HEALTH

STANDARDS FOR LICENSURE OF OUTPATIENT SUBSTANCE USE DISORDER TREATMENT FACILITIES

Notice of Rule Waiver/Modification/Suspension Pursuant to P.L. 2021, c. 103 (2020)

COVID-19 State of Emergency

Relaxation of Rules Pertaining to the Standards for Licensure of Outpatient Substance Use Disorder Treatment Facilities

N.J.A.C. 10:161B-1.3, 6.3, 9.1, 10.1, 11.6, 11.9, 11.12, 11.13, 12.4, 15.1, Appendix B and Appendix C

Authorized: [ ] by Judith M. Persichilli, Commissioner, Department of Health.

Authority: N.J.S.A. App.A:9-45 and App.A:9-47; and P.L. 2021, c. 103.

Effective Date: March 9, 2020.

This is an emergency adoption of a temporary rule modification concerning certain rules at N.J.A.C. 10:161B-1.1 et. seq., Standards for Licensure of Outpatient Substance Use Disorder Treatment Facilities, which apply to all substance use disorder ("SUD") treatment facilities that provide outpatient SUD treatment services to adults, including outpatient, intensive outpatient, partial care, outpatient detoxification (withdrawal management), and opioid treatment. Section 3.a. of P.L. 2021, c. 103 (N.J.S.A. 26:13-34.a) authorizes agency heads to continue and modify

administrative orders or directives issued during the COVID-19 public health emergency. Section 5.a. of P.L. 2021, c. 103 (N.J.S.A. 26:13-36) authorizes agency heads to issue orders, directives, and waivers to implement recommendations of the Centers for Disease Control and Prevention to prevent or limit the transmission of COVID-19, including in specific settings. Pursuant to that authority, the Department of Health is modifying the rules listed below.

The current regulations at N.J.A.C. 10:161B-1.1 et. seq. set out minimum rules and standards of care with which an outpatient SUD treatment facility must adhere to in order to be licensed to operate in New Jersey. The COVID-19 Public Health Emergency has impacted and continues to impact the SUD system of care that provides vital SUD treatment services to residents of New Jersey. In response to COVID-19, the delivery of SUD services continues to be reconfigured in order to minimize community spread, while at the same time ensuring accessibility and continuity of care. Although the COVID-19 Public Health Emergency declared under E.O. 103 has ended in New Jersey, SUD treatment facilities continue to need flexibility to mitigate transmission of COVID-19 in the provision of SUD services, including through the use of telemedicine and telehealth. At the beginning of the pandemic, DMHAS issued guidance regarding the use of telemedicine, telehealth and telecommunication for behavioral health provider agencies, which this rule modification now codifies. This rule modification is consistent with recommendations to reduce the transmission of COVID-19 from the CDC, as well as guidance from federal agencies, such as the Substance Abuse and Mental Health Services Administration (SAMHSA) with respect to telemedicine and telehealth, and medication-assisted treatment, and States agencies, such as the New Jersey Division of Consumer Affairs. It also complies with State laws enacted with respect to telemedicine and telehealth.

Thus, consistent with federal and state guidance, directives, waivers and laws issued in response to the COVID-19 Public Health Emergency, it is necessary to address, formalize and ensure flexibility in the standards in the rules at N.J.A.C. 10:161B-1.1 et. seq. through this temporary rule modification.

Full text of the modified rule text follows (additions indicated in boldface **thus**; deletions indicated in brackets [thus]):

SUBCHAPTER 1. DEFINITIONS AND STAFF QUALIFICATIONS AND RESPONSIBILITIES

10:161B-1.3 Definitions

…

"Telehealth" means the use of information and communications technologies as defined by and in accordance with P.L. 2017, c. 117 (C.45:1-61 et al.) and any amendments thereto, including pursuant to P.L. 2020, c. 47, and corresponding COVID-19 waivers.

"Telemedicine" means the delivery of a health care service using electronic communications, information technology, or other electronic or technological means as defined by and in accordance with P.L. 2017, c.117 (C.45:1-61 et al.) and any amendments thereto, including pursuant to P.L. 2020, c. 47, and corresponding COVID-19 waivers.

…

SUBCHAPTER 6. CLIENT CARE POLICIES AND SERVICES

10:161B-6.3 Standard for preadmission, admission, and retention of clients

(a) –(d) (No change.)

(e) Upon admission to an outpatient substance use disorder treatment facility, the following shall apply:

1. Facilities providing opioid treatment and detoxification services shall ensure that each client has received a physical examination in accordance with N.J.A.C. 10:161B-11 and 12.

i. For clients being treated with buprenorphine, the physical examination required at N.J.A.C. 10:161B-11 and 12 may be conducted via

telemedicine/telehealth so long as the use of telemedicine/telehealth is clinically appropriate and not contraindicated for the client.

