AAOS
American Academy of Orthopaedic Surgeons
American Association of Orthopaedic Surgeons

March 5, 2018

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

Re: CMS-2017-0163-0007 - Improving Drug Utilization Review Controls in Medicare Part D

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS), we commend CMS for taking steps to stop the opioid epidemic and offer our comments on the 2019 Call Letter, specifically on *Improving Drug Utilization Review Controls in Medicare Part D*.

Days Supply Limits for Opioid Naïve Patients

The 2019 Call Letter expects all Part D sponsors to implement hard safety edits for initial opioid prescription fills that exceed 7-days for the treatment of acute pain, citing the CDC Guideline for Prescribing Opioids for Chronic Pain as the rationale. The CDC guideline, while laudable in its attempt to provide much needed direction on opioid prescribing, has been misinterpreted and applied inappropriately to include situations for which it was not intended (i.e., PBMs using the 7-day limit for post-operative orthopaedic patients).

The guideline explicitly states that its use is intended for primary care clinicians (e.g., family physicians and internists) treating chronic pain, defined as pain typically lasting >3months or past the time of normal tissue healing, in the outpatient setting.

Several laws and regulations have applied the 3-7 day opioid prescription limit to all acute pain situations, but the guideline states explicitly, in Recommendation 6 of Opioid Selection, Dosage, Duration, Follow-up, and Discontinuation, experts intended those ranges for acute pain cases NOT RELATED TO SURGERY OR TRAUMA. An example of an appropriate prescription limit, in an acute setting, would be for a patient presenting with an acute low-back sprain, not associated with malignancies, infections, fractures, or neurological signs, where research has shown that pain usually subsides by the fourth day after treatment is initiated. Additionally, in the same recommendation, it is stated explicitly that opioid treatment for post-surgical pain is outside the scope of this guideline. The AAOS strongly recommends that CMS include an exemption for surgical and trauma beneficiaries, in accordance with the CDC Guideline.

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The CDC Guideline, on the whole, provides good information, but it should not be used in a one-size-fits-all manner. The AAOS supports numerous other recommendations in the Guideline that Medicare Part D should consider, including, but not limited to, limiting ER/LA opioid use, increasing PDMP interoperability, fostering access to and coverage for medication-assisted treatment, coverage for comprehensive multi-modal pain management, reimbursement for integrated pain management coordination, and screening at-risk patients. These are all options that can have an impact on reducing the opioid epidemic.

A perioperative and trauma exemption would ensure patients with legitimate pain management requirements have access to proper treatment and not place an undue burden on patients during their recovery period.

Thank you for considering our comments on this issue. If you have any questions or comments, please do not hesitate to contact William Shaffer, MD, AAOS Medical Director by email at shaffer@aaos.org.

Sincerely,

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