TO: Opioid Treatment Programs

FROM: Stephanie Streletz, Executive Director
Division of Certificate of Need & Licensing – Behavioral Health

DATE: February 18, 2025

SUBJECT: Waiver: aligning N.J.A.C. 10:161B with 42 C.F.R. Part 8 for Opioid Treatment Programs

The State of New Jersey is committed to making medications for opioid use disorder (MOUD) available to all individuals in need of this service. To this end, the Department of Health (DOH or the Department) is aligning state rules with recently established federal regulations that apply to opioid treatment programs (OTPs). This will reduce duplicate requirements for behavioral health programs and facilitate access to care for individuals in need of treatment for opioid use disorder.

In accordance with N.J.A.C 10:161B-11.1(a)(4), facilities are required to provide services which meet the federal standards set by accrediting agencies contained in 42 C.F.R. 8.12. With this waiver, the Department is aligning with federal standards to the maximum extent possible by waiving certain programmatic requirements for OTPs contained in subchapter 11.

Please note this waiver does not change several key aspects of the State rules, including:

(1) withdrawal policy, including taper dosing for methadone;
(2) the requirement in section 11.17 that OTPs provide emergency telephone coverage by a designated staff member;
(3) the ability for the Department's Division of Certificate of Need and Licensing ("CN&L") to conduct period surveys;
(4) the requirement for approval from the New Jersey Department of Community Affairs ("DCA") for new construction; and
(5) the DOH licensure requirements for OTPs.

Summary of Waiver

OTP Medical Director and Designee, Qualifications and Responsibilities

N.J.A.C. 10:161B-1.4(a) through (c), 7.2 and 11.2(a)

Waives the requirement that the medical director or designee be American Society of Addiction Medicine (ASAM) certified or have at least one year of experience in addiction medicine and instead aligns with the federal rules at 42 C.F.R. 8.2 (definition of medical director), 8.12(b)(2), and 8.12(d).

Additionally, waives the detailed list of medical director responsibilities at N.J.A.C 161B-1.4 (c) and aligns with the federal rules at 42 CFR 8.12 (b)(2) and definition at 8.2. This waiver also removes the requirement at N.J.A.C. 161B-1.4 (c) for written timeframes in which the medical director must be on-site or available by phone as the federal rules have no such requirement.

<u>OTP Pharmacist</u>
N.J.A.C. 10:161B-1.6

Waives the requirement that OTPs engage or contract with a pharmacist. OTPs shall follow the federal rules at 42 C.F.R. 8.12(h) regarding MOUD administration and dispensing.

<u>OTP Director of Nursing, provision of nursing services, and on-site requirements</u>
N.J.A.C. 10:161B-1.5(a), 8.1(a), 8.2, 11.2(c), 11.2(f), 11.2(g)

Waives the requirements for the appointment of a director of nursing services, nursing services on-site, and director of nursing or designee on-site during normal business hours and whenever medications are being administered. These items are not required in the federal rules.

<u>OTP Director of Substance Abuse Counseling, counseling, and staff to client ratio</u>
N.J.A.C. 10:161B-10.1 (b)(5) and (6), 10.1(d), 10.1(g), 10.2, 11.2(b), 11.8.

Waives the requirement for a full-time director of substance abuse counseling as there is no such requirement in the federal rules. Also, waives the requirements for phase-based counseling and clinical determination for counseling to better align with the federal rules. Finally, waives the requirement that OTPs maintain specific staff-to-client ratios. OTPs shall follow the federal rules regarding counseling at 42 C.F.R. 8.12(f)(5). As required by 42 C.F.R. 8.12(f)(5), the client has the right to refuse counseling and still receive OTP treatment services.

<u>Multidisciplinary Team</u>
N.J.A.C. 10:161B-11.3

This waives the requirement that clinical decisions regarding phase changes, take home privileges and other treatment issues are based on a multidisciplinary team review of each client. There is no equivalent requirement in the federal rules.

<u>Drug Screening</u>
N.J.A.C. 10:161B-11.4, 11.6 and 11.9

To align with the federal rules, requirements to screen for a list of specific substances are waived. Additionally, waives rules regarding the required frequency of random drug screening, and circumstances for when prescription

drugs shall be considered a positive drug screen. OTPs shall follow the federal rules regarding drug screening at 42 C.F.R. 8.12(f)(6).

Discharge Policies
N.J.A.C 10:161B-11.4(a)(4)(iv)(2) and (3)

To align with federal rules, this waives the requirement that OTPs establish policies addressing "discharge of non-compliant clients based on failure to attend counseling sessions, repeated positive urines, missed days," based on phase/progress in treatment.

Treatment Phases
N.J.A.C. 10:161B 10.1(b)(5) and (6), 10.1(g), 11.1(a)(9)(ii), 11.4, 11.8, 11.9, 11.12 11.13, 11.15

To better align with the federal rules, the defined "phases" of treatment based on time, drug screening results, and "compliance with other criteria" are waived, as there is no equivalent in the federal rules.

