

March 31, 2023

The Honorable Anne Milgram
Administrator
U.S. Drug Enforcement Administration
8701 Morrisette 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) AND Expansion of Induction of Buprenorphine (Docket No. DEA-948)

Dear Administrator Milgram:

On behalf of the nearly 5,600 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 two proposed rules referenced above which address telemedicine prescribing of controlled substances for patients who have not received a prior in-person medical evaluation. Given the overlap in topics and similarities in the proposals across the two rules, we offer a consolidated set of comments addressing both but we specifically refer to Docket No. DEA-407 as the “Telemedicine Prescribing” proposed rule and Docket No. DEA-948 as the “Induction of Buprenorphine” proposed rule, as applicable.

AAHPM is the professional organization for physicians specializing in Hospice and Palliative Medicine. Our membership also includes nurses, social workers, spiritual care providers, 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 an increasing number of Americans diagnosed with opioid use disorder (OUD) and staggering 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 the pain and other burdensome symptoms that accompany their condition. (Serious illness is a health condition that carries a high risk of mortality and either negatively impacts a person's daily functioning or quality of life or excessively strains their caregivers.¹) We do not believe that DEA's proposed policies sufficiently take this need into account.

The timely and effective management of pain and other distressing symptoms is central to providing high-quality palliative care to patients with serious illness, and opioid analgesics and other controlled substances are critical tools in alleviating their suffering. ***AAHPM is concerned, that DEA's proposals fail to 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 contend with pain, frailty, or medical instability and/or rely on caregivers to assist with transportation. Additionally, patients with serious illness receiving palliative care may be in the last weeks or months of life; to illustrate, one member reported that about 75 percent of his palliative care patients die each quarter.

In the face of this reality, the proposed policies – which completely restrict access to non-buprenorphine opioid medications without an in-person evaluation – could have devastating impacts on the patients our members serve. Palliative care clinicians would be hampered in their ability to furnish medically necessary and appropriate care and, in turn, patients would be limited in their ability to achieve relief of pain and suffering and to maximize quality of life.

To prevent such outcomes, and as further discussed below, ***AAHPM urges DEA not to finalize the proposals contained in the two proposed rules through at least the end of calendar year 2024, to align with the extension of Medicare telehealth flexibilities Congress enacted via the Consolidated Appropriations Act, 2023. Rather, DEA should use its regulatory authority to extend the telemedicine prescribing flexibilities for controlled substances that have been in place in response to the public health emergency (PHE) for COVID-19. We strongly recommend that DEA then use this time period to work with stakeholders to implement a telemedicine special registration process enabling qualified practitioners to prescribe controlled substances via telemedicine without a prior, in-person medical evaluation so as to support timely, effective care for patients with serious illness, including those who are receiving palliative care. Separately, DEA should clarify that in-person evaluation requirements for prescribing of controlled substances do not apply to patients enrolled in hospice. To the extent that DEA does not clarify that patients receiving hospice care are exempt from in-person evaluation requirements, DEA should also ensure that the telemedicine registration process would allow for such exemption.***

¹ Kelley AS, Bollens-Lund E. Identifying the Population with Serious Illness: The "Denominator" Challenge. J Palliat Med. 2018 Mar;21(S2):S7-S16. doi: 10.1089/jpm.2017.0548. Epub 2017 Nov 10. PMID: 29125784; PMCID: PMC5756466.

Summary of Key Messages and Recommendations

While *AAHPM maintains an overall recommendation to delay finalization of any proposals from the Telemedicine Prescribing and Induction of Buprenorphine proposed rules, to implement a telemedicine special registration process that would support timely, effective care for patients with serious illness, and to clarify that in-person evaluation requirements for prescribing of controlled substances do not apply to patients enrolled in hospice*, we offer the following second-order recommendations for DEA as it contemplates its final policies:

- 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 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.

Additional details on these recommendations are provided below.

