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HEALTH

HEALTH SYSTEMS BRANCH

DIVISION OF CERTIFICATE OF NEED AND LICENSING

Licensure of Outpatient and Integrated Care Facilities

Manual of Standards for Licensing of Ambulatory Care Facilities

General Licensure Procedures and Standards Applicable to All Licensed Facilities

Manual of Standards for Licensure of Outpatient and Integrated Care Facilities

Licensure Standards for Mental Health Case Management and Community Support

Proposed Amendments: N.J.A.C. 8:43A-1.1, 1.3, 2.2, and 33.3; 8:43E-13.4; and 8:121-1.1, 1.3, and 1.6

Proposed Repeals: N.J.A.C. 8:43A-20, 21, 22, 23, and 26; and 10:161B

Proposed New Rules: N.J.A.C. 8:43E-5.7 and 8:43E-5 Appendix; and 8:43K

Authorized By: Kaitlan Baston, MD, MSc, DFASAM, Commissioner, Department of Health, in consultation with Sarah Adelman, Commissioner, Department of Human Services.

Authority: N.J.S.A. 26:2-199 and 200; 26:2B-7 et seq., especially 26:2B-13, 14, and 27; 26:2BB-5, 6, and 10; 26:2G-1 et seq., especially 26:2G-5.m, 23, 25, 26, and 36; 26:2H-1 et seq., especially 26:2H-5.1.g, 12.84, 12.85, and 12.86; 30:1-12; and 30:9A-1 et seq., especially 30:9A-10; P.L. 2019, c. 236, § 2; and Reorganization Plan No. 001-2017 and Reorganization Plan No. 001-2018.

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

Proposal Number: PRN 2025-043.

Submit written comments electronically by June 20, 2025, to www.nj.gov/health/legal/ecomments.shtml or by regular mail postmarked on or before June 20, 2025, to:

Genevieve Raganelli, Regulatory Officer

Office of Legal and Regulatory Compliance

Office of the Commissioner

New Jersey Department of Health

PO Box 360

Trenton, NJ 08625-0360

The agency proposal follows:

Summary

As of 2017, the Department of Human Services (DHS) held jurisdiction to administer the licensure and inspection of facilities providing behavioral health (consisting of mental health and substance use disorder (SUD)) treatment services in outpatient (or ambulatory) care facilities, and the Department of Health (the Department) held jurisdiction to administer the licensure and inspection of facilities providing outpatient physical (consisting of primary and reproductive) health care services. Pursuant to existing, but separate, chapters of the New Jersey Administrative Code, the DHS and the Department-issued separate licenses to facilities providing these services. The Department licensed facilities providing outpatient primary care,

reproductive health, and pediatric services pursuant to N.J.S.A. 26:2H-1 et seq., and N.J.A.C. 8:43A, the Manual of Standards for Licensing of Ambulatory Care Facilities. The DHS-licensed facilities providing outpatient mental health treatment services pursuant to N.J.S.A. 30:1-12 and N.J.A.C. 8:121, Licensure Standards for Mental Health Programs, and 10:37E, Outpatient Service Standards; and facilities providing outpatient SUD treatment services pursuant to N.J.S.A. 26:2B-7 et seq., in particular 26:2B-13.o and 14, 26:2BB-5, 6, and 10, and 26:2G-1 et seq., in particular 26:2G-5.m, 23, 25, 26, and 36, and N.J.A.C. 10:161B, Standards for Licensure of Outpatient Substance Use Disorder Treatment Facilities.

On June 29, 2017, Governor Christie filed Reorganization Plan No. 001-2017, A Plan for the Transfer of Mental Health and Addiction Functions From the Department of Human Services to the Department of Health (effective August 28, 2017), which transferred the Division of Mental Health and Addiction Services (DMHAS) and all functions, powers, and duties associated with the licensure and inspection of mental health and SUD services from the DHS and the DHS Commissioner to the Department and the Commissioner of Health (Commissioner). 49 N.J.R. 2303(a).

On July 13, 2017, Governor Christie approved P.L. 2017, c. 107, codified in part at N.J.S.A. 26:2H-12.84 and 12.85. N.J.S.A. 26:2H-12.84 directs the Department to "permit any licensed health care facility, which is engaged in the provision of primary health care services and the provision of behavioral health care services for mild to moderate behavioral health conditions, to use the same shared clinical space for the purposes of providing both primary health care and behavioral health care," and prohibits requiring or authorizing such a facility "to construct or use duplicative clinical

spaces, such as duplicative waiting rooms, entrances or exits, hallways, bathrooms, or any other duplicative clinical areas in the physical plant, which are designed or intended to separate behavioral health care patients from primary health care patients, or which may otherwise be stigmatizing to any patient, or may facilitate or result in the discriminatory treatment of any patient on the basis of their medical or disability status." N.J.S.A. 26:2H-12.84 states that the purpose of the enactment is "to promote the integrated provision of primary health care services and behavioral health care services by health care facilities in the State, and … reduce any potential stigma associated with a patient's receipt of behavioral health care." N.J.S.A. 26:2H-12.85 directs the Commissioners of Health and the DHS, "in consultation with each other," to promulgate implementing rules.

On October 31, 2017, then-Commissioner of Health Cathleen D. Bennett issued Executive Order 2-2017, which established the Integrated Health Advisory Panel (IHAP), the purpose of which was to advise the Commissioner on the structuring of a system of integrated health care in New Jersey. In December 2017, the Department convened the first meeting of the IHAP, which brought together experts in clinical services, medical care, policy, legal issues, and technology to assist in creating a patient-centered system of care and address regulatory barriers to integrated care.

On January 16, 2018, Governor Murphy approved P.L. 2017, c. 294 (effective February 1, 2019), which, at § 1, amended N.J.S.A. 26:2H-1 to declare as the public policy of the State that "integrating physical and behavioral health care is the most effective way to improve the health of individuals and the population at large." P.L. 2017, c. 294, at § 3, codified at new N.J.S.A. 26:2H-5.1.g, directs the Commissioner to

promulgate, in consultation with the DHS, rules "necessary to develop an integrated licensing system by which facilities licensed under the authority of [N.J.S.A. 26:2B-7 et seq.; 26:2BB-5 and 6; 26:2G-1 et seq.; 26:2H-1 et seq.; and 30:9A-1 et seq.]; or Reorganization Plan No. 001-2017 may provide primary care, mental health care, or SUD treatment services, or a combination of such services, under a single license." The IHAP provided feedback to the Department on how best to implement the integrated facility licensing system pursuant to P.L. 2017, c. 294, and address regulatory barriers to integrated care, pending the development of rules in accordance with N.J.S.A. 26:2H-5.1.g and 26:2H-12.85.

On June 21, 2018, Governor Murphy filed Reorganization Plan No. 001-2018 (effective August 20, 2018), which retransferred the DMHAS back to the DHS, but retained within the Department all functions, powers, and duties associated with the establishment and enforcement of standards for licensure and inspection of SUD and mental health facilities. 50 N.J.R. 1517(a). Reorganization Plan No. 001-2018 at § 2(c) retained and continued within the jurisdiction of the Department and the Commissioner all functions, powers, and duties established at N.J.S.A. 26:2B-14, and 26:2G-23 and 24, which are associated with the establishment and enforcement of standards for licensure and inspection of inpatient, outpatient, and residential aftercare, alcohol use disorder and intoxication treatment facilities, and at N.J.S.A. 30:1-12, which are associated with the establishment and enforcement of standards for licensure and inspection of mental health treatment programs. *Ibid*.

On August 9, 2019, Governor Murphy approved P.L. 2019, c. 236 (effective February 5, 2020), codified in part at N.J.S.A. 26:2-199, which directs the Commissioner

to “develop programs and resources to encourage health care providers, community health workers, and healthcare facilities to encourage and support women in the development of a reproductive life plan, to encourage the integration of reproductive life plans into patient medical records, and to ensure that consultations, treatment, and other services provided to each woman are consistent with her reproductive life plan,” and, at P.L. 2019, c. 236, § 2, directs the Commissioner to promulgate implementing rules.

On October 24, 2023, Governor Murphy approved P.L. 2023, c. 170 (effective April 21, 2024), codified in part at N.J.S.A. 26:2-200, which directs the Commissioner to provide on the “[Department’s] Internet website comprehensive information on reproductive rights under State law, [and] concerning health benefits coverage for reproductive health care services,” and defines the term “reproductive health care services" to mean “all medical, surgical, counseling, or referral services relating to the human reproductive system including, but not limited to, services relating to pregnancy, contraception, or termination of a pregnancy.”

To implement its rulemaking mandates pursuant to the laws described above, the Department, in consultation with the DHS, proposes new N.J.A.C. 8:43K, Manual of Standards for Licensure of Outpatient and Integrated Care Facilities. The Department is proposing corresponding revisions to amend and repeal portions of N.J.A.C. 8:43A, amend portions of N.J.A.C. 8:121, and repeal 10:161B, which would become redundant upon the operation of the proposed new rules at N.J.A.C. 8:43K. The DHS is developing corresponding rulemaking to amend or repeal portions of N.J.A.C. 10:37E that would likewise become redundant upon the effective date of N.J.A.C. 8:43K.

N.J.A.C. 8:43K would establish the standards for licensure of facilities that provide outpatient physical health care (primary, reproductive health, and pediatric) services, outpatient behavioral health care (mental health, or substance use disorder and/or addiction treatment) services, opioid treatment program services, and/or a combination of these services.

The proposed new rules at N.J.A.C. 8:43K would establish licensing standards for facilities providing outpatient health care (consisting of primary care and reproductive health care) services, behavioral health care (consisting of mental health, and SUD and/or addiction treatment) services, opioid treatment program services, and/or a combination of these services, so that entities that want to provide some or all of these services, collectively under "one roof," would not need to apply for separate licenses and be subject to separate licensure and operational standards. Instead, the proposed new rules at N.J.A.C. 8:43K would encourage, but not require, outpatient facilities to offer these services in combination, through one license and one set of standards, to clients in a more convenient and accessible way, and thereby promote integrated "whole person" care, consistent with the declared public policy of the State that "integrating physical and behavioral health care is the most effective way to improve the health of individuals and the population at large." N.J.S.A. 26:2H-1.

The Department reviewed initial concepts for the development of the new rules with the IHAP to ensure the expansion of access to integrated care, by removing existing barriers, and not creating new barriers. In addition, while the rulemaking was in development, the Department issued waivers that allowed facilities to prescribe medication for SUD regardless of licensure, relaxed the qualifications for medical

directors for SUD services, and authorized ambulatory care facilities to provide services in locations not listed on their license. See https://www.nj.gov/health/healthfacilities/certificate-need. The Department developed these waivers in consultation with the IHAP and following several listening sessions with stakeholders, including the New Jersey Primary Care Association, the New Jersey Family Planning League, and the New Jersey Association of Mental Health and Addiction Agencies, Inc., in anticipation of the development of rulemaking to implement these as standard procedures.

Subchapter 1, General Provisions, would establish general provisions. N.J.A.C. 8:43K-1.1, Purpose, would establish the purpose of the chapter, which is to implement the laws described above and to establish standards for the licensure and operation of integrated outpatient health care facilities that provide physical and/or behavioral health care services.

N.J.A.C. 8:43K-1.2, Scope, would identify the entities to which the chapter would apply, that is, entities applying for or obtaining licensure from the Department as integrated outpatient health care facilities.

N.J.A.C. 8:43K-1.3, Definitions, would establish definitions of terms that the chapter uses.

Subchapter 2, Licensure Procedures, would establish licensure procedures.

N.J.A.C. 8:43K-2.1, Application process for initial and renewal of license, would establish the process by which a facility can apply for Department license to operate an outpatient or integrated health care facility that provides physical health care services and/or behavioral health services, alone, or in combination, at the applicant's election.

N.J.A.C. 8:43K-2.2, Ownership; transfer of ownership, would identify the facility ownership information that an applicant for initial or renewal of Department licensure must disclose to the Department, and would identify the procedure by which a licensee can obtain Department approval of the transfer of ownership of a licensed facility.

N.J.A.C. 8:43K-2.3, Compliance with applicable laws; survey before licensure, would require a facility to comply with applicable State and local laws, including zoning, fire, health, construction, and utilities, and would identify the procedure by which the Department would conduct pre- and post-licensure surveys to ensure and enforce compliance with applicable law within the Commissioner's jurisdiction, and by which facilities are to cure deficiencies that the Department might identify during a survey.

N.J.A.C. 8:43K-2.4, Facility construction project review, would establish the procedure by which a facility undertaking alteration, renovation, or new construction must obtain review and approval for compliance with applicable building codes and standards that the Health Care Plan Review Unit in the Department of Community Affairs administers, identify documents that an applicant must submit in support of its application, and reflect the Department's authority to impose conditions on existing licensees while work is ongoing to protect the health and safety of patients, workers, and/or the public.

N.J.A.C. 8:43K-2.5, Facility license issuance, would establish the criteria for Department approval of an application, identify conditions that the Department can impose on a license, establish the ordinary term of licensure, require the facility to post the license and its ownership information, prohibit license assignment or transfer and identify conditions that void a license, and identify conditions for Department issuance of

a short-term provisional license to a mental health provider that is changing or adding service locations.

N.J.A.C. 8:43K-2.6, License renewal by deemed status, would establish a process by which a facility might obtain renewal of its license by presenting documentation of the facility's accreditation by an accrediting body that the Department recognizes as authoritative for purposes of the external review a facility's compliance with applicable standards and best practices, following which the Department would deem the facility to be in compliance with applicable standards for license renewal. Existing N.J.A.C. 8:121, the Licensure Standards for Mental Health Programs, at N.J.A.C. 8:121-1.4, Licensure process, subsection (c), establishes a procedure by which a facility providing mental health services might obtain license renewal by deemed status.

N.J.A.C. 8:43K-2.7, Modification of outpatient facility service or designation, would identify the procedure by which a facility might apply to the Department for authorization to modify the services or identification it selects pursuant to N.J.A.C. 8:43K-2.1(c) and (d); the form of application that a facility is to complete and submit; the information that a facility is to submit in support of the application; and the standard by which the Department would review and determine to approve or deny an application.

N.J.A.C. 8:43K-2.8, Fees, would establish the fees applicable to each type of licensure application, including an application for initial and renewal of licensure, addition of a service or a location at which a facility will provide services, relocation of a facility's service provision location, modification of the type of service a facility will provide, transfer of facility ownership, and/or waiver of licensure rules, and would

establish a periodic inspection fee. The rule would authorize a facility that does not have revenue-generating capacity to apply for a fee waiver and establish the application procedure and the standard of review that the Department would apply to grant or deny a waiver application.

N.J.A.C. 8:43K-2.9, Surrender of license, would establish the procedure by which a licensee might surrender its license.

N.J.A.C. 8:43K-2.10, Waiver, would establish the waiver application procedure and standard of review that the Department would apply to a waiver application.

Proposed new N.J.A.C. 8:43K-2.11, Transitional licensure, would establish the procedure by which a facility that holds existing licensure pursuant to N.J.A.C. 8:43A , 8:121, and 10:161B is to obtain a transitional license as an outpatient facility pursuant to the proposed new rules at N.J.A.C. 8:43K, to be effective during the period between the effective date of proposed new N.J.A.C. 8:43K and the date by which the licensee was to apply for renewal of its existing license issued pursuant to N.J.A.C. 8:43A.

Subchapter 3, Enforcement, would establish enforcement actions and remedies available to the Department to ensure chapter compliance.

N.J.A.C. 8:43K-3.1, Enforcement remedies available, would identify the enforcement remedies that are available to the Commissioner to implement against a noncompliant facility, which would include civil monetary penalties, curtailment of services and/or admissions, appointment of a receiver or temporary manager, provisional licensure, license suspension or revocation, and issuance of an order that an unlicensed facility cease and desist operation.

N.J.A.C. 8:43K-3.2, Notice of deficiency and enforcement action, would establish the notification procedures that the Department would use to inform a facility of the Department's initiation of an enforcement action against the facility.

N.J.A.C. 8:43K-3.3, Action against a license, would identify enforcement actions that the Commissioner might take against a licensee and circumstances that might warrant their implementation. These would include curtailment of admissions, imposition of penalties, removal of patients, and suspension or revocation of a license.

N.J.A.C. 8:43K-3.4, Monetary penalties, would establish monetary penalties for violations of the rules and operating without a license.

N.J.A.C. 8:43K-3.5, License suspension, would establish the process and standards by which the Department might suspend a facility's license.

N.J.A.C. 8:43K-3.6, License revocation, would establish the process and standards by which the Department might revoke a facility's license.

N.J.A.C. 8:43K-3.7, Curtailment of admissions and services, would establish the process and standards by which the Department might issue an order requiring a facility to curtail admissions and/or services.

N.J.A.C. 8:43K-3.8, Cease and desist order, would establish the Commissioner's authority to issue an order directing an unlicensed facility providing services that are subject to licensure pursuant to this chapter, or services that a licensed facility's license does not authorize it to provide, to cease and desist operation.

N.J.A.C. 8:43K-3.9, Conditional license, would establish the process and standards by which the Department might issue a conditional license to a mental health

facility while a facility is undergoing enforcement actions and the facility's obligation to post notices of its conditional licensure.

N.J.A.C. 8:43K-3.10, Hearings, would establish the procedure by which a facility might request a hearing to contest an enforcement action and the hearing process.

Subchapter 4, Operational Standards Applicable to All Licensed Outpatient Facilities, would establish operational standards applicable to all outpatient facilities that the Department would license pursuant to the chapter.

N.J.A.C. 8:43K-4.1, Compliance with law, would require a licensee to comply with applicable Federal, State, and local laws; laws applicable to other services a facility might elect to provide beyond the services for which N.J.A.C. 8:43K would establish licensure standards; if applicable, laws to which facilities that the Department licenses pursuant to the Health Care Facilities Planning Act are subject; and laws establishing the credentialing and scope of practice standards for licensed or adjunctive services that a facility might elect to provide.

N.J.A.C. 8:43K-4.2, Governing authority, would establish the responsibilities of a facility's governing authority, the operational standards and procedures that the governing authority must establish and implement, and the governing authority's oversight obligations.

N.J.A.C. 8:43K-4.3, Administration, would establish the governing authority's obligation to appoint a facility administrator; the criminal background history and minimum educational and experiential qualifications of an administrator; and the administrator's responsibility to designate one or more alternates to act in the administrator's absence; and the administrator's duties.

N.J.A.C. 8:43K-4.4, Quality assurance plan, would establish standards for a facility's establishment and operation of a quality assurance and performance improvement program.

N.J.A.C. 8:43K-4.5, Submission of documents and data, would establish the obligations of all licensees to submit data and information to the Department and the duties of behavioral health services licensees to cooperate with monitoring activities and timely report and submit data and information to DHS-designated electronic information collection platforms.

N.J.A.C. 8:43K-4.6, Policy and procedure manual, would identify a licensee's obligations with respect to the establishment, implementation, governing body review and revision, as necessary, public availability, and minimum content of a facility policy and procedure manual.

N.J.A.C. 8:43K-4.7, Patient records, would establish a licensee's obligations with respect to patient records, including policy development, administration, minimum content, operation, confidentiality, storage, preservation, notification, and patient access; the fees a licensee is authorized to impose for copies of a medical record; the procedures to which a facility and a patient's treating provider are to adhere to in limiting a patient's access to the patient's medical record; and a facility's duty to retain records in a single file, rather than keeping behavioral health treatment records in a file that is separate from physical health records (subject to applicable Federal laws, such as the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, requiring certain psychotherapy notes and SUD and/or addiction treatment records to be maintained separately).

N.J.A.C. 8:43K-4.8, Notices, would identify the written informational material that a facility must post in its waiting room.

N.J.A.C. 8:43K-4.9, Emergency and disaster plans, would require a facility to establish and maintain written emergency plans, policies, and procedures to which it would adhere in the event of a hazard that could necessitate evacuation.

N.J.A.C. 8:43K-4.10, Management of medical emergencies, would require a facility to establish and maintain written policies and procedures for the management of medical emergencies.

N.J.A.C. 8:43K-4.11, Personnel general requirements, at subsection (a), would establish a facility's obligations with respect to minimum personnel standards. Subsection (b) would establish a facility's obligation to screen and test for tuberculosis for each staff member who provides direct patient care.

N.J.A.C. 8:43A-4.12, Employee health, would require facilities to establish policies and procedures for the confirmation and maintenance of employee health in licensed facilities.

N.J.A.C. 8:43K-4.13, General reportable events, would establish each facility's obligation to establish and maintain policies and procedures governing the reporting and managing of events that adversely impact the health and safety of patients; identify the specific events that a facility must report to the Office of Certificate of Need and Facility Licensing (Office), and the manner and deadline by which a facility is to submit a required report; and require a facility to provide certain notices to a patient or staff member who is a victim of an alleged or suspected crime, and the facility's administrator and governing body.

N.J.A.C. 8:43K-4.14, Patient transportation, would establish each facility's obligation to establish and maintain policies and procedures governing patient transportation, if a facility uses a vehicle to transport patients.

N.J.A.C. 8:43K-4.15, General physical plant and functional requirements, at subsection (a), would establish a facility's obligations with respect to maintenance of the facility's physical plant and functioning, including maintenance of a clean and safe environment for patient care; compliance with applicable State, county, and municipal laws governing building, fire, safety, and health; maintenance of adequate space, as required to provide treatment and ensure patient privacy; and compliance with applicable laws governing access for people with disabilities, the Barrier-Free Subcode of the New Jersey Uniform Construction Code, and the New Jersey Smoke Free Air Act. Subsection (b) would establish that a facility providing more than one licensed service need not provide separate entrances or waiting areas at the facility for each service.

N.J.A.C. 8:43K-4.16, Drills, tests, and inspections, would establish a facility's obligation to conduct drills of emergency plans; inspect and test alarm systems; inspect and maintain fire extinguishers; engage in drills, tests, and inspections of its physical plant and emergency operations plans and equipment; and maintain records associated with each activity.

N.J.A.C. 8:43K-4.17, Housekeeping, environmental sanitation, and safety, would establish a facility's obligations with respect to housekeeping, environmental sanitation, and safety, including designation of a person to be responsible for housekeeping and environmental services at the facility; establishment of cleaning and maintenance schedules; compliance with applicable laws and adherence to manufacturer instructions

with respect to cleaning and disinfecting agents, pesticides, herbicides, and other agents; and implementation of various measures for cleanliness, noxious odor prevention, security, and safety throughout the facility.

N.J.A.C. 8:43A-4.18, Housekeeping policies and procedures, would specify additional housekeeping policies and procedures that a facility is to establish and the minimum standards to which a facility is to adhere to, including establishment of cleaning and maintenance schedules; documentation and labeling of, and maintenance of records with respect to, cleaning agents, pesticides, and herbicides the facility uses; and adherence to the Pesticide Control Code, N.J.A.C. 7:30.

N.J.A.C. 8:43K-4.19, Environmental patient care services, would establish a facility's obligations to maintain environmental conditions throughout the facility and perform activities addressing temperature control, cleanliness, food sanitation, fire safety, ventilation, equipment storage and maintenance, and patient and staff protective measures.

N.J.A.C. 8:43K-4.20, Services not described in this chapter, would establish standards and procedures by which a facility could apply to the Department for authorization to use a treatment technology or modality as to which an applicable State or Federal standard does not exist.

Subchapter 5, General Patient Care Policies and Services, would establish patient care standards that would apply to all facilities that the Department would license pursuant to the chapter.

N.J.A.C. 8:43K-5.1, Establishment and implementation of policies and procedures, would require facilities to establish and implement written patient care

policies and procedures to facilitate continuity of care, and identify minimum standards that a facility's policies and procedures are to address.

N.J.A.C. 8:43K-5.2, Patient health history and assessment, would require a facility to ensure that every new patient, as part of an initial assessment, undergoes a comprehensive health screening, and would require the facility to refer the patient for additional care and evaluation, as the health screening might indicate or warrant, to identify and/or address conditions that the facility does not provide.

N.J.A.C. 8:43K-5.3, Physical examination, would require a facility to specify in its policies and procedures, whether, and the circumstances in which, it would perform a physical examination of a patient and if it will conduct physical examinations, to perform them using appropriate hygiene and sanitation measures.

N.J.A.C. 8:43K-5.4, Instructions and information for patients, would require a facility to give each patient written instructions and information that describes the nature and goals of treatment, the tests and/or procedures to be performed, the possible complications of any treatment or tests, a facility telephone number, and instructions for obtaining care in an emergency.

N.J.A.C. 8:43K-5.5, Communication assistance, would require a facility to assist patients who require help to communicate with the facility.

N.J.A.C. 8:43K-5.6, Financial arrangements, would establish standards by which a facility is to engage in financial transactions, including establishment of policies and procedures for recordkeeping and record retention; maintaining a record of each patient's financial transaction; informing each patient of the facility's fees and financial policies and procedures; making available its fee schedule and, if applicable, a sliding

fee scale or special payment plan that the facility offers; refraining from charging a patient additional fees except upon prior notice to the patient and with the patient's written approval and authority, or in an emergency; and describing its contractual arrangements with third parties and other entities.

N.J.A.C. 8:43K-5.7, Telemedicine and telehealth activities, would establish procedures and standards by which a facility that elects to provide telemedicine or telehealth services is to operate.

N.J.A.C. 8:43K-5.8, Designation of medical director, would establish the licensed and adjunctive services that require a facility to designate a medical director, the ways by which a facility could retain its medical director, and that the medical director could serve full-time or part-time.

N.J.A.C. 8:43K-5.9, Rights of each patient, would identify the rights of each patient of a facility, and a facility's obligations with respect to these rights, including the manner by which it is to inform patients of these rights.

Subchapter 6, Behavioral Health Services, would establish standards applicable to facilities that the Department licenses as a behavioral health services facility.

N.J.A.C. 8:43K-6.1, Behavioral health services facility general provisions, would identify the scope of the behavioral health services to which the subchapter would apply, including the types of services, programs, and levels of care, and would require a facility seeking licensure to provide behavioral health services to comply with applicable standards of the DMHAS, including DMHAS contractual or affiliation agreement standards, and applicable standards codified at Title 10 of the New Jersey Administrative Code.

N.J.A.C. 8:43K-6.2, Staffing and personnel requirements, would identify the minimum staffing and personnel standards to which a behavioral health services facility is to adhere.

N.J.A.C. 8:43K-6.3, Program director, would establish the minimum credentials and responsibilities of a behavioral health services facility program director.

N.J.A.C. 8:43K-6.4, Clinical supervisor, would establish the minimum credentials and responsibilities of a behavioral health services facility clinical supervisor.

N.J.A.C. 8:43K-6.5, Counseling and/or therapy staff, would establish the minimum credentials and responsibilities of behavioral health services facility counseling or therapy staff.

N.J.A.C. 8:43K-6.6, Peer staff and peer support services, would establish standards for the provision of behavioral health services facility peer support, including the credentials and responsibilities of staff who provide, or supervise the provision of, peer support services, the types of peer support services that a facility might offer, and the patient record documentation standards.

N.J.A.C. 8:43K-6.7, Patient care policies and procedures, would establish standards by which a behavioral health services facility is to establish, implement, periodically review and update, and make available for review, patient care policies and procedures, and the minimum content thereof.

N.J.A.C. 8:43K-6.8, Behavioral health services facility documentation and treatment records; confidentiality, would require and establish the minimum content of a clinical treatment record that a behavioral health services facility is to maintain for each

patient, in addition to the records that N.J.A.C. 8:43K-4.7 would require a facility to maintain for each patient.

N.J.A.C. 8:43K-6.9, Medical cannabis use by qualifying patient at behavioral health services facility, would implement N.J.S.A. 26:2H-12.86, which requires a facility to establish a policy related to medicinal cannabis use by a qualifying patient pursuant to the Jake Honig Compassionate Use Medicinal Cannabis Act, and subject to applicable laws prohibiting smoking in certain places.

N.J.A.C. 8:43K-6.10, Outpatient mental health, substance use disorder (SUD), and/or other addiction treatment services, would establish standards by which a behavior health services facility is to provide outpatient mental health, SUD, and/or other addiction treatment services.

N.J.A.C. 8:43K-6.11, Intensive outpatient mental health, substance use disorder (SUD), and/or other addiction treatment services, would establish standards by which a behavioral health services facility is to provide intensive outpatient mental health, SUD, and/or addiction treatment services.

N.J.A.C. 8:43K-6.12, Partial care program of mental health, substance use disorder (SUD), and/or addiction treatment, would establish standards by which a behavioral health services facility is to provide a partial care program of mental health, SUD, and/or addiction treatment.

Subchapter 7, Health Care Services, would establish standards applicable to a facility that the Department licenses to provide health care services.

N.J.A.C. 8:43K-7.1, Health care services; general provisions, would establish general standards for the provision of health care services.

N.J.A.C. 8:43K-7.2, General physical plant and functional requirements, would establish physical plant and functional requirements specific to a health care services facility.

N.J.A.C. 8:43K-7.3, Waste management, would establish standards for waste management and disposal of solid, liquid, and regulated medical waste in a health care services facility, and require compliance with applicable law.

N.J.A.C. 8:43K-7.4, Water supply, would establish standards to ensure the maintenance of a safe water supply in a health care services facility, including compliance with applicable law, maintenance of water in patient care areas at appropriate temperatures, and maintenance of a proper sewage disposal system.

N.J.A.C. 8:43K-7.5, Supplies and equipment, would establish standards requiring a health care services facility to provide equipment and supplies that are appropriate to the treatment needs of the patient cohorts the facility serves and, with respect to facilities subject to the Health Care Facilities Planning Act, to adhere to applicable laws relating to the use of sharp instruments and needles, standards at N.J.A.C. 8:43A relating to linen and laundry supplies and manufacturer instructions with respect to measuring equipment calibration.

N.J.A.C. 8:43K-7.6, Sterile equipment, would establish standards requiring a health care services facility to implement measures to ensure proper cleaning, disinfection, sterilization, maintenance, and storage of single-use and reusable medical devices and equipment, decontamination of clean processing areas, and associated recordkeeping and quality improvement activities related to these functions. The section would require adherence to the following standards issued by the Association

for the Advancement of Medical Instrumentation®, which are available for purchase from that entity (see https://www.aami.org/standards/standars/): “Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities,” “Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Nonclinical Settings,” “Safe Use and Handling of Glutaraldehyde-based Products in Health Care Facilities,” and “Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness.” The section would require adherence to the following practice standard of the Society of Gastroenterology Nurses and Associates, Inc., with respect to gastrointestinal devices: “Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes,” which is available from the journal of that Society, *Gastroenterology Nursing*. The section would require adherence to, and applicable manufacturers’ instructions with respect to, other devices and equipment, and the maintenance of decontamination and clean processing areas. The section would also establish standards requiring a facility using a third-party provider for reprocessing devices and equipment to implement a quality control program and addressing a facility’s participation in a network that engages in shared reprocessing by an external vendor.

N.J.A.C. 8:43K-7.7, Documentation and treatment records, would establish standards for the minimum content of patient records in a health care services facility, which would be in addition to the standards for patient record content that would apply to all licensees at N.J.A.C. 8:43K-4.7.

N.J.A.C. 8:43K-7.8, Reportable events, would identify events that a health care services facility is to report, which would be in addition to the reportable events applicable to all facilities at N.J.A.C. 8:43K-4.13.

N.J.A.C. 8:43K-7.9, Medical director; appointment; duties, would establish standards for the appointment, minimum credentials, and responsibilities of a health care services facility medical director.

N.J.A.C. 8:43K-7.10, Director of nursing services; appointment; duties, would establish standards for the appointment, minimum credentials, and duties of the director of nursing services of a health care services facility.

N.J.A.C. 8:43K-7.11, Infection prevention and control, would establish standards for a health care services facility's infection prevention and control activities, and would identify the following CDC publications to which a facility is to adhere in undertaking these activities, which are web-based publications collected at the CDC websites indicated at subsection (d), and available at the publication-specific individual website links adjacent to each paragraph at subsection (d): "Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care (September 2016)," "CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings," "CDC Guideline for the Prevention of Surgical Site Infection, 2017," "Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011," "Infection Control in Healthcare Personnel: Infrastructure and Routine Practices for Occupational Infection Prevention and Control Services (2019)," "Testing and Clinical Management of Health Care Personnel Potentially Exposed to Hepatitis C Virus — CDC Guidance, United States, 2020," "CDC, Healthcare-Associated Pneumonia Prevention

Guideline, 2003," and "Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019."

N.J.A.C. 8:43K-7.12, Quality assurance and performance improvement program, would establish quality assurance and performance improvement activities that a health care services facility is to undertake.

N.J.A.C. 8:43K-7.13, Laboratory and radiological services, would establish standards by which a health care services facility is to provide laboratory and radiological services.

N.J.A.C. 8:43K-7.14, Reproductive health care services; general provisions, would establish standards applicable to a facility that the Department licenses as a reproductive health care services facility. A facility providing reproductive health care services would need to have as its medical director or as a member of staff, a physician who is trained in gynecology and who is either a family practice physician, an obstetrician/gynecologist, or a diplomate in a primary specialty with fellowship training or certification in family planning and/or reproductive health care services.

N.J.A.C. 8:43K-7.15, Primary care services additional requirements, would establish additional requirements applicable to a health care services facility that provides primary care services.

N.J.A.C. 8:43K-7.16, Prenatal and postpartum care additional requirements, would establish additional requirements applicable to a health care services facility that provides prenatal and postpartum care and/or obstetric services.

N.J.A.C. 8:43K-7.17, Pediatric care additional requirements, would establish additional requirements applicable to a health care services facility that provides pediatric care.

N.J.A.C. 8:43K-7.18, Counseling and therapy services, would establish standards by which a health care services facility might elect to provide counseling and therapy services without needing to obtain a separate behavioral health services facility license pursuant to N.J.A.C. 8:43K-6.

N.J.A.C. 8:43K-7.19, Medical specialty services, would establish that a health care services facility might elect to provide medical specialty or subspecialty services, and would provide a non-exhaustive list of medical specialty and subspecialty services.

N.J.A.C. 8:43K-7.20, Anesthesia services, would establish standards for the provision of anesthesia services in outpatient facilities. A facility that administers general anesthesia or performs surgical cases would continue to be subject to licensure as an ambulatory surgical center pursuant to N.J.A.C. 8:43A.

