AMERICAN ACADEMY OF
HOSPICE AND PALLIATIVE MEDICINE

February 16, 2018

United States Senate
Committee on Finance
Washington, D.C. 20510-6200

Submitted to opioids@finance.senate.gov

Re: Request for information on opioid-related Medicare and Medicaid policy

Dear Chairman Hatch and Ranking Member Wyden:

On behalf of the more than 5,000 members of the American Academy of Hospice and Palliative Medicine (AAHPM), thank you for the opportunity to provide input on the eight questions you posed related to our nation's ongoing opioid crisis.

AAHPM is the professional organization for physicians specializing in Hospice and Palliative Medicine. Our membership also includes nurses and other health and spiritual care providers deeply committed to improving quality of life for patients facing serious or life-threatening conditions, as well as their families and caregivers. The timely and effective management of pain and other distressing symptoms is central to providing these patients with high-quality palliative care, and opioid analgesics are a critical tool in alleviating that suffering.

With that in mind, AAHPM is concerned with how best to balance the growing challenges related to managing pain with opioids with the need for ready access to appropriate pain medications for patients with serious or complex chronic illness and those at the end of life — patients for whom high-dose opioids may be necessary and medically appropriate. The Academy recognizes there is an indisputable public health imperative to curb opioid abuse, misuse, and diversion, and is deeply committed to both providing continuing education that results in optimal pain management and optimal care for all patients as well as to collaborating with professional, regulatory and industry stakeholders to maximize individual and public safety. At the same time, AAHPM believes public policies must recognize there is an equally important public health imperative to ensure that our sickest, most vulnerable patients have access to timely, effective treatment of their pain and suffering. We have growing concerns regarding policies that aim to limit opioid production, availability, and/or dosage and duration of prescriptions and would impede the individualization of treatment to patient needs. These efforts serve to paint all pain as the same and threaten access to appropriate care for patients with serious illness.

AAHPM appreciates the Committee's attention to these challenges and applauds you for reaching out to stakeholders for information that may be useful in guiding the important work of leveraging public programs to help turn the tide on this epidemic. Our Academy's feedback on some of the Committee's questions follows below.

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- *How can Medicare and Medicaid payment incentives be used to promote evidence-based care for beneficiaries with chronic pain that minimizes the risk of developing OUD or other SUDs?*

The current payment structure in Medicare and Medicaid is centered on the medicalized treatment of pain, rather than other interventions that may actually be more effective. For example, there are no reimbursement mechanisms for many aspects of multidisciplinary care, which has been shown to be the best way to manage chronic pain. Similarly, cognitive behavioral therapy has been demonstrated to be effective for pain management yet, because it is considered a mental health intervention, it gets discounted in terms of reimbursement.

Last October, AAHPM was proud to be part of the inaugural Integrative Pain Care Policy Congress. This event brought together 70 leaders from more than 50 organizations representing the full scope of licensed and certified health care providers, public and private payers, policy advocates, research organizations, and the patient voice to identify strategies to achieve shared goals. These groups agreed that "Comprehensive integrative pain management includes biomedical, psychosocial, complementary health, and spiritual care. It is person-centered and focuses on maximizing function and wellness. Care plans are developed through a shared decision-making model that reflects the available evidence regarding optimal clinical practice and the person's goals and values." AAHPM believes that the domains of palliative care naturally track with this vision.

Each day, AAHPM members see how patients with multiple chronic conditions or serious illness – and their caregivers – benefit from palliative care and support services that align treatments with their individual preferences. Numerous studies further demonstrate that high-quality, interdisciplinary palliative care services can provide significant benefits for patients, caregivers, and payers, including reducing pain and suffering patients experience due to their illnesses. Despite these proven benefits, many patients and caregivers do not receive palliative care because current payment systems do not provide adequate resources to enable palliative care teams to deliver those services to the right patient in the right place at the right time. As Medicare continues to develop alternative payment models (APMs), our Academy believes the time is right consider an APM for community-based palliative care. AAHPM has proposed such a model to the Physician-Focused Payment Model Technical Advisory Committee: *Patient and Caregiver Support for Serious Illness*. Our leaders would be pleased to work with the Committee and the appropriate regulatory staff at the Department of Health & Human Services to advance such a whole-person approach to care, as we believe it would go a long way towards relieving pain and increasing safety for patients and families now suffering across our nation.

