AMERICAN ACADEMY OF
HOSPICE AND PALLIATIVE MEDICINE

March 18, 2025

The Honorable Derek S. Maltz
Acting Administrator
U.S. Drug Enforcement Administration
Department of Health and Human Services
Attn: CMS-4208-P
7500 Security Boulevard
Baltimore, MD 21244

RE: Special Registrations for Telemedicine and Limited State Telemedicine Registrations [DEA Docket No. DEA-407; RIN 1117-AB40]

Dear Acting Administrator Maltz:

On behalf of the more than 5,200 members of the American Academy of Hospice and Palliative Medicine (AAHPM), we would like to thank the U.S. Drug Enforcement Administration (DEA) for the opportunity to comment on the proposed rule, "Special Registrations for Telemedicine and Limited State Telemedicine Registrations." AAHPM is the professional organization for physicians specializing in Hospice and Palliative Medicine. Our membership also includes nurses, social workers, spiritual care providers, pharmacists, and other health professionals deeply committed to improving quality of life for the expanding and diverse population of patients facing serious illness as well as their families and caregivers. Together, we strive to advance the field and ensure that patients across all communities and geographies have access to high-quality, equitable palliative and hospice care.

AAHPM appreciates DEA's responsibility to ensure that policies regulating prescriptions for controlled substances offer effective controls against diversion and maximize public health and safety. DEA's charge is particularly salient in the context of the ongoing national crisis characterized by the staggering number of Americans diagnosed with opioid use disorder (OUD) and tragically high rates of drug-related overdose and death. AAHPM thus recognizes the risks involved in
allowing physicians to prescribe controlled substances in the absence of an established relationship between a patient and provider, and we stand ready to be an active and engaged partner in efforts to mitigate such risks.

At the same time, we are concerned with how best to balance these risks against the need for our nation's sickest and most medically vulnerable patients – individuals with serious or complex chronic illness, including those near the end of life – to have ready access to medications they require to alleviate pain and other burdensome symptoms that accompany their conditions. We are concerned that DEA's proposed policies do not fully take this need into account.

The timely and effective management of pain and other distressing symptoms is central to providing high-quality hospice and palliative care to patients with serious illness, and Schedule II opioid analgesics and other controlled substances are critical tools in alleviating their suffering. AAHPM is concerned that DEA's proposals fail to sufficiently contemplate the unique needs of seriously ill patients – including those near the end of life – and the challenges they experience in accessing in-person care. Indeed, patients with serious illness may experience mobility and/or cognitive limitations, and they can be particularly susceptible to morbidity and mortality associated with infectious diseases. They also often have pain, frailty, or medical instability that prevent them from leaving home without a caregiver or specialized medical transportation. Unfortunately, while this proposed rule focuses on special registration for the practice of telemedicine, provisions in the rule (e.g., the 50 percent threshold that applies for the prescribing of Schedule II controlled substances, discussed further below) would require prescribers to provide in-person visits in order to prescribe essential medications to a wide swath of patients with serious illness.

The proposed policies also demonstrate limited understanding of how hospice and palliative care practitioners furnish care on a day-to-day basis, given the challenges their patients experience and workforce challenges that pervade the field of hospice and palliative medicine. Thus, while we appreciate that DEA offered special treatment for hospice care physicians and palliative care physicians, allowing such physicians to prescribe Schedule II controlled substances under DEA's proposed Advanced Telemedicine Prescribing Registration, we nonetheless believe that these specialists will be severely limited in their ability to prescribe Schedule II controlled substances to patients with serious illness given a number of additional requirements that have been proposed.

As a whole, the proposed policies could have devastating impacts on the patients our members serve. For example, terminally ill cancer patients who are dying at home may need immediate access to pain-relieving medications. As a result of these proposed restrictions, however, 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 relief of pain and suffering and to maximize quality of life.

To prevent such outcomes, as further discussed below, we offer overarching recommendations to allow practitioners furnishing care to hospice patients to prescribe Schedule II through V controlled substances without a prior in-person evaluation outside of the context of DEA's proposed Special Registration framework. At the same time, we also offer specific feedback on individual proposals included in the

proposed rule, in order to maximize the likelihood that patients with serious illness can readily access Schedule II through V controlled substances in a timely manner. These recommendations would apply both, in case DEA does not adopt our overarching recommendations, and when considering patients with serious illness who have not elected to receive hospice benefits.

Summary of Key Messages and Recommendations

AAHPM offers the following key messages and recommendations, which are further detailed in our comments below. Note, however, that many of the recommendations specific to our hospice patients and physicians may not apply if DEA adopts our overarching recommendation regarding care delivered to hospice patients.