Impact of the PHE for COVID-19 on the Care of Seriously Ill Patients via Telemedicine

While the physical, mental, emotional, and human toll of the PHE for COVID-19 has been devastating on the nation, many agree that some positive outcomes also have emerged. Most notably for our members, the demands the PHE placed on the healthcare workforce and the flexibilities implemented to support those demands have resulted in game-changing advances in the delivery of palliative care, particularly in the expert use of telehealth to evaluate, diagnose,

and treat patients virtually using communications technology. For seriously ill patients, particularly those who experience significant pain, mobility challenges, and/or cognitive limitations, the use of telehealth has been especially important in facilitating access to timely and high-quality medically necessary care.

Over the past three years of the PHE, hospice and palliative medicine practices have developed the skills and experience to comprehensively assess patients using remote technologies. They also have learned how to identify risks, including for potential opioid abuse, and to implement mitigating strategies to maximize patient safety and well-being, consistent with the goals of palliative care. Likewise, patients have become accustomed to receiving care virtually and have expressed satisfaction with the increased access and flexibility that telehealth has afforded.

It is clear that our experience with COVID-19 has fundamentally shifted how healthcare is delivered. *Reverting back to pre-COVID-19 requirements for the prescribing of opioid analgesics for the management of pain and other burdensome symptoms, as envisioned under the proposed rules, would fail to recognize the advances that have been made in patient care in response to the PHE and, in particular, would negatively impact the ability of patients with serious illness to receive needed care.*

Clarification of Application of Policies to Hospice Patients

AAHPM seeks clarification from DEA that its proposed policies for telemedicine prescribing of controlled substances do not apply to typical hospice prescribing practices, including as regulated at the state level.

Hospice patients are a discrete and unique subset of patients who require 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” by two physicians who each attest the patient has 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.² 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, including those resulting from in-person evaluation requirements, deprive patients of the peace and dignity that they deserve.

We understand that the 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

² National Hospice and Palliative Care Organization. “NHPCO Facts and Figures: 2022 Edition.” December 2022. <https://www.nhpc.org/wp-content/uploads/NHPCO-Facts-Figures-2022.pdf>.

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 the same verification and oversight goals. Under the Medicare hospice benefit, which is highly regulated by Centers for Medicare & Medicaid Services, the comprehensive 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.

All hospice care is supervised by a hospice physician but much of the day-to-day care is provided by the interdisciplinary hospice team members – which include advanced practice registered nurses, physician assistants, nurses, social workers, chaplains, and others based on need – are in regular face-to-face contact with patients, further mitigating risk of medication 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. The interdisciplinary team members communicate frequently about patient care, and the full team meets at least every two weeks to review patient care details. Hospice nurses also work 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 medications.

Given this well-documented and managed physician-patient relationship and the close ongoing monitoring involved in furnishing hospice care, ***AAHPM believes that restrictions under the Ryan Haight Act for telemedicine prescribing of controlled substances should not apply to patients enrolled in hospice. We respectfully request that DEA clarify that it agrees with our position by clearly articulating that patients receiving hospice care are exempt from the in-person evaluation requirements.***

Special Considerations for Other Patients with Serious Illness

For patients with serious illness who are not near the end of life or who have not elected to receive hospice care, the DEA's proposals pose numerous challenges that would restrict patients' ability to receive medically necessary care. The Telemedicine Prescribing proposed rule prohibits any dispensing of Schedule II controlled substances, or any narcotic controlled substance for management of pain, without a prior in-person evaluation, except in very limited circumstances. While the qualifying telemedicine referral mechanism may enable access in some cases, we identify several concerns regarding that mechanism in our comments below. Additionally, in cases where patients self-refer, or when patients are referred from practitioners who are not registered with the DEA, the rule requires an in-person evaluation prior to prescribing of controlled substances – medications that our patients require to alleviate their pain and suffering.