- *What barriers to non-pharmaceutical therapies for chronic pain currently exist in Medicare and Medicaid? How can those barriers be addressed to increase utilization of those non-pharmaceutical therapies when clinically appropriate?*

As noted above, multidisciplinary pain management is important, but there are no reimbursement mechanisms for these interventions. While there is an acute need for more research on safe and effective treatments for pain (which AAHPM has pointed to through a provision in the Palliative Care and Hospice Education and Training Act – see S. 693 / H.R. 1676) these treatments must be covered by payers if they are to become mainstream and accessible. When insurers typically cover medications but not non-pharmacologic approaches, or if complementary and alternative therapies that research has shown to be effective are not reimbursed under Medicare, this limits the availability of effective and safe non-opioid therapies. We urge the Committee to encourage Medicare to cover multi-modal and non-pharmacological pain treatment where these are options, otherwise prescribers will necessarily default to treatments, like opioids, that are reimbursed in order to ensure their patients' pain is managed. Further, Congress could urge the Food and Drug Administration (FDA) to prioritize and accelerate approval of adjuvant analgesics to decrease the need for opioids as well as ease barriers to medical research on cannabinoids.

- *How can Medicare and Medicaid payment incentives be used to remove barriers or create incentives to ensure beneficiaries receive evidence-based prevention, screening, assessment, and treatment for OUD and other SUDs to improve patient outcomes?*

An important point to note at the outset is that individuals with OUD may suffer with a serious or terminal illness and require palliative or hospice care – including opioid treatment. AAHPM would be deeply concerned if policymakers sought to preclude prescribing opioids to these patients or restrict coverage or reimbursement for appropriate opioid use for individuals suffering from OUD. Not providing appropriate pain management for a patient suffering from OUD who is seriously ill would have dire consequences, including the patient potentially seeking relief in illicitly obtained opioids and other narcotics.

For this reason, AAHPM urges the Committee to balance the public health imperative to stem the tide of opioid misuse and abuse with the public health imperative to manage untreated pain. Setting aside its financial costs, unrelieved pain causes inordinate human suffering resulting in longer hospital stays, increased readmissions and outpatient visits, and decreased ability to function or enjoy quality of life.

- *Are there changes to Medicare and Medicaid prescription drug program rules that can minimize the risk of developing OUD and SUDs while promoting efficient access to appropriate prescriptions?*

AAHPM's primary concern in this area is emerging state and federal proposals or requirements that aim to limit the dosage and duration of prescriptions. There is no scientific basis to support calls to restrict the dosage and duration of treatment for pain, and AAHPM objects to such considerations as they would unduly burden patients with serious and life-threatening illness. As a population, these patients need higher doses of opioids for a longer duration than most any other group. For example, many palliative and hospice patients with non-cancer-related pain and other symptoms from their serious or terminal illness experience these symptoms for periods of time much longer than, say, an arbitrary 90-day maximum. If there is a 90-day limit for non-cancer opioid pain management, would we have to stop opioids for the last ten days of life for a dying multiple sclerosis patient who happens to live 100 days from the start of care?

Severe limits on the duration of prescriptions, such as those being considered or enacted across many states and more recently proposed by the Centers for Medicaid Services, are particularly burdensome for seriously ill individuals being treated in an outpatient setting. Patients suffering moderate-to-severe chronic pain are often those least capable of meeting the increased hurdles that Schedule II drugs carry. These patients frequently have limited mobility and must be accompanied by caregivers. Requiring office visits with greater frequency simply to obtain a prescription is an even greater hurdle for those living in rural or underserved areas as their healthcare provider may be hours away. Furthermore, and perhaps most critical, access to these medications often has substantial bearing on these patients' quality and length of life, as it allows them to complete their disease-directed treatments, sleep through the night, or continue to work and otherwise engage in daily activities.

Limits on allowable daily dosages can also result in uncontrollable pain and symptom crises for these patients that could otherwise be managed by an amount of medicine that is arbitrarily discouraged.

Palliative and hospice care appropriately emphasize individualization of treatment, including analgesia for pain, and AAHPM would oppose any recommendation that would preclude an individualized approach to palliative care patients' legitimate needs. Dosing and duration limits for opioids would cause unnecessary suffering for hundreds of thousands of patients and paradoxically sacrifice patients' safety by leaving them in terrible pain.

AAHPM believes a better solution is to encourage prescribers and pharmacists to embrace partial fill policies for their patients. Such action would better target the proliferation of large amounts of unused medications which are a key contributor to the opioid crisis. To wit, in a December 2017 letter to the Drug Enforcement Administration's (DEA) acting administrator, U.S. Sen. Chuck Grassley urged the agency to update its regulations and guidance related to the partial filling of Schedule II controlled substances.

