the facility utilizes drugs marked "samples," the Pharmacy and Therapeutics Committee or client care committee shall develop a mechanism for the control and limitations of these drugs in accordance with N.J.A.C. 13:35-6.6; and

16. If the facility 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 administered, are stored in the facility.

10:161A-14.3 Standards for storage of medications

(a) The facility shall keep all medications in locked storage areas, stored in accordance with manufacturer's instructions at or near the medical unit(s).

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

[page=2248] 2. The facility shall store all scheduled medications separate from non-scheduled medication unless unit dose.

3. The facility shall keep all medications for external use physically separated from medications for internal use.

4. Medications for ophthalmic and optic preparations should each be kept isolated from other medications.

5. Each client on medications shall have a separate receptacle labeled with his or her first and last name and room number that contains his or her own medications.

(b) The facility shall keep all medication storage and preparation areas locked and in a secured area when not in use.

10:161A-14.4 Additional standards for facilities that provide medically monitored detoxification services

(a) Any facility that provides medically monitored detoxification services shall, on a quarterly basis, require the pharmacist(s) to inspect all areas of the facility where medications are dispensed, administered or stored. There shall be written policies and procedures requiring the pharmacist(s) to maintain a written record of each inspection.

(b) Each facility providing detoxification services shall appoint a pharmacist as the director of pharmaceutical services or hire a consulting pharmacist to direct, provide and monitor the quality of pharmaceutical services and, in so doing, be responsible for the following:

1. Working with the Pharmacy and Therapeutics Committee or client care policy committee in developing policies and procedures for the delivery of quality pharmaceutical services to clients of the facility;
2. Coordinating and integrating pharmacy services with other client care services to provide a continuum of care;
3. Assisting in the development of job descriptions and assignment of duties to pharmacy personnel, if any;
4. Working with the multidisciplinary team in achieving its goals and duties;
5. Maintaining a record system that identifies the signatures of all authorized prescribers;
6. Maintaining all records of all pharmaceutical services transactions, including a record system for requisition and distribution of pharmaceutical supplies throughout the facility;
7. Conducting a drug regimen review on a schedule developed by the Pharmacy and Therapeutics Committee or client care committee; and
8. Establishing standards to ensure compliance with (c) and (d) below.

(c) Every facility that provides detoxification services shall have a unit dose medication distribution system that complies with the following:

1. Each client shall have a separate receptacle labeled with his or her first and last name and room number that contains his or her own medications;
2. Each medication shall be individually wrapped, labeled with its generic name, trade name (if appropriate), strength, lot number or reference code, expiration date, manufacturer's or distributor's name and ready for administration to the client.
 - i. If the facility repackages medications in single unit packages, the facility shall establish written standards for labeling packages to assure identification of the lot number or reference code and the manufacturer's or distributor's name in accordance with the United States Pharmacopeia (USP) or generally accepted pharmacy practices.
 - ii. Each facility providing detoxification services shall have written standards specifying medications it shall not obtain in single unit packages or repackage as single units at the facility. The Pharmacy and Therapeutics Committee shall

be responsible for making these determinations;

3. Any facility providing detoxification services shall establish a policy for exchange of client medications no less frequently than every three days, with the number of doses during each exchange for each client sufficient for no more than 72 hours. The Pharmacy and Therapeutics Committee shall establish and enforce procedures to insure the accountability for all medications used in the facility; and

4. Any facility providing detoxification services shall establish a process for providing personnel responsible for the administration of the medications with cautionary instructions and additional information as applicable to the medications to be administered.

SUBCHAPTER 15. DIETARY SERVICES

10:161A-15.1 Provision of dietary services

(a) Every residential substance use disorders treatment facility shall provide dietary services to meet the nutritional needs of its clients.

1. To the extent practical, the facility shall provide special dietary services to meet the health, medical needs, religious and cultural beliefs of clients.

(b) Every facility shall engage the services of a dietician to be responsible for the direction, provision and quality of the dietary services.

1. If the dietician is hired on a consulting basis, the facility shall require the dietician to make monthly, or in the case of halfway houses, quarterly, on-site visits at hours that vary on successive visits, so that the dietician is on-site at different times of the day when dietary services are required to be provided to clients.

2. The dietician shall engage in at least the following:

i. Developing and implementing written objectives, policies, a procedure manual, an organizational plan and a quality assurance facility for the dietary service;

ii. Participating in planning and budgeting for the dietary service;

iii. Ensuring that dietary services are provided as specified in the dietary portion of the client treatment plan and are coordinated with other client care services to provide a continuum of care for the client;

iv. Assisting in developing and maintaining written job descriptions for dietary personnel and assigning duties based upon education, training, competencies and job descriptions; and

v. Participating in staff education activities and providing consultation to facility personnel.

(c) Every facility shall appoint a full-time food service supervisor who shall function under the direction of the dietician.

(d) Every facility shall require and ensure that either a dietician or a food

service supervisor shall be on duty seven days a week.

10:161A-15.2 Responsibilities of dietary personnel

(a) Dietary personnel shall provide the following:

1. Assessment and reassessment of the dietary needs of the client and preparation of the dietary portion of the client treatment plan based on the assessment;
2. Provision of dietary services to clients as specified in the dietary portion of each client's treatment plan;
3. Participation in the multidisciplinary team in the development, implementation and revision of the client treatment plan; and
4. Completion of clinical notes, including documentation of the required activities of (a)1 and 2 above, and progress notes.

10:161A-15.3 Requirements for dietary services

(a) The facility shall schedule dietary personnel to ensure that dietary services are operational for a continuous period of at least 12 hours daily.

(b) The facility shall establish its dietary services in compliance with N.J.A.C. 8:24.

(c) The facility shall keep a current diet manual in the dietary service and in each nursing unit.

(d) The facility shall ensure that:

1. Menus are prepared with regard for the nutritional and therapeutic needs, cultural backgrounds, food habits and preferences of clients;
2. Written, dated menus are planned at least 14 days in advance for all diets and that the same menu is not used more than once in one week;
3. Current menus, including any changes, with portion sizes shall be posted in the food preparation area. The menus, including any changes shall be kept on file in the dietary service for at least 30 days;
4. Diets served are consistent with the diet manual and in accordance with physicians' orders;
5. At least three meals, or their nutritional equivalent, be prepared and served daily to clients;
6. Nutrients and calories shall be provided for each client, as ordered by a physician;
7. Between-meal nourishments are to be provided and beverages shall be available at all times for each client, unless medically contraindicated as documented by a physician in the client's clinical record;

8. Substitute foods and beverages of equivalent nutritional value shall be available to clients; and

[page=2249] 9. No more than 14 hours shall elapse between an evening meal and breakfast the next morning.