The in-person evaluation requirement would pose substantial hardship for patients with serious illness, many of whom are in need of palliative care but not eligible for or have chosen not to elect hospice care. As one example, a member reports treating an 86-year-old patient with progressing breast cancer and end-stage dementia. This patient receives oral chemotherapy and is cared for virtually via telehealth, both by her oncology practice and her palliative care team, due to inability to travel for in-person appointments. An in-person evaluation for such a patient would be extremely challenging, and likely extremely distressing, if it were to take place. While an in-person evaluation could potentially occur if the practitioner travels to the patient's home, logistic and staffing challenges would pose significant barriers, particularly given documented shortages among the hospice and palliative care workforce and potentially vast geographies to span to reach such patients in rural areas.

A further challenge for patients with serious illness is their medical instability. Many patients may not require opioid medications at the outset of their palliative care regimen and can readily receive palliative care consultations via telehealth. By the time it is necessary for them to receive opioids to manage the pain and other symptoms of a serious illness, they will likely already be very sick. Demanding that patients make an in-person visit to the clinic at this time – when their symptoms are most severe – would be overly burdensome and, in many cases, would likely prohibit patients from obtaining the medications they need.

Finally, our members report that during the PHE many palliative care practices have leveraged telehealth to expand their capacity to treat patients with serious illness, with some reporting that as high as 70 percent of their practice is now conducted via telehealth. Such practices would not have the physical space to accommodate in-person evaluations required under the proposed rules. Lack of physical space would restrict the ability of these practices to provide timely consultation, contributing to delays in care, or may require that they scale back their practice altogether, leaving many vulnerable patients with no options for care.

The COVID-era telehealth prescribing flexibilities expanded access to palliative care, allowing more patients with serious illness to receive needed treatment. Rolling back these flexibilities will mean many patients who were able to achieve relief of significant pain will no longer be able to do so. Ultimately, patients will lose care that is crucial to their well-being and quality of life, leading to increased suffering and unnecessary and preventable emergency care.

Special Considerations for Patients with Opioid Use Disorder

AAHPM appreciates that DEA has allowed for an initial 30-day telemedicine prescription of buprenorphine for the detoxification or maintenance treatment of OUD. However, we are concerned that DEA's approach is overly restrictive in light of the increasing number of Americans diagnosed with OUD and the limited safety risks posed by the use of buprenorphine for treatment of OUD. Furthermore, *we believe that the DEA's approach again fails to consider the needs of patients who suffer from serious illness in addition to OUD.*

Patients require access to buprenorphine as soon as they are ready to begin OUD treatment. Unfortunately, access to in-person care is impeded by the limited availability of OUD treatment programs, particularly in rural areas. Our members report up to 6-month long waiting lists to receive in-person care, but patients with serious illness often do not have that long. Even if they were to receive an initial 30-day supply, wait lists and limited availability for in-person appointments – compounded by challenges such as pain, mobility, and medical instability – could prevent patients from being able to access continuing buprenorphine treatment. They may be forced to discontinue treatment if they are not able to schedule or present for an in-person evaluation in a timely manner, putting at risk any progress made in addressing their OUD.

As Neale et al. note, buprenorphine prescribing for patients with serious illness who also suffer from OUD is essential to the practice of palliative care because it addresses suffering associated with active OUD, including cravings, withdrawal, and pain.³ Controlling OUD with buprenorphine enables patients with serious illness to receive treatment for their underlying conditions, such as radiation therapy or cardiac rehabilitation. On the other hand, ongoing challenges with OUD can impair patients' ability to contend with their co-occurring conditions, worsening underlying symptoms and potentially speeding patients' decline.

DEA's proposed limitations on buprenorphine prescriptions are further dismaying given the evidence demonstrating the effectiveness of telemedicine prescribing in supporting patients with OUD.^{4,5,6} Data also suggest that COVID-19 flexibilities for prescribing buprenorphine did not increase the likelihood of overdose deaths involving buprenorphine.⁷ ***Given the evidence supporting the substantial benefits of buprenorphine for OUD treatment and the relatively low risk of negative outcomes when prescribing via telemedicine, AAHPM disagrees that restrictions on opioid prescribing for buprenorphine treatment of OUD are necessary, particularly given the harm they can impose on patients suffering from both OUD and serious illness.***