Admissions Criteria and Priority Populations
N.J.A.C. 10:161B-11.5, 11.6 (b) through (e)

To align with federal rules, certain admissions requirements, delineated drug screening and other testing, and admissions priority for certain populations are waived. DOH retains the admissions priority for pregnant patients as it is required in the federal rules. OTPs shall follow federal rules for admissions at 42 C.F.R. 8.12(f).

Take-home Medication
N.J.A.C 10:161B-11.12, 11.13, 11.14

To better align with the federal rules, this waives the requirements that take-home doses be determined based on a defined "phase" of treatment.

Clinic based medical maintenance and Office based opioid treatment
N.J.A.C. 10:161B-11.15 and 11.16

Waives clinic based medical maintenance, as defined "phases" of treatment are waived. OTPs are reminded to follow the federal rules regarding take home doses for clients at 42 C.F.R. 8.12(i). Also, waives additional requirements regarding buprenorphine in office based opioid treatment.

Reference to outdated guidance
N.J.A.C 10:161B-11.1(a)(6), 11.16

To better align with the updated federal rules, waives references to outdated guidance (from the years 2005 and 2007).

Telehealth/telemedicine

In addition, the waiver includes clarification on telehealth for screening and full evaluation for MOUD induction. OTPs shall follow the federal rules at 42 C.F.R. 8.12 (f)(2)(v), which allow telehealth/telemedicine to be used for the required examinations at MOUD induction. The state regulations do not prohibit telehealth/telemedicine for this purpose.

In lieu of the waived requirements at N.J.A.C. 10:161B, OTPs shall follow, and the Department will enforce, the rules contained at 42 C.F.R. Part 8. These rules are published in the Federal Register at 89 FR 7549 (Feb. 2, 2024) and available online at https://www.ecfr.gov/current/title-42/chapter-I/subchapter-A/part-8?toc=1. Guidance regarding these rules is available at the SAMHSA website at https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/42-cfr-part-8%20. For convenience, a copy of the rules contained at Part 8 is attached.

WAIVER: ALIGNING N.J.A.C. 10:161B WITH 42 C.F.R. PART 8 FOR OPIOID TREATMENT PROGRAMS

Further background and individually waived components of N.J.A.C. 10:161B are outlined below. Please note that while N.J.A.C. 10:161B applies to all outpatient substance use disorder treatment facilities including OTPs, **the waived requirements listed below apply only to OTPs**. N.J.A.C. 10:161B remains unchanged for all other facilities and programs, including facilities which may share space or programing with an OTP. This waiver also does not change any other state regulation.

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

Regarding N.J.A.C. 10:161B-1.4 (a) through (c):

> (a) Opioid treatment and detoxification facilities are required under N.J.A.C. 10:161B-7 to hire a physician as medical director who is currently licensed in accordance with the laws of this State to perform the scope of services set forth in this chapter. This physician must be certified by the American Society of Addiction Medicine (ASAM), or its successor certification board, by June 1, 2012.
>
> 1. A physician currently licensed to practice in the State of New Jersey, who has not completed ASAM certification by June 1, 2012, must have worked in a substance use disorder treatment facility a minimum of five* years for at least 20 hours per week and have completed the ASAM/American Association for the Treatment of Opioid Dependence (AATOD) clinicians training course, http://www.aatod.org/resources/additional-education-on-opioid-dependence/providers-clinical-support-system-for-medication-assisted-treatment/.
>
> (b) Although the medical director is not required to be on site on a full-time basis, the medical director is required to be on site as often as necessary in order to perform the responsibilities of the position. The facility shall establish written timeframes in which the medical director is required to be on site and, in the event of emergencies, arrive at the facility. In addition, the facility shall develop written parameters in which the medical director shall be available by telephone. Such parameters shall include the timeframes in which the medical director shall respond to the facility if paged, contacted by cellphone or by other means.
>
> (c) The medical director shall be responsible for the direction, provision, and quality of medical services provided to clients including, but not limited to, the following:
>
> 1. Providing administrative oversight of the facility's medical services;

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

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

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

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

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

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

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

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

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

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

WAIVER: The following is waived from this section and shall not be part of the Department's enforcement of this rule:

In subsection (a), in the first line, the words “Opioid treatment and” are struck.

REVOKED PRIOR WAIVER: The Department issued a waiver dated March 10, 2020, which reduced the number of required years of experience to one year for the medical director and/or designee (WAIVER CONTROL NUMBER: 2020-001).

WAIVER CONTROL NUMBER: 2020-001 is revoked as it pertains to the OTPs.

DEPARTMENT EXPLANATION OF WAIVER AND REVOKED PRIOR WAIVER: To reduce duplication with federal rules, N.J.A.C. 10:161B-1.4 (a) through (c) are waived in

entirety as applicable to OTPs. OTPs are reminded that they must comply with the federal rules at 42 C.F.R. 8.12, which require OTPs to designate a medical director and describes the medical director's required qualifications and responsibilities.

