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

Standards for Licensure of Outpatient Substance Use Disorder Treatment Facilities

Adopted Amendments: N.J.A.C. 8:43E-13.4 and 8:121-1.1, 1.3, and 1.6

Adopted Repeals: N.J.A.C. 10:161B

Adopted New Rules: N.J.A.C. 8:43E-5.7 and 8:43E-5 Appendix; and 8:43K-1, 2.1 through 2.10, 3, 4, 5, 6, 7.1 through 7.7, 7.9 through 7.21, 8, 9.3, 9.7, 10, 11, and 12

Proposed: April 21, 2025, at 57 N.J.R. 743(a).

Adopted: January 15, 2026, by Jeffrey A. Brown, Acting Commissioner, Department of Health, in consultation with Sarah Adelman, Commissioner, Department of Human Services.

Filed: January 16, 2026, as R.2026 d.045, **with non-substantial changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3), **and with proposed new N.J.A.C. 8:43K-2.11, 7.8, 9.1, 9.2, 9.4, 9.5, and 9.6; the amendments at N.J.A.C.**

8:43A-1.1, 1.3, 2.2, and 33.3; and the repeal of N.J.A.C. 8:43A-20, 21, 22, 23, and 26 not adopted.

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.

Effective Date: April 6, 2026.

Expiration Dates: April 13, 2027, N.J.A.C. 8:43E;
April 6, 2033, N.J.A.C. 8:43K; and
October 20, 2028, N.J.A.C. 8:121.

Summary of Public Comments and Agency Responses:

The Department of Health (Department) received comments from the following:

1. Peter Belasco;

2. Alexandra Duncan, DrPH, MPH, CPH, Project Director, Nawshin Ahmed, MPH, MBA, Senior Associate, and Rose Ippolito, Associate I, Substance Use Prevention and Treatment Initiative, The Pew Charitable Trusts, Washington, DC;

3. Henry Edwards;

4. Jenifer Groves, Interim President and CEO, New Jersey Family Planning League, Newark, NJ;

5. Selin Haq, President and CEO, New Jersey Primary Care Association, Trenton, NJ;

6. Dionna King, MPH, Senior Technical Advisor, Kathryn Boulton, JD, MPH, Senior Legal Technical Advisor, Lindsey Kerins, MPH, Program Manager, and Derek Carr, JD, Legal Technical Advisor, Overdose Prevention Program, Vital Strategies, New York, NY;

7. Christopher Lee, MPP, Assistant Vice President, External Affairs and Policy, RWJBarnabas Health, West Orange, NJ;

8. Jessica Mandle, MSN, RN, PMH-BC;

9. Christine Meissner, M.S., RD, New Jersey Academy of Nutrition and Dietetics, Middletown, NJ;

10. Victoria Nagel, LCADC, CCS, LPC, NCC, ACS, BC-TMH, Director of Clinical Training and Workforce Development, New Jersey Prevention Network, Tinton Falls, NJ;

11. Nicole Printup, Manager, Regulatory and Accreditation, Health and Safety Institute, Frisco, TX

12. Linda Schwimmer, President and CEO, New Jersey Health Care Quality Institute, Princeton, NJ, and John V. Jacobi, Dorothea Dix Professor of Health Law and Policy, Seton Hall University School of Law, Newark, NJ, on behalf of Community Health Acceleration Partnership, Hackensack Meridian Health, Human Biology®, New Jersey Association of Mental Health and Addiction Agencies, and Tara Adams Ragone, Assistant Professor, Center for Health and Pharmaceutical Law, Seton Hall University School of Law, Newark, NJ;

13. Debra L. Wentz, Ph.D., President and CEO, New Jersey Association of Mental Health and Addiction Agencies, Inc., Mercerville, NJ; and

14. Kaitlyn Wojtowicz, Chief Government Relations Officer, Planned Parenthood® of Northern, Central, and Southern New Jersey, Morristown, NJ.

Quoted, summarized, and/or paraphrased below are the comments and the Department's responses. The numbers in parentheses following each comment correspond to the numbers representing the commenters above.

General Support

1. COMMENT: A commenter "commend[s] the [S]tate for aligning proposed rules with [F]ederal regulations 42 CFR Part 8 as well as with evidence-based practices for the treatment of opioid use disorder (OUD)." The commenter states, "[i]In February 2024, the Department of Health and Human Services (HHS), through the Substance Abuse and Mental Health Services Administration (SAMHSA), revised [F]ederal regulations [at] 42 CFR Part 8 that govern the establishment, operation, and provision of care at opioid treatment programs (OTPs). OTPs are the only facilities that can offer patients all three forms of FDA-approved medications for OUD (also known as MOUD)—methadone, buprenorphine, and naltrexone. Methadone, which has proven safe and effective for OUD treatment through decades of research, can only be offered in OTP settings. OTPs are also subject to [S]tate rules … To ensure people with OUD can access OTP services, [S]tate-level requirements should not go beyond those imposed by the [F]ederal government."

The commenter "strongly supports the proposed [new] rules [at] N.J.A.C. 8:43K that align with the revised [F]ederal regulations and will result in improved patient care and outcomes. [The] proposed [new] rules, as stated in the Federal Standards Statement, seek to 'meet, but not exceed, applicable Federal standards.' The proposed

[new] rules also state that OTPs must comply with [F]ederal standards at 42 CFR Part 8. Importantly, the proposed [rulemaking would] repeal N.J.A.C. 10:161B, New Jersey's current OTP regulations. [The commenter's] analysis … identified [10] areas where [N.J.A.C. 10:161B is] more restrictive than what the [F]ederal government requires [and] not only impede access to lifesaving treatment but are also out of step with national best practices and negatively impact patient outcomes. [The commenter] is pleased to see the proposed [rulemaking would] remove all elements that go beyond [F]ederal restrictions." (2)

2. COMMENT: A commenter "express[es] deep appreciation to the … Department … for [its] leadership in proposing a single, integrated license for outpatient health care facilities [and] applaud[s] the Department's thoughtful approach to modernizing [the State's] health care regulatory system. This reform has the potential to significantly reduce administrative burden, promote care coordination, and improve access to high-quality, whole-person care across New Jersey." The commenter supports "the ways in which the proposed rules acknowledge and support integration of primary care, mental health, substance use disorder treatment, and reproductive health [and is] especially pleased to see the Department address the unnecessary duplication of licensure for providers who offer co-located services, the burdensome requirement for separate entrances and medical records for different service types, and the opportunity to align physical plant and operational standards with today's evidence-based practices." The commenter "sincerely appreciate[s] the Department's responsiveness to community needs[,] look[s] forward to supporting the final adoption of

a rule that ensures safe, high-quality, and accessible care for all New Jerseyans[, and is] proud to support this important regulatory advancement …" (4)

3. COMMENT: A commenter "supports the … proposed rulemaking [and] recognize[s] the importance of policy reforms that remove barriers to care. This proposed integrated licensing shift aligns with [this] mission by enabling facilities to provide both primary and behavioral health services under a single framework. This is a significant step forward in promoting whole-person care and reducing disorganization within the healthcare delivery system."

The commenter "supports the adoption of the proposed integrated licensure rule as a forward-thinking policy that can meaningfully expand access to care for underserved residents[,] appreciate[s] the Department's transparent and inclusive process in developing [the] proposal[,] commend[s] its responsiveness to stakeholder input[, and] particularly values the Department's engagement with organizations representing frontline safety-net providers …" (5)

4. COMMENT: A commenter "support[s] the … proposed rule governing outpatient and integrated care facilities in New Jersey, including such facilities that provide treatment for substance use disorder (SUD)."

The commenter states that "[d]espite recent declines in overdose deaths, the country's overdose crisis continues. Provisional data from the [CDC] showed that more than 80,000 people died from a drug overdose in 2024 alone [(citation omitted)]. Recent CDC data also showed continued racial and ethnic disparities, with non-Hispanic Black and non-Hispanic American Indian or Alaska Native persons more likely to experience a fatal overdose [(citation omitted)]. Treatment for OUD with agonist

medications buprenorphine and methadone is most effective at reducing overdose and serious opioid-related acute care relative to other treatments, such as naltrexone or inpatient detoxification or residential services. [(Citations omitted.)] Agonist medications for OUD are associated with an estimated mortality reduction of 50 [percent] among people with OUD, supporting the conclusion of the National Academies of Sciences, Engineering, and Medicine in 2019 that 'the verdict is clear: effective agonist medication used for an indefinite period of time is the safest option for treating OUD [(citation omitted)].'"

The commenter states that the "proposed rule for outpatient and integrated care facilities, including those [that] provide opioid treatment program (OTP) and other SUD treatment services, would expand and enhance critical, lifesaving access to agonist medications among New Jerseyans with OUD[,] strengthen the integration of services to treat co-occurring conditions[,] and support patient-centered care across much of the SUD treatment continuum [(citation omitted)]."

The commenter identifies as a "key improvement" that the proposed rulemaking "substantially aligns New Jersey with the recently reformed [F]ederal regulations governing [OTPs, which] include permanent authorization for expanded take-home methadone, permanent authorization for telehealth MOUD induction by OTPs (including audio-only induction for buprenorphine), removal of nonevidence-based admission criteria, protections against denying MOUD to patients who refuse counseling, and an overall shift to a more patient-centered approach to treatment, among other changes [(citation omitted)]. In aligning with these [F]ederal standards, the Department proposes to repeal the [S]tate's existing OTP rules [(at N.J.A.C. 10:161B], which … include

numerous barriers to care [(citations to sections of N.J.A.C. 10:161B, proposed for repeal, omitted.)] The repeal of these barriers and adoption of [F]ederal standards will expand and enhance critical, lifesaving access to agonist medications for New Jerseyans with OUD."

The commenter identifies as another "key improvement" that the proposed rulemaking would integrate "harm reduction services and supports," and states that "[h]arm reduction saves lives and is a critical component of the continuum of care, including for individuals receiving SUD treatment services. [The commenter] strongly supports the Department's thoughtful integration of harm reduction services and supports throughout the proposed rule, including [the] requirement that facilities maintain an accessible, on-site stock of at least one emergency opioid overdose reversal kit [at proposed new N.J.A.C. 8:43K-4.10; the] requirement that facilities ensure patients receiving MOUD receive 'a take-home supply, prescription, and/or information on how to obtain an opioid antidote' [at proposed new N.J.A.C. 8:43K-5.1; v]arious requirements that facilities provide harm reduction information, resources, strategies, products, and/or referrals to specified patients [at proposed new N.J.A.C. 8:43K-5.2, 6.7, and 11.4; and the clarification of a facility's] ability … to provide patients … naloxone, drug testing strips, and sterile syringes to prevent, reduce, or mitigate the adverse effects of substance use without registering as a harm reduction center … and to provide other safer drug use supplies upon registering as an HRC [at proposed new N.J.A.C. 8:43K-9.7]."

The commenter “commends the … proposed rule and its intent to expand access to evidence-based, patient-centered treatment for opioid and other substance use disorders.” (6)

5. COMMENT: A commenter “thank[s] the Department for its continued partnership in advancing integrated, high-quality care across New Jersey” and “commend[s] the Department for advancing [the] proposed [rulemaking] to establish a single, integrated license for outpatient care facilities. Integrated care has consistently demonstrated improved outcomes for patients, by enhancing the efficiency and effectiveness of care. This effort to consolidate licensure processes and requirements for integrated behavioral and physical care is a meaningful step toward reducing structural and regulatory barriers to coordinated care in New Jersey.” The commenter is “encouraged by the Department’s efforts to support best practice models of care while seeking to reduce administrative, time, and cost burdens [and] hope[s] that [the proposed rulemaking] will facilitate greater coordination and standardization of the inspection processes, including integration with inspections conducted by [the DMHAS].” The commenter “requests that this intent be reflected and incorporated into [the proposed rulemaking.]” (7)

6. COMMENT: A commenter “support[s] the main components of the rule proposal[,] which will effectively integrate physical and behavioral health care to improve the health of individuals and the population at large.” (9)

7. COMMENT: A commenter “commend[s] the Department for issuing the proposed [rulemaking] to establish a single integrated license for outpatient care facilities. This long-awaited rulemaking represents a vital step toward breaking down

the structural and regulatory silos that have long impeded access to coordinated physical and behavioral health care in New Jersey. Integrated care, particularly models that co-locate or fully integrate physical, mental health, and substance use disorder services, has been repeatedly demonstrated to improve outcomes, reduce stigma, and enhance efficiency. By enabling providers to deliver comprehensive, whole-person care under one license, [the proposed rulemaking would] lay the foundation for a modernized system that better meets the complex needs of patients and communities." The commenter "support[s] the Department's efforts as these critical reforms move forward [and thanks the Department] for [its] leadership and for advancing a more integrated, person-centered health system in New Jersey." (12)

8. COMMENT: A commenter supports "the concept of an integrated care license to support the movement to and value of integrated care. Behavioral health providers have a long history of providing whole person care and look forward to advancing comprehensive care under the [proposed rulemaking]." (13)

9. COMMENT: A commenter "commend[s] the Department for [its] hard work on combining three sets of [rules] related to ambulatory care and behavioral health services into one set of [rules] to streamline the provision of integrated health care in the [S]tate of New Jersey, a project many years in the making." The commenter supports "the goal of ensuring that reproductive health care remains as accessible as possible within the [S]tate. This has been a key goal of Governor Murphy's Administration, one that has taken on increased urgency since the *Dobbs* decision overturning *Roe v. Wade* … and [the proposed rulemaking would] offer another chance to cement that legacy." The commenter "recognize[s] that the task of integrating necessary standards governing

family planning and primary care agencies from [N.J.A.C.] 8:43A into a body of rules that are shared by behavioral health providers is complex [and] applaud[s] the Department for the excellent work in accomplishing that task as evidenced by the proposed [rulemaking at] N.J.A.C. 8:43K. Given the complexity, [the commenter conducted] a fairly extensive review to ensure that the standards that have been incorporated into [N.J.A.C.] 8:43K are reasonable and appropriate for all levels of care, and found that overall that is in fact the case." The commenter "thanks the Department for all [its] work to date on maintaining and expanding access to reproductive health care in New Jersey." (14)

RESPONSE TO COMMENTS 1 THROUGH 9: The Department acknowledges the commenters' support of the proposed rulemaking.

Equity and Inclusion

10. COMMENT: A commenter "emphasize[s] that equity in access must be matched by equity in regulatory expectations. All providers should be held to the same standards of ambulatory care practices to ensure safe and healthy outcomes. Consistent application of licensing and operational requirements is critical to maintaining the quality and safety of care across all provider settings." The commenter's "overarching commitment to equitable access drives [the commenter] to support a model that can enhance care delivery for underserved populations—especially when it brings primary and preventive care closer to patients who may otherwise face challenges in navigating multiple systems of care."

The commenter states that “the Department [should] ensure that all facilities providing primary care services under this license be subject to the same standards and obligations currently required of [Federally Qualified Health Centers (FQHCs)] and other ambulatory care providers. Doing so will uphold care quality and preserve a level playing field across New Jersey’s primary care delivery system.” (5)

11. COMMENT: A commenter expresses support of the proposed rulemaking and states that “it is vital [that healthcare professionals] examine [their] own bias and provide evidence-based care equally across all patient populations. [R]educing red tape related to integrated care is essential in improving the physical and mental wellness of New [Jerseyans]. Exploring individual bias supports improved delivery of care and supports inclusive care, limited from discrimination. Stigma types associated with persons with a disability include anticipated, experienced, perceived, and internalized stigma. [(Citation omitted.)] [A person] with a disability [is] 4.5 to 7.2 times more likely to not receive behavioral health treatment due to cost of care. [(Citation omitted.)] Integrating care into the primary care setting improves access to mental health care. Wellness is a combination of mind and body, and without collaborative care, it is challenging to obtain exceptional healthcare outcomes. Creating solutions [that] prioritize people with diverse needs is essential to providing equitable care. [(Citation omitted.)] Persons with [disabilities] often face complex comorbidity such as significant medical, mental health, and social difficulties[,] are among the socioeconomically vulnerable[,] and have higher utilization of healthcare consumption. [(Citation omitted.)] [Increased] health care utilization does not equate to quality of care, and often unnecessary and even harmful interventions may be implemented for

vulnerable populations … Persons with disabilities are at higher risk for lower health literacy, [which] places this population [at] risk for reduced understanding of healthcare risk verses benefit. [(Citation omitted.)] Persons with [disabilities] have greater risk of suffering from a mental health condition and rate their state of mental health as more severe than the non-disabled person. [(Citation omitted.)]

[L]egislation can address the challenges faced by persons with [disabilities] by providing access to equitable mental health care and promote positive change. Implementation of evidence-based governance mechanisms and commitments for disabled populations [that] mandate inclusion through policies and legislation is essential for providing this basic human right. [(Citation omitted.)] [The proposed rulemaking would support and empower] persons with [disabilities] to address and optimize their physical and mental wellness." The commenter "supports the [proposed rulemaking] to establish integrated care standards." (8)

RESPONSE TO COMMENTS 10 AND 11: The Department would implement and enforce the rules uniformly across all providers in a manner that promotes equity and inclusion. The Department acknowledges the commenters' support of the proposed rulemaking.

N.J.A.C. 8:43E General Licensure Procedures and Standards Applicable to All Licensed Facilities

Subchapter 5. Licensure Procedures

N.J.A.C. 8:43E-5.7 Application Form

12. COMMENT: With respect to proposed new N.J.A.C. 8:43E-5.7, a commenter requests "that the Department clarify whether applicants providing integrated care at the same site as other outpatient services will be reviewed [pursuant to the proposed new rules at N.J.A.C. 8:43K] for the integrated services, and [pursuant to] N.J.A.C. 8:43A for the other outpatient services. For example, will the Department issue a single license listing integrated behavioral health and primary care as part of the service offerings alongside other services that require licensure under the ambulatory care facility [rules] ([for example], MRI, sleep, etc.) or will this chapter apply only to sites limited to the services specifically identified within it? Additionally, will N.J.A.C. 8:43G-2.11 apply to integrated sites operated by hospitals?" (7)

RESPONSE: The Department has determined that it will not repeal the existing provisions at N.J.A.C. 8:43A originally proposed for repeal. Repealing the rules at N.J.A.C. 8:43A-20, 21, 22, 23, and 26 would inadvertently create a requirement for many ambulatory care facilities to obtain a license pursuant to both N.J.A.C. 8:43A and new N.J.A.C. 8:43K to continue the facility's current operations. While proposed new N.J.A.C. 8:43K would simplify the licensing requirements for facilities that want to offer a specific combination of services, it would simply create the same problem for many other existing facilities. Maintaining the rules proposed for repeal at N.J.A.C. 8:43A-20, 21, 22, 23, and 26 will allow facilities a choice between being licensed pursuant to

N.J.A.C. 8:43A or 8:43K and, therefore, allow more flexibility for providers while not imposing the economic burden of dual licensing costs. Facilities that obtain a license pursuant to proposed new N.J.A.C. 8:43K may be subject to dual licensure if they choose to provide services that fall within the ambulatory surgical requirements at N.J.A.C. 8:43A.

13. COMMENT: A commenter states that the "Department has previously advised that physician specialty services ([for example], cardiology, orthopedics, etc.) should be licensed under the primary care category." The commenter requests that the Department "confirm that such specialty practices will be permitted to offer integrated services." The commenter notes that proposed new N.J.S.A. 26:2H-12.84 would identify "'Primary Health Care Services' to include sick or well care provided to any and all age groups, ranging from perinatal and pediatric care to geriatric care." The commenter states that that the Form CN-7 at proposed new N.J.A.C. 8:43E-5 Appendix "has some opportunities regarding reflection of services to include additional services." The commenter lists the following suggested changes to Form CN-7:

"MRI equipment can be open or closed in either a fixed or mobile setting. The categorization on the [CN-7] form would require a duplicate category count.

Positron Emission Tomography along with 'portable' should include mobile.

Other licensed services [and/or] equipment to consider categorizing [include]:

Add Planning CT

Add comprehensive stroke center and primary stroke center

Add cardiac angioplasty, elective and primary/emergent

Add emergent PCI

Add hybrid OR/Cath lab

Add CyberKnife." (7)

RESPONSE: The Department views physician specialty services as secondary care by the Department and, therefore, not licensable in the primary care category. The commenter's suggested changes to form CN-7 would not affect services that the Department would license pursuant to proposed new N.J.A.C. 8:43K. Therefore, the Department will make no change upon adoption in response to the comment, but will consider making changes to form CN-7 through the formal rulemaking process in the future.

14. COMMENT: A commenter states that "[s]ome of the background questions in the proposed forms ask for multiple responses within one question but then provide one 'yes' or 'no' response. In addition, criminal law terminology is used in the questions when referring to regulatory/civil actions. [The commenter] recommend[s] a review and updating of the forms to be consistent with requirements for licensing and Medicaid program participation." (12)

RESPONSE: The CN-7 form proposed at new N.J.A.C. 8:43E-5.7 would include four questions, in Section III — Operating Entity, that would require an initial "yes" or "no'" response and would only require an additional open-ended response if the initial response is "yes". These questions concern the backgrounds of the principals of the operating entity and would require the applicant to provide more detail if any of the principals answer "yes." These questions are meant to have two parts and are not contradictory in how they are structured.

Regarding the commenter's assertion that criminal law terminology is used in a regulatory/civil context, the Department believes that this is in reference to Question 3 of Section III, which would ask "Have any of the principals of the operating ever been found guilty of a[n] … administrative charge of resident/patient fraud, abuse, and/or neglect?" The Department agrees with the commenter and in response to the comment will make a change upon adoption to delete the term, "found guilty," and replace it with the term "in violation."

N.J.A.C. 8:43K Manual of Standards for Licensure of Outpatient and Integrated Care Facilities

15. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K "should identify doulas and community health workers (CHWs) as optional members of [the] integrated care team and set minimum standards for their participation. These professionals play a key role in advancing equitable and culturally responsive care, particularly in underserved communities." (12)

RESPONSE: Proposed new N.J.A.C. 8:43K would not establish an integrated care team. Nothing at proposed new N.J.A.C. 8:43K would prevent a patient from electing to bring a doula, community health worker, or any other person to an appointment. Nor would any provision at proposed new N.J.A.C. 8:43K limit licensed facilities from incorporating doulas and CHWs as optional members of the facility care team. Proposed new N.J.A.C. 8:43K would only set minimum standards for facilities. Therefore, the Department will make no change upon adoption in response to the comment.

16. COMMENT: A commenter states that "[t]he Social Impact statement correctly describes efficiency gains for regulated entities providing integrated care by 'reducing the administrative, regulatory, and compliance burdens to integrated care and eliminating differing and sometimes conflicting operational standards.' One of the barriers providers now experience is the uncoordinated inspection process for differently licensed modalities of care. [The proposed rulemaking] does not include a coordination/normalization of the inspection process, thereby apparently continuing to cause different schedules and teams for each modality of care. [The commenter] recommend[s] that the integration of inspections, including those required by the [DMHAS], be [addressed in the rulemaking]." (12)

RESPONSE: P.L. 2017, c. 294, at § 3, codified at N.J.S.A. 26:2H-5.1.g, directs the Commissioner of the Department (Commissioner) to promulgate, in consultation with the Department of Human Services (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." Proposed new N.J.A.C. 8:43K would implement the Act by creating a path to providing a combination of services within the umbrella of a single license. The Department understands that preparing for, and undergoing, separate inspections for different modalities (health facilities and behavioral health) is not ideal; however, health care facilities and behavioral health programs and facilities are overseen by two different

Department programs, which perform on-site inspections on different schedules. When appropriate and within the Department's ability, given available resources, the Department would coordinate the inspection process. Therefore, the Department will make no change upon adoption in response to the comment.

17. COMMENT: A commenter states that upon adoption of the proposed rulemaking, “the Department should clarify and publicly affirm that [an] integrated license replaces the three existing outpatient licenses and outline the requirements and timeline for transitional licensure [to] avoid confusion among [existing] licensees and promote a smooth implementation process.” (12)

RESPONSE: The Department disagrees with the commenter that further clarification is necessary. As described in the notice of proposal Summary, P.L. 2017, c. 294, at § 3, codified at 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.” As the Department has decided not to repeal the provisions at N.J.A.C. 8:43A as originally proposed, the Department will work with facilities to ensure the facility license accurately reflects the services offered and provided by the facility. In the event that a facility currently offers only one service covered by proposed new N.J.A.C. 8:43K and the facility wishes to provide two or more of the services included at proposed new N.J.A.C. 8:43K, the

facility will have to apply to add the new service(s) and then be issued an integrated license upon approval of the additional service. Facilities that continue to offer services covered only by N.J.A.C. 8:43A will continue to be licensed subject to that chapter. As the commenter makes no specific recommendations to revise the rule language, the Department will make no change upon adoption in response to the comment.

18. COMMENT: A commenter "urge[s] the Department … and the [DHS] to work jointly ahead of implementation [of the proposed rulemaking] to identify administrative, operational, and payment-related systems within the … DMAHS … and the DMHAS … that will be affected. Clear, coordinated guidance will be essential to supporting providers and ensuring continuity of care. Medicaid payment clarity, in particular, is essential to permit integrated outpatient care to reach the most vulnerable New Jersey residents." (12)

RESPONSE: Matters addressing the funding of behavioral health care services by the Division of Mental Health and Addiction Services (DMHAS) and Medicaid program funding administered by the Division of Medicaid and Health Services (DMAHS) would exceed the scope of this rulemaking and the Department's regulatory mandate pursuant to the statutory rulemaking authority identified above. Accordingly, the Department will make no change upon adoption in response to the comment.

Subchapter 1. General Provisions

N.J.A.C. 8:43K-1.1 Purpose

19. COMMENT: With respect to proposed new N.J.A.C. 8:43K-1.1, a commenter suggests that the rule should "[a]ddress inclusion of [d]ental [s]ervices as one of the listed examples of ambulatory care services covered under this chapter. Dental care is a core component of comprehensive primary health services provided by FQHCs." (5)

RESPONSE: The Department does not regulate dentists or dental services. However, nothing at new N.J.A.C. 8:43K prevents facilities from providing this adjunctive service. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-1.3 Definitions

Abortion Services, Early Aspiration Abortion, and Medication Abortion

20. COMMENT: A commenter suggests that the Department "[c]onsider adding a definition of the term 'abortion services' to avoid future confusion or concerns that procedural abortions may or may not be provided in an [o]utpatient and [i]ntegrated [c]are facility (OICF)." (14)

RESPONSE: The proposed amendments, repeals, and new rules would not use the term "abortion services;" thus, this definition is unnecessary. Therefore, the Department will make no change upon adoption in response to the comment.

21. COMMENT: A commenter suggests that the Department add a definition of the term "early aspiration abortion," to mean "a procedure that terminates a pregnancy in the first trimester of pregnancy utilizing manual or electric suction to empty the

uterus." The commenter states that this definition appears in the State Board of Medical Examiners (BME) rules at N.J.A.C. 13:35-4A.3, "without the definition of what 'first trimester' means, which can be subject to clinical change and assessment." (14)

RESPONSE: The proposed amendments, repeals, and new rules would not use the term "early aspiration abortion"; thus, this definition is unnecessary. Therefore, the Department will make no change upon adoption in response to the comment.

22. COMMENT: A commenter requests "that the term 'medication abortion' not be defined, given that it is a standard clinical procedure that does not require special standards in licensure [rules]." (14)

RESPONSE: The proposed amendments, repeals, and new rules would not define the term "medication abortion"; thus, the commenter's request that the Department not define this term is satisfied. Therefore, the Department will make no change upon adoption in response to the comment.

Accrediting Body

23. COMMENT: A commenter states that the addition of "a more specific definition of the term 'accrediting body' [at proposed new N.J.A.C. 8:43K-1.3] may be helpful. As accreditation may serve as a substitute for annual licensure surveys, the process and thresholds for an organization to qualify as one should be defined." The commenter states "that [the entity the commenter represents] requires all affiliates to meet quality standards and … conducts periodic accreditation surveys of member agencies, and the rules should identify a pathway for [the entity the commenter represents] to at least be considered as meeting this standard." (14)

RESPONSE: The Department declines to list the names of the accrediting agencies and believes that the term is clear as used. The term “accrediting body” is not defined at proposed new N.J.A.C. 8:43K-1.3. Therefore, the Department will make no change upon adoption in response to the comment.

Adjunctive Services

24. COMMENT: A commenter recommends that “[f]or clarity,” the Department should define the term “adjunctive services” at proposed new N.J.A.C. 8:43K-1.3 because “the term appears multiples times throughout the proposed rule. Alternatively, [the Department should add] a cross-reference [at proposed new N.J.A.C. 8:43E-5.7] to [proposed new N.J.A.C.] 8:43K[-]9.” (7)

25. COMMENT: A commenter states that the term “adjunctive services” at proposed new N.J.A.C. 8:43K-1.3 “is somewhat vague … and could benefit from a definition … or clarifying language.” The commenter notes that “a list of adjunctive services” appears at [proposed new N.J.A.C.] 8:43K-9.” (14)

RESPONSE TO COMMENTS 24 AND 25: The Department has determined that, upon adoption, it will not adopt proposed new Subchapter 9, Adjunctive Services. Therefore, the commenters’ concerns with the related provisions are now moot. Accordingly, the Department will make no additional changes upon adoption in response to the comment. However, nothing in proposed new N.J.A.C. 8:43K prevents facilities from providing these adjunctive services.

