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March 31, 2023

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

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

Dear Administrator Milgram:

Since 1982, the National Association for Home Care & Hospice (NAHC) has been the leading association representing the interests of hospice, home health and home care providers across the nation, including the home caregiving staff and the patients and families they serve. Our members are providers of all sizes and types -- from small rural agencies to large national companies -- and including government-based providers, nonprofit organizations, systems-based entities, and public corporations. We appreciate the opportunity to comment on DEA-407 Telemedicine Prescribing of Controlled Substances When the Practitioner and the Patient Have Not Had a Prior In Person Medical Evaluation, and on its potential impact on the delivery of hospice and palliative care.

We have provided recommendations below but have also provided the DEA with details below in the body of the letter.

<u>Recommendations</u>

- **Hospice:** NAHC urges the DEA to exempt prescriptions for individuals receiving hospice care from the Telemedicine Prescribing of Controlled Substances proposed requirements.

- **Alignment with the extension of Medicare telehealth flexibilities:** NAHC urges DEA not to finalize the Telemedicine Prescribing of Controlled Substances proposed rule at this time. Rather, DEA should use its regulatory authority to extend through at least the end of calendar year 2024 the telemedicine prescribing flexibilities for controlled substances that have been in place in response to the COVID-19 Public Health Emergency (PHE). We urge the DEA to work with the many impacted stakeholders, before this deadline, to develop a process to implement this proposed rule with due consideration of the many comments from prescribers and patients.
- **Special registration process:** NAHC strongly recommends that DEA use this time to work with stakeholders to implement a telemedicine special registration process. This could enable qualified practitioners to safely and appropriately prescribe controlled substances via telemedicine without a prior, in-person medical evaluation and would support timely, effective care for hospice patients and patients with serious illness at end-of-life, including those who are receiving palliative care.
- **Serious illness and palliative care:** NAHC has provided specific recommendations on components of the proposed rule and urges DEA to carefully consider those recommendations listed below.

The COVID-19 Public Health Emergency (PHE) presented unique challenges in meeting patient needs while controlling and minimizing the risk for diversion and abuse of certain medications. Beyond these challenges, this pandemic spurred innovation, and improvements in some of the ways healthcare is delivered. One of the most notable is the utilization of telehealth. Congress recognized the potential for continued advancement in care delivery through telehealth by extending the flexibilities associated with telehealth through December 31, 2024[1]. *NAHC urges the DEA not to finalize the proposals contained in the telemedicine prescribing proposed rule until at least the end of calendar year 2024, to align with the extension of the Medicare telehealth flexibilities Congress enacted. The DEA should use this time to work with stakeholders to implement a telemedicine special registration process enabling qualified practitioners to safely and appropriately prescribe controlled substances via telemedicine without a prior, in-person medical evaluation so as to support timely, effective care for hospice patients, home health patients, and patients with serious illness at end-of-life, including those who are receiving palliative care.*

As written, the proposed telemedicine prescribing rule creates the risk of serious harm to hospice patients. Medicare and Medicaid certified hospices provide end-of-life care to terminally ill individuals (life expectancy of six months or less if the illness follows its normal course), addressing their physical, emotional, and spiritual pain and symptoms. The vast majority of hospice patients are Medicare beneficiaries (accounting for more 90 percent of all hospice patient days in 2021)[2] with more than 1.7 million receiving hospice services in 2021 from 5,358 hospice providers.[3] 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. Physician certification of terminal illness is required when hospice care is initiated and at specified intervals

[1] Consolidated Appropriations Act, 2023
[2] MedPAC March 2023 Report to Congress
[3] MedPAC March 2023 Report to Congress

throughout care .[4] The certification is based on review of the individual's medical history and current clinical information.[5]

Hospices are heavily regulated and required to comply with federal and state rules and regulations. Under the Medicare hospice Conditions of Participation (CoPs) hospices must have 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/hospice physician, in conjunction with the patient's attending physician (if the patient has designated one), 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. In addition to a hospice physician, the Medicare CoPs require hospices to have an interdisciplinary team (IDT) for each patient consisting of at least a Registered Nurse (RN), Medical Social Worker (MSW), and pastoral or other counselor who work in conjunction with the patient-designated attending physician (if a patient has designated one). This team is responsible for completing a comprehensive assessment (§418.54(b)) upon which the plan of care is based. The IDT updates the comprehensive assessment (§418.54(d)) and reviews the plan of care (§418.56(d))at least once every 15 days or as the patient's condition requires and the IDT, in its entirety, supervises the care and services (§418.56(a)(1)). The IDT, as part of the review of the plan of care, must determine the ability of the patient and/or family to safely self-administer drugs and biologicals to the patient in his or her home (§418.106(d)). Hospices include an assessment of the risk for diversion and, if present, mitigate the risk through various techniques such as utilizing lock boxes or further limiting the "fill" on prescriptions, even going so far as writing, and delivering medications daily so as not to have any unused medications in the home. Risks for abuse and diversion are continuously assessed throughout an individual's time on hospice and include the patient, their caregiver, and others that are in the home or involved in the patient's care.

