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March 31, 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

Dear Administrator Milgram,

The National Hospice and Palliative Care Organization ("NHPCO") appreciates the opportunity to provide comments on Docket No. DEA-407. the Drug Enforcement Administration ("DEA") proposed rule on telemedicine prescribing of controlled substances.

NHPCO is the nation's largest membership organization for hospice and palliative care providers and professionals who care for people affected by serious and life-limiting illness. NHPCO members provide care in more than 4,000 hospice and palliative care locations and care for over two-thirds of the Medicare beneficiaries served by hospice. In addition, hospice and palliative care members employ thousands of professionals and volunteers. The patients receiving care from hospice and palliative care providers may have a wide range of diagnoses, including, but not limited to, neurodegenerative diseases, circulatory diseases, including congestive heart failure, respiratory diseases, including chronic obstructive pulmonary disease and cancers. Hospice patients regularly require controlled substances, including schedule II drugs, to control pain and other symptoms at the end of life, and hospice physicians and other practitioners have particular expertise in prescribing and managing the care for this special population.[1]

The DEA's proposed rule regarding telemedicine prescribing of controlled substances when the practitioner and patient have not had a prior in-person medical evaluation has raised a great deal

[1] Only physicians are authorized to certify or re-certify patients as eligible to receive hospice benefits, and in most cases, it is physicians who prescribe controlled substances for hospice patients, but some hospices do engage nurse practitioners (NPs) and physician assistants (PAs), so they also may be prescribers in compliance with applicable state law. The Medicare statute also allows patients to select an NP or PA as their hospice "attending physician".

of concern in the hospice community regarding the potential impact on access to hospice care and the ability of hospice physicians and other practitioners to provide timely and effective pain and symptom relief. While we do not believe that "telemedicine prescriptions" (as defined in the proposed rule) are commonly used for hospice patients, and we do not believe it is DEA's intent to interfere with appropriate prescribing of controlled substances for this patient population, we are concerned that it may be interpreted to do so. We want to ensure that DEA understands the needs of hospice patients at the end of life, how the hospice benefit is structured, and care is provided, and why there are concerns with the proposed rule.

In previous rulemaking the DEA has recognized the unique needs of hospice patients and the physicians and other practitioners 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 his or her authorized agent to transmit, a prescription by facsimile, and the facsimile may serve as the original written prescription.[2] Similarly, Congress established special controlled substance disposal provisions that are applicable to patients receiving hospice care.[3]

> **Recommendation for Hospice Patients:**
> With respect to this proposed rule, we request that the DEA recognize the need to allow hospice patients' continued access to receiving timely and essential medications for pain and symptom management under the regulatory framework in place for hospices. Accordingly, we are requesting that DEA exempt prescriptions for individuals receiving hospice care from the proposed Telemedicine Prescribing of Controlled Substances rule and clarify that the proposed telehealth prescribing regulations will not create impediments to the well-established practices of hospice physicians and other practitioners who prescribe controlled substances for hospice patients.

Background

What is Hospice: Hospice care is a comprehensive, holistic approach to treatment of patients at the end of life who have opted to 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 terminal illness and related conditions. 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. Hospice services include physician services, nursing care, medical social services, counseling, hospice aide services, and necessary medical supplies, including drugs and biologicals necessary for pain and symptom management. The hospice is responsible for providing and managing all medications.

The goal of hospice is to make the patient as physically and emotionally comfortable as possible, and for many hospice patients this includes the need for controlled substances, including Schedule

[2] 21 C.F.R. §1306.11(g).
[3] 21 U.S.C. §822(g).

II drugs. Nurses, hospice aides and other team members are regularly in and out of the patient's home, both delivering services and assessing whether changes in medications or other aspects of the plan of care are needed, but an in-person examination by a physician is rarely necessary.

Description of Hospice Patients: The vast majority of hospice patients are Medicare beneficiaries, "accounting for more than 90 percent of all hospice patient days in 2021."[4] Medicare has provided a carefully structured hospice benefit for 40 years. And regardless of the patient's payer source, Medicare certified hospices are required to provide services in accordance with the Medicare Conditions of Participation. Hospice benefits, which include drugs for pain and symptom management, are only available to patients who have been evaluated and certified by a physician to be terminally ill, and whose prognosis is expected to be six months or less if the illness runs an expected course, and who have elected to discontinue curative or disease modifying treatments. Although the hospice benefit does include short-term inpatient care for patients whose pain and symptoms cannot be managed at home, most hospice patients prefer to receive services wherever they call home. Over 98% of hospice days of care are provided at the patient's residence, and of this 98%, based upon 2021 Medicare claims, approximately 61% are in what one may traditionally consider a 'home,' with the remaining 37% in another home-like setting (such as an assisted living or nursing facility).[5] As noted above, terminal diagnoses vary, but may include any number of conditions such as cancer, chronic obstructive pulmonary disease, and neurological diseases (including ALS and Alzheimer's Disease). The need for controlled substances at the end of life, including schedule II drugs, is very common.

