information, materials distributed to applicants or eligible persons, nondiscrimination, and case records.

N.J.A.C. 10:79-6, Beneficiary Rights and Responsibilities, explains notice of eligibility decisions, fair hearing procedures, post-application client responsibilities, grievances and appeals, right to a grievance review, premiums, personal contribution to care, limitations on cost-sharing, and co-payments.

N.J.A.C. 10:79-7, NJ Family Care-Children's Program Beneficiary Fraud and Abuse Policies, explains beneficiary fraud and abuse policies, including when termination of eligibility may take place, application for readmission, how the rules of the chapter apply to the specific NJ FamilyCare plans, as well as the applicability to this chapter of Medicaid provisions relating to fraud and abuse, third-party liability, and administrative and judicial remedies.

N.J.A.C. 10:79-8, explains presumptive eligibility, including the scope of services provided, the period of presumptive eligibility, the presumptive eligibility determination entities, presumptive eligibility processing performed by the entities, responsibilities of the Division of Medical Assistance and Health Services (Division), as well as the county welfare agencies and the Statewide eligibility determination agency, responsibilities of the applicant, the applicable notice and fair hearing rights, the scope of services during the presumptive eligibility period, and the limitation on the number of presumptive eligibility periods.

The Department is issuing this notice of readoption in order to avoid expiration of the chapter. This will ensure that the rules will not expire while the Division works on updating the chapter, which may include deleting any obsolete rules, proposing new rules, clarifying existing policy, and/or memorializing compliance with Federal requirements.

The Department has reviewed the rules and has determined them to be necessary, reasonable, and proper for the purpose for which they were originally promulgated. Therefore, pursuant to N.J.S.A. 30:4D-1 et seq., and 30:4J-8 et seq., and in accordance with N.J.S.A. 52:14B-5.1.c(1), these rules are readopted and shall continue in effect for a seven-year period.

# (a)

# **DIVISION OF MENTAL HEALTH AND ADDICTION** SERVICES

Notice of Readoption

## Standards for Licensure of Outpatient Substance Use Disorder Treatment Facilities

## Readoption with Technical Changes: N.J.A.C. 10:161B

Authority: N.J.S.A. 26:2B-7 et seq., in particular 26:2B-14; 26:2BB-5 through 6; 26:2G-1 et seq.; and 30:1-12; and Reorganization Plan 001-2018.

Authorized By: Sarah Adelman, Commissioner, Department of Human Services.

Effective Dates:

October 16, 2023, Readoption; November 20, 2023, Technical Changes. New Expiration Date: October 16, 2030.

Take notice that pursuant to N.J.S.A. 52:14B-5.1, the rules at N.J.A.C. 10:161B, Standards for Licensure of Outpatient Substance Use Disorder Treatment Facilities, were scheduled to expire on November 22, 2023. The purpose of this chapter is to protect the health and safety of clients by establishing minimum rules and standards of care with which an outpatient substance use disorder treatment facility must adhere to be licensed to operate in New Jersey.

The rules are comprised of 25 subchapters, as follows.

Subchapter 1, Definitions and Staff Qualifications and Responsibilities, outlines the scope and applicability, purpose, and definitions of all words and terms. The subchapter also describes the qualifications and responsibilities of the medical director, director of nursing services, pharmacists, administrator of the facility, director of substance abuse counseling services, substance abuse counseling staff, and dieticians.

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; waivers; enforcement remedies; notice of violations and enforcement actions; 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.

Subchapter 3, General Requirements, describes the provision of services; compliance with laws and rules; ownership requirements; submission of documents and data; personnel; policy and procedure manual; requirements for employee health; reportable events; notices; reporting to professional licensing boards; transportation; and the prohibition on the use of tobacco products in facilities.

Subchapter 4, Governing Authority, describes the responsibility of the profit and/or non-profit governing authority of the facility.

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

Subchapter 6, Client Care Policies and Services, delineates client care policies and procedures; 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; designation of medical director; medical policies and medical staff bylaws; and physician responsibilities.

Subchapter 8, Nursing Services, describes the provision of nursing services; designation of director of nursing services; and responsibilities of licensed nursing personnel.

Subchapter 9, Client Assessment and Treatment Planning, 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: the requirement for a director of substance abuse counseling services; supportive services; and co-occurring services.

