Pursuant to the authority vested in the Commissioner of Health by section 3308(2) of the Public Health Law, Sections 80.62, 80.63 and 80.84 of Title 10 of the Official Compilation of Codes, Rules and Regulations of the State of New York are amended, to be effective upon publication of a Notice of Adoption in the New York State Register, to read as follows:

Subdivision (b) of section 80.62 is amended to read as follows:

(b) Such practitioners shall maintain a written patient record of administration, dispensing and prescription of all controlled substances. The patient record shall contain sufficient information to justify the diagnosis and warrant the treatment. The record shall contain at least the following information: patient identification data; chief complaint; present illness; <u>past medical history; medical evaluation of the patient pursuant to section 80.63 of this Part</u> [physical examination as indicated]; diagnosis; other data which support the diagnosis or treatment; and the regimen including the amount, strength, and directions for use of the controlled substance. This subdivision shall not be construed to require a record distinct from the medical record of the patient.

* * *

Subdivision (d) of section 80.63 is repealed and new sections (d) and (e) are added, to read as follows:

[(d)(1) No controlled substance prescription shall be issued prior to the examination of the patient by the practitioner except as otherwise permitted by this subdivision.

(2) Once the initial examination has been completed, the frequency and necessity for

future examinations prior to prescribing, either for the same acute or chronic condition, will be made by the practitioner utilizing generally accepted medical standards, including taking into account the drug to be prescribed and the patient's condition, history and disposition toward the use of controlled substances.

(3) In the temporary absence of the initial prescriber, an authorized practitioner may issue a controlled substance prescription for a patient as part of a continuing therapy if the practitioner: (i) had direct access to the patient's medical records and such records warrant continued controlled substance prescribing, or (ii) had direct and adequate consultation with the initial prescriber, who assures the necessity of continued controlled substance prescribing and with which the practitioner concurs. If the patient record is not available, the practitioner shall document the activity for his or her own record and shall transmit to the initial prescriber the prescription information. The initial prescriber shall include the prescription information in the patient's record.

(4) A practitioner may prescribe a controlled substance to his or her patient after review of the patient's record if the record contains the result of an examination performed by a consulting physician or hospital and such record warrants the prescribing.

(5) If a patient develops a new condition that would warrant the issuance of a prescription for a controlled substance, a practitioner may issue such prescription prior to performing an examination if: (i) the prescribing practitioner has a previously established practitioner/patient relationship with the patient; and (ii) an emergency exists; and (iii) the prescription does not exceed a 5-day supply as determined by the directions for use. An emergency means that the immediate administration of the drug is

necessary for the proper treatment of the patient and that no alternative treatment is available. If the practitioner prescribes such substance orally, the practitioner must comply with the requirements of section 80.68 and section 80.70 of this Part.]

(d) No controlled substance shall be prescribed prior to an in-person medical evaluation of the patient by the prescribing practitioner for the medical condition for which the controlled substance is being considered. The practitioner shall determine the parameters for the medical evaluation, and frequency of future medical evaluations as part of the patient's continuing treatment, utilizing generally accepted medical standards and taking into account the drug to be prescribed and the patient's medical condition, history and disposition toward the use of controlled substances.

(e) Notwithstanding subdivision (d) of this section, a controlled substance may be prescribed by a practitioner, in the absence of the practitioner performing an in-person medical evaluation, in the following circumstances:

(1) when utilizing a consulting or referring practitioner - for their patient after review of the patient's record if the record contains the result of an in-person medical evaluation performed by a consulting or referring practitioner within the previous 12 months specific to the medical condition for which the prescription is being considered.