- Overarching recommendation. DEA should allow practitioners furnishing care to hospice patients to prescribe Schedule II through V controlled substances, without a prior in-person evaluation, separate and apart from DEA's proposed Special Registration framework. If DEA believes that a prior in-person evaluation is necessary, we request that an in-person evaluation conducted by any member of a hospice interdisciplinary care team be sufficient to allow prescribing of Schedule II through V controlled substances by prescribers on the team.
- Overarching recommendation. DEA should provide additional flexibility for palliative care physicians treating patients with serious illness to prescribe Schedule II through V controlled substances under its Special Registration framework, consistent with further recommendations below.
- Advanced Telemedicine Prescribing Registration qualifications.
    - AAHPM thanks DEA for recognizing the need for hospice and palliative care physicians to prescribe Schedule II controlled substances for patients without conducting a prior in-person medical evaluation.
    - DEA should clearly articulate factors that would qualify individuals as "hospice care physicians" or "palliative care physicians," such that they could prescribe Schedule II controlled substances. At a minimum - the following individuals should be recognized as qualifying as "hospice care physicians" when they are furnishing care to hospice patients, in addition to physicians with board certification in Hospice and Palliative Medicine:
        - Physicians and other prescribing professionals who are employed by or contracted with a Medicare certified hospice to serve as a hospice physician or a hospice medical director, including those who may be temporarily covering as hospice physicians or hospice medical directors in such physicians' absence.
        - Physicians who have received a Hospice Medical Director certification from the Hospice Medical Director Certification Board.
        - Physicians, nurse practitioners, and physician assistants who serve as hospice attending physicians for patients who have elected hospice.
    - DEA should revisit its requirements for allowing "mid-level practitioners" to qualify for the Advanced Telemedicine Prescribing Registration to ensure that they have meaningful ability to prescribe Schedule II controlled substances to patients with serious illness.
    - DEA should adopt the definition of "hospice care" used by the Centers for Medicare & Medicaid Services (CMS) in order to maintain consistency across programs.
- Special Registration application process.
    - DEA should consider options to further reduce Special Registration fees and/or create processes to waive fees when hardship is demonstrated.

    - Reporting requirements for clinician special registrants on the Special Registration application form should focus on relevant employment, contractual relationships, and professional affiliations that are accompanied by financial incentives for the clinician, rather than all professional affiliations more broadly.
- Electronic Prescribing for Controlled Substances (ECPS). DEA should not require the use of ECPS until ECPS systems can fully accommodate electronic retractions.
- Prescription Drug Monitoring Program (PDMP) checks.
    - DEA should exempt hospice patients from requirements to check PDMPs under the Special Registration framework.
    - DEA should only apply the PDMP check to initial prescriptions of controlled substances for a given patient, rather than prior to the issuance of every Special Registration prescription, unless initial review of the PDMP reveals risk of abuse.
    - DEA should not finalize its proposal to expand the PDMP check requirement to all state and territory PDMPs after three years.
- Audio-video telecommunications systems. For patients receiving palliative care, DEA should allow for use of audio-only telecommunications systems for telemedicine encounters under its Special Registration Framework after treatment initiation with audio and video modalities.
- Schedule II controlled substances requirements.
    - DEA should not finalize its proposal to require less than 50 percent of total Schedule II prescriptions to be issued under the Special Registration framework for physicians and other practitioners delivering palliative care to patients with serious illness. At a minimum, hospice patients should be exempted from this requirement.
    - DEA should not finalize its proposal to require clinician special registrants to be located in the same state in which the patient is located in order to prescribe a Schedule II controlled substance under the Advanced Telemedicine Prescribing Registration.
- Patient verification photographic record. DEA should pursue alternative options for patient identity verification that can be accommodated securely using available technologies.
- Special Registration telemedicine encounter record. DEA should provide clarification on whether tracking of telemedicine encounter record data would be required in a separate log, or whether documentation in patients' medical records would be sufficient. DEA should not require separate tracking.
- Annual Special Registrant reporting requirements. DEA should create reports based on pharmacy-reported data in order to understand prescribing patterns and to identify outlier prescribers, rather than imposing a separate reporting requirement on Special Registrants.

Overarching Recommendation: Separate Treatment for Patients Receiving Hospice Care and Added Flexibility for Other Patients with Serious Illness

Separate Treatment for Patients Receiving Hospice Care

We understand that in-person evaluation requirements specified under the Ryan Haight Act are intended to ensure that an established patient-physician relationship is in place, prior to the prescribing of controlled substances via the Internet. The Academy takes the position that a proper physician-patient relationship can be created when a patient is certified as having a terminal illness and enrolled in a

hospice program. Face-to-face evaluation is often the standard for prescribing because of the role that it plays in verifying patient condition and status. However, enrollment in hospice also achieves all of the same verification and oversight goals. In particular with the Medicare hospice benefit, which is highly regulated by Centers for Medicare and Medicaid Services, the extensive skilled admission evaluation and subsequent monitoring intrinsic to the hospice model of care is equivalent to the face-to-face requirement in other prescribing venues.

