March 18, 2025

Drug Enforcement Administration
Attention: DEA Federal Register Representative/DPW
8701 Morrissette Drive
Springfield, Virginia 22152

Subject: Special Registrations for Telemedicine and Limited State Telemedicine Registrations

Dear Acting Administrator Bartels,

On behalf of our more than 5,400 nonprofit and mission-driven aging services providers, LeadingAge is pleased to offer the following comments in response to the Special Registrations for Telemedicine and Limited State Telemedicine Registrations proposed rule. Our members serve older adults across the country and along with a full spectrum of services and supports, such as senior housing including affordable housing, assisted living and memory care, skilled nursing, home health, and hospice, and life plan communities that offer a continuum of housing and services to their residents.

LeadingAge appreciates the opportunity to comment on this proposed rule and understands the difficult situation the Drug Enforcement Administration (DEA) finds itself in regarding protecting against the abuse of controlled substances while also ensuring Americans can access needed medicine and use telemedicine consultations as a method of access. We agree guardrails are needed around telehealth utilization broadly and most especially when there is a high-risk situation such as overprescribing of controlled medications. However, LeadingAge is gravely concerned that the proposed rule laid out by DEA will only further limit access to critical drugs for the vulnerable older adults LeadingAge members serve.

As we indicated in our March 31, 2023 comment letter responding to the first proposed rule for e-prescribing of controlled substances, we were unable to identify any published studies that prescribing controlled medications for hospice patients or residents in long-term care is a major source of the overprescribing in our country. Therefore, we do not believe prescribing controlled medications using telehealth for hospice patients or residents in long-term care is a high-risk situation that requires the guardrails outlined in DEA's proposed rule. Furthermore, the consequences of adding additional oversight to hospice and skilled nursing clinical practitioners, especially with requirements for prescribing schedule II-controlled substances which are critically needed in these settings, would not only be burdensome but would also create catastrophic access issues for the older adults these settings serve. We are most concerned regarding the unduly restrictive nature of the guardrails for schedule II-controlled substances which are commonly found in these care settings.

We urge DEA to specifically exempt hospice and skilled nursing providers from this and any future similar rules under the authority given to the DEA Administrator and the Secretary of Health and Human Services to jointly establish exemptions in regulation under the Ryan Haight Act of 2008.

We also strongly encourage DEA to revise these rules, in consultation with stakeholders, to further account for providers who serve equally vulnerable individuals outside of nursing homes and hospices, including providers serving palliative care patients and home health patients.

Specific Hospice Considerations for Exemption

We are gravely concerned that the proposed rule does not consider the unique structure of hospice practice that been in place for 40 years. The hospice standard of practice is the prescribing of scheduled medications (Schedule II, III-V) following an in-person comprehensive assessment – often multiple hours in length – by a trained hospice nurse where those assessment findings, including patient response to any current medications and patient need for additional medications, are communicated by the nurse to the clinical practitioner and based on that assessment's findings, medications are prescribed. Often the nurse will use telemedicine to bring in the prescriber for additional assessment of the patient's condition, at which time the clinician will order medications, often including schedule II narcotics. Additionally, it is required as part of the hospice Conditions of Participation (CoPs) that the Interdisciplinary Group (IDG) meet every 15 days or as the patient's condition requires the IDT to meet and medications are updated or changed based on subsequent IDT conversations. The interdisciplinary nature of hospice allows the entire team to monitor pain and symptom management and identify potential concerns regarding the possibility of drug diversion during the patient's time in hospice.

More than half, or 56 percent, of hospice patients received care in their homes in 2021.[1] These patients are typically too sick at the end of their lives to travel for any service, let alone an in-person consultation regarding medications necessary to support their comfort. Additionally, many of these patients may live in inaccessible locations either in rural areas or urban areas with limited transportation availability. These conditions make it more difficult for patients to leave their homes and for prescribing clinicians to travel to them. Because prescribing clinicians may not be able to physically visit their patients in time for provide schedule II drugs that will ease the all-too-common pain symptoms associated with terminal illness, they have always relied on the use of telehealth to assess and prescribe medications, based on the clinical assessment of a trained hospice nurse, to support their patients' comfort.