N.J.A.C. 8:43K-7.21, Provision of dietetic and nutritional counseling services, would establish standards by which a health care services facility is to provide dietetic and nutritional counseling, if it elects to provide these services.

Subchapter 8, Opioid Treatment Program, would address an opioid treatment program.

N.J.A.C. 8:43K-8.1, Opioid treatment program, would establish standards by which a facility is to provide an outpatient opioid treatment program.

Subchapter 9, Adjunctive Services, would establish standards by which a facility licensed pursuant to the chapter is to provide adjunctive services.

N.J.A.C. 8:43K-9.1, Provision of adjunctive services, would establish standards applicable to the provision of adjunctive services, which would require a facility to notify the Department of the facility's election to provide adjunctive services, followed by a Department survey of the facility for compliance with applicable standards governing the provision of the service; and comply with applicable credentialing requirements for the professional providing the service. The section would provide a non-exhaustive list of adjunctive services that a facility might elect to provide.

N.J.A.C. 8:43K-9.2, Preventive medicine, would establish standards by which a facility might provide preventive medicine as an adjunctive service.

N.J.A.C. 8:43K-9.3, Wound care, would establish standards by which a facility might provide wound care as an adjunctive service.

N.J.A.C. 8:43K-9.4, Acupuncture and herbology, would establish standards by which a facility might provide acupuncture, or herbology within the practice of acupuncture, as adjunctive services.

N.J.A.C. 8:43K-9.5, Chiropractic services, would establish standards by which a facility might provide chiropractic services.

N.J.A.C. 8:43K-9.6, Dentistry, would establish standards by which a facility might provide dentistry services.

N.J.A.C. 8:43K-9.7, Harm reduction, would establish standards by which a facility might provide harm reduction services as an adjunctive service. Harm reduction services are meant to mitigate the risks of substance use.

Subchapter 10, Storage, Administration, and Dispensing of Medication, would establish standards applicable to a facility's storage, administration, and distribution of medication.

N.J.A.C. 8:43K-10.1, Scope, would establish that a facility that administers, dispenses, and/or stores medication is to comply with Subchapter 10.

N.J.A.C. 8:43K-10.2, Provision of pharmaceutical services, would establish the standards by which a facility might maintain an onsite pharmacy.

N.J.A.C. 8:43K-10.3, Facility policies and procedures for medications, would establish standards by which a facility is to promulgate and maintain policies and procedures governing the administration, control, dispensing, and storage of medication at the facility, and would identify the minimum content of these policies and procedures.

N.J.A.C. 8:43K-10.4, Administration of medications, would establish standards by which a facility is to administer medications to patients.

N.J.A.C. 8:43K-10.5, Storage of medication, would establish minimum standards by which a facility is to store, maintain inventory of, and destroy medication.

Subchapter 11, Administration of Controlled Dangerous Substances for the Treatment of Substance Use, Ambulatory Withdrawal Management, and/or Stabilization, would establish standards by which a facility is to store and administer controlled dangerous substances (CDS) for the treatment of substance use, ambulatory withdrawal management, and/or stabilization.

N.J.A.C. 8:43K-11.1, Scope, would identify the facilities and services to which the subchapter would apply, that is, a facility that stores and administers CDS on an outpatient basis for substance withdrawal management and stabilization and would

establish that the subchapter would not apply to an opioid treatment program, or a pharmacy's fulfillment of written prescriptions, or dispensing of medication, for addiction treatment.

N.J.A.C. 8:43K-11.2, Patient care policies and procedures, would require a facility subject to the subchapter to establish patient care policies and procedures for and would identify the minimum content of these policies and procedures.

N.J.A.C. 8:43K-11.3, Withdrawal management and stabilization, would require a facility subject to the subchapter to establish and maintain policies and procedures for the provision of this service.

N.J.A.C. 8:43K-11.4, Patient education services, would require a facility subject to the subchapter to educate patients about safe use and storage of medication, the risks of substance use, risk mitigation actions, and options for ongoing addiction treatment.

N.J.A.C. 8:43K-11.5, Extended on-site monitoring services, would establish the obligations of a facility subject to the subchapter to provide extended-hours oversight and on-site monitoring services to each patient to whom it administers CDS on an outpatient basis for substance withdrawal management, treatment, or stabilization. These services would include 24-hour access to professionals, clinical supervision, ongoing assessment and reassessment of a patient's vital signs and withdrawal symptoms during CDS administration and immediately prior to a patient's departure from the facility, and laboratory testing. The section would establish limitations on a facility's dispensing of a multiple-day supply of a CDS to a patient and documentation standards applicable to the provision of services.

N.J.A.C. 8:43K-11.6, Physician services, would require a facility subject to the chapter to designate a medical director, establish the minimum credentials of the medical director and physicians providing services at the facility, and identify the medical director's duties.

N.J.A.C. 8:43K-11.7, Nursing services, would require a facility subject to the chapter to designate a director of nursing services and establish the director's minimum credentials and duties.

N.J.A.C. 8:43K-11.8, Pharmacy services, would require a facility subject to the chapter to employ, or retain through written agreement, a pharmacist to provide pharmacy services at the facility.

Subchapter 12, Alternative Care Locations, would establish standards by which a facility could provide regularly scheduled services at locations other than its principal facility location, or by means of a mobile outpatient care vehicle.

N.J.A.C. 8:43K-12.1, Regular provision of licensed services at an alternative service location or using a mobile outpatient care vehicle, would establish a facility's obligation to obtain a separate license to provide regularly scheduled services at an alternate care location or using a mobile outpatient care vehicle. The section would require the facility to establish policies and procedures for the provision of services at the alternative service location or using a mobile outpatient care vehicle, as applicable to the services being provided, and otherwise comply with applicable chapter provisions as if the alternative service location or mobile outpatient care vehicle were the principal licensed facility. The section would authorize staff of the principal licensed facility to serve contemporaneously in the same capacity, as applicable to the services being

provided, for the licensed alternative location or mobile vehicle, provided these staff are available at each licensed location and/or vehicle during operating hours.

N.J.A.C. 8:43K-12.2, Intermittent provision of licensed services at an alternative service location, would establish standards by which a facility could intermittently provide services that are subject to licensure pursuant to this chapter, other than opioid treatment program services, at off-site premises (such as a clinic at a community hall) or using a mobile outpatient care vehicle, without needing a new license for that location, subject to compliance, at the offsite premises or in the mobile vehicle, with applicable provisions of the chapter and prior notice to the Office. As with regularly scheduled services provision at N.J.A.C. 8:43K-12.1, as indicated by the services to be provided, they could serve contemporaneously in the same capacity for the primary facility location and the off-site premises or mobile vehicle, provided the staff remain available to each location or vehicle during operating hours.

N.J.A.C. 8:43K-12.3, Mobile outpatient care vehicle services, would establish standards for a full-time services provision by a facility using a mobile outpatient care vehicle.

N.J.A.C. 8:43E, General Licensure Procedures and Standards Applicable to All Licensed Facilities, establishes standards applicable to all facilities that the Department licenses pursuant to the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq. Subchapter 5, Licensure Procedures, establishes procedures by which the Department processes each licensure application. The Department proposes new N.J.A.C. 8:43E-5.7, Application form, to identify and incorporate by reference at N.J.A.C. 8:43E-5 Appendix, a form and associated facility or service-specific schedules, and the

instructions for completion of the form and schedules, which collectively would specify the information that an entity is to submit to the Department, in either paper or electronic form, in support of an application for licensure or renewal of licensure, or to notify the Department of a change in adjunctive services pursuant to N.J.A.C. 8:43K. The form, schedules, and instructions would be available from the forms page on the Department's internet website.

N.J.A.C. 8:43E-13, Universal Transfer Form, establishes rules governing the use of the Universal Transfer Form. N.J.A.C. 8:43E-13.4, Mandatory use of Universal Transfer Form, establishes a licensee's obligation to use the Universal Transfer Form upon transferring a patient from one facility or program to another. The Department proposes to amend subsection (a) to correct the reference to the Department's internet website's forms page.

To reflect the restatement at proposed new N.J.A.C. 8:43K of standards applicable to outpatient facilities that provide health care services, behavioral health care services, reproductive health care services, and opioid treatment program services, the Department is proposing corresponding repeals and amendments to delete existing provisions in other chapters of the New Jersey Administrative Code addressing these services that would conflict with, and/or become redundant of, N.J.A.C. 8:43K upon its adoption.

N.J.A.C. 8:43A, Manual of Standards for Licensing of Ambulatory Care Facilities, establishes the existing manual of standards applicable to ambulatory care facilities within Department jurisdiction prior to the issuance of Reorganization Plans 001-2017 and 001-2018. The Department proposes to amend the heading at existing Subchapter

1, Definitions and Qualifications, to General Provisions; Qualifications, to indicate that the subchapter addresses general provisions and staff qualifications at ambulatory care facilities.

Existing N.J.A.C. 8:43A-1.1, Scope, states that the chapter establishes licensure and operational standards applicable to ambulatory care facilities that provide the following services: primary care, hospital outpatient, ambulatory surgery, family practice, family planning, outpatient drug abuse treatment, chronic dialysis, computerized tomography, magnetic resonance imaging, extracorporeal shock wave lithotripsy, radiology, abortion, comprehensive outpatient rehabilitation, and birthing. To reflect that proposed new N.J.A.C. 8:43K would establish the licensure and operational standards for outpatient facilities that provide some of these services, the Department proposes to amend N.J.A.C. 8:43A-1.1(a) to delete references to the following services: primary care and family practice (to be subsumed within health care services), family planning and abortion (to be subsumed within reproductive health care services), and outpatient drug abuse treatment (to be subsumed within behavioral health care services).

A facility that obtains licensure pursuant to N.J.A.C. 8:43A would continue to be eligible to provide the services that proposed new N.J.A.C. 8:43K would address, provided the facility satisfies the criteria that N.J.A.C. 8:43K requires for the provision of that service. Proposed new N.J.A.C. 8:43K would establish physical plant standards that a typical facility that the Department licenses pursuant to N.J.A.C. 8:43A, 8:121, and 10:161B already meet, as inherently lesser-included standards. Thus, a facility that the Department licenses pursuant to N.J.A.C. 8:43A, 8:121, or 10:161B seeking authorization to provide a service that proposed new N.J.A.C. 8:43K is to address,

would only need to demonstrate compliance with the standards at N.J.A.C. 8:43K addressing, the minimum personnel and procedural standards applicable to that service. These standards would remain consistent with the existing standards at N.J.A.C. 8:43A, 8:121, and 10:161B, from which they would be relocated to proposed new N.J.A.C. 8:43K.

The Department proposes to amend existing N.J.A.C. 8:43A-1.1(c) to reflect the change in the name of the Department pursuant to N.J.S.A. 26:1A-2.1.

Existing N.J.A.C. 8:43A-1.3, Definitions, establishes definitions of words and terms that the chapter uses. The Department proposes to amend this section to delete the definitions of the following terms, as to which proposed new N.J.A.C. 8:43K would establish standards: “abortion facility,” “drug abuse treatment services,” “family planning services,” and “primary care.”

Existing N.J.A.C. 8:43A-2, Licensure Procedures, establishes standards by which a facility is to apply for licensure as an ambulatory care facility. N.J.A.C. 8:43A-2.2, Application for licensure, establishes procedures for submission of an application. Existing subsection (b) establishes the Department fees for submission of an application for initial and renewal of licensure based on the type of service the facility is to provide. The Department proposes to delete paragraphs (b)5, 6, 7, 11, 12, and 13, which establish fees that, respectively, apply to the following services that proposed new N.J.A.C. 8:43K would address: family planning (principal and satellite), abortion, drug abuse treatment, and primary care (principal and satellite).

The Department proposes to delete existing N.J.A.C. 8:43A-2.2(f), which addresses satellite facility locations for family planning and primary care, because

proposed new N.J.A.C. 8:43K-7 would establish standards applicable to these services, as reproductive health care services and health care services, and N.J.A.C. 8:43K-12 would address the provision of services at alternative care locations.

Recodified N.J.A.C. 8:43A-2.2(l) establishes the biennial inspection fee that the Department assesses for each service type is proposed for amendment to restate the sentence to delete the passive voice, and relocate the fee table at proposed newly codified subsection (m), for consistency with New Jersey Administrative Code style conventions. As at subsection (b), described above, the Department proposes to amend the fee table at proposed newly codified subsection (m) to delete references to the fees for services that proposed new N.J.A.C. 8:43K would address, that is, family planning (principal and satellite), abortion, drug abuse treatment, and primary care (principal and satellite).

The Department proposes to repeal the following subchapters at N.J.A.C. 8:43A, the content of which proposed new N.J.A.C. 8:43K would address: Subchapter 20, Family Practice Services, Subchapter 21, Family Planning, Prenatal, Postpartum and Gynecological Services, Subchapter 22, Pediatric Services, Subchapter 23, Primary Care, and Subchapter 26, Drug Abuse Treatment Services.

Existing Subchapter 33, Programs of All-Inclusive Care for the Elderly (PACE) Organizations, establishes standards by which a PACE organization, established pursuant to 42 CFR Part 460, is to operate. Existing N.J.A.C. 8:43A-33.3, Compliance requirements, establishes compliance standards. The Department proposes to amend N.J.A.C. 8:43A-33.3(b) to change the cross-references from N.J.A.C. 8:43A-23.1(a),

which is proposed for deletion, and N.J.A.C. 8:43A-31, to N.J.A.C. 8:43K-7, which would establish standards for health care facility services.

Existing N.J.A.C. 8:121, Licensure Standards for Mental Health Programs, establishes licensure and operational standards applicable to community mental health facilities in New Jersey pursuant to N.J.S.A. 30:1-12. DHS formerly administered this chapter as N.J.A.C. 10:190. Following the Department's assumption of jurisdiction to license and inspect mental health programs upon the issuance of Reorganization Plans 001-2017 and 001-2018, as described above, the Department readopted and recodified the chapter as N.J.A.C. 8:121 in 2021 (see 53 N.J.R. 2008(a)). To reflect that proposed new N.J.A.C. 8:43K would establish licensure and operational standards for some of the service providers and programs currently licensed pursuant to N.J.A.C. 8:121, the Department proposes to amend the heading at N.J.A.C. 8:121 to Licensure Standards for Mental Health Case Management and Community Support Services, to identify the providers and services that would remain subject to licensure and standards in that chapter.

The Department proposes to amend the heading at existing Subchapter 1, Licensure of Mental Health Programs, to Licensure of Mental Health Case Management and Community Support Services, to indicate that the subchapter addresses licensure requirements for these services.

Existing N.J.A.C. 8:121-1.1, Scope and purpose, states that the chapter establishes licensure and fee requirements for community mental health service providers that are not licensed by the Department as health care facilities and have purchase of service contracts or affiliation agreements with DMHAS, are mental health

clinics as defined by DMHAS within DHS, or provide outpatient, ambulatory, or other nonresidential, non-inpatient mental health services. To reflect that proposed new N.J.A.C. 8:43K would establish the licensure and operational standards for some of the providers currently licensed at N.J.A.C. 8:121, the Department proposes to amend N.J.A.C. 8:121-1.1 to exclude those providers that would require licensure pursuant to proposed new N.J.A.C. 8:43K. The Department proposes to amend N.J.A.C. 8:121-1.1(b)2 to add integrated outpatient services to the list of services that would not require licensure pursuant to N.J.A.C. 8:121. The Department proposes to delete N.J.A.C. 8:121-1.1(b)2ii to remove the reference to mental health clinics defined by the Division of Medical Assistance and Health Services. The Department proposes to amend N.J.A.C. 8:121-1.1(b)2iii to delete the reference to outpatient and ambulatory entities as those entities would obtain licensure pursuant to proposed new N.J.A.C. 8:43K. Finally, the Department proposes to amend N.J.A.C. 8:121-1.1(b)4vi to add an integrated outpatient facility as a facility type excluded from licensure pursuant to the chapter.

Existing N.J.A.C. 8:121-1.3, Level 1 Standards, establishes Level 1 standards for mental health programs. The Department proposes to amend N.J.A.C. 8:121-1.3(a) to delete references to the following service requirements to which proposed new N.J.A.C. 8:43K would establish standards: staffing requirements for outpatient services, therapeutic environment for partial care services; staffing requirements for partial care services, and staffing requirements for children's partial care programs. The Department is also deleting the reference to staffing requirements for youth case management services because those services fall within the purview of the Department of Children

and Families. The Department is updating a cross-reference at recodified N.J.A.C. 8:121-1.3(a)6.

Existing N.J.A.C. 8:121-1.6, Applicable standards, establishes the mental health services that are required to comply with applicable standards. The Department proposes to amend this section to delete references to the following services to which proposed new N.J.A.C. 8:43K would apply: youth partial care services; outpatient services, and partial care services. The Department is also deleting the reference to youth case management because those services fall within the purview of the Department of Children and Families.

Established pursuant to the rulemaking authority at N.J.S.A. 26:2B-7 et seq., especially 26:2B-14, 26:2BB-5 through 6, 26:2G-1 et seq., and 30:1-12, existing N.J.A.C. 10:161B, Standards for Licensure of Outpatient Substance Use Disorder Treatment Facilities, provides licensure, operational, and inspection standards applicable to outpatient facilities that offer adult and juvenile substance (alcohol and drug) use disorder diagnostic and treatment services, including outpatient, intensive outpatient, partial care, outpatient detoxification, and opioid treatment, which includes opioid maintenance and opioid detoxification. DHS formerly administered this chapter, until Reorganization Plans 001-2017 and 001-2018 operated to transfer the licensing aspects of the chapter from DHS to the Department (see 55 N.J.R. 2346(a)). N.J.A.C. 10:161B applies to facilities that the Department licenses pursuant to existing N.J.A.C. 8:43A to provide these services in hospital-based outpatient facilities, primary health care outpatient facilities, and ambulatory care outpatient drug treatment facilities. See N.J.A.C. 10:161B-1.1, Scope and applicability.

The Department proposes to repeal existing 10:161B because proposed new N.J.A.C. 8:43K, specifically N.J.A.C. 8:43K-6, Behavioral Health Services, and 8, Opioid Treatment Program, would address the content of existing 10:161B.

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

Social Impact

The proposed amendments, repeals, and new rules would have a positive social impact on the State.

Persons needing physical health services, reproductive health care services, behavioral health services, adjunctive services, and/or opioid treatment program services would benefit by the proposed rulemaking's effect of facilitating a provider's ability to obtain licensure to situate these services alone, or in combination, in one facility. The rulemaking would enhance patient access to care by enabling a patient to broach and seek different kinds of professional help for both physical and behavioral health care needs at one facility and may help to reduce the stigma potentially associated with obtaining certain types of services by eliminating physical barriers, such as separate entrances for each type of service. A patient in need of medication for SUD treatment would be able to receive it from a facility licensed pursuant to this chapter and would not need to seek out services from a specialized treatment facility.

Outpatient services providers would benefit by the proposed rulemaking's effect of reducing the administrative, regulatory, and compliance burdens to integrated care and eliminating differing and sometimes conflicting operational standards, depending on

the services provided. The rulemaking would enable a provider to submit a single license application to obtain authorization to provide a range of physical and behavioral health services, rather than having to submit a separate application for each type of service. The rulemaking would enable a provider to offer both mental health and SUD treatment services by employing one administrator of behavioral health services instead of having to retain a separate director for each type of service. The rulemaking would eliminate restrictions on prescribing SUD treatment medication, and the obligation to maintain separate sets of records for each type of care a patient receives, which would address a common complaint that facilities seeking to provide integrated services often must maintain two entirely separate medical records on a single patient. The rulemaking would promote efficiency by enabling a facility to establish a single set of core patient care policies and procedures that are the same for both physical and behavioral health services. The rulemaking would enhance a facility's ability to provide integrated, coordinated, "whole person" care by allowing a provider to treat a patient for the conditions presented, regardless of which condition the provider or patient sees as the primary concern or diagnosis.

Proposed new N.J.A.C. 8:43K-2.11, Transitional licensure, would ensure the orderly transition of an existing facility that obtained licensure pursuant to the rules proposed for repeal to maintain its status as in compliance, pending formal license renewal as an outpatient facility pursuant to proposed new N.J.A.C. 8:43K, and enable it to keep its existing license renewal anniversary date.

Proposed new N.J.A.C. 8:43K-7.14, Reproductive health care services general provisions, would offer a facility greater flexibility in its personnel standards by requiring

a facility that provides reproductive health care services to have, either as its medical director or as a staff member, a physician who has the education and experience requisite to the provision of these services, whereas existing N.J.A.C. 8:43A-21, proposed for repeal, requires a facility providing these services to have a medical director who is an obstetrician/gynecologist.

Emerging evidence suggests that integrating behavioral and physical healthcare increases access to care, improves health outcomes, and potentially reduces health care costs; that "populations with co-occurring [physical health, behavioral health, and social determinants of health] needs are likely to benefit from evidence-based integrated interventions in whatever setting they are best engaged"; and that "people with serious mental illness … who have unmet [physical health] needs can achieve demonstrably improved health outcomes if evidence-based [physical health] interventions are integrated into [behavioral health] service settings." National Council for Mental Wellbeing, Center of Excellence for Integrated Health Solutions, *Comprehensive Health Integration (CHI) Framework, White Paper*, Second Edition (January 2025) at 10, available at https://www.thenationalcouncil.org/resources/the-comprehensive-health-integration-framework, and see references listed therein at 38-40.

The proposed amendments, repeals, and new rules would not require licensed facilities to provide mental health, SUD, and/or physical health services but they would remove existing regulatory barriers, such as restrictions on prescribing medications for SUD or requirements for separate medical records, which impede integrated and coordinated care for facilities that elect to provide more than one of these services at a

single facility. These changes would increase access to needed services and reduce the stigma associated with seeking specialized behavioral health care.

The Department does not foresee a negative social impact to result from the proposed amendments, repeals, and new rules.

Economic Impact

The proposed amendments, repeals, and new rules would have an economic impact on facilities that hold licensure pursuant to existing standards proposed for repeal, and new facilities seeking licensure as outpatient providers of one or more licensed services.

Applicants for initial licensure and renewal would continue to incur fees upon application. Whether facilities see an increase in licensure fees will depend on the number of services they provide as the Department is proposing to establish a fee for licensing the facility and then additional fees per services provided.

Facilities providing primary care or SUD services would continue to pay fees for inspections, service modification, and relocation; however, the assessment of these fees would be new for facilities providing outpatient mental health services. The Department is proposing to add a fee to process waiver applications.

Except as described above, the Department does not anticipate that the proposed amendments, repeals, and new rules would impose additional costs on facilities obtaining or renewing licensure to provide outpatient services. The Department anticipates that the proposed amendments, repeals, and new rules would result in cost savings, or at least cost efficiencies, to facilities seeking to provide more

than one licensed integrated service. The proposed amendments, repeals, and new rules would permit flexibility as to the locations at which a licensee could provide services, the professionals who would qualify to provide services, and the types of services that a facility could provide. Subject to limited exceptions, the proposed amendments, repeals, and new rules would require a facility providing more than one licensed service to maintain only one set of core policies and procedures, and have one governing authority, administrator, patient recordkeeping system, quality assurance plan, set of environmental standards, and set of patient rights, regardless of the types of services being provided pursuant to the facility license. A facility that exclusively provides behavioral health services would not need to physically alter its existing location or adhere to infection control standards unless it is newly adding the provision of health care services to its license, in which case it would need to make physical plant modifications, such as access to handwashing stations and the ability to accommodate examination tables. The Department anticipates that these standards would help a facility to realize administrative efficiencies and reduce or minimize operational costs associated with compliance.

The proposed amendments, repeals, and new rules could enable a patient receiving services from an outpatient provider of integrated physical and behavioral health services to realize cost savings associated with the ability to travel to only one location in one trip to receive care, rather than having to travel to separate locations for each licensed service the patient needs. Depending on the payment model that a provider implements, a patient might realize a cost savings resulting from having a

single copayment for a provider visit to receive integrated services addressing the whole of a patient's physical and behavioral health needs.

As described in the Social Impact, integration of physical and behavioral health care services leads to greater efficiencies in achieving better outcomes. Therefore, the proposed amendments, repeals, and new rules could reduce taxpayers' costs to subsidize publicly funded physical and behavioral health care.

Federal Standards Statement

The proposed amendments, repeals, and new rules would require a licensee to adhere to Federal standards applicable to the services the facility provides, but would not exceed applicable Federal standards. For example, the proposed amendments, repeals, and new rules would require a facility to comply with applicable provisions of Health Insurance Portability and Accountability Act of 1996 (HIPAA) and other Federal privacy and security laws with respect to the handling and maintenance of patient records and information. A facility that provides an opioid treatment service would be subject to compliance with 21 U.S.C. § 823 and 42 CFR Part 8. A facility that purchases, stores, administers, and disposes of controlled substances would be subject to the registration and other standards at 21 U.S.C. § 801. A facility would need to comply with applicable Centers for Medicare and Medicaid Services payment and certification standards to participate in Medicare and Medicaid. As the proposed amendments, repeals, and new rules would meet, but not exceed, applicable Federal standards, an exceedance analysis is not required.

Jobs Impact

The proposed amendments, repeals, and new rules might result in the generation of jobs in the State by giving facilities flexibility in retention of qualified staff to provide services instead of limiting the professional services that can be provided within licensed facilities as is currently the case pursuant to licensing rules for outpatient mental health and outpatient SUD services. Facilities would also be able to more easily provide integrated services, which may lead facilities to hire staff to provide additional services.

Agriculture Industry Impact

The proposed amendments, repeals, and new rules would not have an impact on the agriculture industry in New Jersey.

Regulatory Flexibility Analysis

The proposed amendments, repeals, and new rules would impose reporting, recordkeeping, and compliance standards on a facility seeking licensure to operate as a facility providing physical and/or behavioral health care services. A facility could be a small business within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. The Summary describes the reporting, recordkeeping, and compliance requirements that the proposed amendments, repeals, and new rules would establish. The Economic Impact describes the costs of compliance and the professional services that a facility would need to retain. The licensing fee that a facility that is a small business would pay is scaled to the number and types of services that the facility elects to provide. A facility that provides integrated outpatient services, that is, adds on an

additional service at a single facility, would incur a lesser licensing fee than it would pursuant to the existing rules proposed for repeal and amendment, which require a licensee to submit an application for and obtain licensure for each service, and pay accompanying fees that are greater than the fees that the proposed new rules at N.J.A.C. 8:43K would establish. Moreover, the fees applicable to small businesses in the proposed amendments, repeals, and new rules are inherently scaled to business size, as a facility pays fees based on the number of services and adjunctive services it elects to provide.

Except as described above, the proposed amendments, repeals, and new rules would impose no lesser or differing standards based on business size, because the Department has determined that the proposed amendments, repeals, and new rules would impose the minimum standards necessary to ensure the health and safety of patients and staff at facilities providing outpatient health care services, outpatient behavioral health care treatment services, and opioid treatment program services, regardless of facility size.

Housing Affordability Impact Analysis

The proposed amendments, repeals, and new rules would have no impact on the affordability of housing in New Jersey, nor would they evoke a change in the average costs associated with housing because the proposed amendments, repeals, and new rules would establish standards for licensing facilities providing outpatient health care services, behavioral health care treatment services, and opioid treatment program services, and would have no bearing on housing or housing costs.

Smart Growth Development Impact Analysis

The proposed amendments, repeals, and new rules would have no impact on the achievement of smart growth, and would not evoke a change in housing production in Planning Areas 1 or 2, or within designated centers, pursuant to the State Development and Redevelopment Plan in New Jersey because the proposed amendments, repeals, and new rules establish standards for licensing facilities providing outpatient health care services, behavioral health care treatment services, and opioid treatment program services, and would have no bearing on smart growth or housing production.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Department has evaluated this rulemaking and determined that it would not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults and juveniles in the State. Accordingly, no further analysis is required.

Full text of the rules proposed for repeal may be found in the New Jersey Administrative Code at N.J.A.C. 8:43A-20, 21, 22, 23, and 26; 8:121; and 10:161B.

Full text of the proposed amendments and new rules follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

CHAPTER 43A

MANUAL OF STANDARDS FOR LICENSING OF AMBULATORY CARE FACILITIES

SUBCHAPTER 1. [DEFINITIONS AND] **GENERAL PROVISIONS;** QUALIFICATIONS

8:43A-1.1 Scope

(a) This chapter applies to [all] **the following types of ambulatory** health care facilities [that provide ambulatory care services, including, but not limited to]:

1. [Primary care, hospital] **Hospital** outpatient, ambulatory surgery, [family practice, family planning, outpatient drug abuse treatment,] chronic dialysis, computerized tomography, magnetic resonance imaging, extracorporeal shock wave lithotripsy, [and] radiological services[; and

2. Abortion facilities], comprehensive outpatient rehabilitation facilities, and birth centers.

(b) (No change.)

(c) The rules in this chapter constitute the basis for the licensure of ambulatory care facilities by the Department of Health [and Senior Services].

8:43A-1.3 Definitions

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

[“Abortion facility” means a facility which performs termination of pregnancy, in accordance with N.J.A.C. 13:35-4.2, as a single modality. Facilities which offer multiple or comprehensive surgical services, inclusive of termination of pregnancy, are designated as ambulatory surgery facilities. Whereas all of the rules at N.J.A.C. 8:43A-12 apply to ambulatory surgery facilities, only those rules at N.J.A.C. 8:43A-12 which

are relevant to the levels of anesthesia used in a particular abortion facility shall apply to that facility.]

…

[“Drug abuse treatment services” means methadone detoxification, methadone maintenance, and/or drug-free counseling programs.]

…

[“Family planning services” means comprehensive reproductive health care services including contraception, pregnancy detection, options counseling, diagnosis and/or treatment of sexually transmitted diseases, routine gynecological and cancer screening services, health promotion activities, and Level I infertility services. Family planning services may also include prenatal and postpartum care, other gynecological services including colposcopy and cryotherapy, menopausal services, and/or Level II and III infertility care. Family planning services do not include termination of pregnancy.]

…

[“Primary care” means the provision by a health care facility of preventive, diagnostic, treatment, management, and reassessment services to individuals with acute or chronic illness. The term is used in reference to facilities providing family practice, general internal medicine, general pediatrics, obstetrics, gynecology, and/or clinical preventive services, including community health centers providing comprehensive primary care. Comprehensive primary care may include the provision of sick and well care to all age groups, from perinatal and pediatric care to geriatric care. Primary care is further characterized by the fact that it represents the initial point of

contact between an individual and the health care system, by the assumption of responsibility for the person regardless of the presence or absence of disease, by the ongoing responsibility for coordination of medical care for the person, by its family-centeredness, and by its community orientation.]

…

SUBCHAPTER 2. LICENSURE PROCEDURES

8:43A-2.2 Application for licensure

(a) (No change.)

(b) The Department shall charge separate**,** nonrefundable fees for the filing of an application for licensure**,** and each **application for renewal of** licensure [renewal]**,** of an ambulatory care facility**,** in accordance with the following schedule:

	Service	Application	Renewal
1.-4. (No change.)			
[5.	Family planning (principal)	$1,200	$ 200
6.	Family planning (satellite)	$ 600	$ 100
7.	Abortion	$1,750	$ 750]

Recodify existing 8.-10. as **5.-7.** (No change in text.)

[11.	Drug abuse treatment	$1,750	$ 750
12.	Primary care (principal)	$1,750	$ 750
13.	Primary care (satellite)	$ 875	$ 375

Recodify existing 14.-18. as **8.-12.** (No change in text.)

(c)-(e) (No change.)

[(f) Only those ambulatory care facilities which provide family planning or primary care services shall be eligible to file an application for licensure of a satellite facility.

1. Each satellite facility shall be separately licensed.

2. A satellite facility shall be licensed to provide only family planning and/or primary care services.]

Recodify existing (g)-(l) as **(f)-(k)** (No change in text.)

[(m)] **(l)** [Each] **The Department shall assess each** ambulatory care facility [shall be assessed] a biennial inspection fee in accordance with the schedule set forth in the table **at (m)** below.

1.-5. (No change.)

(m) The following table identifies the biennial inspection fee that is applicable to each ambulatory care facility service pursuant to (l) above.

Service		Inspection Fee
1.-4. (No change.)		
[5.	Family planning (principal)	$200
6.	Family planning (satellite)	$200
7.	Abortion	$1,000]

Recodify existing 8.-10. as **5.-7.** (No change in text.)

[11.	Drug abuse treatment	$ 300
12.	Primary care (principal)	$ 300
13.	Primary care (satellite)	$ 200

Recodify existing 14.-19. as **8.-13.** (No change in text.)

SUBCHAPTER 33. PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE) ORGANIZATIONS

8:43A-33.3 Compliance requirements

(a) (No change.)

(b) [All] **A** PACE organization[s] shall comply with [requirements for facilities providing primary care services at] N.J.A.C. [8:43A-23.1(a) and 31] **8:43K-7**.

CHAPTER 43E

GENERAL LICENSURE PROCEDURES AND STANDARDS APPLICABLE TO ALL LICENSED FACILITIES

SUBCHAPTER 5. LICENSURE PROCEDURES

8:43E-5.7 Application form

(a) An applicant for licensure or renewal of licensure, or an entity seeking to notify the Department of a change in adjunctive services pursuant to N.J.A.C. 8:43K, shall submit to the Department, in either paper or electronic form:

1. The information required by the Application for New or Amended Acute Care, Ambulatory Care, or Integrated Outpatient Facility License (CN-7) form and instructions; and

2. The schedules associated with the action sought, as applicable to the facility or service type and/or the form instructions.

(b) The Application for New or Amended Acute Care, Ambulatory Care, or Integrated Outpatient Facility License (CN-7) form, schedules, and instructions,

are available at N.J.A.C. 8:43E-5 Appendix, incorporated herein by reference, and the Department's forms page at https://www.nj.gov/health/forms.

