



AMERICAN ACADEMY OF  
HOSPICE AND PALLIATIVE MEDICINE

*Submitted electronically via regulations.gov*

March 5, 2018

Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Avenue SW  
Washington, DC 20201

**RE: CMS-2017-0163 — Advance Notice of Methodological Changes for Calendar Year 2019 for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter**

Dear Administrator Verma:

On behalf of the more than 5,000 members of the American Academy of Hospice and Palliative Medicine (AAHPM), we would like to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to comment on the Advance Notice of Methodological Changes for Calendar Year 2019 for Medicare Advantage Capitation Rates, Part C and Part D Payment Policies and 2019 Draft Call Letter.

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 illness, as well as their families and caregivers. Serious illness is a condition that carries a high risk of mortality (though cure may remain a possibility); has a strong negative impact on one's quality of life and functioning in life roles, independent of its impact on mortality; and/or is burdensome in symptoms, treatments, or caregiver stress.<sup>1</sup> This may be experienced as physical or psychological symptoms; time and activities dominated by the illness's treatment; and/or the physical, emotional, and financial stress on caregivers and family. Below we offer feedback on select proposed policies in this Notice and Draft Call Letter that affect these vulnerable patients that AAHPM members care for each day. We urge CMS to consider our comments as it finalizes policies for 2019, and we are happy to provide any additional input or assistance as needed.

**Medicare Parts C and D: Enhancements to the 2019 Star Ratings and Future Measurement Concepts**

**New and Changed Measures for 2019 Star Ratings**

CMS proposes to add the following measure to the 2019 Star Ratings (based on 2017 data), Statin Use in Persons with Diabetes (SUPD), with a denominator exclusion for beneficiaries in hospice. CMS also proposes to make technical changes to the calculation of the following existing measures for 2019: Medication Adherence (ADH) for Hypertension, Medication Adherence for Diabetes Medications, and Medication Adherence for

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<sup>1</sup> Kelley Amy S. Defining "Serious Illness." *Journal of Palliative Medicine*. September 2014, 17(9): 985-985.

Cholesterol; in these measures, the Proportion of Days Covered (PDC) is adjusted for hospice enrollment.  
***AAHPM supports these 2019 Star Ratings measures where there is an adjustment for hospice enrollment.***

### Changes to Existing Display Measures

CMS proposes changes to Pharmacy Quality Alliance (PQA) measures addressing Use of Opioids from Multiple Providers and/or at High Dosage in Persons without Cancer, which examines multi-provider and/or high dosage opioid use among adults without cancer and not in hospice care:

- **Measure 1:** Use of Opioids at High Dosage in Persons without Cancer (OHD): The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids with a daily dosage greater than 120 mg morphine milligram equivalents (MME) for 90 consecutive days or longer.
- **Measure 2:** Use of Opioids from Multiple Providers in Persons without Cancer (OMP): The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids from four (4) or more prescribers AND four (4) or more pharmacies.
- **Measure 3:** Use of Opioids at High Dosage and from Multiple Providers in Persons without Cancer (OHDMP): The proportion (XX out of 1,000) of individuals from the denominator receiving prescriptions for opioids with a daily dosage greater than 120 mg morphine milligram equivalents (MME) for 90 consecutive days or longer, AND who received opioid prescriptions from four (4) or more prescribers AND four (4) or more pharmacies.

CMS discusses non-substantial changes to the measures approved by the PQA's Measure Update Panel and Quality Metrics Expert Panel and CMS's proposal to add only Measure 3 to the 2019 Part D display page while continuing to report all three measures to Part D plan sponsors through the Patient Safety reports. CMS also discusses potential future changes to the measures by PQA to better align with the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain and the revised Overutilization Monitoring System (OMS).

