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DEPARTMENT OF HEALTH
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JUDITH M. PERSICILLI, RN, BSN, MA
Commissioner

**CERTIFICATE OF WAIVER
MEDICATION MONITORING IN MENTAL HEALTH FACILITIES**

In anticipation of amended regulations, the Department of Health (DOH) is issuing a waiver of regulations to permit mental health facilities licensed pursuant to N.J.A.C. 10:37E 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 facilities licensed pursuant to N.J.A.C. 10:37E to provide outpatient mental health services

Granting relief from the provisions of Chapter 10:37E and 10:37 of the New Jersey Administrative Code which defines medication monitoring:

N.J.A.C. 10:37E-1.2 Definitions

N.J.A.C. 10:37-6.54 Psychotropic Medication

This waiver grants relief from the provisions of N.J.A.C. 10:37E-1.2 and N.J.A.C. 10:37-6.54 which limit medication monitoring services to the provision of psychotropic medication.


This waiver is subject to the following conditions:

Applies to all facilities in good standing that are licensed to provide outpatient mental health services pursuant to N.J.A.C. 10:37E that currently prescribe psychotropic medications, 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 staff who provide counseling to patients as part of their treatment plan are appropriately licensed or credentialed;
- 7) Ensure that the facility's prescriber(s) are currently licensed and in good standing in the State of New Jersey;
- 8) Ensure that the prescriber(s) adhere to DEA and CDS requirements for the provision of medications for the treatment of substance use disorders;
- 9) 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.
- 10) Submit an attestation to DOH that the facility is in compliance with the above conditions.

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: 2020-02

EXPIRES: Upon adoption of revised regulations (N.J.A.C. 10:37E) or new regulations (N.J.A.C. 8)



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Frequently Asked Questions
Certificate of Waiver-Medication Monitoring in Mental Health Facilities
Licensed pursuant to N.J.A.C. 10:37E

What does the waiver mean for outpatient mental health facilities?

DOH issued a waiver of regulations that currently define medication monitoring in outpatient mental health facilities (N.J.A.C. 10:37E) as the provision of psychotropic medication. Pursuant to the waiver, DOH is permitting facilities to include FDA approved medications for the treatment of substance use disorder, other than Methadone, as part of their medication monitoring services.

Are outpatient mental health facilities permitted to provide medications for the treatment of substance use disorder?

Yes. Pursuant to the Certificate of Waiver-Medication Monitoring, facilities licensed to provide outpatient mental health services (N.J.A.C. 10:37E) that currently prescribe psychotropic medications will be permitted to provide medications for the treatment of substance use disorder, including opioid use disorder, if they meet waiver conditions and submit an attestation that they are in compliance with conditions.

What are the conditions for the waiver?

Facilities licensed pursuant to N.J.A.C. 10:37E that wish to provide medications for the treatment of substance use disorder must comply with the 10 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 staff who provide counseling to patients as part of their treatment plan are appropriately licensed or credentialed;
- 7) Ensure that the facility's prescriber(s) are currently licensed and in good standing in the State of New Jersey and have one year of experience in addiction treatment;
- 8) Ensure that the prescriber(s) adhere to DEA and CDS requirements for the provision of medications for the treatment of substance use disorders;
- 9) 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.
- 10) Submit an attestation to DOH that the facility is in compliance with the above conditions.

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

Facilities licensed pursuant to N.J.A.C. 10:37E may begin providing medications 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 DOHCNLABHwaivers@doh.nj.gov.

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.

My facility doesn't prescribe psychotropic medications. Can we start prescribing medications for the treatment of substance use disorder?

No. The facility must meet regulatory requirements to provide patients with medication management services before adding services. The priority of outpatient mental health facilities should continue to be the treatment of mental illness.

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.

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

Mental health facilities are not required to have a medical director to prescribe and/or administer medications for the treatment of substance use disorder. However, the prescribers 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.

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.

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