RELATED FEDERAL RULES: For further guidance, interested parties should review 42 C.F.R. 8.12 (a), (b) and (d) and the definitions of medical director and program sponsor in 42 C.F.R. 8.2.

10:161B-1.5 Qualifications and responsibilities of the director of nursing services

Regarding N.J.A.C. 10:161B-1.5 (a):

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

In the first line, after "medical director," the words "opioid treatment programs and" are struck. In the last sentence, after the word "In," the words "an opioid treatment program or" are struck.

DEPARTMENT EXPLANATION OF WAIVER: To align with federal rules, N.J.A.C. 10:161B-1.5(a) is waived in its entirety as it applies to OTPs. The federal rules at 42 C.F.R. Part 8 do not require OTPs to hire a director of nursing services.

10:161B-1.6 Qualifications of pharmacists

Regarding N.J.A.C. 10:161B-1.6:

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

In the first line, "Each opioid treatment program and" is struck.

DEPARTMENT EXPLANATION OF WAIVER: N.J.A.C. 10:161B-1.6 is waived in its entirety as it applies to OTPs.

RELATED FEDERAL RULES: The federal rules are silent as to the requirement of a pharmacist and OTPs. OTPs are reminded of the federal rules regarding medication administration, dispensing and use. For further guidance, interested parties should review 42 C.F.R. 8.12(h).

10:161B-7.2 Designation of medical director

N.J.A.C. 10:161B-7.2 currently provides:

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

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

In the first line, after the words "outpatient detoxification," the words "and opioid treatment" are struck.

REVOKED PRIOR WAIVER: The Department issued a waiver dated March 10, 2020 relating to the qualifications of the physician medical director and/or physician designee, which reduced the required years of experience to one year (WAIVER CONTROL NUMBER: 2020-001).

WAIVER CONTROL NUMBER: 2020-001 is revoked as it pertains to the OTPs.

DEPARTMENT EXPLANATION OF WAIVER AND REVOKED PRIOR WAIVER: To reduce duplication with federal rules, N.J.A.C. 10:161B-7.2 is waived in its entirety as it applies to OTPs. OTPs are reminded that they must comply with the federal rules at 42 C.F.R. 8.12, which require OTPs to designate a medical director and describes the medical director's required qualifications and responsibilities.

RELATED FEDERAL RULES: For further guidance, interested parties should review 42 C.F.R. 8.12 (a), (b) and (d) and the definitions of medical director and program sponsor in 42 C.F.R. 8.2.

<u>10:161B-8.1 Provision of nursing services</u>

N.J.A.C. 10:161B-8.1 (a) currently provides:

> (a) Nursing services shall be provided in licensed outpatient substance use disorder treatment programs as follows:
>
> > 1. Outpatient, intensive outpatient, and partial care programs are not required to provide nursing services in treatment facilities offering these services. Outpatient, intensive outpatient and partial care programs shall comply with (b) below.

2. Opioid treatment and opioid detoxification programs shall appoint a director of nursing services and shall provide nursing services on site. The director of nursing services or designee shall be on premises during normal business hours and whenever medications are being administered.

i. The designee for the director of nursing services shall be a registered professional nurse (RN).

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

In the first line of paragraph (2), the words "opioid treatment and" are struck.

DEPARTMENT EXPLANATION OF WAIVER: To align with federal rules which do not require OTPs to provide nursing services, N.J.A.C. 10:161B-8.1(a) is waived in its entirety for OTPs.

RELATED FEDERAL RULES: 42 C.F.R. Part 8 does not address nursing services in OTPs.

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

N.J.A.C. 10:161B-8.2 currently provides:

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

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

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

In the first line, after the words "outpatient detoxification," the words "and/or opioid treatment" are struck.

DEPARTMENT EXPLANATION OF WAIVER: N.J.A.C. 10:161B-8.2 is waived in its entirety as it applies to OTPs. The Department notes that this waiver does not alter other state requirements such as those at N.J.A.C. 13:45H-11.4(b)(2) detailing who may

dispense narcotics: namely a licensed practitioner (e.g., physician) or a registered nurse/licensed practical nurse/pharmacist under the direction of the licensed practitioner."

RELATED FEDERAL RULES: The federal rules do not require OTPs to designate a director of nursing services. Interested parties should review the notes below at 10:161B-11.2 and 42 C.F.R. 8.12(d).

10:161B-10.1 Provision of substance abuse counseling

N.J.A.C. 10:161B-10.1(b)(5) and (6) currently provide:

> (b) Programs shall maintain an average ratio of substance abuse counselors to clients on the basis of each program's daily census, as follows: . . . (5) Opioid treatment Phase(s) I through III: 1:50, with no single counselor's caseload exceeding 1:35; and (6) Opioid treatment Phase(s) IV through VI: 1:50.

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

In subsection (b), paragraphs 5 and 6 are struck in entirety.

