

March 15, 2018

Hon. Kevin Brady Chairman Committee on Ways & Means United States House of Representatives Washington, DC 20515

Hon. Peter Roskam Chairman Subcommittee on Health Committee on Ways & Means United States House of Representatives Washington, DC 20515 Hon. Richie Neal Ranking Member Committee on Ways & Means United States House of Representatives Washington, DC 20515

Hon. Sander Levin Ranking Member Subcommittee on Health Committee on Ways & Means United States House of Representatives Washington, DC 20515

Dear Chairman Brady and Ranking Member Neal,

On behalf of more than 34,000 orthopaedic surgeons and residents, the American Association of Orthopaedic Surgeons (AAOS) commends the Senate Committee on Finance for recognizing the need to address the opioid epidemic devastating so many patients, families, and communities.

The AAOS acknowledges this catastrophic problem and believes that comprehensive reforms must be initiated with input and assistance from all stakeholders. To be successful, stakeholders need to work together to increase research and funding for alternative pain management techniques; improve prescription monitoring; and create more effective education programs for clinicians and patients. For these reasons, the AAOS is working on several initiatives – from public service announcements to a pain relief toolkit – to encourage our members to practice safe and effective pain management and treatment.

Here, we provide our responses on the topics presented to us in the letter dated February 27, 2018.

Perverse Incentives in Medicare

Payment incentives for higher scores on the Pain Management dimension of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey may have created the unintended consequence of overprescribing opioids in the inpatient setting. This scoring system of "Pain as a Fifth Vital Sign" created a culture of opioid expectation that made discontinuation of narcotics challenging. We appreciate the change in the Pain Management

317 Massachusetts Avenue NE Suite 100 Washington, D.C. 20002-5701 PHONE 202.546.4430 www.aaos.org/dc category of HCAHPS. Making evidence-based medicine, developed by medical and surgical specialties, a central part of Medicare and Medicaid programs will help mitigate patients' risk for opioid use disorder.

The therapy payment cap that existed for Medicare patients may have also led to additional opioid prescribing, and we appreciate the permanent repeal of this cap in the Bipartisan Budget Act of 2018. Physical and occupational therapies (PT/OT) are evidence-based treatments with the potential to reduce patients' need for addictive opioids. An arbitrary cap on PT/OT services without regard to the evidence could have created a situation in which a patient's access to care was limited.

Lastly, we support increased access and coverage of comprehensive, multimodal pain management. The AAOS believes physicians' enhanced understanding of opioid analgesics and alternative, multimodal pain management techniques would lead to better patient outcomes. Payers and employers need to improve access to these kinds of treatment for pain, as well as medication assisted treatment for substance use disorders.

Second-Fill Limits

AAOS strongly opposes any hard limits on opioid prescriptions that do not include exceptions for post-operative and trauma care. Several laws and regulations have applied the 3 to 7-day opioid prescription limit to all acute pain situations, many citing the 2016 guidelines published by the Centers for Disease Control and Prevention (CDC). However, the guideline states explicitly that 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 the Centers for Medicare and Medicaid Services (CMS) include an exemption for surgical and trauma beneficiaries, in accordance with the CDC Guideline. A post-operative 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.

The CDC guidelines, 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 extended-release and long-acting (ER/LA) opioid use, increasing Prescription Drug Monitoring Program (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.

Medical and surgical specialties should be responsible for developing opioid protocols and/or guidelines specific to their fields of care so that patients are not inappropriately denied treatment. Unfortunately, there have been several instances where guidelines or recommendations have been misinterpreted, resulting in situations where patients have faced periods of inadequate pain management. This can adversely affect the management of short stay and ambulatory surgical center patients.

AAOS maintains that it is unreasonable to expect physicians to solve the opioid crisis during an acute pain episode. It is important to distinguish between chronic and acute pain when regulating narcotic use. For example, states are restricting narcotics (e.g., the 7-day rule) and have mandated Drug Enforcement Administration (DEA) logging for each narcotic prescription. These stop-gap regulations place extraordinary burden on patients and physicians treating acute pain in the post-operative period, when narcotics are necessary and warranted. Physicians often need to increase pain medication dosing as patients become more active in the days following hospital discharge. This leads patients to prematurely complete the 7-day supply.

The AAOS supports post-operative exemptions to allow surgeons to appropriately manage pain. This is becoming increasingly important as same-day and outpatient procedures rely on adequate pain control to reduce the chance of readmission.

Tools to Prevent Opioid Abuse

The AAOS believes mental health screening needs to be part of patients' treatment protocols. Moderate strength evidence supports that mental health disorders, such as depression, anxiety, and psychosis, are associated with decreased pain relief and quality of life outcomes in patients with symptomatic osteoarthritis of the hip who undergo total hip arthroplasty (THA)¹. Rolfson and Dahlberg, et al², analyzed 6,158 Swedish Registry patients to determine that the EQ-5D anxiety/depression domain was highly predictive for pain relief and patient satisfaction after THA. Using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and SF-36 Short Form, Gandhi, et al³ demonstrated that older age, year of follow-up, and greater

^{1.} Management of Osteoarthritis of the Hip Evidence-based Clinical Practice Guideline http://www.orthoguidelines.org/topic?id=1021

^{2.} Rolfson,O.; Dahlberg,L.E.; Nilsson,J.A.; Macau.; Garellick,G. Variables determining outcome in total hip replacement surgery. J Bone Joint Surg Br; 2009/2: 2

^{3.} Gandhi,R.; Dhotar,H.; Davey,J.R.; Mahomed,N.N. Predicting the longer-term outcomes of total hip replacement. J Rheumatol.; 2010/12: 12

comorbidity were negative prognostic indicators for THA function, and proposed that risk assessment data may be effectively utilized to set realistic patient expectations after THA.