2. Facilities providing services other than opioid and detoxification shall ensure that each client has completed a comprehensive health history assessment and symptom review and has referred each client for appropriate medical screening and services, as necessary.

i. The comprehensive health history assessment and symptom review may be conducted via telehealth/telemedicine.

(f)-(g) (No change.)

SUBCHAPTER 9. CLIENT ASSESSMENT AND TREATMENT PLANNING

10:161B-9.1 Client Assessment

(a) An outpatient substance use disorder treatment facility shall complete, within three visits of admission, a drug screen, and a comprehensive biopsychosocial assessment of all clients using an assessment instrument which assesses medical status, vocational/employment and support, alcohol, tobacco and other drug use, legal status, family/social status, psychiatric status, as well as behavioral risk factors for HIV and hepatitis. The client shall be placed in a treatment facility, the modality and underlying philosophy of which is consistent with the client's preferences and values and which is also consistent with the client's needs based on criteria defined in the ASAM Criteria.

1.-2. (No change.)

3. The comprehensive biopsychosocial assessment may be conducted via telehealth/telemedicine.

(b) In performing a biopsychosocial assessment, the program shall include the following:

1. (No change.)

2. Clients in outpatient detoxification and opioid treatment programs shall receive a physical exam, in accordance with N.J.A.C.10:161B-11.6(c).

i. For clients in outpatient detoxification and opioid treatment programs being treated with buprenorphine, the physical exam required above and at N.J.A.C. 10:161B-11.6(c), may be conducted via telemedicine/telehealth so long as the use of telemedicine/telehealth is clinically appropriate and not contraindicated for the client.

3.-8. (No change.)

SUBCHAPTER 10. SUBSTANCE ABUSE COUNSELING AND SUPPORTIVE SERVICES

10:161B-10.1 Provision of substance abuse counseling

(a) Every outpatient substance use disorder treatment facility shall provide substance abuse counseling on-site, and shall assign every client to a primary substance abuse counselor at admission.

1. Substance abuse counseling services may be provided through telehealth/telemedicine services.

SUBCHAPTER 11. OPIOID TREATMENT SERVICES

10:161B-11.6 Admission and assessment

(a)-(b) (No change.)

(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 methadone. A program physician or other licensed independent practitioner authorized under New Jersey statutes shall conduct a complete physical evaluation, at admission and shall include testing for the following:

1-10. (No change.)

11. For clients being treated with buprenorphine, the complete physical examination required at (c) above, may be conducted via telemedicine/telehealth so long as the use of telemedicine/telehealth is clinically appropriate and not contraindicated for the client.

(d) – (g) (No change.)

10:161B-11.9 Drug Screening

(a) (No change,)

(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.

1. In lieu of the random drug screening set out in (b) above, random drug screening may be implemented by conducting at least eight random drug screenings per year, per patient in maintenance 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.

1. In lieu of the drug screening described in (c) above, clients in clinic-based medical maintenance, Phase VI, must receive at least eight drug screenings per year.

(d) – (e) (No change)

10:161B-11.12 Take-home medication dosage schedule

(a) An opioid treatment program shall develop and implement written policies and procedures consistent with this chapter and all applicable Federal regulations address 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.- vi. (No change.)

vii. An OTP may follow the guidance and procedures set out in Appendix C, Take-home Dosing and Delivery Guidelines incorporated herein by reference.

(b)-(f) (No change.)

10:1161B-11.13 Extended take-home medication

(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:

1-4. (No change.)

5. An OTP may follow the guidance and procedures set out in Appendix C, Take-home Dosing and Delivery Guidelines incorporated herein by reference.

SUBCHAPTER 12. DETOXIFICATION SERVICES.

10:161B-12.4 Required services

(a) All outpatient programs providing detoxification services shall, at a minimum, provide the following services:

1.-11. (No change.)

12. Drug screening shall be conducted at least weekly during the detoxification period in addition to the admission screening.

i. The drug screening may be conducted during the detoxification period as clinically necessary for the client.

(b) (No change.)

SUBCHAPTER 15. EMERGENCY SERVICES AND PROCEDURES

10:161B-15.1 Emergency plans and procedures

(a) The outpatient substance use disorder treatment facility shall maintain written emergency plans, policies, and procedures to be followed in case of hazards that necessitate an evacuation, ensuring that clients receive necessary services during the evacuation or other emergency, including internal and external disasters such as fire, natural disaster, environmental threats, bomb threats, or industrial or radiological accidents.

1. An OTP must include take-home dosing and service procedures being used in response to COVID-19 in their emergency plan, also known as a Continuity of Operations Plan ("COOP"). This plan shall be submitted to the IME COOP Activation email address at imecoop@ubhc.rutgers.edu with a copy to the State Opioid Treatment Authority, Mr. Adam Bucon, via email at adam.bucon@dhs.nj.gov.