Finally, AAHPM strongly supports efforts to improve prescribers' knowledge and skills, but we believe efforts to encourage such education are more appropriately promulgated by FDA or DEA. As the Committee is aware, the FDA has utilized its authority under Risk Evaluation and Mitigation Strategies (REMS) to encourage provider education, and AAHPM has been a strong supporter of this effort, working in collaboration with other provider groups to develop a REMS-compliant curriculum and deliver it to prescribers in our field.

- *How can Medicare or Medicaid better prevent, identify, and educate health professionals who have high prescribing patterns of opioids?*

AAHPM is concerned that this question broadly demonizes "high" prescribing when, in fact, patient-centered care would recognize that pain will not only differ by condition but by the individual (different patients have different pain thresholds) and his or her history and circumstances (e.g. complications in treatment). Patients with pain are not all the same, so managing pain effectively and safely requires an individualized approach based on many factors, including pain syndrome, patient risk factors, underlying illnesses, life expectancy, clinical expertise, degree of control and monitoring available to the treatment team, and appropriate goals of treatment (for many patients not just relief of pain, but also optimal physical and mental function, preserved work and family role, quality of life and survival). Especially when taking care of individuals with serious and life-limiting illness, we must be able to carefully titrate interventions to the circumstance unique to that patient. The primary goal should be ensuring a patient's pain and other distressing symptoms are adequately controlled.

This question is based on the assumption that "high prescribing" equals "bad prescribing." For some specialties, high prescribing patterns may be the norm and completely appropriate. For other specialties, even low prescribing may be inappropriate and not indicated. Medicare and Medicaid must be concerned with identifying health professionals with *inappropriate* prescribing patterns of opioids. Many of AAHPM's members would be considered "high" prescribers, but not inappropriate prescribers. This is because of the patients we treat: many palliative and hospice patients have acute symptoms from non-cancer terminal illnesses and require more than 100 mg of morphine equivalents per day for sufficient pain and symptom control and, depending on the underlying mechanism of pain and degree of development of opioid tolerance, some require much higher doses. By contrast, if an internist were to prescribe most of his or her patients more than 100 mg of morphine equivalents per day, this should raise concern and warrant a closer look, as an internist's patients are not all seriously or terminally ill.

For this reason, AAHPM urges the Committee to delineate among specialties in any policy deliberations on this topic. The question becomes: how do we appropriately do so? When providers enroll in Medicare, they have to designate their specialty with a code. However, the provider chooses that code without proving he or she actually practices said specialty. Thus, the Medicare specialty codes, without any additional information, may not be the most effective way of delineating among prescribers. Instead, Medicare and Medicaid claims that provide information on patient diagnosis could provide better indicators of inappropriate prescribing than simply looking at the *volume* of prescriptions written.

With regard to education, AAHPM believes it is critical to elevate the knowledge of appropriate prescribing of controlled substances across various providers and medical specialties, as well as ensure prescribers are appropriately trained to manage risks for opioid misuse and diversion and knowledgeable in safe storage and disposal. To that end, AAHPM is a founding member of the Collaborative for Relevant Education, or CO*RE,

which was initially formed to develop and disseminate REMS-compliant training in safe prescribing of long-acting/extended-release opioids and has since updated its curriculum to address the CDC Guideline and include immediate-release opioids in anticipation of the FDA adding them to the REMS blueprint. A recording of AAHPM's "Opioid Prescribing: Safe Practice, Changing Lives" webinar is offered free on the Academy website. A volume of AAHPM's *Essential Practices in Hospice and Palliative Medicine* is also focused on Pain Assessment and Management. This book presents the latest in assessing malignant and non-malignant pain, total pain, nociceptive and neuropathic pain, opioid conversions, common side effects of pain treatment, and non-opioid adjuvant medications.

In addition, our annual conference routinely features sessions on topics such as managing pain in opioid-dependent patients and guidelines for methadone safety and effectiveness in hospice and palliative care, with recordings available after the meeting for those unable to attend in person. Through the American Medical Association (AMA) Opioid Task Force – of which AAHPM is a member – our Academy was also invited to assist the AMA in developing a new, interactive CME product on pain management. (This activity is funded by a Substance Abuse and Mental Health Services Administration grant supporting the Prescriber Clinical Support System for Opioid Therapies administered by the American Academy of Addiction Psychiatry.)