AAHPM has significant concerns with these measures, including potential future changes under consideration by the PQA. To begin, there is limited evidence to support the CDC Guideline in establishing a 90 morphine milligram equivalent (MME)/day dosage limit as a standard of care. Further, lack of agreement on an accepted methodology for converting dosage across various opioids challenges the validity of the 90 MME/day limit upon which the draft measure is based. ***As such, we would caution against future changes to the measures that align more closely with this unsupported aspect of the CDC Guideline.*** Moreover, we note that the CDC itself describes the guideline as only applying to patients with chronic pain in the primary care setting and, by extension, not in the setting of specialist hospice or palliative care management of symptoms.

Additionally, while AAHPM appreciates that hospice patients and those with cancer are excluded from these measures, we are extremely concerned about the impact on patients with a serious or life-threatening illness receiving palliative care who do not meet these exclusion criteria — patients with AIDS, chronic obstructive pulmonary disease, end stage renal disease, heart failure, hemophilia, or sickle cell disease, for example. As a population, individuals with serious illness require higher doses of opioids (for pain and other distressing symptoms) for a longer duration than most any other group. Limits on allowable daily dosages can result in uncontrollable pain and symptom crises for these patients that could otherwise be managed by an amount of medicine that is arbitrarily discouraged. ***AAHPM urges CMS not to apply this measure without additional adjustments for those patients with serious illness receiving non-hospice palliative care to ensure against inappropriate restriction of patients' access to medically necessary treatment.***

Lastly, we encourage CMS and PQA to recognize that many clinicians work together in practice settings and maintain shared responsibility for patient care, including for prescribing medications. For example, multiple

providers (including residents in an academic medical center) may cover after-hours call across the inpatient and outpatient services and find it necessary to make changes or authorize refills for a patient seen in the practice. ***In assessing risk associated with multiple prescribers, we urge CMS and PQA to ensure that prescribers associated with the same Tax Identification Number (TIN) be counted as a single prescriber.*** This would be consistent with CMS's proposal to count prescribers under its proposed implementation of provisions of the Comprehensive Addiction and Recovery Act of 2016 (CARA) in its 2019 Policy and Technical Changes to Medicare Advantage and the Prescription Drug Benefits Program proposed rule.

### **Forecasting to 2020 and Beyond: Potential Changes to Existing Measures**

#### *Telehealth and Remote Access Technologies (Part C)*

CMS solicited feedback on the appropriateness of including telehealth and/or remote access technology encounters, as allowed under the current statutory definition of Medicare-covered telehealth services and/or as provided by the MAO as an MA supplemental benefit, as eligible encounters in various Part C quality measures. ***AAHPM supports the expanded use of telehealth to reduce provider burden and increase patient access to high-quality care, including hospice and palliative care, which is routinely subject to face-to-face requirements. As such, AAHPM fully supports the consideration of telehealth services as eligible encounters in quality measures.*** We believe this is a meaningful step to providing enhanced recognition for these services and supporting their greater use throughout the Medicare program (for example, to meet face-to-face requirements for hospice care, which can be especially burdensome in rural geographies).

#### *Cross-Cutting Exclusions for Advanced Illness (Part C)*

CMS notes that the National Committee for Quality Assurance (NCQA) is evaluating the clinical appropriateness and feasibility of excluding individuals with advanced illness from selected HEDIS measures. ***AAHPM believes that exclusion of individuals with advanced illness from some HEDIS measures is appropriate and needed for the patient population involved.*** However, we raise caution that any change in measurement requirements should not lessen incentives for delivering high-quality care to patients with serious and advanced illness simply by excluding them from attention. The measures developed and the identification of appropriate treatments and services must be done carefully and appropriate to ensure quality care for this high-need population. ***AAHPM has experience in measure development and our leaders would be pleased to lend their expertise in identifying appropriate HEDIS measures where adjustments would be appropriate for patient populations with advanced illness, as well as identifying appropriate methodologies for adjusting such measures.*** At the same time, we also recommend that CMS sponsor and promote development of quality measures that are more relevant to patients with serious and advanced illness, so that the quality of care is measured routinely for this most vulnerable population.

