



State of New Jersey
DEPARTMENT OF HEALTH
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JUDITH M. PERSICILLI, RN, BSN, MA
Commissioner

CERTIFICATE OF WAIVER
MEDICATION ASSISTED TREATMENT

In anticipation of amended regulations, the Department of Health (DOH) is issuing a waiver of regulations to permit substance use disorder facilities licensed pursuant to N.J.A.C. 10:161B to prescribe, store, and/or administer medications, other than Methadone, that are approved by the Food and Drug Administration (FDA) for the treatment of substance use disorder.

A waiver is issued to:

All substance use disorder facilities licensed or seeking licensure pursuant to N.J.A.C. 10:161B

Granting relief from the provisions of Chapter 10:161B of the New Jersey Administrative Code:

N.J.A.C. 10:161B-11.1 through N.J.A.C. 10:161B-11.17
N.J.A.C. 10:161B-14.1 through N.J.A.C. 10:161B-14.3

This waiver grants relief from the provisions of N.J.A.C. 10:161B-11 et seq. which implement requirements for Opioid Treatment Programs and the provisions of N.J.A.C. 10:161B-14 et seq. which implement requirements for administering and dispensing medication.

This waiver is subject to the following conditions:

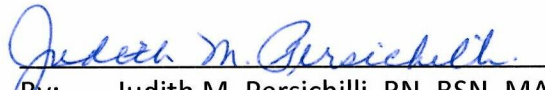
Applies to all facilities licensed or seeking licensure pursuant to N.J.A.C. 10:161B, provided they:

- 1) Develop and implement policies/procedures for assessing the need to prescribe medications to treat substance use disorders;**
- 2) Develop and implement policies/procedures for the processing of toxicology screening or testing and pregnancy tests prior to prescribing medication;**
- 3) Develop and implement policies/procedures to ensure patients in need of inpatient withdrawal management services are referred to the appropriate level of care;**
- 4) Develop and implement policies/procedures to ensure patients have abstained from opioid use prior to treatment, where required for the specific medication;**
- 5) Develop and implement policies/procedures to ensure continuity of care in the event the prescriber separates from the facility;**

- 6) Ensure that the facility's prescriber(s) are currently licensed and in good standing in the State of New Jersey;
- 7) Ensure that the prescriber(s) adhere to DEA and CDS requirements for the provision of medications for the treatment of substance use disorders;
- 8) If medications are stored in the facility, the facility must develop and implement policies/procedures for proper storage and administration including:
 - a. All drugs must be kept in locked storage areas.
 - b. Drug storage and preparation areas must be kept locked when not in use.
 - c. All drugs must be stored and administered in accordance with Federal and state law;
 - d. All drugs must be stored and administered under proper conditions, as indicated by the United States Pharmacopoeia, product labeling, and/or package inserts.
 - e. Drugs for external use shall be kept separate from drugs for internal use.
 - f. Drugs in single dose or single use containers which are open or which have broken seals, drugs in containers missing drug source or exact identification (such as lot number), and outdated, recalled, or visibly deteriorated medications shall be disposed in accordance with Federal and State laws.
 - g. A declining inventory of all drugs in Schedules I through V of the Controlled Dangerous Substances Acts and amendments thereto shall be made at the termination of each shift and shall be retained wherever these drugs are maintained.
- 9) Submit an attestation to DOH that the facility is in compliance with the above conditions.

Facilities licensed to administer and dispense Methadone must continue to comply with N.J.A.C. 10:161B-11 et seq. and N.J.A.C. 10:161B-14 et seq.

This waiver remains valid until the expiration date listed below, unless sooner suspended or revoked by the Department.


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

DATE ISSUED: March 10, 2020

WAIVER CONTROL NUMBER: 2020-003

EXPIRES: Upon adoption of revised regulations (N.J.A.C. 10:161B) or new regulations (N.J.A.C. 8)



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Frequently Asked Questions
Certificate of Waiver-Medication Assisted Treatment
Facilities Licensed pursuant to N.J.A.C. 10:161B

My facility is not licensed as an Opioid Treatment Program (OTP). How can we prescribe and/or administer medications for the treatment of substance use disorder?

Facilities licensed to provide substance use disorder services pursuant to N.J.A.C. 10:161B that are not otherwise licensed to provide OTP services must meet waiver conditions to prescribe and/or administer medications for the treatment of substance use disorder.

What steps do I need to take to provide services pursuant to the waiver?

Facilities licensed pursuant to N.J.A.C. 10:161B may begin providing medications, other than Methadone, for the treatment of substance use disorder if they meet the waiver conditions and submit an attestation to DOH that they are in compliance with the conditions. The facility may use the attestation form provided and submit to DOHCNLBwaivers@doh.nj.gov.

What are the conditions for the waiver?