N.J.A.C. 10:161B-10.1(d) currently provides:

> Programs providing partial care services shall provide weekly family counseling sessions, and intensive outpatient and outpatient programs shall provide monthly family counseling sessions, unless clinically contraindicated or the client and/or their family members refuse to participate. Opioid treatment programs shall provide family counseling sessions based upon the clinical determination of the multidisciplinary team.

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

In subsection (d), in the last sentence after "counseling sessions," the phrase "based upon the clinical determination of the multidisciplinary team" is struck.

N.J.A.C. 10:161B-10.1(g) currently provides:

> Programs providing partial care services and intensive outpatient services shall provide clients with at least weekly individual counseling sessions; outpatient programs shall provide at least monthly individual counseling

sessions, based upon determination of the multidisciplinary team. Opioid treatment programs shall provide individual sessions based upon, at a minimum, client phase of treatment per N.J.A.C. 10:161B-11.8. In addition to the minimum requirements listed in this subsection, providers should be prepared to increase frequency of individual sessions based upon clinical need.

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

In subsection (g), in the sentence that begins "Opioid treatment programs shall provide individual sessions…", the phrase "based upon, at minimum, client phase of treatment per N.J.A.C. 10:161B-11.8" is struck.

DEPARTMENT EXPLANATION OF WAIVERS: As noted below, the Department is waiving the requirement to use the Phase system explained in N.J.A.C. 10:161B-11.8 as there is no federal equivalent. The Department is also waiving the requirement for a multidisciplinary team at 10:161B-11.3, as noted below.

RELATED FEDERAL RULES: The federal rules in 42 C.F.R. 8.12(f) require OTPs to provide counseling and psychoeducation. However, the client has the right to refuse counseling and still receive OTP treatment services, including the right to refuse family counseling sessions. The federal rules do not address a multidisciplinary team. However, OTPs are reminded that they must comply with 42 C.F.R. 8.12, which states the care plan is to be agreed upon between the patient and the OTP clinical team. Interested parties should review 42 C.F.R 8.12 (f).

10:161B-11.1 Authority

N.J.A.C. 10:161B-11.1 (a)6) and (a)(9) currently provides:

(a) 6. Comply with the publication "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs," issued by the Center for Substance Abuse Treatment (CSAT) as part of the Treatment Improvement Protocol Series, TIP 43 (2005), incorporated herein by reference as amended and supplemented; copies are available from the National Clearinghouse for Alcohol and Drug Information, P.O. Box 2345, Rockville, MD 20847-6686, 1-800-729-6686, http://www.cocommunity.net/agency/national-clearinghouse-alcohol-and-drug-information.html or for online download at http://store.samhsa.gov/product/TIP-43-Medication-Assisted-Treatment-for-Opioid-Addiction-in-Opioid-Treatment-Prog ...

9. Opioid treatment programs providing detoxification shall, in addition, comply with the following:
i. Clients receiving short-term detoxification (that is, less than 30 days) shall receive services in accordance with N.J.A.C. 10:161B-12; and
ii. Clients receiving long-term detoxification (that is, 30 days to 180 days) shall receive all services for Phase I clients required by 10:161B-11.8 and 12.

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

Paragraph (a)(6) is struck in its entirety. Sub-paragraph (a)(9)(ii) is struck in its entirety.

DEPARTMENT EXPLANATION OF WAIVERS: To align with the updated federal rules, the Department strikes the paragraph at (a)(6), which refers to outdated federal guidance from 2005 that is no longer available at the links cited. Further, the Department strikes the sub-paragraph referring to long-term detoxification requirements based on Phase 1. As noted elsewhere in this waiver, the Department is waiving the Phases to better align with the federal rules, which have no equivalent.

RELATED FEDERAL RULES: OTPs are reminded they must adhere to withdrawal management requirements at 42 CFR 8.12(e)(3) which requires withdrawal rates to be mutually agreed-upon with the client and minimize taper-related risks. OTPs also must continue to adhere to withdrawal requirements outlined in in this Chapter, including but not limited to those at N.J.A.C. 10:161B-11.4(a)(4)(v)(1) & (2).

10:161B-11.2 Staffing

N.J.A.C. 10:161B-11.2 (a) (b) (c) (f) and (g) currently provides:

(a) All opioid treatment programs shall have a medical director who shall be ASAM certified, or certified by its successor board, by June 1, 2012 in accordance with N.J.A.C. 10:161B-1.4. The medical director or other designated program physician shall be available on site or by telephone during all operating hours of the opioid treatment program. A physician, licensed to practice in the State of New Jersey, who worked a minimum of five years at least 20 hours per week and has completed the ASAM/AATOD clinician's training course, may be considered for a waiver of the above provision.

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

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

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

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

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

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

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

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

Subsections (b) (c) (f) and (g) are struck in their entirety. Subsection (a) is struck in its entirety after the words "medical director," in the first sentence.