### **Forecasting to 2020 and Beyond: Potential New Measures for 2020 and Beyond**

#### *Opioid Overuse (Part C)*

CMS notes that NCQA is collecting data on Use of Opioids at High Doses and Use of Opioids from Multiple Providers, and seeks feedback from stakeholders about the value of including these Part C measures on the display page, given the existence of similar Part D measures.

While AAHPM supports the adoption of valid and reliable measures that hold Medicare Advantage plans accountable for responsible management of opioid usage, we have concerns about potential new measures that might take a blunt approach to controlling opioid use that is neither evidence-based nor inclusive of sufficient protections to ensure access to medically necessary opioid analgesics for the high-need, seriously ill patients that AAHPM members serve.

*As noted above, AAHPM is concerned about broad application of the CDC Guideline – guidance developed for the primary care setting – particularly given the lack of an evidence base to support it. We urge CMS and NQCA to consider appropriate exclusions for patients with serious illness, including but not necessarily limited to patients receiving hospice or palliative care. We are concerned that poorly implemented measures could restrict access for the sickest, most vulnerable patients who require – and deserve – timely and effective treatment of their pain and suffering. Additionally, we request that CMS consider all prescribers associated with the same TIN as a single prescriber for the purposes of identifying so-called “high use” associated with multiple providers. AAHPM would be pleased to engage with CMS and NCQA as these measures continue to be tested prior to adoption.*

#### *Concurrent Use of Opioids and Benzodiazepines*

CMS notes that the PQA developed and endorsed a measure on the Concurrent Use of Opioids and Benzodiazepines, which assesses the percentage of adults with concurrent use. CMS proposes to begin reporting this measure in the Patient Safety reports for the 2018 measurement year and to add the measure to the display page for 2021 (2019 data) and 2022 (2020 data). CMS will also consider this measure for the 2023 Star Ratings (2021 data) pending rulemaking.

For patients with serious illness, appropriate medication management may include both opioids and benzodiazepines. As such, ***AAHPM recommends that CMS and NCQA use caution in the continuing implementation of this measure and take into account the population of patients with serious illness and their unique needs.***

#### **Forecasting to 2020 and Beyond: Measurement and Methodological Enhancements**

CMS and measure developers are exploring for future work additional measurement concepts that will require use of non-claims data, such as functional status or non-pharmacological or non-opioid interventions for pain management. ***AAHPM strongly supports ongoing CMS work in this area.*** Assessment of functional status is of significant importance in palliative care and – in combination with other variables such as diagnosis and health care utilization – has a strong relationship with patient prognosis and other patient quality outcomes. Functional data are available from post-acute care quality reporting, including from skilled nursing facilities and home health agencies. Additionally, data on usage of durable medical equipment has also been found to predict functional status. To the degree that measurement work will align with Medicare coverage of multi-modal and non-pharmacological pain treatment where these are options, AAHPM also supports this approach. Otherwise, prescribers will necessarily default to treatments, like opioids, that are reimbursed in order to ensure their patients’ pain is managed. Overall, ***AAHPM believes research in this area will help to advance the delivery and quality measurement of high-quality palliative care and would welcome the opportunity to engage with CMS as it continues this important work.***

#### **Transparency and Timeliness with Prior Authorization Processes**

CMS reminds Medicare Advantage organizations that they should be transparent and provide adequate notice of coverage restrictions, such as prior authorization requirements, to providers and enrollees. Medicare Advantage organizations should also make prior authorization request forms available and easily accessible, and deliver timely decisions on prior authorization requests.

AAHPM notes that prior authorization requirements impose a significant burden on clinicians seeking to provide medically appropriate treatment to their patients and on patients who may experience delays or denials in care. We note that this burden applies to both Medicare Advantage plans as well as Part D plans, and therefore ***AAHPM urges CMS to consider and implement strategies to reduce burden around prior authorization processes under both Medicare Advantage and Part D.***

## Improving Drug Utilization Review Controls in Medicare Part D

### Opioid Potentiator Drugs

Since the agency developed the Overutilization Management System (OMS) to facilitate compliance with drug utilization review policy (DUR) – which excludes patients with cancer or in hospice – it is our understanding that these patients would also be excluded from the new opioid-gabapentin/pregabalin flag in OMS. ***We urge CMS to explicitly restate this fact prior to rolling out the new flag.***