Alternative Care Location

26. COMMENT: A commenter states that the definition of the term “alternative care location” at proposed new N.J.A.C. 8:43K-1.3 “ignores the opportunities provided in [proposed new N.J.A.C.] 8:43K-12 to also [use] alternate locations on an intermittent basis or with a mobile outpatient vehicle and should be amended to reference them.” (13)

RESPONSE: Proposed new N.J.A.C. 8:43K-1.3 defines the term “alternate care location” to mean “a location at which a facility provides licensed services on a regular basis subject to N.J.A.C. 8:43K-12.” The commenter correctly notes that this definition is inconsistent with proposed new N.J.A.C. 8:43K-12.2, which would allow a facility to provide licensed services on an intermittent basis. To ensure that the definition is consistent with its use at proposed new N.J.A.C. 8:43K-12, the Department will make a change upon adoption to the definition of the term “alternate care location” at new N.J.A.C. 8:43K-1.3 to indicate that the term would include services that a facility would intermittently provide. In addition, to ensure consistent terminology use, the Department will change the defined term to “alternative care location,” which is the formulation that N.J.A.C. 8:43K-12 would use, and change references throughout proposed new N.J.A.C. 8:43K-12 to “alternative services location” and “alternative facility location” to be “alternative care location.”

Affiliation Agreement

27. COMMENT: A commenter states that “[t]he term ‘affiliation agreement’ [at [proposed new N.J.A.C.] 8:43K-9(g) is not commonly used with respect to licensed health care facilities, and [the commenter] recommend[s] that this be clarified to ensure

that it applies only to behavioral health providers. The definition of an affiliation agreement should be expanded [at proposed new N.J.A.C. 8:43K-1.3] to assist reproductive health care services facilities from being confused as to what this refers to." (14)

RESPONSE: The commenter's reference to "[proposed new] 8:43K-9(g)" is unclear because there is no such provision in the notice of proposal and the term "affiliation agreement," is not used in Subchapter 9 of proposed new N.J.A.C. 8:43K.

The Department will not adopt the proposed new definition of the term "affiliation agreement," because N.J.S.A. 30:9A-19 does not describe that term. Proposed new N.J.A.C. 8:43K-2.1 and 6.1 would require an applicant for licensure that is subject to an applicable law, which requires the applicant to enter into an affiliation agreement with a State agency, to provide documentation in support of the application showing that an executed affiliation agreement exists and the applicant is in good standing with respect to its compliance with that agreement. Existing N.J.A.C. 8:121-1.1 requires a mental health program to have an affiliation agreement with DMHAS. Thus, the use of the term "affiliation agreement," as used in proposed new N.J.A.C. 8:43K and existing N.J.A.C. 8:121-1.1 (and as that section is proposed for amendment), would have no impact on an applicant that is not subject to an applicable law requiring its entry into and compliance with an affiliation agreement. As proposed new N.J.A.C. 8:43K would use the term specifically with relevance to an entity as to which an applicable law requires entry into an affiliation agreement, the Department does not agree that the use of the term at proposed new N.J.A.C. 8:43K would be confusing, and will make no other change upon adoption in response to the comment.

Ambulatory Surgical Case and Minor Surgery

28. COMMENT: A commenter states that "[d]ue to the complexity of what an 'ambulatory surgical case' can include," the Department should "cross-reference or incorporate the … definition of 'minor surgery' [from the BME rule at N.J.A.C. 13:35-4A.3, which] incorporates an exception for early aspiration abortion procedures as not constituting surgery. [T]he Department has not updated the related definition in [N.J.A.C.] 8:43A since the BME amended its [rules] in 2021." The commenter recommends that the Department update the definitions at N.J.A.C. 8:43A "accordingly as part of this rulemaking. The proposed definition refers to a procedure that occurs in a licensed ambulatory surgical center (ASC) that typically requires general or regional anesthesia. Early aspiration procedures may incorporate the use of moderate or local anesthesia, and it would be more accurate to refer to ambulatory surgical cases as those typically requiring general or regional anesthesia, to ensure there is no future confusion as to where these procedures may be performed." (14)

RESPONSE: For the reasons stated by the commenter, the Department agrees the definition of "minor surgery" at existing N.J.A.C. 8:43A-12.2 should be consistent with the definition of "minor procedure," formerly "minor surgery," in the Board of Medical Examiners' rule at N.J.A.C. 13:35-4A.3. However, the term "minor surgery" is not used at proposed new N.J.A.C. 8:43K and the Department has not proposed any changes to N.J.A.C. 8:43A-12.2 as a part of this rulemaking—making this comment outside of the scope of this rulemaking. Therefore, the Department will consider making a change to

the definition of “minor surgery” at N.J.A.C. 8:43A-12.2 to be consistent with existing N.J.A.C. 13:35-4A.3 in a future rulemaking.

Behavioral Health Care and Behavioral Health Care Services

29. COMMENT: A commenter notes that proposed new N.J.A.C. 8:43K-1.3 would define “behavioral health care” and “behavioral health care services” by reference to the definitions of these terms at N.J.S.A. 26:2H-12.84 and 12.86, “excluding opioid treatment programs.” The commenter states that “the definitions in N.J.S.A. 26:2H-12.84 and 12.86 appear mutually exclusive, with the former including ‘a drug or alcohol use disorder that is of mild to moderate severity’ while the latter explicitly excludes ‘any drug or alcohol use disorder.’ Compare [N.J.S.A.] 26:2H-12.84(c) (‘Behavioral health care’ and ‘behavioral health care services’ mean *procedures or services*, other than primary health care services, which are *provided* by a health care practitioner to a patient *for the treatment of a* mental illness, emotional disorder, *or drug or alcohol use disorder that is of mild to moderate severity*. ‘Behavioral health care’ and ‘behavioral health care services’ shall not include procedures or services that are provided for the treatment of severe mental illness, severe emotional disorder, or severe drug or alcohol use disorder) (emphasis added) with [N.J.S.A.] 26:2H-12.86(e) (As used in this section, ‘behavioral health care services’ means procedures or services provided by a health care practitioner to a patient for the treatment of a mental illness or emotional disorder that is of mild to moderate severity. *‘Behavioral health care’ and ‘behavioral health care services’ shall not include procedures or services that are provided for the treatment of* severe mental illness, severe emotional disorder, or *any drug or alcohol use disorder’*) [(emphasis added in original comment)].” (6)

RESPONSE: The Department agrees with the commenter that the statutory definitions incorporated in the definition of “behavioral health” at proposed new N.J.A.C. 8:43K-1.3 are inconsistent and, therefore, confusing. The Department seeks to facilitate the provision of behavioral health services broadly in the proposed new rules, and notes that the definition at N.J.S.A. 26:2H-12.86 is only applicable in the context of proposed new N.J.A.C. 8:43K-6.9. Accordingly, the Department will make a change upon adoption to remove reference to N.J.S.A. 26:2H-12.86 in the definition of “behavioral health” because it is already included appropriately at proposed new N.J.A.C. 8:43K-6.9.

Board Certification

30. COMMENT: A commenter states that the proposed definition of the term, “board certification” at proposed new N.J.A.C. 8:43K-1.3 “is not entirely clear what the reference to the [New Jersey] Board of Nursing rules refers to as a source of ‘board certification.’” The commenter “assume[s] this is for [certified registered nurse anesthetists], which [the commenter] support[s], but recommend[s] that the Department verify whether the [BME rules] for physician assistants should also be [included in the definition of board certification].” (14)

RESPONSE: The definition of the term “board certification” at proposed new N.J.A.C. 8:43K-1.3 refers to N.J.A.C. 13:37, the New Jersey Board of Nursing rules, which establishes standards by which that board issues credentials, including N.J.A.C. 13:37-7, Certification of Advanced Practice Nurses. Thus, the term “board certification” at paragraph 3, means a nurse to whom the New Jersey *Board* of Nursing issues *certification* as an advanced practice nurse.

The Board of Medical Examiners licenses physician assistants pursuant to N.J.S.A. 45:9-27.11 and N.J.A.C. 13:35-2B; it does not issue certifications to physician assistants. Proposed new N.J.A.C. 8:43K-1.3 would adequately define the term "physician assistant" to mean a person who holds a license pursuant to N.J.S.A. 45:9-27.11. Thus, the term "board certification" would be inapplicable to a physician assistant. Therefore, the Department will make no change upon adoption in response to the comment.

Dietitian

31. COMMENT: A commenter requests that the Department change the spelling of the term "dietician" at proposed new N.J.A.C. 8:43K-1.3 and throughout the chapter to conform to the preferred and statutory spelling of this term "dietitian." (9)

RESPONSE: The commenter correctly notes that N.J.S.A. 45:16B-1 et seq., uses "dietitian" as the preferred spelling. Therefore, and for the reasons the commenter expresses, the Department will make a non-substantial change upon adoption to use the preferred spelling "dietitian" at N.J.A.C. 8:43K-1.3 and throughout the proposed new rules.

Lived Experience

32. COMMENT: A commenter recommends that the Department change the definition of the term "lived experience" at proposed new N.J.A.C. 8:43K-1.3 to mean "a person's knowledge of mental illness or addictive disorder as gained through the person's direct, personal experience, including in treatment and recovery." The commenter states that the "[i]nclusion of the word 'progress' inappropriately suggests

that individuals must have met certain treatment and recovery milestones to have lived experience." (6)

RESPONSE: The Department finds it in the best interest for the health and safety of New Jersey residents for the peer staff to have met certain recovery milestones. Pursuant to the Department of Health and Human Services, Centers for Medicare & Medicaid Services State Medicaid Directors Letter #07-011, issued August 2007, peer support providers must complete training and certification as defined by the State. The DMAHS, in collaboration with the DMHAS, created guidelines for peer support certification so that NJ FamilyCare providers of SUD treatment would be eligible for reimbursement for peer support services. Consistent with all services billed pursuant to NJ FamilyCare, providers utilizing peer support services must comply with all Federal Medicaid regulations and policies. All peer recovery support specialists employed by agencies contracted with the DMHAS and NJ FamilyCare to provide SUD recovery support services were required to obtain certification by July 1, 2020, and certification remains a requirement. Requirements for both certification and continuing education include self-attestation of ongoing recovery from substance use, which implies that the individuals have met certain recovery milestones. While the above guidelines are specific to SUD billing practices, the Department believes that the peer standards, which apply also to mental health and addiction services, must remain consistent in the rules across facilities and applicable to all behavioral health services. Therefore, the Department will make no change upon adoption in response to the comment.

Mental Health Services and Medication Management

33. COMMENT: A commenter requests that the Department "[c]larify the intended scope and applicability of overbroad definitions." The commenter notes that proposed new N.J.A.C. 8:43K-1.3 would define the term "mental health services" as "counseling, therapy, and/or medication management" and the term "medication management" as "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." The commenter states that the "resulting effect is that 'mental health services' includes any prescribing of medication *regardless* of whether the medication is prescribed to treat a condition related to mental health [(emphasis in original comment)]." (6)

RESPONSE: The Department agrees with the commenter that proposed new N.J.A.C. 8:43K-1.3 would have the unintentional resulting effect that mental health services would include any prescribing of medication regardless of whether the medication is prescribed to treat a condition related to mental health. Therefore, the Department will make a change upon adoption to modify the definition of "mental health services" at proposed new N.J.A.C. 8:43K-1.3 to mean "and/or medication management related to any DSM-V diagnoses" in place of "and/or medication management."

Peer

34. COMMENT: A commenter recommends that the Department change the definition of "peer" at proposed new N.J.A.C. 8:43K-1.3 to mean "a person who has lived experience with 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." The commenter states that "[l]ived experience is not limited to experience 'of recovery' and inclusion of such qualifying language may pose inadvertent barriers to qualified individuals serving as peers. It is … unnecessary to include qualifying language when proposed [new N.J.A.C. 8:43K-6.6(a) would require] peers to have 'an appropriate certification to provide peer support.'" (6)

RESPONSE: The Department finds it in the best interest for the health and safety of New Jersey residents for peer staff to have met certain recovery milestones. The peer support providers training and certification requirements are addressed in the Response to Comment 32. The Department believes that the peer standards, which apply also to mental health and addiction services, must remain consistent in the rules across facilities and applicable to all behavioral health services. Requirements for both peer certification and continuing education include self-attestation of ongoing recovery from substance use, which implies that the individuals have met certain recovery milestones. Additionally, the Department notes that proposed new N.J.A.C. 8:43K would not define "recovery." Therefore, the Department will make no change upon adoption in response to the comment.

Opioid Treatment Program or OTP

35. COMMENT: A commenter recommends that the Department "[c]orrect the definition of 'opioid treatment program' or 'OTP.' [P]roposed [new N.J.A.C. 8:43K-1.3 would define] these terms as a 'certified opioid treatment program' as 21 U.S.C. § 823 defines that term, but 21 [U.S.C.] § 823 includes no such definition. Indeed, neither 'opioid treatment program' nor 'OTP' appears in the [F]ederal Controlled Substances Act

statute." The commenter recommends "mirroring the definition of 'opioid treatment program' in the … SAMHSA … OTP regulation [at 42 CFR 8.2]. A revised definition could read: 'Opioid treatment program' or 'OTP' means a program engaged in OUD treatment of individuals with MOUD registered under 21 U.S.C. § 823(h).'" (6)

RESPONSE: The commenter correctly notes that 21 U.S.C. § 823 does not define the term "certified opioid treatment program" and that 42 CFR Part 8, Medications for the Treatment of Opioid Use Disorder, at 42 CFR 8.2, Definitions, defines that term to mean "an OTP that is the subject of a current, valid certification under [42 CFR] § 8.11." However, the Substance Abuse and Mental Health Services Administration (SAMHSA), of the United States Department of Health and Human Services, promulgated the regulations at 42 CFR Part 8 pursuant to the regulatory authority conferred on that agency pursuant to 42 U.S.C. § 823. 89 FR 7549 (February 2, 2024). The reference to 42 U.S.C. § 823 is inclusive of regulations promulgated pursuant thereto and, therefore, is correct. However, to address the commenter's concerns, and to ensure that the term "opioid treatment program" or "OTP," as used at N.J.A.C. 8:43K is understood to mean an entity that is compliant with applicable Federal standards relating to activities such as the therapeutic dispensing of controlled substances, the Department will make a change upon adoption to the definition of the term "opioid treatment program" or "OTP," at proposed new N.J.A.C. 8:43K-1.3 to add a cross-reference to 42 CFR 8.2, which defines the term "certified opioid treatment program."

Reproductive Health Care Services

36. COMMENT: A commenter states that the proposed rulemaking "reference[s] reproductive health but could benefit from more explicit clarity as to whether perinatal care—including pregnancy, postpartum, and related maternal services—is considered part of the scope. Aligning the licensure standards with the State's maternal-infant health goals would be a critical addition." (12)

RESPONSE: Proposed new N.J.A.C. 8:43K-1.3 would define the term "reproductive health care services" by reference to the statutory definition of that term at N.J.S.A. 26:2-200, which defines the term 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." The Department views this definition as being sufficiently broad to encompass the perinatal services the commenter identifies. Therefore, the Department will make no change upon adoption in response to the comment.

37. COMMENT: A commenter states that the definition of the term "reproductive health care services" at proposed new N.J.A.C. 8:43K-1.3 "does not offer any substantive guidance to licensees or potential licensees … as to what services are included." The commenter recommends that the Department change the definition to refer to "the statutory definition that is referenced in the preface of this rule, as found at N.J.S.A. [26:2-200]." (14)

RESPONSE: The proposed definition of the term "reproductive health care services" would specifically cross-refer to the definition of that term at N.J.S.A. 26:2-200. Therefore, because the text at proposed new N.J.A.C. 8:43K-1.3 would conform to

the change the commenter requests, the Department will make no change upon adoption in response to the comment.

Severe Mental Illness, Severe Emotional Disorder, and Severe Drug or Alcohol Use Disorder

38. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-1.3 would define the terms “severe mental illness,” “severe emotional disorder,” and “severe drug or alcohol use disorder,” but the chapter does not use these terms, and the definitions are, therefore, “not necessary.” (13)

RESPONSE: Proposed new N.J.A.C. 8:43K-1.3 defines the terms “severe mental illness,” “severe emotional disorder,” and “severe drug or alcohol use disorder,” “as used [in the statutory] definition of the terms, ‘behavioral health care’ and ‘behavioral health care services,’” which are terms the chapter uses. As the definitions, therefore, are needed, the Department will make no change upon adoption in response to the comment.

Substance use disorder treatment service or SUD treatment service

39. COMMENT: A commenter notes that proposed new N.J.A.C. 8:43K-1.3 would define the term “substance use disorder treatment service” or “SUD treatment service” to mean, in part, “counseling, therapy, and/or medication management provided to a person who has an addictive disorder, including a substance use disorder.” The commenter states that it “is unclear why this definition includes ‘an addictive disorder’ more broadly (with ‘substance use disorder’ as a mere illustrative example), especially given the proposed rule defines ‘addiction treatment’ to include other, non-SUD behavioral addictions ([for example], gambling).” (6)

RESPONSE: The Department agrees with commenter that the definition of the term “substance use disorder treatment service” at proposed new N.J.A.C. 8:43K-1.3 would unintentionally include behavioral addictions that are not related to substances. Therefore, the Department will make a change upon adoption to change the definition of “substance use disorder treatment service” to mean “counseling, therapy, and/or medication management provided to a person who has a substance use disorder ...” Further, to ensure consistency with DMHAS rules at proposed new N.J.A.C. 10:36-1.2(a), the Department will make a change upon adoption to the definition of “addiction treatment” to include addictive disorders. The Department will also add a definition of addictive disorder that is consistent with the definition of “addictive disorder” at new N.J.A.C. 10:36-2.1.

Wound Care

40. COMMENT: A commenter recommends that the Department delete the phrase “and includes basic first-aid skin treatment” from the definition of the term “wound care” at proposed new N.J.A.C. 8:43K-1.3 because “basic first-aid … is something outpatient clinic staff are trained for and provide, and its inclusion here blurs the line with wound care that may only be provided by a nurse or other medical professional.” (13)

RESPONSE: The Department disagrees with the commenter’s assertion that the inclusion of “basic first aid" in the definition of “wound care” requires that wound care may only be provided by a nurse or other medical professional. The definition does not set a requirement for the level of staff member that may provide the service. An

outpatient clinic staff member is competent to determine whether the care a patient needs would exceed the staff member's regulated scope of practice and require the help of a nurse or medical professional. Therefore, the Department will make no change upon adoption in response to the comment.

Subchapter 2. Licensure Procedures

N.J.A.C. 8:43K-2.1 Application Process for Initial and Renewal of License

41. COMMENT: A commenter recommends that the Department revise proposed new N.J.A.C. 8:43K-2.1(a) "to state that the Department 'issues an approval for an outpatient or integrated care facility license,' as license certificates often follow email or verbal approvals by several months." (7)

RESPONSE: Proposed new N.J.A.C. 8:43K-2.1(a) would state that the Department issues an outpatient or integrated care facility license, not an "approval." The Department does not permit facilities to operate prior to a license being issued. Therefore, the Department will make no change upon adoption in response to the comment.

42. COMMENT: A commenter states that, to ensure "consistency with N.J.A.C. 8:43A-2.5(e)," the Department should revise proposed new N.J.A.C. 8:43K-2.1(b)2 to state that "the facility will receive a request for renewal by the Department at least 90 days prior to the expiration of its existing license. The facility shall submit its renewal application and fee at least 30 days prior to expiration of the existing license." (7)

RESPONSE: The Department believes commenter means to reference existing N.J.A.C. 8:43A-2.6(e) which states "[t]he facility will receive a request for renewal fee 30 days prior to the expiration of the license." For consistency, the Department will make a

change upon adoption to add that “[t]he facility will receive a request for renewal fee 30 days prior to the expiration of the license” at new N.J.A.C. 8:43K-2.1(b)2i.

Proposed new N.J.A.C. 8:43K-2.1(b)2 would require a licensee to apply for license renewal “at least 90 days before the expiration of its existing license.” The change the commenter suggests is not acceptable because the Department requires longer than 30 days to process an application for license renewal. Therefore, the Department will make no change upon adoption in response to this portion of the comment.

43. COMMENT: A commenter notes that proposed new N.J.A.C. 8:43K-2.1(d)2, “states that [a facility] must self-identify in accordance with N.J.S.A. 26:2H-5.1g(b)(3) and provides a long list of options, some of which seem duplicative ([for example], ‘addiction treatment facility’ and ‘substance use disorder or other addiction treatment facility’). Yet N.J.S.A. 26:2H-5.1g(b)(3) simply states [that the Department is to promulgate rules that] ‘permit a facility to hold a designation as an ambulatory care facility, community mental health program, substance use disorder treatment facility, or other type of facility recognized under State or [F]ederal law under the integrated health care facility license without requiring a separate license[.]’ It does not appear that such designation is required [and] it does not appear that the application form at N.J.A.C. 8:43E-5 Appendix provides a field to do so. If a designation is desired, [the form should contain a designation field] and provid[e] a narrower suggested list of options, while still allowing ‘another type of outpatient care facility recognized pursuant to State or Federal law.’ Any designation that is included in the list should then have a definition in [proposed new N.J.A.C.] 8:43K-1.3.”

The commenter notes that “only the Mobile and Intermittent services are listed” at “Alternate Care Locations” on page seven of the CN-7 application form and recommends inclusion of an option for “Regular provision of licensed services,” and the use of “Alternative Care Locations” as the subheading, “to match the language of the [proposed new rule].” (13)

RESPONSE: The Department views N.J.S.A. 26:2H-5.1g(b)(3) as permissive with respect to a facility’s ability to self-identify its designation, but as a requirement with respect to a facility’s obligation to indicate as least one designation of a “type of facility recognized under State or [F]ederal law.” N.J.S.A. 26:2H-5.1g(b)(2) requires the Department to promulgate rules that “require a single integrated health care facility license for a facility, which license shall specify the scope of primary care, mental health care, and substance use disorder treatment services that the facility is authorized to provide under the integrated health care facility license.” The Department would be unable to specify in a facility’s single integrated health care facility license the scope of the services that the facility is authorized to provide unless the facility, in its license application, identifies the services that it seeks approval to provide, presumably by means of the designation by which it elects to self-identify.

The Department will make a change upon adoption to the proposed application form at N.J.A.C. 8:43E-5 Appendix to include a space for facilities to self-identify.

44. COMMENT: A commenter requests that the Department revise proposed new N.J.A.C. 8:43K-2.1(e)1 “to require 30 days’ notice instead of 90. Often for small facilities, loss of service can be related to professional staff resignations, whereby term notices are typically provided with 30 days’ notice. [Existing N.J.A.C.] 8:43A-2.8

requires 30 days' notice for surrendering a license." The commenter requests that the Department likewise change proposed new N.J.A.C. 8:43K-2.9, Surrender of license, to state, "a licensee shall provide written notice to the Department 30 days prior to closure and, if the licensee provides mental health, substance use disorder (SUD), or addiction treatment services, to [the] DMHAS at least 60 days prior to voluntary license surrender." (7)

RESPONSE: The Department agrees with commenter that 30 days' notice would be sufficient for adjunctive services because closure of adjunctive service is not a continuity of care issue. The Department will not adopt proposed new Subchapter 9, Adjunctive Services, and will remove all corresponding references to adjunctive services. Therefore, the Department will make no additional change in response to the comment, as the Department believes removing references to adjunctive services would resolve the commenter's concern.

However, the Department requires 60 days' notice to ensure patient safety for the transfer of patients to new providers for services licensed by the Department. Therefore, the Department will make no change at N.J.A.C. 8:43K-2.9(a) upon adoption in response to this portion of the comment.

45. COMMENT: A commenter notes that proposed new N.J.A.C. 8:43K-2.1(f) "introduces a new requirement that facilities report the last credentialing or accreditation performed, including deficiencies and corrective actions. For Medical Centers, these reports can exceed 64 pages. The current practice is to submit a copy of the accreditation certificate and confirmation of good standing." The commenter recommends that the Department align the proposed new rule "with existing practice

and [allow] additional data to be requested as needed, as reflected on the CN-7 form. Alternatively, if this documentation remains as a standard submission item," it should "be protected from discovery." The commenter states that the Department should consider "listing credentialing and accreditation documentation [at proposed new N.J.A.C.] 8:43K-4.5, Submission of [d]ocuments and [d]ata, to support that the Department may request such items for review." (7)

RESPONSE: The Department finds that proposed new N.J.A.C. 8:43K-2.1(f), which would require facilities report the last credentialing or accreditation performed, including deficiencies and corrective actions, would be in the best interest for health and safety of patients in New Jersey. Proposed new N.J.A.C. 8:43K-2.1(f) would give the Department complete and accurate information. The Department cannot guarantee what documents will be required to disclose during discovery. If the Department is required to disclose the information that would be required by proposed new N.J.A.C. 8:43K-2.1(f), the Department will follow standard procedure to ensure protected information remains confidential. Therefore, the Department will make no change upon adoption in response to the comment.

46. COMMENT: A commenter notes that proposed new N.J.A.C. 8:43K-2.1 at "(g)(p) [(*sic*)] states the Department will convene a [p]re-licensure [c]onsultation within 60 days of a licensing request. For clarity, … the Department [should] define the intake process for such requests ([for example], email, phone). Additionally, there is no defined timeframe included that would encourage an efficient review process. [The] Department [should] provide a completeness review and provide notification of any

deficiencies within 30 days of receipt of the application to encourage an efficient review of licensure requests." (7)

RESPONSE: The applicant is not limited as to how the applicant makes a request for consultation pursuant to proposed new N.J.A.C. 8:43K-2.1. The Department declines to establish a timeline for the internal review process, as response times may vary based on the number of requests received; however, the Department does, and will continue to, let applicants know about deficiencies as soon as the Department becomes aware of such deficiencies. Therefore, the Department will make no change upon adoption in response to the comment.

47. COMMENT: A commenter states that "The concept of a 'transitional license' appears to address the conversion of [ambulatory care facilities,] such as [FQHCs] and reproductive health care agencies, as well as behavioral health licenses[,] to [OICFs], but the purpose is not clearly laid out [at proposed new N.J.A.C. 8:43K-]2.1. The rule could thus benefit from additional procedural steps and purposes." (14)

RESPONSE: The Department will not adopt N.J.A.C. 8:43K-2.11, Transitional Licensure as described in Response to Comment 72 and, thus, the commenter's request that additional procedural steps and purposes be added to the rule is moot. Accordingly, the Department will make no change upon adoption in response to the comment.

48. COMMENT: With respect to proposed new N.J.A.C. 8:43K-2.1, a commenter states that "[g]iven the current backlog generally in processing various types of licensing applications, especially on the behavioral health side, there could be a significant lead time between the effective date of the rules and the time when an eligible provider

receives its first license. The anticipated volume of OICF applications will be considerable, so we recognize that there needs to be an established procedure." (14)

RESPONSE: The Department acknowledges the commenter's recognition of the need for rulemaking to implement licensure of outpatient and integrated care facilities. As the commenter makes no specific recommendation or suggestion with respect to the proposed new rules at N.J.A.C. 8:43K, the Department will make no change upon adoption in response to the comment.

49. COMMENT: With respect to the application form at N.J.A.C. 8:43K Appendix, to which proposed new N.J.A.C. 8:43K-2.1(b) refers, a commenter recommends that the Department establish "a new CN-7 type licensing form specifically designed for the purpose of OICF applications [because,] for example, possibly 90 [percent] of the categories listed on the present licensing application are not applicable to OICF providers." (14)

RESPONSE: The commenter references N.J.A.C. 8:43K Appendix, the Department believes the commenter means to reference N.J.A.C. 8:43E Appendix, which would be cross-referenced at proposed new N.J.A.C. 8:43K-2.1(b). While the Department believes that creating a separate CN-7 licensing form for OICFs may have merit and could warrant a future rulemaking, the Department believes that the proposed CN-7 form is adequate to serve the purposes of the program as it stands. Therefore, the Department will make no change upon adoption in response to the comment but will consider making changes to form CN-7 through the formal rulemaking process in the future, if deemed necessary.