SUBCHAPTER 16. EMERGENCY SERVICES AND PROCEDURES

10:161A-16.1 Emergency plans and procedures

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

(b) The facility shall conspicuously post throughout its premises a clear and concise written evacuation diagram that includes evacuation procedures and location of fire exits, alarm boxes and fire extinguishers.

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

10:161A-16.2 Drills, tests and inspections

(a) The facility shall conduct drills of emergency plans on each shift minimally on a quarterly basis.

1. The facility shall maintain documentation of all drills, including the date, hour, description of the drill, participating staff, signature of the person in charge and the number of occupants (clients, staff and visitors) evacuated.

2. The drills on each shift shall be conducted at least quarterly per annum for emergencies due to fire, and for emergencies due to disasters other than fire, such as storm, flood, other natural disaster, loss of water, loss of power, bomb threat or radiological accident.

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

(c) The facility shall examine its fire extinguishers annually and maintain or replace them in accordance with manufacturer's requirements, National Fire Protection Association (NFPA) 10, 2002 edition, incorporated herein by reference, as amended and supplemented; 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. Monthly testing of the temperature of the hot water used in the facility;
3. Semiannual inspection of the fire detection system;
4. Semiannual inspection of the automatic sprinkler system;
5. Annual fire inspection by the local fire code authority;
6. Annual elevator inspection in accord with N.J.A.C. 5:23-12.3, Elevator safety subcode, Reference Standard ASME A17.1-96; and
7. 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 person conducting the test; and
4. The result of the test.

10:161A-16.3 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 facility, 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, including holidays and weekends.
2. The facility shall make provision for emergency transportation to, and emergency medical services to be provided at, a hospital.
 - i. All agreements and arrangements made with hospitals shall be in writing and revised as needed.
3. The facility shall specify the locations, contents, frequency of review, expiration date and personnel 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 and qualified in the use of the emergency equipment maintained on-site, is available whenever there is a client on-site.

(b) The facility shall post the numbers of emergency transportation along with police, fire, ambulance (911) and the State poison control center number on each of its units.

SUBCHAPTER 17. CLIENT RIGHTS

10:161A-17.1 Establishment of policies and procedures

(a) The residential substance use disorders treatment facility 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 facility 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 facility shall comply with all applicable Federal and State statutes and rules concerning client rights.

10:161A-17.2 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 facility has established governing client conduct in the facility;

3. The right to be informed of services available in the facility, the names and professional status of the staff providing and/or responsible for the client's care, 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 facility's basic rate.

i. Clients shall sign a form verifying that they have been advised of the facility's fee policies. This signed form shall be maintained on file with a copy provided to the client;

4. The right to be informed if the facility has authorized other health care and educational institutions to participate in his or her treatment, the identity and function of these institutions and the right to refuse to allow the participation of other institutions 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 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.

iii. All consents to release information shall be signed by the client or for adolescents their parent, guardian or legally authorized representative. All consents to release information shall comply 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 and the provisions of HIPAA;

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 verified by staff by way of the client's signature and documented as such in the client's clinical record;

[page=2250] 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 a group, free from restraint, interference, coercion, discrimination, or reprisal;

9. The right to be free from mental, sexual and physical abuse, exploitation, coercive acts by staff and other clients and from the use of restraints unless restraints are authorized pursuant to N.J.A.C. 10:161A-6.5.

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 and the determination of such has been documented in the client's medical record and clinical record;

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 consent 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 and the provisions of the HIPAA, 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.

ii. The facility may release data about the client for studies containing aggregated statistics only when the client's identity is protected and de-identified;

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 a facility and clinical staff are discussing the client with others;

12. The right to not be required to perform work for the facility, unless the work is part of the client's treatment, is performed voluntarily, the therapeutic benefit is documented in the treatment plan, and is otherwise in accordance with local, State and Federal laws and rules.

i. A client maintains the right to refuse to perform work for the facility even in those instances in which work activities are a part of the client's treatment and identified as such in the treatment plan;

13. 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;

14. 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. Facilities shall not discriminate against clients taking medications as prescribed;

15. 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 therefor, shall be documented in the client's clinical record.

ii. If a transfer or discharge on a non-emergency basis is planned by the facility, 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 this chapter;

16. The right to be notified in writing, and to have the opportunity to appeal, an involuntary discharge;

17. The right to have access to and obtain a copy of his or her clinical record, in accordance with the facility's policies and procedures and applicable Federal and State laws and rules;

18. The right to retain and use personal clothing and possessions, unless to do so would be unsafe or would infringe on the rights of other clients in the facility.

i. If the client has property on deposit with the facility, he or she will have daily access to such property during specific periods established by the facility.

ii. All client belongings shall be returned to the client when the client is discharged or decides to leave treatment within 30 days; and

19. The right to be allowed visiting time at reasonable hours in accordance with the client treatment plan and, if critically ill, to be allowed visits from his or her family or legally authorized representative at any time, unless medically contraindicated and documented by a physician in the client's medical record.

i. Members of the clergy shall be notified by the facility at the client's request. The hours of visitation by clergy shall be established by the facility.

10:161A-17.3 Complaints

(a) The administrator shall provide all clients and their families with 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
Office of Program Integrity and Accountability
Attention: Office of Licensing
P.O. Box 700
Trenton, New Jersey 08625-0700
Telephone: toll-free 1-877-712-1868

(b) The facility 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.

SUBCHAPTER 18. CONTINUUM OF CARE PLANNING SERVICES

10:161A-18.1 Continuum of care planning

(a) The residential substance use disorders treatment facility shall initiate continuum of care planning for each client upon admission.

1. Goals for discharge shall be incorporated in the client's treatment plan upon admission to the facility 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 multidisciplinary treatment team.