Surgical patients using opioids preoperatively have higher complications rates, require more narcotics postoperatively, and have lower satisfaction rates with poorer outcomes following surgery, suggesting the potential benefit of psychological and opioid screening with a multidisciplinary approach that includes weaning of opioid use in the preoperative period and close opioid monitoring postoperatively.

Physicians and care providers need to identify patients at greater risk for opioid misuse and abuse (e.g., using the opioid risk tool http://www.mdcalc.com/opioid-risk-tool-ort-for-narcoticabuse/), along with patients with symptomatic depression and ineffective coping strategies, prior to elective surgery. Physicians, the public, and policy makers should value interventions to lessen stress, improve coping strategies, and enhance support for patients recovering from injury or surgery.

Medication Therapy Management

AAOS supports improving patient access to medication assisted treatment including the Food and Drug Administration (FDA) approved naloxone. Moreover, according to the World Health Organization (WHO), opioid agonist medication-assisted treatment (OA-MAT) with methadone or buprenorphine is the most effective treatment for opioid use disorder (OUD). Recent literature analyzing the National Survey on Drug Use and Health (NSDUH) data found OA-MAT capacity has increased in the United States, however, a significant gap between treatment need and capacity remains especially in states with the greatest need for such treatment. Policymakers should ensure availability of state and federal funding to expand access to chronic OUD treatment following MAT clinical guidelines.

Prescription Drug Monitoring Program (PDMP)

AAOS supports the MONITOR Act, which would establish minimum standards that PDMPs must meet to receive funding from the State Targeted Response to the Opioid Crisis Grants. The legislation mandates that PMDPs must meet a uniform electronic format for reporting, increase sharing and disclosing of information, meet minimum standards for interoperability, and make information available to physicians on a timely basis. By ensuring prescription information relating to opioids and other controlled substances is available in an easy-to-read system, interoperable across state lines, and available in a timely manner, prescribers will be able to access the most accurate and up-to-date information to help them make the best clinical decisions for their patients. The AAOS strongly believes that electronic prescribing of medications promotes patient safety. E-prescriptions for all opioids would help not only appropriate use and patient convenience, they would also provide data in a format that could provide better surveillance of excessive, inappropriate, and non-therapeutic prescribing.

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The Every Prescription Conveyed Securely Act would aid orthopaedic surgeons in addressing this issue by requiring electronic prescriptions for controlled substances under Medicare Part D, including oxycodone, fentanyl, morphine, and hydrocodone. By requiring prescribers to use an online database where prescriptions are easily monitored and tracked, this bill could help eliminate doctor shopping and duplicative or fraudulent handwritten prescriptions that fuel the opioid epidemic. All federal agencies (VA, DOD, Coast Guard and Indian Health Service) should be required to participate in the state PDMP programs.

Prescriber Notification and Education

Physician and caregiver awareness of the risks and appropriate uses of opioid medications is important. AAOS encourages development of effective education programs for physicians, caregivers, and patients. Periodic continuing medical education (CME) on opioid safety and alternative pain management strategies will help physicians reduce opioid use and misuse. Provider requirements vary from state to state and different medical specialties require education tailored to meet the needs of their respective patients. A one-size-fits-all approach poses significant challenges and may have unintended consequences. AAOS believes that medical professional organizations are best positioned to provide relevant and meaningful education to its members and patients. To this end, AAOS is currently developing CME in this area.

Alternative Options for the Treatment of Pain

Non-narcotic therapies and/or non-pharmaceutical therapies should be considered as first-line treatment options or in combination with judicious opioid use. We support additional research and increased funding for other non-narcotic and/or non-pharmaceutical, including nutritional, alternatives for pain management. In certain instances, these alternatives may be the most clinically appropriate and cost-effective treatment options. The AAOS has several guidelines with recommendations for multimodal pain management:

• Neurostimulation, local anesthetics, regional anesthetics, epidural anesthetics, relaxation, combination techniques, and pain protocols have been shown to reduce pain as well as improve satisfaction, improve function, reduce complications, reduce nausea and vomiting, reduce delirium, decrease cardiovascular events, and reduce opiate utilization. There are a large variety of techniques that result in modest but significant positive improvements in many clinical and patient-centered domains with minimal significant adverse outcomes. Using an array of pain management modalities is appropriate.

- Strong evidence supports that NSAIDs improve short-term pain, function, or both in patients with symptomatic osteoarthritis of the hip.
- Strong evidence supports that peripheral nerve blockade for total knee arthroplasty (TKA) decreases postoperative pain and opioid requirements.
- Pain Relief kit. https://aaos.org/Quality/PainReliefToolkit/

Again, the AAOS commends the committee for taking steps to address the opioid epidemic. Please feel free to contact Catherine Hayes, AAOS Senior Manager of Government Relations (hayes@aaos.org), if you have any questions or if the AAOS can serve as a resource to you.

Sincerely,

David Hurry MD

David A. Halsey, MD President, American Association of Orthopaedic Surgeons

 cc: Kristy L. Weber, MD, AAOS First Vice-President Joseph A. Bosco III, MD, AAOS Second Vice-President Thomas E. Arend, Jr., Esq., CAE, AAOS Chief Executive Officer William O. Shaffer, MD, AAOS Medical Director

Additional AAOS Resources

• AAOS Pain Relief Toolkit: https://www.aaos.org/Quality/PainReliefToolkit/