(b)- (d) (No change.)

10:161B APPENDIX B. ADMINISTRATIVE BULLETIN.

Subject: BUPRENORPHINE GUIDELINES

I. Background

(No change.)

II. Services To Be Provided Post Detoxification

Buprenorphine therapy is an adjunct to the full treatment experience; not in lieu of a full treatment experience which includes stabilization (detoxification or maintenance), rehabilitation (counseling and education) and then follow-up (aftercare counseling and support groups). All patients accepted into buprenorphine therapy must be referred to an OOL licensed substance use disorders treatment facility or individual therapists who are certified and/or licensed to provide substance abuse counseling. Such licensure and certification shall be current and not revoked or suspended.

A. – B. (No change.)

C. Complete History and Physical Examination

Each patient should undergo a complete history and physical examination. The history should include drug and alcohol use, psychiatric, past legal, medical, surgical, and family issues, and previous substance used disorders treatment. The physical examination should be complete and be

specific for signs of addiction. Patients should also undergo a neurological and mental status examination. All patients treated with Suboxone or Subutex should meet DSM-5 criteria for opioid use disorder.

1. The physical examination required herein may be conducted via telehealth/telemedicine so long as the use of telemedicine/telehealth is clinically appropriate and not contraindicated for the client.

D.-G. (No change.)

10:161B APPENDIX C. TAKE-HOME DOSING AND DELIVERY GUIDELINES IN RESPONSE TO COVID-19.

APPENDIX C

Subject: Take-Home Dosing and Delivery Guidelines In Response to COVID-19

Until the expiration of the temporary rule modification at N.J.A.C. 10:161B-11.12(a) and -11.13(a), an opioid treatment program (OTP) may follow the guidance and procedures set out below for the provision and/or delivery of take-home medication.

Take-Home Dosing Procedures

The following shall guide OTP take-home procedures:

1. Patients with laboratory confirmed COVID-19 disease and patients with signs or symptoms of a respiratory viral illness, with or without confirmation of COVID-19 viral testing, may receive up to 28 days of medication, but no less than 14 days immediately. These patients should not present for continued dosing at the clinic. Instruct patients to contact staff if they are experiencing or know whether individuals with whom they have had close contact have been experiencing such symptoms, before coming to the facility, so that appropriate arrangements can be made for obtaining medication. The amount of take-home medication shall be based on patient stability assessed by the agency Medical Director and clinical team. The agency shall document that the patient is medically ordered to be under isolation or quarantine. When possible, confirm the source of information (e.g., doctor's order, medical record).

2. Patients who have chronic medical conditions, signs/symptoms of respiratory infection or viral illness, and/or who are otherwise vulnerable to infection may receive up to a 28-day supply of take-home medication. The amount of take-home medication shall be based on patient stability assessed by the agency Medical Director and clinical team.

3. Patients with significant medical comorbidities and/or older patients (over the age of

60) may be given up to a 28-day supply of take-home medication. The amount of take-home medication shall be based on patient stability assessed by the agency Medical Director and clinical team.

4. Select patients who have already qualified for one or more additional take-home doses, and who suggest likely ongoing compliance and stability, may receive between 7 and 28 days of medication. The amount of take-home medication shall be based on patient stability assessed by the agency Medical Director and clinical team.

5. Patients with no or only one take-home dose (unearned), may be given up to 7 days of take-home medication. For patients who are considered to be less stable, an agency may consider daily dosing or a staggered take-home schedule whereby half the OTP patients present on Monday, Wednesday and Friday and the other half of OTP patients present on Tuesday, Thursday and Saturday, with the remaining doses of the week provided as take-home medication. Patients identified as less stable and at higher risk shall receive no more than two consecutive take-home doses at one time. Prescribers must be extremely cautious with patients who continue to have positive UDS for fentanyl or fentanyl analogues. If this is the case, consider continued daily dosing for these high-risk patients.

6. Agencies shall develop a procedure for routinely monitoring clients who do not attend the clinic and are in receipt of take-home medication, especially those presenting with clinical concerns requiring professional or medical assistance. Contact shall be made with patients and/or caregivers in their homes or residences by a means determined most suitable to them. The procedure for patient monitoring should be conducted by the appropriate clinic staff, including counseling and professional licensed staff, and can utilize messaging, telephone and video.

7. Agencies shall consider ways of promoting social distancing in a non-stigmatizing fashion such as determining if dosing can be provided in additional spaces in the facility, having patients maintain a distance of 6 feet from one another while on line, identifying a non-stigmatizing way to separate individuals who may have been exposed to COVID-19 or any other infectious illness (such as using a separate entrance) and expanding hours of operations so less individuals are awaiting their medicine at any one time.

