American Society of Anesthesiologists®

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March 5, 2018

Centers for Medicare & Medicaid Services
Administrator
Seema Verma
7500 Security Boulevard
Baltimore, MD 21244

Re: **Docket No. CMS-2017-0163;** Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for Medicare Advantage (MA) Capitation Rates, Part C and Part D Payment Policies and 2019 draft Call Letter

Dear Administrator Verma:

On behalf of the American Society of Anesthesiologists® (ASA) and its 52,000 members, I am writing in response to the Federal Register Notice announcing certain changes to Medicare for CY 2019, as captioned above. ASA appreciates the opportunity to comment on the proposed changes to the Part D program. As stakeholders interested in the care of patients, ranging from those with acute pain in the perioperative setting, to patients suffering from severe chronic pain, ASA is writing to voice concerns about proposed changes in the Advance Notice regarding the Part D program, including the overutilization monitoring system (OMS).

Opioid Potentiator Drugs

ASA understands that concurrent benzodiazepine-opioid use is already flagged as part of the OMS to alert Part D sponsors for the chronic pain population. The Society is concerned that this approach over simplifies the clinical situation and expanding this to non-opioid potentiator drugs would be an over simplification in kind. This approach ignores the real-life setting of pain management and is contrary to the emerging research literature supporting the use of multiple classes of medications to ultimately reduce a patient's opiate consumption— a care standard that the country needs to adopt.

The presence of co-prescription of an opioid and the drug gabapentin or pregabalin does not necessarily give cause for flagging that specific patient. The co-prescribing of gabapentin like drugs with opioids leads to opioid sparing, as supported by several RCTs that demonstrate (repeatedly) that multimodal analgesia used in the perioperative period reduces the amount of opioids required. General restriction on all concurrent prescribing of these two medication classes, therefore, is not a meaningful solution, and may be a barrier to implementing evidence-based best practices by providers.

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

ASA is concerned with the Centers for Medicare and Medicaid Services' (CMS) proposal that all sponsors implement a hard edit, triggered when a beneficiary's cumulative daily MME reaches or exceeds 90 mg (meaning the MME threshold should only be set at 90 MME). The Advance Notice

proposes these changes, stating that they are consistent with the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain (Guideline); however, the Guideline was **not meant** to address all patients on opioid therapy— rather, patients in the primary care setting only who are not under the care of specialists in pain medicine.

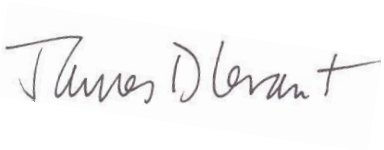
The Society understands that CMS is proposing these changes in good faith to try and address the current public health emergency of addiction and substance use disorders; however, efforts to curb opioid overuse cannot lack regard for the unintended consequences such restrictions will have on beneficiaries living with severe, chronic pain who remain fully functional on stable doses of opioids for years. While 90 MME is a significant opioid exposure, this dose may be deemed the lowest necessary dose by a patient's care team, often determined over years of treatment and trialing of non-opioid/supplemental therapies by pain medicine physicians. Many chronic neurologic, rheumatologic, vascular, hematologic and musculoskeletal diseases cause severe debilitating pain; yet, are not considered malignant nor requiring the care of a palliative medicine clinician. Thus, while ASA acknowledges that sponsors can apply certain exceptions to these edits, as well as prior authorizations, the Society is concerned that there is no mention of patients under the care of a pain specialist. **Therefore, ASA recommends that CMS create a specific exception for patients under the care of a pain specialist.**

Days Supply Limits for Opioid Naïve Patients

ASA also finds the 7-days supply limit of initial fills of prescription opioids problematic. Again, CMS provides the CDC Guideline as justification for this recommendation; however, as discussed above, the CDC Guideline was only intended to guide primary care physicians. **ASA recommends that CMS take into consideration patients that have just undergone surgery**, where the appropriate opioid dose should be at the discretion of the physician, weighing the patient-specific factors in the relevant circumstance. Depending upon the type of surgery, severity of trauma, and differences between patients, a 7-day supply is often not sufficient enough for both opioid naïve, and non- naïve patients.

We thank you for this opportunity to provide comments. Should you have any questions or would like to discuss any of the content of this letter, please do not hesitate to reach out to Ashley Walton, J.D., ASA's Pain Medicine and Federal Affairs Manager at a.walton@asahq.org or (202) 289-2222.

Sincerely,



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