The need for flexibility on prescribing medications, especially opioids in schedule II, is critical in hospice care. Frequently new patients enrolled in hospice care are actively suffering and too often have a very short time between hospice enrollment and death. It is clinically appropriate to address these symptoms immediately upon admission to hospice – in fact, it would be inhumane to not do so. Clinicians do not have the ability to determine when the patient will decline and how quickly that decline will manifest. For many patients it is a short period of time and access to pharmaceutical interventions to promote comfort are critical in these crisis periods. In 2023, the length of stay among hospice patients with the shortest stays was 2 days at the 10th percentile and 5 days at the 25th percentile. The median length of stay in 2023 was only 18 days.[2]

One member organization shared that their median length of stay is 11-12 days, meaning these patients are already in crisis when admitted to hospice. While their organization considers itself well-resourced, they often admit 30-40 patients in a day. If a prescriber visit reached their 50% limit on schedule II e-prescriptions in a month, which would be very easy to do with hospice standards for the last 40 years, it

[1] Medicare Payment Advisory Commission. Report to the Congress: Medicare payment policy [Internet]. Washington (DC): MedPAC; 2023 Mar . Chapter 11, Hospice services; p. 296 Available from: https://www.medpac.gov/wp-content/uploads/2023/03/Ch10_Mar23_MedPAC_Report_To_Congress_SEC.pdf
[2] Medicare Payment Advisory Commission. Report to the Congress: Medicare payment policy [Internet]. Washington (DC): MedPAC; 2025 Mar . Chapter 9, Hospice services; p. 277 Available from: https://www.medpac.gov/wp-content/uploads/2025/03/Mar25_Ch9_MedPAC_Report_To_Congress_SEC.pdf

would mean dedicating that prescribers to just making in-person visits, which would reduce the volume of visits they could conduct in a day due to traveling between patients, and would lead to hospices having to severely limit the number of admissions they take, lead to significant delays in necessary care for patients, and possibly result in agency closures. This provider and other member providers' financial resources would not allow for a larger prescriber base to fill the gaps (assuming such staff even exist), Furthermore, this change in practice would also require the additional documentation per the proposed rule which is unreasonable with the administrative volume they already manage daily. If this rule were to move forward, it would fundamentally change practices that have worked before telemedicine was really a going concern at all.

This proposed rule has the potential to significantly restrict and even prevent patients from receiving support from their prescribing clinicians in a timely manner for palliative pain and symptom management by preventing the prescribing of controlled substances via telemedicine if the patient does not already have an established in person relationship.

50 Percent of Schedule II Controlled Substance Prescribing Must be Done In-Person

The requirement 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 does not align with current CMS requirements for hospice admission. It is not a requirement in hospice for a physician or attending clinician to see a patient at time of enrollment or prior to prescribing controlled medications. As we described above, instituting this requirement in hospice would be unduly burdensome to both patients facing the end of life and hospices which would need to increase staffing to comply with these regulations-at a time when there is a nationwide provider shortage.

The requirement for no more than 50% of a provider's prescriptions be done through telemedicine also overlooks the interdisciplinary approach used in hospice care. If this proposal moved forward, it would delay interventions aimed at ensuring patients have their symptoms managed quickly as nurse assessments would no longer be sufficient for prescribing and a prescriber visit would delay the opportunity to prescribe and treat symptoms at end of life in an expeditious manner. These delays would promote undue suffering and an increase in acute care utilization as a means to more quickly access medications for symptom management.