How Patients Come to Hospice Care: There is no requirement that patients receive a formal "referral" to hospice, and for a small percentage of patients it is the patient or a family member who initiates contact with the hospice. For most patients, however, there is a recommendation or referral to hospice by a physician or other practitioner who has been treating them, or from a health care facility such as a hospital or nursing facility. Regardless of how patients find their way to hospice, admission for hospice care is carefully regulated and requires several steps, as described below.

Eligibility and Admission to Hospice: As required by the Medicare hospice statute and regulations, in order to be eligible for hospice services, the patient's attending physician (if they have one) and the hospice medical director must both certify that the individual is "terminally ill" meaning that the individual has a medical prognosis that their life expectancy is six months or less if the illness runs its normal course.[6] In practice, however, most patients receive hospice care for much less than 6 months. Nationally, the median length of stay in hospice is only 17 days, with 25% of hospice patients dying within 5 days of being admitted, and 69% receiving hospice for less than 30 days.[7] Many patients are referred to hospice when their disease progression leads to a pain crisis. This is why it is so essential that hospice physicians or other practitioners be able to provide

[4] MedPAC 2023 Report to Congress
[5] 2021 Medicare claims data obtained by InfoMAX, Report 16
[6] Social Security Act §1861(dd)(3)(A); 42 C.F.R. §418.22.
[7] Value of Hospice in Medicare; NORC, March 2023

timely assessments and admissions, and to quickly prescribe medications needed for end-of-life pain and symptom management without having to satisfy bureaucratic documentation hurdles and satisfy formal referral requirements.

The hospice regulations require that clinical information and other documentation supporting the medical prognosis accompany the certification of terminal illness and be filed in the medical record with it.[8] The hospice benefit is structured in specific "benefit periods" and patients must be re-certified by a physician as being terminally ill prior to the start of each new benefit period. Additionally, the regulations require that the certification and recertification forms include a brief narrative explanation written by the hospice physician or attending physician explaining the clinical findings that support a life expectancy of six months or less.

Once a hospice is contacted about a potentially eligible patient, the intake staff will work to obtain medical and other records for the patient, and since most hospice care is provided to patients at home, a hospice nurse goes to the patient's home to explain the hospice benefit and conduct an eligibility assessment. This includes a physical exam, and a review of the patient's medical history, current medications, and symptom management needs. The nurse may also have an audio and/or video consult with the hospice physician. The nurse's documentation from this visit, as well as relevant medical records are provided to the hospice physician. Based on the available documentation and any other information deemed to be necessary to assess the patient's eligibility for hospice care, the attending physician and/or hospice physician(s) must sign a certification statement that in their judgment the patient's prognosis is six months or less. Only then may the patient be admitted for hospice care. However, hospice physicians do not perform an in-person examination of most patients prior to certifying that they are terminally ill and prescribing controlled substances deemed necessary, and such an in-person pre-admission exam for each patient is neither feasible nor necessary.

Hospice prescribing and diversion risk: Hospices appreciate and share the DEA's concern with possible abuse and diversion of controlled substances, but we believe hospice care is already well regulated, as noted above, and that the structure of the hospice benefit provides sufficient safeguards while ensuring timely delivery of the care that is critical at this stage of life.

The patient assessment process prior to the start of care includes an assessment for diversion risk, either by the patient or their family members or others who will be in the home on a regular basis. If a risk of diversion or abuse is identified, the hospice will implement safeguards, including a locked medication box if needed and a small prescription fill to avoid more than a couple of days of medications in the home. Hospices have been providing care under the regulatory framework described above for over 40 years, and safely prescribing controlled substances without a prior in-person examination.