APPENDIX

New Jersey Department of Health
Office of Certificate of Need and Healthcare Facility Licensure
PO Box 358
Trenton, NJ 08625-0358

APPLICATION FOR NEW OR AMENDED ACUTE CARE, AMBULATORY CARE OR INTEGRATED OUTPATIENT FACILITY LICENSE

LICENSURE AND CONSTRUCTION REQUIREMENTS

LICENSURE REQUIREMENTS

General

Licensure by the Department of Health, Office of Certificate of Need and Healthcare Facility Licensure is mandatory **PRIOR TO** commencement of new or expanded services. To be licensed as an operator of a health care service in New Jersey, all of the applicable licensing requirements for that service must be met. This includes both physical plant and operational requirements. To obtain the licensing standards for the proposed service and/or additional information regarding the licensure process, please call 609-292-8552 or email CNandLicensingRequests@doh.nj.gov

Application Filing

Ninety (90) days prior to your planned opening, ***one original and two copies*** of a completed license application form, license application fee, biennial inspection fee (if applicable), floor plan (if applicable), and all out- of-state track record reports shall be submitted to the Department of Health, Office of Certificate of Need and Healthcare Facility Licensure, PO Box 358, Trenton, NJ 08625-0358. A schedule of fees for licensure and inspection is attached. The licensing/inspection fee shall be in the form of a certified check or money order made payable to *"Treasurer, State of New Jersey."*

Track Record Requirements

Please be advised that in making a determination as to the applicant's capacity to operate a health care facility/service, the Department will consider the applicant's prior operating history, both in New Jersey and in other states. Any evidence of licensure violations representing a serious risk of harm to patients, or any record of criminal convictions representing a risk of harm to the safety or welfare of patients may result in denial of the applicant's application for licensure. All health care facilities owned, operated or managed by the applicant and any principals of the applicant entity which are similar or related to the service which is the subject of the application must be disclosed. For the purposes of this application, similarity or relatedness of any two services is determined by the inclusion of two services together in one of the following categories:

(1) The acute care category, which includes hospital services such as medical/surgical, pediatric, obstetric, cardiac, psychiatric, and intensive care/critical care; comprehensive rehabilitation; surgical services; magnetic resonance imaging and computerized tomography, lithotripsy; renal dialysis; and birth centers.

(2) The ambulatory care and other category, which includes home health care, ambulatory surgery, and outpatient physical rehabilitation.

(2) The integrated outpatient care category which includes primary care, family planning, reproductive health, outpatient mental health, and outpatient substance abuse treatment.

(4) The acute substance abuse treatment category, which includes residential alcohol treatment and residential drug treatment.

Additional Documents

Staff may request additional documents as necessary to verify compliance with regulations prior to licensure including but not limited to: organizational documents, policies and procedures, governance information, and financial data.

APPLICATION FOR NEW OR AMENDED ACUTE CARE, AMBULATORY OR INTEGRATED OUTPATIENT FACILITY LICENSE

LICENSURE AND CONSTRUCTION REQUIREMENTS (Continued)

Track record reports from out-of-state agencies responsible for licensing these health care facilities must be submitted WITH YOUR LICENSE APPLICATION. Out-of-state track record reports are not required for diagnostic health care facilities/services (e.g., magnetic resonance imaging). The license application will be returned if all required out-of-state track record reports are not provided at the time the license application is filed. Each out-of-state track record report must indicate the history of compliance with standards in the state for the 12 months preceding application submission, as well as a description of any non-compliance, penalties imposed, duration of non-compliance and corrective actions taken.

Operational Survey

Forty-five (45) days prior to your planned opening, contact the Ambulatory/Medicare Inspections Unit (ambulatory care facilities), Certificate of Need and Licensing (hospitals) at (609) 292-6552 or the Division of Addiction Services Inspections Program (residential substance abuse treatment) at (609) 292-0961 to arrange for an operational survey. The licensing standards for the proposed service shall be reviewed for compliance **PRIOR TO** a request for an operational survey. At the time of the operational survey, all written policies and procedures, contracts, plans approved and stamped by the Department of Community Affairs (if applicable), copy of the certificate of occupancy and transfer agreements required by licensure standards must be complete and available to the surveyor.

Functional Review

The Department highly recommends that prospective applicants contact the Department to schedule a functional review to discuss their proposed project included but not limited to physical plant plans, policies and procedures, licensing protocols and applicable rules and regulations. Please schedule the review in accordance with the county in which the facility is located. It is also highly recommended that this functional review occur prior to the submission of any construction plans to the Department of Community Affairs. The Department highly recommends that prospective applicants submit a detailed narrative and schematic drawings of the proposed project to the Department for functional review.

CONSTRUCTION REQUIREMENTS

The Department of Community Affairs' Division of Codes and Standards launched ePlans, a web-based electronic plan and document workflow solution that automates the plan submission, review, and approval process through the use of digital files. ePlans allows all stages of the review process to be transmitted electronically via the internet, thus eliminating paper-based building and code review process and reducing the amount of time between plan submission and final approval.

The plans may be submitted to http://www.state.nj.us/dca/divisions/codes/offices/ePlans.html. You may not proceed with any construction or renovations until you have received final construction plans approval. Upon completion of construction and/or renovations, written notification, and a copy of the certificate of occupancy must be submitted to the Department of Community Affairs.

If new construction and/or renovations are not required, a floor plan of the facility must be submitted with your license application. This plan shall indicate the dimensions and use of each room, door swing direction, corridor widths, exit locations, and locations of all toilets and sinks. You must also note whether the bathrooms and premises are handicapped accessible, in accordance with the latest ADA requirements. You must also submit documentation that the existing unit complies with applicable fire signaling systems and egress requirements and note locations of pull stations, emergency fixtures, and fire extinguisher locations on the plan

.

ISSUANCE OF LICENSE

A license will be issued by the Office of Certificate of Need and Healthcare Facility Licensure upon receipt of a letter of approval from the Department of Community Affairs for construction or renovation, compliance with all regulatory requirements based on the operational survey, copy of the certificate of occupancy and receipt and approval of the application for licensure. You MAY NOT proceed with initiation of new or expanded services until you have received occupancy approval from the Office of Certificate of Need and Healthcare Facility Licensure.

New Jersey Department of Health
Office of Certificate of Need and Healthcare Facility Licensure
PO Box 358
Trenton, NJ 08625-0358

APPLICATION FOR NEW OR AMENDED ACUTE CARE, AMBULATORY CARE OR INTEGRATED OUTPATIENT FACILITY LICENSE

IMPORTANT: Complete and forward an original and two (2) copies to the above address. Please retain a copy for your records.

FOR STATE USE ONLY		
Team	☐Approval ☐Denial	Amount Received License Application Fee $ _____ Biennial Inspection Fee $ _____ TOTAL $ _____
Facility ID No.	Date Received	
Reviewer Signature		Date

Type of Application	Type of Amendment
☐ New Facility - CN # _____ ☐ New Facility - CN Exempt (N.J.S.A. 26:2H-7a) ☐ Amendment Facility ID No. _____	☐ Bed/Service Addition ☐ Bed/Service Reduction ☐ Transfer of Ownership (Licensed facilities as provided for at N.J.S.A. 26:2H-7a and N.J.A.C. 8:33-3.3(b) only) ☐ Relocation ☐ Change in Name of Operating Entity Change in Name of Facility

Official Name of Facility *	Operating Entity/Operator *
Site Address County	Street Address
City State Zip Code	City State Zip Code
Telephone Number / Official Facility Email	Telephone Number
Name of Facility Administrator/Director/CEO	Name of Management Company, If Applicable (Submit copy of management agreement.) Attach
Title	Address
Name of Contact Person	City State Zip Code
Telephone Number	Telephone Number
Name of Emergency Contact Person	Name of Management Company Contact Person
Emergency Telephone Number	Title
Email Address of Sender	

** The official name of facility and operating entity will appear on the license. Please provide complete and accurate information. Please complete the application as to the name, address and telephone number for both the facility and operator even when the information is the same. As used in this application, "operator" or "operating entity" refers to the person or entity which is the holder of the facility license (i.e., licensee) and which has the ultimate responsibility for the provision of health care services.*

APPLICATION FOR NEW OR AMENDED ACUTE CARE, AMBULATORY CARE OR INTEGRATED OUTPATIENT FACILITY LICENSE - CONTINUED

Name of Facility

SECTION I - INPATIENT FACILITIES

Type of Facility (Check one)

☐ General Acute Care Hospital ☐ Psychiatric Hospital ☐ Residential Substance Abuse Treatment Facility

☐ Comprehensive Rehabilitation Hospital ☐ Special Hospital ☐ Pediatric Community Transitional Home Facility

Beds and Services	New Facility Proposed Capacity/ Services	Current Licensed Capacity/ Services	Total Change (+) or (-)	Revised Capacity/ Services
Medical/Surgical Beds				
OB/GYN Beds ☐ LDRP				
Pediatric Beds				
Adult ICU/CCU Beds				
Pediatric ICU Beds				
Psychiatric - Adult Acute				
- Adult Closed Acute				
- Adult Intermediate/Specialized				
- Child/Adolescent Acute				
- Child/Adolescent Intermediate				
Alcohol Detoxification Beds (Hospital Based)				
Comprehensive Rehabilitation Beds				
Burn Unit				
TOTAL BEDS				
Neonatal Bassinets - Intensive				
- Intermediate				
Operating Rooms - Inpatient (Excl. Cardiac)				
- Same Day Surgery				
- Mixed-Use				
- Cardiac Surgery-Adult				
- Cardiac Surgery-Pediatric				
Cystoscopy Rooms				
Cardiac Catheterization Labs - Adult				
- Pediatric				
- Low Risk				
Transplantation Services - Bone Marrow				
- Heart				
- Kidney				
- Liver				
- Lung				
- Pancreas				
Renal Services - Acute Hemodialysis				
- Chronic Hemodialysis Stations				
- Chronic Peritoneal				
- CAPD/Home Training				
Linear Accelerator				
Cobalt Units				
Magnetic Resonance Imaging Unit – Open				
- Closed				
- Fixed				
- Mobile				
Computerized Axial Tomography - Fixed				
- Mobile				
Pediatric Community Transitional Home (PCTH) Beds				
Sleep Lab(s)				
Other (specify):				

APPLICATION FOR NEW OR AMENDED ACUTE CARE, AMBULATORY CARE OR INTEGRATED OUTPATIENT FACILITY LICENSE - CONTINUED

Name of Facility				
SECTION I - INPATIENT FACILITIES, CONTINUED				
Beds and Services	**New Facility Proposed Capacity/ Services**	**Current Licensed Capacity/ Services**	**Total Change (+) or (-)**	**Revised Capacity/ Services**
Lithotripter – Fixed				
- Mobile				
- Transportable				
Positron Emission Tomography - Fixed				
- Portable				
- CT Unit				
Hyperbaric Chamber				
Gamma Knife				
Designations - CPC-Basic				
- CPC-Intermediate				
- CPC-Intensive				
- Regional Perinatal Center				
- Children's Hospital				
- Level I Trauma				
- Level II Trauma				
Hospital-Based Off-Site Ambulatory Care Facility *				
Residential Substance Abuse Treatment Beds - Extended Care Adult				
- Extended Care Adult Female				
- Extended Care Adult Male				
- Extended Care Juvenile				
- Extended Care Juvenile Female				
- Extended Care Juvenile Male				
- Halfway House Adult				
- Halfway House Adult Female				
- Halfway House Adult Male				
- Halfway House Juvenile				
- Halfway House Juvenile Female				
- Halfway House Juvenile Male				
- Long Term Adult				
- Long-Term Adult Female				
- Long-Term Adult Male				
- Long-Term Juvenile				
- Long-Term Juvenile Female				
- Long-Term Juvenile Male				
- Short-Term Adult				
- Short-Term Adult Female				
- Short-Term Adult Male				
- Short-Term Juvenile				
- Short-Term Juvenile Female				
- Short-Term Juvenile Male				
- Non-Hosp. Based Detox. Adult				
- Non-Hosp. Based Detox. Adult Female				
- Non-Hosp. Based Detox. Adult Male				
- Non-Hosp. Based Detox. Juvenile				
- Non-Hosp. Based Detox. Juvenile Female				
- Non-Hosp. Based Detox. Juvenile Male				
Long Term Care Beds **				
Sub-Acute Beds **				
Adult Day Health Care Slots **				

* In addition to the application to amend the hospital's license, a separate license application, with applicable fee, must be submitted for each ambulatory care facility, as well as documentation of compliance with N.J.A.C. 8:43G-2.11.

** For record keeping purposes only, license is issued by Long Term Care Licensing Program.

APPLICATION FOR NEW OR AMENDED ACUTE CARE, AMBULATORY CARE OR INTEGRATED OUTPATIENT FACILITY LICENSE - CONTINUED

Name of Facility				
SECTION II - AMBULATORY CARE FACILITY				
Services Provided	**New Facility Proposed Capacity/ Services**	**Current Licensed Capacity/ Services**	**Total Change (+) or (-)**	**Revised Capacity/ Services**
Ambulatory Surgery Operating Rooms				
Birth Center				
Comprehensive Outpatient Rehabilitation				
Computerized Axial Tomography – Fixed				
- Mobile				
Lithotripter – Fixed				
- Mobile *				
- Transportable				
Home Health Agency **				
Home Health Agency Branch Office **				
Hospice				
Hospice Branch Office				
Hyperbaric Chamber				
Magnetic Resonance Imaging - Open				
- Closed				
- Mobile *				
- Portable				
Renal - Chronic Hemodialysis Stations				
- Chronic Peritoneal				
- CAPD/Home Training				
Linear Accelerator				
Positron Emission Tomography - Fixed				
- Portable				
- CT Unit (Comb.)				
Sleep Lab(s)				
Other Services (specify):				
* Identify name of manufacturer, serial number, and all locations served by mobile MRI/Lithotripter/PET Scanner.				
** Identify Home Health Agency service area:				

APPLICATION FOR NEW OR AMENDED ACUTE CARE, AMBULATORY CARE OR INTEGRATED OUTPATIENT FACILITY LICENSE - CONTINUED

SECTION II – INTEGRATED OUTPATIENT FACILITY				
Services Provided	**New Facility Proposed Capacity/ Services**	**Current Licensed Capacity/ Services**	**Total Change (+) or (-)**	**Revised Capacity/ Services**
Behavioral Health Services:				
Substance Use or Addiction Treatment				
-Outpatient				
-Intensive Outpatient				
-Partial Care				
Mental Health Treatment				
-Outpatient				
-Intensive Outpatient				
-Partial Care				
Health Care Services:				
Primary Care (includes Family Practice)				
Pediatric Primary Care				
Reproductive Health Care Services (Family Planning)				
Specialty/Sub-specialty:				
-Addiction medicine				
-Allergy and immunology				
-Cardiology				
-Dermatology				
-Endocrinology				
-Gastroenterology				
-Geriatric medicine				
-Infectious disease				
-Neurology				
-Nephrology				
-Oncology				
-Ophthalmology				
-Pain medicine				
-Psychiatry				
-Sports medicine				
-Other:				
Satellite:				
-Primary Care				
-Pediatric Primary Care				
-Reproductive Health Care Services				
Opioid Treatment Program (OTP)				
Administration of CDS for SUD Treatment				
Adjunctive Services:				
-Preventative Medicine				
-Wound Care				
-Acupuncture and herbology				
-Chiropractic services				
-Dentistry				
-Harm Reduction				
-Other:				
Alternate Care Locations:				
-Mobile outpatient care vehicle				
-Intermittent provision of licensed services				

APPLICATION FOR NEW OR AMENDED ACUTE CARE, AMBULATORY CARE OR INTEGRATED OUTPATIENT FACILITY LICENSE - CONTINUED

SECTION III - OPERATING ENTITY

Type of Operating Entity

- ☐ Sole Proprietorship
- ☐ General Partnership
- ☐ Limited Partnership
- ☐ Limited Liability Company
- ☐ Professional Association
- ☐ Government Agency
- ☐ Corporation - For Profit *
- ☐ Corporation - Nonprofit *

(Attach list of the names and addresses of board of directors/trustees) Attach

* NOTE: If the corporate entity is a wholly owned subsidiary, please identify the parent corporation:

Name and Title of Individual or Current Registered Agent Upon Whom Orders May be Served (Must be NJ Resident)

Residence Address | City | State | Zip Code

Name of Facility

PRINCIPALS IN OPERATING ENTITY

Attach a list of the names and addresses of partners/stockholders and identify 100% of the ownership, except that for publicly held corporations, identify each principal who has a 10% or greater interest in the corporation. Applicants for transfer of ownership shall provide information for the PROPOSED operator.

1. Have any of the principals of the operating entity ever applied, directly or indirectly, for health care facility approval in New Jersey, or any other state, which was denied or revoked?

☐ Yes ☐ No

If Yes, indicate whom and give details (attach additional sheets if necessary): Attach

2. Do any of the principals of the operating entity have an ownership, operational or management interest in any other licensed health care facility in New Jersey, or any other state?

☐ Yes ☐ No

If Yes, explain the nature of the interest and give the name, address of each facility and license number:

APPLICATION FOR NEW OR AMENDED ACUTE CARE, AMBULATORY CARE OR INTEGRATED OUTPATIENT FACILITY LICENSE - CONTINUED

3. Have any principals of the operating entity ever been found guilty of a criminal or administrative charge of resident/patient fraud, abuse and/or neglect? Have any of these ever been indicted for the same charge?

☐Yes ☐No

If Yes, explain in detail (attach additional sheets if necessary): Attach

4. Have any principals of the operating entity ever been indicted for or convicted of a felony crime?

☐Yes ☐No

If Yes, explain in detail (attach additional sheets if necessary): Attach

APPLICATION FOR NEW OR AMENDED ACUTE CARE, AMBULATORY CARE OR INTEGRATED OUTPATIENT FACILITY LICENSE - CONTINUED

Name of Facility

AFFILIATED HEALTH CARE FACILITIES

Identify the name, address and Medicare Provider Number of all health care facilities, both in New Jersey and in any other state, which are owned, operated or managed by the applicant, any principals or any corporate entity related to the applicant (e.g. parent or subsidiary) which is similar or related to the service which is the subject of the application. If licensed out-of-state facilities are listed, submit track record reports for the preceding 12 months from the respective state agencies responsible for licensing those facilities. Attach additional sheets as necessary.

Name and Address of Facility	Medicare Provider Number

CERTIFICATION

I, _____ of full age, hereby certify that I am employed with _____ in the capacity of _____ and am duly authorized to make the representations contained within this application for licensure on behalf of the applicant and to bind the applicant thereto; that the facility has been and will be operated in accordance with all applicable laws, rules and regulations, both state and federal; and that all information supplied in this application, including any and all attachments, are true, accurate and correct to the best of my knowledge. I am aware that if any of the information contained in this application, including any and all attachments, are willfully false or misleading, I and the applicant may be subject to civil and/or criminal penalties in accordance with applicable laws and/or other licensure enforcement activity, including, but not limited to facility loss of license in accordance with N.J.A.C. 8:43E.

Name of Operator or Authorized Representative ☐ Mr. ☐ Ms.		Title
Signature	Email Address	Date

FOR TRANSFER OF OWNERSHIP

Name of Proposed Operator or Authorized Representative ☐ Mr. ☐ Ms.		Title
Signature	Email Address	Date
Name of Current Operator or Authorized Representative ☐ Mr. ☐ Ms.		Title
Signature	Email Address	Date

SUBCHAPTER 13. UNIVERSAL TRANSFER FORM

8:43E-13.4 Mandatory use of Universal Transfer Form

(a) A licensed healthcare facility or program shall use the Universal Transfer Form, HFEL-7, provided as N.J.A.C. 8:43E-13 Appendix, incorporated herein by reference, and available on the Department's website at [http://web.doh.state.nj.us/apps2/forms/] **https://www.nj.gov/health/forms**, in either paper or electronic version, whenever a patient is transferred to another licensed healthcare facility or program.

1. (No change.)

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

CHAPTER 43K

MANUAL OF STANDARDS FOR LICENSURE OF OUTPATIENT AND INTEGRATED CARE FACILITIES

SUBCHAPTER 1. GENERAL PROVISIONS

8:43K-1.1 Purpose

(a) The purpose of this chapter is to:

1. Establish licensure and operational standards for the development of an integrated licensing system by which an outpatient facility that is subject to licensure pursuant to a law listed at (a)2 below may provide, pursuant to an outpatient or integrated care facility license, in accordance with N.J.S.A. 26:2H-5.1g and 12.84:

i. Health care services, including primary care services and reproductive health care services;

ii. Behavioral health services, including mental health treatment, substance use disorder, and/or other addiction treatment services;

iii. Opioid treatment program services; and/or

iv. A combination of these services; and

2. Implement N.J.S.A. 26:2B-7 et seq., specifically 2B-9.3, 14, and 40, 26:2BB-5 and 6, 26:2G-21 et seq., specifically 26:2G-23, 25, and 36, 26:2H-1 et seq., specifically 26:2H-5.1g, 12.84, 12.85, and 12.86; and 30:9A-1 et seq., specifically 30:9A-3, 5, 7, 8, 9, 9.2, 10, 18, 19, 20, and 21; and Reorganization Plan No. 001-2017 and Reorganization Plan No. 001-2018.

8:43K-1.2 Scope

(a) This chapter applies to an entity seeking, or to which the Department issues, licensure as an outpatient or integrated care facility to provide the following services:

1. Health care services, which include:

i. Primary care; and/or

ii. Reproductive health care services;

2. Behavioral health services, which include:

i. Mental health treatment;

ii. Substance use disorder and/or other addiction treatment services;

3. Opioid treatment program services; and/or

4. A combination of these services.

(b) A facility that seeks to perform ambulatory surgical cases is subject to licensure pursuant to N.J.A.C. 8:43A as an ambulatory surgery center.

8:43K-1.3 Definitions

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

"Addiction treatment" means medical, psychosocial, and/or other evidence-based therapeutic interventions for the management of substance use disorder and/or other behavioral addiction, such as gambling including, but not limited to, counseling, therapy, medication management, medication administration, care navigation, and/or psychosocial supportive services.

"Administer" means "administer" as the New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., specifically at 45:14-41, defines that term.

"Administration of controlled dangerous substance for the treatment of substance use disorder" or "administration of CDS for the treatment of SUD" means an adjunctive service that includes the storage, administration, and/or dispensing of FDA-approved Schedules II, III, and/or IV controlled medications to treat withdrawal or medically manage and stabilize substance use disorder.

"Administrator" means an individual appointed by the governing authority of a facility to provide administrative oversight of licensed services within a facility.

"Admit" means accept to a facility for treatment.

"Advance directive for health care" means "advance directive for health care" as the New Jersey Advance Directives for Health Care Act, N.J.S.A. 26:2H-53 et seq., specifically at 26:2H-55, defines that term.

"Advance directive for mental health care" means "advance directive for mental health care" as the New Jersey Advance Directives for Mental Health Care Act, N.J.S.A. 26:2H-102 et seq., specifically at 26:2H-104, defines that term.

"Advanced practice nurse" or "APN" means an "advanced practice nurse" as N.J.S.A. 45:11-23 and the Advanced Practice Nurse Certification Act, N.J.S.A. 45:11-45 et seq., define and describe that term.

"Advanced practitioner" means an advanced practice nurse or a physician assistant.

"Adverse event" means an event that is a negative consequence of care that results in unintended injury or illness, which may or may not have been preventable.

"Affiliation agreement" means "affiliation agreement" as N.J.S.A. 30:9A-19 describes that term.

"Alcohol use disorder" or "AUD" means "alcohol use disorder" as the DSM-5 defines that term.

"Alternate care location" means a location at which a facility provides licensed services on a regular basis subject to N.J.A.C. 8:43K-12.

"Ambulatory surgical case" means a surgical procedure performed on a patient in an ambulatory surgery center that the Department licenses pursuant to N.J.A.C. 8:43A, which typically requires anesthesia, with a facility-based post-

surgery period of at least one hour, and typically without the requirement of an overnight stay.

"American Board of Medical Specialties" or "ABMS" means the entity by that name for which the contact information is 353 North Clark Street, Suite 1400, Chicago, IL 60654, telephone (312) 436-2600, website https://www.abms.org.

"Association for the Advancement of Medical Instrumentation® " means the entity by that name for which the contact information is Association for the Advancement of Medical Instrumentation, 901 N Glebe Road, Suite 300, Arlington, VA 22203, telephone (703) 525-4890, telefacsimile (703) 276-0793, website www.aami.org.

"Available," if used in relation to:

1. Equipment, means readily accessible for immediate use; and

2. Personnel, means capable of being reached by telephone.

"Behavioral health care" and "behavioral health care services" mean "behavioral health care" and "behavioral health care services" as N.J.S.A. 26:2H-12.84 and 12.86 define these terms, excluding opioid treatment programs.

"Biopsychosocial assessment" means an evaluation of a patient's behavioral, biological, cognitive, emotional, environmental, psychological, and social history and status as identified by the patient, and collateral sources, as appropriate, to inform a plan of care for the patient.

"Board certification" means a certification credential, within a professional specialty or medical or nursing subspecialty, which is issued by:

1. An entity that is a member board of the ABMS or the ABNS, as applicable;

2. A foreign medical specialty board, provided the corresponding ABMS or ABNS member board, as applicable, offers reciprocal certification for, or officially recognizes as equivalent, the foreign board's certification credential; or

3. The New Jersey Board of Nursing pursuant to N.J.A.C. 13:37-7.

"Bylaws" means a set of rules that an entity adopts that govern its operation, and includes, as acceptable equivalents, a charter, articles of incorporation, or a statement of policies and objectives.

"Certificate of occupancy" means "certificate of occupancy" as the State Uniform Construction Code Act, N.J.S.A. 52:27D-119 et seq., specifically at 52:27D-121, defines that term.

"Certified alcohol and drug counselor" or "CADC" means a "certified alcohol and drug counselor" as the Alcohol and Drug Counselor Licensing and Certification Act, N.J.S.A. 45:2D-1 et seq., specifically at 42:2D-3, defines that term.

"Certified nurse midwife" means a certified nurse midwife as N.J.S.A. 45:10-1 et seq., specifically at 45:10-17, defines that term.

"Cleaning" means the removal by scrubbing and washing, as with hot water, soap, or detergent, and vacuuming of infectious agents and organic matter from surfaces on and in which infectious agents may find conditions for surviving or multiplying.

“Clinically monitor” or “clinical monitoring” means to observe, watch, or check intermittently. A clinical monitor is a designated person who performs clinical monitoring.

“Clinical note” means a written, signed, and dated notation that a health care professional who renders a health service to a patient writes, electronically or physically, into the patient’s medical record on the day the professional renders the service. This can be written through a dictation platform.

“Commissioner” means the Commissioner of the Department of Health.

“Communicable disease” means “communicable disease” as N.J.S.A. 26:4-1 et seq., defines that term.

“Construction” means “construction” as N.J.S.A. 26:2H-2 defines that term.

"Construction guidelines" means the Facility Guidelines Institute, Guidelines for Design and Construction of Outpatient Facilities, 2022 edition, incorporated herein by reference, as amended and supplemented, available from the Facility Guidelines Institute, 9750 Fall Ridge Trail, Saint Louis, MO 63127, telephone (800) 798-9296, website www.fgiguidelines.org.

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

“Controlled dangerous substance,” “controlled substance,” or “CDS” means “controlled substance” as the Controlled Substances Act, 21 U.S.C. §§ 801 et seq., specifically at 21 U.S.C. § 802, defines that term, and “controlled

dangerous substance," as the New Jersey Controlled Dangerous Substances Act, N.J.S.A. 24:21-1 et seq., specifically at 24:21-2, defines that term.

"Controlled Dangerous Substances Acts" means the Controlled Substances Act, 21 U.S.C. §§ 801 et seq., and the New Jersey Controlled Dangerous Substances Act, N.J.S.A. 24:21-1 et seq.

"Counseling services" and/or "therapy services" means licensed individual, group, and/or family counseling or therapy provided by a licensed clinician or clinician practicing within the supervision of a licensed clinician within their scope.

1. Such services can include, but are not limited to, psychotherapy, psychotherapeutic counseling, and/or counseling to address issues, such as symptoms of mental illness, SUD or other addiction, psychological stress, difficulties coping with an illness or social environment, assisting with decision-making, and/or problem-solving.

"Curtail" means a Department order directing a facility to limit, or cease and desist, admission and readmission of patients to the facility or a specified service of the facility.

"DCF" means the Department of Children and Families.

"DEA" means the Drug Enforcement Administration of the United States Department of Justice.

"Deemed status" means the status that the Department grants to a facility that an accrediting body accredits, by which the Department recognizes the

accrediting body's standards as adequate equivalents of certain Department facility standards.

"Deficiency" means a finding of a facility's violation of or failure to comply with, in one or more instances, a State facility licensing statute or rule, or Federal law or regulation, or a CMS-certification standard.

"Dentist" means a person whom the State Board of Registration and Examination in Dentistry licenses as a dentist in accordance with N.J.S.A. 45:6-1 et seq., specifically at 45:6-6, and registers in accordance with N.J.S.A. 45:6-10.

"Dentistry" means "dentistry" as N.J.S.A. 45:6-1 et seq., defines and describes that term.

"Department" means the New Jersey Department of Health.

"Designated caregiver" means "designated caregiver" as the Jake Honig Compassionate Use Medical Cannabis Act, N.J.S.A. 24:6I-1 et seq., specifically at 24:6I-3, defines that term.

"Dietician" means "registered dietician" or "dietician nutritionist," as the Dietetics and Nutrition Licensing Act, N.J.S.A. 45:16B-1 et seq., defines those terms.

"Diplomate" means a person who has board certification.

"Disinfect," "disinfecting," or "disinfection" mean killing infectious agents outside the body, or organisms transmitting such agents, by chemical and physical means, directly applied.

"Dispense" or "dispensing" means "dispense" or "dispensing" as the New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., specifically at 45:14-41, defines that term.

"DMHAS" means the New Jersey Division of Mental Health and Addiction Services within the New Jersey Department of Human Services.

"Documented" means written, signed, dated, and recorded, including by electronic means.

"Dosage" means, in the context of administering medication in prescribed amounts, the quantity of a medication to be administered or applied at one time or in fractional amounts over a specified period.

"DSM-5" means American Psychiatric Association, Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition, Text Revision (DSM–5-TR®), American Psychiatric Association Publishing, Washington, DC, https://www.appi.org, incorporated herein by reference, as amended and supplemented.

"Employee" or "staff" means:

1. A full- or part-time employee of a facility, including administrative, salaried, and contracted staff members;

2. A person whom a facility engages to have direct contact with patients or provide patient care;

3. Volunteer staff; or

4. A physician, another provider, and/or another person, whom a facility engages or authorizes by salary, contract, or other grant of privileges, to recommend a course of treatment for a patient at the facility.

"Facility" means a facility that the Department licenses as an outpatient care provider and/or an integrated outpatient care provider pursuant to this chapter.

"Full-time" means relating to a period established by the facility as a full working week, as defined and specified in the facility's policies and procedures.

"Governing authority" means the organization, person, or persons designated to assume legal responsibility for the management, operation, and financial viability of a facility.

"Health care facility" or "facility" means "health care facility" as the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq., specifically at 26:2H-2, defines that term, limited exclusively to a facility that provides, on an outpatient basis, primary care, reproductive health care, mental health care, substance use disorder, or addiction treatment services, or a combination of such services, through a single license, in accordance with N.J.S.A. 26:2H-5.1g and 12.84, and which may elect to provide adjunctive services.

"Health Care Plan Review Unit" means the Health Care Plan Review Unit within the Bureau of Construction Project Review in the Division of Codes and Standards of the Department of Community Affairs, which mailing address is PO Box 817, Trenton, NJ 08625-0817; website https://www.nj.gov/dca/codes/offices/bcpr.shtml.

“Health care service” means “health care service” as the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq., specifically at 26:2H-2, defines that term.

“Herbology” means “herbology” as N.J.S.A. 45:2C-1 et seq., specifically at 45:2C-19, defines that term.

“HIV” means human immunodeficiency virus.

“Hospital” means “hospital” as N.J.A.C. 8:43G, Hospital Licensing Standards, specifically at 8:43G-1.2, defines that term.

“Integrated health care” means “integrated health care” as the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq., specifically at 26:2H-2, defines that term.

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

“Legally authorized representative” means spouse, domestic partner, civil union partner, immediate next of kin, legal guardian, executor, or an individual with power of attorney.

“Licensed associate counselor” or “LAC” means “licensed associate counselor” as the Professional Counselor Licensing Act, N.J.S.A. 45:8B-34 et seq., specifically at 45:8B-36, defines that term.

“Licensed associate marriage and family therapist” or “LAMFT” means “licensed associate marriage and family therapist” as the Practicing Marriage and

Family Therapy Act, N.J.S.A. 45:8B-1 et seq., specifically at 45:8B-2, defines that term.

"Licensed behavioral health services" means:

1. Counseling and therapy services provided in accordance with N.J.A.C. 8:43K-6;

2. Outpatient mental health services provided in accordance with N.J.A.C. 8:43K-6;

3. Outpatient substance use disorder or addiction treatment services provided in accordance with N.J.A.C. 8:43K-6;

4. Partial care mental health services provided in accordance with N.J.A.C. 8:43K-6; and/or

5. Partial care substance use disorder or addiction services provided in accordance with N.J.A.C. 8:43K-6.

"Licensed clinical alcohol and drug counselor" or "LCADC" means "licensed clinical alcohol and drug counselor" as the Alcohol and Drug Counselor Licensing and Certification Act, N.J.S.A. 45:2D-1 et seq., specifically at 45:2D-3 and 16, defines that term.

"Licensed clinical social worker" or "LCSW" means "licensed clinical social worker" as the Social Workers' Licensing Act of 1991, N.J.S.A. 45:15BB-1 et seq., specifically at N.J.S.A. 45:15BB-3, defines that term.

"Licensed marriage and family therapist" or "LMFT" means "licensed marriage and family therapist" as the Practicing Marriage and Family Therapy Act, N.J.S.A. 45:8B-1 et seq., specifically at 45:8B-2, defines that term.

“Licensed nursing personnel” or “licensed nurse” means a registered professional nurse and a licensed practical nurse.

“Licensed practical nurse” means “licensed practical nurse” as N.J.S.A. 45:11-23 et seq., specifically at 45:11-27, defines and describes that term.

“Licensed professional counselor” means “licensed professional counselor” as the Professional Counselor Licensing Act, N.J.S.A. 45:8B-34 et seq., specifically at 45:8B-36, defines that term.

“Licensed psychologist” means “licensed practicing psychologist” as the Practicing Psychologist Licensing Act, N.J.S.A. 45:14B-1 et seq., especially at N.J.S.A. 45:14B-2, defines that term.

“Licensed social worker” means “licensed social worker” as the Social Workers’ Licensing Act of 1991, N.J.S.A. 45:15BB-1 et seq., specifically at N.J.S.A. 45:15BB-3, defines that term.