DEPARTMENT EXPLANATION OF WAIVERS: To align with federal rules, the Department is waiving the requirement that OTPs "employ a full time director of substance abuse services" and a "director of nursing services." Furthermore, as noted above, the Department is waiving requirements regarding nursing services to align with the federal rules. OTPs still must designate a medical director, in accordance with federal rules.

RELATED FEDERAL RULES: OTPs are reminded that the federal rules require OTPs to have credentialed staffing. Interested parties should review 42 C.F.R. 8.12(d).
For further guidance regarding the medical director or designee, interested parties should review 42 C.F.R. 8.12 (a), (b) and (d) and the definitions of medical director and program sponsor in 42 C.F.R. 8.2.

10:161B-11.3 Multidisciplinary Team

N.J.A.C. 10:161B-11.3 currently provides:

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

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

10:161B-11.3 is struck in its entirety.

DEPARTMENT EXPLANATION OF WAIVER: To better align with the federal rules, the Department waives the requirement for a multidisciplinary team review of clinical decisions regarding phase changes, take home privileges and other treatment issues.

RELATED FEDERAL RULES: The federal rules in 42 C.F.R. 8.12(f) require OTPs to provide counseling and psychoeducation. However, the client has the right to refuse counseling and still receive OTP treatment services, including the right to refuse family counseling sessions. The federal rules do not address a multidisciplinary team. However, OTPs are reminded that they must comply with 42 C.F.R. 8.12, which states the care plan is to be agreed upon between the patient and the OTP clinical team. Interested parties should review 42 C.F.R 8.12 (f).

10:161B-11.4 Policies and procedures

N.J.A.C. 10:161B-11.4(a)(2)(iii) currently provides:

> (a) Opioid treatment programs shall develop and implement written policies and procedures to include the following: …
> 2. Drug-screening procedures including, but not limited to: …
> iii. Testing, at a minimum, for opioids, methadone, amphetamines, cocaine, and benzodiazepines, and as appropriate, testing for drugs of choice as evidenced in evaluation and/or intake assessment;

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

Sub-paragraph (a)2.iii is struck in its entirety.

DEPARTMENT EXPLANATION OF WAIVER: The Department is making this change to align with the federal rules regarding drug testing services.

RELATED FEDERAL RULES: OTPs are reminded they must adhere to the federal rules for at 42 C.F.R. 8.12 (f) (6), which require random drug testing to test for "commonly used and misused substances that may impact patient safety, recovery, or otherwise complicate substance use disorder treatment…" Interested parties should review 42 C.F.R. 8.12(f)(6).

N.J.A.C. 10:161B-11.4(a)(4)(iv) provides:

(iv) Referral and discharge;

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

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

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

(3) Except as provided for by the provisions of Phase I-A (see 10:161B-11.8(b)7), the discharge policy shall address the discharge of clients who are not progressing in treatment despite documented efforts by the opioid treatment programs to intensify treatment services and refer the client to supplemental treatment services or other outpatient or residential opioid treatment programs; and (4) Policies shall provide that no client maintained on methadone or other approved medications shall be discharged from an opioid treatment program without facilitating admission to another opioid treatment program or being withdrawn from the opioid agonist medication prior to discharge;

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation.

In sub-paragraph (a)(4)(iv)(2), after the words "the discharge of" the word "non-compliant" is struck. After the word "clients based on" the words "failure to attend counseling

sessions, repeated positive urines, missed days or" are struck. Sub-paragraph (a)(4)(iv)(3) is struck in its entirety.

DEPARTMENT EXPLANATION OF WAIVER: To better align with the updated federal rules, which do not state that non-compliance, failure to attend counseling sessions, repeated positive urines, missed days or other such criteria are cause for discharge, nor based on Phases, the Department is striking such language here. The Department retains here language regarding discharge policy for clients whose behavior jeopardizes the health, safety or welfare of other clients and/or staff, consistent with pre-admission, admissions, and retention criteria defined in this Chapter at 161B-6.3(b)(2) and (g).

RELATED FEDERAL RULES: 42 C.F.R. 8.11(f) describes discharge requirements for interim treatment. The federal rules at 42 C.F.R. 8.12 do not otherwise address discharge criteria.

10:161B-11.5 Admissions priority populations

N.J.A.C. 10:161B-11.5 currently provides:

> (a) Opioid treatment programs shall give preference for admission to pregnant women, intravenous (IV) drug users, and individuals who are HIV-positive.
> (b) All persons admitted to an opioid treatment program shall meet the admission criteria outlined in the Federal standards set by accrediting agencies contained in 42 C.F.R. Part 8.12. Program criteria for admission shall be based on the definition of opioid dependence in DSM-5. The client record shall document a DSM-5 diagnosis by a qualified clinician and/or a determination that opioid maintenance therapy on an outpatient basis is appropriate according to ASAM Criteria.

