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March 31, 2023

Anne Milgram
Administrator
Drug Enforcement Administration
8701 Morrissette Drive
Springfield, Virginia 22152

Submitted electronically via www.regulations.gov

RE: RIN 1117-AB78 Expansion of Induction of Buprenorphine via Telemedicine Encounter (DEA948) and RIN 1117-AB40 Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation (DEA407)

Dear Administrator Milgram:

The Healthcare Association of New York State, on behalf of our member nonprofit and public hospitals, nursing homes, home health agencies and other healthcare providers, writes in response to the DEA's proposed rules to make permanent certain telehealth flexibilities for prescribing controlled substances.

The elimination of in-person visit requirements for the prescription of controlled substances during the public health emergency has addressed longstanding obstacles to care, including transportation, childcare, stigma and access to local prescribing practitioners. This is reflected in the significant decrease in missed appointments since telehealth flexibilities were implemented.

HANYS agrees that an appropriate medical evaluation is essential to prescribing controlled substances. Our members routinely adhere to rigorous care delivery standards for the diverse services they provide. They conduct telehealth visits in compliance with the rules and quality reporting requirements of multiple governing bodies including the Centers for Medicare and Medicaid Services and the State of New York, Medicaid and other payers, accrediting organizations and their own governing boards.

HANYS commends the DEA's efforts to make telehealth prescribing flexibilities permanent. However, the proposed rules as written contain unnecessarily restrictive elements and would likely result in more harm than benefit.

Our comments on specific proposals are below.

In-person medical examination requirement

The proposed rule would require patients to receive an in-person examination if they need more than a 30-day prescription of buprenorphine or non-narcotic schedule III-V controlled medications. While the intent of this requirement is to safeguard the integrity of patient care, the in-person visit requirement has substantial unintended downstream impacts.

Patient harm

Using an inflexible prescribing timeframe would disrupt the treatment of patients who are unable to attend an in-person visit within the specified period. Suspending access to medication would lead to patient harm, especially for medications where there are considerations for withdrawal, overdose, relapse and even death. Without treatment, medical conditions may also deteriorate, potentially impacting the patient's ability to maintain relationships, employment and housing. It is imperative that the DEA's proposals do not contribute to dangerous interruptions in care.

Workforce shortages

Severe workforce shortages are widespread across the country, especially in rural locations. Telemedicine has been a lifeline to patients living in these areas. Hospitals and health systems have been able to successfully meet patient needs by relying on telehealth prescribing practitioners. Requiring an in-person visit when it is not medically necessary would harm access to care in communities with workforce shortages.

Health disparities

Studies have demonstrated that people with unmet social needs are more likely to experience challenges accessing care, resulting in higher rates of missed appointments. Requiring an in-person visit would likely perpetuate health disparities. Controlled substances are also often used to treat behavioral health conditions. Persistent stigma and discrimination against individuals with mental illness and substance use disorders are a well documented barrier to seeking in-person care. Telehealth offers a more discreet way to access treatment.

The 30-day in-person visit requirement is also incompatible with the current healthcare environment. A 2022 report indicated that the average wait time for physician appointments in 2017 was 26 days. This wait time was before the historic workforce shortages we are experiencing now and does not include extensive wait times for the more limited behavioral health prescribers. Further, in-person visit requirements are inconsistent with harm reduction principles promoted in the *National Drug Control Strategy* and the removal of an in-person requirement to prescribe buprenorphine for Opioid Treatment Programs in a recently proposed rule, 42 CFR Part 8.

There is no evidence to date suggesting that an in-person medical evaluation would improve outcomes more than a telehealth evaluation when prescribing controlled substances. Legal remedies already exist for the small number of practitioners who do not provide evidence-based care.

HANYS strongly urges the DEA to remove in-person visit requirements and provide prescribers with the flexibility to determine the type of visit and frequency for which patients need an in-person visit.

Recordkeeping requirements

The DEA proposes that providers maintain extensive records in designated locations, including tracking logs for prescriptions and referrals with details about individual practitioners.

These requirements create a new process outside of existing procedures and are disconnected from current care pathways. They impose onerous administrative burdens that do not contribute to the advancement of patient care. Circuitous rules governing behavioral health services are dissuading desperately needed practitioners, such as psychiatrists, from joining the behavioral health field and deterring the expansion of services.

HANYS urges the DEA to simplify documentation requirements. For example, the DEA should allow reporting logs to reference a medical practice or health system instead of a specific provider.

Special registration regulations are needed

HANYS strongly urges the DEA to propose regulations to establish the special registration required by the *SUPPORT Act of 2018*. The special registration process would centralize the monitoring process for the DEA, eliminate the need for additional regulations and help ensure compliance. The DEA continues to subvert Congress' intent by failing to comply with the deadline orginally imposed by the *Ryan Haight Act of 2008* and reinforced in the *SUPPORT Act*.

Lastly, the estimated administrative time is vastly underestimated for both the recordkeeping requirements and the extensive care coordination necessary to ensure patients return for the 30-day in-person visit.

Thank you for the opportunity to provide feedback on the proposed modifications to the proposed regulations. If you have questions, contact me at 518.431.7889 or vaufiero@hanys.org or Sarah DuVall, director, behavioral health, at 518.431.7769 or sduvall@hanys.org.

Sincerely,

Victoria Aufiero, Esq.
Vice President, Insurance, Managed Care and Behavioral Health