When an individual elects to receive hospice care an RN performs an in person assessment. During the assessment the RN may utilize telemedicine to bring the physician into the assessment at which time the physician orders medications, often including Schedule II narcotics. **Under the proposed rule the physician would be required to travel to the patient for an in-person medical evaluation as hospice patients usually are too ill to leave their homes.** Limited physician availability makes it impossible to make in-person visits to every patient admitted much less complete such visit in as short a timeframe after admission as necessary to quickly address pain and symptoms. Pain is common in terminal illnesses and can be severe. It is clinically appropriate to address it immediately upon admission to hospice care and this would not be possible if in-person visits for a medical evaluation were required. A significant portion of patients would pass away before a physician could complete the in-person visit, meaning that they would die in pain. Half of hospice patients in 2021 received care for only 17 days[6] and 25% of hospice decedents received hospice services for five days or less in 2020.[7]

[4] 42 U.S.C. 1395(f)(a)(7)(A)
[5] §418.102(b) and §418.102(c)
[6] MedPAC 2023 Report to Congress
[7] MedPAC 2022 Report to Congress

Beyond the extreme difficulty in hospice physicians being able to comply with the in-person medical evaluation requirements and the catastrophic result of delaying pain medication to terminally ill individuals, the proposed recordkeeping requirements present significant burden to practitioners. **The detailed documentation required includes items that are already part of prescriptions written and maintained in a hospice clinical record , e.g., date, drug name, strength, dosage form, quantity prescribed and directions for use.** The need to document the same information again in a separate record is duplicative and unnecessary. Similarly, obtaining the NPI of the referring practitioner would be overly burdensome and redundant since this practitioner will have record of the referral a copy of which is usually maintained in the patient's medical record. Having to create another copy for purposes of a log is duplicative and unnecessary.

As outlined above, there is an extensive, skilled admission evaluation, and subsequent monitoring protocols intrinsic to the hospice model of care that offers an equivalent to the in-person requirement in other prescribing venues. *As such,* ***NAHC urges the DEA to exempt prescriptions for individuals receiving hospice care from the Telemedicine Prescribing of Controlled Substances proposed requirements.*** The DEA has recognized the unique features of hospice care in past regulations. For example, DEA allows for an exception to the normal prescribing requirements that allows for a practitioner or the practitioner's agent to FAX to the dispensing pharmacy a prescription prepared in accordance with § 1306.05 written for a Schedule II narcotic substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state. The DEA also permits partial fills of controlled substances for patients having a terminal diagnosis.[8]Likewise, Congress has recognized the unique features of hospice care in the SUPPORT For Patients and Communities Act of 2018 (SUPPORT Act) by allowing hospice staff to handle and dispose of some medications for hospice patients.

The Ryan Haight Act of 2008 amended the Controlled Substances Act to prohibit prescribing of controlled substances via online forms and outlined requirements for in-person evaluations prior to the prescribing of controlled substances. This legislation was enacted to address Internet sites that dispensed controlled substances, including online pharmacies offering controlled substances without a valid doctor-patient relationship. Included in this Act is authority for the DEA to issue a special registration for practitioners engaged in the prescribing of medications through telemedicine and direction to the Attorney General to promulgate regulations for the limited circumstances under which a special registration may be issued as well as the procedure for obtaining a special registration. The SUPPORT Act clarified that final regulations were to be promulgated by October 2019[9] but no such regulations have been issued to date. In the proposed Telemedicine Prescribing rule the DEA indicates it considered allowing the practice of telemedicine pursuant to an application and issuance of a ''special registration'' allowing such practice. However, upon further consideration, this alternative was deemed potentially burdensome for both prospective telemedicine providers and patients. Therefore, the DEA decided against this alternative. It is unclear why the special registration process would be significantly burdensome to patients. Similarly, NAHC is uncertain as to exactly why the DEA has not promulgated the special registration process yet given that it was granted the authority to do so 14 years ago, required to do so per the SUPPORT Act five years ago, and encouraged by members of Congress to do so in the wake

[8] 21 CFR 1306.13
[9] SUPPORT Act 2018, Section 3232

of the SUPPORT Act's passage. **If the special registration process were implemented, hospice and palliative care prescribers should be considered eligible for this program.**

Palliative care is an interdisciplinary model of care aimed at preventing and 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.

NAHC is concerned the proposed rule's policies which include the restricted access to non-buprenorphine opioid medications without an in-person evaluation could cause significant harm to palliative care patients. Palliative care clinicians would be hampered in their ability to furnish medically necessary and appropriate care and medications 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:

Recommendations for Seriously Ill Patients Requiring Palliative Care

- DEA should allow qualifying telemedicine referrals to be made to entire practices, rather than to individual prescribers at the NPI level.
- DEA should allow qualifying telemedicine referrals to take place within integrated health systems, consistent with existing referral practices, without additional documentation or recordkeeping requirements.
- DEA should allow qualifying telemedicine referrals to come from practitioners who do not have active DEA Schedule II registrations.
- 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.
- DEA should defer to states regarding requirements to consult PDMPs, rather than impose PDMP review requirements for telemedicine prescriptions.
- 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.

- 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.
- 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.

In closing, we reiterate our appreciation for the opportunity to comment on this proposed rule and urge the DEA to consider the comments and recommendations above. We are available to answer any questions DEA may have about hospice, home health and palliative care.

Sincerely,

William A. Dombi
President