Furthermore, hospice team members – comprised of social workers, chaplains, bereavement counselors, and hospice nurses, many of whom are highly trained in pain assessment and medication monitoring – are in regular face-to-face contact with patients, further mitigating risk of misuse or abuse. These team members make frequent home visits individualized to each patient, provide extensive education and supervision, and are available 24/7, making them better equipped and available to detect and address questionable drug behavior and safety concerns with both patients and caregivers than a typical non-hospice provider. Hospice teams have standard processes to prevent diversion through activities such as pill counts and use of locked medication boxes, when risks of diversion or abuse are identified, and hospice staff coordinate with pharmacies to further assure accountable prescribing and dispensing of these medications.

Whereas the robustness of the hospice care model provides strong assurances that patients will receive controlled substances that are reasonable and medically necessary to address their treatment and symptom management needs, with minimal risk for abuse or diversion, the singular needs of hospice patients underscore why timely and meaningful access to controlled substances is necessary to manage their pain and other symptoms. As we have previously noted, hospice patients are a discrete and unique subset of patients who require use of opioids and other controlled substances to manage intractable pain and other distressing symptoms of serious illness – and they often present with urgent needs. Hospice patients must be certified to be "terminally ill," with an estimated life expectancy of 6 months or less. Typically, however, patients receive hospice care for much shorter periods, with the median length of stay in hospice only 18 days and 25 percent of hospice patients enrolled in hospice for 5 days or less.[1] And almost all hospice care is home-based care provided in the patient's own home or wherever they live. Timely management of pain and other symptoms is crucial at the end of life, and it is particularly urgent when patients present with pain crises.

Barriers to pain relief during this period – like many that will occur if this rule is finalized as proposed – deprive hospice patients of the peace and dignity that they deserve. Notably, not having prescriptions in the home is one of the most common reasons for hospice patients going to emergency departments to seek care, a tragic outcome that would be extremely distressing for patients and their caregivers and that would only add to patients' suffering. While, relative to requirements to conduct in-person medical evaluations, the Special Registration framework would offer a more flexible and expeditious option for hospice care physicians to conduct a telemedicine encounter that could result in a pain-relieving Schedule II prescription, we note that requiring even telemedicine encounters would be difficult – and even prohibitive – for hospice patients. Patients are admitted to hospice services 24 hours a day, 7 days a week and have symptoms that need to be addressed immediately upon admission. It is not feasible or ethical for hospice agencies to withhold symptom medications until a prescribing team member is available to conduct a telemedicine visit.

[1] National Hospice and Palliative Care Organization. "NHPCO Facts and Figures: 2024 Edition." September 2024. https://www.nhpco.org/wp-content/uploads/NHPCO-Facts-Figures-2024.pdf.

Given the well-documented and managed physician-patient relationship and the close ongoing monitoring involved in furnishing hospice care, paired with the often acute and intensive care needs hospice patients experience, AAHPM believes that restrictions under DEA's proposals for Special Registration for telemedicine prescribing of controlled substances should not apply to patients enrolled in hospice. ***AAHPM therefore respectfully requests that DEA allow practitioners to prescribe Schedule II through V controlled substances to hospice patients without a prior in-person evaluation, separate and apart from DEA's proposed Special Registration framework.***

If DEA believes that a prior in-person evaluation is necessary, we request that an in-person evaluation conducted by any member of a hospice interdisciplinary care team be sufficient to allow prescribing of Schedule II through V controlled substances to hospice patients by prescribers on the hospice team. Such an approach would recognize the continuity of care that hospice interdisciplinary care teams offer, similar to policies that DEA finalized for Veterans Affairs patients. It would also recognize the value of initial nursing assessments conducted by hospice registered nurses, and better reflect the way hospice care is delivered.