Further Limitations of DEA Proposals

Limitations of Qualifying Telemedicine Referral Process

DEA proposes an alternative mechanism by which practitioners may prescribe a controlled substance without a prior in-person evaluation, namely via receipt of a qualifying telemedicine

³ K.J. Neale et al., "Top Ten Tips Palliative Care Clinicians Should Know About Buprenorphine," *Journal of Palliative Medicine* 26 (2023), <https://doi.org/10.1089/jpm.2022.0399>

⁴ L. Wang et al., "Telemedicine Increases Access to Buprenorphine Initiation During the COVID-19 Pandemic," *Journal of Substance Abuse Treatment* 124 (2021), <https://doi.org/10.1016/j.jsat.2020.108272>

⁵ E. Weintraub et al., "Outcomes for Patients Receiving Telemedicine- Delivered Medication-Based Treatment for Opioid Use Disorder: A Retrospective Chart Review," *Heroin Addiction and Related Clinical Problems* 23, no. 2 (2021): 5, <https://pubmed.ncbi.nlm.nih.gov/33551692>

⁶ T.O. Cole et al., "Patient Satisfaction with Medications for Opioid Use Disorder Treatment Via Telemedicine: Brief Literature Review and Development of a New Assessment," *Frontiers in Public Health* 8 (2020), <https://pubmed.ncbi.nlm.nih.gov/33553083>.

⁷ L.J. Tanz et al., "Trends and Characteristics of Buprenorphine-Involved Overdose Deaths Prior to and During the COVID-19 Pandemic," *JAMA Network Open* 6, no. 1 (2023), <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800689>.

referral. Under this mechanism, the referral must note the name and National Provider Identifier (NPI) of the practitioner to whom the patient is being referred.

AAHPM is concerned that this proposal fails to recognize how healthcare is largely practiced today – specifically, via team-based care. Members within single-specialty groups, multispecialty groups, and integrated health systems regularly assume care from other practitioners within the same group or system, including by accessing patient data via electronic health records (EHRs) as applicable and necessary. In this context, referrals are often made at the department or practice level, not to individual clinicians. For example, a treating oncologist will likely refer a patient to the palliative care clinic within the same multi-specialty group practice or health system, or to a standalone palliative care clinic. In such cases, it would not be reasonable or appropriate to specify an individual clinician to whom the referral would be made. The referring clinician would have no way of knowing the name and NPI of the specific provider who will end up taking on the referral, and restricting a referral to an individual clinician may lead to delays in care if other clinicians on the team have more availability to manage a new patient. And for clinicians that do practice within the same system as a referring provider, it is not clear how the recordkeeping and documentation requirements would apply. Would EHRs be required to separately track when a referral is a qualifying telemedicine referral? Would telemedicine prescribers be required to separately document in the patients' visit notes the name and NPI of the referring physician, even though the referral is tracked through the systemwide EHR?

AAHPM also has significant concerns with the requirement for the referring physician to be registered with the DEA. In many cases, practitioners may be able to evaluate and assess patients' health conditions without the expectation that they would prescribe controlled substances. As an example, palliative care practices often receive referrals for patients discharged from hospitals. In many cases involving academic medical centers, discharge summaries and referring orders to palliative care clinics are prepared by trainees who have not yet applied for DEA registration. Under the proposed rules, these types of referrals would not count as qualifying telemedicine referrals, requiring seriously ill patients to return to clinic settings for additional evaluation.

We also highlight the logistical challenge that prescribing practitioners would face in validating required elements of a qualifying telemedicine referral. For example, it is not clear how a prescriber could validate whether a referring provider is registered with the DEA. To our knowledge, there is no automated or low-burden mechanism for prescribers to validate another provider's DEA registration status. Prescribing practitioners would therefore have to take further steps to confirm whether a referral would or would not qualify to serve as the basis for a telemedicine prescription. There is also not an established way for a prescriber to know whether a referring physician had an in-person visit without going through the extra step of separately confirming the in-person status.