50. COMMENT: Presumably with respect to proposed new N.J.A.C. 8:43K-2.1(e), a commenter states that “[t]o the extent that an OICF licensee offers other ambulatory care or behavioral health services that are not eligible for licensure under the [proposed new rules at N.J.A.C. 8:43K], such as ambulatory surgery, advanced imaging, birthing center services, the [rulemaking] may need to address how dual licensure … such as staffing and physical plant sharing, [would] be accommodated.” (14)

RESPONSE: The services listed by the commenter are separately licensed pursuant to existing N.J.A.C. 8:43A and are not eligible for an integrated license pursuant to proposed new N.J.A.C. 8:43K. Therefore, the Department will make no change upon adoption in response to the comment.

51. COMMENT: Presumably with respect to proposed new N.J.A.C. 8:43K-2.1(e), a commenter states, “[t]o the extent that adjunctive services represent ancillary services that are not presently subject to licensure, [the Department should confirm its] legal authority … to [promulgate] these rules … and if there is authority for it, specify it in the definition or a scope section.

Given that these are not presently licensed services subject to [the rulemaking authority that Title 26 of the Revised Statutes of New Jersey confers on the Department], it is not clear why a 90-day prior notice of closure or discontinuation of a potentially small adjunctive service (such as ‘mindfulness’) is necessary as addressed in 1.3(e)1. Updating the license at the time of renewal to reflect any additions or subtractions from adjunctive service lists should be sufficient.

In addition, the inclusion of these services, such as acupuncture and movement therapy, indirectly creates enforcement authority for the Department when it believes that a provider has not met the relevant requirements of another [S]tate or [F]ederal agency, professional board, or an accrediting body for these adjunctive services. The enforcement authority for services that are provided by licensed professionals lies only with their respective licensing boards in the Division of Consumer Affairs in the Office of the Attorney General, and adopting these rules by reference could create authority for the Department to cite violations of professional practice requirements. It is also unclear what the Department's scope of review will be in requiring copies of inspection reports from other licensure bodies or credentialling organizations at [N.J.A.C.] 8:43K-9. Services in the private practice of medicine are not subject to periodic inspections.

[The commenter] understand[s] the potential need for a disclosure of an [OICF]'s provision of an adjunctive service, but … recommend[s that the Department add] the following limitations [within the notification standard at proposed new N.J.A.C. 8:43K-2.1(e)]: … limit [adjunctive services subject to Department notification] to a more finite list of health-related services with a potential significant impact on a patient's health or safety … eliminate any licensing procedure for offering such services and ensure that the Department does not intend to enforce ancillary rules of professional licensing boards and other identified sources[, and, i]f essential for behavioral health providers, exempt reproductive health care and primary care providers from these provisions." (14)

RESPONSE: The notice of proposal's Authority statement identifies the Department's statutory rulemaking authority with respect to the notice of proposal. The

Department does not propose to license adjunctive services that are not within the Department's regulatory jurisdiction, regardless of whether an adjunctive service is subject to an existing credentialing requirement. The Department has determined that, upon adoption, it will not adopt proposed new Subchapter 9, Adjunctive Services, as well as all related references and requirements for adjunctive services, including at proposed new N.J.A.C. 8:43K-2.1(e).

51A. COMMENT: A commenter notes that proposed new N.J.A.C. 8:43K-2.1(l)2 would indicate "that [the Department will conduct] a criminal background check … This is not presently done for ambulatory care facility applicants and is only required for individual applicants to become licensed nursing home administrators or medical day care operators, and it should not be required for reproductive health care services facilities or other [OICF]'s other than by attestation on the licensing application." The commenter recommends that the Department delete this requirement "unless there is specific authority for requiring these for behavioral health providers, [of] which we are unaware …" (14)

RESPONSE: Proposed new N.J.A.C. 8:43K-2.1(l)2 would not require the Department to conduct criminal background checks. Pursuant to proposed new N.J.A.C. 8:43K-2.1(l)2, the Department would assess the records of criminal convictions for offenses indicating that patient safety and welfare would be at risk. The Department disagrees with commenter that proposed new N.J.A.C. 8:43K-2.1(l)2 would not apply to ambulatory care facilities. Pursuant to existing N.J.A.C. 8:43A-2.2(l), the Department considers an applicant's prior history in operating a health care facility, including assessing records of criminal convictions representing a risk of harm to the safety and

welfare of patients. Therefore, the Department will make no change upon adoption in response to the comment.

52. COMMENT: A commenter notes that proposed new N.J.A.C. 8:43K-2.1(m) would establish that the Department "will assess the prior history record of an applicant during the 10 years preceding the date of an application for initial licensure." The commenter states that this "far exceeds [N.J.A.C.] 8:43A, which allow[s] a [two]-year lookback period, and [the Department should change] this rule … to be consistent with [N.J.A.C. 8:43A] and [use] a [two]-year lookback period." (14)

RESPONSE: The Department finds a "lookback period" of 10 years, starting from the date of an application gives the Department enough information to ensure the safety of patients and comprehensively assess the track record of an applicant. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-2.2 Ownership; Transfer of Ownership

53. COMMENT: A commenter recommends that the Department revise proposed new N.J.A.C. 8:43K-2.2(b) "to reflect that a transfer of license to an existing licensed provider with an existing track record should not require up to 120 days. Transfers to known operators with existing licensure in the [S]tate should be subject to an expedited review and approval process." (7)

RESPONSE: The Department disagrees with the commenter because the Department needs sufficient time to review the transfer of license, regardless of the applicant's existing or prior track record. While the Department endeavors to review and process applications in a timely manner, it needs to retain the ability to take the full

120 days if complications were to arise. Therefore, the Department will make no change upon adoption in response to the comment.

54. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-2.2 would require the Department's approval of "a plan to transfer of ownership of the property at which [a licensee] operates the licensed service, whether or not this is directly owned or leased … prior to the title being transferred to a [third] party." The commenter "understand[s] that the Department has obtained specific statutory authority for this with regard to long[-]term care facilities, [but] the authority for extending this requirement for [OICFs] is unclear." The commenter states that the Department should require, "at most, [that] notice of the current property ownership be provided at the time of the application for an initial or renewal [of] license of the OICF." (14)

RESPONSE: The Department agrees with the commenter and will make a change upon adoption at proposed new N.J.A.C. 8:43K-2.2(b) to delete the requirement that a facility obtain the Department's prior approval of a transfer of real property at which a facility operates a licensed service, and instead will add the requirement that a facility must notify the Department when a change in ownership of the real property occurs.

55. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-2.2(b) does "not address the scope of a change for ownership of the operating entity for [an OICF]." The commenter states that the Department should use or cross-refer here to the rule addressing transfers of ownership of health care facilities at N.J.A.C. 8:33-3.3, "which address[es], for example, ownership changes that are exempt from review at

[N.J.A.C. 8:33]-3.3(h), including minority ownership changes, change in the corporate form of the entity with ownership, etc." (14)

RESPONSE: The Department disagrees with the commenter that the Department should add a cross-reference to N.J.A.C. 8:33-3.3. Existing N.J.A.C. 8:33-1.1 requires each licensed health care facility to comply with N.J.A.C. 8:33. Therefore, as N.J.A.C. 8:33-3.3 would apply to a facility that the Department would license pursuant to proposed new N.J.A.C. 8:43K, cross-referring to N.J.A.C. 8:33-3.3 would be unnecessary. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-2.3 Compliance with Applicable Laws; Survey Before Licensure

56. COMMENT: A commenter states that the Department should revise proposed new N.J.A.C. 8:43K-2.3(d)1 "to state that the Department should refrain from issuing licensure approval until the survey process is complete, but continue its review to ensure an effective and timely process." (7)

RESPONSE: The Department disagrees with the commenter as the Department cannot move forward with the review process before the survey process is complete. Therefore, the Department will make no change upon adoption in response to the comment.

57. COMMENT: A commenter states that proposed new "[N.J.A.C. 8:43K-]2.3(9)c [(*sic*; probably should say 2.3(c))] appear[s] to require an on-site inspection for purposes of renewal of the license. While of course there is authority for this to be done, it does not appear to be within the Department's staffing capabilities and is not required for other licensed health care facilities. When deficiencies are found and corrected, the

proposed rule also appears to mandate an on-site revisit by [Department] surveyors. This should be of course again within the discretionary authority of the Department, but the wording here should be revised to use 'may conduct' instead of 'shall conduct.'" (14)

RESPONSE: The Department agrees with commenter and will make a change upon adoption to change "shall conduct" to "may conduct."

N.J.A.C. 8:43K-2.4 Facility Construction Project Review

58. COMMENT: With respect to proposed new N.J.A.C. 8:43K-2.4, a commenter states that "[i]n regard to physical plant and facility operations, [the commenter] recommend[s] expanding the [existing] Department of Community Affairs (DCA) inter-agency agreement for [FQHCs] to all [i]ntegrated [h]ealth [c]enters … allowing the Department … to be the sole reviewing entity for renovation and construction projects. The [existing] requirement for full DCA architectural review is unnecessary for family planning and primary care facilities and can delay critical facility improvements." (4)

RESPONSE: The Department disagrees with the commenter. Proposed new N.J.A.C. 8:43K-2.4 would require all OICFs to follow DCA's Uniform Construction Code, N.J.A.C. 5:23. If FQHCs have an agreement with DCA, the Department does not have the authority to make changes to the agreement or to extend the scope of the agreement to include all other facilities licensed by the Department. The Department cannot unilaterally exempt certain facilities from DCA requirements, as DCA is the sole plan review agency for all health care facilities pursuant to existing N.J.A.C. 5:23-3.11(a)8. Therefore, the Department will make no change upon adoption in response to the comment.

59. COMMENT: With respect to proposed new N.J.A.C. 8:43K-2.4(a), a commenter states that "[t]he proposed rules are legally based upon specific statutory authority that exempts [OICFs] from licensure under the Health Care Facilities Planning Act. To this extent, it is stretching the applicability of plan review requirements to include [OICFs] within projects that are subject to the jurisdiction of the Health Care [Plan] Review Unit in the Department of Community Affairs [(DCA)]. [N.J.A.C.] 5:23-1.4 does not specifically incorporate [OICFs], which is understandable, but the list of services does not include reproductive health or behavioral health services." The commenter requests "that the Department exempt [OICFs] from DCA [plan] review, as the DCA system is not equipped to or necessary to review the types of services addressed here (specifically behavioral health services). Furthermore … the Department has historically reviewed FQHC building projects directly through the [plan] review unit [of the Division of Certificate of Need and Licensing of the Department] by inter-agency agreement with DCA. The DCA [plan] review process adds a full layer of review and multiple building codes that both can extend the building process by months, and also add[s] unnecessary costs such as extensive ventilation units for what could represent a very low[-]risk primary care service."

The commenter further requests that the Department make a corresponding change at proposed new N.J.A.C. 8:43K-2.4(b) "to remove the DCA approval requirement." The commenter states that the requirement therein that an applicant submit its "Certificate of Occupancy and the Department's ability to impose conditions are reasonable, to the extent any conditions imposed relate to health and safety of patients that are 'consistent with these rules.'" (14)

RESPONSE: The Department disagrees with the commenter. Proposed new N.J.A.C. 8:43K-2.4 would require all OICFs to follow DCA's Uniform Construction Code, N.J.A.C. 5:23. The Department cannot unilaterally exempt certain facilities from DCA requirements as DCA is the sole plan review agency for all health care facilities pursuant to existing N.J.A.C. 5:23-3.11(a)8. The commenter offers no support for the assertion that the DCA is not equipped to conduct a review of these facility types. Additionally, proposed new N.J.A.C. 8:43K-2.4(b)2 would only require a facility to submit a copy of a certificate of occupancy if it is applicable. Therefore, the Department will make no change upon adoption in response to the comment.

60. COMMENT: A commenter requests that the Department change proposed new N.J.A.C. 8:43K-2.4 "to ensure any conditions imposed are clearly grounded in [rule] and evidence-based practice" by revising subsection (c) to add the following phrase, shown in italics: "the Department may impose conditions on the licensee, as needed *and supported by existing [rule] and evidence-based practice* …." (7)

RESPONSE: The Department disagrees with the commenter. Proposed new N.J.A.C. 8:43K-2.4 would permit the Department to impose conditions for facility construction after consideration of the fact-specific circumstances of each application and would benefit the health, safety, and welfare of patients, which inherently addresses the commenter's concern. Therefore, the Department will make no change upon adoption in response to the comment.

61. COMMENT: A commenter states that the Department should specifically cross-refer to the FGI Guidelines for Health Care Facilities at proposed new N.J.A.C. 8:43K-2.4(a)2iii, "to the extent that [the Department] retains [plan] review authority …

but only for health-related applications, not behavioral health. This will ensure [that] appropriate standards for room sizes, medication storage and dispensing, and other nursing-related services are conducted in appropriately designed space[s]. [T]o the extent that additional [Department] architectural staff may be required to accommodate this plan review function, perhaps a small project fee could be identified for purpose of these reviews, not only for [OICFs] but all health care facilities." (14)

RESPONSE: The Department disagrees with the comment. Proposed new N.J.A.C. 8:43K-2.4(a)2iii specifically would cross-refer to the "construction guidelines," which proposed new N.J.A.C. 8:43K-1.3 would define to mean Facility Guidelines Institute, *Guidelines for Design and Construction of Outpatient Facilities*, 2022 edition, incorporated by reference, as amended and supplemented, into the chapter. Therefore, the Department will make no change upon adoption based on the comment.

N.J.A.C. 8:43K-2.5 Facility License Issuance and N.J.A.C. 8:43K-2.8 Fees

62. COMMENT: With respect to proposed new N.J.A.C. 8:43K-2.5 and 2.8, a commenter "thank[s] the Department for extending the licensure period to two years and incorporating the ability to request a fee waiver for providers not collecting revenue. These are thoughtful and positive steps that help reduce administrative burden and operational costs for providers." (7)

RESPONSE: The Department acknowledges the commenter's support of proposed new N.J.A.C. 8:43K-2.5 and 2.8.

63. COMMENT: With respect to proposed new N.J.A.C. 8:43K-2.5(c), a commenter "support[s] extending the licensure period for [OICFs] from the traditional one-year period to two years. For purposes of clarity," the commenter recommends that

the Department replace the text at proposed new subsection (c) with the following sentence: “A license for an Integrated Health Care Facility shall be issued for a [two]-year period from its effective date.” (14)

RESPONSE: Proposed new N.J.A.C. 8:43K-2.5(c) would establish a two-year licensure period. Therefore, because the text, as proposed, would satisfy the commenter’s request, the Department will make no change upon adoption in response to the comment.

64. COMMENT: A commenter states that the Department should delete the phrase “either the facility or” from proposed new N.J.A.C. 8:43K-2.5(e) “to ensure that ‘facility’ is not read to include the real property ownership of an OICF.” (14)

RESPONSE: Proposed new N.J.A.C. 8:43K-2.5(e) would state that a license would become void upon a change in either the facility owner or the owner of the entity that holds the license. To the extent that the change in ownership of a facility could include a change in the ownership of the real property on which it stands, then the rule would include a change in the real property ownership of a facility as a license-voiding event. Therefore, the Department will make no change upon adoption in response to the comment.

65. COMMENT: With respect to proposed new N.J.A.C. 8:43K-2.5(f), a commenter states that “[t]he concept of a provisional license during the pendency of a full site review for a new ICH [(*sic*, presumably should be IHC for integrated health care)] facility is realistic and likely necessary, given the current levels of delays in scheduling such surveys. What [is not] clear is why the proposed rule only refers to ‘licensed mental health practitioners,’ [who] may be limited to psychiatrists and/or

psychologists, rather than all OICF providers, such as reproductive health care agencies, primary care centers and FQHC's." (14)

RESPONSE: Proposed new N.J.A.C. 8:43K-2.5(f) would only be applicable to mental health services, not all OICFs, because mental health services do not implicate the same physical requirements as other OICFs, such as reproductive health care agencies and primary care centers.

"Licensed mental health practitioner" was used in error as the Department does not license practitioners. Therefore, the Department will make a change upon adoption at proposed new N.J.A.C. 8:43K-2.5(f) to delete the references to "licensed mental health practitioners" and related terms and add in its place "licensed mental health services facility."

N.J.A.C. 8:43K-2.6 License Renewal by Deemed Status

66. COMMENT: With respect to proposed new N.J.A.C. 8:43K-2.6, a commenter states that the chapter should provide a "listing of acceptable accreditation agencies for … deemed status licensure [and] a procedure for any new or unlisted accreditation bodies to seek approval." (14)

RESPONSE: The Department declines to list the names of the accrediting agencies. The term "accrediting body" is not defined at proposed new N.J.A.C. 8:43K-1.3. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-2.8 Fees

67. COMMENT: A commenter states that "[w]hile [proposed new N.J.A.C. 8:43K-6.11,] Intensive outpatient mental health, substance use disorder, and/or other addiction

treatment services[,] includes intensive outpatient (IOP) mental health in the section heading, and throughout that section, [IOP] is omitted from the list of services in [proposed new N.J.A.C. 8:43K-]2.8(d)." (13)

RESPONSE: The Department erroneously excluded intensive outpatient (IOP) mental health services and will make a change upon adoption to include IOP in the list of services at proposed new N.J.A.C. 8:43K-2.8(d).

68. COMMENT: With respect to proposed new N.J.A.C. 8:43K-2.8, a commenter states that the "continuation of reduced fees for reproductive health providers is appreciated." (14)

RESPONSE: The Department acknowledges the commenter's support of proposed new N.J.A.C. 8:43K-2.8.

69. COMMENT: With respect to proposed new N.J.A.C. 8:43K-2.8, a commenter states that "the listing of an 'adjunctive service' on an OICF license does not appear consistent with the Department's statutory licensure authority. This information may be kept on file with the Department otherwise if it is deemed essential." (14)

RESPONSE: The Department agrees with the commenter that adjunctive services are outside the scope of the Department's licensure authority. The Department has determined that, upon adoption, it will not adopt proposed new Subchapter 9, Adjunctive Services. Accordingly, all related requirements and provisions related to adjunctive services, including the fees at proposed new N.J.A.C. 8:43K-2.8, will be removed.

70. COMMENT: With respect to proposed new N.J.A.C. 8:43K-2.8, a commenter states that "[t]he proposed $375[.00] fee for a filing of a regulatory waiver application

appears to be unprecedented with respect to health care facilities, and [the commenter is] not clear what authority exists to institute these fees for [OICFs]. While … significant staff time may be required to process a waiver … with respect to a complex set of new licensure rules covering multiple types of service providers, especially upon implementation, there may be a significant and unanticipated rise in the need for waivers of all types." The commenter requests "that this fee be removed, and/or instituted only if and when it is implemented for all licensed health care facilities." (14)

RESPONSE: Proposed new N.J.A.C. 8:43K-2.8(g)4 would establish $375.00 as the fee for submission of a waiver application, which would apply to all facilities that the Department would regulate pursuant to N.J.A.C. 8:43K. Waiver applications require considerable time and Department resources, including coordination with licensing, survey, regulatory, and architectural teams to ensure that the waiver, if approved, would not endanger patient health and safety. The waiver application review process is also fact-specific and must be reviewed on a case-by-case basis, and, thus, the process cannot be standardized to decrease review time. The commenter notes that there may be a significant and unanticipated rise in the need for waivers of all types, which actually supports the Department's decision to implement this fee to allow the Department to acquire the additional resources needed to facilitate timely review and response time to increased waiver application activity. The Department plans to make changes to the Department's rules governing other facilities to establish fees for waiver applications in a future rulemaking. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-2.11 Transitional Licensure

71. COMMENT: A commenter notes that proposed new N.J.A.C. 8:43K-2.11(b) would establish “that a transitional license would have the same expiration as the facility’s existing license [and] recommend[s] that [the Department allow] extensions on existing licenses to the latest expiration date of currently held licenses. Having a single license but with varying expiration dates for each category of services would leave providers with multiple license renewal dates and processes, including multiple inspections, missing the opportunity to relieve significant administrative burden via the integrated license and contrary to the Social Impact statement that ‘[o]utpatient services providers would benefit by the proposed rulemaking’s effect of reducing the administrative, regulatory, and compliance burdens.’ Establishing a policy to allow there to be one renewal date and inspection makes sense for both providers and the Department …” (13)

RESPONSE: The Department will not adopt proposed new N.J.A.C. 8:43K-2.11, Transitional license, because the Department will not issue an interim license. The Department will issue new licenses to the providers with multiple existing licenses following the adoption of the proposed new rules. All other facilities that wish to offer a combination of services available pursuant to proposed new N.J.A.C. 8:43K will be able to submit an application to add those services and will be issued a new license, as applicable.

Subchapter 3. Enforcement

N.J.A.C. 8:43K-3.4 Monetary Penalties

72. COMMENT: A commenter notes that proposed new N.J.A.C. 8:43K-3.4(a) "states that an OICF may be subject to civil money penalties. While … enforcement sanctions may be needed from time to time to ensure patient safety, [the commenter requests that] the Department … confirm that [an OICF that is] not licensed [pursuant to N.J.S.A.] 26:2H … may receive the types of penalties identified in [N.J.A.C.] 8:43E." The commenter inquires whether the cross-reference in proposed new N.J.A.C. 8:43K-3.4(a) to N.J.A.C. 8:43E-5.6 "is correct, as this refers to waivers[, whereas] the enforcement remedies cited are [at N.J.A.C.] 8:43E-3.4." (14)

RESPONSE: The commenter correctly notes that the cross-reference to N.J.A.C. 8:43E-5.6 at proposed new N.J.A.C. 8:43K-3.4(a) was in error. The cross-reference should have been to N.J.A.C. 8:43E-3.4, which establishes civil monetary penalties. Therefore, the Department will make a change upon adoption at proposed new N.J.A.C. 8:43K-3.4(a) to delete the reference to N.J.A.C. 8:43E-5.6 and replace it with the correct cross-reference to N.J.A.C. 8:43E-3.4.

Subchapter 4. Operational Standards Applicable to All Licensed Outpatient Facilities

N.J.A.C. 8:43K-4.2 Governing Authority

73. COMMENT: With respect to proposed new N.J.A.C. 8:43K-4.2, a commenter suggests the "[o]mi[ssion of] the requirement for the governing board to approve the granting of privileges for health care professionals and delegate this authority to the

[m]edical [d]irector or qualified administrative designee"; and the "[o]mi[ssion of] the requirement for the governing board to approve medical staff bylaws or their equivalent, which are not relevant to small primary care and family planning centers. Most volunteer board members are not qualified to engage in this responsibility." (5)

74. COMMENT: A commenter notes that proposed new N.J.A.C. 8:43K-4.2 "would [correspond to] the requirements [applicable to a]mbulatory [c]are [f]acilities [at N.J.A.C.] 8:43A-4" and states that existing N.J.A.C. 8:43A-4.2(c), "which requires the governing authority or board to be responsible for appointment, reappointment, and curtailment of all clinical privileges," traditionally has "been burdensome for family planning agencies" because "[b]oards of small non-profit agencies do not typically include medical professionals." The commenter recommends that the Department delete "this requirement and allow this function to be delegated to the medical director or to the medical staff committee, if one has been formed." (14)

RESPONSE TO COMMENTS 73 AND 74: The Department notes the commenters are correct that proposed new N.J.A.C. 8:43K-4.2 would be consistent with existing N.J.A.C. 8:43A-4. The Department also notes that it is normal business practice for governing bodies to approve of bylaws as would be required pursuant to proposed new N.J.A.C. 8:43K-4.2. Pursuant to proposed new N.J.A.C. 8:43K-4.2, the governing body would oversee the acts listed at proposed new N.J.A.C. 8:43K-4.2(c). Proposed new N.J.A.C. 8:43K-4.2 would not prohibit other staff from being involved in the decision-making process. Pursuant to proposed new N.J.A.C. 8:43K-7.9(c)2vi, the medical director specifically would be involved, for example, in 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. Therefore, the Department will make no change upon adoption in response to the comments.

N.J.A.C. 8:43K-4.3 Administration, 8:43K-6.3 Program Director, 8:43K-6.4 Clinical Supervisor, 8:43K-7.9 Medical Director; Appointment; Duties, and 8:43K-7.10 Director of Nursing Services; Appointment; Duties

75. COMMENT: With respect to proposed new N.J.A.C. 8:43K-4.3, 6.3, 6.4, 7.9, and 7.10, a commenter requests "clarification that leadership personnel may hold multiple roles within a facility, provided they meet the qualifications outlined in the [proposed new rules]. For example, a [d]irector of [n]ursing could be dually appointed as the [a]dministrator; an [a]dministrator could be a [c]linical or [p]rogram [d]irector; or a [m]edical [d]irector could serve as the [c]linical [d]irector. Acknowledging this would help ensure operational flexibility." (7)

RESPONSE: The Department interprets these roles as being full-time positions. Proposed new N.J.A.C. 8:43K-6.3 would permit a program director to serve concurrently as administrator. Aside from proposed new N.J.A.C. 8:43K-6.3, proposed new N.J.A.C. 8:43K would not allow concurrent appointments. Proposed new N.J.A.C. 8:43K-2.10 would permit facilities to submit a waiver application to make a request for leadership personnel to hold multiple roles within a facility. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-4.3 Administration

76. COMMENT: A commenter states that, while recognizing that rules that DMHAS, DMAHS, and professional licensing boards administer would "all provide further limitations," the commenter finds proposed new N.J.A.C. 8:43K-4.3(b), which would establish requirements for administrator, "to be severely inadequate." (13)

RESPONSE: Proposed new N.J.A.C. 8:43K-4.3(b) would establish minimum requirements for administrators. If a facility's governance finds additional requirements to be necessary to meet the needs of the facility, it can establish those requirements. As the comment does not provide sufficient information to enable the Department to ascertain how the proposed new rule would be "inadequate," the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-4.6 Policy and Procedure Manual

77. COMMENT: With respect to proposed new N.J.A.C. 8:43K-4.6(a), a commenter recommends that the Department revise "the required policy reviews from annually to once every three … years, in alignment with [N.J.A.C.] 8:43G [and] that this three-year review standard … be applied consistently across" N.J.A.C. 8:43K-4.6(a), 4.7(a), 4.10(a), 7.10(b), 10.3(a), 11.2(a), and 11.3(a). (7)

RESPONSE: The Department reviewed the rules applicable to other types of Department-licensed health care facilities that require policy and procedure reviews and found that to require a facility to conduct its review every three years would be consistent with the rules established for the other types of facilities. See, for example, N.J.A.C. 8:43G-5.2 and 8:42-3.5. Therefore, and for the reasons the commenter states, the Department will make a change upon adoption at proposed new N.J.A.C. 8:43K-

4.6(a), 4.7(a), 4.10(a), 7.10(b)2i (recodified upon adoption as 7.9(b)2i), 10.3(a)2 (recodified upon adoption as 9.3(a)2), 11.2(a)1 (recodified upon adoption as 10.2(a)1), and 11.3(a) (recodified upon adoption as 10.2(a)) to require a facility to review its policies and procedures at a minimum of every three years and more frequently, as needed. This will ensure that the review requirement is not overly burdensome on the facilities while still requiring timely review of patient care standards and the organization and operation of the covered facilities.

78. COMMENT: A commenter states that "additional sub-regulatory implementation guidance would aid in the effective, patient-centered implementation of" proposed new N.J.A.C. 8:43K-4.6(c)13, which would require a facility's policy and procedure manual to address "the confiscation and disposition of illicit substances … within the facility." The commenter states that "[r]esearch shows that punitive responses to substance use within healthcare facilities 'may result in riskier … use, overdose, patient-directed discharges, reduced trust, and increased stigma' [(citation omitted)]. Indeed, a recent published New Jersey appellate decision clarifying and expanding the application of New Jersey's Overdose Prevention Act involved a criminal prosecution resulting from a hospital's punitive policy on the confiscation and disposition of illicit substances possessed by a patient [(citation omitted)]. Guidance from the Department could help facilities implement less punitive approaches, such as ones modeled on a policy adopted by Zuckerberg San Francisco General Hospital and Trauma Center, which limits police contact to circumstances in which 'the clear risk of harm to the patient or others is imminent' and 'where other options are not feasible' [(citation omitted)]." (6)

RESPONSE: Proposed new N.J.A.C. 8:43K-4.6(c)13 would establish a minimum standard requiring each facility to establish policies and procedures addressing the confiscation and disposition of illicit substances in a manner that aligns with the facility's functions, purpose, and mission, and the population the facility serves, while complying with applicable law and evidence-based best practices. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-4.7 Patient Records

79. COMMENT: A commenter notes that N.J.A.C. 8:43K-4.7(k) would require a facility to retain records in accordance with N.J.S.A. 26:8-5, which establishes a 10-year retention period, and states that it "is unclear whether this has applied to behavioral health providers, and if not, whether they will be able to comply. Also, if [OICFs] are not health care facilities, the Department should consider establishing the retention period to be [seven] years or the period [presently used] for behavioral health care providers." (14)

RESPONSE: N.J.S.A. 26:8-5 requires "[t]he person in charge of a hospital, almshouse, lying-in, penal, or other institution" to retain records for 10 years. An OICF that the Department would license to provide behavioral health services pursuant to proposed new N.J.A.C. 8:43K would be a health care facility that is subject to N.J.S.A. 26:8-5. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-4.8 Notices

80. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-4.8 would add “several requirements not presently found in [N.J.A.C.] 8:43A-3.9, and these should be made identical.” (14)

RESPONSE: The Department notes that everything that would be required at proposed new N.J.A.C. 8:43K-4.8 is required by existing provisions throughout N.J.A.C. 8:43A, except for proposed new N.J.A.C. 8:43K-4.8(a)3. The Department will not adopt proposed new N.J.A.C. 8:43K-4.8(a)3 because the Department does not require a facility to post a notice of the last CMS certification survey report for any other facility licensed by the Department.