8. Patients who are unable to physically come to the OTP may have a designee or surrogate pick up their medication on their behalf. A completed chain of custody form is required as part of this procedure.

9. Special consideration shall be taken when patients are in the MAT induction phase or any phase in which they are increasing their medication dose, unless they are in any of the high-risk populations noted above. Patients who are in the induction phase shall be maintained on the dose of methadone ordered on the day that take-home medication is prepared; escalating doses of methadone shall not be given to patients who are receiving multiple days of take-home medication. Rather, the patient shall be held at the dose they are taking and evaluated for an increased dose at the next clinic visit and prior to the preparation of additional take-home doses as needed.

10. For patients who reside out-of-state, consider options for partnering with an out-of-state agency to plan guest medication.

11. Patients dispensed buprenorphine are not restricted to regulatory requirements regarding take-home medication; therefore, they shall be evaluated for flexible take-home doses, as clinically warranted. Based on the more favorable safety profile of buprenorphine, programs shall seek to maximize the ability of patients to take their buprenorphine at home during the COVID-19 crisis. OTPs are strongly encouraged to temporarily switch from dispensing buprenorphine to prescribing it to patients as deemed clinically appropriate and safe by the medical provider.

12. All patients shall be instructed and educated, preferably verbally and in writing, on protecting their medication from theft and exposure to children, pets and other adults.

13. For individuals receiving opioid pharmacotherapy from an OTP that provides the medication to supervised settings such as nursing homes, residential treatment programs or jails/prisons, upon request to minimize the risk of COVID-19 infection and/or contain COVID-19 infection, facilities will be granted up to 28 days of opioid pharmacotherapy medication for each patient residing in the facility and receiving such medication from the OTP. The 28-day supply of medication for each patient must be stored safely under staff supervision in a locked area utilized for medication preparation and dispensing in the facility. Staff at the facility must administer the medication to the patient(s) and document as they would for any controlled substance medication administered at the facility.

14. All patients receiving take-home medication must have a lockable take-home container with written instructions on protecting their medication from theft and exposure to children, other adults and animals.

15. The OTP shall remain open during regular business hours or be given emergency contact information to field calls from any patient who is receiving take-home medication. The efficacy and safety of the take-home strategy shall be continually assessed. All medication exception requests shall provide appropriate and complete documentation on medication safety and diversion risk.

<u>Delivery procedures</u>

The following shall guide OTP delivery-related procedures:

Document that the patient is medically ordered to be under isolation or quarantine. When possible, confirm the source of the information, e.g. physician order, medical record. Ensure the documentation is maintained in the patient's OTP record.

Identify a trustworthy, patient-designated, uninfected third party - e.g. family member, neighbor - to deliver the medications using the OTP's established chain of custody protocol for take-home medication. This protocol should already be in place and in compliance with

respective state and DEA regulations. OTPs should obtain documentation for each patient as to who would have designated permission to pick up medication for them and maintain this process of determining a designee for any new patients.

If a trustworthy third party is not available or unable to come to the OTP, then the OTP should prepare a "doorstep" delivery of take home medications. Any medication taken out of the OTP must be in an approved lockbox. The OTP should always communicate with the patient prior to delivery to reduce risk of diversion. This may involve, but is not limited to:

1. Call placed to the patient prior to staff departure to deliver the medication ensuring that the patient or their approved designee is available to receive the medication at the address provided by the patient and recorded in the patient's OTP medical record.

2. Upon arrival, medication is delivered to the patient's residence door and another call is made to the patient/designee notifying that the medication is at the door.

3. The OTP staff retreat a minimum of 6 feet to observe that the medications are picked up by the patient or the designated person to receive the medications. The OTP staff person must ask the person who is retrieving the medication to identify themselves. Staff should determine that the person appearing to retrieve the medication is the patient or the person named by the patient as having permission to do so. The OTP staff who deliver the medication remain until observed retrieval of the medication by the designated person takes place, and then documents confirmation that medications were received by the individual identified as permitted to pick up the medication.

4. Do not leave medication in an unsecured area. OTP staff must remain with the medication until the designated individual arrives and retrieves the medication.

5. If the person who is to receive the medication is not at the designated location, an attempt should be made to contact the person. If the person does not arrive timely (this wait period will need to be determined by OTP staff), then the staff person must bring the medication back to the OTP where it will be stored in the pharmacy area until a determination is made as to whether another attempt will be made to deliver the medication. Any medication returned to the OTP must be logged in. The medication delivery and pick up by the designated person or return of the medications to the OTP must be documented in the patient's OTP record and appropriate pharmacy records.

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

January 10, 2022

Date

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