Finally, we also highlight the lack of clarity regarding application of the qualifying telemedicine referral to in-person evaluations that occurred prior to the effective date of the Telemedicine Prescribing and Induction of Buprenorphine final rules. Could prior evaluations by referring providers be retroactively documented, for example, to allow them to serve as the basis for telemedicine prescriptions? Or would all patients be required to receive some type of in-person evaluation after

the effective date of the rules to receive new prescriptions for opioids (excepting those for whom there are patient-provider relationships that were established during the COVID-19 PHE)?

Prescription Drug Monitoring Program (PDMP) Review Requirements

For all telemedicine prescriptions where there has not been a prior in-person evaluation, DEA proposes that prescribing practitioners must consult with state PDMPs, where available, and specifies separate recordkeeping requirements that would apply.

AAHPM notes that PDMPs are state-based, and requirements to consult with PDMPs are generally promulgated at the state level. Therefore, *AAHPM believes that DEA should defer to states regarding their requirements to consult PDMPs.*

We also note that some of the proposed recordkeeping requirements are overly onerous, including the requirement to track the time of each PDMP consultation (not simply the date). PDMPs should have auditable records of provider inquiries that would make such a requirement redundant; it merely contributes additional administrative burden and risk of non-compliance if prescribers forget to collect such information.

Onerous Requirements and Related Challenges

Across all its proposals in the Telemedicine Prescribing and Induction of Buprenorphine proposed rules, DEA proposes new requirements that, upon our review, are fairly complicated and nuanced as well as onerous with respect to recordkeeping and documentation requirements. *AAHPM is concerned that these requirements would have a detrimental effect on our members' ability to prescribe opioid medications via telemedicine.*

For example, *we are concerned that the complexity and prescriptive nature of some of the requirements will have a chilling effect on potential referrals, with many clinicians being unwilling to refer patients under the qualifying telemedicine referral mechanism.* They may be concerned that prescriptions based on their referral may result in liability if the prescriptions are later associated with abuse or diversion. Likewise, a member reports that small pharmacy owners are worried about filling prescriptions that are marked as “telemedicine prescriptions,” to the point that they are considering establishing policies not to fill any so-marked prescriptions.

Additionally, *we are concerned about the burden of implementing some of the new documentation and recordkeeping requirements, as well as the feasibility of implementing these requirements in a timely manner.* Some of the requirements would be newly established, such that there is not clear infrastructure within EHRs or processes in place to accommodate the required data elements. These include data like the city and state in which the patient is located during the telemedicine encounter, the address of the prescriber if he or she is not 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. Lack of appropriate infrastructure could impose barriers for providers seeking to rely on these telemedicine prescribing rules in the near future to issue prescriptions for

controlled substances without in-person evaluations, until such time that changes are built into EHR systems to readily track these data. Further, each new required data element would contribute to administrative burden for practitioners who are already at capacity.

Impact on Health Equity

The availability of services via telehealth has contributed to advancements in health equity, particularly for patients in rural areas but also for other patients who may have difficulty accessing care, including in underserved urban and suburban areas. ***Reinstating pre-PHE requirements for in-person evaluations for the prescription of opioids and other controlled medications, as proposed, will roll back these achievements in equity and exacerbate health disparities.*** Seriously ill patients who live in rural areas and those across all geographies who have less access to transportation, reduced or no available caregiver assistance, and less flexibility to leave work will be among those most greatly harmed.

AAHPM Recommendations

Primary Recommendations

AAHPM believes that patients with serious illness – including those near the end of life – should not have to face unnecessary barriers in accessing medications that can alleviate pain and suffering and improve quality of life. Indeed, the Centers for Disease Control and Prevention (CDC) has established a precedent for separate consideration of certain patients with substantial pain management needs. In its most recent Clinical Practice Guideline for Prescribing Opioids for Pain, CDC excluded from application of the Guideline pain management related to sickle cell disease, cancer-related pain treatment, palliative care, and end-of life care.⁸ AAHPM believes that DEA's rules for telemedicine prescribing of controlled substances should also include accommodations that would enable such patients to access opioid medications and other controlled substances without delay, based on the information detailed above.