(2) for a covering practitioner - in the temporary absence of the initial prescriber for a patient as part of a continuing therapy, provided the prescribing practitioner either:

(i) is part of the same practice as the initial prescriber and has direct access to the

patient's medical records, and such records warrant continued controlled substance prescribing, or

(ii) has direct and adequate consultation with the initial prescriber, who assures the necessity of continued controlled substance prescribing and with which the practitioner concurs. If the patient record is not available, the practitioner shall document the activity for their own record and shall transmit to the initial prescriber the prescription information within 72 hours. The initial prescriber shall include the prescription information in the patient's record.

(3) for a new condition in an emergency situation - if a patient develops a new medical condition that would warrant the issuance of a prescription for a controlled substance, provided that:

(i) the prescribing practitioner has a previously established practitioner/patient relationship with the patient;

(ii) an emergency exists such that the immediate administration of the drug is necessary for the proper treatment of the patient and no alternative treatment is available; and

(iii) the prescription does not exceed a 5-day supply as determined by the directions for use. If the practitioner prescribes such substance orally, the practitioner must comply with the requirements of section 80.68 and section 80.70 of this Part.

(4) through telemedicine - as such term is defined by article 29-G of the Public Health Law, consistent with all applicable state laws and regulations and the laws, rules and regulations of the Drug Enforcement Administration, United States Department of

Justice, or any successor agency. This is inclusive of any controlled substance as approved by the Food and Drug Administration (FDA), or its successor agency, and the New York State Department of Health for the treatment of opioid use disorder as listed in section 80.84 of this Part.

* * *

Section 80.84 is amended to read as follows:

80.84 Practitioners and pharmacies; prescribing, administering and dispensing for the treatment of opioid use disorder [narcotic addiction].

[Pursuant to the provisions of the federal Drug Addiction Treatment Act of 2000 (DATA 2000) (106 P.L. 310, Div. B, Title XXXV, Section 3502(a)), an authorized] A practitioner may prescribe, administer or dispense an approved controlled substance, and a licensed registered pharmacist may dispense an approved controlled substance, to a patient, pursuant to a prescription, for the treatment of opioid use disorder. [participating in an authorized controlled substance maintenance program approved pursuant to Article 32 of the Mental Hygiene Law for the treatment of narcotic addiction.]

(a) An *approved controlled substance* shall mean the following controlled substance which has been approved by the Food and Drug Administration (FDA), or its successor agency, and the New York State Department of Health for the treatment of [narcotic addiction] opioid use disorder:

* * *

[(b) An authorized practitioner is a practitioner specifically registered with the Drug

Enforcement Administration to prescribe, administer or dispense an approved controlled substance for the treatment of narcotic addiction, and approved for such purpose pursuant to the provisions of Article 32 of the Mental Hygiene Law.

(1) The total number of such patients of an authorized practitioner at any one time shall not exceed the limit established by DATA 2000 and the Department of Health and Human Services (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA), or its successor agency.

(2) An authorized practitioner prescribing an approved controlled substance for the treatment of narcotic addiction, in addition to preparing and signing an official New York State prescription or an electronic prescription in accordance with Section 3332 of the Public Health Law and Section 80.69 of this Part, shall also include his/her unique DEA identification number on the prescription.

(3)] (b) [An authorized] A practitioner may dispense an approved controlled substance for the treatment of [narcotic addiction] opioid use disorder in accordance with [S]section 3331 of the Public Health Law and [S]section 80.71 of this Part.

* * *

(c) A pharmacist may dispense an approved controlled substance for the treatment of [narcotic addiction] opioid use disorder pursuant to a prescription issued by [an authorized] a practitioner. Such dispensing shall be in accordance with [S]section 3333 of the Public Health Law and [S]section 80.74 of this Part.

REGULATORY IMPACT STATEMENT

Statutory Authority:

Section 3308 of the New York State Controlled Substances Act provides, in part, that the commissioner is authorized and empowered to make any rules, regulations and determinations which in their judgment may be necessary or proper to supplement its provisions to effectuate the purposes and intent thereof or to clarify its provisions so as to provide the procedure or details to secure effective and proper enforcement of its provisions.