81. COMMENT: With respect to proposed new N.J.A.C. 8:43K-4.8(a)3, a commenter states that “CMS certification survey reports are [not] applicable to [OICFs] and should be removed.” (14)

RESPONSE: The Department will not adopt proposed new N.J.A.C. 8:43K-4.8(a)3 because the Department does not require a facility to post a notice of the last CMS certification survey report for any other facility it licenses.

82. COMMENT: With respect to proposed new N.J.A.C. 8:43K-4.8(a)7, a commenter states “that due to privacy and safety issues for reproductive health care services facilities, the names of board members and specifically their addresses do not need to be posted or disclosed.” (14)

RESPONSE: Proposed new N.J.A.C. 8:43K-4.8(a)6 would require the facility to post a notice that the names of board members are available in the facility to patients and the public. This requirement is consistent with the Department’s other rules,

including existing N.J.A.C. 8:43A-3.9. Nothing at proposed new N.J.A.C. 8:43K-4.8(a)7, however, would require the full first and last names of these members to be made available. If privacy and safety is a concern, a facility can choose to provide only the first name of the board members. Proposed new N.J.A.C. 8:43K-4.8(a)7 would not require board members' personal addresses to be made available, only an address for correspondence. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-4.10 Management of Medical Emergencies

83. COMMENT: A commenter requests that the Department revise proposed new N.J.A.C. 8:43K-4.10(a)5i to add the Health and Safety Institute (HSI) to the list of entities who issue certification, which the Department should recognize as authoritative, in basic cardiac life support. The commenter provides the following reasons for the requested change:

"a. The American Heart Association®, Inc. ('AHA'), the American National Red Cross ('ARC') and the … HIS … are the largest providers of cardiopulmonary resuscitation ('CPR') training in the United States [(citation omitted)].

b. The HSI *Basic Life Support for Healthcare Providers and Professional Rescuers* ('BLS') course is equivalent to the BLS courses offered by the AHA, ARC, and NSC.

c. Like the AHA and ARC, (but unlike the National Safety Council[)], HSI is nationally accredited by the Commission on Accreditation of Pre-Hospital Continuing Education ('CAPCE'), the national accreditation body for emergency medical services ('EMS') continuing education courses and course providers, including emergency

medical technicians. The HSI BLS course is nationally approved for EMS provider continuing education hours by CAPCE.

d. HSI emergency care training courses (BLS, cardiopulmonary resuscitation ('CPR'), adult and pediatric first aid) courses are recognized, accepted, or approved as meeting the administrative rules of at least 27 New Jersey [D]epartments, agencies or boards, including the Department of Health, Office of Emergency Medical Services [(OEMS)]. [(Citing OEMS, Department, *CPR – Certification and Documentation*, (July 19, 2021), available at https://www.nj.gov/health/ems/documents/education/Approved%20CPR%20Certifications.pdf, and stating that 'HSI is the successor organization to the American Safety [and] Health Institute (ASHI) and EMS Safety.')]

e. The training business units of the HSI, AHA, ARC, and the NSC are similar.

i. Each corporation develops and markets commercially available, proprietary training programs, products, and services to [its] approved Training Centers, either directly or via distributors.

ii. The business structures of the approved Training Centers include sole proprietorships, partnerships, corporations, LLCs, and non-profits, as well as both large and small government agencies.

iii. Instructors are authorized to certify course participants. Certification requires instructor evaluation of hands-on skills to verify skill competency.

f. As proposed, the rule language:

i. Unfairly restrains competition by prescribing the commercially available, proprietary CPR training programs, products and services of the AHA, the ARC,

the NSC, their Approved Training Centers, Licensed Training Providers and the AHA's own for-profit CPR training company [(citation omitted)] – all of whom have a vested economic interest in CPR training, particularly where it is required for occupational licensing.

ii. Unreasonably harms HSI's reputation as an equivalent, bona fide, nationally approved and accredited training organization.

[g.] HSI's emergency care training courses, including BLS, are currently in use by, and accepted, approved, or recognized as meeting the requirements of thousands of employers, state regulatory agencies, occupational licensing boards, professional associations, commissions, and councils in hundreds of occupations and professions nationwide.

[h.] HSI publishes and administers a set of quality assurance standards designed to monitor and improve the performance of HSI, its approved Training Centers and Authorized Instructors so that the products and services provided meet or exceed the requirements of regulatory authorities and other approvers.

[i.] HSI is a member of the Council on Licensure, Enforcement and Regulation (CLEAR), [which is] the international resource for professional regulation stakeholders. HSI Quality Assurance representatives are Nationally Certified Regulatory Investigators.

[j.] HSI is a member of the American National Standards Institute (ANSI) and ASTM International (ASTM) – both globally recognized leaders in the development and delivery of international voluntary consensus standards."

The commenter concludes by stating: "The AHA, ARC, and HSI are the largest providers of CPR training in the United States. The exclusionary language of the

proposed [amendment] fails to treat similarly situated training programs in the same fashion, unfairly harming competition by eliminating a rival without a plausible justification and restrains competition without a countervailing rationale sufficient to justify its harmful effects. The requested [change would] encourage full and free competition while achieving the goal of maintaining the quality measures necessary to protect public health and safety. [The commenter] support[s rules] that do not harm employment, competition, or innovation [and] value[s], believe[s] in, and promote[s] successful completion of a valid BLS course as an important component in protecting public safety, health, and welfare." (11)

RESPONSE: The American Heart Association, the American Red Cross, and the National Safety Council, included at proposed new N.J.A.C. 8:43K-4.10(a)5i, are all organizations that are specifically mentioned in the other emergency services rules promulgated by the Department. See N.J.A.C. 8:43G, 40, 40A, 41, and 41A. The Health and Safety Institute is not recognized in any of the emergency services rules and, therefore, the Department declines to make a change upon adoption to include this organization in the proposed new rules to maintain consistency with the other existing emergency services rules.

N.J.A.C. 8:43K-4.11 Personnel General Requirements

84. COMMENT: A commenter states that "additional sub-regulatory implementation guidance would aid in the effective, patient-centered implementation of" proposed new N.J.A.C. 8:43K-4.11(a)7i and ii, which respectively would require a facility to establish "policies on conducting criminal history record reviews of prospective and current employees and … regarding preemployment and random drug screening and

responses to positive drug screening." The commenter states that "[g]uidance from the Department can help facilities adopt policies that do not unnecessarily exclude individuals with past criminal-legal involvement and/or individuals with lived experience who may continue to use substances or experience a return to use. This is particularly important in the context of employing peers, a practice endorsed by the proposed rule. See proposed [new N.J.A.C.] 8:43K-6.6." (6)

RESPONSE: Proposed new N.J.A.C. 8:43K-4.11 would set forth minimum requirements for personnel and would require a facility to establish policies that address N.J.A.C. 8:43K-4.11(a)7i and ii in a manner that will best align with each facility. Each facility is in the best position to know what specific policies will serve the community in which the facility operates. Therefore, the Department will make no change upon adoption in response to the comment.

85. COMMENT: A commenter states that "additional sub-regulatory implementation guidance would aid in the effective, patient-centered implementation of" proposed new N.J.A.C. 8:43K-4.11(a)9xii, which would require a facility to ensure that all personnel receive orientation upon employment and annual in-service education on identification, reporting, and documentation of cases of child abuse. The commenter states that "guidance from the Department can encourage facilities to implement non-punitive, patient-centered responses to substance use among pregnant and parenting people [and] could build on existing resources, such as [the publication by Camden Coalition and Vital Strategies,] *Creating Safe Care: Supporting Pregnant and Parenting People Who Use Drugs* (2022)." (6)

RESPONSE: Proposed new N.J.A.C. 8:43K-4.11 sets forth minimum requirements for personnel. Facilities must establish their own orientation in a manner that will best align with each facility. The Department believes each facility is in the best position to know what type of orientation will best serve the community in which the facilities operate. Therefore, the Department will make no change upon adoption based on this comment.

N.J.A.C. 8:43K-4.12 Employee Health

86. COMMENT: A commenter requests that the Department amend proposed new N.J.A.C. 8:43K-4.12 "to allow … the use of CDC[-]approved blood tests and not [be] limited to the two-step Mantoux tuberculin skin test." The commenter cites Sosa LE, Njie GJ, Lobato MN, et al., *Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019,* MMWR Morb Mortal Wkly Rep 2019; 68:439–443, DOI: http://dx.doi.org/10.15585/mmwr.mm6819a3, which the commenter identifies as authorizing "two TB blood tests approved for use in the United States: QuantiFERON®-TB Gold Plus (QFT-Plus) and T-SPOT®.*TB* test (T-Spot)." (7)

RESPONSE: The Department agrees that the use of CDC-approved blood tests should be allowed and that facilities need not be limited to the two-step Mantoux tuberculin skin test. The Department previously provided guidance in a memorandum dated January 6, 2023, permitting the use of any FDA-approved tuberculosis tests in lieu of the tests specifically named in any of the Department's rules. See https://www.nj.gov/health/healthfacilities/certificate-need/guidance/tb-memo-01-06-

2023.pdf. Therefore, the Department will make a change upon adoption to include the updated CDC guidance.

N.J.A.C. 8:43K-4.13 General Reportable Events

87. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-4.13(c)1, which would require "the resignation or termination of an [a]dministrator to be reported within three … days[,] is inconsistent with [other] existing [rule] timeframes. [Existing N.J.A.C.] 8:43G-5.1 requires reporting within 15 days, and [existing N.J.A.C.] 8:43A-3.8 requires reporting within seven … days." The commenter requests that the Department revise proposed new N.J.A.C. 8:43K-4.13(c)1 "to allow a seven[-]day reporting window" and that the Department "clearly identify a standardized reporting process ([such as by] email or phone) for this and other reportable events contained in the existing [rules]." (7)

RESPONSE: The Department's rules require three days for most facility types. The standardized reporting process is noted at proposed new N.J.A.C. 8:43K-4.13(c)1, which requires reporting be in writing. Therefore, the Department will make no change upon adoption in response to the comment.

88. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-4.13(c)5, which would require a facility to "report an alleged or suspected crime that endangers the life or safety of patients or staff, or jeopardizes facility operations or fiscal stability, is addressed in [N.J.A.C.] 8:43E." The commenter recommends "including a cross-reference to the applicable provisions of [N.J.A.C.] 8:43E to ensure consistency." (7)

RESPONSE: The Department finds changes based on this comment unnecessary as all health care facilities licensed by the Department are subject to N.J.A.C. 8:43E, General Licensure Procedures and Standards Applicable to All Licensed Facilities. Therefore, the Department will make no change upon adoption in response to the comment.

89. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-4.13 would establish a "significantly expanded list of reportable events, in comparison to [N.J.A.C.] 8:43A-3.9." The commenter recommends that these rules be made consistent for health care providers now being licensed as [OICFs]. It is not clear that the Patient Safety Act … for example, would apply to [OICFs], and/or particularly to behavioral health providers. (14)

RESPONSE: The Department disagrees with commenter. Existing N.J.A.C. 8:43A-3.9, Notices, does not include a list of reportable events. The Department believes the commenter meant to reference existing N.J.A.C. 8:43A-3.8, which requires facilities to report the resignation or termination of the administrator. Proposed new N.J.A.C. 8:43K-4.13(c)1 would require facilities to report the termination of the administrator. The list at proposed new N.J.A.C. 8:43K-4.13 would be consistent with reporting requirements found throughout Title 8 and Title 10. The Department finds it appropriate to incorporate the reportable requirements from multiple rules, including, but not limited to, N.J.A.C. 10:161B-3.8, proposed for repeal, because proposed new N.J.A.C. 8:43K would apply to outpatient and integrated care facilities.

90. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-4.13(c)3 “is too broadly written, as there is much subjectivity with respect to an ‘inappropriate staff interaction with a patient.’” (14)

RESPONSE: The Department expects facility staff to know what constitutes “inappropriate staff interaction with a patient.” Further, nothing at proposed new N.J.A.C. 8:43K would prevent a facility from developing a policy, in accordance with proposed new N.J.A.C. 8:43K-4.6(c)3, that defines inappropriate staff interactions with a patient. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-4.19 Environmental Patient Care Service

91. COMMENT: A commenter notes that proposed new N.J.A.C. 8:43K-4.19 would require a facility to “ensure that the temperature in the facility is, at a minimum, 72 degrees Fahrenheit (22 degrees Celsius) when patients are in the facility” and that [existing N.J.A.C.] 10:161B [(proposed for repeal)] requires “temperatures within client areas of the facility [to] be maintained within a minimum of 68 to 72 degrees Fahrenheit.” The commenter states that “[p]roviding a range, as is currently done, is more feasible and that language should be maintained.” (13)

RESPONSE: The Department will make a change at proposed new N.J.A.C. 8:43K-4.19(a)10 upon adoption to provide the temperature range of 68 to 72 Fahrenheit and maintain consistency with the existing requirements at N.J.A.C. 10:161B, which is proposed for repeal. Additionally, the Department will propose an amendment at existing N.J.A.C. 8:43A-17.4(a)8 in a future rulemaking to remove the minimum

temperature requirement of 72 degrees Fahrenheit and instead allow facilities to provide the temperature range of 68 to 72 Fahrenheit.

N.J.A.C. 8:43K-4.20 Services Not Described in This Chapter

92. COMMENT: A commenter states that the Department should "[c]larify the intended scope and applicability of proposed [new N.J.A.C.] 8:43K-4.20," which, the commenter states, would authorize "the Commissioner to require supplemental information or documentation and to impose case-by-case conditions to protect public health and safety whenever '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 commenter "supports the presumptive intent of this provision: providing a means by which facilities can employ innovative practices with appropriate safeguards. However, as currently drafted, the provision provides no guidance as to when an 'applicable State or Federal standard' will be deemed to exist, what level of specificity is required, or at what point a modality of care is sufficiently distinct from current practice such that a prior [S]tate or [F]ederal standard will no longer be considered applicable." The commenter "recommends the Department clarify the intended scope and application of proposed [new N.J.A.C.] 8:43K-4.20, ensuring that the provision's current ambiguity does not result in overly conservative practices by covered facilities." (6)

RESPONSE: Proposed new N.J.A.C. 8:43K-4.20 is necessary for the Department to regulate services and technologies that do not currently exist to ensure the health and safety of patients. The Department finds it unnecessary to further describe when an applicable State or Federal standard will be deemed to exist as the

plain text suggests that proposed new N.J.A.C. 8:43K-4.20 would not be applicable once a State or Federal law or rule is enacted or promulgated to regulate the novel service or technology. Accordingly, the Department will make no change upon adoption in response to the comment.

93. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-4.20 would permit "the Department to impose conditions on the loosely defined term 'adjunctive services' or new technology whenever it determines one is needed on a case-by-case basis. This appears to be too broadly written and could be used to expand the Department's licensure authority over discrete new clinical services that it is not authorized to regulate." (14)

RESPONSE: The Department has determined that, upon adoption, it will not adopt proposed new Subchapter 9, Adjunctive Services. Accordingly, this will allay the commenter's concerns that proposed new N.J.A.C. 8:43K-4.20 would permit the Department to impose impermissible conditions on the adjunctive services.

Subchapter 5. General Patient Care Policies and Services

N.J.A.C. 8:43K-5.1 Establishment and Implementation of Policies and Services

94. COMMENT: A commenter "supports the removal of punitive administrative discharge policies impacting OTP patients. [Existing N.J.A.C. … 10:161B-11.4 [(proposed for repeal)] allows OTPs to discharge patients 'based on failure to attend counseling sessions, repeated positive urines, missed days.' Suddenly terminating a patient's MOUD treatment, such as due to administrative discharge, increases their risk for overdose [(citation omitted)]. Furthermore, this is more punitive than [F]ederal rules require and is contrary to SAMHSA guidelines [(citations omitted)]. Proposed [new]

N.J.A.C. 8:43K reduces the circumstances in which administrative discharges are permitted by repealing N.J.A.C. 10:161B-11.4. Further, proposed [new] N.J.A.C. 8:43K explicitly prohibits administrative discharge due to positive drug tests [or] continued substance use ([at N.J.A.C. 8:43K-5.1(a)20iii) and nonparticipation in ancillary services including counseling ([at N.J.A.C. 8:43K-5.1(a)20v]). Below are the three circumstances for which administrative discharge would no longer be permitted:

[(1)] Positive drug tests/continued substance use: 42 CFR Part 8 emphasizes that discharge planning must take a patient-centered approach and aim to avoid treatment disruption. It does not list return to opioid use or the use of multiple substances (also known as 'polysubstance use') as a reason to end methadone treatment [(citations omitted)]. Polysubstance use has become an increasing driver of deaths during the 'fourth wave' of the opioid epidemic in the [United States of America], which has been characterized by the increasing presence of stimulants (such as methamphetamine and cocaine) in opioid overdose fatalities [(citations omitted)]. In 2010 only [one percent] of fentanyl deaths involved the co-use of stimulants, however by 2021 the rate increased to 32 [percent (citation omitted)].

[(2)] Missed doses: Similarly, 42 CFR Part 8 does not list patient missed doses as a reason to end methadone treatment. According to [F]ederal guidelines, OTPs may consider reassessing a patient who experiences an interruption in care (planned or unplanned) [(citation omitted)]. Overall, continuing MOUD is generally safer than terminating it [(citation omitted)].

[3] Nonparticipation in ancillary services: Federal rules at 42 CFR Part 8 state that receiving MOUD should not be contingent on a patient attending counseling. The

American Society of Addiction Medicine (ASAM) concurs with this stance [(citation omitted)]. This aligns with research findings that patients who receive MOUD without counseling show no differences in treatment retention or opioid use outcomes compared to patients who receive counseling [(citation omitted)]." (2)

RESPONSE: The Department acknowledges the commenter's support of proposed new N.J.A.C. 8:43K-5.1 and the proposed repeal of existing N.J.A.C. 10:161B.

95. COMMENT: A commenter "supports removing the required counseling schedule for OTP patients. This aligns with 42 CFR Part 8 which states that "'patient refusal of counseling shall not preclude them from receiving MOUD.'" [Existing] N.J.A.C. 10:161B-11.8 [(proposed for repeal)] requires a minimum number of counseling sessions across six distinct phases of methadone treatment. Patients are required to have negative drug screens to advance through the treatment phases and be allowed to attend fewer counseling sessions. For example, a patient would need to demonstrate negative drug screens for 36 months in a row to qualify for the treatment phase in which counseling session frequency is only as clinically needed (phase VI). The [p]roposed rulemaking] removes the required counseling schedule by repealing N.J.A.C. 10:161B-11.8 and explicitly prohibiting administrative discharge for nonparticipation in ancillary services including counseling ([at proposed new N.J.A.C. 8:43K-5.1(a)20v]).

While counseling can be supportive for some OTP patients, research cited in clinical guidelines from ASAM and a report from the National Academies of Science, Engineering, and Medicine demonstrates that medications for OUD can be effective

without counseling [(citations omitted)]. Research shows that strict requirements for methadone patients to attend counseling, such as those in [existing] N.J.A.C. 10:161B-11.8 [(proposed for repeal)], can reduce treatment retention [(citation omitted)]." (2)

RESPONSE: The Department acknowledges the commenter's support of proposed new N.J.A.C. 8:43K-5.1 and the proposed repeal of existing N.J.A.C. 10:161B.

96. COMMENT: A commenter identifies as a "key improvement" that proposed new N.J.A.C. 8:43K-5.1 would establish "[p]atient protections against administrative or involuntary discharge," and states that "[r]eturn to use, also commonly referred to as 'relapse,' and polysubstance use are common reasons for providers to discharge patients from treatment. Punitive practices in SUD treatment can lead to stigmatization and reduced treatment engagement, and patients' fatal overdose risk is increased in the period following termination from treatment [(citations omitted)]. Effective, evidence-based treatment should employ compassionate, patient-centered responses to the continued and/or return to use as a normal feature of the recovery process and the high prevalence of polysubstance use [(citations omitted)]. This includes ensuring that drug testing is 'used as a tool for supporting recovery rather than exacting punishment [(citation omitted)].' Additionally, although some patients may benefit from more intensive counseling supports, evidence does not support policies mandating that patients receive a pre-determined amount and type of counseling – or, in many cases, any counseling at all, as such a requirement may create no additional benefit to health outcomes and can serve as an obstacle to treatment retention [(citations omitted)]."

The commenter identifies proposed new N.J.A.C. 8:43K-5.1 as providing examples of these patient protections in the following respects: proposed new N.J.A.C. 8:43K-5.1(a)20iii "[p]rohibits all facilities from discharging 'a patient based solely on clinical outcomes, drug screening, or drug or toxicology testing results'" (stating that "[s]imilar requirements apply to behavioral health services facilities and facilities that store and administer controlled dangerous substances (CDS) for SUD [at N.J.A.C. 8:43K-6.7(a)5i(1) and 11.5(a)4i])"; proposed new N.J.A.C. 8:43K-5.1(a)20v "[p]rohibits all facilities from discharging 'a patient who receives medication treatment' based on the patient 'declining counseling or other ancillary services[;]'" proposed new N.J.A.C. 8:43K-5.1(a)20vii "[r]equires all facilities to establish and notify patients of appeal procedures following involuntary discharge[;]" and proposed new N.J.A.C. 8:43K-5.1(a)20iv "[r]equires patient consent and enrollment confirmation prior to a facility 'discharging a patient to a higher, lower, or an alternative level of care.'" The commenter "strongly supports these provisions of the proposed rule, which will promote ongoing treatment by strengthening patient protections and limiting patient termination based on drug screening/toxicology results or a patient declining counseling or other ancillary services." (6)

RESPONSE: The Department acknowledges the commenter's support of proposed new N.J.A.C. 8:43K-5.1.

97. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-5.1(a)3 "should include more explicit language requiring facilities to facilitate access to MOUD, including agonist medications, for patients who desire it[, citing, as an example, to a Michigan code provision that states, "[r]eferrals, including access to medication-assisted

treatment. The policy and procedure must facilitate access to medication-assisted treatment if desired by the recipient.' (citation omitted).]" (6)

RESPONSE: Proposed new N.J.A.C. 8:43K-5.1(a) would set forth minimum requirements for facility policies and procedures. Proposed new N.J.A.C. 8:43K-5.1(a) would not prohibit a facility from developing specific policies and procedures that mirror the Michigan code to which the commenter refers. Further, proposed new N.J.A.C. 8:43K-6.7(a)1viii would set forth requirements for behavioral health services facilities to implement patient care policies and procedures for referral of patients who would 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. Such other services may include medications for addiction treatment if it is not available in the behavioral health program. Therefore, the Department will make no change upon adoption in response to the comment.

98. COMMENT: A commenter states that "additional sub-regulatory implementation guidance would aid in the effective, patient-centered implementation of [the] application of proposed [new N.J.A.C. 8:43K-5.1(a)7], [which would require that] facility admissions policies 'not conflict with applicable Federal and State laws prohibiting discrimination in the admission of patients or in the provision of services.' More specifically, Department guidance should clearly explain how [S]tate and [F]ederal civil rights laws protect people who use(d) drugs and/or have a SUD, including health services for people engaged in current illegal drug use [(citations omitted)]. Resources such as [the publication,] Legal Action [Center], *Clinicians' and Administrators' Legal*

Guide to Non-Discriminatory Health Care for People Who Use Drugs, can inform such guidance." (6)

RESPONSE: Proposed new N.J.A.C. 8:43K-5.1(a) would set forth minimum requirements for facility policies and procedures. Proposed new N.J.A.C. 8:43K-5.1(a) would not prohibit a facility from developing specific policies and procedures that mirror the information in the resources to which the commenter refers. Further, proposed new N.J.A.C. 8:43K-4.1(a) requires "a licensee shall comply with applicable Federal, State, and local laws." Therefore, the Department will make no change upon adoption in response to the comment.

99. COMMENT: A commenter "recommends that the Department [r]equire OTPs to make their methadone take-home policies and procedures publicly available and to disclose them to all patients prior to and upon admission, to the extent such actions are not already required by proposed [new N.J.A.C.] 8:43K-5.1(c)." (6)

RESPONSE: Proposed new N.J.A.C. 8:43K-5.1(c) would require a facility to make available its patient care policies and procedures to staff, patients, and visitors. This would include facility's methadone take-home policies and procedures, to the extent such policies and procedures were to exist. Therefore, the Department will make no change upon adoption in response to the comment.

100. COMMENT: A commenter recommends that the Department "[c]larify and expand substantive and procedural patient protections" and notes that proposed new N.J.A.C. 8:43K-5.1 "includes several key substantive and procedural patient protections against administrative or involuntary discharge." The commenter commends the Department's "recognition that punitive practices[,] particularly involuntary discharge[,]

are antithetical to evidence-based, patient-centered care [(citation omitted)]. The Department could further strengthen the proposed rule by making clear that administrative or involuntary discharge should be a sanction of last resort regardless of the alleged violation [citing, as an example, a West Virginia code provision that states, '[a]dministrative withdrawal shall be used only as a sanction of last resort' (citation omitted)]." (6)

RESPONSE: The Department does not find this change necessary because, as the commenter notes, proposed new N.J.A.C. 8:43K-5.1 would require a facility to establish policies for patient protection. Specifically, proposed new N.J.A.C. 8:43K-5.1(a)20 would require facilities to establish policies and procedures for patient discharge and discharge planning. The Department leaves specific policies up to the individual facilities as the individual facilities are in the best position to know the needs of their community. Nothing at proposed new N.J.A.C. 8:43K would impede a facility's ability to implement a policy mirroring West Virgina's code. Therefore, the Department will make no change upon adoption in response to the comment.

101. COMMENT: A commenter states that the Department should "[e]xpand substantive patient protections to cover punitive responses other than administrative or involuntary discharge. For example, the Department should include language explicitly prohibiting punitive reductions in medication dosages or reductions in medication take-home privileges[, including] prohibiting facilities from denying a patient clinically appropriate medication dosages or restricting take-home medications based on the patient's refusal to engage in counseling or other ancillary services [citing, as an example, a West Virginia code provision that states, '[t]he maintenance dose of

medication prescribed for a patient shall be individually determined. Adjustments upward or downward in dosage shall not be made either as punishment or reward but shall be justified by the clinical documentation of the patient's condition, subjectively and objectively' (citation omitted)]." (6)

RESPONSE: The Department leaves specific policies up to the individual facilities as the individual facilities are in the best position to know the needs of their community. Further, the Department notes that OTPs are subject to 42 CFR Part 8 which states that patient refusal of counseling shall not preclude patients from receiving MOUD, emphasizes patient-centered plans of care, and states that dosing shall be individually determined. This rule does not impede upon a facility's ability to implement a policy mirroring West Virgina's code. Therefore, the Department will make no change upon adoption in response to the comment.

102. COMMENT: A commenter states that the Department should "[a]dopt more explicit language limiting punitive responses to continued substance use (including polysubstance use) and/or return to use. The proposed rule [would prohibit] administrative or involuntary discharge based on drug screening, toxicology, or other laboratory results. However, these provisions would not necessarily preclude adverse responses to continued and/or return to use based on something *other than* screening or toxicology results ([for example], patient self-report) [(emphasis in original)]." The commenter "strongly recommend[s] the Department explicitly prohibit facilities from administratively or involuntarily discharging a patient for continued or return to use, including polysubstance use, unless the risk of such use outweighs the risk of overdose death or other adverse health outcomes following termination of treatment [(citing, as an

example, a Kentucky code provision that states, '[a] patient's participation in an [OTP] may be involuntarily terminated for cause. Cause shall include [p]olydrug use if risk of co-use outweighs risk of overdose death following termination of methadone treatment' (citation omitted)]." (6)

RESPONSE: The Department notes that the DMHAS is responsible for the development, coordination, and operational support of a comprehensive mental health and addiction services system, including a continuum of community-based prevention, early intervention, treatment, and recovery services. The DMHAS is further responsible for providing monitoring and oversight of the community-based system through the establishment of regulatory standards that implement the State's public policy objectives for, and ensure safe and adequate delivery of, behavioral health treatment services in New Jersey. Facilities should ensure compliance with DMHAS rules' minimum standards. The Department otherwise leaves specific policies up to the individual facilities as the individual facilities are in the best position to know the needs of their community. Proposed new N.J.A.C. 8:43K would not impair a facility's ability to implement a policy mirroring the Kentucky code to which the commenter refers. Therefore, the Department will make no change upon adoption in response to the comment.