“Linens” means textiles used in the facility for patient care including pillow covers, gowns, blankets, bed sheets, and towels.

“Lived experience” means a person’s knowledge of mental illness or addictive disorder as gained through the person’s direct, personal experience and progress in treatment and recovery.

“MCHC” means a maternal and child health consortium, which is a voluntarily formed non-profit organization, consisting of all inpatient or ambulatory perinatal and pediatric care providers and related community

organizations in a maternal and child health service region, as described at N.J.A.C. 8:33C.

"Medical record" means all records in a facility that pertain to a patient's care, and is used in this chapter synonymously with the term "patient record."

"Medical subspecialty" means a specialized health service that a physician who is board-certified by the American Board of Medical Specialties, and has completed a fellowship, in the specialization, provides.

"Medication" means "drug or medication" as the New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., specifically at 45:14-41, defines that term.

"Medication for opioid use disorder" or "MOUD" means medications, including opioid agonist medications, approved by the Food and Drug Administration pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355), for use in the treatment of opioid use disorder.

"Medication management" or "medication prescribing" means the prescribing of medication by a licensed physician, or other licensed practitioner authorized by State law to recommend a course of treatment, in accordance with their licensing or accrediting body and within the scope of practice for the prescriber.

"Medication monitoring" means medication services or oversight provided through supervision of a licensed physician, or other licensed practitioner authorized by State law, to recommend a course of treatment, evaluate, prescribe, or administer, and/or monitor the patient's use of medications prescribed as part of their plan of care.

“Mental health practitioner” means “mental health practitioner” as N.J.S.A. 45:1-44 defines that term.

“Mental health services” means counseling, therapy, and/or medication management.

"Minor regional block" means the injection of a local anesthetic to stop a painful sensation in a severely circumscribed area of the body (local infiltration or local nerve block), or the block of a nerve by direct pressure and refrigeration.

“MMWR” means CDC, United States Department of Health and Human Services, *Morbidity and Mortality Weekly Report,* Centers for Disease Control and Prevention, 1600 Clifton Rd., MS V25-5, Atlanta, GA 30329-4027, www.cdc.gov/mmwr.

“Monitor” means observe and check the progress or quality of (something) over a period of time; keep under systematic review or a person who observes and checks the progress or quality of something over a period of time.

“NJSAMS” means the DMHAS New Jersey Substance and Addiction Monitoring System.

“Nutritionist” means “licensed nutritionist” as the Dietetics and Nutrition Licensing Act, N.J.S.A. 45:16B-1 et seq., defines that term.

“Obstetrician/gynecologist” means a physician who has successfully completed a residency program in obstetrics and gynecology that is accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association, or who is a diplomate of either the American

Board of Obstetrics and Gynecology or the American Osteopathic Board of Obstetrics and Gynecology.

"Office of Certificate of Need and Facility Licensing" or "Office" means the health care facility licensing unit within the Division of Health Facilities Evaluation and Licensing of Health Systems Branch of the Department, for which the contact information is, PO Box 358, Trenton, NJ 08625-0358, (609) 376-7888, website address for forms: www.nj.gov/health.forms.

"Opioid treatment program" or "OTP" means a "certified opioid treatment program" as 21 U.S.C. § 823 defines that term.

"Opioid use disorder" or "OUD" means "opioid use disorder" as the DSM-5 defines that term.

"Outpatient facility" means a facility or a distinct part of a facility that provides health care services, behavioral health services, opioid treatment program services, or a combination of these, as outpatient services.

"Outpatient service" means a service provided to a person who arrives at a facility, receives the service, and departs from the facility on the same day.

"Partial care mental health services" means a broad range of licensed individualized, rehabilitative, and structured behavioral health treatment services and supports provided in a community setting that are designed to promote patient stabilization and community integration.

"Partial care substance use disorder and/or addiction treatment services" means a broad range of licensed individualized, rehabilitative, and structured substance use disorder and/or addiction treatment services and supports

provided in a community setting, which promote patient stabilization and community integration.

"Patient" means patient, resident, client, or the terminology used by a specific licensed facility to refer to an individual to whom a facility is providing care.

"Pediatrician" means a physician who has successfully completed a residency program in pediatrics accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association, or who is a diplomate of either the American Board of Pediatrics or the American Osteopathic Board of Pediatrics.

"Pediatrics" means licensed primary care services provided to infants, children, and adolescents.

"Peer" means a person who has lived experience of recovery from a mental health condition and/or an addictive disorder who provides non-clinical assistance and support to a patient who is in recovery or treatment.

"Pharmacist" means "pharmacist" as the New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., specifically at 45:14-41, defines that term.

"Pharmacy" means "pharmacy practice site" as the New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., specifically at 45:14-41, defines that term, to which the New Jersey State Board of Pharmacy issues a permit pursuant to N.J.S.A. 45:14-69.

"Physician" means "physician and surgeon" and "physician or surgeon" as N.J.S.A. 45:9-1 et seq., specifically at 45:9-5.1, defines that term.

“Physician assistant” means “physician assistant” as the Physician Assistant Licensing Act, N.J.S.A. 45:9-27.10 et seq., specifically at 45:9-27.11, defines that term.

“Plan of care” means a written plan that is based on patient assessments and developed with the participation of the patient or the patient’s legally authorized representative.

1. Unless clinically contraindicated, family members and other support persons identified by the patient may be included, subject to applicable Federal and State confidentiality laws and corresponding regulations;

2. A plan of care includes care and treatment to be provided, subject to patient consent and availability; and

3. When available, various disciplines may contribute to the development of a plan of care.

“Plan of correction” means a plan that a facility develops and the Department reviews and approves, which describes the actions the facility will take to correct deficiencies and specifies the time within which the facility will correct those deficiencies.

“Prescriber” means a person who is authorized to write prescriptions or recommend a course of treatment in accordance with applicable Federal and State law.

“Prescription” means “prescription” as the New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., specifically at 45:14-41, defines that term.

“Preventive medicine” means screening and referral services that align with published recommendations from the United States Preventive Services Taskforce, available at https://uspreventiveservicestaskforce.org, and treatment services for chronic conditions, such as medication management and medical education.

“Primary care” means “primary health care” and “primary health care services” as N.J.S.A. 26:2H-12.84 defines these terms.

“Progress note” means a written or electronic summary of the treatment and/or services and relevant clinical information.

“Provider of health care,” “provider,” or “health care provider” means “provider of health care” as N.J.S.A. 26:2H-2 defines that term and includes any health care professional acting within the scope of practice of a valid credential issued pursuant to Title 45 of the New Jersey Revised Statutes.

“Provisional license” means a license to provide mental health services at a specific location for a specified period until a full licensing site review occurs.

“Psychiatrist” means a physician who has successfully completed a residency program in psychiatry accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association, or who is a diplomate of either the American Board of Psychiatry and Neurology or the American Osteopathic Board of Neurology and Psychiatry.

“Psychoeducation services” means a mutual exchange of information and education between qualified staff and a patient, or qualified staff and family members and/or other support persons, to increase the likelihood of family,

support persons, and community support to the patient and to reduce the probability of patient decompensation.

1. The information exchanged may address etiology and symptoms characteristic of the patient's mental illness and/or addictive disorder, effects of medication, coping skills, daily living skills, community resources and supports, and similar mental health or addiction service-related matters.

"Qualifying patient" means "qualifying patient or "patient" as the Jake Honig Compassionate Use Medical Cannabis Act, N.J.S.A. 24:6I-1 et seq., specifically at 24:6I-3, defines that term.

"Reproductive health care services" means "reproductive health care services" as N.J.S.A. 26:2-200 defines that term.

"Screening" means a process for detecting potential health disorders or diseases for a designated population and determining whether a patient should undergo diagnostic testing to identify the presence or absence of a disease or undergo treatment for the presence of disease detected by screening.

"Screening tests" means tools to determine whether a patient has a disease or condition or should have additional testing to determine the presence or absence of a disease.

"Severe mental illness," "severe emotional disorder," and "severe drug or alcohol use disorder," as used in the definition of the terms, "behavioral health care" and "behavioral health care services" at N.J.S.A. 26:2H-12.84 and 12.86,

mean a condition that requires involuntary commitment services pursuant to N.J.S.A. 30:4-27.1 et seq.

"Signature" means a mark or sign, which is handwritten or electronic, that an individual, including a patient and/or prescriber, makes on a document to signify knowledge, approval, acceptance, and/or obligation.

"Staff orientation plan" means a written plan for the orientation of each new employee to the duties and responsibilities of the service to which the employee is assigned, and the personnel policies of the facility.

"Sterilization" means a process of destroying all microorganisms, including those bearing spores, in, on, and around an object.

"Substance use disorder" or "SUD" means "substance use disorder" as the DSM-5 defines that term.

"Substance use disorder treatment service" or "SUD treatment service" means counseling, therapy, and/or medication management provided to a person who has an addictive disorder, including a substance use disorder, and includes services that N.J.S.A. 26:2B-7 et seq., authorizes the facility to perform as an outpatient facility.

"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 the Department, and/or its designees, to determine compliance or non-compliance with applicable State licensing laws, and/or Federal Medicare and Medicaid certification laws.

"Treatment" means health care, reproductive health care, preventive care, wound care, counseling and therapy, and behavioral health care, mental health and/or substance use disorder and/or addiction treatment, and/or medication services provided to patients with a confirmed illness, injury, or disease.

"Tuberculosis Control Program" means the Tuberculosis Control Program within the Division of HIV, STD, and TB Services of the Public Health Services Branch of the Department, for which the contact information is Tuberculosis Control Program, 55 North Willow St, 3rd Floor, PO Box 363, Trenton, NJ 08625-0369, (609) 826-4878.

"Tuberculosis guidelines" means Jensen PA, Lambert LA, Iademarco MF, and Ridzon R, Division of Tuberculosis Elimination, National Center for HIV, STD, and TB Prevention, *Guidelines for Preventing the Transmission of Mycobacterium Tuberculosis in Health-Care Settings*, Morbidity and Mortality Weekly Report 54 (No. RR-17) (2005), as updated by Sosa L E, Njie G J, Lobato M N, et al., *Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC*, 2019, Morbidity and Mortality Weekly Report 68(19); 439–443 (2019), incorporated herein by reference, as amended and supplemented, both of which are available at CDC, *Clinical Testing Guidance for Tuberculosis: Health Care Personnel*, https://www.cdc.gov/tb-healthcare-settings/hcp/screening-testing/index.html (last updated December 15, 2023).

"Wound care" means services to clean and treat breaks in the skin, such as an abscess, cellulitis, and necrosis, and includes basic first-aid skin treatment

and office-based procedures to treat skin wounds and infections using incision and drainage.

1. Wound care requiring surgical debridement that requires anesthesia shall be performed in compliance with N.J.A.C. 8:43A-12, with respect to the levels of anesthesia that a particular facility is authorized to use.

SUBCHAPTER 2. LICENSURE PROCEDURES

8:43K-2.1 Application process for initial and renewal of license

(a) An entity shall not operate an outpatient or integrated care facility or admit patients until the Department issues an outpatient or integrated care facility license to the entity pursuant to this chapter, or a transitional license to the entity in accordance with this subchapter.

(b) An entity shall submit to the Office of Certificate of Need and Health Care Facility Licensing, the information requested in the form at N.J.A.C. 8:43E-5 Appendix, and schedules applicable to the services the applicant seeks to provide, available at https://www.nj.gov/health/forms, to apply for:

1. Initial licensure to operate an outpatient or integrated care facility; or

2. Renewal of an existing license issued pursuant to N.J.A.C. 8:43A to provide outpatient services as a new license pursuant to this chapter, at least 90 days before the expiration of its existing license.

(c) An applicant may apply for licensure to provide any one outpatient care service listed at N.J.A.C. 8:43K-1.2(a), or a combination thereof, pursuant to an integrated care facility license.

(d) An applicant shall indicate in the application it submits pursuant to (a) above:

1. The service or services that it seeks licensure to provide; and

2. The designation by which the facility proposes to self-identify, in accordance with N.J.S.A. 26:2H-5.1g(b)(3), be it as an ambulatory care facility that is not subject to licensure pursuant to N.J.A.C. 8:43A, a community mental health facility, an addiction treatment facility, a behavioral health services facility, a primary care facility, a health care services facility, a reproductive health care services facility, a substance use disorder or other addiction treatment facility, an integrated outpatient care facility, and/or another type of outpatient care facility recognized pursuant to State or Federal law.

(e) If an applicant elects and intends to provide adjunctive services at an outpatient facility, the applicant shall submit, with its licensure application, the completed schedules of the form at N.J.A.C. 8:43E-5 Appendix that apply to the adjunctive services the applicant seeks to provide, or the information requested in those schedules.

1. A licensee may add or discontinue the provision of an adjunctive service at any time, provided the licensee shall notify the Office at least 90 days prior to the addition or discontinuation of the service, by submitting the form at N.J.A.C. 8:43E-5 Appendix, and the completed schedules thereto that apply to the adjunctive services the licensee plans to add or discontinue.

2. N.J.A.C. 8:43K-9 applies to a facility's provision of an adjunctive service.

(f) An applicant shall submit, with respect to each other health care facility that the applicant, and/or a subsidiary or parent of the applicant, owns or operates, in the State of New Jersey or another jurisdiction, as applicable, the report of the last inspection that a credentialing and/or an accrediting body performed, identifying deficiencies noted, the plan of correction that the credentialing or and/or accrediting bodies approved or directed, and the credentialing and/or accrediting bodies' report of the status of the facility's compliance with the plan of correction.

(g) An applicant shall indicate in its application whether any applicable law (see, for example, N.J.S.A. 30:9A-19) requires the applicant to enter into an affiliation agreement with DMHAS, DCF, or another agency of State government (affiliate agency), to provide an outpatient service that is the subject of its application for Department licensure.

(h) Upon receiving an application for initial or renewal of licensure of an outpatient facility to provide services as to which any applicable law requires the applicant to enter into an affiliation agreement in accordance with (g) above, the Department shall notify the affiliate agency of the application's pendency and request that the affiliate agency inform the Department as to the status of:

1. The applicant's affiliation agreement;

2. The applicant's compliance with the affiliation agreement;

3. Any plan of correction the affiliate agency approved or directed that remains in effect (that is, which the affiliate agency has yet to determine to have been fully implemented and discharged); and

4. The applicant's compliance with applicable laws within the enforcement jurisdiction of the affiliate agency.

(i) The Department shall refrain from further processing an application for initial or renewal of licensure to perform services that are subject to an affiliation agreement until the affiliate agency informs the Department that:

1. The applicant's performance of the affiliation agreement and any plan of correction that is in place, and compliance with applicable laws and standards that the affiliate agency has jurisdiction to enforce, are satisfactory; and

2. The applicant is in good standing with the affiliate agency.

(j) Maintenance of the status of being in good standing with the affiliate agency is a condition of initial, ongoing, and renewal of, Department licensure.

1. A facility's failure to maintain the status of being in good standing with an affiliate agency may be grounds for the Department to take enforcement action against a facility's license.

(k) If an applicant is not subject to an affiliation agreement, or upon receiving notification that an applicant that is subject to an affiliation agreement is in good standing with the affiliate agency, the Office shall conduct a completeness review of an application, following which the Office shall notify the applicant in writing:

1. That the application is complete, in which case the Office shall commence the prior history assessment in accordance with (m) below; or

2. Of any incompleteness in the application that the applicant must correct before the Office further processes the application.

(l) Following a determination that an application is complete, the Department will assess an applicant's prior history record of operating a facility, in New Jersey or other jurisdictions, including:

1. Evidence of a deficiency representing a serious risk of harm to patients or the continuity of care; and

2. Records of criminal convictions for offenses indicating that patient safety and welfare would be at risk.

(m) The Department will assess the prior history record of an applicant during the 10 years preceding the date of an application for initial licensure.

(n) A person who is convicted of a crime relating adversely, either directly or indirectly, to the entity's capability of owning, managing, or operating a facility is ineligible to own, manage, or operate a facility unless the entity is rehabilitated pursuant to N.J.S.A. 2A:168A-1 et seq.

(o) If the prior history assessment that the Department conducts pursuant to (l) and (m) above demonstrates an acceptable history of performance and compliance, and the owner, manager, and operator of the facility is eligible pursuant to (n) above, the Department will survey the facility that is the subject of the application for initial or renewal of licensure in accordance with N.J.A.C. 8:43K-2.3.

(p) Within 60 days of an applicant's request, the Office will convene a pre-licensure consultation with the applicant to review an application's completeness, the Department's prior history assessment of the applicant, the Department's determination as to the eligibility of the proposed owner, manager, and/or operator, the Department's survey of the facility premises, and/or other licensing and operating standards, and to provide the applicant with other technical guidance and information, as needed.

8:43K-2.2 Ownership; transfer of ownership

(a) An applicant for initial or renewal of licensure shall disclose in its application for licensure, and provide supporting documentation of, the ownership of the facility and the property at which it is located.

1. An applicant seeking initial or renewal of licensure to provide two or more outpatient facility services at a facility must be owned by and/or incorporated as one legal entity.

(b) To avoid or minimize interruption of services, an entity to which a licensee plans to transfer ownership of a facility or the real property at which it exists should apply for Department approval of the proposed transfer of ownership at least 120 days before the date of the planned closing of the ownership transfer.

8:43K-2.3 Compliance with applicable laws; survey before licensure

(a) An applicant for initial or renewal of licensure shall ascertain and comply with applicable State and local laws of the jurisdiction in which the applicant seeks to operate the facility.

1. Failure of the applicant to maintain compliance with applicable local laws may be grounds for the Department to deny an initial or renewal of a license or take enforcement action against a licensee, as needed to ensure the health and safety of patients, workers, and/or the public.

(b) If local law requires zoning, fire, health, construction, and/or other authorities to issue written approvals of a facility, including, if applicable, approval of a water supply or sewage disposal system that is not connected to an approved municipal system, the applicant shall submit copies of the required written approval documents to the Office.

1. If local law requires periodic updating and/or renewal of the required written approvals that (b) above describes, the applicant shall obtain and submit to the Office copies of the updated and/or renewed written approvals.

(c) The Department shall:

1. Conduct an on-site survey of the premises at which an applicant for initial or renewal of licensure proposes to operate an outpatient facility; and

2. Issue a written report to the applicant that provides the onsite survey result and identifies any deficiencies that the applicant must correct to bring the premises into compliance with applicable provisions of the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq., the rules that the Department promulgates

pursuant thereto, this chapter, and other applicable laws that the Department has jurisdiction to administer.

(d) If the report that the Office issues pursuant to (c) above identifies one or more deficiencies, the applicant shall notify the Office when it completes the corrective actions needed to cure the deficiencies, following which, the Office shall perform one or more resurveys of the premises to confirm that the applicant has cured identified deficiencies.

1. The Office shall refrain from further processing an application for initial or renewal of licensure until the Office finds that the premises are satisfactory, and the applicant corrects identified deficiencies.

(e) The Department may conduct on-site surveys of a facility at any time, which may include facility and patient medical record reviews, conferences with patients, and any other inspection or survey activity that the Department determines to be relevant to the facility's compliance with the law within the Department's enforcement and/or administration jurisdiction.

8:43K-2.4 Facility construction project review

(a) The owner or operator of a facility that is the subject of an application for initial or renewal of licensure shall demonstrate compliance with the applicable requirements at N.J.S.A. 52:27D-119 et seq., the State Uniform Construction Code Act, and the rules promulgated pursuant thereto at N.J.A.C. 5:23, Uniform Construction Code, in undertaking new construction of a facility, or altering, expanding, reconstructing, or renovating an existing facility.

1. Information regarding the requirements applicable to a facility's compliance with (a) above is available from the Health Care Plan Review Unit.

2. See specifically:

i. N.J.A.C. 5:23-1.4 (definition of "health care facility") and 3.11(a)8;

ii. Health Care Plan Review Unit, Supplemental Guide to Health Care Plan Review Submission (December 15, 2022), as amended and supplemented, available as "Guide" at https://www.nj.gov/dca/codes/offices/bcpr.shtml and https://www.nj.gov/dca/divisions/codes/forms/pdf_bcpr/HCPR_Supplemental_Guide.pdf; and

iii. The construction guidelines.

(b) The owner or operator of a facility that is subject to (a) above shall demonstrate compliance therewith by submitting to the Office:

1. The Health Care Plan Review Unit's written determination indicating either its approval of the plan or its determination that the plan is not subject to its review; and

2. If applicable, a copy of the certificate of occupancy, certificate of continuing occupancy, certificate of approval, or a comparable written document that the municipality, in which the facility exists or at which the planned construction activity is to occur, issues upon completion of construction.

(c) During construction, alteration, expansion, reconstruction, or renovation of a facility holding an existing Department-issued license, the Department may

impose conditions on the licensee, as needed, to ensure the health and safety of patients, workers, and/or the public.

8:43K-2.5 Facility license issuance

(a) Subject to the Department's survey and applicable resurveys, in accordance with applicable provisions at N.J.A.C. 8:43K-2.3 and 2.4, of the premises at which an applicant proposes to operate, and determination that the premises are without deficiency and in satisfactory compliance with applicable laws, the Department will conclude its review of an application for initial or renewal of licensure of an outpatient facility.

(b) The Department will grant the application for initial or renewal of licensure if the application demonstrates that the premises, equipment, personnel, finances, bylaws, procedures, and standards of care, are fit and adequate, and the Department is assured and satisfied that the applicant's prior history of compliance indicates that the applicant will operate the facility in accordance with applicable laws and standards.

(c) The period of full outpatient facility licensure is two years.

1. If a license is subject to conditions, a plan of correction, or another compliance or enforcement action, the Department may shorten the licensure period to less than two years, as described in the terms and conditions of the license, the plan of correction, or other enforcement action.

(d) A licensee shall post in the facility in a conspicuous location that is readily accessible for viewing by patients and the public:

1. Its license; and

2. Information identifying the owner of the facility and the property at which it exists.

(e) A license is not assignable or transferable, and immediately becomes void if:

1. A licensee ceases to operate a facility;

2. The ownership of either the facility or the licensee changes; or

3. The licensee relocates facility operations to a different site without prior Department approval.

(f) The Department may issue a provisional license, which is valid for up to six months or until the Department completes a full site review, to either an existing licensed mental health practitioner that seeks to change its existing location or add an additional location, or an applicant for new licensure as a mental health practitioner, if:

1. The provider submits a complete application and the appropriate fee; and

2. The Department has reviewed the program's policies and procedures and has conducted a program site tour.

(g) The Department may renew a provisional license, if needed.

8:43K-2.6 License renewal by deemed status

(a) An applicant for renewal of licensure through deemed status shall submit the following to the Office:

1. The information and documentation required pursuant to N.J.A.C. 8:43K-2.1, 2.2, 2.3, and 2.4;

2. An accrediting body's certificate of accreditation of the licensee that bears the seal of an accrediting body and identifies the effective period of the accreditation; and

3. The report of the accrediting body's last inspection and audit of the facility that the accrediting body performed preceding the filing of the application for renewal, identifying, if applicable:

i. Deficiencies noted;

ii. A plan of correction that the accrediting body approved or directed; and

iii. A report of the status of the applicant's compliance with the plan of correction.

(b) The Office shall review an applicant's record of accreditation, compliance with approved and/or directed plans of correction, and prior history of compliance in every jurisdiction in which the applicant, and/or a subsidiary or parent of the applicant, owns or operates an accredited health care facility, and shall deem the applicant to be eligible for renewal of licensure by deemed status if the Office determines that the premises, equipment, personnel, finances, bylaws, procedures, and standards of care, are fit and adequate, and the Department is assured and satisfied that the applicant's prior history of compliance indicates that the applicant will operate the facility in accordance with applicable laws and standards.

8:43K-2.7 Modification of outpatient facility service or designation

(a) A facility shall apply for a modification of the outpatient facility services or designation it identifies, pursuant to N.J.A.C. 8:43K-2.1(c) and (d), by submitting to the Office in the form at N.J.A.C. 8:43E-5 Appendix, and schedules applicable to the services the applicant seeks to provide, available at https://www.nj.gov/health/forms.

(b) An applicant shall indicate in an application it submits pursuant to (a) above:

1. Whether the change in outpatient facility service or designation requires substantive modification or supplementation of a facility's operational procedures, personnel, physical premises, and/or other operating characteristics to bring the facility into compliance with standards in this chapter applicable to the service or designation; and

2. If so, the applicant's plan to achieve compliance.

(c) The Department will review the application and notify the applicant whether an application submitted pursuant to (a) above and, if applicable, a plan submitted pursuant to (b)2 above to achieve compliance is acceptable, in accordance with the procedure in this subchapter for review of an application for initial licensure, to the extent needed to ensure compliance with this chapter.

8:43K-2.8 Fees

(a) Subject to (b) and (c) below, the Department will charge an initial application and licensure fee of $1,750 for each facility location.

(b) The Department will charge a facility that is to provide only mental health services:

1. An initial application and licensure fee of $575.00 and $287.50 for every additional program or site license with each program service; and

2. A renewal of licensure application fee of $1,150, billed every other year, plus $575.00 for every additional program or site license within each program element.

(c) The Department will charge a facility that is to provide only reproductive health care services:

1. An initial application and licensure fee of $1,200; and

2. A renewal of licensure application fee of $400.00, billed every other year.

(d) The Department will charge an additional fee for each service that a licensee provides at each facility location in accordance with the following schedule:

Primary Licensing Service(s)	Fee
Primary care	$250.00
Reproductive health care	$250.00
Outpatient behavioral health: - Outpatient mental health and/or SUD or other addiction treatment services; - Intensive outpatient SUD or other addiction treatment services; and/or - Partial care.	$250.00
Opioid treatment program	$250.00

Adjunctive Services	
Adjunctive service added after initial licensure	**$100.00**
Alternate Care Locations and Mobile Units	
Alternate care location	**$1,000**
Mobile van	**$250.00**

(e) The total application fee for initial licensure is the sum of the applicable fees at (a), (b), (c), and/or (d) above for each service that an applicant is applying for licensure to provide, subject to any maximum amount that an applicable law establishes, including N.J.S.A. 26:2H-12.

(f) The total biennial renewal fee is the sum of the applicable fees at (a), (b), (c), and/or (d) above, for each service that the facility's existing license authorizes the licensee to provide, subject to any maximum amount that an applicable law establishes, including N.J.S.A. 26:2H-12.

(g) The Department will charge a nonrefundable fee of:

1. $375.00 for the filing of an application to add or reduce services at an existing facility license;

2. $1,500 for the filing of an application for the transfer of ownership of a facility;

3. $375.00 for the filing of an application for the relocation of a facility; and

4. $375.00 for the filing of an application for a waiver of a regulatory requirement.

(h) Subject to (i) below, every other year, the Department shall assess a fee for a periodic inspection, to be collected with the biennial licensure fee, upon each facility providing:

1. Primary care, in the amount of $200.00; and

2. SUD or other addiction treatment services, in the amount of $300.00.

(i) The periodic inspection fee established at (h) above is subject to the following:

1. A facility that exclusively provides mental health services is exempt from the assessment of a periodic inspection fee;

2. The periodic inspection fee is included as part of the initial licensure fee for new facilities;

3. Failure to pay the periodic inspection fee will result in the nonrenewal of the license for existing facilities; and

4. The Department will not assess a periodic inspection fee for any other type of inspection.

(j) A facility without revenue-generating capability may apply to the Department for a waiver of the license fee requirement, provided the facility complies with each of the following:

1. A previously licensed facility must submit a written waiver request to the Office;

2. An applicant for initial licensure must submit a waiver request with the licensure application.

i. An existing licensee seeking a waiver must submit the application for a fee waiver annually at least 60 days before the anniversary date of the expiration of the license; and

3. The written waiver request must include the following information:

i. The number of patients the facility serves, or expects to serve, weekly at the facility;

ii. The days and hours of operation;

iii. The facility's total budget, including all revenue sources;

iv. A justification demonstrating that strict enforcement of the fee requirement would impose a detrimental, disproportionate, and unreasonable hardship on the facility; and

v. A description of how payment of the fee would adversely affect the health, safety, welfare, or rights of any individual.

8:43K-2.9 Surrender of license

(a) A licensee shall issue written notice to the Office and, if the licensee provides mental health or SUD and/or addiction treatment services, to DMHAS, at least 60 days prior to the licensee's voluntary surrender of its license.

(b) Unless the Department specifies otherwise in writing, and subject to (d) below, a licensee shall issue a written notice by electronic or regular mail, at least 30 days prior to the licensee's voluntary or involuntary (that is, pursuant to an enforcement action such as a revocation order or a denial of renewal) surrender of its license, to the following:

1. Each patient who has received a service from the facility within the preceding year and who was not since discharged from care, and, if known, the patient's primary care provider; and

2. Each guarantor of payment.

(c) The notice that a licensee issues pursuant to (a) and (b) above shall:

1. Indicate the last date on which the facility will provide services (last date of service); and

2. Identify a procedure by which a patient can obtain a copy of the patient's medical record from the facility, both before and after the facility's last date of service.

(d) A licensee shall submit a surrendered license to the Office within seven working days after the last date of service.

8:43K-2.10 Waiver

(a) The Commissioner, in consultation with the Commissioner of the Department of Human Services, may waive provisions of this chapter, including for pilot programs, if, in the Commissioner's opinion, a requested waiver would not endanger the life, safety, or health of patients or the public.

(b) A facility seeking a waiver of a provision of this chapter shall apply, in writing, to the Department.

(c) A written request for waiver shall include the following:

1. The specific rule provision of which the applicant seeks waiver;

2. The applicant's reasons for requesting a waiver, including a statement of the type and degree of hardship that would result to the facility if the Department does not grant the waiver;

3. An alternative proposal that would ensure patient safety to a comparable or equivalent degree; and

4. Documentation to support the request for waiver.

(d) The Department reserves the right to request additional information before processing a request for waiver.

8:43K-2.11 Transitional licensure

(a) The Department shall deem an existing outpatient facility that is fully licensed and operational in accordance with N.J.A.C. 8:43A and/or 8:121 as of (the effective date of this chapter), to be licensed in accordance with this chapter, and thereby authorized to continue existing operations in the State without interruption until the existing license becomes due for renewal, provided the facility:

1. Is in compliance with applicable State and Federal standards and any standards of an accrediting body, including approved or directed plans of correction, and, if the entity operates another facility in the state or in another jurisdiction, the other facility is in compliance with, as applicable, standards of the State in which it is located, the other jurisdiction, the Federal government, and/or an accrediting body, including approved or directed plans of correction;

2. By (60 days after the effective date of this chapter), submits to the Office, a written notice of its intention to apply for renewal of its license in accordance with this chapter and certifies therein that it is complying as indicated at (a)1 above; and

3. Applies to the Office for renewal of its existing licensure in accordance with this chapter when the submission of its application for renewal of the provisional licensure is due, as provided at N.J.A.C. 8:43K-2.1(c).

(b) Upon receipt of an existing licensed facility's notice of intention to apply for renewal of licensure pursuant to (a)2 above, the Office will issue a certificate of transitional licensure pursuant to this chapter, which shall have the same expiration as the facility's existing license issued pursuant to N.J.A.C. 8:43A.

(c) A facility's transitional licensure status shall remain effective until the earlier of either:

1. The Office's issuance of a final determination on the facility's next application for renewal of its transitional license pursuant to this chapter; or

2. The facility's abandonment of an application for licensure renewal.

(d) A facility, as described at (a) above, that operates in the State without having obtained transitional licensure in accordance with this section is subject to enforcement action for unlicensed operation.

SUBCHAPTER 3. ENFORCEMENT

8:43K-3.1 Enforcement remedies available

(a) The Commissioner may impose the following enforcement remedies against a facility for violations of applicable laws within the Commissioner's enforcement jurisdiction and this chapter:

1. Civil monetary penalty;

2. Curtailment of services and/or admissions;

3. Appointment of a receiver or temporary manager;

4. Provisional licensure;

5. License suspension;

6. License revocation;

7. Issuance of an order to cease and desist operation of an unlicensed facility; and

8. Other remedies for violations of applicable Federal and State laws, and survey, certification, and enforcement standards and agreements.

8:43K-3.2 Notice of deficiency and enforcement action

(a) The Department shall notify a facility of the proposed imposition of an enforcement action by serving a written notice on the facility or its registered agent for service of process, either in person or by certified mail, setting forth the specific deficiencies, charges, or reasons for the action.

(b) The Department will serve a notice of an enforcement action upon a licensee or its registered agent, in person or by certified mail.

8:43K-3.3 Action against a license

(a) If the Department determines that operational or safety deficiencies exist at a facility, the Department may direct the cessation of services that the facility provides or admissions to the facility by issuance of a written order to the facility for curtailment of services or admissions pursuant to N.J.A.C. 8:43K-3.7, which may occur concurrently with other enforcement actions.

(b) The Department may issue a written order imposing a penalty on a facility for violation of this chapter or other applicable law.

(c) The Department may suspend or revoke the license of a facility pursuant to N.J.A.C. 8:43K-3.5 or 3.6 for failure to correct a violation of this chapter or other applicable law that poses a risk of harm to a patient.

8:43K-3.4 Monetary penalties

(a) A facility that the Department licenses to provide health care services in accordance with N.J.A.C. 8:43K-7 is subject to the imposition of monetary penalties in accordance with N.J.A.C. 8:43E-5.6.

(b) A facility that is subject to licensure pursuant to this chapter that operates without a license is subject to the following penalties:

1. For operation of a facility without a license to provide licensed mental health services or licensed medical services, or continued operation of a facility after suspension or revocation of a license, $2,500 per day for a first occurrence

and $5,000 per day for a subsequent occurrence, from the date of initiation of services;

2. For operating, or continuing to operate, a facility providing SUD and/or addiction treatment services without a license or upon suspension or revocation of a license, $25.00 per day for a first occurrence and $50.00 per day for each subsequent occurrence, from the date of initiation of services; and

3. For failure of an SUD and/or addiction treatment services provider to report information to the Department as required by applicable law, after reasonable notice and an opportunity to cure the failure, $500.00 per day, pursuant to N.J.S.A. 26:2B-14.

