



AMERICAN ACADEMY OF  
HOSPICE AND PALLIATIVE MEDICINE

Submitted electronically via regulations.gov

April 6, 2020

Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
7500 Security Boulevard  
Baltimore, MD 21244-1850

**RE: Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly Proposed Rule [CMS-4190-P]**

Dear Administrator Verma:

On behalf of the nearly 5,400 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 Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly Proposed Rule.

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 patients facing serious illness, as well as their families and caregivers. Below we offer feedback on select proposed policies that affect the vulnerable patients that AAHPM members care for each day. We urge CMS to consider our comments as it finalizes policies for Contract Year 2021 and 2020, and we are happy to provide any additional input or assistance as needed.

***Implementation of Several Opioid Provisions of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act***

**Mandatory Drug Management Programs (DMPs)**

Under the DMPs in place today, CMS identifies “potential at-risk beneficiaries” (PARBs) who meet the clinical guidelines described in § 423.153(f)(16), referred to as the minimum Overutilization Management System (OMS) criteria. The OMS criteria are based on a history of filling opioids from multiple doctors and/or multiple pharmacies. Once PARBs are identified, plan sponsors engage in case management of these beneficiaries through contact with their prescribers to determine whether the beneficiary is at-risk for misuse or abuse. If a sponsor determines that a PARB is at-risk, after notifying the beneficiary in writing, the sponsor may limit their access to coverage of opioids and/or benzodiazepines to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale (POS) claim edit. This process does not apply to “exempted beneficiaries, which currently include those being treated for active cancer-related pain, residing in a long-term care facility, receiving hospice care or receiving palliative or end-of-life care. CMS is proposing to exempt beneficiaries with sickle cell disease beginning with plan year 2021.

***AAHPM supports the continued exclusion of beneficiaries receiving hospice, palliative or end-of-life care. We further support CMS' proposal to add those beneficiaries with sickle cell disease to the exempted population,*** as these patients have a life-limiting illness whose treatment often falls within the scope of palliative medicine. We also wish to underscore the importance of accurate attribution in determining DMP-exempted beneficiaries. Our leaders would be pleased to lend their expertise to help ensure that appropriate patient populations are correctly identified.

#### Information on the Safe Disposal of Prescription Drugs

Given requirements outlined in the SUPPORT Act, CMS proposes to revise the § 422.111, Disclosure Requirements, to add a paragraph (j), which would require MA plans that furnish an in-home health risk assessment on or after January 1, 2021, to include both verbal (when possible) and written information on the safe disposal of prescription drugs that are controlled substances in such assessment. The information must include details on drug takeback programs and safe in-home disposal methods. While AAHPM supports increased beneficiary education about the safe disposal of prescription drugs, we believe that *access to drug disposal sites is a larger barrier to safe disposal, given limited availability of safe disposal locations. AAHPM urges CMS to work with the Drug Enforcement Administration (DEA) to expand access to drug takeback sites and increase the number of collection locations.* Even then, take-back programs may not be sufficient. Requiring pharmacies to include a destruction device when dispensing any opioid may be another effective solution for CMS to pursue.

#### Suspension of Pharmacy Payments Pending Investigations of Credible Allegations of Fraud and Program Integrity Transparency Measures

CMS proposes that inappropriate prescribing means that, after consideration of all the facts and circumstances of a particular situation identified through investigation or other information or actions taken by MA organizations and Part D Plan Sponsors, there is an established pattern of potential fraud, waste and abuse related to prescribing of opioids, as reported by the Plan Sponsors. Plan Sponsors may consider any number of factors including, but not limited to the following: documentation of a patient's medical condition; identified instances of patient harm or death; medical records, including claims (if available); concurrent prescribing of opioids with an opioid potentiator in a manner that increases risk of serious patient harm; levels of Morphine Milligram Equivalent (MME) dosages prescribed; absent clinical indication or documentation in the care management plan, or in a manner that may indicate diversion; State level prescription drug monitoring program (PDMP) data; geography, time and distance between a prescriber and the patient; refill frequency and factors associated with increased risk of opioid overdose. CMS also seeks comment on specific populations or diagnoses that could be excluded for the purposes of this definition, and offers cancer, hospice, and/or sickle cell patients as potential examples for exclusion.

***AAHPM is concerned that this proposal provides too broad of an authority to plan sponsors to limit access to opioids. At a minimum, CMS should exclude those patients CMS identified – i.e. patients with cancer, patients receiving hospice care, and patients with sickle cell disease.*** Without such exclusions, we are concerned that this definition could create harmful incentives to limit access to opioid medications for the medically necessary management of patients' pain and other distressing symptoms of serious illness. We also urge CMS to consider for exclusion patients with advanced stage serious illness, such as end-stage chronic lung disease, given that many patients may face barriers that prevent access to hospice care, including culturally-linked patient preferences, residence in rural or underserved communities, or physician failure to refer.

We also note that a consensus definition of MME dosages does not exist, as the equianalgesic calculations are not defined, and therefore ***AAHPM would be concerned with a policy that allows Plan Sponsors to rely on MME dosages***— particularly if they adhere to the Centers for Disease Control and Prevention (CDC) guideline for prescribing opioids for chronic pain, which does not apply to the seriously ill patients our members serve. Further, we note that the proposed definition does not take into account the professional training of the prescriber when ascertaining the appropriateness of an opioid prescription. Given that, for some specialists, high prescribing patterns may be the norm and completely appropriate, ***we believe considering the professional training of the prescriber could help to limit improper identification of inappropriate prescribing and encourage CMS to incorporate this element into the definition.***

Finally, we note that the National Academies of Sciences, Engineering, and Medicine (NAEM) Opioid Collaborative is currently working to collate guidelines on opioid prescribing across specialties and procedures. We believe this work could serve as a resource for the agency's future rulemaking.

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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 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,

A handwritten signature in black ink that reads "Rodney O. Tucker, MD, MMM". The signature is written in a cursive, flowing style.

Rodney O. Tucker, MD MMM FAAHPM  
AAHPM President