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

In paragraph 11.5(a), after "pregnant women," the words ", intravenous (IV) drug users, and individuals who are HIV-positive" is struck. In paragraph 11.5 (b), after the words "42 C.F.R. Part 8.12," the following sentences are struck "Program criteria for admission shall be based on the definition of opioid dependence in DSM-5. The client record shall document a DSM-5 diagnosis by a qualified clinician and/or a determination that opioid maintenance therapy on an outpatient basis is appropriate according to ASAM Criteria."

DEPARTMENT EXPLANATION OF WAIVER: The Department is making this change to align with the federal rules. The Department maintains admissions priority for pregnant patients.

RELATED FEDERAL RULES: Interested parties should review 42 CFR 8.12(f)(3).

<u>10:161B-11.6 Admissions and assessment</u>

N.J.A.C. 10:161B-11.6(b) through (e) currently provides:

> (b) Drug screening shall be analyzed, at a minimum, for opioids, methadone, cocaine, amphetamines, and benzodiazepines, and, as appropriate, for drugs of choice as evidenced in evaluation and/or intake assessment. Screening for alcohol, marijuana and other drugs shall be conducted based on individual and/or community drug use patterns in accordance with program policy established by the multidisciplinary team. Positive drug screens for other substances shall be documented in the client's case record and an appropriate clinical intervention will occur.
>
> (c) An opioid treatment program shall conduct a complete physical examination, a medical history including drug use and current medications, treatment history and personal history before dispensing or administering medication. A program physician or other licensed independent practitioner authorized under New Jersey statutes shall conduct a complete physical examination at admission and shall include testing for the following:
>
> 1. Serological test for syphilis and testing for other sexually transmitted diseases as medically indicated;
> 2. Mantoux tuberculin skin test at admission and annually thereafter and chest x-ray if medically indicated. Testing shall be provided in accordance with the Tuberculosis Surveillance Procedures for Substance Abuse Treatment Facilities (SATFs), incorporated herein as chapter Appendix A;
> 3. Urine or other approved screening to identify drug use;
> 4. Routine and microscopic urinalysis;
> 5. Complete Blood Count (CBC);
> 6. SMA 12 or comparable screening;
> 7. Pregnancy test for women;
> 8. Screening for Hepatitis C and Hepatitis B surface antigen and antibody is highly recommended but not required;
> 9. All clients shall receive HIV pre-test counseling, and shall be offered HIV testing onsite or at a DOH/HIV, STD, and TB Services approved rapid HIV testing clinic, with referral documented in the client file; however, a client has the right to refuse HIV testing. Documentation of refusal must be contained in the client file; and
> 10. Mental health status evaluation to include previous psychiatric admissions, and a history of suicidal ideation, outpatient psychiatric treatment, psychotropic medications and, when clinically indicated, an assessment by a psychiatrist or other licensed clinician of clients

diagnosed and identified as having a co-occurring mental health disorder.

(d) If the client submits documentation of the testing in (c) above performed within 30 days of admission, those tests need not be repeated with the exception of the drug screening and pregnancy testing.

(e) Clients re-entering an opioid treatment program after discharge shall be examined by the physician, screened for drugs and pregnancy, tested for tuberculosis (if it has been 12 or more months since the previous test), and offered HIV counseling and testing.

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

Subsections (b), (d), and (e) are struck in entirety. In subsection (c), in the first sentence after "treatment history and personal history," the phrase "before dispensing or administering medication" is struck. In subsection (c) the section is struck in its entirety after the part of the second sentence that reads "conduct a complete physical examination".

DEPARTMENT EXPLANATION OF WAIVER: This waiver aligns the New Jersey standard with the federal rules. Under the waiver, OTPs shall comply with 42 C.F.R. 8.12. OTPs may begin treating patients with MOUD upon completion of the screening examination and complete a physical and behavioral health assessment for each patient within 14 calendar days following admission.

RELATED FEDERAL RULES: Interested parties should review 42 C.F.R. 8.12(f).

<u>10:161B-11.8 Counseling services</u>

N.J.A.C. 10:161B-11.8 currently provides:

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

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

1. For Phase I: Upon admission.

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

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

In subsection (b) after the phrase "All opioid treatment programs shall provide counseling services," the remainder of 10:161B-11.8 is struck in its entirety.

DEPARTMENT EXPLANATION OF WAIVER: An opioid treatment program shall provide counseling services. The federal rules require the counseling services to be provided "as clinically necessary and mutually agreed-upon" with the patient. The Phase program for OTPs is not required by federal regulations, and thus as part of this alignment is waived.

RELATED FEDERAL RULES: Interested parties should review 42 C.F.R. 8.12(f)(5).

10:161B-11.9 Drug Screening

N.J.A.C. 10:161B-11.9 currently provides:

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

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

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

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

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

WAIVER: The following is struck from this subsection and shall not be part of the Department's enforcement of this regulation:

Subsections 11.9 (a) (b) (c) and (d) are struck in entirety.

DEPARTMENT EXPLANATION OF WAIVER: To align with the federal rules, New Jersey's additional overlays on drug screening for OTPs are waived.