Added Flexibility for Other Patients with Serious Illness

While hospice patients present a unique set of challenges and needs, we highlight that other patients with serious illness suffer from many of the same physical and cognitive challenges, including related to mobility, frailty, medical instability, and pain management needs. Indeed, many patients with serious illness may be eligible for hospice care, but unwilling or unable to elect to receive hospice benefits, for example due to limited hospice availability or desire to continue curative treatments. Even without terminal illnesses, however, patients with serious illness may experience pain episodes that require medication on an urgent or emergency basis, including Schedule II controlled substances. However, the proposed restrictions on Special Registration prescribing controlled substances would impose severe restrictions on palliative care practitioners' ability to rely on this framework to prescribe medications for patients without a prior in-person visit. ***Greater flexibility is imperative for ensuring meaningful and reliable access to controlled substances for patients with serious illness under the Special Registration framework, and we offer recommendations in our comments below in response to specific proposals.***

Comments on Specific Proposals

Three Types of Special Registration; Registrant Eligibility; State Telemedicine Registrations

DEA proposes a framework for Special Registration that offers three distinct categories of Special Registrations:

- Telemedicine Prescribing Registration, which would authorize the prescribing of Schedules III through V controlled substances by clinician practitioners;
- Advanced Telemedicine Prescribing Registration, which would authorize certain specialized clinician practitioners the privilege to prescribe Schedule II controlled substances as well as Schedule III through V controlled substances; and
- Telemedicine Platform Registration, which would authorize covered online telemedicine platforms to dispense Schedules II through V controlled substances through a clinician

practitioner possessing either a Telemedicine Prescribing Registration or an Advanced Telemedicine Prescribing Registration.

DEA proposes that an applicant for one of the three types of Special Registration would be required to already have one or more DEA registrations under 21 U.S.C. 823(g) to prescribe (if an clinician practitioner) or dispense (if a platform practitioner) controlled substances in a state in which they are licensed, registered, or otherwise permitted to prescribe or dispense controlled substances through telemedicine, unless they are otherwise exempted.

To be eligible for the Advanced Telemedicine Prescribing Registration (and therefore eligible to prescribe Schedule II controlled substances under the Special Registration framework), physicians and mid-level practitioners, as clinician practitioners, would need to demonstrate they have a legitimate need for the Special Registration and that such need warrants the authorization of prescribing of Schedule II controlled substances in addition to Schedules III through V controlled substances. DEA proposes that only certain specialized physicians and board-certified mid-level practitioners have a legitimate need to prescribe Schedule II controlled substances via telemedicine when treating particularly vulnerable patient populations, in the following limited circumstances or practice specialties:

(1) psychiatrists;
(2) hospice care physicians;
(3) palliative care physicians;
(4) physicians rendering treatment at long term care facilities;
(5) pediatricians;
(6) neurologists; and
(7) mid-level practitioners and physicians from other specialties who are board certified in the treatment of psychiatric or psychological disorders, hospice care, palliative care, pediatric care, or neurological disorders unrelated to the treatment and management of pain.

DEA also proposes a limited type of registration for a lower fee, the State Telemedicine Registration. DEA proposes that a clinician special registrant would be required to obtain a DEA-issued State Telemedicine Registration for every state in which they intend to issue prescriptions for controlled substances to patients via telemedicine. The State Telemedicine Registration would operate as an ancillary credential, contingent on the Special Registration held by the clinician practitioner or platform practitioner, and would only allow the special registrant to prescribe via telemedicine encounters as to that state and only for the schedules authorized by their Special Registration.

AAHPM thanks DEA for recognizing the need for hospice and palliative care physicians to prescribe Schedule II controlled substances for patients without conducting a prior in-person medical evaluation. However, we are also concerned that DEA's proposed approach for determining the practitioners who would be allowed to prescribe Schedule II controlled substances under the special registration framework would be too limiting and would also benefit from further clarification.

To begin, ***we recommend that DEA clearly articulate factors that would qualify individuals as "hospice care physicians" or "palliative care physicians," such that they could prescribe Schedule II controlled substances. To begin, DEA should specify that board certification in Hospice and Palliative Medicine would qualify physicians to be eligible for the Advanced Telemedicine Prescribing Registration.*** We do not believe, however, that such designation should be limited to only such physicians. ***Rather, we recommend that – at a minimum - the following individuals be recognized as qualifying as "hospice care physicians" when***

they are furnishing care to hospice patients, in addition to physicians with board certification in Hospice and Palliative Medicine:

- *Physicians and other prescribing professionals who are employed by or contracted with a Medicare certified hospice to serve as a hospice physician or a hospice medical director, including those who may be temporarily covering as hospice physicians or hospice medical directors in such physicians' absence.* Physicians and other prescribing professionals who are employed or contracted with a Medicare certified hospice fulfill an important role in overseeing hospice patients' care, even when they are doing so in a temporary capacity as a covering physician. Enabling these professionals to prescribe Schedule II controlled substances is imperative for ensuring that hospice patients receive treatments for pain and other symptoms as expeditiously as possible.
- *Physicians who have received a Hospice Medical Director certification from the Hospice Medical Director Certification Board.* The Hospice Medical Director certification demonstrates competence, dedication, and specialized knowledge in caring for hospice patients, including in the areas of patient and family care, medical knowledge, medical leadership and communication, professionalism, and regulatory, compliance, and quality improvement. In order to be eligible to receive certification, physicians must have already demonstrated a minimum of 400 hours of broad hospice-related activities during the previous 5 years, among other requirements.
- *Physicians, nurse practitioners, and physician assistants who serve as hospice attending physicians for patients who have elected hospice.* Hospice attending physicians, who may or may not be employed by or contracted with a hospice, serve as integral members of the hospice interdisciplinary care team and support hospice patients' overall plan of care. They are chosen by the patient at time of hospice admission, as the clinician they most trust to order the care and medications needed to control their symptoms as they approach death. If hospice attending physicians are unable to prescribe Schedule II controlled substances, patients may not receive the symptom management they expect and need from their trusted provider. To ensure ready access to pain and other symptom relieving medications, hospice attending physicians must be able to prescribe Schedule II controlled substances.

We also call attention to DEA's proposal to allow mid-level practitioners to qualify for the Advanced Telemedicine Prescribing Registration only if they are board certified in one of the specialty areas proposed. We first note that greater clarity is needed in defining who qualifies as a "mid-level practitioner." We also highlight that mid-level practitioners generally do not receive board certification in the same manner as physicians, that specialty boards for mid-level practitioners are not universally adopted, and that states have varying requirements for licensure and certification for non-physician practitioners. In some regions, these mid-level practitioners represent the only available access to hospice and palliative care due to limitations in the physician workforce. As a result, we are concerned that a board certification requirement in hospice or palliative care for "mid-level practitioners" would result in many non-physician practitioners being ineligible for the Advanced Telemedicine Prescribing Registration, which in turn would limit patients' ability to access symptom-managing Schedule II controlled substances in a timely manner, particularly in states where certification is not broadly adopted. *We therefore recommend that DEA revisit its requirements for allowing "mid-level practitioners" to qualify for the Advanced Telemedicine Prescribing Registration to ensure that they have meaningful ability to prescribe Schedule II controlled substances to patients with serious illness.*

Finally, we appreciate DEA's stated interest in adopting definitions for the terms hospice and palliative care that align with definitions used by the Centers for Medicare & Medicaid Services (CMS), and we note that

the proposed definition of "hospice care" at 21 CFR 1300.04 does not align with the CMS definition at 42 CFR 418.3.

- DEA proposes to define "hospice care" as a set of special services that are provided to individuals who are terminally ill. The focus is on comfort, not on curing an illness. Hospice programs can be delivered in a person's home or in a hospice center.
- In contrast, CMS defines "hospice care" to mean a comprehensive set of services described in 1861(dd)(1) of the Act, identified and coordinated by an interdisciplinary group to provide for the physical, psychosocial, spiritual, and emotional needs of a terminally ill patient and/or family members, as delineated in a specific patient plan of care.

AAHPM requests that DEA adopt the CMS definition of "hospice care" in order to maintain consistency across programs. We also highlight that certain elements of the CMS hospice definition are particularly important, such as the "comprehensive set of services . . . identified and coordinated by an interdisciplinary group."

Special Registration Application Process

DEA proposes that fees for each Special Registration would be $888 and that fees for each State Telemedicine Registration would be $888 for each state for platform registrants and $50 for each state for clinician special registrants.

While we appreciate the lower proposed State Telemedicine Registration fee for clinician special registrants, AAHPM is concerned that these costs are excessive and would be overly burdensome and expensive for clinician special registrants who are already responsible for fees associated with state medical licenses and existing DEA registrations totaling >$1000 annually. For clinicians who practice across multiple states, the expenses would add up. Ultimately, we are concerned that these barriers would limit timely access to symptom management support for patients with serious illness. ***AAHPM therefore recommends that DEA consider options to further reduce Special Registration fees and/or create processes to waive fees when hardship is demonstrated.***

DEA also proposes that the Special Registration application form would require applicants to provide certain disclosures and attestations with the goal of enhancing transparency, patient safety, and anti-diversion efforts, including:

- Attestation to all employment, contractual relationships, or professional affiliations
- Attestation to have devised, and are committed to maintaining, anti-diversion policies and procedures
- Disclosure of practice specialties for Advanced Telemedicine Prescribing Registration
- Attest to legitimate need

While AAHPM agrees with goals of enhancing transparency, patient safety, and anti-diversion, ***we suggest that the reporting requirements for clinician special registrants should focus on relevant employment, contractual relationships, and professional affiliations that are accompanied by financial incentives for the clinician.*** In many cases, our members take on professional affiliations that may support education or advocacy efforts wholly unrelated to prescribing of controlled substances, and we believe the value of reporting such affiliations may be outweighed by clinicians' privacy interests in such cases.