8:43K-3.5 License suspension

(a) The Department may issue a notice of proposed order suspending a facility's license to perform services or a component of the facility's licensed services, upon finding that:

1. A deficiency relating to patient care exists; or

2. The physical facility poses an immediate threat to the health, safety, and welfare of the public or a patient.

(b) A notice of proposed suspension order may direct a facility to cease and desist the provision of services, arrange the orderly transfer of patient care to other appropriate facilities, and/or implement other remedial and protective measures.

1. The written notice shall specify the identified deficiency, the finding upon which the order is based, and the terms of the suspension order.

2. Absent exigent circumstances, the notice will allow the facility 72 hours from its receipt of the notice to correct the deficiency and provide proof of the correction to the Department.

3. The notice will indicate that the facility can contest the proposed suspension by submitting a written request for a hearing in accordance with N.J.A.C. 8:43K-3.11 within 48 hours of the facility's receipt of the notice.

(c) The Department will review a facility's submission, pursuant to (b)2 above, of notice of its correction of the deficiency and the corrective actions the facility undertook and determine whether the deficiency is corrected.

1. If the Department determines that the facility has not corrected the deficiency, then the Department will issue a suspension order that has immediate effect.

2. If the facility requests a hearing pursuant to (b)3 above, the Department shall convene an immediate hearing and the Commissioner shall issue a final agency decision within 48 hours of the hearing that has immediate effect, in which the Commissioner affirms, modifies, or rescinds the suspension order.

3. Following a hearing pursuant to (b)3 above, a facility may appeal the decision to the Superior Court of New Jersey, Appellate Division.

(d) Upon a suspension order becoming a final agency decision, a facility's activities to implement the suspension order, including cessation of services

and/or patient transfers, are subject to Department review, approval, and coordination.

(e) Notwithstanding the issuance of a suspension order, the Department may concurrently or subsequently impose other enforcement actions.

(f) The Department may issue an order lifting a suspension upon finding that the facility has corrected the conditions that were the basis for the action.

8:43K-3.6 License revocation

(a) The Department may issue a notice of the proposed revocation of a facility license if:

1. The facility fails to comply with this chapter or other applicable law and:

i. Does not correct the noncompliance in accordance with an approved plan of correction; and

ii. The failure poses a risk of harm to, or does harm, the health, safety, and welfare of patients;

2. The facility exhibits a pattern and practice of violating this chapter or other applicable law, posing a risk of harm to the health, safety, and welfare of residents or patients.

i. A pattern and practice may be demonstrated by repeated identical or related violations during three consecutive surveys; and

ii. The issuance of civil monetary penalties pursuant to N.J.A.C. 8:43K-3.4 or other enforcement actions for unrelated violations following three or more consecutive surveys;

3. The facility's failure to correct an identified deficiency leads to the issuance of an order for suspension of a license, pursuant to N.J.A.C. 8:43K-3.5; or

4. A facility remains on provisional licensure status for 12 months or more.

(b) The Department will serve a notice of revocation in accordance with N.J.A.C. 8:43K-3.2, and the facility has a right to request a hearing pursuant to N.J.A.C. 8:43K-3.11.

8:43K-3.7 Curtailment of admissions and services

(a) The Department may issue an order curtailing new admissions or readmissions and/or a facility's provision of services if:

1. The Department determines that the facility's violation of this chapter or other applicable law poses an immediate and serious threat of harm to the facility's patients;

2. To limit new admissions when the Department issues a notice of proposed revocation or suspension of the facility's license that will lead to facility closure and a corresponding need to transfer patients to other facilities upon the closure; or

3. The admission or readmission of new patients to the facility would impair the facility's ability to correct serious or widespread violations of this chapter or other applicable law related to direct patient care and diminish the quality of care.

(b) The Department may issue an order lifting a curtailment following a survey upon which the Department finds that the facility is in substantial compliance with this chapter or other applicable law, and there is no immediate and serious threat to patient safety.

1. An order lifting the curtailment may limit patient admissions, as necessary, to protect patient safety.

8:43K-3.8 Cease and desist order

The Commissioner may issue an order requiring an unlicensed or unauthorized facility or service to cease and desist operation pursuant to N.J.S.A. 26:2H-5.1g.

8:43K-3.9 Conditional license

(a) The Department may issue a conditional license to a facility that provides mental health treatment services if:

1. The Department determines, following a review, that the facility is not in compliance with this chapter;

2. The facility fails to timely submit a remediation plan to the Department;

3. The Department determines that the facility's submitted remediation plan is inadequate; or

4. The Department identifies deficiencies following an investigation of a complaint or serious incident that warrant conditional status.

(b) The Department will upgrade a conditional license to a full license when the Department determines in a follow-up review that the facility meets all relevant licensing requirements.

(c) The Department may impose conditional licensure status on a facility providing any type or category of SUD and/or addiction treatment services when the purposes and intent of the proposed program are outside the scope of a regular license.

(d) A conditional license is subject to applicable provisions of this chapter unless the conditional license specifically identifies the terms of an alternative compliance requirement.

(e) A licensee operating pursuant to a conditional license shall post the conditional license letter and the conditional license in a conspicuous location in the facility.

(f) The Department may issue a conditional license if it determines that it is in the best interest of the clients benefiting from the treatment program in question and to preserve and/or improve the proper functioning of the program.

(g) The Department may issue a conditional license to address contingencies and/or special program needs that the applicant can address, and the Department can monitor, as agreed upon between the Department and the applicant, with the safety and well-being of the clients and staff of the program as the overriding priority.

(h) The Department may issue a conditional license to a licensee that the Department reviewed before the licensee began to provide services.

1. Within 30 working days of the Department's receipt from the licensee of written notification that the facility it is fully operational, the Department shall schedule a follow-up visit to determine whether the facility is functioning in accordance with this chapter and is eligible to receive a full license.

(i) A conditional license is not assignable or transferable, and immediately becomes void if the ownership of a conditionally licensed facility changes, or the facility ceases to operate or is relocated to a different site.

8:43K-3.10 Hearings

(a) Following the Department's issuance of notice to a facility of a proposed enforcement action in accordance with N.J.A.C. 8:43K-3.2, the facility may request an administrative hearing to contest the action.

(b) A facility shall notify the Department of its intention to request a hearing, in the manner that the notice of proposed enforcement action specifies, within 30 days of the date of the notice.

(c) The Department shall transmit a hearing request submitted pursuant to (b) above to the Office of Administrative Law.

(d) The Office of Administrative Law shall conduct a hearing in accordance with 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.

SUBCHAPTER 4. OPERATIONAL STANDARDS APPLICABLE TO ALL LICENSED OUTPATIENT FACILITIES

8:43K-4.1 Compliance with law

(a) A licensee shall comply with applicable Federal, State, and local laws.

(b) If a licensee provides services in addition to those for which it obtains licensure pursuant to this chapter, the facility shall comply with the rules in this chapter and the applicable service-specific standards for the other services it provides.

(c) A facility that the Department licenses to provide services that are subject to licensure pursuant to the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq., is subject to N.J.A.C. 8:43E, the General Licensure Procedures and Standards Applicable to All Licensed Facilities, and applicable provisions at N.J.A.C. 8:43A.

(d) If applicable law requires a licensed or adjunctive service to be performed by a professional holding a specific credential, the facility shall ensure that the service is provided only by a professional who holds the credential required by law and who is acting within the professional's credentialed scope of practice.

8:43K-4.2 Governing authority

(a) A licensee shall have a governing authority that is responsible for the management, operation, and fiscal stewardship of the facility.

(b) The governing authority shall act in accordance with bylaws that set forth policies and procedures for its conduct and oversight of the operation of the facility, which, at a minimum:

1. Establish the methodology by which the governing authority is to establish, review, approve, and/or amend bylaws and facility policies and procedures, and create written records memorializing these activities;

2. Identify the frequency of meetings of the governing authority and its committees, or equivalent, the procedures by they will conduct meetings, and the documentation of meeting activity through the establishment of written meeting minutes;

3. Delineate the duties of the officers and any committees, or equivalent, of the governing authority.

i. When the governing authority establishes committees, document each committee's purpose, structure, responsibilities, authority, and relationship to other entities within the facility; and

ii. Establish the qualifications of members and officers of the governing authority, the procedures for electing and appointing officers, and the terms of service for members, officers, and committee chairpersons or equivalent; and

4. Establish conflict of interest and disclosure policies for members of the governing authority, paid employees, and volunteers.

(c) The governing authority, at a minimum, shall oversee:

1. The services the facility provides and the quality of care the facility renders to its patients;

2. The provision and maintenance of a safe physical plant that is equipped and staffed to provide services;

3. The appointment, reappointment, assignment of privileges, and curtailment of privileges of providers, and the written documentation of such actions;

4. The development, review, and revision, as necessary, of facility policies and procedures in accordance with a schedule that the governing authority establishes;

5. The establishment and implementation of a system by which patients and staff can submit grievances and/or recommendations that includes a mechanism for documentation of the review of the submission, and any action taken;

6. The implementation of proper financial controls;

7. The establishment of a scope of an administrator's work that is reconciled with the facility's mission; and

8. The appointment and supervision of an administrator following review and verification of the administrator candidate's references, credentials, and criminal history record.

8:43K-4.3 Administration

(a) A governing authority shall appoint an administrator who is accountable to the governing authority.

1. The governing authority shall ensure the administrator has not been convicted of a crime relating adversely to the administration of the facility unless there is evidence of rehabilitation pursuant to N.J.S.A. 2A:168A-1 et seq.

(b) The administrator shall have:

1. An associate degree and two years of full-time, or full-time equivalent, administrative experience in a clinical setting; or

2. Four years of full-time, or full-time equivalent, administrative experience in a clinical setting.

(c) The administrator shall designate, in writing, one or more alternates, who have credentials that are equivalent or comparable to those at (b) above, to act in the absence of the administrator.

1. The administrator, or the administrator's designee, shall be always available when patients are on site at the facility.

(d) The administrator, at a minimum, shall:

1. Ensure the development, implementation, and enforcement of all policies and procedures;

2. Participate in the quality assurance and performance improvement program;

3. Ensure that all personnel are assigned duties based upon their education, training, competencies, and job descriptions;

4. Ensure the provision of staff orientation and staff training;

5. Ensure maintenance of the physical plant, as necessary, to ensure patient and staff safety; and

6. Develop a continuity of operations plan in case of facility closure, staff unavailability, or other impediment to routine provision of services.

8:43K-4.4 Quality assurance plan

(a) The administrator shall appoint an individual responsible for coordinating the quality assurance and performance improvement program.

1. The facility shall establish a multidisciplinary committee to develop the facility's quality assurance and performance improvement program.

2. The multidisciplinary committee shall consist of representatives from administration and the treatment staff of each service discipline that the facility offers.

3. The committee shall establish a mechanism to identify areas for review and improvement of patient care throughout the facility.

4. The committee shall establish, implement, and annually review and revise, as necessary, a written plan for a quality assurance and performance improvement program for patient care and safety, which describes the process for ongoing monitoring and evaluation of patient care.

8:43K-4.5 Submission of documents and data

(a) A licensee shall collect and submit to the Department, upon request, the number of:

1. Patient visits, by payment source;

2. Distinct patients served, by payment source;

3. New patients accepted; and

4. Practitioners, by type and credential, providing services in the facility.

(b) A facility that the Department licenses to provide behavioral health services pursuant to this chapter shall:

1. Cooperate with monitoring activities (for example, audits, complaint reviews, and investigations), and provide access to data, medical records, and information, upon request, to the Department, DHS, and/or DMHAS, as part of each entity's separate or combined monitoring activities and/or obligations; and

2. Timely report and submit data and information into electronic databases and/or management systems (such as NJSAMS) that DHS and/or DMHAS designate.

8:43K-4.6 Policy and procedure manual

(a) A facility administrator shall develop, implement, and ensure the periodic review, at least annually and more frequently, as needed, and revision of, a policy and procedure manual for the organization and operation of the facility.

(b) The governing authority shall review the manual and make it available to patients, staff, and the Department.

(c) A facility's policy and procedure manual shall include, at a minimum:

1. A written statement describing the facility's treatment philosophy, objectives, and staffing patterns, and the services provided by the facility;

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

3. A description of the quality assurance and performance improvement program for patient care and staff performance, including methods for at least annual review of staff qualifications, credentials, performance, supervision, orientation, and education;

4. A specification of the facility's hours of operation, including all times in which patients are present in the facility, business hours, and a full working week;

5. Privacy and confidentiality policies and procedures ensuring the confidential maintenance of patient information while the facility is in operation and if the facility were to cease to operate, in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Public Law 104-191 (enacted August 21, 1996), and regulations promulgated pursuant thereto at 45 CFR Parts 160, 162, and 164, and 42 U.S.C. §§ 290dd-2 et seq., and regulations promulgated pursuant thereto at 42 CFR Chapter I, Subchapter A, Part 2, Confidentiality of Substance Use Disorder Patient Records;

6. Policies and procedures ensuring adherence to laws restricting payment and incentives for patient referrals, including the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), and the Physician Self-Referral Law, 42 U.S.C. § 1395nn;

7. Policies and procedures for the safe storage, dispensing, and/or administration of medications, if applicable;

8. Policies and procedures for responding to emergency situations, including assaultive and suicidal behavior and ideation, acute decompensation, and medical emergencies;

9. Policies and procedures for reporting critical incidents, complaints, abuse, and threats in accordance with N.J.A.C. 8:43K-4.13;

10. Policies and procedures regarding patient rights in accordance with N.J.A.C. 8:43K-5.9;

11. Policies and procedures that ensure continuity of care for patients;

12. Policies and procedures for the maintenance of personnel records pursuant to this subchapter; and

13. Policies and procedures addressing the confiscation and disposition of illicit substances and weapons within the facility.

8:43K-4.7 Patient records

(a) A facility shall establish and implement written policies and procedures regarding patient physical and/or electronic medical records that it reviews at least annually and revises, as necessary, and which address:

1. The protection of medical record information against loss, tampering, alteration, destruction, or unauthorized use;

2. The specific period, not to exceed 30 days, within which the medical record is to be completed following treatment or discharge; and

3. The transfer of patient information when a facility transfers patient care to another facility or provider.

(b) A facility shall establish and maintain a current, complete medical record for each patient.

1. A patient's medical record shall include, at a minimum:

i. Patient identification data, including name, date of admission, address, date of birth, race, religion (optional), sex at birth, gender identity as of the admission, and language; and

ii. The name, address, and telephone number of a person or persons that a facility is to notify in an emergency.

(c) A facility shall ensure that every entry in a patient's medical record is typewritten or written legibly in ink, dated, and either signed by the person entering it, if it is a physical record, or authenticated, if the facility uses an electronic medical record system.

1. A provider shall verify or countersign a spoken order within seven days.

2. A facility that uses computer-generated orders with a prescriber's electronic signature shall establish and implement a procedure to ensure the confidentiality of each electronic signature and prohibit the improper or unauthorized use of a computer-generated signature.

(d) A facility shall ensure that a patient's medical record is completed within the period that the facility's medical record policies and procedures specify, which shall be no longer than 30 days from the later of either the facility's last treatment of a patient or the patient's discharge.

(e) A facility shall prohibit and prevent the removal of an active patient's original medical record, or any portion thereof, from facility premises unless applicable law requires the removal of the record from the premises or as needed to safeguard the record in an emergency, such as a physical plant failure or natural disaster.

1. A facility that uses off-site storage of archived physical records shall provide details of the storage arrangement to the Department, including the location at which records are stored and how the facility will ensure retrieval and delivery of a patient's record within one business day.

(f) A facility shall maintain a system in which a patient's complete medical record is filed as one unit, except for psychotherapy notes pursuant to 45 CFR 164.501 or certain SUD and/or addiction treatment information pursuant to 42 CFR Part 2.

(g) A facility shall have an internal system of access and identification for the medical record of each patient.

(h) A facility shall preserve the confidentiality of information included in a patient's medical record in accordance with applicable Federal and State law, including applicable provisions at 42 U.S.C. §§ 290dd-2 and 290ee-2, 42 CFR Part 2, and HIPAA.

(i) A facility shall ensure that each patient's medical record is always available during facility operating hours to facility health care practitioners who participate in the patient's care.

(j) A facility shall designate an employee to function as coordinator of medical record services and an employee to act in the absence of the coordinator, to always ensure staff access to the medical records during facility operating hours.

(k) A facility shall preserve medical records in accordance with N.J.S.A. 26:8-5.

1. A facility intending to cease operations shall notify the Department, in writing, at least 30 days before cessation of operations of the location at which the facility will store patient medical records, the procedure by which a patient or the Department can retrieve records, and the name of the person or entity responsible for retrieving records upon request.

(l) A facility shall maintain the confidentiality of patient records and shall not disclose patient information, except in accordance with applicable Federal and State law, including 42 CFR Part 2 and 45 CFR Parts 160 and 164.

(m) A patient, the patient's legally authorized representative, or a third-party insurer, as permitted by law, may request or authorize, in writing, that a copy of the patient's medical record be provided to one of them or released to a third party.

(n) A facility, upon receiving a duly authorized patient request, shall furnish a legible, written copy of a patient's record within 30 days of the request. The facility may charge a fee for such production based on actual cost, in accordance with the following:

1. The fee for copying a patient's medical record shall not exceed $1.00 per page, or $50.00 for the record, whichever is less;

2. In addition to authorized fees per page, a facility is authorized to impose:

i. A search fee of no more than $10.00 per patient per request; and

ii. A postage charge for the actual cost of mailing;

3. A facility shall not impose charges other than, or exceeding, those permitted at (n)1 and 2 above;

4. A facility shall establish a policy to ensure that a patient who does not have the ability to pay can obtain copies of medical records; and

5. A facility shall establish a fee policy that provides an incentive for the use of abstracts or summaries of medical records, provided an authorized person requesting a medical record has the right to receive a full and/or certified copy of the medical record.

(o) A facility shall limit access by a patient to the patient's medical record only to the extent necessary to protect the patient.

1. A patient's treating provider shall give the patient or the patient's legally authorized representative a written or spoken explanation for any denial of access to the patient's medical record, and document in the medical record, the explanation for denial of access and the manner in which the treating provider explained the denial.

2. If a patient's treating provider determines, and documents in the patient's medical record, that the patient's direct access to the patient's medical record is medically contraindicated, the facility shall make the medical record available to the patient's a legally authorized representative or the patient's duly authorized physician or other health care provider.

(p) The fees authorized by this section shall not be imposed on a patient or an attorney representing a patient who has a pending application for, or is currently receiving, Federal Social Security disability benefits provided pursuant to Title II or Title XVI of the Federal Social Security Act, Pub L.92-603 (42 U.S.C. §§ 1351 et seq.).

8:43K-4.8 Notices

(a) A facility shall post a notice in the facility waiting room stating that the following information is available in the facility during business hours to patients and the public:

1. All waivers that the Department has granted the facility;

2. A list of deficiencies identified during the last licensure inspection of the facility;

3. The facility's last CMS certification survey report;

4. A list of deficiencies identified during a complaint investigation conducted on the facility during the preceding 12 months;

5. A statement of patient rights;

6. The names of the members of the facility's governing authority;

7. The addresses to which one may send correspondence to the facility and its governing authority; and

8. The operating and business hours of the facility.

8:43K-4.9 Emergency and disaster plans

(a) A facility shall establish and implement written emergency plans, policies, and procedures to be followed in case of potential hazards that could necessitate an evacuation, including internal and external disasters, such as fire, natural disaster, active shooter, bomb threat, or industrial or radiological accidents.

(b) A facility's emergency procedures shall include, at a minimum:

1. Protocols for notification of emergency services providers and officials;

2. Locations of emergency equipment and alarm signals;

3. Evacuation routes;

4. Procedures for evacuating patients;

5. Identification of one or more facilities to which the facility would refer patients in the event of extended closure of the facility;

6. Procedures for reentry after evacuation;

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

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

9. Procedures for alternative plans of care if patients cannot be returned to the facility.

8:43K-4.10 Management of medical emergencies

(a) A facility shall establish written policies and procedures that it reviews annually and revises, as needed, for the management of medical emergencies

based on the types of patients typically treated at the facility, which, at a minimum:

1. Specify the locations, contents, frequency of and assignment of responsibility for checking contents (including expiration dates) of emergency kits;

2. Ensure that emergency kits are secure but not kept under lock and key;

3. Enable the facility to respond to medical emergencies occurring on-site during its hours of operation;

4. Enable the facility to coordinate emergency transportation to, and emergency medical services at, a nearby hospital, which can include using 911;

5. Whenever there is a patient on site, require at least one staff member to be available who has training in the use of the emergency equipment that the facility maintains on site, and holds certification:

i. In basic cardiac life support by the American Heart Association, the American Red Cross, or the National Safety Council; or

ii. As an emergency medical technician;

6. Require the facility to have at least one defibrillator available in a central location and a written protocol on the use of the defibrillator that addresses:

i. The testing and maintenance of the defibrillator according to the manufacturer's operational guidelines; and

ii. The training of staff in the use of the defibrillator;

7. Require posting in each area in which patients may receive services, the telephone numbers of:

i. Police, fire, and ambulance services; and

ii. The State poison control center; and

8. Require the facility to maintain at least one emergency opioid overdose reversal kit containing a minimum of two doses of an opioid antidote and to have a written protocol on its use that addresses:

i. The training of staff in the use of emergency opioid antidotes;

ii. Availability of emergency opioid overdose reversal kit near to a defibrillator; and

iii. A protocol to check and monitor the expiration date of opioid antidotes doses and replacement thereof prior to expiration.

8:43K-4.11 Personnel general requirements

(a) A facility shall:

1. Develop written job descriptions;

2. Assign duties to an employee based on, as applicable to the position, the employee's credential and associated scope of practice, education, training, and competencies;

3. Maintain personnel schedules to ensure continuity of care within the facility;

4. Maintain personnel records for each employee, which include, copies of the employee's credentials, if applicable to the employee's position;

5. Have at least one person always present during operating hours who holds certification in basic cardiac life support;

6. Maintain compliance with applicable State and Federal labor law and be in good standing with applicable labor law enforcement authorities;

7. Develop policies and procedures identifying the circumstances pursuant to which:

i. The facility will conduct a criminal history record review history of prospective and current employees, and the methods by which it will conduct the assessment; and

ii. The facility will require pre-employment and random drug screening and respond to a positive drug screening;

8. Establish and implement a staff orientation plan and a staff education plan, including plans for each service and designation of personnel responsible to provide training; and

9. Require all personnel to receive orientation at the time of employment and at least annual in-service education, which activities the facility shall document in each employee's employment record, addressing, at a minimum:

i. Emergency plans and procedures;

ii. The infection prevention and control program, if required pursuant to N.J.A.C. 8:43K-7;

iii. Standard precautions;

iv. Policies and procedures concerning patient and staff rights;

v. Use of new clinical procedures, new equipment, and innovative technologies, where required;

vi. Cultural competency and cultural humility;

vii. Policies concerning conflict of interest;

viii. Confidentiality;

ix. Areas identified in the quality assurance and performance improvement program as needing educational programs;

x. Human trafficking pursuant to N.J.A.C. 8:43E-14, if applicable;

xi. Pain management pursuant to N.J.A.C. 8:43E-6.5, if applicable;

xii. If appropriate, given the patient population of the facility, identification, reporting, and documentation of cases of child abuse and/or elder abuse; and

xiii. Lactation rooms pursuant to N.J.A.C. 8:43E-15, if applicable.

(b) A facility shall screen and test every personnel member who is to provide direct care to patients for tuberculosis in accordance the tuberculosis guidelines, regardless of the member's status as being directly employed, under contract, and/or volunteering.

1. Guidance material for implementing this standard is available at CDC, TB Prevention in Health Care Settings, https://www.cdc.gov/tb-healthcare-settings/index.html.

8:43K-4.12 Employee health

(a) A facility's policies and procedures manual shall include policies and procedures to ensure that physical examinations of employees are performed upon employment and subsequently shall specify:

1. The circumstances through which other persons providing direct patient care services shall receive a physical examination; and

2. The content and the frequency of the examinations for employees and other persons providing direct patient care services.

(b) Each employee who cannot document the result of a previous rubella screening test shall be given a rubella screening test using the rubella hemagglutination inhibition test or other rubella screening test approved by the Department.

1. A facility shall administer the rubella screening test upon employment to each new employee who cannot document the result of a previous rubella screening test.

i. An employee who can document seropositivity from a previous rubella screening test or who can document inoculation with rubella vaccine shall not be required to have a rubella screening test.

2. A facility shall inform each tested employee in writing of the results of the employee's rubella screening test.

3. A facility shall ensure that each employee's personnel record includes documentation of all tests performed and the results.

4. A facility shall maintain a list of all employees who are seronegative and unvaccinated, to be used in the event that an employee is exposed to rubella and a determination is needed as to whether or not the employee may continue to work.

(c) A facility shall administer a measles (rubeola) screening test using the hemagglutination inhibition test, or other rubeola screening test to each employee who was born in 1957 or later, by (180 days after the effective date of this rulemaking), with respect to an existing employee, and upon employment, with respect to a new employee upon employment.

1. A facility shall not require an employee who was born in 1957 or later to receive a measles (rubeola) screening test if the employee can provide documentation of:

i. Receipt of a live measles vaccine on or after their first birthday;

ii. Having contracted physician-diagnosed measles; or

iii. Serologic evidence of immunity.

2. A facility shall inform each tested employee, in writing, of the results of the employee's measles (rubeola) screening test.

3. A facility shall ensure that each employee's personnel record includes documentation of all tests performed and the results.

4. A facility shall maintain a list all employees who are seronegative and unvaccinated, to be used in the event that an employee is exposed to measles (rubeola) and a determination is needed as to whether or not the employee may continue to work.

(d) A facility shall establish policies and procedures for the detection and control of the transmission of *Mycobacterium tuberculosis* that include, but are not limited to, development of a tuberculosis exposure control plan (TB plan), according to the guidelines set forth in the "Guidelines for Preventing the

Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005," incorporated herein by reference, as amended and supplemented, published in the Morbidity and Mortality Weekly Report, at MMWR 2005; 54 (No. RR-17) (December 30, 2005), Coordinating Center for Health Information and Service, available at https://www.cdc.gov/mmwr/PDF/rr/rr5417.pdf and at https://www.cdc.gov/mmwr/preview/mmwrhtml/rr5417a1.htm, pursuant to the Occupational Safety and Health Act of 1970, Public Law 91-596.

1. A facility shall establish policies and procedures to identify each new employee's baseline status of exposure to *Mycobacterium tuberculosis* upon employment, and shall administer a two-step Mantoux tuberculin skin test, using five tuberculin units of purified protein derivative, to all employees.

i. A facility shall administer a second Mantoux test in one to three weeks after the first Mantoux test to each employee who has a "negative" result (that is, less than 10 millimeters of induration or less than five millimeters of induration if the individual is immunosuppressed) following the first Mantoux skin test.

ii. A facility shall refer each employee who has a "positive" result (that is, greater than or equal to 10 millimeters of induration or greater than or equal to five millimeters of induration if the individual is immunosuppressed), following either the first or second test, for medical evaluation to determine whether there is evidence of latent tuberculosis infection or active tuberculosis disease, which medical evaluation shall include, but not be limited to, a chest X-ray.

(1) A facility shall permit an employee who has a positive Mantoux test result to begin working after the employee submits written medical clearance to the facility.

iii. Subparagraphs (d)1i and ii above are subject to the following exceptions:

(1) A facility shall require an employee who provides documentation of negative results of a single Mantoux skin test performed within the 12 months preceding the start of employment to receive only one Mantoux skin test upon hire.

(2) A facility shall not require an employee who provides documentation of negative results of two Mantoux skin tests performed within the 12 months preceding the start of employment, and who shows no signs or symptoms of active tuberculosis, to receive a Mantoux skin test upon hire, but shall require the employee to receive a Mantoux skin test within 12 months of the last tuberculin skin test.

(3) A facility shall not require an employee who provides documentation of a positive Mantoux skin test result to receive a Mantoux skin test.

(4) A facility shall not require an employee who provides documentation of having received and completed appropriate medical treatment for active tuberculosis disease or latent tuberculosis infection to receive a Mantoux skin test.

2. A facility shall establish policies and procedures for the periodic screening of employees for *Mycobacterium tuberculosis* that include at least the following requirements:

i. The facility shall administer a Mantoux skin test to all tuberculin-negative employees at least annually;

ii. The frequency of testing shall be determined by the level of risk the facility's TB plan establishes; and

iii. The facility shall maintain records of the results of employee Mantoux tuberculin testing.

3. Questions regarding tuberculosis control may be directed to the Tuberculosis Control Program.

(e) A facility shall establish policies and procedures to address employee safety, which include procedures for the care of employees who become ill, or are injured, at the facility.

8:43K-4.13 General reportable events

(a) A facility shall establish and implement policies and procedures governing the reporting and management of adverse events.

(b) A facility shall establish and implement policies and procedures, including deadlines, for verbal and written notification to the governing authority of reportable events in this chapter.

(c) A facility shall report to the Office, in writing:

1. The resignation or termination of the administrator, along with the name of the replacement within three days;

2. A known death of a patient of the facility, including deaths known or suspected to have resulted from misuse of medications prescribed or dispensed by the facility, when applicable;

3. A disciplinary action initiated toward a staff member, including termination, resulting from inappropriate staff interaction with a patient;

4. A criminal conviction of, or a credentialing board's imposition of a disciplinary sanction against, a staff member, a board member, or a representative of the governing authority, since the most recent of either the facility's initial license application or last application for renewal of licensure; and

5. An alleged or suspected crime that endangers the life or safety of patients or staff or that jeopardizes facility operations or fiscal stability.

(d) A facility shall inform a patient or staff member against whom an alleged, suspected, or confirmed crime has been committed of the patient's or staff member's right to report an incident to local police or another law enforcement authority, and shall document the provision of this notice in the patient's medical record or staff member's personnel record, as applicable.

1. If a patient or staff member, having received the notice required pursuant to (d) above declines or refuses to notify a law enforcement authority of an alleged, suspected, or confirmed crime, the facility shall document the declination or refusal in the patient's medical record or staff member's personnel record, as applicable.

(e) A facility shall ensure that:

1. The administrator receives notice of an alleged, suspected, or confirmed crime that endangers the life or safety of patients or staff or that jeopardizes facility operations or fiscal stability and whether the patient or staff member elected to report the event to law enforcement authorities; and

2. The governing body receives notice of an alleged or suspected crime endangering the life and/or safety of a patient or a staff member, or suspected crimes that jeopardize the facility's operations or fiscal stability.

(f) Notwithstanding the declination or refusal of a patient or staff member to report the alleged or suspected crime, nothing in this chapter shall be construed to limit either:

1. The ability or authority of any entity, including a facility, to report an alleged or suspected crime; or

2. The responsibility of any entity to report a confirmed or suspected event that the entity has an affirmative duty to report pursuant to applicable law.

8:43K-4.14 Patient transportation

(a) Facilities that use a vehicle for patient transportation, whether the facility or another entity owns or operates the vehicle, must be in good standing and shall:

1. Establish and implement policies and procedures to ensure passenger and driver safety, including responses to emergencies during transportation;

2. Ensure that the vehicle and the operator of the vehicle follow applicable motor vehicle and insurance law;

3. Maintain a copy of the vehicle registration, insurance information, and maintenance and service logs;

4. Confirm the validity or status of the driver's license of each operator who engages in patient transportation at least every six months, and maintain on file, a copy of each operator's driver license; and

5. Prohibit tobacco use at all times by staff members and patients in vehicles used for patient transportation, regardless of the presence of a patient during the tobacco use.

8:43K-4.15 General physical plant and functional requirements

(a) A facility shall:

1. Maintain a clean and safe environment for patient care;

2. Demonstrate compliance with applicable State and local building, fire, safety, and health code requirements;

3. Ensure that there is adequate space for the provision of services and the privacy of patient care and treatment;

4. Ensure facility compliance with applicable laws governing access for people with disabilities, including the Barrier-Free Subcode of the New Jersey Uniform Construction Code, N.J.A.C. 5:23-7; and

5. Ensure compliance with the New Jersey Smoke-Free Air Act, N.J.S.A. 26:3D-55.

(b) A facility that provides multiple licensed services is not required to maintain separate entrances or waiting areas.

8:43K-4.16 Drills, tests, and inspections

(a) A facility shall conduct drills of emergency plans on each shift at least quarterly.

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

2. The drills on each shift shall include at least one drill for emergencies due to fire and one drill for emergencies due to disasters other than fire, such as a storm, flood, other natural disaster, bomb threat, or radiological accident.

(b) A facility shall perform semi-annual visual inspections and annual operational tests of the building's manual-pull alarm system and shall maintain documentation of inspections, test dates, locations of tested manual-pull alarms, persons testing the alarms, and test results.

(c) A facility shall ensure that fire extinguishers are examined annually and maintained in accordance with manufacturers' requirements, National Fire Protection Association (N.F.P.A.) 10, as amended and supplemented, and N.J.A.C. 5:70, the New Jersey Uniform Fire Code.

(d) A facility shall:

1. Request, at least annually, the local fire code authority to perform a fire inspection of the facility, and maintain documentation of the date of inspection, the results, and the inspector or agent conducting the inspection;

2. Ensure that an inspection of the fire detection system is performed at least semiannually, and maintain documentation of the date of inspection, the results, and the inspector or agent conducting the inspection;

3. Ensure that an inspection of the automatic sprinkler system, if applicable, is performed at least semiannually, and maintain documentation of the date of inspection, the results, and the inspector or agent conducting the inspection;

4. Perform, at least monthly, testing of emergency lighting, and maintain a logbook that documents the date of each test, the results, and the person conducting the test;

5. Ensure that an elevator inspection, if applicable, is performed in accordance with N.J.A.C. 5:23-12.3 of the Elevator Safety Subcode, and maintain documentation of the date of inspection, the results, and the licensed official or inspector conducting the inspection;

6. Ensure that the heating and ventilation system is inspected at least annually and maintain documentation of the date of inspection, the results, and the inspector or agent conducting the inspection; and

7. Ensure that the temperature of the hot water used in the facility is tested in accordance with the policies and procedures of the facility, and maintain a logbook that documents the date of each test, the results, and the person conducting the test.

8:43K-4.17 Housekeeping, environmental sanitation, and safety

(a) A facility administrator shall designate a person or entity responsible for housekeeping and environmental services in the facility, who may be a contracted provider.