In palliative medicine, gabapentin and pregabalin are not regarded as “potentiator” drugs. Although we are aware of sporadic reports of their illicit misuse, these are essential medicines in the management of neuropathic pain that are used broadly as adjuvant pain medications for patients with serious illness receiving palliative care. When a palliative physician manages someone’s pain, in particular complex pain in serious or terminal illness, he or she determines whether the pain has a neuropathic component, a musculoskeletal component, an anxiety component, and so on. It is these different aspects of pain that result in differing combinations of treatment.

The current focus of physicians is on finding a way to appropriately use lower doses of opioids if there are other medications that can be used in combination that will result in the same level of symptom relief. If there is a neuropathic component to pain, a gabapentin or pregabalin and opioid combination is an appropriate and effective option and, indeed, can be a way to minimize a patient’s need for opioids. If the agency’s goal is to find ways to decrease opioid prescribing, potentially limiting or flagging these medications is concerning, as these medicines are not opioids but can be effective tools to fight pain.

As we have seen with the flag on concurrent use of opioids and benzodiazepines, a flag may lead to an edit. ***We urge CMS to proceed cautiously with any new OMS flags that may lead to limitations on use of these neuropathic pain medications, to ensure that patients who appropriately take these combinations are not swept up by an assumption that the combinations are inherently inappropriate.***

### Patient Safety Reporting

CMS notes that it “expects sponsors to [...] assess their progress in reducing the number of beneficiaries using high doses of opioids [...]” This statement is based on the assumption that “high utilization” equals “inappropriate utilization.” Many palliative care and hospice patients have acute symptoms from non-cancer terminal illnesses and require more than 100 milligrams 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. ***AAHPM is concerned that any directive by CMS to payers to arbitrarily reduce the number of beneficiaries using high doses of opioids must necessarily come at the expense of patient-centered care, which 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). The primary goal should be ensuring a patient’s pain and other distressing symptoms are adequately controlled.



### Cumulative Morphine Milligram Equivalent (MME) Daily Dose Safety Edits for High, Chronic Prescription Opioid Users

CMS proposes that all sponsors should implement a hard edit in 2019 that is triggered when a beneficiary's cumulative daily MME reaches or exceeds 90 mg, noting that this value aligns with the CDC Guideline, which recommends to generally avoid increasing the daily dosage of opioids to 90 MME for patients in the primary care setting. Sponsors should continue to apply specifications to account for known exceptions, such as hospice care; cancer diagnoses; reasonable overlapping dispensing dates for prescription refills or new prescription orders for continuing fills, and high-dose opioid usage previously determined to be medically necessary. CMS seeks feedback on whether all sponsors have the capacity to implement hard edits at 90 MME as well as the seven days allowance proposal for 2019 (see below).

With regard to beneficiaries who are in medical need of higher doses, if the only issue in dispute is the MME, the agency expects the Part D sponsor to only rely on prescriber attestation that the higher MME is medically necessary to approve dosing that is higher than the hard edit when a coverage determination is requested. The authorization of the higher MME level should be considered an approved exception and be valid through the remainder of the plan year. Generally, coverage determination requests seeking exceptions to the MME edit are expected to meet the criteria for expedited review, which means the plan sponsor must issue a decision within 24 hours of receipt of the prescriber's supporting attestation. Notably, the sponsor should also remove the edit if it is determined that the beneficiary meets established criteria for exceptions, such as cancer or hospice. Finally, CMS expects sponsors to ensure that their staff are trained to appropriately identify enrollee requests for a coverage determination.

While we thank the Agency for its continued exceptions for cancer and hospice care, ***AAHPM is extremely concerned about a default denial that can ultimately only be overridden by the payer, as it amounts to the payer dictating care rather than the provider.*** There are many individuals with serious illness who are not in hospice and who do not have a cancer diagnosis for whom a dosage limitation such as this would be a cruel denial of needed pain and symptom control.