Special Registration Prescriptions Issued by Clinician Special Registrants under 21 CFR Part 1306

Use of Electronic Prescribing for Controlled Substances

DEA proposes that all special registration prescriptions must be issued through electronic prescribing for controlled substances (ECPS). AAHPM has some concerns with this requirement, given technology limitations that exist with some of the more affordable ECPS systems. Specifically, some ECPS systems do not allow for retraction of electronic prescriptions, for example when a pharmacy does not have enough supply. Without a retraction, the prescription may remain available for filling, even if a separate prescription has been transmitted to a different pharmacy. This creates added risk for diversion and abuse. ***Until ECPS systems can fully accommodate electronic retractions, we recommend that use of ECPS not be required.***

Nationwide Prescription Drug Monitoring Program (PDMP) Check

DEA proposes that clinician special registrants perform a check of relevant PDMPs before issuing any Special Registration Prescription, with relevant PDMPs including the following:

- For a period of 3 years from the date that a final rule becomes effective, the PDMPs for:
    - The state or territory where the patient is located;
    - The state or territory where the practitioner is located; and
    - Any state or territory with PDMP reciprocity agreements with either the state or territory where the patient is located or the state or territory where the clinician practitioner is located.
- After the initial three-year period, the PDMPs of all 50 of the United States and any other U.S. district or territory that maintains its own PDMP. If there is no mechanism to perform such a nationwide check after the first three years, then individual special registrants would remain required to continue performing PDMP checks of the states required for the initial 3-year period, and they would only be able to issue special registration prescriptions for Schedule II controlled substances to patients located within the same state as the individual special registrant.

AAHPM has significant concerns around these PDMP check requirements, which we believe are operationally infeasible, overly burdensome, and of limited value for patients with serious illness – particularly those who are receiving hospice care.

To begin, there are numerous challenges with checking multiple PDMPs given the current lack of interoperable data exchange. For hospice providers, the challenges are exacerbated as hospice adoption of certified electronic health record (EHR) technology (CEHRT) has been limited due to hospices' historic exclusion from participation in the Medicare and Medicaid EHR Incentive Program. As a result, few EHR vendors have developed CEHRT that is applicable to hospice settings, and hospices have not been able to make the investments in core health information technology (HIT) necessary to interface readily with PDMPs. Checking two or more PDMPs for every Special registration prescription is infeasible in these systems and checking *all* states and territories currently is not possible. Notably, hospice patients are exempt from PDMP checks in many states. Furthermore, PDMP checks may lead to unnecessary and harmful delays when the need to prescribe pain medications and other controlled substances is in response to urgent or emergency circumstances, which hospice patients and other patients with serious illness experience all too frequently.

To address these concerns, ***AAHPM recommends that DEA exempt hospice patients from requirements under the Special Registration framework to check PDMPs and to complete associated documentation and tracking requirements.*** Notably, hospice programs have systems in place to protect against potential abuse or diversion, including through regular home visits, medication reviews, and PDMP checks. However, we believe that checking PDMPs should remain a clinical decision at the discretion of hospice physicians and hospice medical directors – a flexibility that is particularly crucial in urgent and emergency situations.

Furthermore, ***AAHPM recommends that DEA only apply the PDMP check to initial prescriptions of controlled substances for a given patient, rather than prior to the issuance of every Special Registration prescription, unless initial review of the PDMP reveals risk of abuse. Further, given the technological challenges of reviewing all state and territory PDMPs with a single query, we recommend that DEA not finalize its proposal to expand the PDMP check requirement to all state and territory PDMPs after three years.*** We believe this recommendation balances concerns around potential abuse with the need to minimize unnecessary barriers to timely symptom management.

Special Registration Prescriptions and Audio-Video Telecommunications Systems

DEA proposes that a clinician special registrant must utilize both audio and video components of an audio-video telecommunications system to prescribe under the Special Registration framework for every telemedicine encounter, whether an initial visit or subsequent visit or follow-up. However, DEA proposes that a clinician special registrant may use an audio-only telecommunications system when prescribing Schedule III-V controlled substances approved by FDA for the treatment of opioid use disorder (OUD), provided that the treatment was initiated through the use of an audio-video telecommunications system.

AAHPM has concerns with the video requirements when considering the need to prescribe controlled substances for patients with serious illness. As noted above, patients with serious illness often experience cognitive and/or mobility challenges that limit the ways in which they interact with their social and physical environments. These same challenges may make it difficult for patients to sit upright or participate in video components of telehealth encounters. Furthermore, many patients experience technological barriers to using audio and video capabilities, including lack of broadband access and unstable internet connections in rural communities. Others are unwilling to use video capabilities as a matter of personal preference. In such cases, the use of audio-video capabilities could interfere with the patient-clinician relationship by failing to allow clinicians to meet patients where they are most comfortable.