(b) A facility shall ensure that:

1. Upon hire, at least annually thereafter, and more frequently, as necessary, the facility trains housekeeping personnel in the facility's cleaning procedures, including the selection and use of appropriate chemicals in the cleaning and care of equipment and surfaces;

2. The facility establishes and implements written policies and procedures that are reviewed, and revised, as necessary, at least every three years, and more frequently, as needed, which identify, at a minimum, the scope of responsibility, assignment by designated unit, and responsibility for cleaning tasks;

3. The facility establishes a written schedule that determines the frequency of cleaning and maintaining cleanliness for all equipment, structures, areas, and systems;

4. With respect to cleaning and disinfecting agents, pesticides, herbicides, and other materials the facility uses, including products that are repackaged from a bulk source, the facility complies with applicable State and Federal law, including the State Pesticide Control Code, N.J.A.C. 7:30, and manufacturer instructions, regarding:

i. Acquisition and labeling;

ii. Handling, preparation, measurement, and use;

iii. Appropriate and secure storage in a location that is inaccessible to patients; and

iv. The maintenance and availability of records and each product's respective Safety Data Sheet;

5. The facility keeps all areas, including areas with limited access, such as cabinet drawers, locked medication rooms, and storage areas, clean to sight and touch and free of condensation, mold growth, and noxious odor;

6. The facility keeps toilets and bathrooms clean to sight and touch, in good repair, and free of odors that reflect poor housekeeping practices;

7. In each bathroom, the facility always makes available toilet tissue, soap, and either disposable towels or air dryers;

8. At each handwashing sink, the facility always makes available soap and either disposable towels or air dryers;

9. The facility keeps reusable hand-cleanser dispensers clean and recleans each dispenser entirely between each refilling;

10. The facility keeps carpeting clean and odor-free, and ensures that the carpeting is not frayed, worn, torn, or buckled;

11. The facility keeps partitioning curtains, walls, ceilings, and vents, clean to sight and touch, and odor-free;

12. The facility keeps windows and screens clean to sight and touch, and in good repair;

13. The facility uses safe and effective controls to minimize and eliminate the presence, prevent the breeding, harborage, or feeding, and effectively protect

openings to the outer air against the entrance of insects, vermin, and rodents in the facility;

14. The facility uses nonskid wax on all waxed floors;

15. The facility washes communal toys after each use and does not use or make available communal stuffed or fabric-based toys; and

16. The facility prohibits the presence of live plants and flowers in procedure rooms or sterile processing areas.

8:43K-4.18 Housekeeping policies and procedures

(a) The housekeeping service shall have written policies and procedures that are reviewed every three years or, as needed, revised, as needed, and implemented.

1. The housekeeping policies and procedures shall include, at a minimum, scope of responsibility, assignment by designated unit, and responsibility for all cleaning tasks.

(b) The housekeeping service shall have a written schedule that determines the frequency of cleaning and maintaining cleanliness for all equipment, structures, areas, and systems within its scope of responsibility.

(c) There shall be a list available, at all times of all cleaning and disinfecting agents used in the facility together with their Safety Data Sheets.

(d) Records of all pesticides and herbicides used at the facility shall be maintained on site, together with their Safety Data Sheets.

(e) All cleaning and disinfecting agents shall be correctly labeled with the name of the product and its use, as specified by the manufacturer, including agents that have been repackaged from a bulk source.

(f) All pesticides shall be applied in accordance with the State Pesticide Control Code, N.J.A.C. 7:30.

8:43K-4.19 Environmental patient care services

(a) A facility shall ensure compliance with the following environmental conditions:

1. In refrigerators, freezers, and storerooms used for perishable and other items subject to deterioration, thermometers are in place that are accurate to within three degrees Fahrenheit, and the facility collects and records temperature readings and maintains these records for at least 12 months from collection;

2. The facility elevates articles in storage from the floor and keeps them away from walls, ceilings, and air vents to facilitate cleaning;

3. Storage units in the facility are non-porous and cleanable;

4. The facility maintains separate refrigerators for medications, laboratory specimens, and food, and maintains separate designated areas for food items and beverages;

5. Facility draperies, upholstery, and other fabrics or decorations are fire-resistant and flameproof;

6. The facility prohibits the use of latex foam pillows;

7. The facility ensures that equipment requiring drainage, drains to a sanitary connection, in accordance with State and local law;

8. During warm weather conditions, the facility ensures that the indoor temperature of the facility does not exceed 82 degrees Fahrenheit, and shall establish a written heat emergency action plan that specifies procedures to be implemented if the indoor air temperature exceeds 82 degrees Fahrenheit for a continuous period of four hours or longer;

9. The facility provides adequate ventilation in all areas used by patients;

10. The facility shall ensure that the temperature in the facility is, at a minimum, 72 degrees Fahrenheit (22 degrees Celsius) when patients are in the facility;

11. The facility prohibits the use of throw rugs or scatter rugs;

12. The facility ensures that all equipment has unobstructed space for operation;

13. The facility does not store combustible materials in heater rooms or within 18 feet of a heater located in an open basement;

14. The facility stores paints, varnishes, lacquers, thinners, and other flammable materials outside the building, provided the facility can maintain a minimal quantity of such materials for immediate, necessary use in the facility in a locked storage room or in a closed, locked metal cabinet or container in a non-patient area of the facility;

15. The facility shall maintain all furnishings in good repair and clean condition;

16. The facility shall maintain mechanical equipment in good working order, covered to protect from contamination, and accessible for cleaning and inspection, and shall promptly repair, replace, and/or remove broken or worn equipment;

17. The facility shall thoroughly clean and disinfect reusable patient care items and equipment upon discharge of each patient; and

18. When areas of the facility are undergoing renovation or new construction, the facility shall take protective measures to contain dust and redirect traffic in patient care areas.

8:43K-4.20 Services not described in this chapter

If an entity seeks licensure to provide a health or adjunctive service or use a technology or modality of care as to which an applicable State or Federal standard does not exist, the Commissioner may impose conditions on a facility's authorization to provide the service or use the technology on a case-by-case basis, as necessary, to protect public health and safety, and may require the applicant to provide supplemental information or documentation as to the proposed service or technology, as necessary, to enable the Commissioner to issue an informed decision as to the appropriateness of authorizing the provision of the service or the use of the technology or modality.

SUBCHAPTER 5. GENERAL PATIENT CARE POLICIES AND SERVICES

8:43K-5.1 Establishment and implementation of policies and procedures

(a) A facility shall establish patient care policies and procedures to facilitate continuity of care, and, in addition to service-specific policies and procedures applicable to each outpatient facility service type, which address, at a minimum:

1. Identification of services that the facility is to provide;

2. Service coordination with providers serving mutual patients and the use of consultant services;

3. Referral of patients to other providers for care that the facility cannot provide;

4. The provision of care in an emergency, including a definition of emergency;

5. Methods for obtaining and documenting informed consent, including definition or a listing of types of procedures for which the facility will require informed consent;

6. Advance directives for health care and mental health care, including:

i. The circumstances under which the facility will inquire of adult patients as to the existence and location of an advance directive for health care and/or mental health care;

ii. The provision of a written statement of patient rights regarding advance directives upon admission of an adult patient; and

iii. Documentation of discussions with patients regarding advance directives in a patient's record;

7. Admission of patients, including limitations on admission based on diagnosis, type or degree of disability, medical condition, patient age, or other factors, provided that any limitation shall not conflict with applicable Federal and State laws prohibiting discrimination in the admission of patients or in the provision of services;

8. A written plan for informing a patient and/or the patient's legal representative of financial arrangements and fees in accordance with N.J.A.C. 8:43K-5.6;

9. The facility's registration and appointment system;

10. Follow up of missed or broken appointments, including specification of the circumstances in which the facility will perform follow-up services;

11. The provision of screening as a component of patient evaluation, if offered, including indications for, and frequency of, screening;

12. Obtaining health histories and physical examinations, if applicable;

13. Initiation, implementation, review, and revision of a written plan of care, including indication of the types of patients for whom the facility is to write a plan of care;

14. A system through which a patient receives care from the same health care professionals to the extent possible;

15. Methods for protecting visual and auditory patient privacy;

16. Maintaining vaccination records, if applicable;

17. Patient instruction and/or health education;

18. Provision of services to patients during the facility's hours of operation;

19. Continuity of care planning for a patient whose receipt of services from a facility is to discontinue, including a plan by which the patient is to refill prescription medication;

20. Patient discharge and discharge planning, including:

i. Incorporating discharge or transition planning into a patient's plan of care upon admission, and revising the plan of care over time, as necessary;

ii. Establishing criteria for voluntary, administrative, and involuntary discharge;

iii. Ensuring that the facility does not discharge a patient based solely on clinical outcomes, drug screening, or drug or toxicology testing results;

iv. Ensuring that the facility does not discharge a patient to a higher, lower, or an alternative level of care without patient consent and enrollment confirmation, to the extent possible;

v. Ensuring that a patient who receives medication treatment is not discharged for declining counseling or other ancillary services;

vi. Providing a patient with post-discharge instructions and a plan of care;

vii. Establishing, and notifying a patient of, appeal procedures and timeframes following involuntary discharge;

viii. Determining when and how to involve a patient, family members, and/or other support persons whom the patient identifies, in discharge planning;

ix. Referring and linking a patient to continuing services and resources upon discharge; and

x. Conducting post-discharge outreach to patients, family members, and/or support persons whom the patient identifies; and

21. Other activities, as required by this chapter and other applicable law.

(b) A facility that prescribes medication shall establish and implement policies and procedures that address the prescribing of medication, including:

1. Ensuring a medication history is obtained prior to prescribing medication;

2. Documenting and reviewing adverse medication reactions;

3. Communicating among a patient's other providers to avoid drug interactions;

4. Ensuring that patient care is coordinated in case a prescriber separates from the facility;

5. Ensuring that prescribers adhere to applicable Federal and State training, certification, and credentialing requirements, including registration with the DEA in accordance with 21 CFR Part 1301 and the New Jersey Division of Consumer Affairs, in accordance with the New Jersey Controlled Dangerous Substances Act, N.J.S.A. 24:21-1 et seq.;

6. Maintaining records of prescribers' DEA certifications and CDS registration numbers; and

7. Ensuring that all patients receiving MOUD receive a take-home supply, prescription, and/or information on how to obtain an opioid antidote.

(c) A facility shall make available to staff, patients, and visitors all patient care policies and procedures.

(d) If applicable law requires a licensed or adjunctive service to be performed by a professional holding a specific credential, the facility shall ensure that the service is provided only by a professional who holds the credential required by law and who is acting within the professional's credentialed scope of practice.

8:43K-5.2 Patient health history and assessment

(a) A facility shall perform a comprehensive health screening of every newly admitted patient, as part of an initial patient assessment, to collect at least the following information:

1. Contact information for the patient's primary care provider, if applicable;

2. Past surgical procedures;

3. Past and current health condition and medical history with respect to HIV and STDs, including, at a minimum.

i. The patient's known history of hepatitis, HIV, and/or recent hepatitis or HIV test results; and

ii. The patient's risk of contracting syphilis and other sexually transmitted infections, recent infections, and recent screening results;

4. Allergies, including, at a minimum:

i. Documentation of medication allergies in the medical record and documentation of other allergies in the medical record;

ii. If a facility has a prescriber on staff or who provides medical services through a contract, medication allergies shall be displayed prominently in the medical record; and

iii. If a facility maintains patient records in a physical, paper format, medication allergies shall be documented on the outside front cover of the record;

5. Adverse reactions to medications;

6. Current medications; and

7. Alcohol, substance use, and tobacco use history;

(b) A facility shall ensure that each patient undergoes at least one biopsychosocial assessment, with follow-up assessments, as necessary.

(c) A facility shall refer each patient to on- or off-site pre-exposure prophylaxis and harm reduction information, resources, and/or treatment, if a patient:

1. Has HIV or STD infection or known risk of contracting HIV and/or STDs; and/or

2. Currently uses alcohol, tobacco, or other substances in excessive amounts.

(d) A facility shall refer a patient for additional care and evaluation, such as physical examination, routine laboratory screening, and diagnostic testing, as the

comprehensive health screening might indicate, to identify and/or address conditions that:

1. The facility's license does not authorize it to provide; or

2. The facility elects not to provide.

8:43K-5.3 Physical examination

(a) A facility shall specify in its policies and procedures the circumstances in which it will conduct a physical examination of a patient and/or refer a patient for medical assessment and treatment.

(b) A facility that performs physical examinations shall use appropriate equipment for physical exams and shall comply with CDC guidance for hand hygiene, as well as surface and equipment sterilization, as applicable.

8:43K-5.4 Instructions and information for patients

A facility shall give each patient written instructions and information, in multilingual format, as needed, including, as applicable, and at a minimum, the nature and goals of treatment, the tests and/or procedures to be performed, the possible complications of any treatment or tests, a telephone number at which the patient can call the facility, when needed, and instructions for obtaining care in an emergency.

8:43K-5.5 Communication assistance

A facility shall establish and implement procedures to ensure the timely provision of written, spoken, and/or sign language interpretation services and other resources, as a patient's situation might indicate, especially in urgent and emergency circumstances, for patients who have alternative communication needs, such as persons who do not speak English, who are deaf or hard-of-hearing, and/or who are blind.

8:43K-5.6 Financial arrangements

(a) A facility shall establish and implement policies and procedures specifying the form in which it will create and retain records of financial transactions with patients and third-party payers, and the retention schedule.

(b) A facility shall maintain a record of each financial transaction with a patient and provide a written record of each transaction to the patient.

(c) A facility shall inform each patient, in advance, of the fees it will charge for the types of services and supplies that it expects to provide the patient, including the facility's payment, fee, deposit, and refund policy, and its charges for services not covered by sources of third-party payment or by the facility's basic rate based on a predetermined fee schedule.

(d) A facility shall notify a patient in advance if a physician or another practitioner affiliated with the facility will send a separate bill to the patient.

(e) A facility shall post in a prominent location in the facility that is readily accessible by the public either its fee schedule or a notice indicating that the fee

schedule is available upon request to the facility, and, if the latter, shall make the fee schedule readily available upon request.

(f) A facility shall establish a written description of any sliding fee scale or special payment plan it maintains and shall post in a prominent location in the facility that is readily accessible by the public either the description or a notice indicating that the description is available upon request to the facility, and if the latter, shall make the description readily available upon request.

(g) A facility shall impose no additional charges, expenses, or financial liabilities on a patient that exceed the predetermined rate, except:

1. Upon written approval and authority of the patient, to whom the facility shall give a copy of the written approval; or

2. When a health emergency involving the patient requires the facility to provide special services or supplies during which the patient is unable to provide written approval and authority.

(h) A facility shall be the sole billing authority for services provided pursuant to this chapter.

(i) A facility shall describe to a patient its agreements with third-party payers, financial assistance patient referral systems, and financial assistance sources.

8:43K-5.7 Telemedicine and telehealth activities

(a) A facility that provides services using telemedicine or telehealth shall comply with applicable Federal and/or State laws governing this activity, including N.J.S.A. 45:1-61 et seq.

(b) A facility shall ensure that it provides services through telemedicine and/or telehealth in accordance with appropriate clinical decision-making and professional responsibility, including applicable standards of professional licensing, registration, or credentialing boards or similar entities, and in consideration of principles of shared decision-making.

(c) A facility shall make in-person services available for:

1. Patients who choose to receive services in person, and not through telemedicine/telehealth; and

2. Patients for whom telemedicine and telehealth services are clinically contraindicated.

(d) A facility shall establish and implement policies and procedures for telemedicine and telehealth services that address, at a minimum:

1. The services available through telemedicine or telehealth;

2. The identification of levels of staff who are eligible and authorized to provide services through telemedicine and telehealth;

3. Clinical considerations for the provision of telemedicine and telehealth services, including clinical appropriateness for telemedicine and telehealth services and any exclusionary criteria;

4. The manner of providing telemedicine and telehealth services to ensure confidentiality, privacy, and security in compliance with applicable Federal and State law;

5. Patient choice regarding the use of telemedicine and telehealth, and the availability of alternatives, including:

i. A patient's right to elect to receive services in person, and not through telemedicine and telehealth;

ii. Patient safety and emergency management protocols during telemedicine and telehealth visits;

iii. Prescribing medication consistent with applicable Federal and State law; and

iv. Staff training.

8:43K-5.8 Designation of medical director

(a) The governing body of a facility shall appoint a medical director if the facility provides:

1. One or more of the following licensed services:

i. Primary care; or

ii. Reproductive health care services; and/or

2. One or more of the following adjunctive services:

i. Preventive medicine; or

ii. Administration of CDS for SUD treatment.

(c) A facility shall either employ or otherwise retain, through a written agreement, its medical director, on a full- or part-time basis.

8:43K-5.9 Rights of each patient

(a) Each patient receiving services from a facility that the Department licenses pursuant to this chapter shall have the following rights:

1. To be informed of these rights, as evidenced by the patient's written acknowledgement, or by documentation by staff in the medical record, that the patient was offered a written copy of these rights and given a written or verbal explanation of these rights, in terms the patient could understand.

i. The facility shall have a means to notify patients of any rules and regulations it has adopted governing patient conduct in the facility;

2. To be informed of services available in the facility, of the names and professional status of the personnel providing and/or responsible for the patient's care, and of fees and related charges, including the payment, fee, deposit, and refund policy of the facility and any charges for services not covered by sources of third-party payment or not covered by the facility's basic rate;

3. To be informed if the facility has authorized other health care and educational institutions to participate in the patient's treatment.

i. The patient shall have a right to know the identity and function of these institutions and to refuse to allow their participation in the patient's treatment;

4. To receive from the patient's physician(s) or clinical practitioner(s), in terms that the patient understands, an explanation of the patient's complete medical or health condition or diagnosis, recommended treatment, treatment options, including the option of no treatment, risk(s) of treatment, and expected result(s).

i. If this information would be detrimental to the patient's health, or if the patient is not capable of understanding the information, the explanation shall be provided to the patient's next of kin or legal representative; and

ii. This release of information to the next of kin or legal representative, with the reason for not informing the patient directly, shall be documented in the patient's medical record;

5. To participate in the planning of the patient's care and treatment, and to refuse medication and treatment;

6. To be included in experimental research only when the patient gives informed, written consent to such participation, or when a guardian gives such consent for an incompetent patient in accordance with applicable law.

i. The patient may refuse to participate in experimental research, including the investigation of new drugs and medical devices.

ii. Such refusal shall be documented in the patient's medical record;

7. To voice grievances or recommend changes in policies and services to facility personnel, the governing authority, and/or outside representatives of the patient's choice either individually or as a group, and free from restraint, interference, coercion, discrimination, or reprisal;

8. To be free from mental and physical abuse, free from exploitation, and free from use of restraints unless a physician authorizes the use of restraints for a limited period to protect the patient or others from injury.

i. Drugs and other medications shall not be used for discipline of patients or for convenience of facility personnel;

9. To confidential treatment of information about the patient.

i. Information in the patient's medical record shall not be released to anyone outside the facility without the patient's approval, unless:

(1) Another health care facility to which the patient was transferred requires the information;

(2) The release of the information is required and permitted by law, a third-party payment contract, or a peer review; or

(3) The Department needs the information for statutorily authorized purposes;

ii. The facility may release data about the patient for studies including aggregated statistics when the patient's identity is deidentified in accordance with applicable law;

10. To be treated with courtesy, consideration, respect, and recognition of the patient's dignity, individuality, and right to privacy, including, but not limited to, auditory and visual privacy.

i. The patient's privacy shall be respected when facility personnel are discussing the patient;

11. To be free from any obligation to perform work for the facility unless the work is part of the patient's treatment, the patient performs the work voluntarily, and the work is performed in accordance with applicable law;

12. To exercise civil and religious liberties, including the right to independent personal decisions, and to be free from the imposition of religious beliefs or practices, or attendance at religious services;

13. To be free from discriminatory treatment because of age, race, religion, sex, nationality, or ability to pay, and to not be deprived of any constitutional, civil, and/or legal rights solely because of receiving services from the facility; and

14. To expect and receive appropriate assessment, management, and treatment of pain as an integral component of the patient's care in accordance with N.J.A.C. 8:43E-6.

SUBCHAPTER 6. BEHAVIORAL HEALTH SERVICES

8:43K-6.1 Behavioral health services facility; general provisions

(a) This subchapter applies to a facility that the Department licenses to provide behavioral health services.

(b) Behavioral health services consist of the following programs, services, and levels of care:

1. SUD or other addiction outpatient treatment;

2. Mental health outpatient treatment;

3. SUD or other addiction intensive outpatient treatment;

4. SUD or other addiction treatment partial care; and

5. Mental health partial care.

(c) A facility seeking licensure to provide behavioral health services at a level of care listed at (b) above is subject to compliance with:

1. Applicable standards and requirements of DMHAS;

2. Applicable requirements at Title 10 of the New Jersey Administrative Code that DMHAS administers; and

3. Applicable DMHAS requirements to enter into a contract or an affiliation agreement with DMHAS.

8:43K-6.2 Staffing and personnel requirements

(a) A behavioral health services facility shall:

1. Employ staff who are appropriately credentialed and sufficiently trained to provide services;

2. Ensure that only staff possessing the appropriate clinical background, education, credentials, and/or qualifications perform and provide diagnosis, screening, assessment, treatment, and recovery support of patients, including those patients with co-occurring mental health and addiction disorders;

3. Maintain current and proper documentation of staff credentials, education, licensure, training, and qualifications in personnel files;

4. Identify staff responsible for and qualified to perform diagnosis, screening, assessment, and treatment of patients, including those with co-occurring mental health and addiction disorders;

5. Facilities providing medication management services shall employ, either directly or through contract, a medical doctor or advanced practitioner credentialed and licensed in New Jersey to prescribe medications; and

5. Employ and designate the following staff:

i. Program director;

ii. Clinical supervisor; and

iii. Counseling and/or therapy staff.

8:43K-6.3 Program director

(a) A behavioral health services facility program director shall:

1. Possess, at a minimum, a master's degree and two years of administrative and/or supervisory experience in behavioral health program services;

2. Be on site at all times when patients are present and during operating hours (unless a designated alternate is on site pursuant to (b) below);

3. Oversee and manage all operations of the behavioral health treatment program, including administrative, fiscal, managerial, personnel, reporting, and quality assurance, management, and improvement activities;

4. Develop an organizational plan;

5. Develop a continuity of operations plan;

6. Ensure the development and implementation of all required policies and procedures; and

7. Ensure that staff members have the proper credentials, education, qualifications, supervision, and training for their positions and duties.

(b) A behavioral health services facility program director shall designate, in writing, at least one alternate who, in the absence of the program director:

1. Is to act and function as the program director;

2. Has credentials that are equivalent or comparable to those at (a) above; and

3. Is available at all times when patients are on site and during operating hours.

(c) A behavioral health services facility program director may serve concurrently as a facility administrator.

8:43K-6.4 Clinical supervisor

(a) Subject to (b) below, a behavioral health services facility program clinical supervisor shall be:

1. An advanced practice nurse;

2. A licensed clinical social worker;

3. A physician or psychiatrist;

4. A licensed professional counselor;

5. A licensed marriage and family therapist; or

6. A licensed psychologist.

(b) If a behavioral health services facility provides only SUD treatment services, the behavioral health services facility program clinical supervisor shall be either a professional listed at (a)1 through 6 above or a licensed clinical alcohol and drug counselor.

(c) A behavioral health services facility program clinical supervisor shall administer the direction, provision, and quality of clinical behavioral health services, and shall:

1. Develop and implement:

i. Clinical policies and procedures; and

ii. Screening, assessment, and treatment practices and procedures;

2. Directly provide or arrange:

i. The clinical supervision of staff in accordance with applicable professional licensure requirements; and

ii. The education, orientation, and training of staff; and

3. Ensure:

i. The implementation of best and/or evidence-based practices in the delivery of clinical behavioral health services;

ii. The proper credentialing and supervision of behavioral health services clinical staff;

iii. The maintenance of behavioral health services clinical program staff supervision documentation; and

iv. The conduct of quality improvement activities.

8:43K-6.5 Counseling and/or therapy staff

(a) Counseling and/or therapy staff of a behavioral health services facility shall:

1. Assess the counseling and/or therapy needs of each patient using evidence-based and peer-reviewed tools;

2. Clearly present patient information and treatment status, as needed, during case conferences, interdisciplinary team meetings, and case consultations;

3. Diagnose and/or develop clinical impressions of patients using the DSM-5;

4. Participate as a member of an assigned patient's interdisciplinary team;

5. Provide counseling services, as specified in each patient's plan of care;

6. Obtain a patient's historical medical records that may be relevant to the patient's presenting treatment episode, consistent with applicable Federal and State confidentiality laws;

7. Review and reassess each assigned patient throughout the patient's treatment episode to determine the need for continued services, transition to an appropriate clinical level of care, or discharge from services;

8. Serve as a contact for referral sources, and other agencies, systems, and services, such as criminal justice agencies, social services agencies, and health care providers; and

9. Determine the appropriate level of care for each patient based on the patient's individual clinical needs and severity.

8:43K-6.6 Peer staff and peer support services

(a) A peer shall have lived experience and an appropriate certification to provide peer support services consistent with certifications required pursuant to DMAHS, another State licensing or credentialing authority, or as otherwise approved by DMHAS.

(b) Peer support services are:

1. Activities that engage each patient and promote each patient's recovery, self-determination, self-advocacy, well-being, independence, and community relationships; and

2. Individualized, recovery-focused, and based on a relationship that supports each patient's ability to promote the patient's recovery and, as applicable, support relapse prevention.

(c) An appropriately licensed and credentialed behavioral health services facility staff member shall direct the provision of peer support services.

(d) A licensed behavioral health services facility staff member or a peer with certification consistent with (a) above shall supervise the provision of peer support services, which may be through a collaborative process, including group supervision, unless otherwise prohibited by Federal or State law.

(e) Peer support services may include:

1. Assisting a patient in personal goal development, problem-solving, and skill building, including, if applicable, relapse prevention skills;

2. Informing a patient about social and other support services;

3. Engaging a patient in treatment and/or recovery, including reinforcing the patient's interest in maintaining treatment services and exploring the patient's recovery needs;

4. Organizing recovery-oriented activities, such as recreational and social activities, which may include sporting or social gatherings;

5. Participating in a patient's care planning process;

6. Providing a patient non-clinical support;

7. Providing a patient information and/or referrals about, or linkages to, community resources and/or support services;

8. Sharing experiential knowledge, hopes, and skills; and

9. Supporting a patient's development of life skills, such as budgeting, connecting to community resources, and self-advocacy.

(f) A peer shall document in the patient's treatment record, the peer support services that the peer provides.

8:43K-6.7 Patient care policies and procedures

(a) A behavioral health services facility shall establish, maintain on site, and implement policies and procedures addressing:

1. The admission process, which shall include, at a minimum:

i. Admission criteria and time frames for the admission process;

ii. For a behavioral health services facility providing addiction treatment services, admission criteria that are consistent with N.J.S.A. 26:2B-15 and 26:2G-25, which prohibit denial of admission to an individual currently receiving medication treatment for an SUD;

iii. The interdisciplinary team's review of patient information that the facility compiles as part of the admission process, to ensure the clinical appropriateness of the patient's admission;

iv. The identification and evaluation of clinical appropriateness for treatment, including diagnosis and level of care determination;

v. Screening and assessment procedures using validated, appropriate, evidence-based, and peer-reviewed screening tools;

vi. Referral and/or linkage procedures for immediate needs identified during the admission process;

viii. Referral procedures for patients who require an alternate level of care or other type of service, if that alternate level of care or other type of service is not available at the behavioral health program; and

viii. Patient orientation to the behavioral health services facility program, including information about available services, fees, payment schedules, and patient rights;

2. Counseling and therapy services, which shall include, at a minimum:

i. A description of counseling and therapy services the facility offers;

ii. Procedures to ensure that only properly qualified staff conduct and direct counseling, therapy, and psychoeducation sessions; and

iii. The identification of qualified staff members who are to provide counseling and therapy services;

3. Behavioral health services care planning, which shall include, at a minimum:

i. Identification of the responsibilities of staff who are to participate in the development, review, approval, and implementation of a patient's plan of care;

ii. Minimum content and form of a plan of care to ensure consistency and standardization across the behavioral health program; and

iii. Standards for patient participation in the development and ongoing review of the patient's plan of care;

4. Laboratory procedures and testing, including urine drug screening; and

5. Discharge planning and processes, which shall include, at a minimum:

i. The criteria for voluntary, administrative, and involuntary discharge, subject to the following:

(1) A facility shall not administratively or involuntarily discharge a patient based on the patient's laboratory results including toxicology or drug screening or testing results; and

(2) A facility may discharge a patient to an alternative level of care only with the patient's consent, and upon confirmation of availability of, and the patient's acceptance, into the alternative level of care;

ii. The documentation necessary for discharge, including discharge instructions, discharge summary, and plan of care, as revised, to address discharge;

iii. The incorporation of discharge planning into the patient's plan of care;

iv. Appeal procedures and timeframes for involuntary discharge;

v. The use and role of the interdisciplinary team in discharge planning;

vi. Communication with, and the involvement of, a patient, and patient-identified family members and/or other support persons, in discharge planning, subject to clinical appropriateness and consistent with applicable Federal and State confidentiality laws;

vii. The referral and/or linkage of a patient to other services and/or resources upon discharge;

viii. Post-discharge follow-up and outreach to a patient, and patient-identified family members and/or other support persons, subject to clinical appropriateness and consistent with applicable Federal and State confidentiality laws; and

ix. Protocols to ensure safe care transitions for a patient who is at risk for suicide and/or overdose, such as referral and linkage of the patient to the appropriate services based upon clinical need, provision of harm reduction resources, products, and strategies, and contact with the patient to follow up immediately after discharge.

(b) The behavioral health services facility shall review and revise the policies and procedures required by this subchapter, as necessary, and at least annually.

(c) The behavioral health services facility shall make the policies and procedures required by this subchapter available for review by staff, patients, the Department, and DMHAS within DHS.

8:43K-6.8 Behavioral health services facility documentation and treatment records; confidentiality

(a) In addition to the general requirements for the establishment and retention of patient records at N.J.A.C. 8:43K-4.7, a behavioral health services facility shall establish a clinical treatment record for each patient as part of the patient's facility record.

(b) A behavioral health services facility shall maintain and record notes in a patient's clinical treatment record that provide documentation of:

1. The patient's plan of care and any revisions thereto;

2. Implementation of the patient's plan of care;

3. Immediate patient needs;

4. Progress notes; and

5. A patient's course of treatment, including:

i. The clinical rationale and support for treatment services provided;

ii. Changes in the patient's condition or situation, if any;

iii. The patient's response to services; and

iv. The basis for, and follow-up of, any referrals for needed services not provided by the program.

(c) A behavioral health services facility shall provide a patient's plan of care to the patient:

1. Upon request during treatment; and

2. At discharge.

(d) A behavioral health services facility shall comply with applicable Federal and State confidentiality laws, including, but not limited to, 42 CFR Part 2, 45 CFR Parts 160 and 164, and N.J.S.A. 30:4-24.3.

8:43K-6.9 Medical cannabis use by qualifying patient at behavioral health services facility

(a) In accordance with N.J.S.A. 26:2H-12.86, the chief administrator of a facility that offers behavioral health services shall develop a policy authorizing a parent, guardian, or designated caregiver to assist a qualifying patient in the use of,

and/or administer to a qualifying patient, medical cannabis at the facility, if the qualifying patient is receiving behavioral health services at the facility.

(b) A policy required pursuant to (a) above shall be consistent with and implemented in accordance with:

1. N.J.S.A. 2C:33-13;

2. N.J.S.A. 26:2H-12.86;

3. The New Jersey Smoke-Free Air Act, N.J.S.A. 26:3D-55 et seq., and the implementing rules at N.J.A.C. 8:6, Smoke-Free Air Rules; and

4. The Jake Honig Compassionate Use Medical Cannabis Act, N.J.S.A. 24:6I-1 et seq.

8:43K-6.10 Outpatient mental health, substance use disorder, and/or other addiction treatment services

(a) A behavioral health services facility shall ensure that a patient admitted for outpatient mental health, SUD, and/or other addiction treatment services is eligible for services and document that the patient:

1. Has a DSM-5 diagnosis of a mental illness, an SUD, and/or other addiction, irrespective of primary or secondary diagnoses;

2. Is clinically appropriate for an outpatient level of behavioral health services; and

3. Is willing to participate in outpatient behavioral health services.

(b) A behavioral health services facility that provides outpatient mental health, SUD, and/or other addiction treatment services shall establish and implement a

policy and procedure to ensure that it prioritizes admission for the following populations:

1. Individuals in the community at risk of admission or readmission to a hospital or inpatient behavioral health treatment and/or decompensation in the community;

2. Individuals receiving acute inpatient behavioral health treatment who could live in the community with appropriate services;

3. Pregnant and postpartum individuals;

4. Individuals who inject drugs;

5. Individuals with recent and multiple overdoses; and

6. Referrals directly from screening or affiliated emergency services.

8:43K-6.11 Intensive outpatient mental health, substance use disorder, and/or other addiction treatment services

(a) A behavioral health services facility shall ensure that a patient admitted for intensive outpatient services is eligible for services and shall document in the patient's medical record that:

1. The patient has a DSM-5 diagnosis of a mental illness, a substance use disorder, and/or other addiction, irrespective of primary or secondary diagnoses;

2. Mental health, substance use disorder, and/or addiction treatment services at the intensive outpatient level of care are clinically appropriate for the patient;

3. The patient meets the number of treatment hours for intensive outpatient services as established by the DMHAS program standards; and

4. The patient is willing to participate in intensive outpatient SUD and/or addiction treatment services.

(b) A facility may, on a weekly basis, transition a patient who does not attend the minimum number of treatment hours established by the DMHAS program standards for intensive outpatient services to the outpatient behavioral health level of care and retain the patient for treatment.

