March 30, 2023

The Honorable Anne Milgram, Administrator
United States Drug Enforcement Administration
800 K Street NW, Suite 500
Washington, D.C. 20001

RE: Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation
Docket No. DEA–407  RIN:1117-AB40

Submitted electronically on regulations.gov

Dear Administrator Milgram:

Thank you for the opportunity to submit comments on the proposed rules, “Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In-Person Medical Evaluation.”

The Hospice and Palliative Nurses Association (HPNA) is the national professional organization that represents the specialty of palliative nursing, which includes hospice and palliative nurses. Established in 1986, HPNA is the only nursing organization of its kind. Our mission is to advance nursing expertise in hospice and palliative care through education, advocacy, leadership, and research, and our vision is for every person living with serious illness to receive equitable, comprehensive, and innovative hospice and palliative nursing care. The nearly 10,000 members of HPNA are hospice and palliative care nurses committed to providing the highest level of treatment and dignity to their patients and families, including at the end of life.

Quality palliative care starts with successful symptom management. While ensuring effective symptom management should be a primary objective in every clinical setting, it is especially important in those settings that provide end-of-life care. The timely and effective management of pain and other symptoms is integral to the practice of high-quality palliative care, and opioid analgesics and other controlled substances are critical tools in alleviating the suffering of seriously ill patients.

HPNA is concerned that the above-referenced rule that addresses telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation (Docket No. DEA-407) could significantly reduce access to medically necessary opioid medications for seriously ill patients. We are also concerned that the 30-day comment period to analyze this rule is not a sufficient amount of time to fully analyze its potential impact on our members and the patients they serve.
Although we believe more time is needed to fully analyze the potential impact of these rules, initial feedback from our members raises several concerns about the policies outlined in the proposed rules. These concerns are highlighted below.

**Hospice clarification**

Medical prescribers, such as physicians, physician assistants, and nurse practitioners, are often tasked with prescribing controlled substances for patients who are in hospice, although the prescriber has never and will never meet the patient in person, due to the nature of providing care for patients with serious illness. Additionally, hospice patients may not always have had a recent in-person exam upon acceptance to hospice. The rule, as written, does not address the unique situation of providing care to hospice patients, and we urge DEA to provide a clarification or exemption for hospice prescribing to avoid any unintended consequences of the proposed rule. Congress has already recognized the unique role that hospice providers play and that the use of telehealth in hospice care is both efficient and safe. At the end of 2022, Congress passed, and the President signed, the Consolidated Appropriations Act, 2023 which extended Section 3706 of the CARES Act (PL 116-136) until the end of 2024. This important provision allows hospice organizations to perform the required face-to-face hospice eligibility recertification via telehealth rather than in person. We ask that the DEA follow the lead of Congress and recognize the unique situations that face hospice providers and patients before publishing your final rule.

**Team-based care for palliative patients**

Many palliative care patients, particularly those in rural areas, are homebound and unable to travel to their primary clinic. For these patients, telehealth is their main connection to healthcare. Additionally, there are concerns about various types of referrals, including palliative care referrals that come from home health rather than a medical office and initial palliative telehealth visits that are hosted on an electronic health record platform with a palliative nurse at the bedside and prescribing provider located remotely, with the nurse visiting on a monthly basis. As the rule is currently written, it is unclear whether either of these prescribing examples meets the threshold.

While we believe more time is needed to adequately analyze the potential impact of this proposed rule, we urge you to at the very least provide clarification for the situations outlined above. Additionally, we urge you to consider the hospice community consensus recommendations outlined by the National Coalition for Hospice and Palliative Care, of which HPNA is a member.

These recommendations include:

- Exempting prescriptions for individuals receiving hospice care from the Telemedicine Prescribing of Controlled Substances;
- Providing clarity that in-person evaluation requirements for prescribing controlled substances, including Schedule II medications, do not apply to patients enrolled in hospice;
- Clearly articulating that patients receiving hospice care are exempt from the in-person evaluation requirements;
- Allowing qualifying telemedicine referrals to be made to entire practices, rather than to individual prescribers at the NPI level, as the practice of medicine has evolved to team-based care; and
Providing clarification that the proposed regulations in 21 C.F.R. §1304.03 and §1304.04 regarding recordkeeping and reports related to telemedicine prescriptions and telemedicine referrals do not apply to hospice physicians prescribing medications to patients admitted to hospice under the regulatory framework described above. Requiring hospice practitioners whose patients are referred to hospice to create and maintain the types of documentation described by the proposed regulations noted above would result in delays for patients to receive time-sensitive and urgent end-of-life care.

Additionally, we support the Coalition’s recommendation to use regulatory authority to extend through at least the end of calendar year 2024 the telemedicine prescribing flexibilities for controlled substances – including buprenorphine – that have been in place in response to the COVID-19 PHE. This time period could then be used to work with stakeholders to implement a telemedicine special registration process that enables qualified practitioners to prescribe controlled substances via telemedicine without a prior in-person medical evaluation. This would support timely, effective care for patients with serious illness, including those who are receiving palliative care.

We are very concerned that without clarification of how the rule applies to hospice and palliative care providers, access to quality care for seriously ill patients could be severely impacted.

Thank you again for the opportunity to comment on this proposed rule. If you have any questions, please do not hesitate to reach out to Chad Reilly, MBA CAE, senior vice president, credentialing and health policy, at 412-787-9320 or by email at ChadR@HPNA.org.

Sincerely,

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