



State of New Jersey
DEPARTMENT OF HEALTH

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Governor

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SHEREEF M. ELNAHAL, MD, MBA
Commissioner

November 5, 2018

TO: Stakeholders

FROM: John Calabria, Director
Division of Certificate of Need and Healthcare Facility Licensure

RE: "Certificate of Waiver for Medication Assisted Treatment in Ambulatory Care Facilities Pursuant to N.J.A.C. 8:43A"

Attached is a waiver known as the "Certificate of Waiver for Medication Assisted Treatment in Ambulatory Care Facilities Pursuant to N.J.A.C. 8:43A" (the Waiver). If you have any questions, please contact Sarah Kaplan at sarah.kaplan@doh.nj.gov.

Attachment

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CERTIFICATE OF WAIVER
MEDICATION ASSISTED TREATMENT IN AMBULATORY CARE FACILITIES
PURSUANT TO N.J.A.C. 8:43A

Medication Assisted Treatment (MAT) involving buprenorphine or any other medication approved by the Substance Abuse and Mental Health Services Administration (SAMHSA) for the treatment of opioid use disorders¹ in ambulatory care facilities licensed pursuant to N.J.A.C. 8:43A

This waiver grants relief from the provisions of N.J.A.C. 8:43A-1.3, which defines “drug abuse treatment services” as “methadone detoxification, methadone maintenance, and/or drug-free counseling programs.” Pursuant to this waiver the Department of Health (the Department or DOH) will be interpreting the definition of “drug abuse treatment services” to include buprenorphine or any other medication approved by SAMHSA for the treatment of opioid use disorders. This document and waiver does not change or modify the requirements of methadone treatment in any manner. This waiver shall remain in effect until the DOH promulgates new or amended rules at N.J.A.C. 8:43A-1.3.

There are four options available to facilities licensed under N.J.A.C. 8:43A:

1. The first option is for ambulatory care facilities that are currently licensed under N.J.A.C. 8:43A that currently prescribe buprenorphine or any other medication approved by SAMHSA for the treatment of opioid use disorders and provide related counseling (either on-site or through an affiliation agreement) but do *not* store and/or dispense buprenorphine or any other medication approved by SAMHSA for the treatment of opioid use disorders; and that do *not* plan or intend to store and/or dispense buprenorphine or any other medication approved by SAMHSA for the treatment of opioid use disorders.

¹ See <https://www.samhsa.gov/medication-assisted-treatment/treatment>

- a. The licensee shall submit a letter of intent to continue to only prescribe buprenorphine or any other medication approved by SAMHSA for the treatment of opioid use disorders to the Department's Office of Certificate of Need & Licensing within 30 days of the effective date of this waiver.
- b. Such facilities may continue to only prescribe buprenorphine or any other medication approved by SAMHSA for the treatment of opioid use disorders by employing a DATA 2000² waived physician, nurse practitioner, or physician assistant without taking any further action at this time.

Note: It remains the responsibility of each facility to comply with any local, State, Medicaid, Drug Enforcement Agency (DEA), or other Federal requirements, regarding notification, updates, etc.

2. The second option is for ambulatory care facilities that are currently licensed under N.J.A.C. 8:43A and whose license includes drug abuse treatment (outpatient) services pursuant to N.J.A.C. 8:43A-26; that are currently providing methadone; and that wish to add buprenorphine or any other medication approved by SAMHSA for the treatment of opioid use disorders. Such facilities shall comply with the following conditions to use this waiver

- a. The licensee shall submit a letter of intent to prescribe, administer, or otherwise provide buprenorphine or any other medication approved by SAMHSA for the treatment of opioid use disorders³ to the Department's Office of Certificate of Need & Licensing; and
- b. The licensee shall provide evidence that the licensee employs a DATA 2000 waived physician, nurse practitioner, or physician assistant who, under their professional scope of services, is able to prescribe and/or administer medications for MAT services.

Note: It remains the responsibility of each facility to comply with any local, State, Medicaid, DEA, or other Federal requirements, regarding notification, updates, etc.

3. The third option is for ambulatory care facilities that are currently licensed under N.J.A.C. 8:43A and whose license includes drug abuse treatment (outpatient) services pursuant to N.J.A.C. 8:43A-26; that are *not* currently providing methadone; and that wish to add buprenorphine or any other medication approved

² See https://www.deadiversion.usdoj.gov/pubs/docs/dwp_buprenorphine.htm

³ See <https://www.samhsa.gov/medication-assisted-treatment/treatment>

by SAMHSA for the treatment of opioid use disorders. Such facilities shall comply with the following conditions to use this waiver:

