March 31, 2023

Docket No. DEA-948

To Whom It May Concern:

I am submitting comment as President, and on behalf, of the New York County Psychiatric Society (NYCPS), a non-profit membership association representing over 1600 psychiatrists in Manhattan and Staten Island. Our members work in a variety of settings including outpatient clinics, inpatient hospitals, emergency departments, jails and prisons, and homeless shelters and will be directly impacted by the proposed changes in the “Expansion of Induction of Buprenorphine via Telemedicine Encounter”, Docket No. DEA-948. We recognize the DEA’s obligation to prevent drug diversion, in turn promoting public health, and appreciate the opportunity to comment on these rules.

As public health advocates and psychiatrists treating complex substance use disorders in a post-pandemic country during an ongoing opioid public health crisis, we wish to focus our recommendations on opportunities for DEA enforcement of the legitimate prescription of controlled substances while reducing harm to access to care and public health.

**PRIORITIZED RECOMMENDATIONS**

1. **Allowance for referring practitioners to not be DEA-registered.**

A requirement for DEA registration for qualified telemedicine referrals would significantly restrict access to care without a compelling benefit to law enforcement. To require a DEA registration to even make a referral to a licensed and registered practitioner ignores the reality that many in the community, including midlevel practitioners, do not hold a DEA registration and would be prevented from referring to a qualified practitioner.

Requiring that an initial DEA-registered practitioner conduct a physical exam leads to significant barriers to care. It penalizes patients with unmet health-related social needs including uninsurance or underinsurance, mobility and transportation challenges, and geographic disparity – all significant, preventable risks to population health. Telemedicine during the pandemic allowed the New York City Department of Homeless Services shelter system to prevent opioid overdoses in a dramatic way due to the ability to initiate medications for opioid use disorder in the most low-barrier way possible. Reducing access barriers is particularly important for immigrants, people who are unhoused, and a significant population of people already experiencing systemic racism; all of whom may have limited access to care within establish health systems. Telemedicine has continued to be used to great effect to allow patients to access care in the way that is most safe and convenient, not to mention cost effective to them. Requiring additional DEA registered practitioners conduct a physical exam eliminates these benefits to the underserved populations we treat.

1. **Removal of any in-person requirements for buprenorphine for the duration of the opioid public health emergency.**

The requirement for an in-person evaluation to initiate buprenorphine creates a significant barrier for people with opioid use disorder (OUD). As mental health professionals, we recognize the importance of initiating medications for OUD as soon as the patient is interested in order to engage them in care and prevent an opioid overdose. There is no clinical reason to uniformly delay started buprenorphine with an in-person evaluation requirement. At various community service health care organizations in New York City, telepsychiatry has been essential to delivering high quality care to those in the most need. Whether this be audio only, or combined audio-visual, clients can safely be treated for OUD via telehealth. This benefits patients and health systems because it reserves on-site resources for only those most medically complex cases of OUD. Additionally, evidence suggests that telepsychiatry (both via telephone and videoconferencing) is both feasible and acceptable for individuals with SMI and may improve client outcomes (Baker et al. 2018; Kasckow et al. 2014). This is a particularly hard-to-reach population when there is a co-morbid OUD, making telehealth an even more crucial option.

At the very least*,* if DEA does not remove the in-person requirements for maintenance of buprenorphine following a virtual initiation of treatment, DEA should ensure that the 180-day off-ramp discussed in the companion proposed rule (“Telemedicine Prescribing of Controlled Substances when the practitioner and the patient have not had a prior in-person medical evaluation”) will be applicable for buprenorphine as well. As many patients will need to find new providers within a travelable distance with this in-person requirement, a rapid transition to mandatory in-person evaluations will likely lead to patients dropping out of care or experiencing lapses in medication, which can greatly increase their risk of overdose.

1. **Reduction in administrative requirements for referring and prescribing practitioners.**

The administrative burden of these proposed rules is significant. Clinical data management systems are not configured with these components in them, and those upgrades are expensive and time-consuming – certainly not feasible within the timeframe of the finalization and implementation of these rules. Our members who built templates for telepsychiatry during the COVID 19 pandemic for imbedded substance use disorder and psychiatric services in the New York City Department of Homeless Services Shelters and affiliated federally qualified health centers (FQHCs) reported the difficulty of creating and implementing these types of functionalities into an electronic health record. This process could realistically take months to draft, test, and implement.

Specific administrative requirements that must be removed in the final rules include:

* The requirement for the practitioner to report their physical address during the telemedicine encounter; practitioners should be able to use a business address.
* The requirement for the prescribing practitioner to be identified by NPI by the referring practitioner, as the referring practitioner may not know the prescribing practitioner’s availability; the referring practitioner should be able to refer to a practice or to a DEA-registered practitioner in general.
* The requirement to only issue a 7-day prescription if the PDMP is not accessible. Most states already require clinicians to access the PDMP prior to issuing a prescription for a controlled substance, but those states *do not* restrict access to care for the patient as a result of this requirement. This is a patient safety issue.
* Remove the requirement to have telemedicine prescription written on the prescription. Patients are already facing barriers to having prescriptions filled due to pharmacy policies. We are concerned that this will create further barriers to having legitimate prescriptions filled in a timely manner. This is completely unnecessary and does not enhance patient care or patient safety.
* Finally, the implementation of administrative requirements in clinical information systems must have at least a 12-month grace period to allow for upgrading and configuration of the electronic medical record. We reinforce that these requirements are not feasible on DEA’s proposed timeline.

1. **Reduction in additional state-based registration requirements.**

The requirement that prescribing practitioners have a DEA registration in the state they are in when they are issuing the prescription is a needless restriction on access to care. The requirement that the prescriber be DEA-registered, as well as hold an active medical license, in the state the patient is in at the time is a reasonable mechanism to ensure patient protection. This is an opportunity for the DEA to promulgate rules for a telemedicine special registration for eligible prescribing physicians. Allowing for this type of flexible telehealth will improve access for patients and also ensure continuity of care by reducing the barriers to clinically appropriate, regular follow-up appointments with the prescribing physician.

We encourage the DEA to consider what the impact would be to patients if their prescriber is, for example, traveling to attend a professional conference when the patient needs a refill or, as is often the case in NYC, visiting family in nearby states like New Jersey and Connecticut. Is the patient to be denied life-saving medication and continuity of care? Instead, these rules should adopt language from the Ryan Haight Act: that the practitioner may prescribe from a state in which the practitioner is not registered if the practitioner is temporarily out-of-state. This exception can be documented in the patient’s clinical record if needed.

1. **Removal of clinical decision-making from regulation in these proposed rules.**

We note that there are significant components of this rule that constitute clinical decision-making, including the 30-day telemedicine supply allowance and the requirement for a physical examination prior to initiation of controlled substances. Duration of treatment, a physical examination, and the specific data needed to prescribe are clinical decisions and vary based on the medication being prescribed; there is not a unified standard of care that describes prerequisites for all these classes of medications.

Recognizing the need for DEA to establish objective guardrails that can be enforced to reduce diversion, DEA is encouraged to defer to clinical decision-making in these instances. DEA is encouraged to instead identify and investigate markers of overprescribing and prescribing practices that objectively lead to increased diversion in close partnership with HHS agencies and clinical advisors.

With the acute shortage of mental health professionals and psychiatrists, NYCPS encourages the DEA to exercise law enforcement authority to prevent diversion and inappropriate prescribing rather than enforce upstream restrictions on care, furthering stigma on legitimate mental health and substance use disorder treatment.

Sincerely,

Jeremy Kidd, MD, MPH

President