

STATE OF NEW JERSEY
DEPARTMENT OF HEALTH
NOTICE OF RULE WAIVER/MODIFICATION/SUSPENSION
PURSUANT TO EXECUTIVE ORDER NO. 103 (MURPHY)(MARCH 9, 2020)
COVID-19 STATE OF EMERGENCY

Temporary Rule **WAIVER/MODIFICATION OF N.J.A.C. 10:161B-11.10 – ELIGIBILITY FOR TAKE-HOME MEDICATION** adopted by **THE COMMISSIONER OF THE DEPARTMENT OF HEALTH**

Date: **May 8, 2020**

Authority: N.J.S.A. App.A:9-45 & App. A:9-47; Executive Order No. 103 (Murphy)(“EO 103”)

Effective Date: **May 8, 2020**

Expiration Date: Concurrent with End of COVID-19 Public Health Emergency

This is an emergency adoption of a temporary rule waiver/modification of the rules at N.J.A.C. 10:161B-11.10 permitting individuals receiving opioid treatment services to receive medication that they can take at home. Section 6 of EO 103, issued in response to the COVID-19 pandemic, authorizes agency heads to waive/suspend/modify any existing rule, where the enforcement of the rule would be detrimental to the public welfare during the emergency, notwithstanding the provisions of the Administrative Procedure Act or any law to the contrary. Pursuant to that authority, and with the approval of the Governor and in consultation with the State Director of Emergency Management, the Commissioner of the Department of Health is waiving/modifying its rules as follows:

COVID-19 is a contagious, and at times fatal, respiratory disease that is responsible for the 2019 novel coronavirus outbreak. As of April 20, 2020, there were at least 88,806 positive cases of COVID-19 in New Jersey, with at least 4,377 of those cases having resulted in death. The outbreak, as well as the operational changes necessary to mitigate the spread of COVID-19, has adversely affected the normal operation of multiple health care facilities, including outpatient substance abuse disorder treatment facilities. Of particular concern, individuals enrolled in Opioid Treatment Programs (OTPs) are unable to maintain access to medication necessary for managing the symptoms of withdrawal. Individuals who are unable to maintain access to these medications could suffer serious or life-threatening withdrawal symptoms or may resort to continued opioid use in order to manage withdrawal symptoms.

Under N.J.A.C. 10:161B-11.10, OTPs are required to apply the federal standards set by accrediting agencies at 42 CFR Part 8.12 in order to determine whether or not a client is eligible to receive take-home medication. The rule further specifies that clients may only receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and

Federal holidays. Finally, the rule requires OTP facilities to make arrangements to provide the clinically appropriate take-home dose to clients should the facility remain closed for business on a non-emergency basis.

In order to ensure the clients of OTPs have access to needed medications, the Department is waiving the requirements of N.J.A.C. 10:161B-11.10 and permitting facilities to provide medication to clients at locations other than the location listed on their OTP facility license, in accordance with the guidance issued by the Drug Enforcement Agency (DEA078) on April 7, 2020. The intent of the guidance is to provide OTPs greater flexibility in the delivery of take-home doses of methadone to their patients. Consistent with that intent, OTPs must still adhere to certain standards. Specifically, before using the unregistered off-site location, the OTP must first contact its State Opioid Treatment Authority (SOTA) and receive the SOTA's approval to use the offsite location. Additionally, the OTP must receive approval from the local DEA field office. Once the SOTA approves the location, it should contact the local DEA field office. If the SOTA does not contact the DEA field office, the OTP must contact the field office itself. The facility must submit the approvals received from the SOTA and the DEA field office to the Department. Each day, the facility may only transport those take-home methadone doses to the off-site location that the facility reasonably anticipates will be delivered to clients that day. The facility cannot transport a reserve of methadone to the off-site location. Any methadone not delivered to clients at the off-site location must be returned to the facility's DEA-registered location the same day. No methadone may be stored at the off-site location when a facility staff member is not present.