Legislative Objectives:

The proposed rule clarifying patient evaluation requirements with regards to the issuance of a controlled substance prescription accords with the policy objectives the Legislature sought to advance by enacting the statutory authority, in that it will help ensure patients in the State have access to medically necessary controlled substance medications while mitigating risk of diversion.

Needs and Benefits:

This rule serves to clarify existing language with regard to the requirement for a practitioner to conduct an in-person medical evaluation prior to the issuance of a prescription for a controlled substance medication. Further, this rule serves to align allowances for the prescribing of controlled substance medications by telemedicine in New York State with federal law and regulation and to align New York State with changes made to 21 USC § 823, and reduce stigma associated with substance use

disorders.

The COVID-19 public health emergency (PHE) and associated quarantine and business closures resulted in reduced access to care for patients nationwide. This prompted the federal government to issue guidance for practitioners which expanded access to controlled substance prescribing via telemedicine. While this guidance permitted a practitioner federally to prescribe a controlled substance medication to a patient prior to conducting an in-person medical evaluation, New York State regulations at Title 10 of the New York Codes, Rules and Regulations (NYCRR) sections 80.62 and 80.63 continued to require a physical examination prior to the issuance of a controlled substance prescription. Subsequently, on January 31, 2023, the New York State Commissioner of Health issued a determination permitting controlled substance prescribing through telemedicine pursuant to the same processes as federal law and Drug Enforcement Administration (DEA) policy permit, limited to the duration of the federally declared public health emergency due to COVID-19, and provided it occurs in compliance with all other applicable Federal and New York State laws.

On February 24, 2023, the Drug Enforcement Administration announced proposed permanent rules for the prescribing of controlled substance medications via telemedicine, expanding patient access to critical therapies beyond the scheduled end of the COVID-19 public health emergency on May 11, 2023. The proposed rules provide regulations for a narrow subset of telemedicine consultations, consisting of telemedicine consultations by a medical practitioner that has never conducted an in-person evaluation of a patient, and which result in the prescribing of a controlled substance medication.

For these types of telemedicine consultations, the proposed rules allow medical practitioners to prescribe without having conducted an in-person evaluation or without a referral from a medical practitioner that has conducted an in-person evaluation: a 30-day supply of Schedule III-V non-narcotic controlled substance medications; or a 30-day supply of buprenorphine for the treatment of opioid use disorder. In both instances, the prescription must be otherwise consistent with all applicable Federal and State laws.

Further, existing language relating to the requirement to conduct a patient evaluation prior to issuing a controlled substance differs between state and federal regulations. Specifically, New York State regulations refer to an "examination" and "physical examination" while federal regulations require an "in-person medical evaluation". This variance contributed to confusion among the healthcare practitioner community with respect to the parameters and circumstances of the required examination or evaluation during the federally declared public health emergency due to COVID-19.

Beginning prior to the COVID-19 public health emergency, drug overdose deaths and opioid-involved deaths were already increasing in the United States. According to the Centers for Disease Control and Prevention, since 1999 more than 932,000 people have died from a drug overdose, and the number of overdose deaths involving opioids have quadrupled. In 2020 alone, 91,799 drug overdose deaths occurred in the United States, with opioids accounting for 74.8% of all drug overdose deaths.

As a means to combat this deadly epidemic, medication treatment of opioid use disorder (OUD) has been associated with reduced overdose and overall mortality. One

such FDA-approved medication indicated for the treatment of OUD is buprenorphine. Buprenorphine is a partial mu-opioid receptor agonist which works to suppress and reduce cravings for opioids. Due to its classification as an opioid, federal law placed strict limitations upon practitioners regarding its use in the treatment of opioid use disorder.