Electronic Prescribing for Controlled Substances (EPCS)

Until the last decade, prescriptions for controlled substances were written on paper. During the last decade the practice of "e-prescribing" has grown due to its efficiency, its ability to efficiently and quickly transmit data and, in many states, because the state has mandated its use. While there is nothing substantially different about prescribing on paper and prescribing via an e-prescribing system, it seems that using an e-prescribing system has been interpreted as "an internet prescription." It is not. Hospice has an explicit regulated exemption that DEA has failed to consider in their rulemaking. According to 21 CFR 1306.11(g):

> 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 may be transmitted by the practitioner or the practitioner's agent to the dispensing pharmacy by facsimile. The practitioner

> or the practitioner's agent will note on the prescription that the patient is a hospice patient. The facsimile serves as the original written prescription for purposes of this paragraph (g) and it shall be maintained in accordance with § 1304.04(h).

The proposed requirement that all special registration prescriptions be issued through EPCS contradicts DEA's own previous rulemaking which was an attempt to eliminate barriers to these critical drugs.

Duplicative and Burdensome Reporting for Hospices

Many hospice providers work with specialty pharmacies which already provide information on prescribing patterns and concerns regarding dose escalation to the providers as needed. The proposed rule requires clinicians to report on the total number of new patients issued a schedule special registration prescription in each state individual is registered, in aggregate for all states they were registered, and the total number of schedule III-V controlled substance in aggregate across all states. The requirement to have each clinician special registrant report is simply a burdensome duplication of efforts already taken by the dispensing pharmacy.

Specific Skilled Nursing Facilities Considerations for Exemption

Telemedicine support to post-acute, long-term care, and assisted living communities provides timely and effective access to care. Residents in nursing homes face barriers in accessing timely care from a medical director or primary provider who may visit the facility infrequently, especially in smaller facilities and rural areas. These vulnerable older adults often experience transitions of care between hospital and post-acute settings that result in unintended lapses in the medication regimen that contribute to unnecessary suffering and avoidable rehospitalizations. This population has higher prevalence of conditions for which it is appropriate to use controlled substances, including post-surgical care, chronic pain, and pain at end of life.

Many nursing home residents experience the same palliative care needs as patients on hospice programs. A recent report from the National Academies of Sciences, Engineering, and Medicine (NASEM) found that nursing home residents often do not receive enough support in palliative and end-of-life care.[3] NASEM made recommendations in several areas to improve the quality of palliative and end-of-life care for nursing home residents and we believe that this rule as proposed would hinder these recommendations . Ensuring quick access to necessary pharmaceutical interventions, especially in underserved areas, will only help to promote better patient outcomes – and allowing this rule to move forward with an exemption for nursing home residents would likely lead to worse outcomes.

50 Percent of Schedule II-Controlled Substance Prescribing Must be Done In-Person

As with hospices, the requirements for clinician practitioners to limit their schedule II-controlled substance electronic prescribing to less than 50% of all prescriptions in a month, would be incredibly difficult and risk serious consequences for residents. In nursing homes, many physicians conduct rounds in group practices, relying on the previous assessment of their colleagues when they are on call for the group. Additionally, many nursing homes contract this service to a fully virtual medical group to ensure

[3] National Academies of Sciences, Engineering, and Medicine (NASEM). *The National Imperative to Improve Nursing Home Quality: Honoring Our Commitment to Residents, Families, and Staff.* Washington (DC): Available from: https://www.nationalacademies.org/our-work/the-quality-of-care-in-nursing-homes

full coverage in the event of crisis or emergency situations. It is not uncommon to have a resident admitted to the facility after hours who needs critical medications before their attending can make rounds during normal hours. These are normal practices for most nursing homes. However, this rule would undermine that standard of consultation and the ability to contract with virtual medical groups for coverage. Especially for nursing homes with some kind of telehealth coverage overnight or on weekends, the burden of limiting the e-prescribing of schedule II-controlled substances to under 50% of all the clinician practitioners schedule II-controlled substances in a month would simply be unworkable and the likelihood of an on-call, in-person alternative equally as unlikely. Unfortunately, it is most likely that residents would simply go without needed medications in times of crisis.