Subchapter 11, Opioid Treatment Services, describes the special requirements for facilities to be licensed to operate opioid treatment services, including authority; staffing; multidisciplinary team reviews and composition; policies and procedures; minimum standards for admission to an opioid treatment program; admissions and assessment; medical assessments; counseling services; drug screening; eligibility for takehome medication; labeling of take-home medication; take-home medication dosage schedule; extended take-home medications; take-home exceptions; clinic-based medical maintenance; office based opioid treatment; and emergency phone coverage requirements.

Subchapter 12, Detoxification Services, sets out the standards and requirements for facilities approved to provide outpatient detoxification services: staff qualifications: client eligibility for outpatient detoxification; required services; and policies and procedures.

Subchapter 13, Laboratory Services, describes provision of laboratory services that must be provided directly or ensured by licensed outpatient facilities.

Subchapter 14, Pharmaceutical Services, describes the required provision of pharmaceutical services; standards for drug administration; and standards for storage of medications.

Subchapter 15, 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 16, Client Rights, delineates policies and procedures to ensure client rights; the rights of each client; and how complaints may be brought by clients or their families internally with the facility, or externally with outside oversight agencies.

Subchapter 17, Discharge Planning Services, describes required discharge/continuum of care planning; discharge/continuum of care planning policies and procedures; and client and family education.

Subchapter 18, Clinical Records, describes how licensed facilities must create and maintain 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 19, Infection Prevention and Control Services, describes the requirements for infection prevention and control.

Subchapter 20, Housekeeping, Sanitation and Safety, delineates requirements for the provision of services; housekeeping; client care environment; waste removal and regulated medical waste; and water supply.

Subchapter 21, Quality Assurance Program, describes the quality assurance program; and quality assurance activities.

Subchapter 22, Volunteer Services, describes the provision of volunteer services; and volunteer policies and procedures.

Subchapter 23, Physical Plant and Functional Requirements, describes the physical plant general compliance for new construction or alteration; physical plant general compliance for construction or alteration completed prior to June 1, 2009; plan review; alterations, replacements, and damage to existing facilities; provision for the handicapped; restrictions; ventilation; exit access passageway and corridors; fire alarm and detection systems; interior finish requirement; and attached structures.

Subchapter 24, Physical Environment, delineates requirements for kitchens; fire extinguisher specifications; and ceiling heights.

Subchapter 25, Existing Facilities, describes physical plant standards for all existing licensed facilities; and fire safety.

In addition to readopting the existing rules, the Department of Human Services (Department) is making technical changes to reflect Reorganization Plan No. 001-2018, pursuant to which the Division of Mental Health and Addiction Services retained responsibility for program services on transfer to the Department, while responsibility for licensing facilities remained with the New Jersey Department of Health (DOH).

While the Department is readopting these rules with technical changes, it recognizes that further rulemaking may be necessary to update this chapter to reflect substantial changes in response to Reorganization Plan 001-2018 and P.L. 2017, c. 294. Thus, the Department will continue to review the rules and may consider making substantial amendments prior to the next scheduled chapter expiration.

The Department has reviewed the rules and has determined them to be necessary, reasonable, and proper for the purpose for which they were originally promulgated. Therefore, pursuant to N.J.S.A. 30:1-12 and 30:4-27.8-10, and in accordance with N.J.S.A. 52:14B-5.1c(1), these rules are readopted and shall continue in effect for a seven-year period.

**Full text** of the technical changes follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

# SUBCHAPTER 1. DEFINITIONS AND STAFF QUALIFICATIONS AND RESPONSIBILITIES

## 10:161B-1.1 Scope and applicability

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

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

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

(d) (No change.)

#### 10:161B-1.3 Definitions

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

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

"Curtailment" means an order by [OOL] **DCN&L** which requires a licensed substance use disorder treatment facility to cease and desist all admissions and readmissions of clients to the facility.

## "DCN&L" means the Division of Certificate of Need and Licensing within the Health Services Branch of the DOH.

"Deficiency" means a determination by [OOL] **DCN&L** of one or more instances in which a State licensing regulation has been violated.

"Department" or "DHS" means the New Jersey Department of Human Services.

["DHS" means the New Jersey Department of Human Services.]

["Office of Licensing" or "OOL" means the Office of Licensing within the DHS Office of Program Integrity and Accountability.]

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

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

"Survey" means the evaluation of the quality of care and/or the fitness of the premises, staff, and services provided by the facility as conducted by [OOL] **DCN&L** and/or its designees to determine compliance or noncompliance with these and other applicable State licensing rules or statutes.