RELATED FEDERAL RULES: Interested parties should review 42 C.F.R.8.12(f)(6)

<u>10:161B- 11.12 Take-home medication dosage schedule</u>

N.J.A.C. 10:161B-11.12 currently provides:

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

1. A client meeting the standards set by accrediting agencies for consideration of take-home medication may be permitted take-home medication in accordance with the following schedule based upon the review and documented approval by the multidisciplinary team:
i. For six-day programs, on admission--one daily take-home dose;

ii. For all programs, after three consecutive months of negative drug screens--one to two daily take-home doses;
iii. After an additional three consecutive months, or a total of six consecutive months of negative drug screens--three daily take-home doses;
iv. After an additional three consecutive months or a total of nine consecutive months of negative drug screens--four daily take-home doses;
v. After an additional three consecutive months, or a total of 12 consecutive months of negative drug screens--five daily take-home doses; and
vi. After an additional six consecutive months or a total of 18 consecutive months of negative drug screens --six daily take-home doses.

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

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

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

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

(e) Clients receiving six or fewer daily take-homes who have two positive drug screens within any 90-day period shall result in the revocation of all weekday take-home bottles pending review and documentation by the multidisciplinary team and an increase in drug screening frequency to two times per month. Restoration of weekend take-home medication shall be at

the documented discretion of the multidisciplinary team. The multidisciplinary team may restore two additional take-home doses for each additional month of negative drug screening results. The multidisciplinary team, with the approval of the medical director, may make exceptions to the 90-day period when clinically indicated and documented.

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

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

Subsection (a) is waived in entirety after the following : "An opioid treatment program shall develop and implement written policies and procedures consistent with this chapter and all applicable Federal regulations…" The subsections (b) thru (f) are struck in their entirety.

DEPARTMENT EXPLANATION OF WAIVER: See the explanation after 10:161B-11.14.

<u>10-161B-11.13 Extended take-home medications</u>

N.J.A.C. 10:161B-11:13 currently provides:

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

1. A Phase V client who has had no positive drug screening results within the last twenty-four consecutive months may be permitted up to a 14-day supply of take-home medication, provided the client meets the criteria for stability and functioning contained in the standards set by accrediting agencies as determined and documented by the multidisciplinary team.
2. A Phase VI client who has no positive drug screening results within the last 36 consecutive months may be permitted up to a 30-day supply of take-home medication, provided the client meets the criteria for stability and functioning contained in the standards set by accrediting agencies as determined and documented by the multidisciplinary team.
3. Clients receiving up to 14 or up to a 30-day supply of daily take-home doses who have a positive drug screen shall be assessed by the multidisciplinary team. This shall be documented and shall include a medication call back, drug screen and appropriate clinical

interventions, which shall be documented in the client record. Any client who has been determined to have mishandled take-home medication shall no longer be eligible for take-homes until he or she has again met the initial criteria for take-homes, and been reviewed and approved by the multidisciplinary team.

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

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

The section is struck in its entirety.

DEPARTMENT EXPLANATION OF WAIVER: See the explanation after 10:161B-11.14.

<u>10-161B-11.14 Take-home exceptions</u>

N.J.A.C. 10-161B-11.14 currently provides:

(a) An opioid treatment program may request an exception of the take-home requirements contained in the standards set by accrediting agencies for a client deemed responsible in handling take-home medication who is unable to be medicated at the program due to illness, family emergency, job training, travel, etc. A request for exception is only necessary if the program physician makes a treatment decision that differs from the Federal regulatory requirements at 42 C.F.R. Part 8. A client's request for an exception of the take-home requirements contained in standards set by accrediting agencies shall be reviewed and approved by the multidisciplinary team, signed by a program physician and submitted by fax to the CSAT at 240-276-1630, or online per instructions at http://dpt.samhsa.gov/webintro.htm. A copy of the exemption request shall be concurrently submitted by fax to DMHAS, at 609-292-3816.

WAIVER: The following is struck from these sections and shall not be part of the Department's enforcement of this regulation:

This section is struck in its entirety.

DEPARTMENT EXPLANATION OF WAIVER: The Department is aligning its unsupervised or take-home medication dose rules at N.J.A.C. 10-161B-11.12, 10-161B-11.13 and 10:161B-11.14 with the federal rules at 42 C.F.R. 8.12(i). OTPs are reminded that N.J.A.C. 10:161-11.12 continues to require OTPs to have written policies and procedures that are consistent with 10:161B and 8.12. Interested parties should review 42 C.F.R. 8.12(i).