Existing Diversion Oversight

The proposed rules fail to recognize the safeguards and audits these facilities already have in place to prevent abuse and diversion. The State Operations Manual Appendix PP, has specific expectations of nursing homes regarding related drug diversion allegations including requirements for state surveyors to refer any confirmed diversions to DEA, local law enforcement, and relevant State Boards. Nursing homes are surveyed yearly on this guidance and have strict penalties to enforce their Requirements of Participation. In both short-stay and long-stay residential settings, similar to hospitals, clinics, Indian Health Services, and Veterans Affairs facilities, there is a professional infrastructure that reduces the likelihood of diversion and overdose.

Duplicative and Burdensome Reporting for Long Term Care

Just as in hospice, many long-term care providers work with specialty pharmacies which already provide information on prescribing patterns and concerns regarding dose escalation to the providers as needed. The proposed rule requires clinicians to report on the total number of new patients issued a schedule special registration prescription in each state individual is registered, in aggregate for all states they were registered, and the total number of schedule III-V controlled substance in aggregate across all states. The requirement to have each clinician special registrant report is simply a burdensome duplication of efforts already taken by the dispensing pharmacy.

Considerations for Other Clinical Practitioners

The same urgency of access often arises in patients receiving services from palliative care prescribing clinicians and clinicians overseeing home health services. Palliative care is a growing field of specialized medical care for people living with serious illnesses, such as heart failure or cancer. We heard from many LeadingAge members who have palliative care programs that incorporate telehealth visits, which can be critical to supporting patients in times of crisis. Palliative care is built on the philosophy of meeting the patient's needs quickly and efficiently. If the need arises from a telehealth visit and a patient is actively suffering, providers prescribe the appropriate supports, which look very similar to prescribing practices of scheduled drugs in hospice. This rule would make it extremely difficult to operate palliative care programs in the community for many of the same reasons hospice clinicians would struggle to meet the requirements.

The Conditions of Participation for Medicare home health services do not require a medical director, meaning that agencies are often at the mercy of unresponsive referring community clinicians or acute care clinicians. Currently, referring and certifying eligible clinicians can conduct the face-to-face visit

required prior to home health commencing via telehealth. The Full-Year Continuing Appropriations and Extensions Act, 2025 extended telehealth flexibilities authorized during the COVID-19 Public Health Emergency (PHE) through September 30, 2025. This rule would further complicate patients' access to schedule II drugs since, by statutory definition, these patients are homebound and would struggle to see the clinician overseeing their plan of care who they may have only met via telehealth previously.

As we have outlined above, the restrictions for 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, are equally unworkable for palliative and home health patient populations. Therefore, **we strongly encourage DEA to return to the table with stakeholders and revise the proposed rule to further account for providers who serve equally vulnerable individuals outside of nursing homes and hospices, including providers serving palliative care patients and home health patients.**

Below are additional provisions in the rule we believe could increase the barriers to accessing needed substances for vulnerable older adults in settings other than hospice and nursing homes, which should be excluded from this or any other future rulemaking on telehealth prescribing of controlled substances.

Schedule II Prescribing Restrictions for Non-Certified Mid-Level Practitioners

We understand that the goal of requiring all advanced practice registered nurses (APRNs) and physician assistants (PAs) to be board certified is to increase the quality of care and oversight for patients receiving schedule II-controlled substances. However, there is a monetary and planning impact for these individuals to comply. Not only do these practitioners have to pay for the board certification, but they must also practice for a period of time before taking the exam for certification. As a result, there would be a period of time where current APRNs and PAs would not be able to practice in support of their employers and the patients that they serve while they seek the specific credentials required by this rule. This gap would add to the already enormous healthcare workforce shortage in this country. To quantify this gap, while the majority of APRNs had a certification, the majority were in either family medicine or some type of primary practice.[4] In a recent survey of PAs, only 28% of respondents reported that they held a Certificate of Additional Qualification, or a specialty certificate.[5] Requiring immediate board certification as a requirement for telemedicine prescribing would severely limit access to hospice, nursing home care, and the other services our members provide. Additionally, to our knowledge, a board certification for NPs or PAs rendering treatment at long term care facilities does not exist. If a certification requirement must move forward, it should be as broad as possible and account for the lack of specific certifications for many of our settings.

