Physician and Pharmacies; Prescribing, Administering and Dispensing for the Treatment of Narcotic Addiction

Effective date: 8/1/17

Pursuant to the authority vested in the Commissioner of Health by section 3308(2) of the Public Health Law, section 80.84 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon filing with the Secretary of State, to read as follows:

Section 80.84 is amended as follows:

Section 80.84 [Physicians] Practitioners and pharmacies; prescribing, administering and dispensing for the treatment of 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 [physician] practitioner may prescribe, administer or dispense an approved controlled substance, and a licensed registered pharmacist may dispense an approved controlled substance, to a patient 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:

(1) buprenorphine

(b) An authorized [physician] practitioner is a [physician] 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 [physician] practitioner at any one time shall not exceed [30] 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 [physician] 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) An authorized practitioner may dispense an approved controlled substance for the treatment of narcotic addiction in accordance with Section 3331 of the Public Health Law and Section 80.71 of this Part.

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

Regulatory Impact Statement

Statutory Authority:

Section 3308(2) of the Public Health law authorizes and empowers the Commissioner to make any regulations necessary to supplement the provision of Article 33 of the Public Health Law in order to effectuate their purpose and intent.

Legislative Objectives:

The legislative purpose of Article 33, and its associated regulations, is to combat illegal use of and trade in controlled substances and to allow legitimate use of controlled substances in health care authorized by the article or other law. This amendment will provide for increased access to treatment for persons addicted to opioids.

Needs and Benefits:

The rise of heroin and pharmaceutical opioid use has increased the need and demand for treatment throughout New York State. Deaths in New York have risen 50 percent in the last five years due to opioid overdose. Many of these deaths can be attributed to untreated opioid use disorder.

Statistics published in the "2015 New York State Opioid Poisoning, Overdose and Prevention Report to Governor Cuomo and the NYS Legislature" provide significant information of the widespread epidemic that has reached this state. According to the Report:

> In 2009, there were 1,538 reported deaths from unintentional drug poisonings in NYS. Toxicology tests identified heroin in 242 (16 percent) of these deaths and opioid analgesics in 735 (48 percent). In 2013, the latest full year for which data are available, the number of reported drug overdose deaths increased to 2,175, a 41 percent increase from 2009. The number of heroin-related deaths increased in 2013 to 637, and opioid analgesics related deaths rose to 952, increases of 163 percent and 30 percent from 2009, respectively. Opioid-related emergency department visits increased 73 percent from 2010 to 2014, 75,110 opioid-related inpatient hospital admissions were reported in 2014, an increase of 3 percent from 2010, and 118,875 (42 percent) of the 281,800 admissions to NYS certified substance abuse treatment programs in 2014 included "any opioid" as the primary, secondary or tertiary drug problem, up 19 percent from 2010 (100,004).

(See 2015 New York State Opioid Poisoning, Overdose and Prevention Report to Governor Cuomo and the NYS Legislature, page 1, available at: https://www.health.ny.gov/diseases/aids/general/opioid_overdose_prevention/docs/annual_report2015.pdf)

Under the federal Drug Addiction Treatment Act of 2000 (DATA 2000), qualified physicians are authorized to treat patients with opioid dependency, including heroin, with buprenorphine. Prior to the legislation the only treatment option for patients dependent on opioids was in a methadone treatment clinic. DATA 2000 increased the accessibility

of treatment for opioid use disorder, or more commonly referred to as, opiate addiction, in a community setting.

Many patients with substance use disorders, especially those living in rural areas, are underserved due to the lack of authorized physicians under DATA 2000. In July 2016, to address this issue, President Obama signed the Comprehensive Addiction and Recovery Act of 2016 (CARA) into law. CARA allows nurse practitioners and physician assistants to treat patients dependent on opioids with buprenorphine in an office-based setting. (See P.L. 114-198.) However, the Department's regulations, which were drafted in 2004, do not currently allow for this expanded field of providers and should be amended.