However, on December 29, 2022, the Consolidated Appropriations Act for 2023, was signed into law. This legislation included the Mainstreaming Addiction Treatment Act (MAT Act) provision. Prior to the MAT Act, federal law (21 USC § 823) required practitioners to obtain a special registration prior to prescribing buprenorphine to treat patients with opioid use disorder and placed limitations on the number of patients a practitioner may treat for opioid use disorder with buprenorphine. The MAT Act modified the restrictions in 21 USC § 823 to enable all health care providers with a standard Drug Enforcement Administration registration to prescribe buprenorphine for opioid use disorder, just as they prescribe other controlled substance medications. The limitation on the number of patients a practitioner may treat for opioid use disorder with buprenorphine was eliminated as well.

In its current form, 10 NYCRR § 80.84 references the special DEA registration requirement and the patient number limitations that are no longer in effect. Alignment of state regulations with federal law is necessary to avoid confusion among practitioners and pharmacies and to maintain access to lifesaving care for individuals with opioid use disorder. In addition to the conforming changes required to align with these recent changes to federal law, amendments to section 80.84 also include the removal of

stigmatizing language. Specifically, the outdated phrase “narcotic addiction” is replaced with commonly accepted term “opioid use disorder.”

Based on the foregoing, the Department has made the determination that this regulation is necessary to ensure that all patients continue to have access to medically necessary controlled substance medications through the practice of telemedicine, to resolve practitioner confusion regarding the required in-person medical evaluation, to further facilitate the prescribing of buprenorphine for OUD, and to mitigate the risk of diversion.

Costs:

Costs for the Implementation of, and Continuing Compliance with the Regulation to the Regulated Entity:

The proposed revisions do not impose any additional costs to the regulated parties.

Costs to State and Local Governments:

The proposed amendments will not require state and local governments to perform any additional tasks; therefore, it is not anticipated to have an adverse fiscal impact.

Costs to the Department of Health:

The proposed amendments will not impose additional costs to the New York State Department of Health.

Local Government Mandates:

The proposed regulations do not impose new mandates on any county, city, town or

village government; or school, fire or other special district.

Paperwork:

The proposed regulations do not require any additional forms or paperwork from regulated parties.

Duplication:

Sections 1300, 1304 and 1306 of Title 21 of the Code of Federal Regulations (CFR) regulate the issuance of prescriptions for controlled substance medication via telemedicine. This rule does not exceed any minimum standards for the same or similar subject areas, since it permits said practice in New York State to the extent allowed by federal law and regulation. Consequently, there is no duplication.

Alternatives:

None. The failure of the State to adopt this rule could result in restrictions in access to care, particularly for populations in rural and underserved areas, as well as for those seeking care for opioid use disorder. In light of these factors, there does not appear to be any viable alternative to the proposals in this rulemaking.

Federal Standards:

Sections 1300, 1304 and 1306 of Title 21 of the Code of Federal Regulations (CFR) regulate the issuance of prescriptions for controlled substance medication via telemedicine. This rule does not exceed any minimum standards for the same or similar subject areas, since it permits said practice in New York State to the extent allowed by

federal law and regulation.

Compliance Schedule:

It is anticipated that regulated persons would be able to comply with the rule upon publication of a Notice of Adoption in the New York State Register.

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STATEMENT IN LIEU OF

REGULATORY FLEXIBILITY ANALYSIS

No regulatory flexibility analysis is required pursuant to section 202-(b)(3)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse economic impact on small businesses or local governments, and it does not impose reporting, record keeping or other compliance requirements on small businesses or local governments.

STATEMENT IN LIEU OF

RURAL AREA FLEXIBILITY ANALYSIS

A Rural Area Flexibility Analysis for these amendments is not being submitted because amendments will not impose any adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no professional services, capital, or other compliance costs imposed on public or private entities in rural areas as a result of the proposed amendments.

STATEMENT IN LIEU OF

JOB IMPACT STATEMENT

A Job Impact Statement for these amendments is not being submitted because it is apparent from the nature and purposes of the amendments that they will not have a substantial adverse impact on jobs and/or employment opportunities.