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

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

10:161A-18.2 Continuum of care planning policies and procedures

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

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

i. Making referrals to community agencies (for example, mental health agencies, housing 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 continuum of care planning in the treatment plan and including accompanying supervision;

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

4. The criteria for client discharge;

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

[page=2251] 6. Written criteria for the discharge of adolescent clients only to parent(s) or legal guardian, except as provided for by N.J.S.A. 9:17A-4.

10:161A-18.3 Client and family education

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

1. Community agencies and resources available for support and housing 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;

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;

3. The symptoms, effects and treatment of substance abuse;

4. Codependency and its effect on the treatment of substance abuse; and

5. Implementation of self-care rehabilitation measures following discharge.

SUBCHAPTER 19. CLINICAL RECORDS

10:161A-19.1 Maintenance of clinical records

(a) The residential substance use disorders treatment facility shall establish and implement policies and procedures for production, maintenance, retention and destruction of clinical records (including electronic 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. 10:161A-19.6; 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 and the provisions of HIPAA.
 - (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 written 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. 10:161A-19.5.

10:161A-19.2 Assignment of responsibility

- (a) The administrator and director of substance abuse counseling services shall ensure that clinical records are maintained and procedures for client clinical recordkeeping are followed.
- (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.

10:161A-19.3 Contents of clinical records

(a) The facility shall require, at a minimum, the following 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, fee schedule and payment policy;
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 residential or outpatient substance abuse services;
6. A client treatment plan signed and dated by medical and clinical personnel as required by this chapter;
7. Clinical notes shall be entered on the day the service is rendered;
8. A log recording the clothing, personal effects, valuables, funds and other property deposited by the client with the facility for safekeeping, signed by the clients, his or her family or legally authorized representative and substantiated by receipts given to the client, his or her family or legally authorized representative;
9. 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;
10. 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 or clinically contraindicated;
11. 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;
12. A record of self-administered medications, in accordance with the facility's policies and procedures and this chapter;
13. Documentation of the client's allergies in the clinical record on the outside front cover of the client record;

14. The results of laboratory, radiological, diagnostic, and/or screening tests performed;
15. Reports of accidents or incidents required to be reported to the administrator, governing authority and/or DAS;
16. A record of referrals to other health care and social service providers, including those made to mental health providers;
17. Summaries of consultations;
18. Any signed, written informed consent forms or an explanation of why an informed consent was not obtained from the client;
19. A record of any treatment, drug or service offered by appropriate staff and refused by the client;
20. Record of psychotropic medications or mood altering medications prescribed to the client;
21. Instructions given to the client and/or the client's family for care following discharge;
22. The continuum of care plan; and
23. The continuum of care summary, in accordance with N.J.S.A. 26:8-5.

10:161A-19.4 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 laws.

1. All medical orders, including verbal and telephone orders, shall be verified by authorized medical personnel or countersigned in writing [page=2252] within 72 hours by the medical director or physician who issued the original order and in accordance with State laws.

(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 and/or electronic clinical records system is used.

1. If computer-generated and/or electronic 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 facility 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 timeframe 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 counselor or clinical treatment staff involved in the client's care at all times during the hours of operation.

10:161A-19.5 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; and

3. No charges shall be assessed other than those permitted in (a)1 and 2 above.

(b) The facility shall establish a policy ensuring 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 complete original or certified copy of the clinical record.

10:161A-19.6 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 20. INFECTION PREVENTION AND CONTROL

10:161A-20.1 Infection prevention and control

(a) The administrator shall ensure the development and implementation of an infection prevention and control program.

(b) The residential substance use disorders treatment facility shall establish an infection control committee composed at least of the medical director, a representative of administration and a representative from nursing services and a person with a health care background designated by the administrator to be responsible for implementing the policies and procedures regarding infection prevention and control in the facility.

(c) The infection control committee, 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 system 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 system within the facility for identifying and monitoring nosocomial and other infections in accordance with the latest CDC infection control guidelines incorporated herein by reference, and available from the CDC Division of Healthcare Quality Promotion website, "Infection Control in Healthcare Settings," at www.cdc.gov/hai; or toll free 1-800-311-3435; in particular, the "Guideline for Prevent Healthcare-Associated Pneumonia (2003)" accessible at <http://www.cdc.gov/hicpac/pubs.html> and the "Guidelines for Hand Hygiene in Healthcare Settings" (2002), accessible at <http://www.cdc.gov/hicpac/pubs.html>, incorporated herein by reference, as amended and supplemented;

3. The facility's infection and control practices shall be in compliance with the CDC infection control guidelines in (c)2 above, and with the Occupational Safety and Health Administration (OSHA) rules at 29 CFR 1910.1030, Bloodborne Pathogens, incorporated herein by reference, issued under 29 U.S.C. § 653,

available from the OSHA website, www.osha.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, procedures to ensure employee health in accordance with N.J.A.C. 10:161A-3.7 and staff training;
6. Care of clients with communicable diseases;
7. Exclusion of personnel 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 disinfection and cleaning practices and techniques, including:
 - i. Care of instruments, solutions, dressings, articles and surfaces; and
 - ii. Section, storage use and disposal of single use and other client care items;
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; and
11. The facility shall not reuse single use client care items and shall reprocess and reuse other client care items in accordance with manufacturers' recommendations.

10:161A-20.2 Regulated medical waste

The facility shall comply with N.J.S.A. 13:IE-48.1 et seq., Comprehensive Regulated Medical Waste Management Act, and rules promulgated pursuant thereto, and all other applicable Federal, State and local laws that may apply to the collection, storage, handling and disposal of regulated medical waste, including, but not limited to, N.J.A.C. 7:26-3A.

[page=2253] SUBCHAPTER 21. HOUSEKEEPING, SANITATION AND SAFETY

10:161A-21.1 Provision of services

- (a) The residential substance use disorders treatment facility shall provide and maintain a sanitary and safe environment for clients.
- (b) The facility shall provide housekeeping, laundry and pest control services.
- (c) The facility shall perform, develop and implement written objectives, policies and procedures, an organizational plan and a documented review of housekeeping, dietary, sanitation and safety services.

10:161A-21.2 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.