103. COMMENT: A commenter states that the Department should "[c]larify and/or establish procedural protections regarding administrative or involuntary discharge or other adverse actions" and notes that proposed new N.J.A.C. 8:43K-5.1 would require "facilities to establish and notify patients of appeal procedures and timeframes following involuntary discharge. This requirement presumably refers to an

appeals process *internal* to the facility discharging a patient. Moreover, the requirement for an appeal process does not apply to adverse action short of involuntary discharge ([for example], reduction of take-home medication)." The commenter "recommends that the Department:

[(1)] Expand procedural protections to forms of adverse action other than involuntary discharge, including by requiring facilities to provide patients with notice and an opportunity to appeal any adverse action[;]

[(2)] Establish more specific requirements and guardrails for facilities' policies and procedures regarding patient appeals [(citation omitted)]. This should include a prohibition on a facility taking adverse action during the pendency of any appeal(s) absent documentation of a serious medical risk or an immediate and substantial threat of physical harm to other patients or program staff that cannot be eliminated or reduced by reasonable accommodation[; and]

[(3)] Clarify the existence of any existing process or establish a new process by which a patient may file an appeal with the [S]tate to challenge a facility's determination in a patient appeal [(citation omitted)]." (6)

RESPONSE: Proposed new N.J.A.C. 8:43K-5.1(a)20 would create a process between the patient and provider. The Department's role in licensing and regulating health care facilities is to promote the delivery of safe and quality care. The Department's role is not to function as arbiter or legal advisor in disputes between providers and patients. Therefore, the Department will make no change upon adoption in response to the comment.

104. COMMENT: A commenter states that the Department should "[e]xtend more robust patient protections to individuals receiving OTP services." The proposed new rulemaking "includes additional protections against administrative or involuntary discharge for patients receiving behavioral health services or services in a facility that stores and administers CDS for SUD. However, because opioid treatment program services are explicitly *excluded* from the sections of the proposed rule applicable to such facilities, patients receiving OTP services would be afforded fewer substantive protections. See proposed [new N.J.A.C. 8:43K-1.1(a)1] (distinguishing 'behavioral health services' and 'opioid treatment program services'), 8:43K-1.2(a) (same), 8:43K-1.3 (defining 'behavioral health care' and 'behavioral health care services' as 'excluding opioid treatment programs'), 8:43K-11.1(b) ([stating that S]ubchapter 11 governing facilities that store and administer CDS for SUD does 'not apply to a licensed opioid treatment program governed pursuant to 42 CFR Part 8 and N.J.A.C. 8:43K-8')." The commenter "recommends the Department extend the full scope of patient protections to patients receiving OTP services." (6)

RESPONSE: The protections referenced by the commenter are in the programmatic requirements that are outlined in the companion rules proposed by the DMHAS at N.J.A.C. 10:36, Behavioral Health Program Service Standards, published in the New Jersey Register at 57 N.J.R. 1779(a). In addition to the facility's licensing standards at proposed new N.J.A.C. 8:43K applicable to behavioral health provider agencies, behavioral health provider agencies must adhere to the program standards set forth at proposed new N.J.A.C. 10:36 that apply to the level, or levels, of care offered by their provider agency, and for which they are licensed to provide in their

facility. Proposed new N.J.A.C. 10:36 would consolidate and simplify program standards, while remaining consistent with current practices, and is also applicable to OTP facilities. The minimum standards relating to administrative and involuntary discharge at proposed new N.J.A.C. 10:36 and 8:43K would be sufficient to address the commenter's concerns. Therefore, the Department will make no change upon adoption in response to the comment.

105. COMMENT: A commenter states that the Department should "[e]stablish the provision of naloxone as the standard of care for all patients at risk of overdose. Naloxone should be widely accessible to communities, particularly people who use drugs … and their networks, yet access remains almost universally inadequate in the United States [(citation omitted)]. Proposed [new N.J.A.C. 8:43K-5.1(b)7 would require a facility] to ensure that 'all patients receiving MOUD receive a take-home supply, prescription, and/or information on how to obtain an opioid antidote.'" The commenter "commends the Department for recognizing the importance of naloxone access. However, given the current drug supply and prevalence of polysubstance use, it is critical that all patients at risk of overdose are offered naloxone, including patients not receiving medication treatment for OUD." The commenter "recommends the Department require facilities to offer a naloxone kit to, at minimum, all recipients with a history of opioid use or who are otherwise determined to be at risk for opioid-related overdose [citing, as an example, a Michigan code provision that states, '[t]his policy and procedure must include protocol to offer a naloxone kit to, at a minimum, all recipients with a history of opioid use or who are otherwise determined to be at risk for overdose' (citation omitted)]." The commenter "recommends the Department require naloxone kits

include only formulations containing no more than [four milligrams] of naloxone per dose unless a patient specifically requests a higher dose product, consistent with consensus recommendations for compassionate overdose response [(citation omitted)]. The Department should also consider requiring a facility's emergency opioid overdose reversal kit to include at least one kit in a formulation containing no more than [four milligrams] naloxone per dose. Establishing the direct provision of standard dose naloxone as a standard of care among outpatient and integrated care facilities will better meet the needs of patients, and importantly gets this lifesaving tool directly into the hands of those at risk." (6)

RESPONSE: The Department agrees with commenter that all patients with a history of opioid use should receive a take-home supply, prescription, and/or information on how to obtain an opioid antidote. Therefore, the Department will make a change upon adoption at proposed new N.J.A.C. 8:43K-5.1(b)7 to delete "all patients receiving MOUD" and add "all patients with a history of opioid use." The Department declines to mandate that facilities only provide certain opioid antidote formulations. However, proposed new N.J.A.C. 8:43K-5.1(b) would require a facility establish and implement minimum policies and procedures. Nothing at proposed new N.J.A.C. 8:43K-5.1(b) would prevent a facility from establishing more specific policies and procedures. Therefore, the Department will make no change upon adoption in response to this portion of the comment.

106. COMMENT: A commenter states that "[h]arm reduction saves lives and is a critical component of the continuum of care, including for individuals receiving SUD treatment services." The commenter "strongly supports the Department's thoughtful

integration of harm reduction services and supports throughout the proposed rule, including: [a] requirement that facilities maintain an accessible, on-site stock of at least one emergency opioid overdose reversal kit, [a] requirement that facilities ensure patients receiving MOUD receive 'a take-home supply, prescription, and/or information on how to obtain an opioid antidote,' [v]arious requirements that facilities provide harm reduction information, resources, strategies, products, and/or referrals to specified patients, and [c]larifying the ability of facilities to provide patients with naloxone, drug testing strips, and sterile syringes to prevent, reduce, or mitigate the adverse effects of substance use without registering as a harm reduction center (HRC), and to provide other safer drug use supplies upon registering as an HRC." (6)

RESPONSE: The Department acknowledges the commenter's support of the proposed rulemaking.

107. COMMENT: A commenter states that the Department should "[c]larify substantive differences or ensure consistent verbiage throughout the rule. Various sections of the proposed rule use different verbiage to describe similar requirements and/or limitations, and it is unclear whether these variations are intended to reflect substantive differences. [(Citation omitted.)] The issue is particularly pronounced with respect to protections against discharge …" The commenter notes that proposed new N.J.A.C. 8:43K-5.1(a)20iii would prohibit a facility "from discharging a patient 'based solely on clinical outcomes, drug screening, or drug or toxicology testing results.' A similar provision [at proposed new N.J.A.C. 8:43K-6.7(a)5i(1)] specific to behavioral health services facilities prohibits administrative or involuntary discharge 'based on the patient's laboratory results, including toxicology or drug screening or testing results.'

This language is arguably both broader (lacking the qualifying ‘solely’ and applying to all laboratory results) and narrower (not addressing clinical outcomes more generally). Still yet, a provision specific to facilities that store and administer CDS for SUD [at proposed new N.J.A.C. 8:43K-11.5(a)4i] prohibits discharging … ‘a patient based on the patient's laboratory results,’ without any illustrative examples. Similar discrepancies exist among provisions regarding discharge to different levels of care. Compare proposed [new N.J.A.C. 8:43K-5.1(a)20iv] (“‘[e]nsuring 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*’) with proposed [new N.J.A.C. 8:43K-6.7(a)5i(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’”) (emphasis added) (lacking qualifying language). It is unclear whether these differences are intentional or drafting oversights. For example, if a facility is not a behavioral health services facility and does not store and administer CDS for SUD, may the facility discharge a patient based on laboratory results unrelated to drugs or toxicology? Are behavioral health services facilities and facilities that store and administer CDS for SUD categorically prohibited from discharging patients based on drug screening or other laboratory results, while all other facilities may consider such factors in discharge decisions so long as they are not the *sole* reason for discharge? [Emphasis in original.]” (6)

RESPONSE: The Department will make changes throughout proposed new N.J.A.C. 8:43K upon adoption to ensure consistent language is used throughout the chapter. Specifically, the Department will make a change upon adoption at proposed

new N.J.A.C. 8:43K-5.1(a)20iii to add the phrase, “whether administratively, involuntarily, or otherwise,” to strengthen the patient protections regarding discharge from a facility. Furthermore, the Department will add the phrase “consistent with applicable Federal and State confidentiality laws” at proposed new N.J.A.C. 8:43K-5.1(a)20viii to ensure patient confidentiality. The Department will make a change upon adoption at proposed new N.J.A.C. 8:43K-6.7 to delete subparagraphs (a)5i, ii, iii, iv, vi, vii, and viii. The Department will make a change upon adoption at proposed recodified N.J.A.C. 8:43K-10.5 to delete redundant subparagraph (a)5i.

108. COMMENT: A commenter states that “[g]eneral guidance on non-punitive, patient-centered policies and practices regarding drug screening and non-abstinent patients [would] aid in the effective, patient-centered implementation of [proposed new N.J.A.C. 8:43K]. Such guidance could draw from — or directly incorporate — the [publication, ASAM], *Engagement and Retention of Nonabstinent Patients in Substance Use Treatment: Clinical Consideration for Addiction Treatment Providers* [(October 2024)].” (6)

RESPONSE: The proposed new rules at N.J.A.C. 8:43K would confer discretion on each facility to establish specific policies and practices, in reliance on each facility’s ability to identify the needs of the community it would serve. Proposed new N.J.A.C. 8:43K would not limit a facility’s ability to implement a policy incorporating the resource to which the commenter refers, assuming the resource provides peer-reviewed, evidenced based guidelines. Therefore, the Department will make no change upon adoption in response to the comment.

109. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-5.1(b)7, which would require that "'all patients receiving MOUD receive a take-home supply, prescription, and/or information on how to obtain an opioid antidote' is good practice and [the commenter] fully support[s] this new rule." (13)

RESPONSE: The Department acknowledges the commenter's support of proposed new N.J.A.C. 8:43K-5.1.

110. COMMENT: A commenter states that the "acronym 'MOUD' … used in [proposed new N.J.A.C. 8:43K-5.1(b)7,] should be spelled out for clarity purposes." (14)

RESPONSE: Proposed new N.J.A.C. 8:43K-1.3 would define the term "medication for opioid use disorder" or "MOUD" as used in the chapter. As the term would, thus, be "spelled out" the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-5.2 Patient Health History and Assessment

111. COMMENT: A commenter "supports the inclusion of regulatory language that requires the addition of lifesaving strategies for client treatment planning. Federal rules at 42 CFR Part 8 now require the provision of clinically necessary and mutually agreed-upon services, including lifesaving strategies and recovery support services. Lifesaving strategies, also known as harm reduction, is defined by … SAMHSA … as 'a practical and transformative approach that incorporates community-driven public health strategies—including prevention, risk reduction, and health promotion—to empower people who use drugs (and their families) with the choice to live healthy, self-directed, and purpose-filled lives [(citation omitted)].' Decades of research point to the efficacy of

these strategies in preventing overdose and increasing sterile syringe access [(citation omitted)].

[Existing] N.J.A.C. 10:161B-10.3 [(proposed for repeal)] does not include lifesaving strategies as part of client treatment planning. However, [the proposed rulemaking would repeal existing N.J.A.C. 10:161B-10.3 and] proposed [new] N.J.A.C. 8:43K-5.2[(c)] would] require facilities to '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.' Furthermore, proposed [new] N.J.A.C. 8.43K-[5.1(b)7 would] require that all patients receiving medication receive a take-home supply, prescription, and/or information on how to obtain naloxone. These added requirements ensure the integration of lifesaving strategies as part of a patient's treatment plan." (2)

RESPONSE: The Department acknowledges the commenter's support of proposed new N.J.A.C. 8:43K-5.1 and 5.2.

112. COMMENT: A commenter recommends that the Department "[c]larify and expand requirements related to harm reduction services and supports" and notes that proposed new N.J.A.C. 8:43K "includes multiple requirements to provide harm reduction services and supports directly or via referral … but these requirements are limited to certain types of facilities and/or patients meeting specified criteria. [T]hese criteria are underinclusive of all individuals who may benefit from harm reduction services and supports. For example, [proposed new N.J.A.C. 8:43K-5.2(c)] applicable to all facilities applies only when a patient has or is at risk for STDs or 'currently uses alcohol, tobacco,

or other substances in excessive amounts.' However, even patients who use drugs infrequently or in low amounts are at risk of overdose and other health complications." The commenter "strongly recommends the Department require that all facilities provide harm reduction and overdose prevention education, information, resources, products, and strategies to all patients with current substance use or a history of substance use. Additionally, should the Department opt to maintain … proposed [new N.J.A.C.] 8:43K-5.2(c), [the commenter] recommend[s modifying] the qualifying language 'in excessive amounts.' The qualifier 'in excessive amounts' makes little sense in the context of tobacco, and even people who use drugs more casually could benefit from harm reduction services and supports yet facilities may interpret the 'in excessive amounts' qualifier as rendering the provision inapplicable to such individuals." (6)

RESPONSE: The Department agrees with the commenter that the language at proposed new N.J.A.C. 8:43K-5.2(c) should be changed. "Excessive amount" is not a diagnostic term and is not used when these referrals are made. Therefore, the Department will make a change upon adoption to delete the language at proposed new N.J.A.C. 8:43K-5.2(c) and replace the language with "currently engages in or has a recent history of substance use."

N.J.A.C. 8:43K-5.6 Financial Arrangements

113. COMMENT: A commenter states that the reference at proposed new N.J.A.C. 8:43K-5.6(h) "to the licensee being the 'sole billing authority' is not clear and should be clarified or removed. The rule shouldn't prevent providers from subcontracting for patient billing services as needed. This is not incorporated into

[existing N.J.A.C. 8:43A] and the Department … may not have authority to impose such a requirement." (14)

RESPONSE: A licensee would be responsible for the financial operations of a facility and, therefore, be the "sole billing authority." The Department does not interpret this language to imply that billing, payment processing, and similar services cannot be subcontracted provided that the licensee is still ultimately responsible for the financial operations of a facility. The Department will make no change upon adoption in response to the comment.

114. COMMENT: A commenter recommends that the requirement at proposed new N.J.A.C. 8:43K-5.6(i) that a provider "describe its 'agreements with third-party payers,' be revised to say 'arrangements with managed care plan networks and other third[-]party payers' so as to not allow patients to demand copies of provider agreements and other legal documents, but allow them to be informed about in and out[-]of[-]network arrangements." (14)

RESPONSE: Pursuant to proposed new N.J.A.C. 8:43K-5.9(a)2, patients would have a right to be informed about fees and charges related to their medical care including about agreements with third-party payers. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-5.7 Telemedicine and Telehealth Activities

115. COMMENT: A commenter states that if "the intent of … proposed new … N.J.A.C. 8:43K is to encourage outpatient facilities to offer behavioral health, primary care, and mental health services in combination to clients, [proposed new N.J.A.C.] 8:43K-5.7(c) … could … dissuade a facility from expanding to a service where the only

available provider is through a telehealth option. For example, if a primary care facility in rural New Jersey wants to expand to offer mental health services but can only find a provider that is an hour and [a] half away, the primary care facility may not feasibly attract a provider willing to travel that far to accommodate a required in-person visit [pursuant to proposed new N.J.A.C.] 8:43K-5.7(c) and thus [may] be unable to provide expanded mental health services. [The Department should allow] a facility to exempt one or more services from this requirement if [it] can only offer the service through telehealth." (1)

RESPONSE: Proposed new N.J.A.C. 8:43K would establish licensure and operational standards for the development of an integrated licensing system that integrates primary care services with behavioral health, mental health, and substance use disorder programs. A primary care practice can hire clinicians to provide behavioral health, mental health, and substance use disorder services without seeking licensure as an outpatient or integrated care facility pursuant to N.J.A.C. 8:43K.

116. COMMENT: A commenter "supports the inclusion of regulatory language that allows OTPs to provide services through telehealth, including medication initiation and patient assessment. Federal rules at 42 CFR Part 8 permanently allow OTPs to provide services through telehealth, including the initiation of buprenorphine and assessment of methadone patients. Telehealth services enhance the patient experience by allowing increased privacy, reducing stigma, and encouraging the continuity of treatment [(citation omitted). Furthermore, telehealth services can improve access to treatment for historically marginalized communities [(citation omitted).

[Existing] N.J.A.C. 10:161B [(proposed for repeal)] does not explicitly allow the use of telehealth for outpatient treatment. However, proposed [new] N.J.A.C. 8:43K-5.7 cite[s F]ederal and [S]tate law to govern facilities' use of telemedicine or telehealth. Under … 42 CFR Part 8, OTPs may conduct patient screenings, full examinations, and MOUD initiation through telehealth." (2)

RESPONSE: The Department acknowledges the commenter's support of proposed new N.J.A.C. 8:43K-5.7.

117. COMMENT: A commenter identifies the proposed rulemaking's authorization of "use of telemedicine and telehealth to treat SUD" as promoting "flexible, patient-centered care," noting that "[r]esearch demonstrates the value and efficacy of telehealth-based access to MOUD treatment [(citation omitted)]. Patient access to OUD treatment via telehealth is associated with 'improved MOUD retention and lower odds of medically treated overdose,' and audio-only telehealth access is particularly important for reaching underserved populations [(citations omitted)]." The commenter supports proposed new N.J.A.C. 8:43K-5.7, "which broadly authorizes outpatient and integrated care facilities to use telemedicine and/or telehealth to treat patients, including patients with SUD, to the full extent permitted by [S]tate and [F]ederal law. Importantly, the proposed rule focuses on shared decision[-]making and appropriately balances the ability to use telemedicine and/or telehealth while protecting a patient's right to receive care in person if [the patient] so choose[s (citation omitted)]." (6)

RESPONSE: The Department acknowledges the commenter's support of proposed new N.J.A.C. 8:43K-5.7.

118. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-5.7(d)3 "should specify that exclusionary criteria for telemedicine and telehealth services must not conflict with applicable [F]ederal and [S]tate antidiscrimination laws. See, [for example], proposed [new N.J.A.C. 8:43K-5.1(a)7] (specifying that a facility's admissions policy must address '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*'") (emphasis added)." (6)

RESPONSE: To ensure nothing at proposed new N.J.A.C. 8:43K would be read to conflict with applicable Federal and State laws, the Department will make a change upon adoption to add new subsection N.J.A.C. 8:43K-1.2(c) to state "licensees must comply with all applicable Federal, State, and local laws." The Department will also make a change upon adoption to remove this language in specific sections, so that it is clear all facilities must comply with all applicable Federal, State, and local laws, not just select facilities. These changes would resolve commenter's concerns about conflicting Federal and State antidiscrimination laws.

N.J.A.C. 8:43K-5.9 Rights of Each Patient

119. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-5.9(a)13 "should include disability as a ground upon which patients have a right to be free from discriminatory treatment [(citation omitted)]." (6)

RESPONSE: The Department agrees with commenter that disability should be included in the list of discriminatory treatment at proposed new N.J.A.C. 8:43K-5.9(a)13.

Therefore, the Department will make a change upon adoption to add “disability” before “ability to pay” at proposed new N.J.A.C. 8:43K-5.9(a)13.

Subchapter 6. Behavioral Health Services

N.J.A.C. 8:43K-6.1 Behavioral Health Services Facility; General Provisions

120. COMMENT: A commenter inquires, “Where would [an] applicant or licensee find … the [‘applicable standards and requirements’ of the DMHAS, with which proposed new N.J.A.C. 8:43K-6.1(c) would require compliance]? Is there a list of these requirements posted somewhere in the proposed rules [?]” (3)

RESPONSE: The DMHAS proposed companion rules that set minimum programmatic requirements at N.J.A.C. 10:36, Behavioral Health Program Service Standards, proposed in the New Jersey Register at 57 N.J.R. 1779(a), and adopted elsewhere in this issue of the New Jersey Register. The proposed new rules would be used in conjunction with the proposed new rules at N.J.A.C. 8:43K. The Department will make a change upon adoption in response to the comment to cross-reference the applicable DMHAS rules.

N.J.A.C. 8:43K-6.5 Counseling and/or Therapy Staff

121. COMMENT: With respect to proposed new N.J.A.C. 8:43K-6.5, a commenter “recommend[s] that specific counseling and related licenses be explicitly identified as credentials required to provide counseling services ([that is], LPC, LAC, LCADC, CADC, LMFT, LCSW, LSW, [and the like].). This would help avoid situations where individuals without proper credentials are delivering services to vulnerable clients.” (10)

RESPONSE: Proposed new N.J.A.C. 8:43K-6.5 sets forth responsibilities of staff. Proposed new N.J.A.C. 8:43K-6.2 would require staff to have proper credentials. These credentials are set forth by each respective professional licensing board within the Division of Consumer Affairs. Therefore, the Department will make no change upon adoption in response to the comment.

122. COMMENT: With respect to proposed new N.J.A.C. 8:43K-6.5, a commenter “suggest[s] that interns for all identified specialties be recognized, but with a clear time limit for how long they may remain in an intern status before they must become fully licensed … to continue in their roles. This policy will help promote competency and protect the health and safety of individuals receiving care.” (10)

RESPONSE: Proposed new N.J.A.C. 8:43K-6.5 does not discuss interns; however, the commenter may have intended to refer to proposed new N.J.A.C. 8:43K-6.12, which mentions “drug counselor counselor-intern." Proposed new N.J.A.C. 8:43K-6.5 sets forth responsibilities of staff. Proposed new N.J.A.C. 8:43K-6.2 would require staff to have proper credentials. These credentials are set forth by each respective professional licensing board within the Division of Consumer Affairs. To the extent the respective professional licensing board does not set forth a time limit for interns, nothing at proposed new N.J.A.C. 8:43K impedes a facility from establishing their own policies for how long someone can work at the facility as an intern. Therefore, the Department will make no change upon adoption in response to the comment.

123. COMMENT: With respect to proposed new N.J.A.C. 8:43K-6.5, a commenter states that “LCADC and CADC appear to be left out of acceptable credentials to provide counseling and therapy services.” (10)

RESPONSE: Proposed new N.J.A.C. 8:43K-6.5 would set forth responsibilities of staff. Proposed new N.J.A.C. 8:43K-6.5 would not list acceptable credentials and, therefore, would not exclude LCADCs or CADCs. Proposed new N.J.A.C. 8:43K-6.2 would require staff to have proper credentials. These credentials are set forth by each respective professional licensing board within the Division of Consumer Affairs. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-6.6 Peer Staff and Peer Support Services

124. COMMENT: A commenter states that "[p]rovisions regarding peer staff and peer support services are … located in proposed [new N.J.A.C.] 8:43K-6.6, meaning they are applicable only to behavioral health services facilities. See proposed [new N.J.A.C.] 8:43K-6.1(a) ('This subchapter applies to a facility that the Department licenses to provide behavioral health services'), [8:43K-1.1(a)1] (distinguishing 'behavioral health services' and 'opioid treatment program services'), 8:43K-1.2(a) (same), [and] 8:43K-1.3 (defining behavioral health care services to exclude OTPs). The Department should relocate these provisions to either authorize the provision of peer support services in all facilities or, at minimum, authorize the use of peer staff and provision of peer support services in facilities providing OTP services." (6)

RESPONSE: The Department disagrees with the commenter's suggestion to relocate the applicable peer support services provisions and further disagrees with the assertion that the proposed new rules would prohibit OTPs from using peer support services. Proposed new N.J.A.C. 8:43K-8.1 would require an OTP to obtain certification

in accordance with Federal standards, including 42 CFR Part 8. 42 CFR Part 8 requires an OTP to provide physical and behavioral health services, which that regulation defines as including peer support services. Therefore, the Department will make no change upon adoption in response to the comment.

125. COMMENT: With respect to proposed new N.J.A.C. 8:43K-6.6(a), a commenter "recommend[s] adding that peers should be defined as individuals with first-person, direct lived experience. [The commenter states that this] definition is in keeping with SAMHSA's National Model of Standards for Peer Recovery Support Services. Additionally, … this [rule] inadvertently restricts the peer workforce to only those who already hold a peer certification. [The commenter] encourage[s] consideration of those who are currently working toward their peer certification to be recognized as 'candidates working towards certification' and to be included within the workforce." (10)

RESPONSE: Proposed new N.J.A.C. 8:43K-6.6(a) would require a peer to have lived experience, which would encompass first-person, direct lived experience, and an appropriate certification to provide peer support services. Proposed new N.J.A.C. 8:43K-6.6(a) would intentionally restrict the peer workforce to those who hold a peer certification. The Department believes that the peer standards, which apply also to mental health and addiction services, must remain consistent in the rules across facilities and applicable to all behavioral health services. The Department finds it in the best interest for the health and safety of New Jersey residents for the peer staff to have completed the peer certification. Therefore, the Department will make no change upon adoption in response to the comment.

126. COMMENT: With respect to proposed new N.J.A.C. 8:43K-6.6(c), a commenter "suggest[s] adding greater clarity to the definition of 'appropriately licensed and credentialed behavioral health services facility staff.' [T]here appears to be some confusion stemming from the way this is presented, especially [at proposed new] N.J.A.C. 8:43K-6.6(d), where the [rule] provide[s] additional details, including allowing … supervision by certified peers. Providing additional specificity or aligning the language across these subsections would aid in reducing confusion and ensuring consistent implementation." (10)

RESPONSE: For clarity, the Department will make a change upon adoption at proposed new N.J.A.C. 8:43K-6.6(d) to use the term "appropriately licensed and credentialed behavioral health services facility staff member" to be consistent with the language used at proposed new N.J.A.C. 8:43K-6.6(c). However, the Department does not find it necessary to define "appropriately licensed and credentialed." Proposed new N.J.A.C. 8:43K-6.2 would require staff to have proper credentials, which are set forth by each respective professional licensing board.

N.J.A.C. 8:43K-6.7 Patient Care Policies and Procedures

127. COMMENT: A commenter acknowledges the "statutory justification for limiting the scope of proposed [new N.J.A.C. 8:43K-6.7(a)1ii] regarding denial of admission to individuals currently receiving medication treatment for SUD." The commenter "recommends the Department make clear that facilities may not draw any negative inferences based on such limitations. In other words, the Department should make explicit that even facilities not subject to [N.J.S.A.] 26:2B-15 and/or 26:2G-25 are

prohibited from denying admission to individuals receiving medication treatment for SUD based on other [S]tate and [F]ederal laws, including the Americans with Disabilities Act and New Jersey Law Against Discrimination." (6)

RESPONSE: To ensure nothing at proposed new N.J.A.C. 8:43K would be read to conflict with applicable Federal and State laws, the Department will make a change upon adoption to add new N.J.A.C. 8:43K-1.2(c) to state "licensees must comply with all applicable Federal, State, and local laws." The Department will also make a change upon adoption to remove this language in specific sections, so that it is clear all facilities must comply with all applicable Federal, State, and local laws, not just select facilities. These changes would resolve commenter's concerns about conflicting Federal and State antidiscrimination laws.

128. COMMENT: A commenter identifies proposed new N.J.A.C. 8:43K-6.7(a)5ix as an example of a requirement to provide harm reduction services and supports "that is limited to certain types of facilities and/or patients meeting specified criteria[, which] are underinclusive of all individuals who may benefit from harm reduction services and support a harm reduction [because the rule] applicable to behavioral health service facilities applies only when a patient is discharged." (6)

RESPONSE: Proposed new N.J.A.C. 8:43K-6.7(a) would set forth minimum requirements for facility policies and procedures. Proposed new N.J.A.C. 8:43K-6.7(a) would not impede a facility from developing specific policies and procedures requiring the facility to provide harm reduction services to all patients. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-6.9 Medical Cannabis Use by Qualifying Patient at Behavioral Health Services Facility

129. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-6.9 "require[s] further clarification. First, it appears this [rule] applies only to programs that provide behavioral health services to minors. [The commenter] recommend[s] clarifying whether this [rule] applies exclusively to those programs or[… there are broader implications for all behavioral health service providers.