Despite this commitment to prescriber education, AAHPM remains opposed to *mandated* CME, particularly as the effectiveness of mandates has not been well established. Today, practitioners may face multiple state requirements for continuing education covering such topics as suicide or domestic violence screening, infectious disease, and cultural competence and, as such, end up less engaged and simply "checking the boxes" to obtain the required credits. Before the Committee considers adding to such requirements, we believe more research is needed to determine the actual impact of mandated CME on provider behaviors, treatment access, and patient outcomes. That said, any requirement for provider education in this area may be best operationalized by requiring practitioners who request DEA registration to prescribe controlled substances to be trained on responsible opioid prescribing practices as a precondition of registration or renewal.

Overall, we would caution the Committee that, as more training and practice burden is placed on practitioners, it is unknown what effects theses mandates, coupled with new guidelines and payer policies, will have on clinician interest or feasibility to care for the complex population of patients with pain, particularly those on opioids. Numerous overlapping policies and guidance for practitioners that aim to stem the crisis of opioid abuse and overdose death have already had a cooling effect on prescribing by primary care providers, with these practitioners confused and in fear of retribution for prescribing opioid analgesics. In fact, we have seen such unintended consequences as physicians trying to get their non-terminal patients into hospice so the hospice can take over prescribing of opioids and overall pain management. To ensure there are no such further unintended outcomes, prescriber education must be properly targeted and incentivized so practitioners actually learn when opioids are appropriate along with best practices for prescribing them, rather than opt out of doing so altogether.

- ***What can be done to improve data sharing and coordination between Medicare, Medicaid, and state initiatives, such as Prescription Drug Monitoring Programs?***

While PDMPs have been invaluable tools in our response to the opioid crisis, there is room for improvement. Most pressingly, these programs need real-time data and coordination across state lines. Some states have tackled the lack of coordination; for example, in Texas, providers can run a check across 22 states. However, not all states have done so, which enables individuals to prescription- and pharmacy-shop across state lines. Additionally, PDMPs must be easily interoperable with electronic health records.

There are key information gaps in PDMPs that Medicare could help remedy. Currently, monitoring programs contain no patient-level data that would enable a provider to distinguish an appropriate from an inappropriate

opioid patient. The PDMP does not include the diagnosis, indicate whether the patient already suffers with an OUD, is enrolled in a methadone maintenance program, or whether the patient is currently enrolled in a hospice program. Connecting Medicare claims and notes to the PDMP would serve to better inform prescribers of the patient's need for opioids or other medications.

- *What human services efforts (including specific programs or funding design models) appear to be effective in preventing or mitigating adverse impacts from OUD or SUD on children and families?*

To the degree the Committee can leverage Medicare and/or Medicaid to help develop better, expanded options for safe disposal, we encourage you to do so. While take-back programs are important, they are simply not sufficient. Requiring pharmacies to include a destruction device when dispensing any opioid may be a more effective solution. We also ask the Committee to work with the DEA to examine that agency's regulations which, since 2014, prohibit hospice and home care providers from taking possession of unused pharmaceutical controlled substances following a patient's death, unless authorized under state law to dispose of a decedent's property. We see hospices stepping up efforts to educate and assist families with disposal and, through the AMA Opioid Task Force, AAHPM helped develop a backgrounder on these issues for providers. Still, since the Office of National Drug Control Policy has found that more than 70 percent of people using opioid analgesics for nonmedical reasons get them from family or friends, this is an important gap that is being left to the states to address (see H. 3132 enacted last year in South Carolina and S.978 pending in Pennsylvania).

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Thank you again for the opportunity to provide input regarding the critical issues the Committee raised in its February 2 letter to stakeholders. As you move forward with efforts to address these important questions, we urge you to ensure that policy proposals are not applied globally to all patients that require treatment of acute or chronic pain but in fact include appropriate exclusions for both cancer patients and other individuals being treated under a palliative care or hospice program, along with the practitioners who care for them. To be clear, AAHPM recognizes the public health imperative to diminish abuse, misuse and diversion of opioids and applauds congressional efforts to closely examine how best to achieve this goal. We are committed to partnering with the Committee and other federal stakeholders in efforts designed to enhance prescribers' knowledge and skills to improve care and outcomes for patients and improve public health and safety while at the same time ensuring seriously ill patients' continued, legitimate access to medications essential to their care. This will require additional research; extensive, honest dialogue; and recalibration as unintended consequences become clear. Above all, it will require recognition that overdose deaths and untreated suffering are both unacceptable.

We would welcome any opportunity to provide additional information regarding this request for comments or any other initiatives, particularly with regard to the unique and important needs of patients with serious or life-threatening conditions. Please address questions to Jacqueline M. Kocinski, MPP, AAHPM Director of Health Policy and Government Relations, at jkocinski@aahpm.org or 847-375-4841.

Sincerely,

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