Facilities licensed pursuant to N.J.A.C. 10:161B that wish to provide medications for the treatment of substance use disorder must comply with the 9 conditions listed in the waiver. They must:

- 1) Develop and implement policies/procedures for assessing the need to prescribe medications to treat substance use disorders;
- 2) Develop and implement policies/procedures for the processing of toxicology screening or testing and pregnancy tests prior to prescribing medication;
- 3) Develop and implement policies/procedures to ensure patients in need of inpatient withdrawal management services are referred to the appropriate level of care;
- 4) Develop and implement policies/procedures to ensure patients have abstained from opioid use prior to treatment, where required for the specific medication;
- 5) Develop and implement policies/procedures to ensure continuity of care in the event the prescriber separates from the facility;
- 6) Ensure that the facility's prescriber(s) are currently licensed and in good standing in the State of New Jersey;

- 7) Ensure that the prescriber(s) adhere to DEA and CDS requirements for the provision of medications for the treatment of substance use disorders;
- 8) If medications are stored in the facility, the facility must develop and implement policies/procedures for proper storage and administration including:
 - a. All drugs must be kept in locked storage areas.
 - b. Drug storage and preparation areas must be kept locked when not in use.
 - c. All drugs must be stored and administered in accordance with Federal and state law.
 - d. All drugs must be stored and administered under proper conditions, as indicated by the United States Pharmacopoeia, product labeling, and/or package inserts.
 - e. Drugs for external use shall be kept separate from drugs for internal use.
 - f. Drugs in single dose or single use containers which are open or which have broken seals, drugs in containers missing drug source or exact identification (such as lot number), and outdated, recalled, or visibly deteriorated medications shall be disposed in accordance with Federal and State laws.
 - g. A declining inventory of all drugs in Schedules I through V of the Controlled Dangerous Substances Acts and amendments thereto shall be made at the termination of each shift and shall be retained wherever these drugs are maintained.
- 9) Submit an attestation to DOH that the facility is in compliance with the above conditions.

My facility meets the conditions of the waiver to provide medications for the treatment of substance use disorder. When can we begin seeing new patients?

The facility may begin providing medications for the treatment of substance use disorder as soon as they submit an attestation that the waiver conditions are met and receive confirmation of receipt from DOH.

Is my facility required to have a medical director to prescribe medications to treat substance use disorder?

Facilities are required to have a medical director in the following circumstances:

- The facility is licensed as an Opioid Treatment Program under N.J.A.C. 10:161B-11; and/or
- The facility is licensed to provide ambulatory withdrawal management services under N.J.A.C. 10:161B-12.

Facilities prescribing and/or administering medication, other than Methadone, for the treatment of substance use disorder that are not providing ambulatory withdrawal management services do not need a medical director. However, the prescribers for these facilities must be licensed in the State of New Jersey and comply with DEA/CDS requirements for the provision of particular medications.

My facility doesn't employ a physician. Can we still provide medications for the treatment of substance use disorder?

Yes. The facility must have a prescriber that adheres to DEA and CDS requirements, but this prescriber does not need to be a physician. Prescribers that are not physicians must meet professional requirements for physician supervision.

Can my facility provide medications for the treatment of substance use disorder in the place of ambulatory withdrawal management services?

No. Facilities that are not licensed to provide ambulatory withdrawal management services must refer patients in need of withdrawal services.

Can we prescribe medications for the treatment of substance use disorder before providing counseling?

Yes. Counseling should be provided with medication but it is not required. The facility should provide treatment pursuant to the patient's plan of care.

What requirements does my facility need to meet to store and administer medications for the treatment of substance use disorder?

The facility needs to ensure that basic safeguards are in place for the proper storage and administration of medication. Specifically, the facility must ensure that:

- The prescribers adhere to DEA and CDS requirements.
- All drugs are kept in locked storage areas.
- Drug storage and preparation areas are kept locked when not in use.
- All drugs are stored and administered in accordance with Federal and state law;
- All drugs are stored and administered under proper conditions, as indicated by the United States Pharmacopoeia, product labeling, and/or package inserts.
- Drugs for external use are kept separate from drugs for internal use.
- Drugs in single dose or single use containers which are open or which have broken seals, drugs in containers missing drug source or exact identification (such as lot number), and outdated, recalled, or visibly deteriorated medications are disposed in accordance with Federal and State laws.
- A declining inventory of all drugs in Schedules I through V of the Controlled Dangerous Substances Acts and amendments thereto is made at the termination of each shift and shall be retained wherever these drugs are maintained.

Facilities licensed to provide Methadone must continue to comply with standards in N.J.A.C. 10:161B-14.

When does the waiver take effect?

The waiver is effective immediately.

Does the waiver expire?

The waiver remains valid until new or revised regulations are adopted or they are suspended or revoked by DOH.

3/10/2020