Further, to address the rapidly growing need to treat opioid use disorder in the office-based setting nationwide, the Department of Health and Human Services (HHS) recently adopted a rule to lift the limits on the number of patients doctors can treat with buprenorphine from 100 to 275. The rule increased access to medication-assisted treatment (MAT), which includes opioid treatment programs (OTPs). (See 81 FR 44711.) MAT combines medications, such as buprenorphine, and behavioral therapy to treat substance use disorders. With the adoption of this new federal rule, the Department's regulations refer to the now outdated prescribing limits.

The Department is proposing amendments to Section 80.84 to ensure consistency with these federal laws and regulations.

Costs:

Costs to Regulated Parties:

The amendment would not impose costs to regulated parties. The regulations simply increase access to treatment for persons addicted to opioids.

Costs to State Government:

There will be no additional costs to state government as a result of the proposed amendment.

Costs to Local Governments:

There will be no additional costs to local government as a result of the proposed amendment.

Costs to the Department of Health:

There will be no additional costs to the Department.

Local Government Mandates:

This amendment will not impose any program, service, duty, additional cost, or responsibility on any county, city, town, village, school district, fire district, or other special district.

Paperwork:

The proposed amendments would not increase paperwork requirements.

Duplication:

There are no duplicative or conflicting rules identified.

Alternatives:

The Department could choose to retain existing standards. This option was rejected because the discrepancy between federal and State standards would confuse practitioners and defeat the purpose of CARA, which is to expand access to treatment of people addicted to opioids.

Federal Standards:

The regulatory amendment does not exceed any minimum standards of the federal government.

Compliance Schedule:

This regulation will become effective upon filing with the Secretary of State.

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Statement in Lieu of Regulatory Flexibility Analysis

for Small Businesses and Local Governments

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

No rural area flexibility analysis is required pursuant to section 202-bb(4)(a) of the State Administrative Procedure Act. The proposed amendment does not impose an adverse impact or significant reporting, record keeping or other compliance requirements on public or private entities in rural areas. There are no other compliance costs imposed on public or private entities in rural areas as a result of the amendments.

Statement in Lieu of Job Impact Statement

No job impact statement is required pursuant to section 201-a(2)(a) of the State Administrative Procedure Act. It is apparent, from the nature of the proposed amendment, that it will not have an adverse impact on jobs and employment opportunities.

Emergency Justification

Drug addiction and accidental overdoses due to opioid prescription medication and heroin are at an all-time high in New York State and across the nation. The Drug Addiction Treatment Act of 2000 (DATA 2000) and New York State regulations currently permit qualified physicians to prescribe or dispense buprenorphine for the treatment of individuals with substance use disorder (SUD). Buprenorphine has been shown to be an effective treatment option for opioid dependence, providing a safe, controlled level of medication to overcome the use of a problem opioid. Recently enacted federal law and regulations allow for the expanded access to buprenorphine. However, to implement this in New York State, the Department's regulations must be amended.

In September 2016, the federal Substance Abuse and Mental Health Services Administration (SAMHSA) adopted a new rule that increased the number of patients that a practitioner can treat for opioid addiction in an office-based practice setting. Further, on July 22, 2016, the Comprehensive Addiction and Recovery Act of 2016 (CARA) was signed into law by President Obama, extending prescribing privileges to nurse practitioners and physician assistants to treat patients for opioid addiction with buprenorphine. Regulations in 10 NYCRR Part 80 are now outdated because they refer to a patient limit of thirty and restrict prescribing privileges to physicians.

According to the New York State Office of Alcohol and Substance Abuse Services (OASAS) data, more than 107,000 people were treated for opioid addiction in 2015, with

approximately 1,540 physicians certified to prescribe buprenorphine. It is clear that increased access to treatment is necessary, based upon the ratio of certified physicians to patients suffering from SUD. Expanding the authority to treat patients with SUD to physician assistants (PAs) and nurse practitioners (NPs), will greatly improve access for thousands of individuals across the state.

To ensure that individuals addicted to opioids have immediate access to treatment from authorized providers, including PAs and NPs, the Commissioner of Health has determined it necessary to file these regulations on an emergency basis. State Administrative Procedure Act § 202(6) empowers the Commissioner to adopt emergency regulations when necessary for the preservation of the public health, safety or general welfare and that compliance with routine administrative procedures would be contrary to the public interest. Removing the outdated legal obstacles in the current regulations would immediately allow experienced practitioners to treat addiction.