"Waiver" means a written approval by [OOL] **DCN&L** following a written request from a facility, to allow an alternative to any section(s) in this chapter provided that the alternative(s) proposed would not endanger the life, safety, or health of clients or the public, as described at N.J.A.C. 10:161B-2.13.

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

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

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

1.-13. (No change.)

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

i. (No change.)

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

## HUMAN SERVICES

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

15.-18. (No change.)

### SUBCHAPTER 2. LICENSURE PROCEDURES AND ENFORCEMENT

### 10:161B-2.1 Applications for licensure

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

(b) Any person, organization, or corporation planning to operate an outpatient substance use disorder 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] Health

[Office of Licensing] **Division of Certificate of Need and Licensing** PO Box [707] **358** 

Trenton, NJ [08625-0707] 08625-0358

(c) [OOL] **DCN&L** will maintain and update initial license application, renewal application, and inspection fees pertinent to newly

licensed applicants [and or] **and/or** ongoing licensure and will update such fees by amending the fee section of this chapter as needed.

(d) (No change.)

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

1. First time applicants of newly created treatment agencies:

i. (No change.)

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

2. Licensed programs maintaining their licensure status:

i. (No change.)

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

3.-4. (No change.)

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

	License	License Modification to Add Beds or	License Modification to Relocate or	Transfer of Ownership	Initial or Biannual [DHS] <b>DOH</b>
New Facility Fee	Renewal Fee	Services	Reduce Services	Interest	Inspection Fee
\$1,750	\$750	0	\$250	\$1,500	\$300
		New Facility Fee Renewal Fee	Modification to License Add Beds or <u>New Facility Fee Renewal Fee Services</u>	Modification to Modification to   License Add Beds or Relocate or   New Facility Fee Renewal Fee Services Reduce Services	Modification to Modification to Transfer of   License Add Beds or Relocate or Ownership   New Facility Fee Renewal Fee Services Reduce Services Interest

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## (g) (No change.)

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

(i)-(j) (No change.)

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

#### 10:161B-2.2 Licenses

(a) (No change.)

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

(c) (No change.)

10:161B-2.3 Application requirements

(a) (No change.)

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

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

(d) (No change.)

(e) If a program adds any service listed [in] **at** N.J.A.C. 10:161B-2.1(j) during the annual licensure period, the program shall submit an application to [OOL] **DCN&L** for an amended license as well as adhere to all applicable local, State, and Federal approvals prior to providing the additional service. An amended license shall be based upon compliance with this chapter, and may be contingent upon an onsite inspection by representatives of [OOL] **DCN&L**. Opioid treatment and detoxification services shall not be added during the license period without amending the license application.

(f) (No change.)

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

(h)-(i) (No change.)

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

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

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

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

(c) Once the application is deemed complete, [OOL] **DCN&L** shall review it to determine whether the applicant meets the licensing criteria

to operate a program, and whether the facility is safe as demonstrated by the information contained in the application. [OOL] **DCN&L** may also, at its discretion, consider information obtained from other State agencies and/or agencies in other states, in determining whether to license the program.

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

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

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

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

ii. If [OOL] **DCN&L** documents deficiencies, [OOL] **DCN&L** shall schedule additional surveys of the outpatient substance use disorder treatment program upon notification from the applicant that the documented deficiencies have been corrected. Additional surveys shall be scheduled by [OOL] **DCN&L** within 15 working days after receipt of the applicant's notification that the documented deficiencies have been corrected.

(d) [OOL] **DCN&L** shall approve a complete application for licensure if:

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

i. (No change.)

2. (No change.)

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

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

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

## 10:161B-2.6 Surveys

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

1. [OOL] **DCN&L** 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 [OOL] **DCN&L**.

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

### 10:161B-2.7 Conditional license

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

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

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

(d) (No change.)

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

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

10:161B-2.8 Periodic surveys following licensure

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

(b) (No change.)

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

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

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

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

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

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

### 1.-2. (No change.)

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

1.-2. (No change.)

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

(d) A decision will be issued by [DHS] **DOH** within 20 business days of the conference or the review, and if the determination is to agree with the facility's contentions, the deficiencies will be removed from the record. If the decision is to disagree with the request to remove deficiencies, a plan of correction is required within 10 business days of

receipt of the decision. The facility retains all other rights to appeal deficiencies and enforcement actions taken pursuant to these rules.