NHPCO believes that the hospice patient population is unique, and the regulatory framework governing hospices provides safeguards against the concerns DEA is seeking to address in the proposed rule regarding prescribing of controlled substances for a patient the prescriber has not

[8] 42 C.F.R.§418.22(b)(2).

examined in person. In addition to the regulatory requirements limiting admission to hospice, hospice care involves frequent in-person visits by hospice personnel, including nurses, so hospice patients have regular, on-going interactions with health care providers even when this does not involve in-person examinations by the physicians on the hospice team. Given the short length of time most patients receive hospice care, and the crucial need for controlled medications, including schedule II drugs to alleviate pain and suffering during patients' final days, any DEA roadblocks to allowing hospice physicians to prescribe these drugs will, at a minimum, result in patients suffering or having to endure costly and inappropriate ambulance trips to the ER in order to be seen in person. At worst, in many cases the delay would just prevent them from being able to access hospice care at all in their dying days.

NHPCO Recommendations:

NHPCO urges the DEA to carefully consider the 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.

We request that you make clear that hospice physicians may continue to prescribe controlled medications, including schedule II drugs, without having to conduct an in-person examination of each patient, and without having to have received a formal "qualifying telemedicine referral" with the name and NPI number of the hospice practitioner to whom the patient is being referred. In many cases, a treating physician may recommend to a patient that hospice be considered, and their medical records will be sent to a hospice for review and an eligibility determination, but occasionally there is limited formal "referral" documentation and the patient's medical history is gathered by the hospice team. Patient generally aren't referred to a particular hospice physician, as proposed in the "qualifying telemedicine referral" noted above.

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.[9] However, 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. As noted, it would be rare for a hospice patient to have had a "telemedicine encounter" with a hospice physician, or that their referral for hospice care would be based on a "telemedicine referral" as these terms are defined in the proposed rule. Requiring hospice physicians and 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 in patients accessing needed, and often urgent, end of life care.

[9] 42 C.F.R. §418.104 and 418.106.

Patients with serious illness needing palliative care

Some seriously ill patients receive palliative care, either before a referral to hospice or, at a patient's choice, in place of hospice. The Centers for Medicare and Medicaid Services defines palliative care as, "patient and family centered care that optimizes quality of life by anticipating, preventing, and treating suffering. Palliative care throughout the continuum of illness involves addressing physical, intellectual, emotional, social, and spiritual needs and to facilitate patient autonomy, access to information, and choice." [10]

An interdisciplinary team provides palliative care to treat the impact of serious, complex, and progressive disease, including cancer, cardiac disease, respiratory disease, kidney failure, Alzheimer's, ALS, and multiple sclerosis. Treatment involves the management of pain and other symptoms with a goal of improving both quality of care and quality of life. Patients receiving palliative care are often medically fragile, with mobility issues or cognitive limitations, pain, and frailty, and often need caregivers to help with activities of daily living or to provide transportation. Often palliative care is a step in the patient's disease process before qualifying for hospice.

Recommendations for patients needing palliative care:

The policies outlined in this proposed rule could limit palliative care patient access to non buprenorphine opioid medications without an in person evaluation. We urge the DEA to consider recommendations made by our colleagues at the American Academy of Hospice and Palliative Medicine (AAHPM), who have offered a number of recommendations that will, if implemented, assist palliative care prescribers to offer timely, medically necessary, and appropriate care for their patients.

In closing:

We note that statutory authority directs the DEA, in conjunction with the Department of Health and Human Services (HHS), to establish a special registration for the practice of telemedicine. We urge the agency(ies) to either promulgate a hospice-specific regulation or make clear that the circumstances under which controlled substances are prescribed to hospice patients, which involves physician review of medical records and other documentation, as well as the regular in-person involvement of the hospice clinical care team, meet the conditions of the DEA regulations.

We recognize that telehealth raises difficult issues and demands the careful balancing of the risk of diversion and appropriate patient care. We appreciate the agency's consideration of the unique issues faced by hospice and palliative care providers and their patients. Given the short period of time until the Public Health Emergency is lifted, we request that DEA exercises enforcement discretion to maintain the status quo until it is able to finalize a regulation that ensures appropriate hospice patient care is not disrupted.

We appreciate your consideration of NHPCO's comments on the DEA Docket No: 407 proposed rule. We appreciate your attention to our comments and our concerns for the use of telehealth

[10] Medicare Hospice Regulations, Definitions

prescribing and hope that you will consider an exception for prescribing for hospice patients. We welcome continued engagement with you and your staff. If you have questions related to hospice regulatory or compliance areas, your staff should feel free to contact Judi Lund Person, Vice President, Regulatory and Compliance at jlundperson@nhpco.org or for palliative and advanced care topics, you may contact Rory Farrand, Vice President, Palliative and Advanced Care at rfarrand@nhpco.org.

Sincerely,

Ben Marcantonio
Interim President and CEO