For patients with serious illness, we do not believe consistent use of audio-video capability is appropriate or necessary. ***We recommend, instead, that DEA adopt policies that are more aligned with its policies for patients receiving treatment for OUD – that is, allowing use of audio-only telecommunications systems after treatment initiation with audio and video modalities for patients with serious illness receiving palliative care.*** We emphasize such an approach would reduce confusion, support access to care, and maintain consistency in rules and requirements for populations that have significant overlap of care needs.

Schedule II Controlled Substance Prescriptions

DEA proposes to require that the average number of special registration prescriptions for Schedule II controlled substances constitutes less than 50 percent of the total number of Schedule II prescriptions

issued by the clinician special registrant in their telemedicine and non-telemedicine practice in a calendar month.

AAHPM strongly disagrees with this requirement, which will cripple the ability of physicians caring for patients with serious illness to timely and effectively address patients' symptom management needs. This is almost universally true for physicians dedicated to hospice care whose patient rosters are primarily comprised of patients with terminal illness who receive their care in the home. For these physicians, this 50 percent threshold could require hospice physicians to conduct home visits for as many as (or more than) half the patients under their care, in order to conduct an in-person medical evaluation that would result in prescriptions not dispensed under the Special Registration. This level of travel and face-to-face time with patients is not feasible under current hospice staffing structures, where hospice medical directors and hospice physicians provide high level oversight of care plans and patient care and lead interdisciplinary care teams, but where other team members conduct the bulk of in-person and virtual care. Alternatively, hospices will be unable to provide urgent care without disruptive and non-beneficial in-person visits for actively dying and suffering patients.

Even for hospice physicians who only see hospice patients part-time, the 50 percent threshold could be prohibitive as such physicians do not write a high volume of Schedule II prescriptions for non-hospice patients. Therefore, the pool of their Schedule II prescriptions would likely be limited to the hospice patients they manage, again requiring disruptive, time-intensive, and often unnecessary visits by hospice physicians instead of other members of the hospice interdisciplinary care team.

For these reasons, as discussed elsewhere in this letter, ***AAHPM strongly urges DEA to exempt practitioners furnishing care to hospice patients from the DEA's proposed Special Registration framework and instead create a separate, less burdensome pathway for hospice patients to be prescribed Schedule II controlled substances.*** Should DEA finalize requirements that practitioners prescribing controlled substances to hospice patients obtain Special Registrations and prescribe controlled substances under this Special Registration framework, ***we urge DEA to exempt prescriptions for hospice patients from the 50 percent requirement for Schedule II drugs.***

Palliative care physicians who provide outpatient palliative care to patients with serious illness may also struggle with the 50 percent threshold requirement. Because these patients often contend with pain, frailty, or medical instability and/or rely on caregivers to assist with transportation, they have an increased need to access health care via telecommunications technology. Indeed, our members have reported palliative care practices furnishing up to 70 percent of their services via telecommunications technology, with telehealth enabling practices to expand their capacity to treat patients with serious illness. Requiring such practices to meet a 50 percent threshold for prescribing based on a previous in-person encounter would disrupt the way these practices deliver care and reduce access to timely care for patients in need of Schedule II prescriptions.

We also highlight that requiring compliance based on the percentage of prescriptions issued under the Special Registration framework will come with its own set of challenges given the need to establish new processes and systems for tracking Special Registration patients and prescriptions. As a result, we fear that, if this policy is finalized as proposed, hospice and palliative care physicians will issue Special Registration prescriptions at a rate lower than 50 percent in order to avoid the processes needed to track prescriptions, , thereby reducing access to effective symptom management via telemedicine.

For these reasons, ***we urge DEA not to finalize its proposal to require less than 50 percent of total Schedule II prescriptions to be issued under the Special Registration framework for patients receiving palliative care.*** We believe this threshold is arbitrary and will significantly harm patients with serious illness who require symptom relief.

DEA also proposes to require that clinician special registrant be physically located in the same state as the patient when issuing a Special Registration Prescription for a Schedule II controlled substance, in addition to requiring that the clinician special registrant have the Advanced Telemedicine Prescribing Registration and a State Telemedicine Registration in the state in which the patient is located. AAHPM also has concerns with this proposal, which we believe does not take into account the numerous cases when patients receive care from physicians across state lines, and ***we urge DEA not to finalize this policy as proposed***. This may include cases where health systems and practices are located near state borders and serve patients across multiple states. It may also include cases when patients living in rural areas seek care via telehealth at out-of-state institutions best equipped to handle their care needs. Patients in such scenarios should have the ability to access care via telehealth, and to receive Schedule II prescriptions via telemedicine as reasonable and medically necessary, even if their physicians are not located in the same state.