Additionally, behavioral health services encompass both mental health and substance use disorder treatment. This broadly worded definition may inadvertently enable medical cannabis to be used within substance use disorder treatment programs. This is a significant concern, as [the] DMHAS … previously issued guidance stating that providers receiving DMHAS funding may not serve clients who are using medical cannabis due to [F]ederal regulations." The commenter "suggest[s] adding clarifying language to prohibit this practice … to align with existing policy and avoid confusion for providers." (10)

RESPONSE: Proposed new N.J.A.C. 8:43K-1.3 would define "qualifying patient" as a "qualifying patient" or "patient" "as the Jake Honig Compassionate Use Medical Cannabis Act, N.J.S.A. 26:6I-1 et seq., specifically at 24:6I-3, defines that term." The definition "qualifying patient" at N.J.S.A. 24:6I-3 does not limit the meaning of term to minors. It is unclear to which DMHAS guidance the commenter refers to, so the Department is unable to address the second aspect of the comment. Accordingly, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-6.10 Outpatient Mental Health, Substance Use Disorder (SUD), and/or Other Addiction Treatment Services

130. COMMENT: A commenter states that the Department should "[c]larify substantive differences or ensure consistent verbiage throughout the rule. Various sections of the proposed rule use different verbiage to describe similar requirements and/or limitations, and it is unclear whether these variations are intended to reflect substantive differences [(citation omitted)]. This issue is particularly pronounced with respect to … priority admissions[.] There are numerous language variations in provisions addressing priority admissions. For example, [proposed new N.J.A.C. 8:43K-6.10(b)5 and 6.12(i)6 would require] a behavioral health services facility that provides either (1) outpatient mental health, SUD, and/or other addiction treatment services; or (2) a partial care program for mental health and/or substance use disorder and/or other addiction services … to prioritize admission for 'individuals with recent *and* multiple overdoses' ([that is], conjunctive 'and' requiring *both* recent overdoses *and* multiple overdoses). In contrast, [proposed new N.J.A.C. 8:43K-6.11(c)6 would require] a behavioral health services facility that provides intensive outpatient mental health, SUD, and/or addiction treatment services [to] prioritize admission for 'persons who have had recent *and/or* multiple overdoses' ([that is], disjunctive 'and/or' requiring *either* a recent overdose, multiple overdoses, or both). Still yet, [proposed new N.J.A.C. 8:43K-11.2(a)2iii would require] facilities that store and administer CDS for SUD [to] prioritize admissions for 'persons having histories of overdoses or hospitalizations due to substance use including alcohol use disorder' (excluding any temporal qualifier and including hospitalizations due to substance use even if not specific to overdose). Small

but potentially substantive differences also exist regarding priority admissions for direct referrals[: compare] proposed [new N.J.A.C. 8:43K-6.12(i)7] (partial care services must prioritize admissions for 'individuals referred directly from screening or affiliated emergency services or crisis services') (excluding general 'affiliated programs') with proposed [new N.J.A.C. 8:43K-6.11(c)8] (intensive outpatient services must prioritize 'persons referred directly from affiliated programs or affiliated emergency services or crisis services') (excluding 'screening') with proposed [new N.J.A.C. 8:43K-6.10(b)6] (outpatient services must prioritize admission only for 'referrals directly from screening or affiliated emergency services') (excluding 'crisis services' and general 'affiliated programs'). No analogous priority admissions category exists for facilities that store and administer CDS for SUD[.]

[S]everal priority admissions populations appear in provisions applicable to some but not other services without a clear rationale. See, [for example], proposed [new N.J.A.C. 8:43K-6.11(c)5] (priority admissions for 'persons at elevated risk for suicide,' unique to intensive outpatient services), 8:43K-11.2(a)[2ii] (priority admissions for 'persons who have HIV infection,' unique to facilities that store and administer CDS for SUD), 8:43K-11.2(a)[2v] (priority admissions for 'persons recently released or discharged from … hospitalization, including psychiatric hospitals, inpatient SUD treatment facilities, skilled nursing or long-term care facilities, and/or another institutionalization or inpatient program,' unique to facilities that store and administer CDS for SUD). Similarly, intensive outpatient services and facilities that store and administer CDS for SUD must prioritize admissions for people recently released from correctional or detention facilities, [8:43K-6.11(c)7] and [8:43K-11.2(a)2v], but outpatient

and partial care services are not. See proposed [new N.J.A.C.] 8:43K-6.10(b) [and] 6.12(i). Note that the intensive outpatient priority admissions language refers specifically to '*State or county* correctional or detention facilities' while the language applicable to facilities that store and administer CDS for SUD refer simply to 'correctional or detention facilities.'

There are also likely non-substantive variations in verbiage that should nevertheless be made consistent. Compare, [for example], proposed [new N.J.A.C. 8:43K-6.10(b)1] ('*Individuals* in the community at risk of …') (emphasis added) with proposed [new N.J.A.C. 8:43K-6.11(c)3] ('*Adults* in the community *who are* at risk of:') (emphasis added)." (6)

RESPONSE: The Department disagrees with the commenter's assertion that the priority admissions populations appear in provisions applicable to some but not other services without a clear rationale. The type of service determines the population type that may be prioritized. As such, the populations that are prioritized may, and indeed, are, different in different segments of the rule by design. The proposed new rules would prioritize populations that are subject to higher mortality risks and facilitate access to lifesaving care based on those determinations. Therefore, the Department will make no change upon adoption in response to this comment.

131. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-6.10 "[m]entions 'DMHAS program standards,' but these standards do not seem to be defined. For example, '[t]he patient meets the number of treatment hours for IOP services as established by DMHAS program standards,' but there is no clear outline of the number of treatment hours." (10)

RESPONSE: Proposed new N.J.A.C. 8:43K-6.10 does not mention DMHAS program standards. The commenter may have intended to refer to proposed new N.J.A.C. 8:43K-6.11, which would require a patient to receive treatment hours for intensive outpatient services in accordance with the DMHAS program standards. The companion rules proposed by DMHAS at N.J.A.C. 10:36, Behavioral Health Program Service Standards, proposed in the New Jersey Register at 57 N.J.R. 1779(a), and adopted elsewhere in this issue of the New Jersey Register, would establish the programmatic requirements to which proposed new N.J.A.C. 8:43K-6.11 would refer. In addition to the facility licensing standards at proposed new N.J.A.C. 8:43K applicable to behavioral health provider agencies, a behavioral health provider agencies would be obliged to adhere to the program standards set forth at proposed new N.J.A.C. 10:36 that apply to the level, or levels, of care it offers, and for which it is licensed to provide. The proposed new rules at N.J.A.C. 10:36 include requirements for the number of treatment hours for IOP services. Therefore, the Department will make no change upon adoption in response to the comment.

132. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-6.10 “seem[s] to outline credentialing requirements for medical supervisors and case management staff but [does] not seem to have any requirements for clinical supervisors.” (10)

RESPONSE: Proposed new N.J.A.C. 8:43K-6.10 does not address credentialing requirements for medical supervisors and case management staff. The Department believes the commenter meant to reference proposed new N.J.A.C. 8:43K-6.12. Proposed new N.J.A.C. 8:43K-6.4 would establish the requirements for clinical

supervisors. Clinicians operate within the scope of the clinician's license. Proposed new N.J.A.C. 8:43K-6.12 would establish specific requirements for the provision of partial care services because of the critical status of the patient population. Therefore, the Department will make no change upon adoption in response to the comment.

133. COMMENT: A commenter states that "[t]here is a list at [proposed new N.J.A.C.] 8:43K-6.10(b) for outpatient programs to prioritize admissions [and] a similar list at [proposed new N.J.A.C.] 8:43K-6.11(c) for … IOPs. [The commenter] question[s] whether the lists should be further distinguished between mental health … and [SUD] outpatient, [that is], whether individuals who inject drugs or have had recent or multiple overdoses are appropriate for such a list for a [mental health] clinic. [The commenter] also question[s] whether the outpatient list should include 'persons for elevated risk of suicide' and perhaps even 'persons who were recently released from State or county correctional or detention facilities,' both of which are included for IOPs."

The commenter "believes that [proposed new N.J.A.C. 8:43K-6.11(c)8] was intended to read 'persons referred directly from *screening* or affiliated emergency services or crisis services' [rather than 'persons referred directly from *affiliated programs* or affiliated emergency services or crisis services.']"

The commenter notes that "the similar item [at proposed new N.J.A.C.] 6.10(b) does not include crisis services. Language regarding those at risk of admission, readmission[,] or decompensation also differs between the two lists."

The commenter "recommend[s] that identical language be used in these two lists, as appropriate; that consideration be given to distinguishing priority populations for

[mental health] and [substance use]; and that other corrections be made in accordance with the above [comments]." (13)

RESPONSE: The Department agrees with the commenter that the language at proposed new N.J.A.C. 8:43K-6.10(b) and 6.11(c) should be consistent and will, therefore, make a change upon adoption to revise the language, accordingly.

N.J.A.C. 8:43K-6.11 Intensive Outpatient Mental Health, Substance Use Disorder (SUD) and/or Other Addiction Treatment Services

134. COMMENT: A commenter states that "[m]ental health [IOP] is included in the [heading] of [proposed new N.J.A.C. 8:43K-6.11 and paragraph (a)2 states] that mental health services at the IOP level must be clinically appropriate; and [proposed new N.J.A.C. 8:43K-6.11(c)], which addresses prioritizing admissions, also specifically identifies IOP mental health services. However, [proposed new N.J.A.C. 8:43K-6.11(a)4] only [refers] to [SUD] IOP regarding a patient's willingness to participate." The commenter reiterates a previous comment noting that proposed new N.J.A.C. 8:43K-2.8(d) "omits identifying mental health IOP as a service. The inconsistencies should be addressed and clarification provided regarding the provision of mental health IOP services." (13)

RESPONSE: The Department agrees with the commenter that the language at proposed new N.J.A.C. 8:43K-6.11(a) and (c) is inconsistent. Therefore, the Department will make a change upon adoption to include mental health at proposed new N.J.A.C. 8:43K-6.11(a)4. Furthermore, the Department will make a change to identify mental health IOP as a service at proposed new N.J.A.C. 8:43K-2.8(d) upon adoption.

135. COMMENT: “[The commenter] greatly appreciate[s] the flexibility provided in 8:43K-6.11(b) that allows a facility, on a weekly basis, to 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.” (13)

RESPONSE: The Department acknowledges the commenter’s support of proposed new N.J.A.C. 8:43K-6.11(b).

Subchapter 7. Health Care Services

N.J.A.C. 8:43K-7.2 General Physical Plant and Functional Requirements

136. COMMENT: With respect to proposed new N.J.A.C. 8:43K-7.2, a commenter states that “[N.J.A.C. 8:43K-7.2(a)6] states that if 50 [percent] of a general physical plant is being repaired, the entire space must conform to the new standards. [The commenter] recommend[s] increasing the threshold to 75 [percent], or alternatively, [the commenter recommends the Department] provide clarity on how the threshold is defined. [The commenter provides for] example, if flooring is being replaced throughout, would that constitute 100 [percent] of the space?” (7)

RESPONSE: The Department agrees with commenter that proposed new N.J.A.C. 8:43K-7.2(a)6 and 7 would establish an unclear threshold. Proposed new N.J.A.C. 8:43K-7.2(a)4 would adequately address facility performance of repairs and alterations. Therefore, the Department will not adopt proposed new N.J.A.C. 8:43K-7.2(a)6 or 7 upon adoption.

137. COMMENT: With respect to proposed new N.J.A.C. 8:43K-7.2, a commenter requests that the Department exempt all OICFs from “full plan review

requirements … including reproductive health care services facilities … from the DCA plans review process. Specific guidance, if needed, for reproductive health care facilities offering minor procedures, such as the use of specialty examination rooms, can be addressed by cross-reference to the relevant FGI standards that apply." (14)

RESPONSE: Proposed new N.J.A.C. 8:43K-7.2 would require all OICFs to follow DCA's Uniform Construction Code, N.J.A.C. 5:23. The Department cannot unilaterally exempt certain facilities from DCA requirements as DCA is the sole plan review agency for all health care facilities pursuant to N.J.A.C. 5:23-3.11(a)8. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-7.8 Reportable Events

138. COMMENT: With respect to proposed new N.J.A.C. 8:43K-7.8, a commenter recommends "that reportable events be consolidated (inclusive of [N.J.A.C.] 8:43K-4.13) and, where appropriate, cross-referenced to [N.J.A.C.] 8:43E. The requirements and timelines for reporting should be aligned with the Administrator ([for example], the [p]resident, CEO, [c]hief [a]dministration [o]fficer) notification requirements in [N.J.A.C.] 8:43A-3.8, which requires seven … days, as opposed to the [m]edical [d]irector. For reference, [the Hospital Licensing Standards at N.J.A.C.] 8:43G-5.1(d) provide … a 15-day notice requirement for similar reporting by the [h]ospital [a]dministrator." (7)

RESPONSE: The Department agrees with commenter that the reportable events at proposed new N.J.A.C. 8:43K-7.8 can be consolidated with proposed new N.J.A.C. 8:43K-4.13. The Department will make changes upon adoption to add "and medical director, as applicable" at proposed new N.J.A.C. 8:43K-4.13(c)1. The Department will

not adopt proposed new N.J.A.C. 8:43K-7.8 because proposed new N.J.A.C. 8:43K-4.13(c)1 and 2 would address the two reportable events at N.J.A.C. 8:43K-7.8.

The Department will make no change upon adoption in response to the notification requirement aspect of this comment. The facility licensure rules at Title 8 require a three-day notice requirement for most facility types.

139. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-7.8 "appears to duplicate N.J.A.C. 8:43K-4.13] and this subchapter, as written, should be the requirements that apply only to health care facilities that become [OICFs]." (14)

RESPONSE: The Department agrees with commenter that the reportable events at proposed new N.J.A.C. 8:43K-7.8 can be consolidated with proposed new N.J.A.C. 8:43K-4.13. The Department will make changes upon adoption to add "and medical director, as applicable" to proposed new N.J.A.C. 8:43K-4.13(c)1. The Department will not adopt proposed new N.J.A.C. 8:43K-7.8 because proposed new N.J.A.C. 8:43K-4.13(c)1 and 2 would address the two reportable events at N.J.A.C. 8:43K-7.8.

The Department disagrees that proposed new N.J.A.C. 8:43K-4.13 should only apply to health care facilities that become OICFs. Proposed new N.J.A.C. 8:43K-4 would set forth operational standards applicable to all licensed outpatient facilities. Therefore, the Department will make no change upon adoption in response to the aspect of the comment addressing the applicability of proposed new N.J.A.C. 8:43K-4.13.

N.J.A.C. 8:43K-7.9 Medical Director; Appointment; Duties

140. COMMENT: With respect to proposed new N.J.A.C. 8:43K-7.9, a commenter states that the Department should "review and revise administrative

requirements that place unnecessary burdens on small health centers and governing boards by allowing the [m]edical [d]irector — not the governing board — to approve professional privileges. Most volunteer board members are not equipped to oversee clinical governance and should not be expected to do so." (4)

RESPONSE: The Department will make no change upon adoption in response to this comment because proposed new N.J.A.C. 8:43K-7.9(c)2vi would already allow the medical director to review credentials and delineate privileges.

141. COMMENT: A commenter states that "[t]his proposal … clarifies the qualifications and [requirements] of [a medical director]. [The commenter further requests clarification as to whether] one person serving as [a] medical director [may serve as a medical director] for more than one modality of care, [should] that person [be] qualified for each modality." (12)

RESPONSE: Nothing at proposed new N.J.A.C. 8:43K would prohibit a facility from hiring one person to serve as medical director for more than one modality of care. However, if the facility hires one individual to serve as medical director for more than one modality of care, the individual must meet the requirements of each applicable subsection, which may require that individual be qualified in a specific modality. The Department will make no change upon adoption in response to the comment as the commenter does not request any change.

142. COMMENT: A commenter states that, "assuming [OICFs] are not eligible to provide chronic dialysis services, [proposed new N.J.A.C. 8:43K-7.9(b)] appears to be unnecessary." (14)

RESPONSE: If a facility is not eligible to provide chronic dialysis services, proposed new N.J.A.C. 8:43K-7.9(b) would not apply to that facility. Therefore, the Department will make no change upon adoption in response to the comment.

143. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-7.9(c)1 "specifies that the medical [d]irector must be 'physically present a minimum of eight hours per week and available at all times patients are onsite.' The rule should provide flexibility for alternate care [and/or] satellite locations of reproductive health care and primary care providers, as this standard exceeds the [existing] rule for the availability of a of a medical director … at [N.J.A.C.] 8:43[A]-7.2[.]" (14)

RESPONSE: Proposed new N.J.A.C. 8:43K-7.9(c)1i would require the medical director, or the acting medical director, be physically present a minimum of eight hours per week and available at all times when patients are on site. Pursuant to proposed new N.J.A.C. 8:43K-7.9(c)1, a facility would designate the acting medical director to serve in the medical director's absence. The Department finds that the designation of an acting medical director would provide sufficient flexibility. Further, the requirement at proposed new N.J.A.C. 8:43K-7.9(c)1 that would require the medical director be available at all times patients are onsite is consistent with, and less burdensome than, the requirement at existing N.J.A.C. 8:43A-7.2, which requires the medical director be available to the facility at all times. The Department also believes having a medical director physically present a minimum of eight hours per week is in the best interest of the health and safety of patients in New Jersey. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-7.10 Director of Nursing Services; Appointment; Duties

144. COMMENT: A commenter "appreciates the flexibility provided by [proposed new N.J.A.C. 8:43K-7.10] by allowing the [d]irector of [n]ursing [s]ervices to be available at the facility when patients are on site. [The rule] reflects the staffing realities of smaller reproductive health centers." (4)

RESPONSE: The Department acknowledges the commenter's support of proposed new N.J.A.C. 8:43K-7.10.

145. COMMENT: With respect to proposed new N.J.A.C. 8:43K-7.10, a commenter states, "[t]o address the lower need for RN services at smaller [h]ealth [c]enters, [the commenter suggests the] eliminat[ion of] the requirement to have a [director of nursing] on the premises of the facility on a full-time basis, [and] instead, use the term 'available at all times.'" (5)

RESPONSE: Nothing at proposed new N.J.A.C. 8:43K-7.10 would require a director of nursing to be on the premises of the facility on a full-time basis, as the commenter suggests. Proposed new N.J.A.C. 8:43K-7.10(a) would require a director of nursing to have full-time or full-time equivalent experience. However, proposed new N.J.A.C. 8:43K-7.10(b)1 would require the director of nursing to "be available to the facility when patients are onsite." Pursuant to proposed new N.J.A.C. 8:43K-1.3, "available" in relation to personnel would mean "capable of being reached by telephone." Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-7.11 Infection Prevention and Control

146. COMMENT: A commenter "supports [proposed new N.J.A.C. 8:43K-7.11, which would allow] a consultant who does 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." (4)

RESPONSE: The Department acknowledges the commenter's support of proposed new N.J.A.C. 8:43K-7.11.

147. COMMENT: With respect to proposed new N.J.A.C. 8:43K-7.11(d), a commenter "support[s] and understand[s] the CDC requirements listed," and states, "many of them may not be applicable to a family planning-only center." The commenter recommends that the Department add the phrase, "as applicable to the services offered,"' following the phrase, "the CDC Guidelines listed below." (14)

RESPONSE: The Department agrees with the commenter and will make a change upon adoption to add "as applicable" after "the CDC Guidelines listed below" recodified at N.J.A.C. 8:43K-7.10(d).

N.J.A.C. 8:43K-7.14 Reproductive Health Care Services; General Provisions

148. COMMENT: A commenter "strongly supports [proposed new N.J.A.C. 8:43K-7.14,] which expands the qualifications for [m]edical [d]irectors of reproductive health centers to include family practice physicians." (4)

RESPONSE: The Department acknowledges the commenter's support of proposed new N.J.A.C. 8:43K-7.14.

149. COMMENT: A commenter "support[s proposed new N.J.A.C. 8:43K-7.14], but [the rule] seem[s] to be inconsistent with other requirements ([for example,] the requirement for a [m]edical [d]irectors at [proposed new N.J.A.C. 8:43K-]7.9(c) is [eight] hours a week)." The commenter notes "that 'available' is used here, which [the commenter] support[s], but it should be defined as 'capable of being reached.' If this subsection identifies exceptions for [r]eproductive [h]ealth [c]are providers, these requirements should cross-reference the other standards that address these topics." (14)

RESPONSE: Facilities that plan to provide reproductive health care services in accordance with proposed new N.J.A.C. 8:43K-7.14 would need to meet the requirements at recodified N.J.A.C. 8:43K-7.13 and the requirements for the medical director at recodified N.J.A.C. 8:43K-7.8. The Department disagrees that these sections are inconsistent. Recodified N.J.A.C. 8:43K-7.13(a) would require, in relevant part, a physician who is either the medical director or on staff to be "available during the facility's hours of operation." A medical director would be capable of meeting the requirement at recodified N.J.A.C. 8:43K-7.13(a) and be onsite at least eight hours a week as recodified N.J.A.C. 8:43K-7.8(c) would require. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-7.18 Counseling and Therapy Services

150. COMMENT: With respect to recodified N.J.A.C. 8:43K-7.17(a), a commenter requests clarification "as to what types of providers this rule addresses. As written, it authorizes a 'health care facility' to provide counseling and therapy without obtaining an OICF license. If this is intended to be permissive for all [a]mbulatory [c]are

[f]acilities, it should note this, of[sic] if it applies only to [r]eproductive [h]ealth [c]are and [p]rimary [c]are [OICFs], then clearly state this. The definition of 'health care facility' appears to encompass only [OICFs]." (14)

RESPONSE: The commenter correctly notes that, as proposed, the rule authorizes a "health care facility" to provide counseling and therapy without obtaining an OICF license. The licensure requirement applies to facilities that wish to provide behavioral health programs, mental health programs, or substance use programs in addition to either primary care and/or reproductive health care services. Facilities that provide programs must obtain a license pursuant to this proposed rule and comply with the applicable program requirements outlined by corresponding DHS rules. If a facility provides, for example, only primary care services and wants to hire a clinician to provide counseling services to patients, that would be permitted, provided that the clinician acts within the clinician's scope of practice. Therefore, the Department will make no change upon adoption in response to this comment.

N.J.A.C. 8:43K-7.19 Medical Specialty Services

151. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-7.19 "appears to limit the types of professional medical subspecialty services that an OICF may provide under its license. While perhaps meant to clarify the scope of services intended, it goes beyond the current regulatory framework of N.J.A.C. 8:43A, and thus raises questions as to what an OICF must do … to hire a physician whose specialty is not within the identified list. The source of the specialties identified … is not clear or

based upon any existing regulatory or statutory framework [and should] be removed ….” (14)

RESPONSE: The Department disagrees with the commenter’s assertion that recodified N.J.A.C. 8:43K-7.18 limits the types of medical services that an OICF may provide. Recodified N.J.A.C. 8:43K-7.18 specifically identifies the list as “non-exhaustive” and would not require OICFs to provide any additional medical specialty services. Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-7.20 Anesthesia Services

152. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-7.20(a) “may unintentionally but potentially serve to preclude reproductive health care services facilities offering abortion services from being eligible for OICF licensure, as moderate/conscious sedation is a routine service provided during these minor procedures for pain relief.” (14)

RESPONSE: The Department has determined to not repeal any sections from N.J.A.C. 8:43A upon adoption to minimize the instances where a facility may need more than one license. The Department believes this addresses commenter’s concerns. However, the Department notes that some facilities may need dual licenses depending on the facility’s services. Therefore, the Department will make no change upon adoption in response to the comment.

153. COMMENT: With respect to proposed new N.J.A.C. 8:43K-7.20, a commenter states that “[t]here is … no definition of ‘deep or dissociative conscious sedation … thus creating uncertainty as to the meaning of this for future interpretation.”

The commenter “suggest[s] clarifying it … to avoid any future confusion that [OICFs] offering procedural abortions may administer moderate sedation to patients when indicated for pain relief.” The commenter “request[s] that the rule specify that the service location for moderate sedation must be either a [p]rocedure [r]oom or a [s]pecialty [e]xamination [r]oom as defined by the FGI [Guidelines], which is not presently stated in N.J.A.C. 8:43A-12, but is the Department’s policy.” (14)

RESPONSE: The Department will make a change upon adoption to revise the language and use the term “conscious sedation” at recodified N.J.A.C. 8:43K-7.19(e) to be consistent with the existing rules at N.J.A.C. 8:43A. The terms used at N.J.A.C. 8:43A and recodified N.J.A.C. 8:43K-7.19(e) will then be consistent.

Recodified N.J.A.C. 8:43K-7.19(g)6 would require facilities to have policies and procedures addressing the clinical monitoring of patients in a procedure room or other location at which patients receive anesthesia. Further, existing N.J.A.C. 8:43A-12.2 defines “special procedure room” as meaning the appropriately equipped facility location in which special procedures are performed. Existing N.J.A.C. 8:43A-12.2 also defines “special procedure” as meaning various diagnostic or therapeutic interventions which may require the administration of sedation, analgesia, or anesthesia. Therefore, the Department disagrees with commenter that existing N.J.A.C. 8:43A-12 does not specify service location and will make no change upon adoption in response to this portion of the comment.

154. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-7.20(e) is consistent with existing N.J.A.C. 8:43A-12, “but … would be more clear if the term

‘conscious sedation’ was used together with ‘moderate sedation,’ perhaps cross-referencing the Board of Medical Examiner[s rules].” (14)

RESPONSE: The Department will make a change upon adoption to revise the language and use the term “conscious sedation” at recodified N.J.A.C. 8:43K-7.19(e) to be consistent with the existing rules at N.J.A.C. 8:43A. The terms used at N.J.A.C. 8:43A and recodified N.J.A.C. 8:43K-7.19(e) will then be consistent. The Department also, therefore, declines to make a cross-reference to the Board of Medical Examiner’s rules as the new rules would not use those terms.

155. COMMENT: With respect to proposed new N.J.A.C. 8:43K-7.20, a commenter states that the “use of nitrous oxide for minor pain relief should be specifically exempted, which is common in the provision of dental services and certain minor [gynecological] procedures.” (14)

RESPONSE: The Department has declined to adopt the proposed rules addressing adjunctive services, which would have included dental services. No rules exist addressing the used of nitrous oxide pursuant to existing N.J.A.C. 8:43A and the Department declines to set forth new standards at recodified N.J.A.C. 8:43K-7.19. Therefore, the Department will make no change in response to the comment.

156. COMMENT: A commenter requests that proposed new N.J.A.C. 8:43K-7.20(e)2, “requiring a supervising physician to be ‘immediately available’ be [changed to] ‘available and capable of being reached.’ The [Board of Medical Examiners] and the Department during the Public Health Emergency has and continues to authorize [CRNAs] to perform conscious sedation without on-site physician supervision in ambulatory surgery centers. Adopting this approach also for [OICFs] would streamline

operations in a safe and effective manner. No public safety issues to [the commenter's] knowledge have arisen as a result of this exception." (14)

RESPONSE: The commenter provides no specific citation or reference that supports the assertion that the BME authorizes CRNAs to perform conscious sedation without onsite physician supervision in ambulatory surgery centers and the Department is unable to locate any rule that supports this assertion. Therefore, the Department will make no change upon adoption in response to the comment.

Subchapter 8. Opioid Treatment Program

157. COMMENT: A commenter "supports the removal of the requirement that OTPs in New Jersey either employ or contract with a pharmacist. The repeal of N.J.A.C. 10:161B-1.6 aligns with [F]ederal rules at 42 CFR Part 8, which allow a variety of licensed health care professionals to administer methadone at OTPs, stating that a practitioner is defined as 'a health care professional who is appropriately licensed by a State to prescribe and/or dispense medications for [OUD]s and, as a result, is authorized to practice within an OTP.' This approach provides states with flexibility to authorize a range of providers to dispense methadone in OTPs based on their availability and distribution, thus lowering the barriers to opening and operating OTPs [(citation omitted)]." (2)

RESPONSE: The Department acknowledges the commenter's support of the proposed rulemaking and the proposed repeal of existing N.J.A.C. 10:161B.

158. COMMENT: A commenter "supports removing requirements for OTP patients to undergo more drug tests per year than required by [F]ederal rules. [Existing], N.J.A.C. 10:161B-11.9 [(proposed for repeal)] requires OTP patients to

undergo random biweekly drug screening until the screening results are ‘drug-free’ for three months in a row followed by a minimum of monthly random screenings. This far exceeds [F]ederal rules at 42 CFR Part 8, which only require eight drug tests each year. [The p]roposed [rulemaking] repeals N.J.A.C. 10:161B-11.9, thus removing the requirement that OTPs conduct more than the [F]ederal standard of eight drug screens annually.

There is insufficient evidence on the effect of drug testing on patient safety and health outcomes [(citation omitted)]. Furthermore, drug testing can be a source of humiliation for patients which eventually may reduce their retention in treatment [(citations omitted)]. Thus, requiring patients to undergo additional tests beyond the [F]ederal minimum is a barrier to treatment.” (2)

RESPONSE: The Department acknowledges the commenter’s support of the proposed rulemaking and the proposed repeal of existing N.J.A.C. 10:161B.