## 10:161B-2.11 Plan of correction

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

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

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

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

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

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

1. The program shall provide [OOL] **DCN&L** with at least 45 days prior notice;

2.-4. (No change.)

(b) When a program is ordered by [OOL] **DCN&L** 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] **pursuant to** (a)2, 3, and 4 above, unless the order sets forth other or additional notice requirements.

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

#### 10:161B-2.13 Waiver

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

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

1.-5. (No change.)

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

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

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

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

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

# 1.-7. (No change.)

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

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

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

The assessment of civil monetary penalties, suspension or revocation of a license, or the placement of a license on provisional status shall become effective 30 business days after the date of mailing or the date personally served on a licensee, unless the licensee shall file with [OOL] **DCN&L** a written answer to the charges and give written notice to [OOL] **DCN&L** 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 **DOH** Commissioner or designee. Hearings shall be conducted in accordance with N.J.A.C. 10:161B-2.24.

## 10:161B-2.17 Enforcement actions

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

1. (No change.)

2. For a violation of an order for curtailment of admissions, [OOL] **DCN&L** 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 [OOL] **DCN&L** 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 [OOL] **DCN&L** 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 [OOL] **DCN&L** shall impose penalties consistent with (a)1 above, until the newly constructed or renovated facility is determined by [OOL] **DCN&L** to be in compliance with licensure standards. This determination shall take into account any waivers granted by [OOL] **DCN&L**; and

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

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

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

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

be construed as operation of an unlicensed facility and [OOL] **DCN&L** shall impose penalties consistent with (a)1 above.

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

i.-viii. (No change.)

4. For violations resulting in either actual harm to a client, or in an immediate and serious risk of harm, [OOL] **DCN&L** shall reduce the license to provisional status, or move to suspend or revoke the license, and may seek an injunction pursuant to N.J.S.A. 26:2G-29 and 30:1-12.

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

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

1.-8. (No change.)

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

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

(a) Within 30 days after the mailing date of a Notice of Proposed Assessment of a Penalty, a facility that intends to challenge the enforcement action shall notify [OOL] **DCN&L** 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 [OOL] **DCN&L**. If a hearing has been requested, the penalty is due 45 days after the issuance of a Final Agency Decision by the Commissioner, or designee, if [OOL] **DCN&L**'s assessment has not been withdrawn, rescinded, or reversed, and an appeal has not been timely filed with the New Jersey Superior Court, Appellate Division, pursuant to New Jersey Court Rule 2:2-3.

(c) (No change.)

10:161B-2.19 Curtailment of admissions

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

1. (No change.)

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

3. (No change.)

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

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

### 10:161B-2.20 Provisional license

(a) [OOL] **DCN&L** may place a substance use disorder treatment facility on provisional license status as follows:

1. (No change.)

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

3.-4. (No change.)

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

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

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

2. [OOL] **DCN&L** shall notify any government agency that provides funding or [third party] **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, [DHS] **DOH** shall notify the same government agencies and third parties; and

3. (No change.)

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

(e) (No change.)

10:161B-2.21 Suspension of a license

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

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

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

(d) Within five working days after suspension becomes effective, [OOL] **DCN&L** 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, [DHS] **DOH** 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 **DOH** Commissioner, or designee, as soon as possible, adopting, modifying, or rejecting the initial decision by the OAL. If the **DOH** 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, [DHS] **DOH** may concurrently or subsequently impose other enforcement actions pursuant to these rules.

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

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

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

1. (No change.)

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

3.-4. (No change.)

(b) (No change.)

10:161B-2.23 Injunction

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

(b) Upon a finding described [in] **at** (a) above, the **DOH** Commissioner or the Commissioner's authorized representative shall refer the matter to the Office of the Attorney General to file for an injunction [and or] **and/or** temporary restraints consistent with the New Jersey Court Rules.

(c) Within five working days, [DHS] **DOH** 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 disorder treatment services and effect an orderly transfer of clients to substance use disorder treatment facilities or other services approved by [DHS] **DOH** and the facility shall document all transfers.

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

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

10:161B-2.24 Hearings

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

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

(d) (No change.)

10:161B-2.25 Settlement of enforcement actions

(a) (No change.)

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

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

(d) (No change.)