(c) A behavioral health services facility that provides intensive outpatient mental health, SUD, and/or addiction treatment services shall establish and implement a policy and procedure to ensure that it prioritizes admission for treatment services to the following populations:

1. Persons who are pregnant or postpartum;

2. Persons who inject drugs;

3. Adults in the community who are at risk of:

i. Admission or readmission to an inpatient behavioral health treatment program or hospital; and/or

ii. Decompensation in the community;

4. Adults receiving acute inpatient behavioral health treatment who could live in the community with appropriate services;

5. Persons at elevated risk for suicide;

6. Persons who have had recent and/or multiple overdoses;

7. Persons who were recently released from State or county correctional or detention facilities; and

8. Persons referred directly from affiliated programs or affiliated emergency services or crisis services.

8:43K-6.12 Partial care program of mental health, substance use disorder, and/or addiction treatment

(a) A behavioral health services facility that provides a partial care program of mental health, SUD, and/or addiction treatment shall employ and designate the following additional staff:

1. Medical services supervisor;

2. Medical staff; and

3. Primary case coordinator.

(b) A medical services supervisor of a partial care program of mental health, SUD, and/or addiction treatment shall be:

1. A physician who has board certification in general psychiatry and at least one year of experience working full-time, or full-time equivalent (such as two years working part-time), in a behavioral health treatment program setting; or

2. An APN with board certification in psychiatric nursing, or another commensurate certification, with prior approval from DMHAS, and at least one year of experience working full-time, or full-time equivalent, in a behavioral health treatment program setting.

(c) A medical services supervisor of a partial care program of mental health treatment, SUD, and/or addiction treatment shall:

1. Have appropriate credentials to recommend a course of treatment;

2. Perform general supervision of treatment provided to patients;

3. Provide medical input into the development of the behavioral health treatment program;

4. Provide consultation and training to staff; and

5. Ensure that all psychiatric and medical services that a facility provides meet accepted standards of medical practice.

(d) Medical staff of a partial care program of mental health treatment, SUD, and/or addiction treatment shall:

1. Prescribe patient medication, when clinically appropriate, and provide medication management and monitoring;

2. Ensure that treatment and services are medically appropriate for each patient;

3. Provide input into the patient's treatment and treatment program plan of care; and

4. Provide an initial psychiatric assessment and ongoing psychiatric review at least annually.

(e) A primary case coordinator of a partial care program of mental health treatment, SUD, and/or addiction treatment shall:

1. Have, at a minimum:

i. A bachelor's degree in human services discipline, rehabilitation, or social work;

ii. A bachelor's or an associate degree in psychosocial rehabilitation or mental health services;

iii. A Bachelor of Science degree in nursing;

iv. An associate degree and two years' experience in providing human services; or

v. A relevant professional credential, such as certified psychiatric rehabilitation practitioner, certified rehabilitation counselor, certified alcohol and drug counselor, certified alcohol and drug counselor counselor-intern, or community mental health associate;

2. Perform service coordination;

3. Provide or arrange needed services;

4. Undertake personal advocacy; and

5. Develop, review, and update each patient's plan of care.

(f) A behavioral health services facility shall ensure that patients admitted to a partial care program for mental health treatment, SUD treatment, and/or addiction treatment are eligible for services by documenting that a patient admitted:

1. For partial care mental health services:

i. Has a DSM-5 diagnosis for a serious mental illness;

ii. Is clinically appropriate for partial care mental health treatment, including demonstrating a need for psychiatric rehabilitation and active treatment; and

iii. Is willing to participate in mental health partial care services.

2. For partial care substance use disorder and/or other addiction services:

i. Has a DSM diagnosis for a substance use disorder and/or other addiction;

ii. Is clinically appropriate for partial care substance use disorder and/or other addiction treatment services, including demonstrating a need for active treatment; and

iii. Is willing to participate in substance use disorder and/or other addiction partial care services.

(g) Patients may be admitted into a partial care program for either a primary diagnosis of mental illness or primary diagnosis of substance use disorder and/or other addiction services.

(h) Patients shall receive appropriate treatment addressing both mental illness and substance use disorder and/or other addiction within the partial care program treatment plan, when applicable.

(i) The following populations shall be given priority for admission to a partial care program for mental health and/or substance use disorder and/or other addiction services:

1. Adults in the community at risk of admission or readmission to a hospital or inpatient behavioral health treatment;

2. Adults at risk of decompensation in the community;

3. Adults receiving acute inpatient behavioral health treatment who could live in the community with appropriate services;

4. Pregnant and postpartum individuals;

5. Individuals who inject drugs;

6. Individuals with recent and multiple overdoses; and

7. Individuals referred directly from screening or affiliated emergency services or crisis services.

SUBCHAPTER 7. HEALTH CARE SERVICES

8:43K-7.1 Health care services; general provisions

(a) This subchapter applies to a facility that the Department licenses to provide health care services.

(b) A facility that the Department licenses pursuant to this chapter to provide health care services shall:

1. Provide services either directly or through written agreement;

2. Ensure that each health care professional through whom the facility provides services does so acting within the health care professional's applicable credentialed scope of practice; and

3. Make reasonable efforts to follow up with each patient following a referral or order for diagnostic testing or treatment.

8:43K-7.2 General physical plant and functional requirements

(a) A licensee or an applicant for licensure as a health care services facility pursuant to this subchapter shall ensure that:

1. Any planned construction of a new building and/or planned alteration of an existing building, at which the licensee or applicant plans to provide services, conforms to applicable provisions of the construction guidelines and the New Jersey Uniform Construction Code, N.J.A.C. 5:23;

2. An existing building, at which the licensee or applicant plans to provide services, which was constructed or altered prior to (the effective date of this chapter), conforms to applicable Federal, State, and local standards that were in effect at the time of construction or alteration, or as of the date of the Department's approval of the construction or alteration plans;

3. Prior to any construction or alteration of a building at which the licensee or applicant plans to provide services, the licensee or applicant submits the construction or alteration plans for review and approval to the Healthcare Plan Review Unit;

4. The repair, renovation, alteration, and/or reconstruction of an existing structure, at which the licensee or applicant plans to provide services, conform to N.J.A.C. 5:23-6, Rehabilitation Subcode;

5. The restoration of an existing structure that is damaged by fire or any other cause, at which the licensee or applicant plans to provide services, conforms to N.J.A.C. 5:23-6, Rehabilitation Subcode;

6. If the licensee or applicant plans to alter or repair, within any 12-month period, 50 percent or greater of the physical space of a building at which the applicant or licensee plans to provide services, the entire building conforms to

standards applicable to the construction of new structures, including portions of the building that the licensee or applicant does not propose to alter or repair;

7. If the licensee or applicant plans to alter or repair, within any 12-month period, less than 50 percent of the physical space of a building at which the applicant or licensee plans to provide services, the alteration or reparation of the building conforms to standards applicable to the construction of new structures;

8. The licensee or applicant planning to perform construction or renovation, at or around a facility at which the applicant or licensee plans to provide services, conducts a risk assessment to determine the impact of the project on patient areas, personnel, and mechanical systems;

9. The infection control program of the applicant or licensee, if applicable, reviews areas of potential risk and populations at risk and approves necessary control measures;

10. The design phase of a construction or renovation project includes commissioning specifications of ventilation requirements used during, and at completion of, the construction project; and

11. The facility establishes, for facility and contractor personnel who will work in areas affected by construction at or near a facility at which the applicant or licensee plans to provide services, an education program to identify the impact, risks, interventions, and compliance issues, subject to applicable Federal standards, including applicable provisions of the Occupational Safety and Health Act of 1970 and the Public Employees' Occupational Safety and Health Act.

8:43K-7.3 Waste management

(a) A health care services facility shall establish and implement policies and procedures for collection, storage, and disposal of solid waste and recyclable material, consistent with, at a minimum, the following:

1. If the facility uses bags for solid waste removal, the bags shall be of sufficient strength to safely contain waste from point of origin to point of disposal and closed effectively prior to disposal;

2. If the facility uses an outside storage container for solid waste, the facility shall keep the container covered, unless it uses the container for corrugated cardboard, recyclables, or construction materials;

3. If the facility uses a garbage compactor, the facility shall locate the compactor on an impervious pad that is graded to a drain that it keeps clean, which is connected to the sanitary sewage disposal system;

4. The facility shall dispose of solid waste, liquid waste, and regulated medical waste in compliance with applicable laws for disposal thereof and as frequently as necessary to prevent nuisance creation;

5. If the facility uses an indoor storage container for solid waste, it shall use a fireproof container and keep the container covered, as necessary, to control odors and prevent nuisance creation;

6. The facility shall keep clean the area surrounding a container in which it stores solid waste;

7. The facility shall ensure that stored waste is collected regularly from the storage area to prevent nuisance creation, including odor, insects, vermin, and

rodents, and to prevent waste overflow and/or accumulation beyond the capacity of storage containers and the storage area; and

8. The facility shall comply with applicable provisions of the Comprehensive Regulated Medical Waste Management Act, N.J.S.A. 13:1E-48.1 et seq.

8:43K-7.4 Water supply

(a) A health care services facility shall ensure that:

1. The water supply it uses for drinking or culinary purposes is:

i. Adequate in quantity and safe and sanitary in quality; and

ii. From a water system that has no back-siphonage condition and is constructed, protected, operated, and maintained in conformance with applicable Federal, State, and local law, including the New Jersey Safe Drinking Water Act, N.J.S.A. 58:12A-1 et seq.;

2. Hot running water (between 105 and 120 degrees Fahrenheit or 41 to 49 degrees Celsius) and cold running water are available in patient care areas; and

3. The facility maintains its sewage disposal system in good repair and operates it in compliance with applicable State and local law.

8:43K-7.5 Supplies and equipment

(a) A health care services facility that shall provide equipment and supplies that are appropriate to the treatment needs of the types and ages of patients the facility serves.

(b) A health care services facility that is subject to licensure pursuant to the Health Care Facilities Planning Act, N.J.S.A. 26:2H-1 et seq., and uses:

1. Needles and sharp instruments shall comply with applicable provisions at P.L. 1999, c. 311 (codified in part at N.J.S.A. 26:2H-5.10 et seq.), and rules promulgated pursuant thereto at N.J.A.C. 8:43E-7, Requirement to Use Needles and Sharp Instruments Containing Integrated Safety Features or Needleless Devices; and

2. Linens or laundry that shall comply with applicable provisions at N.J.A.C. 8:43A-31.2 through 31.7.

(c) A health care services facility that uses measurement equipment shall calibrate all instruments of measurement in accordance with the manufacturer's instruction and maintain a record of instrument calibration.

8:43K-7.6 Sterile equipment

(a) A health care services facility that uses reusable medical devices shall ensure that it processes reusable medical devices in conformity with the following publications issued by each of the entities listed below, which are incorporated herein by reference, as amended and supplemented:

1. Association for the Advancement of Medical Instrumentation® (AAMI), 3330 Washington Building, Suite 400, Arlington, VA 22209 or at the AAMI website at www.aami.org:

i. ANSI/AAMI ST79:2017/(R)2022 w/AMDs A1:2020, A2:2020, A3:2020, A4:2020, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities;

ii. ST 35, Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Nonclinical Settings;

iii. ST 58, Safe Use and Handling of Glutaraldehyde-Based Products in Health Care Facilities; and

iv. ST 41R, Ethylene Oxide Sterilization in Health Care Facilities: Safety and Effectiveness; and

2. Society of Gastroenterology Nurses and Associates, Inc., Practice Committee 2017-2018, Loyola M, Babb E, Bocian S, et al. "Standards of Infection Prevention In Reprocessing Flexible Gastrointestinal Endoscopes," *Gastroenterology Nursing,* Vol. 43, No. 3, pp. E142-E158 (May/June 2020), doi: 10.1097/SGA.0000000000000536, 330 North Wabash, Suite 2000, Chicago, IL 60611, telephone: (800) 245-SGNA or (312) 321-5165, telefacsimile: (312) 673-6694, website: www.SGNA.org.

(b) A health care services facility shall clean reusable medical devices prior to sterilization or disinfection.

(c) A health care services facility shall select and use disinfection and/or sterilization methods for patient care items or equipment depending on the classification of the item or equipment among the following categories:

1. Critical items, that is, objects that enter sterile tissue or the vascular system, which a facility shall sterilize by a process that can demonstrate a

sterility assurance level of 10 to the minus-six, except with respect to laparoscopes, arthroscopes, and other scopes that enter normally sterile areas of the body, which a facility shall sterilize or to which it shall apply high-level disinfection after each use, according to either the manufacturers' written recommendations or a policy that the facility's infection control committee establishes;

2. Semi-critical items, that is, objects that come into contact with mucous membranes or skin that is not intact, to which a facility shall apply high-level or intermediate-level disinfection using, at a minimum, a disinfectant that is labeled as tuberculocidal; or

3. Noncritical items, that is, objects that come in contact with intact skin but not with mucous membranes, which a facility shall expose, at a minimum, to a low-level disinfectant.

(d) A health care services facility shall verify the efficacy of chemicals used for high-level disinfection using a test method specific to the chemical, if a valid and reliable test method is available and feasible for use in an ambulatory setting.

(e) At the completion of each sterilization cycle, a health care services facility shall record and maintain, on site, for at least one year, or pursuant to facility policy, whichever is greater, the following documentation:

1. Verified time, temperature, and pressure readings, and the printout or chart initialed by the operator before items are removed; and

2. A record of each sterilization and/or disinfection load, including the date, load, and/or cycle number, and the specific contents of the load.

(f) A health care services facility shall ensure that:

1. The manufacturer's instructions for cleaning, testing, disassembly, and sterilization of equipment are readily accessible and adhered to by employees;

2. Hinged instruments are processed in an open position;

3. Instruments that can be disassembled are disassembled for decontamination and sterilization;

4. Sterilized materials are stored, handled, and transported to maintain sterility and package integrity is maintained until use;

5. Each package is labeled with sterilization date and load number;

6. The expiration date of sterile supplies does not exceed the shelf-life date as recommended by the manufacturer of the packaging or the device contained therein; and

7. The facility establishes and enforces a policy and procedure to retrieve and reprocess sterile supplies as to which the expiration date has passed.

(g) A facility that the Department licenses pursuant to this subchapter using an event-related sterility program shall establish a process that includes a continuous quality plan, and as part of which, the facility shall document facility compliance with the following:

1. Proper transportation of sterile product;

2. Proper storage of sterile product;

3. Proper rotation of sterile product; and

4. Maintenance of sterile pack integrity.

(h) A health care services facility shall install and operate sterilization equipment in accordance with the sterilizer manufacturer's written instructions.

(i) A health care services facility shall ensure that single-use patient care items are reprocessed in accordance with the following:

1. The manufacturer provides written documentation for cleaning and sterilization of the item and the facility has the resources to meet those specifications;

2. The methods the facility uses to process single-use patient care items conform to:

i. Premarket notification, registration, and listing regulations at 21 CFR Part 807; and

ii. Quality system regulations at 21 CFR Part 807; and

3. If the facility retains an outside firm to provide its sterile processing, the facility establishes a quality control program to ensure the delivery of a safe product, as specified in the contract with the third-party processor.

(j) A health care services facility that participates in shared reprocessing by an outside healthcare device reprocessing center shall ensure that:

1. Each facility in the network, in conjunction with each facility's infection control manager, approves the policies and procedures to be used for all processing protocols;

2. Each facility inventories and pre-cleans instruments and devices, which are to be transported off site for processing, prior to transportation.

i. Soiled instruments are contained in impervious, closed containers that are either locked or sealed in covered carts;

3. The processing facility performs decontamination, assembly, and sterilization according to the device manufacturer's written recommendations.

i. The processing facility obtains, follows, and keeps on file at the processing facility, the manufacturer's written instructions for processing specialty devices;

4. The processing facility maintains at the facility the following records:

i. Sterilization logs for all sterilized items; and

ii. Logs of biological monitoring in accordance with N.J.A.C. 8:43A-14.5(a);

5. The processor immediately notifies the receiving facility upon a positive biological result; and

6. The processing facility transports sterile product using disinfected, impervious containers that are either locked or sealed and in covered carts.

(k) A health care services facility that engages in sterilization using ethylene oxide, peracetic acid, low temperature gas, plasma, and steam shall:

1. Perform biological monitoring with live spores, or an FDA-approved equivalent, using:

i. Ethylene oxide, in each load;

ii. Peracetic acid, weekly;

iii. Low temperature gas plasma, daily in the working load; and

iv. Steam sterilizers, weekly;

2. Perform biological monitoring with live spores following repair or breakdown of equipment;

3. Perform biological monitoring with live spores or a spore-based enzyme in each load that contains an implantable device, which shall not be used until a negative biological test is received;

4. Use a biological indicator that is applicable to the sterilization process used, and store and use the indicator in accordance with the manufacturer's written instructions or recommendations;

5. Incubate a rapid readout biological monitor to obtain a spore kill reading, for the incubation duration that the manufacturer of the biological indicator specifies in its written instructions or recommendations;

6. Use a chemical indicator and/or integrator, as applicable to the sterilization process in use, with respect to each:

i. Package processed in steam;

ii. Package processed in ethylene oxide;

iii. Package processed in low-temperature gas plasma; and

iv. Load, as directed by the manufacturer, for peracetic acid;

7. Perform a pre-vacuum air removal test daily on each pre-vacuum sterilizer and following repair or breakdown of the pre-vacuum sterilizer;

8. Implement effective corrective action, including retesting and recall, if indicated, upon obtaining a positive biological test result using a sterilizer.

i. Establish, and maintain on site, written documentation of actions taken in response; and

ii. Ensure that a recall system is in place and put into effect, as needed;

9. Ensure that the person responsible for reprocessing reusable medical instruments obtains and maintains certification by a national central service certification program upon hire or within two years of employment; and

10. Ensure that all personnel involved in the use of ethylene oxide have the appropriate licensure from the New Jersey Department of Environmental Protection.

(l) A health care services facility shall ensure the maintenance of environmental surfaces in decontamination and clean processing areas in accordance with the following:

1. Hard-surface floors are kept clean;

2. Walls are kept clean of spills and splashes;

3. Ceilings, ventilation system vents, and sterilizer vents are kept clean and free from dust;

4. Storage shelves are kept clean; and

5. All horizontal surfaces are disinfected at each shift and more frequently, as needed.

(m) A health care services facility shall ensure that clean and contaminated work areas and activities are separated.

8:43K-7.7 Documentation and treatment records

(a) In addition to the requirements for medical records at N.J.A.C. 8:43K-4.7, a health care services facility shall ensure that the health care medical record of each patient includes, at a minimum:

1. Documentation of the health history and physical examination of the patient, if performed pursuant to N.J.A.C. 8:43K-5.3, which the examiner signs and dates;

2. Any orders for laboratory, radiologic, or diagnostic tests and procedures, and/or screening tests and the results thereof, which the prescriber sign and dates;

3. All orders for treatment, medication, and other orders (such as dietary instruction), signed and dated by the prescriber;

4. A record of medication administered to a patient, including the name and strength of the medication, date and time of administration, dosage administered, method of administration, and signature of the person who administered the medication;

5. A record of any treatment, medication, or service offered by personnel of the facility that the patient refuses;

6. Documentation that appropriate personnel of the facility obtain the patient's informed consent for any procedure or treatment that the facility provides to the patient, and which the facility's policies and procedures identify as requiring informed consent;

7. Documentation of any advance directive for health care or advance directive for mental health care that the patient executes;

8. The patient's signed acknowledgement that the facility has informed the patient of patient rights pursuant to N.J.A.C. 8:43K-5.9, which the facility issues either by spoken discussion or in writing, and that the facility has offered the patient a written document including these rights;

9. Any authorization the patient issues for release of the patient's medical record; and

10. The patient's immunities and vaccinations, in accordance with the facility's policies and procedures.

(b) A health care services facility shall maintain, within each patient's medical record, documentation relating to the patient's mortality, morbidity, complication, infection, and readmission, in accordance with N.J.S.A. 26:2H-12.2a.

8:43K-7.8 Reportable events

(a) A health care services facility shall notify the Department of:

1. The death of a patient under the supervision of the facility, including a death known or suspected to have resulted from the misuse of medication that the facility prescribed or dispensed; and

2. The resignation or termination of the medical director, and the name of the replacement medical director, in writing, within three days of the resignation or termination.

8:43K-7.9 Medical director; appointment; duties

(a) The governing body of a health care services facility shall appoint a medical director in accordance with N.J.A.C. 8:43K-5.8, who is a physician, at a minimum, and, subject to (b) below:

1. Has successfully completed a residency program accredited by the Accreditation Council for Graduate Medical Education or approved by the American Osteopathic Association in a medical specialty related to services provided by the facility;

2. Is a diplomate of a member board of the American Board of Medical Specialties in a medical specialty related to services that the facility provides; or

3. Holds certification from a certifying board of the American Osteopathic Association in a medical specialty related to services that the facility provides.

(b) The governing body of a facility that provides chronic dialysis services shall appoint, as the facility medical director, a nephrologist who is a diplomate of the American Board of Internal Medicine in the subspecialty of nephrology or is certified in the subspecialty of nephrology by the American Osteopathic Board of Internal Medicine, Bureau of Osteopathic Specialists, of the American Osteopathic Association.

(c) A medical director appointed pursuant to (a) and/or (b) above shall:

1. Designate, in writing, a physician to serve as acting medical director in the medical director's absence, who has at least the credentials required for the medical director pursuant to (a) and/or (b) above.

i. The medical director, or the acting medical director, shall be physically present a minimum of eight hours per week and available at all times patients are onsite; and

2. Direct, provide, and ensure the quality of medical services that the facility's patients receive, in accordance with N.J.A.C. 8:43K-4, by:

i. Developing and maintaining objectives, policies, an organizational plan, and a quality assurance and performance improvement program for physician services;

ii. Developing, implementing, and reviewing medical policies and procedures, reviewing these at least annually and more frequently, as needed, and sharing these with medical staff;

iii. Participating in planning and budgeting for physician and medical staff services;

iv. Coordinating and integrating physician services with other patient care services to provide a continuum of care for each patient;

v. Ensuring the implementation of medical staffing patterns;

vi. Assisting in the development and maintenance of job descriptions for the medical staff, participating in the review of credentials and delineation of privileges of medical staff members, and assigning duties based upon education, training, competencies, and job descriptions;

vii. Participating in staff orientation and staff education activities, as appropriate;

viii. Approving the content, location, and frequency of inspection, of emergency kits, carts, equipment, and supplies, confirming that the respective expiration dates for materials available for use have not elapsed, and assigning responsibility for the inspection of these materials;

ix. Supervising the facility's medical providers, physicians, and prescribers; and

x. Developing, implementing, reviewing at least annually, and revising, as necessary, written medical policies, including medical staff bylaws, in cooperation with the medical staff, subject to governing authority approval, in accordance with (b) above.

(d) The medical policies and medical staff bylaws required pursuant to (c)2x above shall address, at a minimum:

1. A plan for medical staff meetings and their documentation through the maintenance of written minutes;

2. A mechanism for establishing and implementing procedures relating to credentials review, delineation of qualifications, medical staff appointments and reappointments, evaluation of medical care, and the granting, denial, curtailment, suspension, or revocation of medical staff privileges;

3. Specifications for verbal orders, including the identification of personnel who may issue spoken orders and who may receive and implement them; and

4. A system for completion of entries in each patient's medical record by members of the medical staff, including, but not limited to, specification of a time limit for completion of the medical record, not to exceed 30 days following the

patient's last treatment or discharge, and compliance with signatory requirements at N.J.A.C. 8:43K-4.7 and the facility's policies and procedures.

8:43K-7.10 Director of nursing services; appointment; duties

(a) The governing body of a health care services facility shall appoint a director of nursing services who is a registered professional nurse and who has at least one year of full-time, or full-time equivalent, experience in nursing supervision and/or nursing administration in a licensed health care facility.

(b) The governing body of a health care services facility shall designate, in writing, a registered professional nurse to serve as acting director of nursing services in the absence of the director of nursing services, who has at least the credentials required for the director of nursing services pursuant to (a) above.

1. The director of nursing services, or the acting director of nursing services, shall be available to the facility when patients are onsite; and

2. Direct, provide, and ensure the quality of nursing services provided to patients by, at a minimum:

i. Developing, maintaining, and reviewing at least annually, written objectives, policies, a procedure manual, an organizational plan, and a quality assurance and performance improvement program for the nursing service;

ii. Participating in planning and budgeting for the nursing services;

iii. Coordinating and integrating the nursing services with other patient care services to provide a continuum of care for each patient;

iv. Establishing and ensuring compliance with staffing schedules and plans for the nursing services;

v. Assisting in the development and maintenance of written job descriptions for nursing personnel, and assigning duties based upon education, training, competencies, and job descriptions;

vi. Participating in staff orientation and staff education activities;

vii. Providing administrative oversight of the facility's nursing services and, directly or indirectly supervising, as appropriate, the facility's nursing staff; and

viii. Participating in multidisciplinary team conferences and/or other team care activities.

(c) A facility shall provide required nursing services in compliance with this chapter either directly or through written agreement and:

1. Ensure that each member of a facility's licensed nursing personnel provides services at the facility that are within the member's applicable scope of practice, in accordance with N.J.S.A. 45:11-23 et seq., and written job description;

2. Ensure the documentation of provided services in a patient's medical record;

3. If the facility provides wound care services, designate a nurse to oversee wound care protocols, which must include triage for skin infections or severe wounds requiring additional medical treatment and infection control procedures;

4. In accordance with written job descriptions, ensure that nursing personnel enter the following in the nursing portion of each patient's medical record:

i. The nursing portion of the patient's plan of care, in accordance with the facility's policies and procedures;

ii. Clinical notes; and

iii. A record of medications administered, when applicable; and

5. Ensure that after each medication administration, the nurse who administers the medication documents:

i. The name and strength of the medication;

ii. The date and time of administration;

iii. The dosage administered;

iv. The method of administration;

v. Adverse reactions and interventions; and

vi. The signature of the nurse who administers the medication.

8:43K-7.11 Infection prevention and control

(a) The administrator of a health care services facility shall:

1. Ensure the development, implementation, and up-to-date maintenance of an infection prevention and control program.

i. A facility that an acute care hospital owns or operates may participate in the hospital's infection prevention and control program; and

2. Designate an infection prevention and control professional to direct, provide, and ensure the quality of infection prevention and control services at the facility who:

i. Has education or training in surveillance, prevention, and control of healthcare-associated infections;

ii. Possesses CBIC® certification in infection prevention and control within five years of beginning the practice of infection prevention and control; and

iii. May be a consultant and need not be a full-time employee, provided a health care professional is on site who is responsible for the day-to-day activities of the facility related to infection prevention and control.

(b) An infection prevention and control professional designated pursuant to (a) above, at a minimum, shall develop and maintain written objectives, policies and procedures, an organizational plan, and a quality improvement program for the infection prevention and control service.

(c) A health care services facility shall develop, implement, and review, at least every three years and more frequently, as necessary, written policies and procedures regarding infection prevention and control, addressing, at a minimum:

1. The establishment and implementation of a system for:

i. Investigating, reporting, and evaluating the occurrence of reportable communicable diseases, infections, and conditions in accordance with N.J.A.C. 8:57, Communicable Diseases;

ii. Investigating and evaluating medical conditions that may be related to activities and procedures of the facility; and

iii. Identifying and reporting suspected and confirmed cases of HIV infection in accordance with N.J.A.C. 8:65, HIV Infection Reporting;

2. Infection prevention and control practices, including standard precautions, in accordance with 29 CFR Part 1910, Occupational Safety and Health Standards, Subpart Z, Toxic and Hazardous Substances, at 29 CFR 1910.1030, Bloodborne Pathogens;

3. Control measures or studies that the facility is to initiate following identification of an infection prevention and control problem;

4. Aseptic technique, employee health, and staff training in infection prevention and control;

5. Care of patients with communicable diseases;

6. Exclusion from work, and authorization to return to work, for personnel with communicable diseases; and

7. Surveillance techniques to identify sources and minimize transmission of infection.

(d) A health care services facility shall conduct Infection prevention and control activities based on the CDC Guidelines listed below, incorporated herein by reference, as amended and supplemented, which are collected at

https://www.cdc.gov/infection-control/hcp/guidance/index.html (page last updated April 8, 2024) or https://www.cdc.gov/healthcare-associated-infections/site.html:

1. Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care (September 2016), available at https://www.cdc.gov/healthcare-associated-infections/hcp/prevention-healthcare/outpatient-expectations.html (page last updated April 15, 2024);

2. CDC Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings, available at https://www.cdc.gov/infection-control/hcp/core-practices/index.html (page last updated April 12, 2024);

3. CDC Guideline for the Prevention of Surgical Site Infection, 2017, available at *JAMA Surg.* 2017; 152(8):784–791, doi:10.1001/jamasurg.2017.0904, https://jamanetwork.com/journals/jamasurgery/fullarticle/2623725, and https://www.cdc.gov/infection-control/hcp/surgical-site-infection/index.html (page last updated April 12, 2024);

4. Guidelines for the Prevention of Intravascular Catheter-Related Infections, 2011, available at https://www.cdc.gov/infection-control/hcp/intravascular-catheter-related-infection/index.html (page last updated April 12, 2024);

5. Infection Control in Healthcare Personnel: Infrastructure and Routine Practices for Occupational Infection Prevention and Control Services (2019), available at https://www.cdc.gov/infection-control/hcp/healthcare-personnel-infrastructure-routine-practices/index.html (page last updated April 12, 2024);

6. Moorman AC, de Perio MA, Goldschmidt R, et al., Testing and Clinical Management of Health Care Personnel Potentially Exposed to Hepatitis C Virus — CDC Guidance, United States, 2020, MMWR Recomm Rep 2020; 69 (No. RR-6):1–8, available at http://dx.doi.org/10.15585/mmwr.rr6906a1;

7. CDC, Healthcare-Associated Pneumonia Prevention Guideline, 2003, available at https://www.cdc.gov/infection-control/hcp/pneumonia-prevention/index.html; and

8. Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019 (May 17, 2019), available at MMWR 2019;68:439–443, doi: http://dx.doi.org/10.15585/mmwr.mm6819a3, available at https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w.

(e) The Department may allow a facility to diverge from the guidelines and recommendations listed at (d) above, if it finds that the facility has identified a sound infection control rationale based upon scientific research or epidemiologic data for the diversion.

(f) A health care services facility shall develop and implement an infection prevention and control quality improvement program.

(g) If a health care services facility identifies infection prevention and control concerns, or data that a facility collects indicate a need for corrective action, a facility's administrator shall recommend, implement, and monitor the needed infection prevention and control corrective actions.

8:43K-7.12 Quality assurance and performance improvement program

(a) A health care services facility shall establish an ongoing process for monitoring and evaluating patient care services, staffing, infection prevention and control, housekeeping, sanitation, safety, maintenance of physical plant and equipment, patient care statistics, and discharge planning services.

(b) A facility shall ensure that the quality assurance process it establishes pursuant to (a) above:

1. Incorporates periodic reviews of patient medical records; and

2. Includes evaluation by patients of the care and services they receive from the facility and, as appropriate, patients' families.

(c) If the monitoring and evaluation activities of a facility's quality assurance coordinator, conducted pursuant to this section, might indicate the need for corrective action, the quality assurance coordinator shall submit its findings to the administrator.

(d) Unless an administrator determines that corrective action in response to findings reported pursuant to (c) above are unnecessary or no longer indicated, the administrator of an outpatient primary health care facility shall:

1. Follow up on the findings to ensure that the facility implements effective corrective actions, including, as appropriate, policy revisions, procedural changes, educational activities, and follow-up recommendations; and

2. Submit a written report of the results of the quality assurance and performance improvement program to the governing authority, at least annually (subject to (e) below), and include therein, as applicable:

i. Deficiencies identified and recommendations for corrections or improvements; and/or

ii. The basis of the administrator's determination that additional actions were unnecessary or no longer needed.

(e) A facility administrator shall report immediately to the governing authority upon the identification of a deficiency that may jeopardize patient safety.

(f) The quality assurance and performance improvement program shall identify and establish indicators of quality care specific to the facility, which the administrator shall monitor and evaluate.

8:43K-7.13 Laboratory and radiological services

(a) A health care services facility that provides laboratory and radiological services shall provide the services either directly or through written agreement with an external provider.

(b) A health care services facility that offers laboratory services:

1. That require Department licensure pursuant to N.J.S.A. 45:9-42.26 et seq., shall use only Department-licensed facilities; and

2. Shall establish and implement policies and procedures for obtaining, identifying, storing, and transporting laboratory specimens.

(c) A health care services facility that offers radiological services shall use only radiological services that the New Jersey Department of Environmental Protection registers in accordance with N.J.A.C. 7:28, Radiation Protection Programs.

8:43K-7.14 Reproductive health care services; general provisions

(a) This section applies to a facility that the Department licenses to provide reproductive health care services.

(b) Subject to (c) below, a reproductive health care services facility shall have, as either the medical director or on staff, a physician who is available during the facility's hours of operation, trained in gynecology, including procedural abortion care, and:

1. A family practice physician;

2. An obstetrician/gynecologist; or

3. A diplomate in a primary specialty, such as internal medicine or emergency medicine, and has fellowship training or certification in family planning and/or reproductive health care services.

(c) In addition to complying with N.J.A.C. 8:43K-5.2, a reproductive health care services facility shall obtain each patient's obstetrical and gynecological history.

(d) A reproductive health care services facility shall ensure that a patient record includes, in addition to the content required pursuant to N.J.A.C. 8:43K-4.7, a history of psychological and social problems, including any trauma history.

8:43K-7.15 Primary care services additional requirements

(a) A health care services facility that provides primary care services shall:

1. Provide services within the facility's scope of licensure; and

2. Refer a patient who needs screening, diagnostic testing, and/or treatment services that exceed the facility's scope of licensure, to ensure coordinated service provision.

(b) A health care services facility that provides primary care services shall ensure that each patient record includes, in addition to the content required pursuant to N.J.A.C. 8:43K-4.7, at a minimum:

1. The patient's complaint or purpose of the visit;

2. The diagnosis, indication, or clinical impression for treatment that the patient is being provided;

3. Clinical notes, which are to be entered on the day service is rendered;

4. Patient assessments that each service providing care to the patient develops;

5. A patient plan of care, in accordance with the facility's policies and procedures;

6. A medication record indicating at least the name, date, dosage, and duration of all medication prescribed;

7. Documentation of any referrals to other health care providers;

8. Documentation of any consultations ordered or provided; and

9. Instructions given to the patient and/or the patient's family for follow-up care.

8:43K-7.16 Prenatal and postpartum care additional requirements

(a) A health care services facility that provides prenatal and postpartum care and/or obstetric services shall:

1. Comply with N.J.A.C. 8:43K-4.7 and 7.15;

2. Obtain membership in an MCHC, in accordance with N.J.A.C. 8:33C;

3. Have, as either the medical director or on staff, a physician trained in obstetrics and gynecology who is:

i. Either a physician who is board-certified in family medicine with obstetrics and gynecology training or an obstetrician/gynecologist; and

ii. Available during the facility's hours of operation.