159. COMMENT: A commenter “supports the inclusion of regulatory language that allows OTP clinicians to provide take-home doses of medication as clinically appropriate. Take-home medications can enhance the patient experience by allowing treatment flexibility [(citation omitted)]. Research also suggests that allowing take-home medication results in high patient satisfaction, which is associated with higher retention in treatment [(citation omitted)]. Federal standards at 42 CFR Part 8 permanently extend COVID-19-era flexibilities that allow patients to receive up to 28 days of take-home medication during early stages of treatment [(citation omitted)]. During the COVID-19 pandemic, New Jersey took advantage of these flexibilities and studies showed no increase in overdose among individuals enrolled in methadone maintenance

treatment [(citing Lloyd J, Treitler P, Lister J J, Nowels M, and Crystal S, "Methadone treatment utilization and overdose trends among Medicaid beneficiaries in New Jersey before and during the COVID-19 pandemic," *Journal of Substance Use and Addiction Treatment,* 167:209476 (December 2023), available at https://doi.org/10.1016/j.josat.2024.209476].

"[Existing] N.J.A.C. 10:161B-11.12 [(proposed for repeal) includes a phased take-home schedule, with doses increasing based on time in treatment and negative urine drug tests [with] allowances rang[ing] from one daily take-home dose upon admission to a 30-day supply of take-home medication after 36 months of negative urine drug screens. However, [the] proposed [rulemaking] repeals N.J.A.C. 10:161B-11.12 and, further, states that 'a facility that provides an opioid treatment service would be subject to compliance with 21 U.S.C. § 823 and 42 CFR Part 8.' In subjecting New Jersey OTPs to comply with [F]ederal standards at 42 CFR Part 8, patients that meet stability criteria may now be allowed up to a 28-day supply of take-home medication after 31 days of treatment." (2)

RESPONSE: The Department acknowledges the commenter's support of the proposed rulemaking and the proposed repeal of existing N.J.A.C. 10:161B.

160. COMMENT: A commenter states that "Federal rules at 42 CFR Part 8 emphasize client involvement in setting treatment goals by developing patient-centered care plans that meet the unique needs of every client. Patient-centered care focuses on an individual's physical symptoms as well as [the individual's] mental and emotional well-being [(citation omitted)]. This model integrates the [patient's] perspective with that of the care provider. Studies show that implementing patient-centered care practices

significantly increase a patient's utilization of behavioral health treatment and routine medical care [(citation omitted)].

[Existing] N.J.A.C. 10:161B-9.2 [(proposed for repeal)] cite[s] client and family participation in the development of a treatment plan. However, [standards at N.J.A.C. 10:161B addressing] standardized counseling and take-home schedules do not support the provision of an individualized care plan. Ultimately, in subjecting New Jersey OTPs to comply with [F]ederal standards at 42 CFR Part 8, patient-centered care is now included as part of treatment planning." (2)

RESPONSE: The Department acknowledges the commenter's support of the proposed rulemaking and the proposed repeal of existing N.J.A.C. 10:161B.

161. COMMENT: A commenter states that the Department should "build on [F]ederal reforms to ensure OTP services employ patient-centered practices [by s]trengthen[ing] and expand[ing] access to take-home methadone. Federal regulations, to which … proposed [new N.J.A.C. 8:43K] almost exclusively defer[s], continue to grant OTPs vast discretion to determine the number of methadone take-home doses a patient is permitted, or even whether to allow a patient to receive take-home doses at all. Many OTPs continue to treat take-home doses as a privilege to be earned by patients rather than a routine aspect of evidence-based care." The commenters assert that "OTPs are also frequently disinclined to support increased take-home doses due to financial incentives or outdated beliefs about effective treatment approaches, making it unlikely their policies and procedures will enable most patients to be eligible for the maximum number of take-home doses unless the [S]tate establishes such an expectation " however, do not provide significant supporting evidence.

The commenter “recommends that New Jersey reverse this framework by establishing a presumption that patients receiving methadone OTP services are eligible for the maximum number of take-home doses corresponding with their time in treatment. OTP practitioners would still retain clinical discretion to allow fewer take-home doses or even deny take-home doses entirely, consistent with their responsibilities under [S]tate and [F]ederal law. However, the OTP practitioner would be required to justify and document any downward departure in allowable take-homes for *each individual patient* based on the criteria in 42 CFR § 8.12(i)(2). Requiring OTP practitioners to justify why a patient should *not* receive take-home doses would more appropriately reflect the evidence-base by establishing that take-home doses should be the norm, not the exception. It would also reduce the likelihood of OTP providers systematically denying clinically appropriate take-home doses, a practice that was common with the COVID-19 flexibilities [(citation omitted)], and which evidence suggests has continued following the permanent adoption of these flexibilities [(citation omitted)]. [(Emphasis in original.)]” (6)

RESPONSE: Facilities are subject to compliance with Federal requirements at 42 CFR Part 8, which requires OTP providers to provide services "as clinically necessary and based on an individualized assessment and a mutually agreed-upon care plan." Thus, the Department declines to establish a standard that would allow a patient to take home the maximum number of take-home doses because this would conflict with the applicable Federal standard. Therefore, the Department will make no change upon adoption in response to the comment.

162. COMMENT: A commenter recommends that the Department "[e]stablish a presumption that a patient may maintain [the patient's] current take-home medication doses upon transferring from one OTP to another." (6)

RESPONSE: Facilities are subject to comply with Federal requirements at 42 CFR Part 8. Specifically, 42 CFR 8.12, at subsections (h), (i), and (j), establishes requirements for unsupervised or "take-home" medication doses, transfers, and referrals. Thus, the Department declines to establish a standard independent of the Federal requirements. Therefore, the Department will make no change upon adoption in response to the comment.

163. COMMENT: A commenter recommends that the Department "[c]larify authorization for methadone guest dosing," and states that "[a]lthough evidence suggests that methadone guest dosing already takes place in New Jersey … proposed [new N.J.A.C. 8:43K] does not explicitly authorize such practices or address how regulatory requirements ([such as] mandatory [intake] procedures) apply in the context of methadone guest dosing." The commenter "strongly supports the ability of OTPs to provide guest dosing to patients of other OTPs, which facilitates patients' ability to remain in treatment while traveling, and recommends the Department modify its rule to explicitly authorize such practices." The commenter notes that "Federal regulations recently expanded the circumstances in which an individual may obtain treatment from an OTP that is not their home OTP. See 42 CFR § 8.12(g)(2) ('Such circumstances include, but are not limited to, travel for work or family events, temporary relocation, or an OTP's temporary closure')." (6)

RESPONSE: Facilities are subject to compliance with Federal requirements at 42 CFR Part 8. Specifically, as noted by the commenter, 42 CFR 8.12(g)(2) establishes standards for travel for work or family events, temporary relocation, or an OTP's temporary closure. Thus, the Department declines to establish a standard independent of the Federal requirements. Therefore, the Department will make no change upon adoption in response to the comment.

164. COMMENT: A commenter recommends that the Department "[e]xplicitly authorize interim treatment in alignment with [F]ederal regulations" and states that the "recent changes to 42 CFR Part 8 included notable improvements regarding interim OTP treatment. These changes include (1) increasing the maximum length of interim treatment from 120 to 180 days in any 12-month period; (2) reducing the minimum number of required drug screens; (3) authorizing take-home doses for patients in interim treatment: (4) requiring OTPs to provide information on 'locally available, community-based resources for ancillary services;' and (5) prohibiting the discharge of a patient in interim treatment without the approval of an OTP practitioner. SAMHSA's Final Rule also repealed [a Federal regulation] that provided that no medications may be dispensed to patients in short-term detoxification or interim maintenance treatment for unsupervised or take-home use. Studies show that interim treatment reduces illicit drug use and increases the likelihood that patients will enter comprehensive treatment." The commenter "recommends the Department explicitly authorize interim treatment in accordance with current [F]ederal regulations. SAMHSA's Final Rule also removed the prohibition on the provision of interim treatment by for-profit OTPs, 'to expand access to

interim treatment among all OTPs [and] in recognition of a need to bring individuals into treatment and in response to public comment.'" (6)

RESPONSE: The Department was unable to verify the accuracy of the commenter's assertions regarding 42 CFR Part 8. Regardless, OTP facilities are subject to compliance with Federal standards at 42 CFR Part 8. Thus, the Department declines to establish a standard independent of the Federal requirements. Therefore, the Department will make no change upon adoption in response to the comment.

165. COMMENT: A commenter "recommends that the Department [e]stablish a patient advisory structure" and states that proposed new N.J.A.C. 8:43K "reflects New Jersey's commitment to a more patient-centered model of care, including for patients receiving OTP services. Various provisions of the proposed rule emphasize shared decision-making and the voluntariness of services." The commenter "recommends that the Department extend the shift toward patient-centered models of care even further so that people with direct experience receiving OTP services can guide the policies, procedures, and practices that directly affect them on a more systemic level. This could be accomplished by establishing an OTP Patient Advisory Board at the [S]tate level to inform the work of the Department and … DMHAS… including the [S]tate's opioid treatment authority (SOTA). The advisory structure should include patients across the treatment continuum, including individuals who currently use illicit drugs. A similar but distinct patient advisory board may also be considered for non-OTP services. [The commenter's] recommendation to establish a patient advisory board specific to OTP services is based on the unique historical and current regulatory and societal context of methadone treatment for OUD." (6)

RESPONSE: There are a number of patient advisory boards already in use for a variety of specialized areas of focus throughout the State. State-level councils like the New Jersey Rare Disease Advisory Council, the Medical Assistance Advisory Council (MAAC), and the Beneficiary Advisory Council (BAC), are all established by either Federal law or State statute, or both. No such statutory requirement exists for the commenter's suggested board. As such, the Department will make no change on adoption in response to the comment.

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N.J.A.C. 8:43K-8.1 Opioid Treatment Program

166. COMMENT: A commenter "supports the inclusion of regulatory language that would explicitly allow guest dosing to enhance the patient experience. Guest dosing is the practice of allowing patients to receive methadone from an OTP other than the one at which someone is a patient [(citation omitted)]. Guest dosing provides flexibility for patients who may have difficulty accessing services at their home OTP [(citation omitted)]. [A] 2018 study describes the experiences of OTP patients, staff, and directors affected by Hurricane Sandy in 2012, which led to a disruption in services [(citation omitted)]. In the study, patients described a variety of challenges related to transportation, guest dosing, and take-home medications. Based on these experiences, [the] authors [of the study] provide recommendations for care continuity such as OTPs developing guest relationships with nearby OTPs.

[Existing] N.J.A.C. 10:161B [(proposed for repeal)] does not … explicitly [permit] guest dosing. However, [the] proposed [rulemaking] repeals N.J.A.C. 10:161B and, further, states that 'a facility that provides an opioid treatment service would be subject

to compliance with 21 U.S.C. § 823 and 42 CFR Part 8.' In subjecting New Jersey OTPs to comply with [F]ederal standards at 42 CFR Part 8, New Jerseyans may receive treatment at another OTP 'in circumstances involving an inability to access care at the patient's OTP of record.' These circumstances include but are not limited to 'travel for work or family events, temporary relocation, or an OTP's temporary closure.' Furthermore, proposed [new] N.J.A.C. 8:43K-[8.1(a)4] would require OTPs to '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.' These added requirements go beyond [F]ederal rules in ensuring reliable, patient-centered care for patients receiving methadone and also support emergency preparedness." (2)

167. COMMENT: A commenter recommends that the Department "[c]larify authorization for methadone guest dosing," and states that "[a]lthough evidence suggests that methadone guest dosing already takes place in New Jersey … proposed [new N.J.A.C. 8:43K] does not explicitly authorize such practices or address how regulatory requirements ([such as] mandatory [intake] procedures) apply in the context of methadone guest dosing." The commenter "strongly supports the ability of OTPs to provide guest dosing to patients of other OTPs, which facilitates patients' ability to remain in treatment while traveling, and recommends the Department modify its rule to explicitly authorize such practices." The commenter notes that "Federal regulations recently expanded the circumstances in which an individual may obtain treatment from an OTP that is not their home OTP. See 42 CFR § 8.12(g)(2) ('Such circumstances

include, but are not limited to, travel for work or family events, temporary relocation, or an OTP's temporary closure')." (6)

RESPONSE TO COMMENTS 166 AND 167: As the commenters note, facilities are subject to compliance with Federal requirements at 42 CFR Part 8. Thus, the Department declines to establish a standard independent of the Federal requirements. Therefore, the Department will make no change upon adoption in response to the comments.

168. COMMENT: A commenter notes that proposed new N.J.A.C. 8:43K-8.1(a)5 establishes minimum requirements for policies that address client methadone withdrawal, and states that the rule "would have more clarity if, instead of all stated [at proposed new N.J.A.C. 8:43K-8.1(a)5i], they were listed as [i and ii] with [i] specifying for individuals starting at 100 [milligrams] or less and [ii] for individuals starting at a dosage greater than 100 [milligrams] per day." The commenter "also recommend[s] greater clarity and elaboration on the maximum reduction allowed for those who started over 100 [milligrams] per day once they are reduced to 100 [milligrams] per day." (13)

RESPONSE: The Department agrees with the commenter that separation of proposed new N.J.A.C. 8:43K-8.1(a)5i into two provisions would enhance comprehension. The Department will make a change upon adoption in response to the comment to split proposed new N.J.A.C. 8:43K-8.1(a)5i into two subparagraphs. New N.J.A.C. 8:43K-8.1(a)5i would allow the dosage to be reduced at a rate that is greater than 10 mg every two days after the client is at a dose of 100 mg or less. Therefore, the Department will make no change upon adoption in response to this aspect of the comment.

Subchapter 9. Adjunctive Services

169. COMMENT: A commenter states that "[S]ubchapter [9 requires] an OICF provider [to] notify the Department … prior to initiating the provision of [adjunctive] services … [The commenter expresses concern] that this broad language extends and … exceeds the Department's licensure authority to exercise jurisdiction [over adjunctive] services such as these not incorporated into the Health Care Facilities Planning Act at N.J.S.A. 26-2H, or for licensure authority for community-based behavioral health services. The proposed rule[making would] require an application to [identify an adjunctive service the facility would provide]." The commenter states that this "will add significant time to the provider's schedule for implementing an adjunctive service." The commenter expresses concern that requiring notice that a facility will provide an adjunctive service will create "enforcement authority for the Department when it believes that a provider has not met the relevant requirements of another state or [F]ederal agency, professional board, or an accrediting body for these adjunctive services"… and requests clarification of the Department's authority to "review … copies of inspection reports from other licensure bodies or credentialling organizations at [N.J.A.C.] 8:43K-9." The commenter states that services "in the private practice of medicine are not subject to periodic inspections." The commenter "understand[s] the potential need for a disclosure of an IOCF's provision of an adjunctive service, but [recommends] the following limitations be included in the [rulemaking]: a) limit these to a more finite list of health-related services with a potential significant impact on a patient's health or safety, b) eliminate any licensing procedure for offering such services and ensure that the Department does not intend to enforce ancillary rules of professional licensing boards

and other identified sources, and c) If essential for behavioral health providers, exempt reproductive health care and primary care providers from these provisions." (14)

N.J.A.C. 8:43K-9.1 Provision of Adjunctive Services

170. COMMENT: With respect to proposed new N.J.A.C. 8:43K-9.1, a commenter "request[s] that [a facility] adding adjunctive services that do not alter compliance with existing Federal or State standards – such as those [involving regulat[ed] medical waste, sterilization, maintenance, and/or calibration of equipment, facility staffing, and/or facility infection prevention and control practices as outlined in [proposed new N.J.A.C.] 8:43K-7.11 — not be required to obtain supplemental licensure or operational approval." (7)

171. COMMENT: A commenter states that "[t]o the extent [that adjunctive services] are either services offered pursuant to a professional board license or other non-regulatory authority, [N.J.A.C. 8:43K-9.1 should] be [changed] consistent with the Department's statutory authority. In the alternative, to the extent that these are services related to behavioral health providers … [r]eproductive [h]ealth [c]enters and [p]rimary [c]are [c]enters [should] be exempted." (14)

172. COMMENT: A commenter "note[s] that … [proposed new N.J.A.C. 8:43K-]9.1(c) [would require] on-site inspections when the adjunctive service implicates infection control or medical waste practices, and offers exemptions when these services do not involve these safety issues. That said, it appears that none of the services listed [at proposed new N.J.A.C. 8:43K-9.1(c)1i] realistically involve infection control concerns." (14)

RESPONSE TO COMMENTS 169, 170, 171, AND 172: As described above, the Department has determined that, upon adoption, it will not adopt proposed new Subchapter 9, Adjunctive Services. Therefore, the commenter's concerns with the related provisions are now moot. Accordingly, the Department will make no additional changes upon adoption in response to the comments.

N.J.A.C. 8:43K-9.3 Wound Care

173. COMMENT: With respect to proposed new N.J.A.C. 8:43K-9.3, a commenter requests that "[f]or clarity … the requirement to obtain licensure as an ambulatory surgical center be specifically tied to the use of general anesthesia. There are wound care treatments and procedure that can be performed in exam or procedure rooms using topical or moderate sedation." The commenter suggests that the Department change proposed new N.J.A.C. 8:43K-9.3(a)2 as follows (suggested addition in italic): "The facility obtains a 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 *general* anesthesia." (7)

RESPONSE: The Department agrees with the commenter that revisions to the specified provision are necessary because the language at proposed new N.J.A.C. 8:43K-9.3(a)2 is incongruent with the anesthesia provisions outlined at proposed new N.J.A.C. 8:43K-7.20. The Department will not adopt proposed new Subchapter 9, Adjunctive Services, but will retain proposed new N.J.A.C. 8:43K-9.3, recodified as proposed new N.J.A.C. 8:43K-7.22, with minor grammatical changes to ensure readability. Accordingly, the Department will make a change to recodified N.J.A.C.

8:43K-7.22(a)2 upon adoption to specify that licensure as an ambulatory surgical center must be obtained if the facility provides wound care procedures in accordance with N.J.A.C. 8:43K-7.20(a).

174. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-9.3 would "permit wound care only if there is no anesthesia provided for this service at the OICF, otherwise the provider must become an [a]mbulatory [s]urgical [f]acility[. T]his distinction is not presently contained in [N.J.A.C.] 8:43A, and [the commenter] question[s] its necessity, as wound care most likely requires at least local anesthesia to be used and there is no distinction as to the level of anesthesia identified in the rule proposal." (14)

RESPONSE: As described in the Response to Comment 173, the Department will make a change upon adoption to the requirements at proposed new N.J.A.C. 8:43K-9.3(a)2 to ensure that the language at proposed new N.J.A.C. 8:43K-9.3(a)2 is consistent with the anesthesia provisions outlined at proposed new N.J.A.C. 8:43K-7.20. The Department disagrees with the commenter's assertion that the proposed new rules prohibit the provision of wound care services without anesthesia. Proposed new N.J.A.C. 8:43K-7.20(b) already addresses the requirements for facilities that administer only local anesthesia or minor conduction injection nerve blocks for outpatient procedures. Therefore, the Department will make no change upon adoption in response to that portion of the comment.

N.J.A.C. 8:43K-9.7 Harm Reduction

175. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-9.7(a) and (b) should be changed to state:

"(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."

The commenter states that, 'for clarity,' proposed new N.J.A.C.] 8:43K-9.7(b) should include language noting an exception for the needles and syringes mentioned [at proposed new N.J.A.C.] 8:43K-9.7(a)." (13)

RESPONSE: The Department will make no change upon adoption in response to the comment because proposed new N.J.A.C. 8:43K-9.7(a) would already include language that explains the needles and syringes at proposed N.J.A.C. 8:43K-9.7(a) would be exempt from obtaining Department registration as a harm reduction center. However, the Department notes that proposed new Subchapter 9, Adjunctive Services, will not be adopted but proposed new N.J.A.C. 8:43K-9.7, Harm reduction, will be retained and recodified as N.J.A.C. 8:43K-6.13.

Subchapter 10. Storage, Administration, and Dispensing of Medication

N.J.A.C. 8:43K-10.2 Provision of Pharmaceutical Services

176. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-10.2(a) "should specify that this means either a retail pharmacy or an institutional pharmacy as

licensed by the [New Jersey] Board of Pharmacy. There should be no requirement for a reproductive health care center to have a pharmacist on staff or on site for the routine function of dispensing a standard supply of medication following a medical visit and prescription." (14)

RESPONSE: Proposed new N.J.A.C. 8:43K-10.2(a) would only be applicable to facilities that maintain an "on-site pharmacy." Proposed new N.J.A.C. 8:43K-10.2(a) would not require facilities without an "on-site pharmacy" to have a pharmacist on staff or on site. Therefore, the Department will make no change upon adoption in response to the comment.

Subchapter 11. Administration of Controlled Dangerous Substances for the Treatment of Substance Use, Ambulatory Withdrawal Management, and/or Stabilization

N.J.A.C. 8:43K-11.4 Patient Education Services

177. COMMENT: A commenter identifies proposed new N.J.A.C. 8:43K-11.4(a)2 as an example of a requirement to provide harm reduction services and supports "that is limited to certain types of facilities and/or patients meeting specified criteria[, which] are under-inclusive of all individuals who may benefit from harm reduction services and support a harm reduction [because] the education requirement [in the rule] would not include individuals receiving SUD treatment in a facility that does not store and administer CDS for SUD." The commenter "strongly recommends the Department require that all facilities provide harm reduction and overdose prevention education, information, resources, products, and strategies to all patients with current substance use or a history of substance use." (6)

RESPONSE: The Department disagrees with the commenter that proposed new N.J.A.C. 8:43K-11.4(a)2 is underinclusive. Proposed new N.J.A.C. 8:43K-11.4(a)2 would require a facility that stores and administers controlled dangerous substances for the treatment of substance use, including withdrawal management, initial stabilization, and treatment of substance use disorders in the outpatient setting to educate each patient as to the risks of substance use and ways to mitigate those risks, including harm reduction strategies and overdose prevention. Not all facilities dispense dangerous substances to patients; therefore, the Department does not find it necessary for every facility to provide the education that would be required pursuant to proposed new N.J.A.C. 8:43K-11.4. The Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-11.5 Extended On-site Clinical Monitoring Services

178. COMMENT: A commenter states that proposed new N.J.A.C. 8:43K-11.5(a)5 "prohibits a facility that stores and administers CDS for SUD from dispensing greater than a [three-]day supply of controlled medication for withdrawal management and/or stabilization 'until the treating physician or advanced practitioner determines the patient to be medically stable' or the patient qualifies for an exemption. The Department's rationale for this limitation is unclear, particularly as no analogous limit applies when a patient is *prescribed* a controlled medication for such purposes. If intended to align with [F]ederal law on the dispensing of Schedule II narcotic medications for SUD outside a licensed OTP [(citing to 21 CFR § 1306.07(b))], the Department should modify the provision to explicitly limit its applicability to such Schedule II narcotics."

The commenter states that "[t]o the extent the provision is intended to apply to the dispensing of Schedule II narcotics for SUD outside a licensed OTP, it may conflict with … outdated rules [of the Department of Law and Public Safety in Title 13 of the New Jersey Administrative Code]. [N.J.A.C.] 13:45H-7.7(a) (restricting direct dispensing of narcotic drugs for detoxification or maintenance treatment to practitioners separately registered under [N.J.A.C.] 13:45H-11.2), 13:45H-7.7(b) (providing an exception for the *administration* of narcotic drugs for up to [three] days but not authorizing dispensing, contrary to the analogous [F]ederal regulation), [and] 13:45H-11.2(a) (establishing annual registration requirement for any person who engages in a narcotic treatment program)." The commenter "recommends the Department of Law and Public Safety amend its rules to align with … Federal law, including 21 CFR § 1306.07(b)."

The commenter states, "[i]f intended to apply to controlled medications more generally, [the commenter] recommends the provision be excluded from a final rule. If retained in its current form, the Department should, at minimum, explain the need to impose unique limits on controlled medications that are directly dispensed rather than prescribed, and clarify the meaning of 'medically stable' in this context." (6)

RESPONSE: The Department declines to extend the three-day supply period at proposed new N.J.A.C. 8:43K-11.5(a)5 because 21 CFR 1306.07(b) does not allow for more than a three-day supply of narcotics. Further, the Department leaves it up to the clinicians to determine whether a patient is "medically stable." Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-11.6 Physician Services

179. COMMENT: A commenter requests that the Department "exempt facilities that only temporarily store and administer depo-buprenorphine (medications like [SUBLOCADE®] or [Brixadi®] as a part of their office-based substance use treatment services from [compliance with proposed new N.J.A.C.] 8:43K-11 … or at least certain elements [thereof,] such as N.J.A.C. 8:43K-11.6. If [a facility] that temporarily store[s] and administer[s] depo-buprenorphine (CDS) for the treatment of [OUD]—a substance use disorder—[would] be subject to [N.J.A.C. 8:43K-11], requiring the facility to have a medical director with an addiction medicine or addiction psychiatry board certification[, N.J.A.C.] 8:43K-11.6 … could … serve as a limiting factor in encouraging facilities to expand access to this type of medication for [OUD] during a time when expanded, liberal access to all medications for [OUD] is needed." (1)

RESPONSE: The Department finds that it is in the best interest of the health and safety of patients to have a medical director with experience in addiction medicine or addiction psychiatry whenever dangerous substances are used or implicated in patient care. Therefore, the Department will make no change upon adoption in response to the comment.

Subchapter 12. Alternative Care Locations

180. COMMENT: A commenter "supports the [Department's] decision to align with [F]ederal standards at 42 CFR Part 8, which explicitly permit OTPs to operate medication units and allows these units to offer the full range of services available at a typical OTP. [Existing] N.J.A.C. 10:161B [(proposed for repeal)] does not contain language that explicitly permits medication units. [The proposed rulemaking would

repeal existing] N.J.A.C. 10:161B and [p]roposed [new] N.J.A.C. 8:43K … specifies in Subchapter 12, Alternative Care Locations, how OTPs can apply to provide services at a location separate from its principal licensed facility. These changes help clarify that [the operation of] medication units is permissible in New Jersey.

Medication units are satellite sites of an OTP, either mobile or brick-and-mortar. These settings can increase patient access to care by expanding the number and geographic distribution of locations where they can receive methadone (and other medications for [OUD]) services, especially in rural and underserved areas [(citation omitted)]. For example, a treatment provider in Kentucky reported that treatment options increased by 28 [percent] after [it] opened several medication units [(citation omitted)]." (2)

RESPONSE: The Department acknowledges the commenter's support of the proposed repeal of existing N.J.A.C. 10:161B and proposed new N.J.A.C. 8:43K-12.

181. COMMENT: A commenter identifies proposed new N.J.A.C. 8:43K-12.1, 12.2, and 12.3, which would authorize the provision of services at alternative locations, including through mobile vehicles, as promoting "flexible, patient-centered care," stating that "[p]atients must often travel substantial distances to access treatment services [(citation omitted)], which can directly and negatively affect treatment retention and outcomes. This is particularly true for individuals receiving methadone to treat their OUD via an OTP given the increased frequency with which patients must visit their OTP in person. Indeed, a 2022 study in a [United States] metropolitan area found that even a '10-min drive was associated with a 33 [percent] reduction in the completion of methadone treatment plans [(citation omitted)].'" The commenter "supports proposed

[new N.J.A.C.] 8:43K-12.1, [12.2], and [12.3], which authorize the regular provision of services at an alternative service location, the intermittent provision of services at an alternative service location, and the permanent provision of services using one or more mobile outpatient care vehicles, respectively, including the use of mobile outpatient care vehicles to provide [OTP] services." (6)

RESPONSE: The Department acknowledges the commenter's support of the proposed rulemaking at N.J.A.C. 8:43K-12.1, 12.2, and 12.3.

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

182. COMMENT: A commenter "support[s proposed new N.J.A.C. 8:43K-12], as it provides a flexible approach to off-site or satellite service locations." The commenter "recommend[s] that the Department review [N.J.A.C.] 8:43A-27 to determine [whether] any other exceptions to the full chapter of OICF [rules] are necessary." (14)

RESPONSE: The Department reviewed existing N.J.A.C. 8:43A-27 and determined that it does not require the establishment of exceptions at proposed N.J.A.C. 8:43K-12. Therefore, the Department will make no change upon adoption in response to the comment.

183. COMMENT: A commenter states, "with respect to personnel requirements [at proposed new N.J.A.C. 8:43K-12.1(c)], [the commenter requests confirmation] that centralized key clinical staff, such as a medical director or director of nursing, do not have to be present at all times. The [rule] states that they must be present 'to the same degree and extent that the staff member would be required to be available at the primary facility location.' The term 'available' is defined as 'capable of being reached.' If

this is the Department's intent, which [the commenter] support[s], this should be clarified at [proposed new N.J.A.C. 8:43K-]12.1(c)." (14)

RESPONSE: Proposed new N.J.A.C. 8:43K-1.3 would define "available" in relation to personnel as meaning "capable of being reached by telephone." Therefore, the Department will make no change upon adoption in response to the comment.