Physical Location for Schedule II Controlled Substance Prescribing

The proposed rule would also require clinician practitioners to be physically located in the same state as the patient to whom they are prescribing a schedule II-controlled substance. LeadingAge represents many members who serve in states that border one another – for example, Indiana and Kentucky. For example, we have members that serve both states as hospice and palliative care practitioners, but the

[4] Why Dual Certifications Are Growing: Demand and Benefits. *Maryville University.* May 19, 2023. https://online.maryville.edu/blog/why-dual-certifications-are-growing/

[5] The Certificate of Added Qualifications Credential: PAs Evaluate the Pros and Cons. *Medscape.* September 9, 2022. https://www.medscape.com/viewarticle/980489?form=fpf

majority of their clinical prescribers live in Indiana. If this provision in the rule were to move forward, the providers would need to physically relocate from Indiana to Kentucky in order to have a telehealth visit to write a prescription for a schedule-II drug. The requirement would cripple the ability of providers to serve across state lines, which is a crucial need in so many underserved areas of the country.

Consider Adding Telehealth onto DEA Licensure Instead of a New Process

While we understand the broader community of practitioners requested DEA consider a special registration process for the e-prescribing of controlled substances, the rule put forward by the former Administration further complicates the issue and adds additional burdens to an already clearly defined process for DEA licensure. It would go a long way to streamlining the process if telehealth were an option to add to a clinical practitioners' already established DEA license. That would reduce both the burdens of a second registration process and reduce the fees associated with registration which again could create a barrier for clinicians that serve populations most in need of telehealth services such as rural communities and the seriously ill.

Finally, we would like to cite additional precedents for hospice and nursing homes exemptions at the state level. Arizona, Georgia, Maine, Ohio, and Virginia exempt both hospice and nursing homes from their opioid prescribing laws and Maryland, South Carolina, and Wisconsin explicitly exclude hospice.[6] DEA should follow these state precedents in decision-making and create continuity across the health care system.

We urge DEA to specifically exempt hospice and skilled nursing providers from this and any future rules under the authority given to the DEA Administrator and the Secretary of Health and Human Services to jointly establish exemptions in regulation under the Ryan Haight Act of 2008. Additionally, we strongly encourage DEA to return to and revise the proposed rule in consultation with stakeholders to further account for providers who serve equally vulnerable individuals outside of nursing homes and hospices, including providers serving palliative care patients and home health patients.

Thank you for the opportunity to share our recommendations with you on telemedicine prescribing of controlled substances. My contact information is below should you wish to discuss any of these comments.

Sincerely,

Katy Barnett Director, Home Care and Hospice Operations and Policy
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About LeadingAge: We represent more than 5,400 nonprofit aging services providers and other mission driven organizations that touch millions of lives every day. Alongside our members and 36 partners in 41 states, we use applied research, advocacy, education, and community-building to make America a better place to grow old. Our membership encompasses the continuum of services for people as they age, including those with disabilities. We bring together the most inventive minds in the field to lead and innovate solutions that support older adults wherever they call home. For more information, visit leadingage.org.

[6] State-by-State Summary of Opioid Prescribing Regulations and Guidelines. *Arizona Department of Health Services.* https://www.azdhs.gov/documents/prevention/womens-childrens-health/injury-prevention/opioid-prevention/appendix-b-state-by-state-summary.pdf