## SUBCHAPTER 3. GENERAL REQUIREMENTS

10:161B-3.3 Ownership

(a) [OOL] **DCN&L** shall hold the licensee for a facility responsible for ensuring that the facility is and remains in compliance with all applicable statutes and rules related to the construction and maintenance of the physical plant, regardless of whether the licensee owns the physical plant. (b) Programs in which ownership of the physical plant, and/or the property on which it is located is by an entity other than the licensee for the facility, shall provide notice of the current ownership of the property(ies), upon request.

1. (No change.)

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

(c) (No change.)

10:161B-3.6 Policy and procedure manual

(a) (No change.)

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

1.-9. (No change.)

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

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

11.-12. (No change.)

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

i. (No change.)

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

iii.-iv. (No change.)

14. (No change.)

10:161B-3.8 Reportable events

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

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

(e) (No change.)

10:161B-3.9 Notices

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

1. All waivers granted by [OOL] DCN&L;

2.-5. (No change.)

## SUBCHAPTER 4. GOVERNING AUTHORITY

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

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

1.-24. (No change.)

25. Reviewing any notices issued by [OOL] **DCN&L** regarding noncompliance 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 [OOL] **DCN&L** of such corrective measures;

26.-28. (No change.)

(b) (No change.)

#### SUBCHAPTER 6. CLIENT CARE POLICIES AND SERVICES

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

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

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

1. (No change.)

(e)-(g) (No change.)

## SUBCHAPTER 11. OPIOID TREATMENT SERVICES

## 10:161B-11.1 Authority

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

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

2. Be certified as an opioid treatment program by the Substance Abuse and Mental Health Services Administration (SAMHSA) and accredited by an accreditation body approved by SAMHSA in accordance with 42 CFR Part 8, available at <u>http://www.samhsa.gov/laws-regulationsguidelines/substance-use-regulations-mandates#opioid</u>. Revocation of certification by SAMHSA shall constitute the immediate withdrawal of licensure approval to operate an opioid treatment program by [OOL] **DCN&L**;

## 3.-9. (No change.)

10:161B-11.15 Clinic based medical maintenance

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

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

(d) (No change.)

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

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

#### SUBCHAPTER 12. DETOXIFICATION SERVICES

10:161B-12.1 Provision of outpatient detoxification services

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

(b) (No change.)

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

(a) Outpatient substance use disorder treatment programs approved by [OOL] **DCN&L** to provide outpatient detoxification shall establish policies and procedures which are consistent with the ASAM Criteria, the CSAT Treatment Improvement Protocol (TIP 19, 1995) publication "Detoxification From Alcohol and Other Drugs," incorporated herein by reference (accessible to download from <u>http://www.taadas.org/</u> <u>publications/prodimages/TIP%2019.pdf</u>), and acceptable medical treatment practices within the disciplines providing client services for the following:

1.-10. (No change.)

(b) (No change.)

#### SUBCHAPTER 18. CLINICAL RECORDS

10:161B-18.1 Maintenance of clinical records

(a) The outpatient substance use disorder treatment program shall establish and implement policies and procedures for production, maintenance, retention, and destruction of clinical records, which shall be reviewed at least annually by the administrator. The policy and procedure manual shall address the written objectives, organizational plan, and quality assurance program for all clinical records, subject to the following: 1.-2. (No change.)

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

i.-ii. (No change.)

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

4. (No change.)

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

10:161B-18.6 Preservation, storage, and retrieval of clinical records (a) (No change.)

(b) If the facility plans to cease operation, it shall notify [OOL] **DCN&L**, 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 [OOL] **DCN&L**.

2. [OOL] **DCN&L** shall approve off-site storage if the notice from the facility requesting approval ensures that off-site storage shall maintain: i.-ii. (No change.)

#### SUBCHAPTER 21. QUALITY ASSURANCE PROGRAM

10:161B-21.2 Quality assurance activities

(a) (No change.)

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

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

2. (No change.)

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

# SUBCHAPTER 23. PHYSICAL PLANT AND FUNCTIONAL REQUIREMENTS

10:161B-23.3 Plan review

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

(c) Simultaneously with any plan(s) submission to the local Building Code Official, each agency shall submit one set of floor and furniture plans to [OOL] **DCN&L**, for a cursory review and inclusion in [OOL]

 DCN&L facility files. Submit floor and furniture plans to: New Jersey Department of [Human Services] Health [Office of Licensing] Division of Certificate of Need and Licensing PO Box [707] 358

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