Recordkeeping and Reporting under 21 CFR Part 1304

Patient Verification Photographic Record

DEA proposes that a clinician special registrant, or a delegated employee or contractor under the direct supervision of the clinician special registrant, must verify the identity of a patient seeking treatment via telemedicine by requiring that the patient present a state or federal government-issued photo identification card through the camera of the audio-video telecommunications system. At the first telemedicine encounter, the clinician special registrant would also be required to capture a photographic record of the patient presenting their federal or state-issued photo identification card or other acceptable documents. They must then use the photographic records to confirm the patient's identity in subsequent telemedicine encounters.

If the patient does not consent to their photo being captured, DEA proposes to allow the clinician special registrant to accept a copy of the patient's federal or state photo identification card or other forms of documentation provided by the patient. The photographic records would have to be securely stored in the patient's medical record or chart, separate from the special registration prescription records/data that would be reported to DEA as discussed further below.

DEA also proposes to allow a clinician special registrant to verify the identity of the patient with other forms of documentation and, in such cases, to require maintenance of a record of how they verified the patient's identity and what documents were used to verify the patient's identity.

AAHPM raises significant system and operational concerns with these proposals, which do not appear to take into account available health information technology (HIT) capabilities. Our members report, for example, that the Epic and Cerner electronic health record systems are secured against taking screen shots during telemedicine visits. As a result, it is likely that photo would need to be taken and transmitted using devices and mechanisms that are not secure or HIPAA compliant, raising the potential for potential improper disclosures.

We also again highlight that requirements such as these interrupt and interfere with the patient-clinician relationship. Rather than allowing physicians to connect and build rapport with these patients, a patient

identity verification mandate would increase the risk of distrust and unease, which would undermine the process and goals of providing high-quality palliative care.
AAHPM therefore recommends that DEA pursue alternative options for patient identity verification that can be accommodated securely using available technologies. For example, we highlight that many telemedicine encounters are conducted through systems that are designed to ensure patient identify – for example, encounters that are initiated through secure, password-protected patient portals. At the same time, we reiterate that many provider types (including hospices) may not have access to CEHRT given the historic lack of EHR incentive payments that were available to physicians and hospitals, and that such limitations should be accommodated in any patient verification policies that are finalized.

Special Registration Telemedicine Encounter Record

DEA proposes that, for every telemedicine encounter resulting in a special registration prescription, clinician special registrants must maintain a record of the date and time of the telemedicine encounter, the address of the patient during the encounter, and the home address of the patient. These encounter records would have to be retained for a minimum of 2 years from the date of the encounter.

AAHPM requests clarification on whether tracking of this data would be required in a separate log, or whether documentation in patients' medical records would be sufficient and recommends that a separate log should not be required. We highlight that a separate record or log would be burdensome and could lead to concerns about the privacy and security of protected health information under HIPAA. We also note that some EHRs do not capture all of the data being required (e.g., the address of the patient during the encounter, if they are not at home), so practitioners would have to bear additional costs to update their systems.

Annual Special Registrant Reporting of Special Registration Prescription Data

DEA proposes to require that individual special registrants and platform special registrants report annual data on:

- the total number of new patients in each state for which they issued at least one special registration prescription for a Schedule II controlled substance or certain Schedule III-V controlled substances, including Ketamine, Tramadol, and any depressant constituting a benzodiazepine;
- the total number of special registration prescriptions for Schedule II controlled substances issued by the special registrant, in aggregate and across all states;
- the total number of special registration prescriptions for certain Schedule III-V controlled substances, including Ketamine, Tramadol, and any depressant constituting a benzodiazepine (including their salts, isomers, and salt of isomers), which were issued by the special registrant, in aggregate and across all states.

AAHPM notes that these reporting requirements appear duplicative with those required for pharmacies filling Special Registration prescriptions, while significantly increasing the burden associated with reporting requirements. ***We therefore suggest that DEA could create similar reports based on pharmacy-reported data in order to understand prescribing patterns and to identify outlier prescribers, rather than imposing a separate reporting requirement on Special Registrants.*** We note that EHRs are not currently equipped to report all the proposed data, and while some EHR systems could accommodate custom data extractions, others would be unable, and data would have to be collected manually. We question whether this added burden is necessary and whether the benefits outweigh the costs.

Conclusion

Thank you, again, for the opportunity to provide feedback in response to the Special Registrations for Telemedicine proposed rule. AAHPM would be pleased to work with DEA to address our feedback and recommendations above. Please direct questions or requests for additional information to Wendy Chill, Director of Health Policy and Government Relations, at wchill@aahpm.org.

Sincerely,

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