

August 15, 2022

The Honorable Mary T. Bassett Commissioner, New York State Department of Health New York State Department of Health Corning Tower, Empire State Plaza Albany, NY 12237

RE: CONCERN REGARDING NEW YORK DEPARTMENT OF HEALTH POLICY REGARDING CONTROLLED SUBSTANCES

Dear Commissioner Bassett,

On behalf of undersigned organizations focused on health care access and public health, we are writing to express our concern and to ask the New York State Department of Health ("NYSDOH") to clarify recent confusion regarding the appropriate prescribing of controlled substances via telehealth.

In recent months, our organizations have heard from multiple members who have been unable to obtain Drug Enforcement Agency (DEA) registrations for New York-licensed practitioners who live out-of-state. Representatives from both the DEA and the NYSDOH have reportedly indicated that New York State does not allow the prescription of controlled substances without a initial in-person visit from the prescriber and have asked certain applicants to withdraw their DEA applications since they would not be able to meet this standard without having an in-state brick-and-mortar facility.

We are concerned about these application delays because New York state law or regulation does not mandate an initial in-person physical examination before the prescription of controlled substances. While we have heard specific representatives at the DEA and NYDOH cited NY Rules and Regulation 80.62 and 80.63(d)(1) in their explanations, these regulations only require that providers conduct an "examination of the patient" and a "physical exam as indicated," respectively.

The requirement of a "physical exam" is not the statutory equivalent to an in-person encounter. Our members in New York and across the country routinely conduct appropriate virtual physical examinations¹ via telehealth when indicated by the standard of care (and of note, mental and behavioral health examinations rarely require a physical component). When a practitioner is unable to obtain the data they need during a virtual physical examination, clinical best practice

¹ See also, Benzinger et al, The Telehealth Ten: A Guide for a Patient-Assisted Virtual Physical Examination, Amer.J. of Medicine (2020) (here); U.S. Dept Health and Human Services Guide to Conduct a Telehealth Physical Exam (here); Stanford Medicine: How to Administer a Virtual Physical Exam (here); ATA ACTION



indicates that then they should certainly recommend a patient be seen in-person. Such decisions should be based on clinical discretion rather than state mandates.

Prior to and throughout the pandemic, New York licensed providers have safely prescribed controlled substances remotely using telemedicine to new and existing patients, increasing access to clinically appropriate medications, including for mental health and substance use disorder treatment. The Journal of Substance Abuse Treatment published a study on two harm reduction primary care programs providing buprenorphine treatment for opioid use disorder via telehealth and found the absence of in-person requirements greatly increased access to care and addressed health inequities.²

Further, the recent references to an in-person evaluation being required under New York regulations surprised our organizations because this interpretation does not align with prior statements and actions from the State on telehealth policy and promotion. A May 10, 2022 "Informational Bulletin" from the New York Office of Mental Health (OMH)3 references the requirement for an in-person examination for prescribing controlled substances under federal law (currently waived), but makes no reference to any corresponding requirement under New York state law or regulation. Additionally, earlier this year, Governor Hochul announced funding to allow providers to expand telehealth services for substance use disorder services – including medication assisted treatment (typically a controlled substance)—and stressed that "New Yorkers struggling with addiction should have access to telehealth services that will provide the treatment they need." This pronouncement and subsequent request for information, which we applaud, would have limited reach if providers were expected to see each patient in-person.

We respectfully request the NYDOH issue guidance quickly to clarify that New York does not have a mandate for an initial in-person exam to prescribe controlled substances and that providers may conduct any requisite examinations under NY Rules and Regulation 80.62 and 80.63(d)(1) via telehealth where appropriate and in accordance with the clinical standard of care. Without such clarity, we are concerned that inconsistent interpretations from the NYDOH will cause confusion and could result in many patients, especially new patients seen for the first time by a clinician during the pandemic, being arbitrarily left without access to care. This would be especially dire considering the shortage of behavioral health providers in New York, the ongoing drug overdose crisis, and a burgeoning mental health crisis precipitated by the pandemic.

If the NYDOH determines that an in-person examination is now required for all patients, this substantive change in policy should only occur following public comment and engagement, and at a minimum, give New York licensed practitioners sufficient time to ensure continuity of care for their patients. Indeed, requiring the prescriber to conduct an initial in-person exam would

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² Wang et al., *Telemedicine increases access to buprenorphine initiation during the COVID-19 pandemic* Journal of Substance Abuse Treatment 104 (2021) available here

³ https://omh.ny.gov/omhweb/guidance/prescription-controlled-substances-after-emergency.pdf

⁴ NYS OASAS Request for Applications for SUD Telehealth Services (Feb 2022)



make New York regulations more restrictive than federal law and could even foreclose practitioners' longstanding use of the telehealth exemptions in the federal Ryan Haight Act, including the in-patient exemption.

We appreciate the NYDOH's timely attention to this matter, especially in light of a global pandemic. The shift to telemedicine has quickly evolved over the past two years and the data proves that it is an effective tool for safe and timely care of patients in need of treatment requiring controlled substances. If possible, we would welcome a discussion with NYDOH to bring resolution to this issue. To facilitate this meeting, please contact kzebley@ataaction.org at ATA Action.

Sincerely,

American Academy of Child and Adolescent Psychiatry American Psychiatric Association The American Telemedicine Association ATA Action New York Council on Child and Adolescent Psychiatry New York State Psychiatric Association