Additionally, the fact that CMS seeks feedback with regard to whether payers have the capacity to implement the proposed hard edit is concerning, as it speaks to the rollout of a requirement for which payers are potentially unprepared. To ensure that no beneficiary is adversely affected, a more cautious approach would be to determine implementation capacity *before* a program-wide rollout. This will help mitigate some of the challenges related to sponsor infrastructure, such as were experienced with the rollout of Part D prior authorization in hospice. ***We urge CMS to take a more streamlined approach by allowing for the statement of medical necessity to be written on the prescription, which would avoid the need for a second, currently unknown attestation step that plans may not be able to operationalize without harming beneficiaries.***

With regard to the CDC Guideline for chronic pain in the primary care setting, as noted above, we have concerns about the general application of this guidance and the lack of an evidence base to support an arbitrary MME as a standard of care. The Guideline was never intended to apply to every patient situation, and we are concerned that CMS is extrapolating it much too broadly, especially by applying it outside of the primary care setting.

CMS notes that, in the case of opioid prescriptions that trigger the 90 MME hard edit where the packaging is only available in a days' supply greater than seven days, the agency would not expect any supply to be provided. ***This is of grave concern, as there are seriously ill patients receiving non-hospice palliative care – such as those with head and neck cancer with dysphagia – who require concentrated liquid morphine as a standard medication, but this only comes in 15 and 30 milliliter bottles.***

*Finally, we are skeptical of sponsors ensuring their staff is trained on the new edit and its accompanying override policy.* There has been much media coverage of recent comments by an insurer employee who admitted under oath he never looked at patients' medical records when deciding whether to approve or deny care.<sup>2</sup> While outrageous, these comments were not particularly surprising to physicians. Even when medical directors and other insurer staff are cooperative partners with physicians, they usually lack specialized training in palliative care or pain management. Thus, it is concerning to provide these individuals with the ability to deny access to pain management for medically complex patients who desperately need it.

### Days Supply Limits for Opioid Naïve Patients

In addition to the daily dose hard edit, CMS expects all Part D sponsors to implement a hard safety edit for initial opioid prescription fills that exceed seven days for the treatment of acute pain in opioid naïve patients. This proposal has a concerning lack of detail regarding who might be considered "opioid naïve" and what might be considered "acute pain." The following case example illustrates the potential pitfalls in defining "acute pain" and "opioid-naïve" and setting an arbitrary time limit on the duration of the initial opioid prescription: *A woman with breast cancer and bone metastases is receiving hormonal therapy and palliative care and continues to work full time. A year ago, she developed a painful metastasis in her arm. She received palliative radiotherapy and needed opioids to manage her bone pain for about four weeks before the radiotherapy provided long-term relief. She sees her palliative care physician today for new pain in her thigh caused by another bone metastasis. She is scheduled for palliative radiotherapy and receives a new prescription for an opioid. Her pain is likely to flare before subsiding over a matter of weeks.*

This patient's underlying metastatic cancer is a chronic condition, but would this new pain due to disease progression be considered "acute pain"? She has a history of benefitting safely from a few weeks of opioids for a similar problem in the past but has not had an opioid in the last twelve months. Would she be considered "opioid naïve" for purposes of this prescription? Her physician knows that she'll need the opioids for at least a few weeks, but would she be limited by rule to a seven-day prescription? For such a patient, seven days would not be appropriate; rather, follow up in two or three weeks would be appropriate, and the prescription should cover that interval. In light of examples like that above, *AAHPM urges CMS to work with stakeholders, including physicians, to establish a definition of "opioid naïve" prior to directing plans to implement the proposed supply limit.*

