

March 31, 2023

**COALITION MEMBERS**

American Academy of Hospice  
and Palliative Medicine  
(AAHPM)

Association of  
Professional Chaplains  
(APC)

The Catholic Health Association  
of the United States  
(CHA)

Center to Advance  
Palliative Care  
(CAPC)

HealthCare  
Chaplaincy Network™  
(HCCN)

Hospice and Palliative  
Nurses Association  
(HPNA)

National Association for Home  
Care & Hospice  
(NAHC)

National Hospice and  
Palliative Care Organization  
(NHPCO)

National Palliative  
Care Research Center  
(NPCRC)

Palliative Care Quality  
Collaborative  
(PCQC)

Physician Assistants in Hospice  
and Palliative Medicine  
(PAHPM)

Social Work Hospice &  
Palliative Care Network  
(SWHPN)

Society of Pain & Palliative  
Care Pharmacists  
(SPPCP)

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**

Dear Administrator Milgram,

On behalf of the thirteen member organizations of the National Coalition for Hospice and Palliative (Coalition), we would like to thank the U.S. Drug Enforcement Administration (DEA) for the opportunity to comment on the proposed rule referenced above which addresses telemedicine prescribing of controlled substances for patients who have not received a prior in-person medical evaluation. The Coalition is dedicated to improving the care of people with serious or life-limiting illnesses by convening the field, advocating for equitable policies and improved health outcomes, establishing best practices, and sharing resources. We have worked with our thirteen national member organizations to develop these comments and recommendations.

Our members, which include organizations representing health professionals in both hospice and palliative care, have carefully reviewed the DEA's proposed rule regarding telemedicine prescribing of controlled substances when the practitioner and the patient have not had a prior in-person medical evaluation. While we recognize the difficult balance required to protect people in the context of the current opioid epidemic, we must note that the proposed rule has raised significant concerns among these dedicated professionals for whom the overarching goal is to treat pain and other distressing symptoms in a timely manner to alleviate the suffering of patients with serious illness and at the end of life. We offer four key recommendations below and provide further details on the pages that follow.

**[Summary of Coalition Recommendations](#)**

- **Hospice:** The Coalition urges the DEA to exempt prescriptions for individuals receiving hospice care from the proposed Telemedicine Prescribing of Controlled Substances rule and provide clarity that in-person evaluation requirements for prescribing controlled substances, including Schedule II medications, do not apply to patients enrolled in hospice.

- **Serious illness and palliative care:** The Coalition has also provided specific recommendations on components of the proposed rule for palliative care patients and urges DEA to carefully consider those recommendation listed below.
- **Alignment with the extension of Medicare telehealth flexibilities:** The Coalition urges DEA not to finalize the proposals contained in the two proposed rules. We urge the DEA to extend the current controlled substance telehealth prescribing flexibilities – including buprenorphine -- through the end of 2024. The intervening time can be used to work with the many impacted stakeholders to develop a process to implement this proposed rule with due consideration of the many concerns from prescribers and patients.
- **Special registration process:** The Coalition strongly recommends that DEA use this extension to work with stakeholders to implement a telemedicine special registration process. That could enable qualified practitioners to prescribe controlled substances via telemedicine without a prior, in-person medical evaluation and would support timely, effective care that meets the unique needs of patients with serious and life limiting illness receiving hospice and palliative care. If the special registration process was implemented, palliative care prescribers could specifically be considered as eligible for this program. DEA should issue regulations for such a special registration process with the goal of implementing such a process prior to the end of the PHE-related flexibilities. The Ryan Haight Act required DEA to establish a telemedicine special registration process that would allow controlled substances to be prescribed without an in-person medical evaluation of the patient. Congress again directed the promulgation of final regulations for a telemedicine special registration as part of the SUPPORT for Patients and Communities Act in 2018, but DEA has yet to issue such regulations.

### ***Background on Hospice***

Hospice care is a comprehensive, holistic approach to treatment of patients at the end of life who have opted to discontinue life-sustaining treatment or disease-modifying therapies. To be covered under the Medicare hospice benefit, services must be reasonable and necessary for the palliation and management of the terminal illness and related conditions. Under the Medicare hospice benefit, which is highly regulated by Centers for Medicare & Medicaid Services (CMS), there is an extensive, skilled admission evaluation, and subsequent monitoring intrinsic to the hospice model of care offers an equivalent to the in-person requirement in other prescribing venues.