N.J.A.C. 8:43K-12.2 Intermittent Provision of Licensed Services at an Alternative Service Location

184. COMMENT: A commenter notes that proposed new N.J.A.C. 8:43K-12.2(a)1 would require "a facility that intermittently provides non-OTP services at off-site premises and/or using a mobile outpatient care vehicle to provide at least 30 days' notice 'of the proposed location at which services are to be provided.'" The commenter states that "[t]o ensure maximum flexibility, the Department should clarify that for mobile outpatient care vehicles, the 'proposed location' required in such notices may reflect the general vicinity or area(s) in which services are to be provided rather than a specific address or exact location." (6)

RESPONSE: The Department disagrees with the commenter that the identification of the proposed location requires clarification and, in fact, believes that the rules, as drafted, allow providers maximum flexibility. Therefore, the Department will make no change upon adoption in response to the comment.

185. COMMENT: With respect to proposed new N.J.A.C. 8:43K-12.2(a), a commenter requests that the Department "identify the appropriate communication channel ([for example], email, phone) for providing notification. If a provider is already approved to provide mobile services, [the commenter] recommend[s] that advance

notice not be required, as it may unnecessarily restrict access to care and services. As an alternative, facilities could be required to publish a calendar on their website[s] to inform the public. If advance notice is deemed necessary, [the commenter requests] that the requirement for intermittent, non-mobile services be limited to no more than five … days to preserve operational flexibility." (7)

RESPONSE: The Department disagrees with the commenter that the identification of the notification channel requires clarification and, in fact, believes that the rules, as drafted, allow providers maximum flexibility. Further, the Department believes that advance notice of the time, place, and manner in which facilities intend to provide offsite services is imperative for the health and safety of the patients seeking those services. Therefore, the Department will make no change upon adoption in response to the comment.

186. COMMENT: The commenter states that "[t]he [proposed rulemaking would require a provider] at [an alternative site or mobile facility] notify the Office [of Certificate of Need and Facility Licensing (Office)'] at least 30 days in advance[']] of the location, dates, and services to be provided." The commenter further states that "[s]ome providers of [alternative site or mobile] care serve unhoused and other vulnerable populations, and [advanced notice of, and what services will be provided,] would be difficult to [identify prior to] outreach [to unhoused and other vulnerable populations who require] care." The commenter "recommend[s] shortening the [notice] time to five days, and allowing … an approximate location of services." (12)

187. COMMENT: A commenter states that "[t]he opportunity to provide regular, intermittent[,] and mobile services at alternative locations is greatly appreciated and a

significant step toward ‘meeting individuals where they are.’ [The commenter] believes that the rules for intermittent services need to be more flexible … for providers to be able to take advantage of, and clients to be able to benefit from, such opportunity.

By their nature, intermittent services are not regularly scheduled. Having to provide a 30[-]day notice for such services precludes providers from responding to new admissions, [for example,] at shelters, and to emerging crises and increased risks, [for example], for students. It would also preclude being able to follow up in less than 30 days after initial engagement. The opportunity to provide services at alternative locations should accommodate all of these situation[s] by allowing same[-]day notice and giving consideration to retrospective notice.” (13)

RESPONSE TO COMMENTS 186 AND 187: The Department disagrees with the commenters’ suggestion to lower the alternative care location advance notice requirement from 30 days’ notice to five days. The Department believes that it is in the best interest of patient health and safety for providers to carefully plan for the provision of services that are offsite of the primary location. Furthermore, it is imperative for the Department’s oversight of the provision of services at alternative locations to have advance notice of the offsite service events. Therefore, the Department will make no change upon adoption in response to this comment.

N.J.A.C. 8:111 Standards for Licensure of Residential Substance Use Disorders Treatment Facilities

188. COMMENT: A commenter states that “[i]n addition to the updates to the [S]tate’s OTP [rules], the proposed [rulemaking would] also repeal New Jersey’s existing [rules] for prescribing buprenorphine in outpatient SUD treatment programs [at existing]

N.J.A.C. 10:161B-11.16 … However, buprenorphine [rules] for residential SUD treatment programs, [at] N.J.A.C. 8:111[, Standards for Licensure of Residential Substance Use Disorders Treatment Facilities] continue to impede access to MOUD treatment. As such, [the commenter] strongly recommends also repealing the [S]tate's existing buprenorphine prescribing [rules] for residential SUD treatment programs, [at] N.J.A.C. 8:111 … to allow providers to prescribe buprenorphine for OUD as medically necessary across various treatment settings."

The commenter states that "[i]n addition to methadone, buprenorphine is another FDA-approved medication for opioid use disorder that is safe and highly effective at reducing overdose deaths and disease transmission. Compared to methadone, buprenorphine is subject to substantially fewer regulatory barriers. Buprenorphine can also be prescribed in a variety of settings, including primary care offices, by physician assistants, physicians, and nurse practitioners. Buprenorphine is not subject to the strict [F]ederal regulations governing methadone administration and distribution. The Consolidated Appropriations Act, 2023 removed the [F]ederal requirement that buprenorphine prescribers complete a special registration (known as the 'X-waiver'). Despite these advantages, buprenorphine is still vastly underutilized. Black and Hispanic people are particularly less likely to receive it compared to white people. One strategy for expanding access to buprenorphine is removing state regulatory barriers.

New Jersey regulates buprenorphine at both N.J.A.C. 10:161B-11.16 [(proposed for repeal)] — for outpatient treatment programs -- and N.J.A.C. 8:111 — for residential treatment programs**.** These [rules] require compliance with [N.J.A.C. 8:111 Appendix B, 'the DMHAS Buprenorphine Guidelines, Administrative Bulletin 2007-03.' The DMHAS

Buprenorphine Guidelines include several provisions that are not evidence-based and reduce access to care, such as mandated counseling and restrictions on buprenorphine formulations. Other sections of N.J.A.C. 8:111 … include restrictive buprenorphine [rules]. [The p]roposed rulemaking would repeal existing] N.J.A.C. 10:161B-11.16, thus removing the requirement that outpatient SUD treatment programs comply with these outdated guidelines. [The commenter] supports this change.

However, [the notice of proposal would] not affect [existing] N.J.A.C. 8:111, meaning that these restrictive regulations would still apply to buprenorphine prescribing in residential facilities. [The commenter] recommends that New Jersey consider removing buprenorphine prescribing [rules] at N.J.A.C. 8:111 to allow residential providers to prescribe buprenorphine for OUD as medically necessary. This would be an important step towards increasing access to this lifesaving medication for OUD.

[Following] is a list of some elements of N.J.A.C. 8:111 (and existing N.J.A.C. 10:161B-11.16 [(which is proposed for repeal) [that] are not evidence-based, can block or delay access to buprenorphine, and should be removed:

(1) Requirement for patients to participate in counseling with a specified minimum frequency and format[;]

(2) Restriction on specific buprenorphine formulations that can be prescribed[;]

(3) Requirement regarding initial patient evaluations/examinations[; and]

(4) Inclusion of outdated provisions of federal law requiring a DEA-licensed provider to obtain a specific waiver to prescribe buprenorphine." (2)

189. COMMENT: A commenter states that the proposed rulemaking "includes reforms critical to expanding access to lifesaving, evidence-based SUD care. [The

commenter] believes these reforms should not be limited to outpatient and integrated care facilities. [The commenter] encourage[s] the Department to assess current [S]tate rules governing residential SUD treatment facilities ([that is, N.J.A.C. 8:111 …]) and expeditiously issue a proposed rule that extends analogous patient protections and best practices to such facilities. In the interim, the Department should issue a rule waiver for provisions that do not align with current evidence-based best practices, particularly the requirement [at N.J.A.C.] 8:111-7.1(a) that facilities comply with the outdated Buprenorphine Guidelines [at N.J.A.C. 8:111] Appendix B." (6)

RESPONSE TO COMMENTS 188 AND 189: The Department did not propose any changes at existing N.J.A.C. 8:111, and these comments are, therefore, beyond the scope of this rulemaking. Therefore, the Department will make no change upon adoption in response to these comments. The Department will consider these comments in the course of future rulemaking.

Summary of Agency-Initiated Changes:

1. At proposed new N.J.A.C. 8:43K-1.3, the definition of the term "board certification" uses the term "ABNS" without providing identifying information for that entity. Therefore, the Department is adding a definition of the term "American Board of Nursing Specialties" or "ABNS" at new N.J.A.C. 8:43K-1.3, to provide contact information for that entity.

2. At proposed new N.J.A.C. 8:43K-1.3, the Department is adding a definition of the term "addictive disorder" to be consistent with DMHAS rules, which the definition of "addiction treatment" would use at proposed new N.J.A.C. 8:43K-1.3.

3. At proposed new N.J.A.C. 8:43K-1.3, the definition of the term “addiction treatment” does not specifically include addictive disorders. To ensure consistency with DMHAS rules, the Department is replacing the term “behavioral addiction” with “addictive disorder” in the definition of “addiction treatment.” The Department does not define “behavioral addiction” nor is the term used anywhere else in proposed new N.J.A.C. 8:43K.

4. At proposed new N.J.A.C. 8:43K-1.3, the Department is changing the definition of the term, “substance use disorder treatment service” or “SUD treatment service” to remove a reference to “addictive disorder” which unintentionally would include behavioral, non-substance addictions, such as gambling. The Department is changing the definition to read “counseling, therapy, and/or medication management provided to a person who has a substance use disorder.”

5. At proposed new N.J.A.C. 8:43K-1.3, the Department is adding a definition of the term “temporary license” to mean a type of interim license available to a mental health services facility pending completion of full site review; and deleting the proposed definition of the term “provisional license” because existing N.J.A.C. 8:43E, specifically at N.J.A.C. 8:43E-3.1 and 3.10, use the term “provisional license” in the sense of a Department enforcement remedy that allows a facility to continue to operate, typically pursuant to Department-imposed conditions, pending resolution of an enforcement action. The Department is making corresponding changes to replace occurrences of the term “provisional license” at proposed new N.J.A.C. 8:43K-2.5(f) and (g), with the new term “temporary license.”

6. The Department will not adopt proposed new N.J.A.C. 8:43K-2.11, Transitional license, because the Department will not issue an interim license. The Department will issue new licenses to the providers with multiple existing licenses following the effective date of this rulemaking. All other facilities that wish to offer a combination of services available pursuant to proposed new N.J.A.C. 8:43K will be able to apply to add those services and will be issued a new license, as applicable.

7. The Department will remove “Subject to (c) below” at recodified N.J.A.C. 8:43K-7.13(b) because the provisions of subsection (b) are independent of subsection (c).

8. The Department will not repeal the existing provisions at N.J.A.C. 8:43A proposed for repeal. Repealing the rules at N.J.A.C. 8:43A-20, 21, 22, 23, and 26 would inadvertently create a requirement for many ambulatory care facilities to obtain a license pursuant to both N.J.A.C. 8:43A and 8:43K to continue the facility’s current operations. While N.J.A.C. 8:43K would simplify the licensing requirements for facilities that want to offer a specific combination of services, it would simply create the same problem for many other existing facilities. Maintaining the rules proposed for repeal at N.J.A.C. 8:43A-20, 21, 22, 23, and 26 will allow facilities a choice between being licensed pursuant to N.J.A.C. 8:43A or 8:43K and, therefore, allow more flexibility for providers while not imposing the economic burden of dual licensing costs. Furthermore, the Department will not repeal the provisions proposed for repeal at N.J.A.C. 8:43A-1.1, 1.3, 2.2, and 33.3 to provide the requisite licensing flexibility. The Department will, therefore, make a change upon adoption of the application form at page 6, Ambulatory Care Facility, to ensure it represents all available categories of service, including

primary care, reproductive health care, and satellite facilities. The Department will continue to monitor and evaluate the licensing process for ambulatory care facilities with the implementation of N.J.A.C. 8:43K and pursue future rulemakings to address issues as they arise to streamline the application and licensing process, if necessary.

Federal Standards Statement

The adopted 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 adopted 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 adopted amendments, repeals, and new rules would meet, but not exceed, applicable Federal standards, an exceedance analysis is not required.

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

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.-2. (No change from proposal.)

(b) (No change from proposal.)

CHAPTER 43K

MANUAL OF STANDARDS FOR LICENSURE OF OUTPATIENT AND INTEGRATED CARE FACILITIES

SUBCHAPTER 1. GENERAL PROVISIONS

8:43K-1.2 Scope

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

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

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]* ***addictive disorder***, such as gambling including, but not limited to, counseling, therapy, medication management, medication administration, care navigation, and/or psychosocial supportive services.

“Addictive disorder” means a clinical presentation that demonstrates signs and symptoms that substantiate diagnosis of an addictive disorder as defined in the DSM, such as a gambling disorder and/or substance use disorder.

…

“Administration of controlled dangerous substance for the treatment of substance use disorder” or “administration of CDS for the treatment of SUD” means *[an adjunctive]* ***a*** 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.

…

[“Affiliation agreement” means “affiliation agreement” as N.J.S.A. 30:9A-19 describes that term.]

…

"*[Alternate]* ***Alternative*** care location" means a location at which a facility provides licensed services on a regular ***or an intermittent*** basis***,*** subject to N.J.A.C. 8:43K-12.

…

"American Board of Nursing Specialties" or "ABNS" means the entity by that name for which the contact information is 85 Swanson Road, Suite 135, Boxborough, MA 01719-1443, website https://www.nursingcertification.org.

…

"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***s*** these terms, excluding opioid treatment programs.

…

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

…

"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]*.

…

"Mental health services" means counseling, therapy, and/or medication management ***related to any DSM-5 diagnoses***.

…

"Opioid treatment program" or "OTP" means a "certified opioid treatment program" as 21 U.S.C. § 823 ***and 42 CFR 8.2*** define*[s]* that term.

…

["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.]

…

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

…

SUBCHAPTER 2. LICENSURE PROCEDURES

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

(a) (No change from proposal.)

(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. (No change from proposal.)

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.

i. The Department will transmit a request for renewal and the attendant fee to a licensee 30 days prior to the expiration of its license.

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

*[(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.]*

Recodify proposed (f)-(p) as ***(e)-(o)*** (No change in text from proposal).

8:43K-2.2 Ownership; transfer of ownership

(a) (No change from proposal.)

(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.

1. An entity shall notify the Department when there is a change in ownership of real property at which the facility exists.

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

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

(c) The Department *[shall]*:

1. *[Conduct]* ***May 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]* ***If the Department conducts a survey pursuant to (c)1 above, then it shall issue*** a written report to the applicant that provides the on-site survey results 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 ***Department issues a*** report *[that the Office issues]* pursuant to *[(c)]* ***(c)2*** above ***that*** identifies one or more deficiencies, the applicant shall notify the *[Office]* ***Department*** when it completes the corrective actions needed to cure the deficiencies, following which, the *[Office]* ***Department*** shall perform one or more resurveys of the premises to confirm that the applicant has cured identified deficiencies.

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

(e) (No change from proposal.)

8:43K-2.5 Facility license issuance

(a)-(e) (No change from proposal.)

(f) The Department may issue a *[provisional]* ***temporary*** 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]* ***services facility*** that seeks to change its existing location or add an additional location, or an applicant for new licensure as a mental health *[practitioner]* ***services facility***, if:

1. The *[provider]* ***facility or applicant*** submits a complete application and the appropriate fee; and

2. The Department has reviewed the *[program's]* policies and procedures ***of the facility or applicant*** and has conducted a program site tour.

(g) The Department may renew a *[provisional]* ***temporary*** license, if needed.

8:43K-2.8 Fees

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

(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:	$250.00

- Outpatient mental health and/or SUD or other addiction treatment services;

- Intensive outpatient ***mental health and/or*** SUD or other addiction treatment services; and/or

- Partial care.

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)-(i) (No change from proposal.)

SUBCHAPTER 3. ENFORCEMENT

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]****3.4***.

(b) (No change from proposal.)

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.]

Recodify proposed (b)-(c) as ***(a)-(b)*** (No change in text from proposal).

[(d)] ***(c)*** 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-4.6 Policy and procedure manual

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

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

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]* ***every three years*** and revises, as necessary, and which address:

1.-3. (No change from proposal.)

(b)-(p) (No change from proposal.)

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.-2. (No change from proposal.)

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

[4.] ***3*** A list of deficiencies identified during a complaint investigation conducted on the facility during the preceding 12 months;

*[5.]****4*** A statement of patient rights;

*[6.]****5*** The names of the members of the facility's governing authority;

*[7.]****6*** The addresses to which one may send correspondence to the facility and its governing authority; and

*[8.]****7*** The operating and business hours of the facility.

8:43K-4.10 Management of medical emergencies

(a) A facility shall establish written policies and procedures that it reviews *[annually]* ***at least every three years*** 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.-8. (No change from proposal.)

8:43K-4.12 Employee health

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

(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)]* ***October 3, 2026***, with respect to an existing employee, and upon employment, with respect to a new employee upon employment.

1.-4. (No change from proposal.)

(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]***:***

1. 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*.***; and/or**

2. "Tuberculosis Screening, Testing, and Treatment of U.S. Health Care Personnel: Recommendations from the National Tuberculosis Controllers Association and CDC, 2019," incorporated herein by reference, as amended and supplemented, published in the Morbidity and Mortality Weekly Report, at MMWR 2019; 68(19);439–443 (May 17, 2019), available at https://www.cdc.gov/mmwr/volumes/68/wr/mm6819a3.htm?s_cid=mm6819a3_w.*

[1.] ***(e)*** 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.] ***1.*** 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.] ***2.*** 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)] ***i.*** 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.] ***3.*** *[Subparagraphs (d)1i and ii]* ***Paragraphs (e)1 and 2*** above are subject to the following exceptions:

[(1)] ***i.*** 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)] ***ii.*** 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)] ***iii.*** A facility shall not require an employee who provides documentation of a positive Mantoux skin test result to receive a Mantoux skin test.

[(4)] ***iv.*** 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.] ***(f)*** A facility shall establish policies and procedures for the periodic screening of employees for Mycobacterium tuberculosis that includes at least the following requirements:

[i.] ***1.*** The facility shall administer a Mantoux skin test to all tuberculin-negative employees at least annually;

[ii.] ***2.*** The frequency of testing shall be determined by the level of risk the facility's TB plan establishes; and

[iii.] ***3.*** The facility shall maintain records of the results of employee Mantoux tuberculin testing.

[3.] ***(g)*** Questions regarding tuberculosis control may be directed to the Tuberculosis Control Program.

[(e)] ***(h)*** (No change in text from proposal.)

8:43K-4.13 General reportable events

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

(c) A facility shall report to the Office, in writing:

1. The resignation or termination of the administrator ***and medical director, as applicable***, *[along with]* ***and*** the name of the replacement within three days;

2. A known death of a patient ***who is under the supervision*** of the facility, including deaths known or suspected to have resulted from misuse of medications prescribed or dispensed by the facility, when applicable;

3.-5. (No change from proposal.)

(d)-(e) (No change from proposal.)

8:43K-4.19 Environmental patient care services

(a) A facility shall ensure compliance with the following environmental conditions:

1.-9. (No change from proposal.)

10. The facility shall ensure that the temperature in the facility is, at a minimum, ***68 to*** 72 degrees Fahrenheit *[(22 degrees Celsius)]* when patients are in the facility;

11.-18. (No change from proposal.)

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.-19. (No change from proposal.)

20. Patient discharge and discharge planning, including:

i.-ii. (No change from proposal.)

iii. Ensuring that the facility does not discharge a patient***, whether administratively, involuntarily, or otherwise,*** based solely on clinical outcomes, drug screening, or drug or toxicology testing results;

iv.-vii. (No change from proposal.)

viii. Determining when and how to involve a patient, family members, and/or other support persons whom the patient identifies, in discharge planning***, consistent with applicable Federal and State confidentiality laws***;

ix. (No change from proposal.)

x. Conducting post-discharge outreach to patients, family members, and/or support persons whom the patient identifies***, consistent with applicable Federal and State confidentiality laws***; and

21. (No change from proposal.)

(b) A facility that prescribes medication shall establish and implement policies and procedures that address the prescribing of medication, including:

1.-6. (No change from proposal.)

7. Ensuring that all patients *[receiving MOUD]* ***who have a history of opioid use*** receive a take-home supply, prescription, and/or information on how to obtain an opioid antidote.

(c) (No change from proposal.)

(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.-7. (No change from proposal.)

(b) (No change from proposal.)

(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. (No change from proposal.)

[2. Currently uses alcohol, tobacco, or other substances in excessive amounts.]

2. Currently engages in, or has a recent history of, substance use.

(d) (No change from proposal.)

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.] ***iii.*** Administration of CDS for SUD treatment.

(b) 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.-12. (No change from proposal.)

13. To be free from discriminatory treatment because of age, race, religion, sex, nationality, ***disability,*** 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. (No change from proposal.)

(Agency Note: The text of N.J.A.C. 8:43E-5 Appendix, CN-7 Form, following without boldface or brackets to indicate changes upon adoption. The changes are discussed in the responses to comments above and the appendix is in its final form.)

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				
Community Based Primary Care				
Community Based Primary Care Satellite				
Comprehensive Outpatient Rehabilitation				
Computerized Axial Tomography – Fixed				
- Mobile				
Lithotripter – Fixed				
- Mobile *				
- Transportable				
Family Planning				
Family Planning Satellite				
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:

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				
-Other				

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:

3. Have any principals of the operating entity ever been found in violation 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 6. BEHAVIORAL HEALTH SERVICES

8:43K-6.1 Behavioral health services facility; general provisions

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

(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 ***at N.J.A.C. 10:36***; ***and***

[2. Applicable requirements at Title 10 of the New Jersey Administrative Code that DMHAS administers; and]

*[3.]****2.*** Applicable DMHAS requirements to enter into a contract or an affiliation agreement with DMHAS.

8:43K-6.6 Peer staff and peer support services

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

(d) *[A]* ***An appropriately*** licensed ***and credentialed*** 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)-(f) (No change from proposal.)

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.-4. (No change from proposal.)

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.] ***i.*** The use and role of the interdisciplinary team in discharge planning; ***and***

*[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.] ***ii.*** 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. (No change in text from proposal.)

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

8:43K-6.10 Outpatient mental health, substance use disorder, and/or other addiction treatment services

(a) (No change from proposal.)

(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.-5. (No change from proposal.)

6. Referrals directly from screening *[or]* ***,*** affiliated emergency services***, or crisis 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.-3. (No change from proposal.)

4. The patient is willing to participate in intensive outpatient ***mental health,*** SUD***,*** and/or addiction treatment services.

(b) (No change from proposal.)

(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.-5. (No change from proposal.)

6. Persons who have had recent *[and/or]* ***and*** multiple overdoses;

7. (No change from proposal.)

8. Persons referred directly from *[affiliated programs or]***screening,*** affiliated emergency services***,*** or crisis services.

8:43K-*[9.7]* ***6.13*** (No change in text from proposal.)

SUBCHAPTER 7. HEALTH CARE SERVICES

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. (No change from proposal.)

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)]* ***April 6, 2026***, 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.-5. (No change from proposal.)

*[6. If the licensee or applicant plans to alter or repair, within any 12-monthperiod, 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] ***6***. 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] ***7***. 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] ***8***. 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] ***9***. 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-*[7.9]* ***7.8*** Medical director; appointment; duties

8:43K-*[7.10]* ***7.9*** Director of nursing services; appointment; duties

(a) (No change from proposal.)

(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. (No change from proposal.)

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]* ***every three years and more frequently as necessary***, written objectives, policies, a procedure manual, an organizational plan, and a quality assurance and performance improvement program for the nursing service;

ii.-viii. (No change from proposal.)

(c) (No change from proposal.)

8:43K-*[7.11]* ***7.10*** Infection prevention and control

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

(d) A health care services facility shall conduct infection prevention and control activities based on the CDC Guidelines listed below, ***as applicable to the services offered,*** 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://ww.cdc.gov/healthcare-associated-infections/site.html:

1.-8. (No change from proposal.)

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

8:43K-*[7.12]* ***7.11*** Quality assurance and performance improvement program

(a)-(f) (No change in text from proposal.)

8:43K-*[7.13]* ***7.12*** Laboratory and radiological services

(a)-(c) (No change in text from proposal.)

8:43K-*[7.14]* ***7.13*** Reproductive health care services; general provisions

(a) (No change from proposal.)

(b) *[Subject to (c) below, a]* ***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.-3. (No change from proposal.)

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

8:43K-*[7.15]****7.14*** (No change in text from proposal.)

8:43K-*[7.16]* ***7.15*** 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]* ***7.14***;

2.-7. (No change from proposal.)

8:43K-*[7.17]* ***7.16*** 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]* ***7.14*** and:

1.-3. (No change from proposal.)

8:43K-*[7.18]* ***7.17*** Counseling and therapy services

(a)-(c) (No change in text from proposal.)

8:43K-*[7.19]* ***7.18*** Medical specialty services

(a) (No change in text from proposal.)

8:43K-*[7.20]* ***7.19*** 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]* ***7.10***;

2.-3. (No change in text from proposal.)

(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)-(g) (No change from proposal.)

8:43K-*[7.21]* ***7.20*** 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]* ***dietitian*** 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.

8:43K-*[9.3]****7.21*** Wound care

(a) A facility *[is authorized to]* ***may*** provide wound care *[as an adjunctive service,]* provided:

1.-6. (No change from proposal.)

SUBCHAPTER 8. OPIOID TREATMENT PROGRAM

8:43K-8.1 Opioid treatment program

(a) A facility that provides opioid treatment program services shall:

1.-4. (No change from proposal.)

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.]*

***i. For clients starting at 100 milligrams (mg) per day, the dosage of methadone shall be reduced by up to, but no greater than, 10 milligrams (mg) every two days; and**

ii. For clients receiving greater than 100 mg per day, the dosage of methadone 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 *[10.]* ***9.*** STORAGE, ADMINISTRATION, AND DISPENSING OF MEDICATION

8:43K-*[10.1]* ***9.1*** 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]****9.2*** Provision of pharmaceutical services

(a) A facility that maintains an on-site pharmacy shall designate a pharmacist who:

1. -2. (No change from proposal.)

8:43K-*[10.3]***9.3*** Facility policies and procedures for medications

(a) A facility shall:

1. (No change from proposal.)

2. Review and revise, as necessary, the policies and procedures at least *[annually]* ***every three years*** and more frequently, as needed; and

3. (No change from proposal.)

(b) (No change from proposal.)

8:43K-*[10.4]* ***9.4*** Administration of medications

(a)-(g) (No change from proposal.)

8:43K-*[10.5]* ***9.5*** Storage of medication

(a) (No change from proposal.)

SUBCHAPTER *[11.]* ***10.*** ADMINISTRATION OF CONTROLLED DANGEROUS SUBSTANCES FOR THE TREATMENT OF SUBSTANCE USE, AMBULATORY WITHDRAWAL MANAGEMENT, AND/OR STABILIZATION

8:43K-*[11.1]***10.1*** Scope

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

8:43K-*[11.2]***10.2*** 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]* ***every three years*** 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.-5. (No change from proposal.)

8:43K-*[11.3]***10.3*** Withdrawal management and stabilization

(a) A facility that is subject to this subchapter shall establish, implement, and at least *[annually]* ***every three years*** and more frequently, as necessary, review and revise, withdrawal management policies and procedures for:

1.-4. (No change from proposal.)

8:43K-*[11.4]***10.4*** Patient education services

(a) (No change from proposal.)

8:43K-*[11.5]***10.5*** 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. (No change from proposal.)

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]***10.3(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]***10.3(a)4***;

3. (No change from proposal.)

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]***10.3(a)4***; provided:

[i. A facility shall not administratively or involuntarily discharge a patient based on the patient's laboratory results;]

Recodify proposed ii.-iii. as new ***i.-ii.***(No change in text from proposal.)

5.-6. (No change from proposal.)

Recodify proposed 8:43K-11.6, 11.7, and 11.8 as ***10.6, 10.7, and 10.8*** (No change in text from proposal.)

8:43K-*[11.6]* ***10.6*** Physician services

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

8:43K-*[11.7]* ***10.7*** Nursing services

(a) (No change from proposal.)

8:43K-*[11.8]* ***10.8*** 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 .]* ***11.*** ALTERNATIVE CARE LOCATIONS

8:43K-*[12.1]* ***11.1*** Regular provision of licensed services at an alternative *[service]* ***care*** 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]* ***care*** 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]* ***care*** 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]* ***care*** 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]* ***care*** 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]* ***11.2*** Intermittent provision of licensed services at an alternative *[service]* ***care*** 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]* ***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. (No change from proposal.)

8:43K-*[12.3]****11.3*** Mobile outpatient care vehicle services

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