- a. The licensee shall submit a letter of intent to prescribe, administer, or otherwise provide methadone, buprenorphine or any other medication approved by SAMHSA for the treatment of opioid use disorders to the Department's Office of Certificate of Need & Licensing. The letter shall state that the facility will comply with the conditions stated in items i & ii below.
 - i. The licensee shall ensure policies and procedures are developed and implemented for drug abuse treatment services per N.J.A.C. 8:43A-26.1-2, and 26.4 through 26.9, subject to the Department's interpretations described in paragraph (3)(a)(iv) below.
 - ii. The licensee shall ensure each patient receiving MAT services receives a physical examination and assessment which results in a plan of care specific to each individual patient.
 1. The ASAM criteria, developed by the American Society of Addiction Medicine,⁴ shall be used to assess the patient's level of care. The licensee may refer a patient, or provide care at a higher or lower level of intensity, when determined to be clinically appropriate by a qualified practitioner. Changes made to the ASAM level of care recommendations shall be documented in the patient's plan of care.
 - iii. The facility shall provide the following to the patient: in-person education of the proper use, dosage, frequency, effects, benefits, and risks of the use of buprenorphine or any other medication approved by SAMHSA for MAT services, and shall document compliance with this requirement in the patient's medical record.
 - iv. For purposes of this waiver, while DOH works towards the harmonization of outpatient licensing regulations, DOH interprets the provisions of subchapter 26 cited in paragraph (a) above as follows:
 1. N.J.A.C. 8:43A-26.4 shall be satisfied by the on-site presence of a DATA 2000 waived physician, nurse practitioner, or physician assistant whose professional board allows for the prescribing and/or administering of methadone,

⁴ See <https://www.asamcontinuum.org> and <https://www.asam.org>

buprenorphine or any other medication approved by SAMHSA for MAT services.

2. N.J.A.C. 8:43A-26.5(a) shall be read to permit facilities that are not providing methadone, but are providing buprenorphine or any other medication approved by SAMHSA for the treatment of opioid use disorders other than methadone, to provide drug abuse counseling services directly in the facility or by referral to an appropriately qualified provider, based on the patient's assessed level of care.
3. N.J.A.C. 8:43A-26.5(b)(1) shall be read to require that, when drug counseling services are provided on-site, a professional, whose professional scope of services allows for drug abuse counseling services to be provided, shall ensure that the caseload for drug counseling either provided by the professional or provided by any other professional whose professional scope of services permits drug abuse counseling services, shall be maintained at levels in accordance with ASAM/SAMSHA⁵ best practices/standard of care.
4. N.J.A.C. 8:43A-26.5(b)(6) shall be read to permit facilities that are not providing methadone treatment to refer patients to the appropriate range of services described therein.

Note: It remains the responsibility of each facility to comply with any local, State, Medicaid, DEA, or other Federal requirements, regarding notification, updates, etc.⁶

4. The fourth option is for ambulatory care facilities that are currently licensed under N.J.A.C. 8:43A but the license does not indicate that drug abuse treatment (outpatient) services may be provided. Such facilities who wish to provide such treatment must submit an application to amend the facility's license, including the required fees, to add Drug Abuse Treatment (Outpatient) services. Please use the CN/Licensing Form CN -7, the Application for New or Amended Acute Care Facility

⁵ See <https://www.asam.org/docs/default-source/practice-support/guidelines-and-consensus-docs/asam-national-practice-guideline-supplement.pdf>; https://www.asam.org/docs/default-source/practice-support/quality-improvement/asam-standards-of-care.pdf?sfvrsn=338068c2_10; and <https://www.samhsa.gov/ebp-resource-center>

⁶ It is important to note that the fact that a facility is permitted under its license to provide MAT services does not ensure that the facility will be reimbursed by NJ FamilyCare or other insurers for providing these services. See generally State of N.J. Dep't of Human Servcs., Div. of Medical Assistance & Health Servcs., "Outpatient Facility Behavioral Health Integration Billing Frequently Asked Questions (FAQs)," at 5 (Jan. 10, 2018) https://www.state.nj.us/humanservices/dmahs/info/Behavioral_Health_Outpatient_Facility_Billing_FAQs_&_FQHC_Behavioral_Health_Allowable_Billing_Codes.pdf (last visited August 24, 2018).

License, (found on the Department's website: <http://healthapps.state.nj.us/forms/>) along with the letter of intent referenced above in option #3.

- a. MAT-related services such as pharmaceutical storage and/or dispensation shall not be provided until the facility has been appropriately licensed by the Department to provide such services and demonstrates compliance with any applicable local, state, Medicaid, DEA, or other Federal requirements. An on-site inspection by DOH may be part of the licensure process.

Note: Once approved by the Department, the provisions of this waiver shall be applicable to the applicant facility.

Contact Information

Questions regarding MAT in ambulatory care facilities should be directed via email to integratedhealth@doh.nj.gov or to Sarah Kaplan at sarah.kaplan@doh.nj.gov. DOH encourages facilities to take advantage of functional reviews, which DOH offers to provide technical assistance to those preparing to apply for licensure, renewal, or expansion of scope of services.

November 5, 2018