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HOSPITALS & HEALTH SYSTEMS

March 30, 2023

Ms. Anne Milgram
Administrator
United States Drug Enforcement Administration
8701 Morrissette Drive
Springfield, VA 22152

RE: DEA-948, Expansion of Induction of Buprenorphine via Telemedicine Encounter

Dear Administrator Milgram:

On behalf of our more than 200 hospital and health system members, of which more than half have dedicated behavioral health beds, several participate in substance use treatment programs, and many employ prominent health care leaders who dedicate their work to aiding Floridians with mental illness and substance use disorders, the Florida Hospital Association (FHA) is grateful for the opportunity to comment on the Drug Enforcement Administration's (DEA) proposed rule regarding telemedicine for prescribing buprenorphine. FHA is pleased that the proposed rule seeks to expand access to substance use disorder treatment compared to the pre-pandemic landscape; however, FHA is concerned that the requirement to conduct an in-person examination to prescribe refills of medication for opioid used disorder (OUD) beyond an initial 30-day supply is not medically necessary and will unnecessarily limit access to this vital medication.

According to the Centers for Disease Control and Prevention (CDC), an estimated 107,956 Americans died from a drug overdose between September 2021 and September 2022; of those overdose deaths 8,098 were Floridians. Treatment for substance use disorders, including use of evidence based OUD medication, can help move individuals towards recovery. Unfortunately, a variety of factors, including stigma and inadequate access to transportation, have historically limited access to treatment.

Data on substance use treatment during the pandemic suggests that the use of telehealth visits dramatically expanded access to OUD medication. The 2021 National Survey on Drug Use and Health found that, among individuals aged 12 or older in 2021

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who received treatment for substance use disorder, 72.9 percent received medication for OUD – a substantial increase from just under one-third in 2020. A CDC study, published in *JAMA Psychiatry*, found that receiving OUD related telehealth services was generally associated with significantly better OUD medication treatment retention and lower risk of medically treated overdose.

Our members have also seen a positive impact in their communities. One public system noted that telemedicine has opened up psychiatric services to a large community that otherwise would not be able to find local or nearby psychiatric care. They have observed that patients are more comfortable seeing mental health care professionals virtually, in the comfort of their chosen environment. In addition, parents of minor patients have reported that utilization of telemedicine has reduced the burden required to ensure their children get the mental health care they need – ie., they do not need to take off work, pick a child up from school, take the child to the mental health professional, return the child to school and then go back to work. In short, telehealth increases the availability of care.

FHA appreciates that the DEA is charged with overseeing the safe prescribing of controlled substances, including via telehealth. During the COVID-19 public health emergency (PHE) the DEA enacted flexibilities to ensure continued patient access to lifesaving medications while minimizing exposure to COVID-19 and preserving provider capacity. One such waiver eliminated the requirement for an initial in-person visit prior to prescribing controlled substances via telehealth and allowing the use of telephone evaluations to initiate buprenorphine prescribing. The DEA's actions during the PHE proved critical in providing access to patients; the DEA should apply the lessons learned during the PHE to future telemedicine treatment rules.

The proposed rule does not take advantage of the authority granted to the DEA in the Ryan Haight Act of 2008, which outlined several categories where an in-person evaluation could be waived including during a PHE and for other circumstances such as "treatment by a practitioner who has obtained a special registration." Instead of relying on lessons learned during the PHE and extending flexibilities, the DEA has proposed to impose burdensome restrictions and additional administrative requirements on providers and patients, which FHA believes will adversely impact patient access to medically necessary OUD treatment. FHA offers the following recommendations to

maintain safe and accessible telemedicine care for patients with OUD. The DEA should:

- **Develop a special registration process and identify a pathway to waive in-person evaluations prior to the prescribing of controlled substances**, especially buprenorphine, for practitioners who register with the DEA. The DEA has ample authority to do so – the Ryan Haight Act authorizes such registries and 2019s SUPPORT for Patients and Communities Act reinforced the requirement.

- Establishing the special registry may take time and should involve significant stakeholder input. As the DEA considers a methodology that should be less administratively burdensome for providers and certainly less burdensome for patients they will need to establish an interim telemedicine rule regime. **Therefore, the DEA should extend the waivers for in-person visit requirements for prescribing of controlled substances until it develops and proposes an in-person waiver registry.**

- **Remove the 30-day supply limit and allow clinicians to determine the appropriate frequency of in-person exams**. In the proposed rule, the DEA proposes that initial prescriptions would not be able to exceed a 30-day supply. To receive additional quantities, the patient would need to be examined in-person by the prescribing practitioner; be examined remotely by the prescribing practitioner while in the physical presence of another DEA registered practitioner participating in an audio-video telemedicine encounter; or receive a qualifying telemedicine referral from a DEA-registered practitioner prior to issuing a prescription. The referring practitioner would also need to complete a face-to-face evaluation. **These requirements, and supply limits, are arbitrary, unnecessarily burdensome and could reduce access to care.** Supply limits and visit frequency should be left to clinical-judgement.

- The DEA has proposed regulations that would require practitioners to review Prescription Drug Monitoring Program (PDMP) data prior to prescribing buprenorphine. **FHA agrees that PDMPs can be a successful tool to combat OUD and we recommend that the DEA create exceptions to any proposed rule where state law already requires prescribers to consult a PDMP.**

Florida statute 893.055, requires the state Department of Health to maintain an electronic system to collect and store controlled substance dispensing information. The state requires a prescriber to "consult the [PDMP] to review a patient's controlled substance dispensing history before prescribing or dispensing a controlled substance for a patient age 16 or older." Florida's PDMP has proven successful. Year after year the state sees fewer opioid prescriptions dispensed, and those that are dispensed contain fewer morphine milligram equivalents. In addition, there have been annual reductions in multiple provider episodes or "doctor shopping."

The Florida law recognizes that computer systems experience technical glitches and are not always operational. Exceptions on PDMP usage exist when the state system, or the prescriber's system, is not accessible. In instances of technical difficulties prescribers must document the reason for not consulting the system. Unlike the proposed rule, which would limit a prescription to 7 days, the state law does not place limits on the length of a prescription for system outage. **We encourage DEA to eliminate prescription restrictions when a technical issue prevents a prescriber from consulting the PDMP.**

- **Reconsider the burdensome record keeping requirements found in the proposed rule.** The proposed rule would impose significant administrative burden on prescribing practitioners, and where applicable, the referring provider or provider physically present with the patient during a telemedicine visit. For example, it would require practitioners to keep written or electronic logs of each prescription issued. It also states that in instances where the prescribing practitioner is virtually connected to another DEA practitioner who is physically with a patient for the medical evaluation, both the prescribing practitioner and the practitioner physically with the patient would have to maintain logs of the visit and prescription. If a practitioner makes a referral for a telemedicine prescription, the referring provider will also need to keep records of the written referral.

  The DEA states that these additional recordkeeping barriers, in addition to the in-person visit requirement for ongoing prescriptions, are necessary to mitigate the risk of diversion. However, the agency did not provide data demonstrating that access to OUD medication via telemedicine poses an increased risk. Instead, data from the National Institute on Drug Abuse and the Centers for Disease

Control and Prevention demonstrate that the proportion of opioid overdose deaths involving buprenorphine did not increase in the months after prescribing flexibilities were put in place during the COVID-19 pandemic. Further, investigators found that most people who died of an overdose involving any opioid had no evidence of current treatment for substance use disorders.

We thank you for considering these comments. If you have any questions please do not hesitate to contact me or Michael Williams at mwilliams@fha.org.

Sincerely,

Mary C. Mayhew
President and CEO
Florida Hospital Association