10:161A-21.3 Client care environment

(a) The facility shall meet the following housekeeping and sanitation conditions and develop and maintain policies that reflect such conditions as noted in this subchapter:

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 kept unobstructed;
7. Controls safe for clients, staff and pets shall be used to minimize and eliminate the presence of rodents, flies, roaches 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 and other vermin;
8. Toilet tissue, soap and disposable towels or air driers shall be provided in each bathroom at all times, with soap and disposable towels or air driers provided at each hand washing sink.
 - i. Bathrooms with multiple hand washing sinks shall provide at least one soap dispenser and one disposable towel dispenser or air drier for every two hand washing sinks.
 - ii. A soap dispenser and towel dispenser shall be provided by each hand washing sink and utility sink throughout the facility;
9. Mattresses, pillows, blankets, draperies, upholstery and other fabrics or decorations shall be fire-resistant and flameproof;
10. Latex foam pillows shall be prohibited;
11. Equipment requiring drainage shall be drained to a sanitary connection, in accordance with State and local codes;
12. The temperature within client areas of the facility shall be maintained at a

minimum of 72 degrees Fahrenheit, and shall not exceed 82 degrees Fahrenheit.

i. The facility shall maintain adequate ventilation in all areas used by clients.

ii. The facility shall establish a written heat emergency action plan to be implemented whenever the indoor air temperature is 82 degrees Fahrenheit or higher for four consecutive hours; and

13. Facilities serving women with dependent 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. Non-skid wax shall be used on all waxed floors;

2. Throw rugs or scatter rugs shall not be used;

3. All equipment shall be located in an unobstructed space that has been provided for operation;

4. Pesticides shall be applied in accordance with the 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 that is inaccessible to clients.

i. In halfway houses, all household and cleaning products may be accessible to adult clients, except that if children under the age of five years old are residents of the halfway house or are visiting. In those instances the halfway house shall store such products in locked cabinets;

6. Combustible materials shall not be stored in heater rooms or within 18 feet of any heater located in an open basement.

7. Paints, varnishes, lacquers, thinners and all other flammable materials shall be stored outside buildings in which clients are housed or otherwise have general access to, except that minimum supplies may be kept in such buildings 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; and

9. The following shall apply to all areas accessible to children for facilities

serving women with dependent children:

- i. No poisonous plants shall be present;
- ii. Toxic chemicals including cleaning agents shall be stored in locked cabinets or enclosed in areas not accessible to the children;
- iii. All electrical outlets shall have protective covers;
- iv. All fluorescent and incandescent light bulbs shall have protective covers or shields;
- v. All windows and other glass surfaces that are not made of safety glass and that are located within three feet above the floor shall have protective guards;
- vi. Non-permanent safety barriers (such as safety gates) shall be installed if the facility has stairs, ramps, balconies, porches or elevated play areas;
- vii. Materials and furniture for indoor and outdoor use shall be of sturdy and safe construction, be easy to clean and free of hazards;
- viii. Children shall be kept away from hot stoves, irons and ironing boards, knives, glassware and other equipment within the facility that may cause injury;
- ix. Poisons, insect traps, rodent traps and similar products shall be kept out of reach of children;
- x. All indoor and outdoor areas are maintained in a safe and sanitary manner; and
- xi. All smoke detectors shall be fully operational.

(c) The residence shall ensure that children do not have access to medications administered by the facility.

(d) The facility shall develop policies and procedures addressing the client care environment that include safety precautions and a risk management process.

10:161A-21.4 Waste removal

(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, in addition, the facility shall:

1. Store solid waste in insect-proof, rodent-proof, fire-proof, nonabsorbent and water tight 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.

[page=2254] (c) The facility shall comply with N.J.S.A. 13:1E-48.1 et seq., the Comprehensive Regulated Waste Management Act, and all rules promulgated pursuant thereto, that may apply to other collection, storage, handling and disposal of regulated medical waste.

10:161A-21.5 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 (35 to 49 degrees Celsius) and the temperature of the hot water used for client bathing between 95 degrees and 110 degrees Fahrenheit (35 to 43 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.

10:161A-21.6 Laundry services

(a) The facility shall establish and implement written policies and procedures for laundry services including, but not limited to, policies and procedures for the following:

1. The provision of clean laundry for each client, including blankets;
2. The collection of soiled laundry, so as to avoid microbial dissemination into the environment and placement in impervious bags or containers that are closed at the site and time of collection.
 - i. Containers shall be in good repair, kept clean and identified for use with either clean or soiled laundry;
3. The protection of clean laundry from contamination during processing, transporting and storage; and
4. The sanitizing of equipment surfaces that comes into contact with laundry.

(b) The facility shall provide for soiled laundry to be stored in a ventilated area separate from any other supplies.

1. Soiled laundry shall not be stored, sorted, rinsed or laundered in client areas, bathrooms, areas of food preparation and/or storage or areas in which clean laundry and/or equipment are stored.

(c) If the facility has an in-house laundry, it shall have a receiving, holding, sorting and folding area with hand washing facilities in the room. The walls, floors and ceilings of the area shall be clean and in good repair and its ventilation shall be adequate to prevent heat and odor build-up.

1. In-house laundering shall follow policies and procedures designed to reduce the number of bacteria to a safe level during the laundering process.
2. The infection control officer shall establish a protocol for bed linen or clothing that cannot be adequately processed in a normal wash cycle, for example, clothing or bed linen contaminated by scabies.

SUBCHAPTER 22. QUALITY ASSURANCE PROGRAM

10:161A-22.1 Quality assurance program

(a) The residential substance use disorders treatment facility shall establish and implement an integrated comprehensive quality assurance program for client care, review the program at least annually and revise the program 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 affect 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.

10:161A-22.2 Quality assurance activities

(a) The facility's quality assurance program shall provide for an ongoing process, including documentation, that monitors and evaluates 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 practice 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. 10:161A-1.3;
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 actions by the facility 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 facility;
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 that includes core functions addressing ASAM (ASAM PPC-2R), medication assisted treatment and professional ethics.

(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 facility and in response to those emerging issues related to client care and/or deficiencies.

1. The indicators shall be consistent with and include, but not be limited to, the Federal SAMHSA National Outcome Measures (NOMs), as defined at <http://www.samhsa.gov/dataOutcomes/>.
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 facility 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 23. VOLUNTEER SERVICES

10:161A-23.1 Provision of volunteer services

(a) Residential substance use disorders treatment facilities 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 including, but not limited to, the following topics:

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.

[page=2255] (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, supervision requirements and the rules set forth in this subchapter.

