

# Now & Next

## Healthcare Alert

May 29, 2024

### **NYS Department of Health proposes amendments to controlled substances regulations**

By Justin D. Pfeiffer, Tina Sciocchetti, Jéna M. Grady, Rebecca Simone, and Mukta Chilakamarri

Changes would create exceptions to “in-person” examination requirements for prescribing, but further action may be necessary following anticipated new federal telemedicine guidance.



#### **What’s the impact?**

- NYSDOH acts to reduce discrepancies between federal and state controlled substance prescribing requirements by permitting healthcare providers to use telemedicine for patient evaluations before prescribing controlled substances.
- Although the proposed regulations appear to seek to align New York with federal DEA regulations proposed in February 2023, those were not finalized—DEA is working on new proposed regulations and NYSDOH may have to revise their proposed regulations in response.

On May 15, 2024, the New York State Department of Health (NYSDOH) [proposed regulations](#) that would revise its patient evaluation requirements when issuing a controlled substance

prescription. Although the COVID-19 pandemic prompted the federal government to issue guidance permitting controlled substances to be prescribed via telemedicine, NYSDOH initially did not provide guidance on whether New York State regulations, which require an “evaluation” before a provider may prescribe a controlled substance, meant that the evaluation could be provided via telehealth during the pandemic. In January 2023, [NYSDOH issued a determination letter](#), clarifying that controlled substances may be prescribed through telemedicine, pursuant to the same processes permitted under federal law and Drug Enforcement Administration (DEA) policies. The January letter cited provider “confusion” regarding the differences between New York State laws and regulations and the DEA federal public health emergency guidance and sought to provide clarity.

## **When can doctors prescribe medication without an in-person evaluation?**

The NYSDOH proposed regulations would limit circumstances in which a practitioner could prescribe a controlled substance medication without an in-person evaluation, thereby implicitly requiring an in-person evaluation for all other situations. The circumstances allowing a controlled substances prescription without an in-person evaluation would include:

- / when the patient’s record contains an in-person medical evaluation performed by a consulting or referring practitioner within the previous 12 months;
- / a covering practitioner prescribes the controlled substance as part of a continuing therapy in the temporary absence of the initial practitioner;
- / an emergency situation, wherein a patient develops a new medical condition that warrants the issuance of a prescription for a controlled substance, no alternative treatment is available, and the prescribing practitioner has an established practitioner/patient relationship with the patient; and
- / through telemedicine pursuant to all applicable state laws and regulations and the laws, rules, and regulations of the DEA and United States Department of Justice, or any successor agency.

The proposed regulations also attempt to minimize variances between DEA and state regulations by, for example, adopting the term “in-person medical evaluation,” and dispensing with the phrase “physical examination.”

## **Removing barriers to treating opioid use disorder**

The proposed regulations would also remove outdated references to a DEA registration requirement for prescribing buprenorphine to treat patients with opioid use disorder and a patient number limitation for buprenorphine prescriptions. Lastly, the proposed regulations

would remove the stigmatizing term “narcotic addiction” and replace it with the more commonly accepted term “opioid use disorder.”

## **Aligning state and federal controlled substance regulations**

NYSDOH’s proposed regulations are meant to align with the [DEA’s March 2023 proposed rules](#) for the prescribing of controlled substance medications through telemedicine. The DEA’s proposed rules would have permitted medical practitioners to prescribe a 30-day supply of Schedule III-V non-narcotic controlled substance medication, or a 30-day supply of buprenorphine for the treatment of opioid use disorder, without first having conducted an in-person evaluation or without a referral from a medical practitioner who has conducted such an evaluation.

Significantly, however, the DEA indicated that it would make significant changes to the rules it proposed in March 2023, citing the high volume of public comments. In September 2023, the DEA held two listening sessions to gather feedback from various stakeholders, and the agency indicated that it anticipated issuing a final rule in fall 2024 that would address the various issues raised by stakeholders.

Further, in October 2023, the DEA released a [Second Temporary Rule](#) that, among other things, extends the ability of providers to prescribe controlled substances via telemedicine without first performing an in-person evaluation until December 31, 2024. This raises a question as to whether the changes that are anticipated in the DEA’s final regulations will prompt NYSDOH to make similar revisions to its regulatory proposal, in the interest of consistency and alignment.

NYSDOH’s proposed regulations are open to public comment until July 14, 2024.

For more information on the content of this alert, please contact your Nixon Peabody attorney or:

**[Justin D. Pfeiffer](#)**

518.427.2742

[jpfeiffer@nixonpeabody.com](mailto:jpfeiffer@nixonpeabody.com)

**[Tina Sciocchetti](#)**

518.427.2677

[tsciocchetti@nixonpeabody.com](mailto:tsciocchetti@nixonpeabody.com)

**[Jéna M. Grady](#)**

212.940.3114

[jgrady@nixonpeabody.com](mailto:jgrady@nixonpeabody.com)

**[Rebecca Simone](#)**

516.832.7524

[rsimone@nixonpeabody.com](mailto:rsimone@nixonpeabody.com)

**[Mukta Chilakamarri](#)**

518.427.2665

[mchilakamarri@nixonpeabody.com](mailto:mchilakamarri@nixonpeabody.com)

