



AMERICAN ACADEMY OF  
ORTHOPAEDIC SURGEONS

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March 16, 2018

Scott Gottlieb, MD  
Commissioner  
Food and Drug Administration (FDA)  
10903 New Hampshire Ave.  
Silver Spring, MD 20993

Re: FDA-2017-N-6502- Opioid Policy Steering Committee: Prescribing Intervention-Exploring a Strategy for Implementation

Dear Dr. Gottlieb,

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS), we commend the FDA's Opioid Policy Steering Committee in its efforts to solve the opioid abuse and misuse epidemic. Here we offer our comments in response to the public hearing held on January 30, 2018.

### **Prescriber Documentation**

A prescription should only include the amount of pain medication that is expected to be used and deemed appropriate by the prescriber. A pain management plan should be developed between the physician and patient, after a thorough conversation, during which reasonable expectations are set. AAOS is concerned that national prescription thresholds, without the requisite evidence, could inappropriately limit patients' access to necessary pain management and place an unnecessary burden on physicians and patients.

Medical and surgical specialties have the expertise and should be responsible for developing pain management protocols and/or guidelines specific to their fields of care. 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.

Several laws and regulations have inappropriately applied a 3- to 7-day opioid prescription limit to all acute pain situations, citing the Centers for Disease Control and Prevention (CDC) opioid guideline. The guideline states explicitly, in Recommendation 6 of Opioid Selection, Dosage, Duration, Follow-up, and Discontinuation, that experts intended that range for acute pain cases NOT RELATED TO SURGERY OR TRAUMA. Post-operative orthopaedic patients face circumstances where it is medically necessary to prescribe opioid therapies for adequate pain management.

An appropriate application of the CDC guideline 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.

The AAOS supports surgical exemptions to allow surgeons to appropriately manage pain. Requiring documentation for an opioid prescription beyond an arbitrary threshold would place undue burden on physicians, patients, and the health system. This is becoming increasingly important as same-day and outpatient procedures rely on adequate pain control to reduce the chance of readmission.

### **Prescription Drug Monitoring Program Use**

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 PDMPs 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 CDC and the Substance Abuse and Mental Health Services Administration (SAMHSA) recently released a report<sup>1</sup> on its PDMP Electronic Health Records (EHRs) Integration and Interoperability Expansion (PEHRIIE) program, the goals of which were to increase PDMP use and effectively reduce prescription opioid misuse and overdose. The study noted that a serious obstacle to effective PDMP use was poor integration into health information technology (HIT) systems at the point of care, inefficient workflow, and limited data sharing across state lines. The program was successful in reducing these obstacles in several states:

- Illinois achieved PDMP integration into EHRs at a local hospital, where over a two-year period, opioid prescriptions decreased 22% and saw a 41% decrease in the number of patients who received at least one prescription over the same period. The data remained hosted within the PDMP, but direct linkages from the PDMP to EHRs were established so that end users could request data through a portal within their EHRs or directly via the web.
- Washington's PDMP became interoperable with OneHealthPort, a statewide Health Information Exchange (HIE), enabling integration with the Emergency Department Information Exchange (EDIE), a hub connecting hospital emergency departments, in late November 2014. In calendar year 2014, the PDMP provided 26,546 solicited reports to prescribers via EDIE. This number increased more than 80-fold to 2,222,446 EDIE reports in calendar year 2015.
- Some states connected their PDMPs to hubs to help facilitate interstate PDMP data sharing. Florida, Illinois, Kansas, and West Virginia created PDMP/EHR and PDS integration by connecting the state to a PDMP hub (e.g., PMPi, RxCheck).
- Other important lessons learned in the study included:
  - Learn from the field
  - Start small, then expand
  - Consider state context
  - Engage stakeholders early and often

Additionally, 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 provide data in a format that could provide better surveillance of excessive, inappropriate, and non-therapeutic prescribing. 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.

### **Education**

Physician and caregiver awareness of the risks and appropriate uses of opioid medications is critical. AAOS encourages development of effective education programs for physicians, caregivers, and patients. Periodic CME on opioid safety and alternative pain management strategies will help physicians reduce opioid use and misuse. Currently, 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. AAOS is currently developing CME in this area.

### **Storage and Disposal**

The AAOS believes better means of disposing unused opioid analgesics is a critical way to reduce opioid diversion, misuse, and abuse. National Drug-Take Back Events have worked in disposing countless unused medications and several pharmacy chains now offer ways to render medications inert. Walmart<sup>2</sup> now includes a free DisposeRx packet with an FDA-safe chemical blend that, when mixed with a medication, lets patients safely dispose of unused medications in the trash. The AAOS, as part of its [Pain Relief Toolkit](#), includes information for patients on how to properly use, store, and dispose of unused medications.

A significant step in reducing the number of unused opioids was new regulations enacted in September 2014 implementing the Secure and Responsible Drug Disposal Act (Disposal Act) of 2010<sup>3</sup>, which allowed industry registrants to voluntarily become collectors (manufacturers, distributors, reverse distributors, and retail pharmacies). But, because it is voluntary to become a collector, the AAOS believes incentives to maximize the number of entities that are willing to become collectors would go a long way in reducing the number of unused medications in circulation.

AAOS strongly supports a combination of patient education, chemical means to inactivate medications, and incentivizing drug take-back locations to significantly reduce the chances of opioid diversion and addiction.

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](mailto:shaffer@aaos.org).

Sincerely,



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#### References

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