10:161A-23.2 Volunteer policies and procedures

(a) If the facility uses 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 (of at least one year) 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 their education, credentials, employment experience, driver abstracts, sanctions by licensing boards and arrests or convictions;
3. Photo identification cards, which shall include the volunteer's first name and last initial 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 criminal history background checks, physical examination and testing, verification of credentials, photo identification cards and program policies and procedures relating to staff conduct.

1. Volunteers shall not be used by the facility to supplant paid staff.

(d) The facility's volunteer program shall be approved by the governing authority.

SUBCHAPTER 24. PHYSICAL PLANT AND FUNCTIONAL REQUIREMENTS

10:161A-24.1 Physical plant general compliance for new construction or alteration

(a) New buildings and alterations or additions to existing buildings, for freestanding residential substance use disorders treatment facilities shall conform with the New Jersey Uniform Construction Code, N.J.A.C. 5:23, incorporating specified subchapters of the model code of the International Building Code 2006, New Jersey Edition published by the International Code Council, 4051 W. Flossmoor Road, County Club Hills, IL 60477-5795, appropriate to Use Groups I-1, as amended and supplemented; and the Guidelines for Design Construction of Hospital and Healthcare Facilities 2006, published by the American Institute of Architects Press, 1735 New York Avenue, NW, Washington, DC 20006, 800-242-3837, www.aia.org, incorporated herein by reference, as amended and supplemented.

(b) New buildings and alterations and additions to existing buildings for residential substance use disorders 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, incorporating specified subchapters of the International Building Code 2006 New Jersey Edition, published by the International Code Council, 4051 W. Flossmoor Road, County Club Hills, IL 60477-5795, appropriate to Use Group I-2, as amended and supplemented, and the Guidelines for Design and Construction of Hospital and Health Care Facilities, 2006, published by The American Institute of Architects Press, 1735 New York Avenue, NW, Washington, DC 20006, 202-626-7475, www.aia.org, incorporated herein by reference, as amended and supplemented.

10:161A-24.2 Physical plant general compliance for construction or alteration completed prior to (the effective date of this chapter)

Buildings constructed or altered prior to (the effective date of this chapter), 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 DCA.

10:161A-24.3 Plan review and fees

(a) Prior to any construction, plans shall be submitted for review and approval, in accordance with the provisions of this chapter to:

Supervisor
Health Care Plan Review
Department of Community Affairs
P.O. Box 815
Trenton, NJ 08625-0815

(b) Review fees shall be paid pursuant to N.J.A.C. 8:31-1.1.

(c) 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:

Department of Human Services
Office of Program Integrity and Accountability
Attention: Office of Licensing
P.O. Box 700
Trenton, NJ 08625-0700

10:161A-24.4 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 that 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.

10:161A-24.5 Provision for persons with physical disabilities

All facilities shall be made available and accessible to the persons with physical disabilities pursuant to the New Jersey Uniform Construction Code, N.J.A.C. 5:23; and the American National Standard ICC/ANSI A117.1-2003, incorporated by reference, as amended and supplemented, available through the ANSI website, www.webstore.ansi.org.

10:161A-24.6 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), incorporated herein by reference, as amended and supplemented. The Accessibility Guidelines are available at the United States Access Board website, www.access-board.gov/adaag/html/adaag.htm or from the Superintendent of Documents, Government Printing Office, Washington, DC 20402.

10:161A-24.7 Ventilation

Ventilation shall be provided in accordance with the International Mechanical Code/2009 as incorporated in N.J.A.C. 5:23-3.20, incorporated herein by reference, as amended and supplemented.

10:161A-24.8 Exit access passageway and corridors

The width of passageways including doors, aisles and corridors in a facility shall not be less than 44 inches. If an existing building(s) is being converted to a residential substance use disorders treatment facility, in whole or part, the authority having jurisdiction may consider an exception [page=2256] that would allow a 36-inch corridor, in accordance with N.J.A.C. 10:161A-2.13.

10:161A-24.9 Automatic fire alarm and detection systems

(a) The facility shall have fire alarm and smoke detection systems throughout the physical plant, which shall be in accordance with all applicable rules of the Department of Community Affairs at N.J.A.C. 5:23 and 5:70, incorporated herein by reference.

(b) Smoke detectors are also required in all bedrooms, record storage rooms, mechanical and electrical equipment rooms, computer and telephone equipment rooms, living rooms, dining rooms, kitchens and recreation rooms.

(c) The facilities shall connect their alarm systems to a full-time fire station or police station or other State licensed monitoring agency.

(d) All detectors, including those for doors, windows, shelters and smoke detectors shall be hardwired and connected to a fire alarm system.

10:161A-24.10 Fire suppression systems

The facility shall have an automatic fire suppression system(s) in accordance with all applicable rules of N.J.A.C. 5:23 and 5:70, incorporated herein by reference.

10:161A-24.11 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.

10:161A-24.12 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.

10:161A-24.13 Multiple occupancy

Where an outpatient (ambulatory) care facility is part of a residential facility, clear separation and access between the outpatient and residential parts shall be designed and maintained. Building entrances used to reach outpatient services shall be at grade level, clearly marked, and located, so that outpatient clients need not pass through residential activity areas (lobbies of multi-occupancy buildings may be shared). Design shall preclude unnecessary and unrelated traffic between the outpatient and residential parts of a shared facility.

SUBCHAPTER 25. PHYSICAL ENVIRONMENT

10:161A-25.1 Resident bedrooms and baths

(a) Residential substance use disorders treatment facilities shall provide sleeping rooms for each client, subject to the following:

1. Rooms for a single occupant shall have a minimum of 70 square feet of clear floor space;
2. Rooms for multiple clients shall have a minimum of 50 square feet of clear floor space per occupant, with three feet of clear floor space between and at the foot of beds.
 - i. Storage space and a non-folding chair shall be provided for each client;
3. Rooms for mothers in treatment with one or more children shall have a minimum of 50 square feet of clear floor space per occupant.
 - i. Bunk beds shall not be used by pregnant women or preschool age children.
 - ii. Crib and playpen slats shall be no more than 2 3/8 inches apart.
 - iii. Mattresses shall be fire retardant and all mattresses used in cribs and playpens shall fit snugly.
 - iv. The top rails of cribs and playpens shall be at least 19 inches above the mattresses.
 - v. Locks or latches on the dropside of cribs shall be safe from accidental release.
 - vi. Playpens may be used for recreational purposes only, but shall not be used as beds;
4. Sleeping room doors shall be lockable only from the corridor side using a key, and exit from the room shall be possible at all times by turn of a knob or a lever.
 - i. Duplicate keys shall be carried by designated staff at all times;