4. Obtain the patient's obstetrical and gynecological history, as appropriate, including a history of psychological and social problems;

5. Ensure that the patient record for a prenatal patient includes, at a minimum:

i. Routine laboratory testing in accordance with American Academy of Pediatrics Committee on Fetus and Newborn and American College of Obstetricians and Gynecologists Committee on Obstetric Practice, Guidelines for Perinatal Care, Eighth Edition (2017), incorporated herein by reference, as amended and supplemented, available at https://www.acog.org/store/products/clinical-resources/guidelines-for-perinatal-care;

ii. Routine screening in accordance with evidence-based, peer-reviewed prenatal care guidelines, such as Ramírez SI, Prenatal Care: An

Evidence-Based Approach, *Am Fam Physician* (August 2023) 108(2):139-150, PMID: 37590852, available at https://www.aafp.org/pubs/afp/issues/2023/0800/prenatal-care.html, including validated spoken screening for alcohol and substance use in pregnancy; and

iii. Screening for HIV in accordance with N.J.A.C. 8:61, AIDS Drug Distribution Program; HIV Counseling and HIV Testing of Pregnant Persons; and Neonatal HIV Testing;

6. Transfer a copy or summary of the patient's prenatal medical record by no later than the patient attaining 34 weeks of gestation to the inpatient facility at which the patient plans delivery; and

7. Obtain a copy or summary of the patient's labor, delivery, and postpartum record from the inpatient facility at which delivery occurs prior to any scheduled postpartum visits.

8:43K-7.17 Pediatric care additional requirements

(a) An outpatient primary care facility that provides services to a pediatric population shall comply with N.J.A.C. 8:43K-7.15 and:

1. Obtain membership in an MCHC, in accordance with N.J.A.C. 8:33C;

2. Have a board-certified family medicine physician or a board-certified pediatrician:

i. As either the medical director or on staff; and

ii. Available to the facility when pediatric patients are onsite; and

3. Ensure that the patient record of a pediatric patient includes, in addition to the content required pursuant to N.J.A.C. 8:43K-4.7 and 7.7, at a minimum:

i. Documentation of growth, including at least a record of weight and length or height;

ii. Documentation of a basic developmental assessment, including sensory screenings; and

iii. Administered immunizations.

8:43K-7.18 Counseling and therapy services

(a) A health care services facility may elect to provide counseling and therapy services without obtaining a behavioral health services license pursuant to N.J.A.C. 8:43K-6, provided:

1. The health care professional who is to provide counseling and therapy services has the applicable credentialing, educational, and experiential requirements that N.J.A.C. 8:43K-6 establishes, such as a licensed professional counselor, licensed clinical social worker, licensed marriage and family therapist, psychologist, and/or psychiatrist, and the services are within the professional's credentialed scope of practice.

i. Trainees and other licensed or certified professionals, such as licensed associate counselors, licensed associate marriage and family therapists, and/or certified social workers, may work under the supervision of fully clinical licensed professionals provided the clinical licensed supervisor has appropriate supervising credentials.

2. The facility retains an appropriately qualified licensed provider, either by employment or written contract, and full- or part-time, as necessary, to ensure the appropriate oversight and provision of counseling and therapy services.

(b) Certified social workers, peers, navigators, and other interdisciplinary team members may work as part of an integrated clinical team addressing psychosocial needs within their designated scopes of practice.

(c) Psychoeducation services may be provided by appropriately credentialed providers as a routine part of integrated care.

8:43K-7.19 Medical specialty services

(a) A health care services facility may elect to offer additional medical specialty or subspecialty outpatient services without obtaining an additional license.

1. The paragraph sets forth a non-exhaustive list of medical specialty and subspecialty care services that a health care services facility may elect to provide:

i. Addiction medicine, allergy and immunology, cardiology, dermatology, endocrinology, gastroenterology, geriatric medicine, infectious disease, neurology, nephrology, oncology, ophthalmology, pain medicine, psychiatry, and sports medicine.

8:43K-7.20 Anesthesia services

(a) A facility that performs ambulatory surgical cases, general anesthesia, or deep or dissociative conscious sedation shall obtain licensure as an ambulatory

surgical center in accordance with N.J.A.C. 8:43A-12 and comply with N.J.A.C. 8:43A.

(b) A facility that administers only local anesthesia or minor conduction injection nerve blocks for outpatient procedures shall:

1. Comply with N.J.A.C. 8:43K-7.11;

2. Ensure that the local anesthesia is administered by credentialed providers within their scope of practice in accordance with medical staff bylaws and policies and procedures; and

3. Develop policies and procedures for:

i. Obtaining patient consent for both the performance of the procedure and the use of the local anesthesia to be administered; and

ii. Provision of written instructions to each patient (including multilingual instructions, if needed) about post-procedural care, including, at a minimum, wound or site care to reduce infection risk, and signs and symptoms of common complications and when to seek medical attention in response thereto.

(c) A facility that administers minor regional blocks and/or minimal or moderate conscious sedation for outpatient office-based procedures shall ensure that at least one of the following, who is trained in advanced cardiac life support, is present at all times when a patient is receiving or recovering from anesthesia.

(d) A facility shall ensure that the administration of minor regional blocks is performed in accordance with medical staff bylaws, policies, and procedures for the administration of minor regional blocks and:

1. By a physician, podiatrist, or dentist who has privileges at the facility in accordance with medical staff bylaws; or

2. With a collaborating physician who has privileges at the facility in accordance with medical staff bylaws to administer or supervise minor regional blocks and who is immediately available by:

i. A certified registered nurse anesthetist;

ii. A registered nurse anesthetist;

iii. A physician resident, dental resident, or student nurse anesthetist participating in a nationally approved graduate training program leading to a recognized specialty; or

iv. A certified nurse midwife, a physician assistant, or an advanced practice nurse.

(e) A facility shall ensure that that administration of an anesthetic agent for conscious sedation is performed only by the following:

1. A physician or dentist who has privileges at the facility in accordance with medical staff bylaws to administer anesthetic agents used for conscious sedation; or

2. In collaboration with a physician who has privileges at the facility in accordance with medical staff bylaws to administer or supervise anesthetic agents used for conscious sedation who is immediately available:

i. A certified registered nurse anesthetist;

ii. A registered nurse anesthetist;

iii. A physician resident, dental resident, or a student nurse anesthetist participating in a nationally approved graduate training program leading to a recognized specialty; or

iv. A registered nurse who is trained and experienced in the use of anesthetic agents used for conscious sedation to administer supplemental doses, after the initial dose is given by a privileged or supervising physician who remains present.

(f) A clinical monitor shall be present continuously to clinically monitor a patient during a procedure that another person is performing during which an anesthetic agent is used that creates conscious sedation in the patient.

1. The primary purpose and function of the clinical monitor is the monitoring of the patient; that is, the clinical monitor shall have no other primary function to perform during the procedure.

2. The clinical monitor shall have completed advanced cardiac life support and be:

i. A person identified at (e) above; or

ii. A registered professional nurse.

(g) A facility that the Department licenses pursuant to this subchapter that provides minor regional blocks and/or conscious sedation for outpatient office-based procedures shall establish, implement, and, at least every three years and more frequently, as needed, review and revise written bylaws, rules, regulations, policies, and procedures for minor anesthesia services, in accordance with the governing authority and medical staff bylaws; which address, at a minimum:

1. The identification of the anesthesia services that the facility is authorized to perform;

2. The identification of the responsibilities of medical staff members in providing procedural and/or minor anesthesia care to patients;

3. The use of analgesia and anesthesia, including identification of the types that are to be used for each procedure;

4. Safety, and responsibilities and qualifications of persons who administer anesthesia and clinically monitor patients;

5. The processes to obtain patient consent for the performance of a procedure and the anesthesia to be administered;

6. The clinical monitoring of patients in a procedure room or other location at which patients receive anesthesia;

7. The post-procedural observation and/or care required for each type of procedure; and

8. The provision of written instructions to each patient (including multilingual instructions, if needed) about post-procedural care, including, at a minimum, wound or site care to reduce infection risk, and the signs and symptoms of common complications and when to seek medical attention in response thereto.

8:43K-7.21 Provision of dietetic and nutritional counseling services

A health care services facility that elects to provide dietetic and nutritional counseling services shall provide these services directly, by written agreement,

or using a documented referral mechanism, by a provider such as a dietician or a nutritionist whose credentialed scope of practice includes the level of dietetic and nutritional counseling that is indicated in the circumstances of each case.

SUBCHAPTER 8. OPIOID TREATMENT PROGRAM

8:43K-8.1 Opioid treatment program

(a) A facility that provides opioid treatment program services shall:

1. Obtain certification as an opioid treatment program in accordance with applicable Federal standards, including 21 U.S.C. § 823 and 42 CFR Part 8;

2. Register with the DEA as a narcotic treatment program in accordance with 21 CFR Part 1201, and adhere to applicable DEA standards;

3. Register with the New Jersey Division of Consumer Affairs to administer and/or dispense CDSs;

4. Provide, either directly by a designated staff member or through written agreement with an external provider, emergency telephone coverage that is available 24-hours-per-day, seven-days-a-week, to respond to clients in crisis, verify client dose levels, and provide related support, as appropriate; and

5. Establish and implement written policies and procedures that address client methadone withdrawal, consistent with, at a minimum, the following:

i. The dosage of methadone shall be reduced by up to, but no greater than, 10 milligrams (mg) every two days, except that the dosage of a client receiving greater than 100 mg per day shall be reduced by up, to but no greater than, 20 percent of the starting dose every two days until the client

is at a dose of 100 mg or less, and thereafter, the dosage may be reduced at a rate that is greater than 10 mg every two days.

SUBCHAPTER 9. ADJUNCTIVE SERVICES

8:43K-9.1 Provision of adjunctive services

(a) This subchapter applies to a facility that seeks to provide an adjunctive service as of or following initial licensure.

(b) A facility that the Department licenses pursuant to this chapter that elects to provide an adjunctive service shall:

1. Notify the Department in accordance with N.J.A.C. 8:43K-2.1(d); and

2. Comply with Federal and/or State law applicable to the provision of the service, for example:

i. If applicable Federal and/or State law requires a service provider to have a specified credential, education, and/or experience, the facility shall satisfy the credentialing, educational, and/or experiential requirement by retention of an appropriately qualified provider, either by employment or written contract, and full- or part-time, as necessary, to ensure the appropriate oversight and/or provision of the service; and shall ensure that the service to be provided is within the provider's applicable scope of practice; and

ii. If applicable Federal and/or State law requires the provider of a regulated service to use and maintain certain equipment or adhere to certain operational protocols, the facility shall ensure that the service

provider uses and maintains the required equipment and adheres to the mandated protocols.

(c) Upon the Department receiving a facility's submission of a Notice of Change in Outpatient Facility Adjunctive Service pursuant to N.J.A.C. 8:43K-2.1(d), the Department may conduct an on-site licensing survey of a facility that seeks to provide, as an adjunctive service, a service that an applicable Federal or State standard requires the facility to address regulated medical waste, sterilization, maintenance, and/or calibration of equipment, facility staffing, and/or facility infection prevention and control practices as described at N.J.A.C. 8:43K-7.11, and will notify the facility, in writing, as to the date on which the Department authorizes the facility to commence the provision of these services.

(d) A facility that the Department licenses pursuant to this chapter that elects to provide an adjunctive service that does not implicate the generation of regulated medical waste, the need for equipment sterilization, or the implementation of healthcare facility infection control practices, in accordance with N.J.A.C. 8:43K-7.11, may provide the adjunctive service without the Department conducting an on-site licensing survey or requiring the facility to obtain supplemental licensure prior to the facility's commencement of the provision of the adjunctive service;

1. This paragraph sets forth a non-exhaustive list of services to which (d) above applies:

i. Acupuncture, herbology in the practice of acupuncture, massage therapy, chiropractic, dietary and nutritional counseling, optometry,

physical therapy, counseling, therapy, tai chi, yoga, art therapy, music therapy, movement therapy, dance, and mindfulness-based therapy.

8:43K-9.2 Preventive medicine

(a) Subject to (b) below, a facility that the Department licenses pursuant to this chapter can provide preventive medicine services without submitting a separate or additional licensure application.

(b) A behavioral health services facility that the Department licenses pursuant to N.J.A.C. 8:43K-6 can provide preventive medicine as an adjunctive service, if the facility employs, or otherwise retains through a written agreement:

1. A medical director on a full- or part-time basis who can oversee the providers, protocols, and practice of preventive medicine at the facility; and

2. The provision of preventive medicine services is within the applicable scope of practice and credential of the physician or advanced practitioner, including the ability to order screening, testing, and medication treatment.

(c) The requirements at (b) above do not apply to a health care services facility that the Department licenses pursuant to N.J.A.C. 8:43K-7.

8:43K-9.3 Wound care

(a) A facility is authorized to provide wound care as an adjunctive service, provided:

1. The facility designates a nurse to oversee wound care protocols, which include triage for skin infections or severe wounds requiring additional medical treatment and infection control procedures;

2. The facility obtains licensure as an ambulatory surgical center in accordance with N.J.A.C. 8:43A if the facility provides wound care as a surgical service or with anesthesia;

3. The facility adheres to NASTAD, Wound Care and Medical Triage for People Who Use Drugs (April 2023), incorporated herein by reference, as amended and supplemented, available at https://nastad.org/resources/wound-care-medical-triage-people-who-use-drugs-and-programs-serve-them and https://nastad.org/sites/default/files/2023-04/PDF-Wound-Care-And-Triage.pdf in providing wound care as an adjunctive service for people with SUD;

4. The facility provides appropriate protective equipment to personnel providing wound care including, at a minimum:

i. A hand-washing station;

ii. Personal protective equipment including gloves, gowns, and eye protection; and

iii. Appropriate wound care supplies;

5. If the facility uses procedural medical equipment that requires sterilization, the facility complies with N.J.A.C. 8:43K-7.3, 7.5, 7.6, and 7.11; and

6. Personnel providing wound care services perform these services within each provider's applicable scope of practice and subject to credentialing standards applicable to the services being performed.

8:43K-9.4 Acupuncture and herbology

(a) A facility that elects to provide acupuncture services as an adjunctive service shall provide the services in accordance with N.J.S.A. 45:2C-1 et seq.

(b) A facility that elects to provide herbology in the practice of acupuncture as an adjunctive service shall comply with N.J.S.A. 45:2C-19, Herbology in practice of acupuncture, certification.

8:43K-9.5 Chiropractic services

A facility that elects to provide chiropractic services as an adjunctive service shall provide the services in accordance with N.J.S.A. 45:9-41.4 et seq.

8:43K-9.6 Dentistry

A facility that elects to provide dentistry as an adjunctive service shall comply with N.J.S.A. 45:6-1 et seq., and N.J.A.C. 8:43K-7.2 through 7.8, 7.11, 7.13, and 7.20, as applicable to the services provided.

8:43K-9.7 Harm reduction

(a) A facility is authorized to provide hypodermic needles and/or syringes for use in preventing, reducing, or mitigating the adverse effects of substance use, and is exempt from any obligation to obtain Department registration as a harm reduction center.

(b) A facility that seeks to distribute supplies designed for ingesting, inhaling, or otherwise introducing a controlled substance other than marijuana or hashish, as defined at N.J.S.A. 2C:36-1, shall register with the Department as a harm reduction center, in accordance with N.J.S.A. 26:5C-25 through 31 and N.J.A.C. 8:63.

(c) Nothing in this subchapter shall be interpreted as restricting the distribution of naloxone hydrochloride and other opioid antidotes, drug testing strips (such as xylazine or fentanyl test strips), or the integration of other harm reduction strategies, such as psychoeducation, to mitigate the risks of substance use.

SUBCHAPTER 10. STORAGE, ADMINISTRATION, AND DISPENSING OF MEDICATION

8:43K-10.1 Scope

A facility that the Department licenses pursuant to this chapter to administer, dispense, and/or store medication is subject to the requirements of this subchapter.

8:43K-10.2 Provision of pharmaceutical services

(a) A facility that maintains an on-site pharmacy shall designate a pharmacist who:

1. Has a DEA registration certificate and a New Jersey CDS registration certificate in accordance with the Controlled Dangerous Substances Acts; and

2. Directs, provides, and ensures the quality of pharmaceutical services, including:

i. Developing and maintaining written objectives, policies, a procedure manual, an organizational plan, and a quality assurance program for the pharmaceutical service;

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

iii. Coordinating and integrating the pharmaceutical service with other patient care services to provide a continuum of care for the patient; and

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

8:43K-10.3 Facility policies and procedures for medications

(a) A facility shall:

1. Establish and implement written policies and procedures for the administration, control, dispensing, and storage of medications;

2. Review and revise, as necessary, the policies and procedures at least annually and more frequently, as needed; and

3. Document the review.

(b) A facility's policies and procedures for the administration, control, dispensing, and storage of medications shall address, at a minimum:

1. The discontinuation of medication orders;

2. The purchase, storage, safeguarding, accountability, use, and disposition of medications, in accordance with the New Jersey Pharmacy Practice Act, N.J.S.A. 45:14-40 et seq., and the Controlled Dangerous Substances Acts;

3. The control of the administration of toxic and dangerous medications, including, at a minimum, narcotics, sedatives, anticoagulants, antibiotics, oxytocic agent, corticosteroid products, intravenous infusion solutions, and other medications specified in the facility's policies and procedures;

4. The control of medications in accordance with applicable Federal and State laws concerning procurement, storage, dispensing, administration, and disposition thereof, including the Controlled Dangerous Substances Acts, and N.J.A.C. 13:39, which shall address, at a minimum:

i. Establishment of a verifiable record system for CDS;

ii. Policies and procedures to be followed if CDS inventories cannot be verified, or medications are lost, contaminated, unintentionally wasted, or destroyed, and the establishment of a written report of any such incident signed by the persons involved and any witnesses present; and

iii. In all areas of the facility where medications are dispensed, administered, or stored, procedures for the intentional wasting of CDS, including the disposition of partial doses, and for documentation, including the signature of a second person who must witness the disposition;

5. If applicable, the use of parenteral nutrition, including the labeling of intravenous infusion solutions, such that a supplementary label is affixed to the container of any intravenous infusion solution to which a medication is added;

6. The procurement, storage, use, and disposition of needles and syringes in accordance with applicable Federal and State laws, including those specified at N.J.A.C. 8:43A-14.6(b), and the storage of all needles and syringes in locked storage areas;

7. Accessing specific information on medications and other drugs, including indications, contraindications, actions, reactions, interactions, cautions, precautions that should be taken, toxicity, and dosages.

i. The maintenance of a list of abbreviations, metric apothecary conversion charts, and a list of chemical symbols, approved by the medical staff, in areas where medications are prepared for administration;

8. Medication administration;

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

10. Disposal of medication pursuant to local, State, and Federal law, including N.J.S.A. 26:2H-12.69.

8:43K-10.4 Administration of medications

(a) A facility shall administer medications only in accordance with:

1. A written or electronically documented prescription order that specifies the name of the medication, dose, frequency, and route of administration which the prescriber has signed and dated; and

2. Prescriber orders, medical staff policy, and applicable law.

(b) A facility shall store medication in its original prescription container until the time of medication administration.

(c) A facility shall ensure that the person administering medication to a patient identifies the patient prior to medication administration.

(d) A facility that dispenses a medication to one patient shall not administer medication from that container to another patient.

(e) A facility shall ensure:

1. The immediate reporting of a medication error or an adverse drug reaction to the nurse in charge and the prescriber, and the documentation of the error or reaction in the patient's medical record; and

2. The reporting of the incident in accordance with facility procedures.

(f) A facility shall ensure that medication administration occurs in a clean, appropriate clinical location for the type of medication being administered.

1. The facility shall administer oral medication in any room that offers privacy for the patient and provider, such as in a consultation room.

i. No minimum square footage requirement applies to this type of medication administration; and

2. The facility shall administer injectable or implantable medications in an exam room that has the appropriate equipment, such as a routine examination room.

i. No procedure room requirement applies to this type of medication administration.

(g) A facility that administers medications shall comply with CDC, Core Infection Prevention and Control Practices for Safe Healthcare Delivery in All Settings, as amended and supplemented, incorporated herein by reference, which is available at https://www.cdc.gov/infection-control/hcp/core-practices/index.html (page last updated April 12, 2024).

8:43K-10.5 Storage of medication

(a) A facility shall ensure that:

1. All medication is kept in locked storage areas;

2. Medication storage and preparation areas are kept locked when not in use;

3. Only licensed nursing, medical, or other authorized personnel retain the keys or security codes to storage areas in which medications are kept;

4. Medication is stored under proper conditions, as indicated by the United States Pharmacopoeia, product labeling, and/or package inserts;

5. Medication for external use is kept separate from medication for internal use;

6. A declining inventory of medications in Schedules I through V of the Controlled Dangerous Substances Acts is made at the termination of each shift and retained wherever these medications are maintained; and

7. Medications are disposed of in accordance with applicable local, State, and Federal law, if they are:

i. In single-dose or single-use containers that are open or have broken seals;

ii. In containers missing medication source or exact identification (such as lot number); or

iii. Are outdated, recalled, or visibly deteriorated.

SUBCHAPTER 11. ADMINISTRATION OF CONTROLLED DANGEROUS SUBSTANCES FOR THE TREATMENT OF SUBSTANCE USE, AMBULATORY WITHDRAWAL MANAGEMENT, AND/OR STABILIZATION

8:43K-11.1 Scope

(a) This subchapter applies to a facility that stores and administers CDSs for the treatment of substance use, including withdrawal management, initial stabilization, and treatment of SUDs in the outpatient setting, using FDA-approved Schedules II, III, or IV medications of the Controlled Dangerous Substances Acts.

(b) This subchapter does not apply to a licensed opioid treatment program governed pursuant to 42 CFR Part 8 and N.J.A.C. 8:43K-8.

(c) This subchapter does not apply to a pharmacy's fulfillment of written prescriptions, or dispensing of medication, for addiction treatment.

8:43K-11.2 Patient care policies and procedures

(a) A facility that is subject to this subchapter shall:

1. Develop policies and procedures with the involvement of the medical director and clinical staff, review these at least annually and more frequently, as needed, and revise these, as necessary, to ensure conformity with applicable and evolving best practices for drug classification and clinical standards of practice;

2. Ensure that a member of any of the following populations, which are not in order of preference, receives priority in admission:

i. Persons who inject drugs;

ii. Persons who have HIV infection;

iii. Persons having histories of overdoses or hospitalizations due to substance use including alcohol use disorder;

iv. Pregnant and postpartum persons; and

v. Persons recently released or discharged from correctional or detention facilities, hospitalization, including psychiatric hospitals, inpatient SUD treatment facilities, skilled nursing or long-term care facilities, and/or another institutionalization or inpatient program;

3. Ensure that each newly admitted patient undergoes a comprehensive health screening that includes:

i. An offer of pregnancy testing to a patient who can become pregnant;

ii. Assessment and documentation of the patient's clinical appropriateness to receive CDSs for the treatment of ambulatory substance withdrawal management and stabilization, including demonstration that the patient:

(1) Meets DSM-5 diagnostic criteria for SUD, withdrawal, or intoxication, and criteria set forth in clinical protocol(s) for administration of CDSs by the medical director; and

(2) Is willing to participate in services;

4. Ensure that each newly admitted patient receives a plan of care that addresses the patient's medical, psychiatric, and social needs, which the facility reviews and revises at least every three months during the first year of treatment and at least every six months thereafter, or more frequently, as needed; and

5. Collect from each newly admitted patient the following additional intake information as part of a medical evaluation:

i. Significant medical history including hospitalizations, active medical problems, and current treatments;

ii. Pregnancies and reproductive health history; and

iii. Review of systems and current symptomatology.

8:43K-11.3 Withdrawal management and stabilization

(a) A facility that is subject to this subchapter shall establish, implement, and at least annually and more frequently, as necessary, review and revise, withdrawal management policies and procedures for:

1. Medical assessments, including physical examinations;

2. Admission criteria based on medical stability for outpatient level of care;

3. Staffing, including ensuring sufficient medical supervision; and

4. Drug-specific withdrawal management protocols, including:

i. Identification of withdrawal assessment instruments to be used;

ii. Medications to be used, including purpose, frequency of administration, and effectiveness;

iii. Treatment of protracted withdrawal from certain substances; and

iv. Frequency with which staff are to clinically monitor a patient's vital signs, including pulse, respiration, blood pressure, and temperature.

8:43K-11.4 Patient education services

(a) A facility that is subject to this subchapter shall educate each patient receiving this service as to:

1. The safe use and storage of medication;

2. The risks of substance use and ways to mitigate those risks, including harm reduction strategies and overdose prevention; and

3. Options for ongoing addiction treatment including the benefits of long-term use of medication, biopsychosocial stabilization, and ongoing recovery support.

8:43K-11.5 Extended on-site clinical monitoring services

(a) A facility that is subject to this subchapter shall provide extended-hours oversight and on-site clinical monitoring services including, at a minimum:

1. Twenty-four-hour access to on-call advanced practitioner or physician services for patients, which may include use of registered nurse services to provide call triaging;

2. Medical supervision of withdrawal provided by a physician or an advanced practitioner during regular business hours when patients are present and receiving services, provided:

i. A registered nurse can see and evaluate a patient to provide medical supervision pursuant to (a)2 above in accordance with a clinical protocol established pursuant to N.J.A.C. 8:43K-11.3(a)4, provided a physician or an advanced practitioner is physically on site and available to see and evaluate the patient; and

ii. Medical supervision pursuant to (a)2 above shall include serial medical assessments of vital signs and withdrawal symptoms using appropriate measures of withdrawal in accordance with a clinical protocol established pursuant to N.J.A.C. 8:43K-11.3(a)4;

3. Immediately before the patient's departure from a facility, a physician, an advanced practitioner, or a registered nurse shall reassess the vital signs and withdrawal symptoms of a patient receiving withdrawal, treatment, or stabilization CDS medication on site;

4. The facility shall conduct laboratory testing to inform appropriate clinical care, including urine drug screening, in accordance with the facility's clinical protocol established pursuant to N.J.A.C. 8:43K-11.3(a)4; provided:

i. A facility shall not administratively or involuntarily discharge a patient based on the patient's laboratory results;

ii. A facility may refer a patient to a higher level of care based on the patient's laboratory results, with the patient's consent; and

iii. A facility may modify a patient's treatment plan based on the patient's laboratory result(s);

5. Absent a documented medical reason and/or social impediment (such as insurmountable transportation or acute childcare difficulties) supporting the dispensing of additional days of medication supply for withdrawal management and/or stabilization, a facility shall dispense no greater than a three-day supply of controlled medication for each patient, until the treating physician or advanced practitioner determines the patient to be medically stable; and

6. A facility shall document each dispensing of medication in the patient's medical record and include a description of the clinical findings and rationale supporting the number of days and doses dispensed.

8:43K-11.6 Physician services

(a) The medical director of a facility that is subject to this subchapter shall:

1. Have:

i. Or be eligible for, board certification in addiction medicine or addiction psychiatry; or

ii. At least three years of clinical experience in the practice of addiction medicine or addiction psychiatry, such as medical detoxification, medication for addiction treatment, management of acute intoxication, and management of substance-related or toxicologic emergencies, including overdose;

2. Establish medical staffing schedules and plans to ensure medical staff coverage 24-hours-a-day, seven-days-a-week;

3. Evaluate and clinically monitor ambulatory withdrawal management and stabilization services;

4. Establish medical policies and procedures addressing:

i. Withdrawal management and supervision;

ii. Stabilization;

iii. Management of acute intoxication and/or overdose; and

iv. Medical management of emergencies.

(b) A facility that administers CDS for the treatment of ambulatory substance withdrawal management and stabilization that employs physicians, who are under the direction of the medical director, shall have a minimum of one year of experience in the direct provision of SUD treatment.

8:43K-11.7 Nursing services

(a) A facility that administers CDS for the treatment of ambulatory substance withdrawal management and stabilization shall:

1. Designate a director of nursing services who:

i. Has one year of full-time experience, or the equivalent thereof, in:

(1) Nursing supervision or nursing administration in the management of addiction in a licensed addiction and/or SUD treatment facility; or

(2) A clinical setting providing ambulatory withdrawal management, inpatient withdrawal management, or opioid treatment provider services; and

ii. Participates in team conferences, and the patient care committee, if the facility establishes such a committee; and

2. Ensure that an RN is on site during all operating hours and/or whenever medication is administered to patients.

8:43K-11.8 Pharmacy services

A facility that is subject to this subchapter shall employ or retain pursuant to a written agreement, a pharmacist on a part-time or full-time basis.

SUBCHAPTER 12. ALTERNATIVE CARE LOCATIONS

8:43K-12.1 Regular provision of licensed services at an alternative service location or using a mobile outpatient care vehicle

(a) A facility shall apply to the Department for licensure using the form at N.J.A.C. 8:43E-5 Appendix to provide regularly scheduled services that are subject to licensure pursuant to this chapter at an alternative service location, other than its principal licensed facility location, or using a mobile outpatient care vehicle.

(b) A facility that the Department licenses pursuant to (a) above shall establish and implement policies and procedures and comply with this chapter, as applicable, to the services to be provided at the alternative service location or the mobile outpatient care vehicle, to the same extent as at its principal facility location.

(c) Required staff members, as applicable to the services provided, such as the administrator, medical director, director of nursing services, behavioral health services program director, and/or behavioral health services clinical supervisor of the licensee may serve in the same capacity for both the primary facility location and for the alternative facility location and/or mobile outpatient care vehicle; provided the staff member, or the staff member's designee, is available to personnel at the alternative facility location during its hours of operation, to the same degree and extent that the staff member would be required to be available to personnel at the primary facility location.

8:43K-12.2 Intermittent provision of licensed services at an alternative service location

(a) A facility is authorized intermittently to provide services (other than opioid treatment program services) at off-site premises (such as a clinic at a community hall) and/or using a mobile outpatient care vehicle, provided the licensee complies with standards in this chapter that are applicable to the services being provided.

1. A licensee shall notify the Office, at least 30 days prior to the scheduled date of the off site or mobile provision of services, of the proposed location at which services are to be provided and the services to be provided.

2. Required staff of the licensee's primary facility location may serve contemporaneously in the same capacity for both the primary facility location and the off-site premises and/or mobile outpatient care vehicle, as applicable to the services provided, if the staff member, or the staff member's designee, remains available to the licensee during hours of operation at the primary facility location and the off-site premises and/or mobile outpatient care vehicle.

8:43K-12.3 Mobile outpatient care vehicle services

(a) A facility that seeks to provide full-time services using one or more mobile outpatient care vehicles shall apply for prior authorization to the Certificate of Need and Healthcare Facility Licensing Program.

1. Upon receiving a facility's application for prior authorization, the Department will conduct an on-site inspection of the vehicle.

(b) The facility shall establish and implement policies and procedures for the use of a mobile outpatient care vehicle in the provision of primary care services, which shall address, at a minimum, patient care, control of drugs, medical records, and infection prevention and control.

(c) The facility shall establish and implement policies and procedures for the use of a mobile outpatient care vehicle in the provision of behavioral health services or opioid treatment program services, which shall address, at a minimum, patient care, control of drugs, if applicable, and medical records, and shall be in accordance with applicable DMHAS program standards.

CHAPTER 121

LICENSURE STANDARDS FOR MENTAL HEALTH [PROGRAMS] **CASE MANAGEMENT AND COMMUNITY SUPPORT SERVICES**

SUBCHAPTER 1. LICENSURE OF MENTAL HEALTH [PROGRAMS] **CASE MANAGEMENT AND COMMUNITY SUPPORT SERVICES**

8:121-1.1 Scope and purpose

(a) (No change.)

(b) No mental health program shall operate, unless it is licensed by the Commissioner of the Department of Health as a mental health program and has a purchase of service contract or an affiliation agreement with the Division of Mental Health and Addiction Services or is licensed by the Commissioner of the Department of Health as a health care facility.

1. (No change.)

2. “Mental health program” means a program of mental health services not licensed by the Department as a health care facility **or integrated outpatient facility** and which is subject to rules adopted by the Department and is provided by either:

i. An agency [which] **that** has a purchase of service contract or **an** affiliation agreement with the Division; **or**

[ii. A mental health clinic as defined by the Division of Medical Assistance and Health Services (DMAHS) at N.J.A.C. 10:66-1 and 2.5; or]

[iii.] **ii.** An entity [which] **that** provides [outpatient, ambulatory, or other] nonresidential, non-inpatient mental health service(s).

3. (No change.)

4. Provisions of this chapter shall not apply to:

i.-v. (No change.)

vi. A mental health program licensed by the Department as a health care facility **or integrated outpatient facility**, provided that each site of such program holds a separate Department license or is specified on the main facility's Department license.

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

8:121-1.3 Level [I] **1** standards

(a) The following rules shall be Level 1 standards for mental health programs:

1.-5. (No change.)

[6. Staffing requirements for outpatient services at N.J.A.C. 10:37E-2.6(a);

7. Therapeutic environment for partial care services at N.J.A.C. 10:37F-2.9;

8. Staffing requirements for partial care services at N.J.A.C. 10:37F-2.10;]

[9.] **6.** Staffing requirements for family support services at N.J.A.C. [10:37F]**10:37I**-5.9(b);

Recodify existing 10.-13. as **7.-10.** (No change in text.)

[14. Staffing requirements for children's partial care programs at N.J.A.C. 10:191-1.11(a);

15. Staffing responsibilities for children's partial care programs at N.J.A.C. 10:191-1.12(b), (d), (f), and (h);

16. Staffing requirements for youth case management services at N.J.A.C. 10:37H-2.10(b), (c), and (e);]

Recodify existing 17.-18 as **11.-12.** (No change in text.)

8:121-1.6 Applicable standards

(a) (No change.)

(b) Mental health programs shall comply with the applicable standards for the following mental health services that they provide:

[1. Youth partial care services (YPC) at N.J.A.C. 10:191;

2. Outpatient services (OP) at N.J.A.C. 10:37E;

3. Partial care services (PC) at N.J.A.C. 10:37F;

4. Youth case management (YCM) at N.J.A.C. 10:37H;]

Recodify existing 5.-7. as **1.-3.** (No change in text.)

(c)-(e) (No change.)