Congress has established a precedent for extending PHE flexibilities related to the delivery of care furnished via telehealth. Specifically, federal lawmakers extended numerous Medicare telehealth flexibilities, including to allow Medicare beneficiaries to receive care via telehealth regardless of where they are located in the country, through calendar year 2024, as part of the *Consolidated Appropriations Act, 2023*. AAHPM believes that such an extension provides a reasonable basis for exercising DEA's administrative authority with respect to PHE telemedicine flexibilities.

Finally, we note that the *Ryan Haight Act* required DEA to establish a telemedicine special registration process that would allow controlled substances to be prescribed without an in-person medical evaluation of the patient. Congress again directed the promulgation of final

⁸ Centers for Disease Control and Prevention. "CDC Clinical Practice Guideline for Prescribing Opioids for Pain – United States, 2022. *MMWR* 71, no. 3 (2022), <https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm>.

regulations for a telemedicine special registration as part of the *SUPPORT for Patients and Communities Act* in 2018, but DEA has yet to issue such regulations.

Based on the above, AAHPM urges DEA not to finalize the proposals contained in the two proposed rules. 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 – including buprenorphine – that have been in place in response to the COVID-19 PHE. We strongly recommend that DEA then use this time period to work with stakeholders to implement a telemedicine special registration process enabling qualified practitioners to prescribe controlled substances via telemedicine without a prior, in-person medical evaluation so as to support timely, effective care for patients with serious illness, including those who are receiving palliative care. Separately, DEA should clarify that in-person evaluation requirements for prescribing of controlled substances do not apply to patients enrolled in hospice. To the extent that DEA does not clarify that patients receiving hospice care are exempt from in-person evaluation requirements, DEA should also ensure that the telemedicine registration process would allow for such exemption.

AAHPM believes that a meaningful patient-provider relationship can be established, and thorough evaluation and ongoing monitoring can still occur, through telemedicine encounters. A telemedicine special registration process would ensure that patients with serious illness have unhindered access to medically necessary medications intended to manage their pain and other distressing symptoms. Our members have indicated that more robust requirements under such a registration would be reasonable for the added flexibility they would have in supporting optimal palliative care for their patients.

Secondary Recommendations

While AAHPM stands by our primary recommendation to delay finalization of DEA's proposed policies and to implement a special registration that would help ensure timely, appropriate care for patients with serious illness – including those near the end of life – AAHPM believes that the limitations of DEA's policies would create significant challenges for patients with serious illness if they are finalized without refinement. We therefore offer the following recommendations to address the limitations we have identified above:

- 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 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.

Request for Information: FDA-Approved Indications

DEA requests comment on whether its rules should limit the issuance of prescriptions for controlled medications to FDA-approved indications contained in the FDA-approved labeling for medications. *AAHPM strongly opposes such a limitation, which would cripple our members' ability to provide adequate pain management and relief of other burdensome symptoms for patients with serious illness* given the frequent use of drugs off-label for these purposes. We believe that limiting telemedicine prescriptions to FDA-approved indications would severely interfere with the practice of palliative medicine and our physicians' judgement in determining the best course of treatment for their patients. In many cases, such a policy would also contradict evidence supporting the benefits of drugs for off-label uses, as documented through expert consensus statements or practice guidelines.

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Thank you again for the opportunity to comment on the Telemedicine Prescribing and Induction of Buprenorphine proposed rules and share our members' concerns regarding potential barriers to providing high-quality, patient-centered care for patients with serious illness. AAHPM stands ready to partner with DEA in addressing the many challenges we have discussed here and achieving balanced policy that maximizes individual and public safety while ensuring our nation's sickest and most vulnerable patients receive timely, appropriate treatment for their pain and suffering. Please address questions or requests for further information to Jacqueline M. Kocinski, MPP, AAHPM Director of Health Policy and Government Relations, at jkocinski@aahpm.org or 847-375-4841.

Sincerely,



Holly Yang, MD HMDC FACP FAAHPM
AAHPM President