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5. There shall be a bedside light for each bed, in addition to ceiling lights or other fixtures suitable for lighting the entire room; and

6. There shall be at least a duplex outlet for each bed.

(b) Facilities shall provide on each floor with client sleeping rooms, toilets and baths accessible from a common corridor (if not otherwise adjacent to each sleeping room), as follows:

1. There shall be one water closet for every eight occupants;

2. There shall be one hand-washing sink for every eight occupants;

3. There shall be one shower or tub for every eight occupants, but not less than one tub for every 50 clients per floor, whichever method provides the greater tub-to-occupant ratio; and

4. Facilities serving both male and female clients shall provide separate designated shower and toilet facilities in accordance with ratios designated in (b)1 through 3 above.

(c) Facilities shall provide at least one water closet and hand washing sink accessible from a common corridor on all other floors.

1. If individual bathroom facilities are unavailable for male and female clients, then the single bathroom must be clearly marked to indicate usage by both.

(d) Facilities serving both male and female clients shall maintain adequate separation of sleeping quarters in order to ensure safety and privacy.

10:161A-25.2 Living and recreation rooms

(a) Facilities shall have a living room or rooms of sufficient size to seat two-thirds of the licensed capacity of the facility with at least 15 square feet per client.

(b) The facility shall have living room(s) with ample space for socialization and other client activities, including letter writing, card playing, board games, reading, listening to radio or television.

10:161A-25.3 Dining rooms

(a) Facilities shall have a dining room or rooms equipped to seat at least half of its clients at one time, with 15 square feet allotted for each client.

(b) Facilities may use the dining room(s) for client recreation activities other than during service times, but the dining room shall not be a part of any other room in the facility.

10:161A-25.4 Storage

Facilities shall provide a minimum of 10 square feet of individual and separated lighted storage space per client for the storage of clothing, linens and personal items and sundries.

10:161A-25.5 Laundry equipment

(a) Facilities shall provide at least one noncommercial washer and dryer for client use.

(b) The facilities that use commercial laundry equipment shall install such equipment in a separate laundry room, with the remainder of the facility protected from the laundry room by fire separation assemblies of at least one hour fire resistance and doors that provide protection (to the laundry room) in accordance with the rules of the Department of Community Affairs at N.J.A.C. 5:23.

(c) Facilities shall vent all dryers to the outside of the buildings in which the dryers are located.

10:161A-25.6 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 Department of Community Affairs at N.J.A.C. 5:23.

10:161A-25.7 Fire extinguisher specifications

(a) The facility shall keep a minimum of two fire extinguishers in the basement or in a place that will ensure that there is a fire extinguisher [page=2257] 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)1 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.

10:161A-25.8 Employee rooms

Facilities shall equip employee's room(s) with a four-inch alarm bell that is connected to the fire alarm system.

10:161A-25.9 Sounding devices

(a) Facilities shall have an intercom system with an alarm on every floor, which shall ring in the employee's room(s) and at any area staffed 24 hours a day.

(b) Facilities shall equip self-locking doors at main entrances and entrances to a roof or balcony with a sounding device affixed to the outside of the door or adjacent wall that shall ring at an area staffed 24 hours a day and the

employee's room(s) when engaged.

10:161A-25.10 Ceiling heights

The facilities shall have ceiling heights in corridors, storage rooms, client rooms, bathrooms and lavatories in accordance with the rules of the 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 26. EXISTING FACILITIES

10:161A-26.1 Physical plant standards for all existing licensed facilities

Existing licensed residential substance use disorders treatment facilities shall comply with, and shall continue to be inspected according to, those physical plant codes and standards that were in effect at the time of their initial licensure.

10:161A-26.2 Fire safety

Smoke detectors, fire suppression systems, and building separations shall be in compliance with the Uniform Fire Code, N.J.A.C. 5:70-3 and 4, as applicable.

10:161A-26.3 Resident bedrooms

Existing licensed facilities shall have 70 square feet of floor space for single rooms and 50 square feet of floor space per resident in multi-bed rooms.

SUBCHAPTER 27. CONFIDENTIALITY

10:161A-27.1 Confidentiality

All substance (alcohol and drug) abuse treatment facilities that provide residential substance use disorders treatment to adults and adolescents including, but not limited to, halfway houses, extended care facilities, long-term residential facilities, short-term residential treatment facilities and non-hospital-based (medical) detoxification or any other similar such organization shall comply with the confidentiality provisions as set forth in HIPAA 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>.

[page=2258] **APPENDIX A**

TUBERCULOSIS SURVEILLANCE PROCEDURES

SUBSTANCE ABUSE TREATMENT FACILITIES (SATFs)

INTRODUCTION

TB Problem among Substance Abusers

-- New Jersey reported 422 verified TB cases in CY2008. This was a decline of 9.9 percent from 467 cases in CY2007. Prior to CY2005, TB incidence had decreased or remained constant in the state every year since the most recent

peak in CY1992. A 5.4 percent increase observed from CY2004 to CY2006 has been reversed with a decline in TB incidence in NJ since CY2004 (3.1 percent) is slower than the 4.25 percent annually over the previous 12 years (CY1992 to CY2004).

-- The TB case rate decreased in CY2008 to 4.9 per 100,000 in population, compared to 5.4 in CY2007, 5.8 in CY2006, 5.6 in CY2005, 5.5 in CY2004 and 5.7 in CY2003. The 2.7 percent annual decline in case rate since CY2004 does not compare favorably to the historic 4.6 percent annual decline from CY1992 to CY2004.

-- The number of individual TB cases self-reporting excess alcohol use, injecting drug use and/or non-injecting drug use was 42 or 10.0 percent of 422 cases in CY2008. This is up from 8.6 percent in CY2007. Of these 42 TB cases, 24 (57.1%) reported alcohol use from exclusively, 11 (26.2%) reported non-injection drug use exclusively, none reported injection drug use exclusively, one (2.4%) reported use of alcohol and non-injection drugs, two (4.8%) reported use of alcohol and injection drugs, one (2.4%) reported the use of injection and non-injection drugs and three (7.1%) reported use of alcohol, injection and non-injection drugs. Forty (95.2%) of the 42 cases reporting substance abuse in CY2008 were tested for HIV and 12 (30.0%) of these 40 were HIV co-infected.