Hospices are required under the Medicare Conditions of Participation (CoPs) to directly employ or hire under contract a medical director (medical doctor or doctor of osteopathy) whose role it is to oversee all the medical care provided by the hospice. The hospice medical director, physician employees, and contracted physicians, in conjunction with the patient's attending physician, are responsible for the palliation and management of the terminal illness and conditions related to the terminal illness (§418.64(a)). As such they write prescriptions for medications including Schedule II and/or narcotic

controlled medications and Schedule III, IV, or V non-narcotic controlled medications. Nurse Practitioners (NPs) employed by the hospice are also able to write such prescriptions, as permitted by state law.

Once patients are admitted to hospice, an interdisciplinary group (“IDG”) of health care practitioners, which must include a physician, develops, and then regularly updates an individualized plan of care. Other hospice services include nursing care, medical and social services, counseling, hospice aide services and, if necessary, medical supplies, including drugs and biologicals necessary for pain and symptom management. The hospice is responsible for providing and managing all such medications. Hospice team members, including advanced practice registered nurses, physician assistants, nurses, social workers, chaplains, and others based on need – are in regular face-to-face contact with patients, conducting a risk assessment to determine risk of diversion and implementing the use of lock boxes or limiting the “fill” to mitigate risk of medication misuse or abuse.

The vast majority of hospice patients are Medicare beneficiaries (accounting for more 90 percent of all hospice patient days in 2021)<sup>1</sup> with more than 1.7 million receiving hospice services in 2021 from 5,358 hospice providers.<sup>2</sup> The average age of a Medicare hospice patient in fiscal year (FY) 2020, the most current year for which such data is available, was 82 years. Care is delivered primarily in patients’ homes, but is also delivered in facilities – hospitals, hospice inpatient units, skilled nursing facilities, long term care facilities, and assisted living facilities.

### ***Hospice Exceptions***

In previous rulemaking, the DEA has recognized the unique needs of hospice patients and the physicians who care for them and has created hospice exceptions. (For example, practitioners prescribing schedule II drugs for a patient receiving hospice care from a Medicare-certified hospice program or a hospice program licensed by the state may transmit, or direct their authorized agent to transmit, a prescription by facsimile, and the facsimile may serve as the original written prescription.<sup>3</sup> Similarly, Congress and the DEA have established special controlled substance disposal procedures that are applicable to patients receiving hospice care.<sup>4</sup>

The Coalition urges the DEA to carefully consider the unique needs of terminally ill patients before finalizing the proposed rule, and to recognize the safeguards against abuse and diversion that are built into the existing framework for hospice care.

### ***Coalition Recommendations for Patients Receiving Hospice Care***

- The Coalition urges the DEA to exempt prescriptions for individuals receiving hospice care from the Telemedicine Prescribing of Controlled Substances and provide clarity that in-person evaluation requirements for prescribing controlled substances, including Schedule II

---

<sup>1</sup> [MedPAC March 2023 Report to Congress](#)

<sup>2</sup> [MedPAC March 2023 Report to Congress](#)

<sup>3</sup> 21 C.F.R. §1306.11(g).

<sup>4</sup> 21 U.S.C. §822(g)

medications, do not apply to patients enrolled in hospice.

- Given the well-documented and managed physician-patient relationship and the close ongoing monitoring involved in furnishing hospice care, the Coalition believes that restrictions under the Ryan Haight Act for telemedicine prescribing of controlled substances should not apply to patients enrolled in hospice. We respectfully request that DEA clarify that it agrees with our position by clearly articulating that patients receiving hospice care are exempt from the in-person evaluation requirements.
- The Coalition requests that DEA allow 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. Referrals come from many sources and a patient is typically not referred to a particular hospice physician.
- Hospice regulations address requirements for maintaining clinical records, including records related to medications, as well as regulations specific to drugs and biologicals provided to hospice patients.<sup>5</sup> We urge the DEA to clarify 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. We believe that hospice physicians and other advance practice providers (such as nurse practitioners and physician assistants) should not be required to create and maintain these separate types of clinical documentation described in the proposed rule, apart from what is required for hospice clinical documentation.

#### ***Background on Patients with Serious Illness Needing Palliative Care***

Palliative care is specialized medical care delivered by an interdisciplinary team of specially-trained clinicians whose care is aimed at treating the debilitating effects of serious and complex chronic illness – such as cancer, cardiac disease, respiratory disease, kidney failure, Alzheimer’s, ALS, and MS – and involves the relief of pain and other symptoms that cause discomfort. Palliative care has been shown to improve quality of care and quality of life for persons with serious or life-threatening illnesses. These medically vulnerable patients may experience mobility and/or cognitive limitations, and they can be particularly susceptible to morbidity and mortality associated with infectious diseases. They often contend with pain, frailty, or medical instability and/or rely on caregivers to assist with transportation. Additionally, patients with serious illness receiving palliative care may be in the last weeks or months of life; to illustrate, one palliative care physician reports that approximately 75 percent of his patients die each quarter.