<u>10:161B-11.15 Clinic based medical maintenance</u>

N.J.A.C. 10:161B-11.15 currently provides:

> (a) An opioid treatment program may elect to provide on-site clinic based medical maintenance services to Phase VI clients under the care of a licensed opioid treatment program physician according to program policy and the provisions of this chapter.
>
> (b) Prior to initiating clinic based medical maintenance, an opioid treatment program shall:
>
> > 1. Submit a written notice to DMHAS of its intent to initiate clinic based medical maintenance to Phase VI clients who meet the criteria in (c) below. The opioid treatment program shall identify the physician who will direct the clinic based medical maintenance program and submit documentation of the physician's qualifications to oversee the program;
> >
> > 2. Provide written assurance that counseling services, drug screenings and ancillary services will be provided as needed in accordance with this chapter;
> >
> > 3. Provide written assurance that the opioid treatment program can demonstrate internal protocols for reviewing client eligibility for clinic based medical maintenance utilizing a multidisciplinary team approach to minimally include: the program's medical director, director of substance abuse counseling, director of nursing services and the client's counselor;

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

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

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

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

8. Ensure that clients in clinic based medical maintenance with a positive urine screening result shall be assessed by the physician, in consultation with the multidisciplinary team, to determine if the client has been responsible in handling take home medication, and can be retained in medical maintenance based on an assessment of other client factors for stability. The physician shall refer the client for counseling in accordance with the provisions of this subchapter. Clients determined to have not been responsible in handling extended take-home medication shall be removed from clinic based medical maintenance. A second positive urine screening within 12 months shall result in the client being removed from clinic based medical maintenance and returned to the general program.

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

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

1. Clients shall be physically and emotionally stable;

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

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

Section 10:161B-11.15 is struck in its entirety.

DEPARTMENT EXPLANATION OF WAIVER: To align with the federal rules, the Department is waiving the Phase system, including the "clinic based medical maintenance" for take home doses of up to 30 days for clients in Phase VI. As noted above, the Phase system has no equivalent in the federal rules.

RELATED FEDERAL RULES: OTPs are reminded that they shall follow the federal rules at 42 C.F.R. 8.12 regarding take-home medications for clients. Interested parties should review 42 C.F.R. 8.12(i).

<u>10:161B-11.16 Office based opioid treatment</u>

N.J.A.C. 10:161B-11.16 currently provides:

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

WAIVER: The following is struck from this section and shall not be part of the Department's enforcement of this regulation:

In the first sentence, after the words “request an exemption,” the words “from the CSAT” are struck. The last two sentences, which begin “Opioid treatment programs utilizing Suboxone…” and ending “herein as chapter Appendix B” are struck.

DEPARTMENT EXPLANATION OF WAIVER: To further align with the federal rules, portions of 10:161B-11.16 with additional requirements regarding Suboxone and Buprenorphine are omitted. OTPs are reminded that they must comply with 42 C.F.R. 8.11(g) regarding requests for exemptions.

RELATED FEDERAL RULES: Interested parties should review 42 C.F.R. 8.11(g).

<u>Telehealth for screening and full evaluation for MOUD induction</u>

54 N.J.R. 301(b) explicitly allows telehealth/tele-medicine to be used in the physical exam for buprenorphine induction at OTPs. Furthermore, nothing in N.J.A.C. 161B explicitly prohibits the use of telehealth for MOUD induction, including methadone induction.

DEPARTMENT EXPLANATION OF ALIGNMENT: As noted above, State regulations at N.J.A.C. 10:161B require OTPs to adhere to the federal rules at 42 C.F.R. Part 8.12. The State regulations do not prohibit the use of telehealth for physical exams. The Department clarifies that OTPs should adhere to the federal rules regarding telehealth for MOUD induction at 42 C.F.R. 8.12.

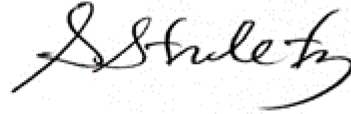
RELATED FEDERAL RULES:
42 C.F.R. 8.12 (f)(2)(v) allows telehealth for those patients being admitted for treatment at the OTP with either buprenorphine or methadone, as follows:

> (v) The screening and full examination may be completed via telehealth for those patients being admitted for treatment at the OTP with either buprenorphine or methadone, if a practitioner or primary care provider, determines that an adequate evaluation of the patient can be accomplished via telehealth. When using telehealth, the following caveats apply:
>
> (A) In evaluating patients for treatment with schedule II medications (such as Methadone), audio- visual telehealth platforms must be used, except when not available to the patient. When not available, it is acceptable to use audio-only devices, but only when the patient is in the presence of a licensed practitioner who is registered to prescribe (including dispense) controlled medications. The OTP practitioner shall review the examination results and order treatment medications as indicated.
>
> (B) In evaluating patients for treatment with schedule III medications (such as Buprenorphine) or medications not classified as a controlled medication (such as Naltrexone), audio-visual or audio only platforms may be used. The OTP

practitioner shall review the examination results and order treatment medications as indicated.

CONCLUSION

The waived requirements of Chapter 10:161B listed above will remain valid until replaced by revised rulemaking or otherwise suspended or revoked by the Department, whether in full or in part. If you have any questions or require further information, please contact cn-lbh-helpdesk@doh.nj.gov.



By: Stephanie Streletz, Executive Director
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