-- Without treatment, approximately 20 percent of persons with latent TB infection (LTBI), 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.

-- 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.

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 Treatment for 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.

-- 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.

6. Directly observed therapy (DOT) *will be provided by the SATF* for clients receiving treatment for latent TB infection or TB disease.

7. 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.

[page=2259] 7. At least 85% of employees placed on treatment will complete the recommended regimen within 12 months.

Federal and State Requirements for TB Testing

Federal: 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 suggestive 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)-826-4878 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 shall be performed.

Note: Tuberculin **testing is not contraindicated for persons** who have been vaccinated **with BCG**. These persons should receive a TST 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 fails to return within 48 to 72 hours and has a negative test, the TST shall be repeated.

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 00 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 shall 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	0- 4 mm	Negative
	5 + mm	Positive
Negative or Unknown	0 - 9 mm	Negative
	10 + mm	Positive

[page=2260] -- 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.**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)-826-4878.

-- *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)-826-4878.

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 populations and ensure completion of treatment for LTBI.

-- **Treatment Regimens for LTBI**

The recommended treatment regimen for LTBI in adults is isoniaid (INH) 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) shall 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)-826-4878.

-- **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 shall receive each dose on a DOT basis. Referral for consultation on this matter is available by contacting the NJDHSS, TB Program at (609)-826-4878.

-- **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, for example, 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)-826-4878.

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 treated with HAART.
- History of, or at risk for, chronic liver disease (for example, hepatitis B or C, alcoholic hepatitis, or cirrhosis).
- Pregnancy and immediate postpartum period (within 3 months of delivery).
- Alcohol abuse
- Concomitant hepatotoxic medication(s).
- In these persons taking isoniazid, baseline and routine hepatic measurements of serum AST (SGOT), ALT (SGPT) and total 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:** The frequency of routine monitoring may be monthly, every other month or at 1, 3 and 6 months for patients prescribed a 9 month treatment regimen depending on perceived hepatotoxicity risk and the stability of ALT. Laboratory testing should be used to evaluate possible adverse effects that occur during the course of treatment whether baseline testing was done or not.

[page=2261] 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)).

Clients with suspected or confirmed active TB disease must 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-adherence 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.

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 sputum smears negative for AFB collected on different days.

E. ANNUAL TESTING

Clients with an Initially Negative TST:

-- Annual tuberculin skin testing is required.

Clients with an Initially Positive TST:

-- For clients in whom active TB has been ruled out (for example, 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 TB-like symptoms may be considered for clients with a positive TST who are at increased risk for developing TB (for example, clients with HIV-infection, clients who are otherwise severely immunocompromised 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 shall be performed.

Note: Tuberculin skin **testing is not contraindicated** for persons who have been vaccinated **with BCG**, and, if positive, should be considered to indicate 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) shall be completed for a post-exposure episode to an infectious tuberculosis case by a representative of the 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 local or regional chest clinic, within three weeks after completion.

These forms will be used by the local or regional chest clinic to report to the NJDHSS, TB Program as required by regulation.

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 will be used by the local or regional chest clinic to report to the NJDHSS, TB Program as required by regulation.

[page=2262] **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, REFEREED FOR CHEST X-RAY

DATE OF CHEST X-RAY (MOBILE CHEST X-RAY UNIT): _____

RESULTS: _____

INTERVENTIONS TAKEN: _____

SUBMITTED BY: _____ PHONE: _____

[page=2263] **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. *M.M.W.R.* 47(No.RR-11):36-42.
5. CDC. Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005 MMWR Vol.54 (No.RR-17).

RESOURCES

- **New Jersey Department of Health and Senior Services and the New Jersey Department of Human 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 609-826-4878.**

-- 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 (http://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

-- **Rulers - 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 Settings, 2005 MMWR Vol.54 (No.RR-17).**

-- **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)

[page=2264]-- 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/products.htm>) or by fax (212-939-8259).

[page=2265] **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 use disorders treatment facility or individual therapists who are certified and/or licensed to provide substance abuse counseling. Such licensure and certification shall be current and not revoked or suspended.**

A. Primary and Aftercare Counseling

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

B. Patient Assessments/Screening Tools

All patients in all medical encounters should be screened for substance use disorders. Those patients who are presenting for substance use disorders

treatment need to undergo a screening process to determine diagnosis, severity of illness, and the selection of an appropriate level of care for rehabilitation counseling. Providers should select a screening tool to utilize for each and every patient routinely (e.g. CAGE; COWS; CAGE-AID; and Narcotic Withdrawal Scale).

C. Complete History and Physical Examination

Each patient should undergo a complete history and physical examination. The history should include drug and alcohol use, psychiatric, past legal, medical, surgical, and family issues, and previous substance use disorders treatment. The physical examination should be complete and be specific for signs of addiction. Patient should also undergo a neurological and mental status examination. **All patients treated with Suboxone or Subutex should meet 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-2R**). **Primary counseling** can occur as **residential**, [page=2266] **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 use disorders 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.

[page=2267] **APPENDIX C**

Administrative Bulletin

Division of Addiction Services

November 30, 2010

Subject: Vivitrol Injectable Guidelines

Introduction

The FDA approved the use of Naltrexone in the injectable formulation of Vivitrol for the use in treatment of Alcohol Dependence (2006) and Opiate Dependence (2010). Vivitrol is approved for use in Alcohol and Opiate maintenance therapy in conjunction with a full treatment experience which includes psychological counseling and aftercare programs. ***Opioid dependent patients, including those being treated for alcohol dependence, must be opioid free for a minimum of seven (7) days at the time of initial VIVITROL administration.***

Vivitrol is indicated for use in patients who are abstinent from use of alcohol and who have undergone detoxification from opioid use. Patients should not use Vivitrol while they are actively using alcohol or opioids or are detoxifying from either substance.