The OTP facility shall maintain policies and procedures required by N.J.A.C. 10:161B-11.4. The facility must also maintain policies and procedures required by N.J.A.C. 10:161B-14 et seq. that address the proper storage, administration, and dispensation of medication. The facility shall ensure that only physicians, registered professional nurses, licensed practical nurses (working under the supervision of a registered professional nurse), pharmacists or other persons authorized under New Jersey statutes or rules dispense or administer medications. Finally, the facility shall develop and implement policies and procedures for delivery protocols, including the documentation of medications being received by the client.

All OTPs that take action under the terms of N.J.A.C. 10:161B-11.10 shall provide a written report to the Department detailing the extent to which the facility implemented the terms of this waiver/modification and any adverse outcomes attributable to such implementation. OTPs may operate under the terms of this waiver/modification as necessary until the conclusion of the public health emergency declared by Governor Philip D. Murphy in Executive Order Nos. 103. Upon the conclusion of the public health emergency, OTP facilities will be required to resume determining eligibility for take-home medication under the criteria set forth in N.J.A.C. 10:161B-11.10(a).

OTPs are advised to maintain contact with their local and/or County Office of Emergency Management during the COVID-19 public health emergency. Questions concerning this waiver/modification may be directed to Jean DeVitto, Executive Director, Certificate of Need and Healthcare Facility Licensure Program at jean.devitto@doh.nj.gov.

Full Text of the proposed waiver/modification follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

10:161B-11.10 Eligibility for take-home medication

(a) The multidisciplinary team shall utilize the criteria outlined in the Federal standards set by accrediting agencies at 42 CFR Part 8.12, in determining whether or not a client is eligible to receive take home medication and meets all the eligibility criteria.

1. Any client in an opioid treatment program receiving comprehensive maintenance treatment may receive a single take-home dose for a day that the clinic is closed for business, including Sundays and State and Federal holidays.

i. The facility shall make arrangements to provide the clinically appropriate take-home dose should the facility remain closed for business, on a non-emergency basis, for more than one day. This provision shall have been approved by the medical director, reviewed by the treatment team, and supported by documentation in the client record.

(b) During the COVID-19 public health emergency, Opioid Treatment Programs (OTPs) shall be permitted to provide take-home doses of medication to clients who are eligible to receive them pursuant to (a) above, in locations other than the location listed on the OTP facility license, and may deliver medications to clients under the following conditions:

1. The facility must comply with Drug Enforcement Agency (DEA) guidance, including the following:

a. Before using the unregistered off-site location, the OTP must first contact its State Opioid Treatment Authority (SOTA) and receive the SOTA's approval to use the offsite location.

b. Before using the unregistered off-site location, the OTP must receive approval from the local DEA field office. Once the SOTA approves the location, it should contact the local DEA field office. If the SOTA does not contact the DEA field office, the OTP must contact the field office itself.

c. Each day, the facility may only transport those take-home methadone doses to the off-site location that the facility reasonably anticipates will be delivered to clients that day. The facility cannot transport a reserve of methadone to the off-site location.


d. Any methadone not delivered to clients at the off-site location must be returned to the facility's DEA-registered location the same day. No methadone may be stored at the off-site location when a facility staff member is not present.

2. The OTP shall submit the approvals received from the SOTA and the DEA field office to the Department.

3. The OTP shall maintain policies and procedures required by N.J.A.C. 10:161B-11.4.
4. The facility shall maintain policies and procedures required by N.J.A.C. 10:161B-14 et seq. that address the proper storage, administration, and dispensation of medication.
5. The OTP shall ensure that only physicians, registered professional nurses, licensed practical nurses (working under the supervision of a registered professional nurse), pharmacists or other persons authorized under New Jersey statutes or rules dispense or administer medications.
6. The OTP shall develop and implement policies/procedures for delivery protocols; including the documentation of medications being received by the client.

I find that waiver/modification of the rule above is necessary because enforcement of the existing rules would be detrimental to the public welfare during this emergency.

5/8/2020
DATE


Judith M. Persichilli, RN, BSN, MA
Commissioner
Department of Health

WAIVER: 20- N.J.A.C. 10:161B-11.10