In the face of this reality, the proposed policies – which include the restricted access to non-buprenorphine opioid medications without an in-person evaluation – could have significant impacts on

---

<sup>5</sup> 42 C.F.R. §418.104 and 418.106.

the seriously ill patients our member organizations serve. Palliative care clinicians would be hampered in their ability to furnish medically necessary and appropriate care and, in turn, patients would be limited in their ability to achieve timely relief of pain and suffering and to maximize quality of life. To prevent such outcomes, our recommendations include the following:

#### *Coalition Recommendations for Patients with Serious Illness Requiring Palliative Care*

1. DEA should allow qualifying telemedicine referrals to be made to entire practices, rather than to individual prescribers at the NPI level.
2. DEA should allow qualifying telemedicine referrals to take place within integrated health systems, consistent with existing referral practices, without additional documentation or recordkeeping requirements.
3. DEA should allow qualifying telemedicine referrals to come from practitioners who do not have active DEA Schedule II registrations, so long as the consulting practitioner is indeed registered.
4. DEA should clarify the conditions under which in-person evaluations from referring providers that occurred prior to the effective date of the rules may serve as the basis for telemedicine prescriptions.
5. DEA should defer to states regarding requirements to consult PDMPs, rather than impose PDMP review requirements for telemedicine prescriptions.
6. DEA should eliminate overly onerous documentation requirements for which existing infrastructure is not in place, including documentation of the city and state in which the patient is located during the telemedicine encounter, the address of the prescriber if he or she is engaging in telehealth from a usual practice location (including the prescriber's residence), the NPI of the referring practitioner, DEA registration status of a referring practitioner, and the time of a PDMP consultation.
7. DEA should not impose a limitation on the issuance of prescriptions for controlled medications to FDA-approved indications contained in the FDA-approved labeling for medications.
8. DEA should remove restrictions on telemedicine prescribing of buprenorphine for the treatment of OUD, including requirements for in-person evaluation and restrictions on quantity that may be prescribed.

#### *Conclusion*

Based on the above, the Coalition urges DEA to:

1. Exempt prescriptions for individuals receiving hospice care from the Telemedicine Prescribing of Controlled Substances and provide clarity that in-person evaluation requirements for prescribing controlled substances, including Schedule II medications, do not apply to patients enrolled in hospice.
2. Postpone finalizing these proposals contained in the proposed rule. We urge the DEA to extend the current controlled substance telehealth prescribing flexibilities – including buprenorphine -- through the end of 2024. The intervening time can be used to work with the many impacted stakeholders to develop a process to implement this proposed rule with due consideration of the many concerns from prescribers and patients.

3. Use this extension to work with stakeholders to implement a telemedicine special registration process. This process could enable qualified practitioners to prescribe controlled substances via telemedicine without a prior, in-person medical evaluation and would support timely, effective care that meets the unique needs of patients with serious and life limiting illness receiving palliative care. If the special registration process was implemented, hospice and palliative care prescribers could specifically be considered as eligible for this program. DEA should issue regulations for such a special registration process with the goal of implementing such a process prior to the end of the PHE-related flexibilities.

\*\*\*\*\*

Thank you again for the opportunity for our Coalition submit comments on the Telemedicine Prescribing proposed rule and share concerns raised by many organizations and individuals regarding potential barriers to providing high-quality, patient-centered care for patients with serious and life-limiting illness. The Coalition would be pleased to have the opportunity to meet and discuss with DEA the impact of this proposed rule or other potential changes on the patients our members serve. If you have any questions or would like to discuss in more detail, please contact Amy Melnick, MPA, Executive Director, at the Coalition at 202.306.3590 or [amym@nationalcoalitionhpc.org](mailto:amym@nationalcoalitionhpc.org).

Sincerely,

American Academy of Hospice and Palliative Medicine  
Association of Professional Chaplains  
Center to Advance Palliative Care  
HealthCare Chaplaincy Network  
Hospice Palliative Nurses Association  
National Association of Home Care & Hospice  
National Hospice and Palliative Care Organization  
National Palliative Care Research Center  
Palliative Care Quality Collaborative  
Physician's Assistants in Hospice and Palliative Medicine  
Social Work Hospice and Palliative Care Network  
Society for Pain and Palliative Care Pharmacists