Primary and Aftercare Counseling

Primary counseling providers need to accept Vivitrol injectable therapy as adjunctive to addiction treatment, just as outpatient treatment programs (OTPs) accept methadone treatment as adjunctive and not contrary to the concept of effective treatment for opioid dependence. Treatment professionals will need ***initial and ongoing education*** to effect this significant change in treatment philosophy. Those patients who are receiving Vivitrol 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 Vivitrol should not be segregated either. ***Patients on Vivitrol therapy should be permitted to participate alongside patients not receiving Vivitrol therapy in primary and aftercare substance abuse counseling.***

1. Screening Tools:

All patients admitted to licensed substance use disorders treatment facilities need to meet the established admission criteria as per DAS regulations. ***All patients must meet DSM-IV-TR criteria for Opiate or Alcohol Dependence.***

Those persons presenting for substance use disorders treatment must undergo a screening process to determine their diagnosis, severity of illness, and the selection of the appropriate level of care for rehabilitation counseling. The American Society of Addiction Medicine Patient Placement Criteria-2R (***ASAM PPC-2R***) is the only peer reviewed beta instrument currently available for patient placement assessment. Licensed substance use disorders treatment agencies should select and use consistently a screening tool for each and every patient (e.g., ***CAGE, COWS, CAGE-AID, Narcotic Withdrawal Scale, or CIWA.***)

2. Complete History and Physical Examination:

All patients admitted to licensed substance use disorders treatment facilities will undergo a complete history and physical examination, including blood work (LFT). The history should include current and past drug and alcohol use, allergies, psychiatric, legal, medical, surgical, family, and previous drug treatment. Patients should also be screened for Hep A & B. The physical examination should be comprehensive and be specific for signs of addiction. In addition, patients should undergo a neurological and mental status evaluations. ***All patients that are to be treated with Vivitrol must meet DSM-IV-TR criteria for Opioid or Alcohol Dependence. All patients must meet ASAM PPC-2R Criteria for Level I or Level II treatment.***

3. Comprehensive Patient Management and Referrals:

All patients must be referred for follow-up for primary medical conditions not being addressed in the licensed substance use disorders treatment facility to primary care or other medical specialists as may be warranted.

All patients with major psychiatric diagnoses must be referred to a Psychiatrist, or licensed mental health facility, qualified to manage patients with addictions.

4. Signed Informed Consent to Treatment of Vivitrol must be obtained by a physician explaining the risks and benefits of Vivitrol.

Patient Selection

Patients who currently meet DSM criteria for Alcohol or Opioid Dependence are eligible for Vivitrol therapy. These patients must have recently received detoxification from opioids and should be ***opioid-free for a minimum of 7 days.***

Patient Exclusion

Any patient with the following conditions should not be started on Vivitrol therapy:

1. Patients with acute hepatitis or liver failure
2. Patients receiving opioid analgesics
3. Patients with current opioid dependence
4. Patients in acute opioid withdrawal
5. Patients with positive urine screens for opioids
6. Patients with a known previous allergic response to naltrexone or Vivitrol
7. Patients who fail a naloxone challenge test

Dosage and Administration

The FDA approved and recommended dose is **380mg (plus 4mg diluent)** delivered **intramuscularly every 4 weeks, or once a month.** The injection is to be administered by a **healthcare professional** as an **intramuscular (IM) gluteal injection,** alternating buttocks for each subsequent injection, **using carton provided components, only.**

VIVITROL MUST NOT BE ADMINISTRED INTRAVENOUSLY OR SUBCUTANEOUSLY!

Vivitrol must be kept refrigerated (36-46 degrees F) and not frozen. Do not expose to temperatures over 77 degrees.

Vivitrol is to be given in a hospital or clinic and should not be stored at home by patients.

Pretreatment with oral Naltrexone is not required.

Warnings and Precautions

1. Hepatotoxicity: Naltrexone can cause hepatotoxicity when given in excessive dosages. It is contraindicated in patients in acute hepatitis and liver failure, and its use in patients with active liver disease must be carefully considered in light of its hepatotoxic effects.

2. Injection Site Reactions: Naltrexone injections may be followed by pain, tenderness, induration, swelling, local erythema, bruising, or pruritus. Severe reactions such as ***prolonged induration, hematoma, cellulitis, abscess, sterile abscess, and necrosis may require a surgical consult and intervention.***

3. Eosinophilic Pneumonia: Eosinophilic pneumonia requires hospitalization and treatment with steroids and antibiotics.

4. Hypersensitivity Reactions Including Anaphylaxis: Cases of urticarial, angioedema, and anaphylaxis have occurred with Vivitrol injections. Patients should seek ***immediate medical attention and should not continue with Vivitrol therapy.***

5. Unintended Precipitation of Opioid Withdrawal: This can occur when providers are unaware of patient opioid use, or in instances where a naloxone challenge test was not performed.

6. Opioid Overdosage: Opioid overdoses can occur after patients attempt to use (abuse) opioids after being on Vivitrol following an injection period, or immediately thereafter.

7. Depression and Suicidality: Alcohol and opioid dependent patients should be screened and monitored for the development of depression or suicidal thinking. These patients require psychiatric evaluations and treatment for their depression.

8. Reversal of Vivitrol Blockade for Pain Management: In emergency situations when Vivitrol treated patients develop pain, ***regional analgesia or use of non-narcotic analgesics*** is recommended. If opioid medication is required, the patient should be managed in a [page=2268] ***hospital setting*** or a setting that can provide ***cardio-pulmonary resuscitation services.***

Special Populations

1. Pregnancy: Vivitrol is a ***Pregnancy Category C*** drug. There are no adequate or well controlled studies of either naltrexone or Vivitrol in pregnant women. ***Patients should sign a waiver*** documenting that they have been informed of Vivitrol's pregnancy category status.

2. Labor and Delivery: The potential effects on labor and delivery are unknown.

3. Nursing Mothers: Naltrexone has been reported to be found in the milk of nursing mothers. A decision needs to be made regarding avoiding breast feeding or discontinuation of Vivitrol. Tumorigenicity has been found in animal studies.

4. Pediatric Use: The efficacy and safety has not been established for any

individuals under the age of 18.

5. Geriatric Use: Vivitrol has not been evaluated in the geriatric population (>65 years old).

Clinical Guideline References

CSAT TIP #28, 43, 45, 49

MANUFACTURER'S MEDICATION GUIDE

www.vivitrol.com

1-800-VIVITROL