Further, while the CDC Guideline for chronic pain in the primary care setting includes some examples of "acute pain" – such as the pain resulting from minor procedures like varicose vein stripping – it does not offer a definition that can be easily operationalized by a payer. A strain or fracture on an otherwise healthy individual would likely be appropriate for a maximum of seven days of opioids, but that may not be the case for an elderly individual with preexisting mobility or pain issues. *Instead of relying on payers to determine a definition of "acute pain," a better approach would be to restrict prescriptions to seven days for acute problems that present with pain (e.g., a stand-alone fracture or serious strain without complications or comorbidities), as this would more effectively tease out patients for whom such a limitation is appropriate.*

Besides these definitional concerns, as AAHPM has stated in other submissions to governmental bodies, any recommendations or requirements that aim to limit the duration of prescriptions can inflict terrible suffering in a seriously ill patient each day that he or she lives past an arbitrary cutoff of their medication. Those that limit allowable daily dosages can result in uncontrollable pain and symptom crises for these patients that could otherwise be managed by an amount of medicine that is arbitrarily discouraged. Moreover, while it would be ideal if label recommendations were one of a number of rational considerations that prescribers use to guide treatment, along with evidence for best practices and an individual's unique circumstances and goals of care, we expect it is more likely that any suggested restrictions would be adopted as rules. While the CDC's

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<sup>2</sup> See, e.g., <https://www.cnn.com/2018/02/15/health/aetna-investigations-widen/index.html>.

recommendations are meant to apply to primary care outside of cancer, palliative and end-of-life care, health systems, pharmacy benefit managers and payers are using the Guideline to impose limits on opioid prescriptions regardless of a patient's diagnosis or goals. ***AAHPM therefore strongly cautions against moving forward with such restrictions in Medicare Part D, even if the above outlined definitional concerns can be addressed.***

***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](#) sent 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. CMS might also work with the U.S. Food and Drug Administration to consider how opioids commonly prescribed for acute indications (e.g. post-procedure, post-operatively, post-acute injury) could be packaged in a three- to five-day blister packs (similar to a Z-pak or Medrol dosepak) to facilitate dosing that is in line with the typical needed duration.

### Opioid Duplicative Therapy Safety Edits

CMS expects all Part D plan sponsors to implement a soft POS edit for duplicative long-acting (LA) opioid therapy beginning in 2019, with or without a multiple prescriber criterion. Duplicate LA use is defined as a second prescription for a LA opioid that occurred before 75% of a prior LA opioid's days' supply expires. This subsection does not have an explicit reaffirmation of exemptions for hospice and cancer patients; ***thus, we urge CMS to clarify that these patients – as well as seriously ill patients receiving non-hospice palliative care – are exempted, consistent with all other flags, edits, and limitations set forth elsewhere in the proposal.***

### Concurrent Use of Opioids and Benzodiazepines

CMS already flags concurrent opioid and benzodiazepine use. CMS now proposes that Part D sponsors implement a concurrent opioid and benzodiazepine soft POS safety edit. Again, ***AAHPM reiterates its concern that this will be used by payers as a reason for coverage denials, even though this combination of medicines can represent appropriate prescribing for certain patients. Additionally, we are concerned about the lack of implementation details around this proposed edit.*** Will a beneficiary who has previously filled appropriate prescriptions of these two products "trigger" the soft edit every time a refill is needed? Or will the edit be only periodically revisited for beneficiaries already on these products, perhaps every six months or every plan year? We are concerned that this well-intended limitation by CMS will provide plans with a reason to deny coverage or create administrative barriers. As noted above, there are cases in which concurrent use of certain medications may actually reduce a patient's need for opioids, which is a goal CMS and other government agencies have repeatedly articulated.

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Thank you, again, for the opportunity to provide feedback on these policy proposals. We are eager to collaborate with CMS to address the many important issues discussed here and advance our shared goal of improving care for our nation's Medicare beneficiaries. Please direct questions or requests for additional information to Jacqueline M. Kocinski, MPP, AAHPM Director of Health Policy and Government Relations, at [jkocinski@aahpm.org](mailto:jkocinski@aahpm.org) or 847-375-4841.

Sincerely,



Janet Bull, MD MBA HMDC FAAHPM  
President, American Academy of Hospice and Palliative Medicine