

Submitted via email to EPAEDEAreport@HHS.gov

August 26, 2019

To: Office of the Assistant Secretary for Planning and Evaluation (ASPE), HHS

From: American Society of Anesthesiologists

Re: Request for Information: Ensuring Patient Access and Effective Drug Enforcement

On behalf of the American Society for Anesthesiologists (ASA) and our 53,000 members, we are pleased to submit our response to the U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation's recent Request for Information (RFI) for the Ensuring Patient Access and Effective Drug Enforcement Act of 2016 (EPAEDEA) Report to Congress.

The EPAEDEA is an important step in combatting the opioid crisis. As the nation comes together to tackle the opioid crisis, physicians play an important role in ensuring the responsible prescribing of opioid medications. The specific role that physician anesthesiologists' play in the delivery of care makes these specialists uniquely positioned to help curb inappropriate use and abuse of opioids throughout the perioperative period and upon discharge, as well as managing complex chronic pain patients. We look forward to continue acting as a resource as discussions evolve and to reading the final Report to Congress on this important topic.

Below we have provided our feedback and recommendations to the major aspects of the Report to Congress, as outlined in the RFI.

Obstacles to Legitimate Patient Access to Controlled Substances

Physician anesthesiologists have extensive experience with the intricacies of short-term pain management, such as following a surgical procedure or minor injury, and can effectively employ non-opioid alternative treatment options. Additionally, a subset of the ASA membership specializes in long-term pain management, related to chronic pain and other diseases. These pain medicine specialists can closely monitor patients on long-term opioids, safely help reduce opioids for patients when appropriate, as well as provide interventional treatment options for conditions like low back pain. Physician anesthesiologists also partner with patients and families in order to manage expectations around pain treatment, and the prevention of opioid misuse and abuse.

In our practices, we often see obstacles that many patients face in receiving access to legitimately prescribed controlled substances. Therefore, ASA believes the Report to Congress needs to analyze the effects and consequences of administrative processes, such as prior authorization and claims approvals. These processes can be burdensome for providers and patients alike and have potential to slow or deny access to necessary services for patients.

Preventing Diversion and Abuse

Safe disposal of unused pills is especially important to reduce the stockpile of excess opioid medications in family homes, which pose great risk of abuse or misuse. ASA strongly supports the Drug Enforcement Agency (DEA)'s decision in 2014 to permit consumers to return unused prescription medications like opioids to pharmacies through an amendment to the Secure and Responsible Drug Disposal Act of 2010 ("Disposable Act"). Previously, drugs could be disposed of only by the consumer (typically flushed down the toilet) or surrendered to law enforcement. Drug take-back programs not only encourage and facilitate safe disposal, but they also reduce the amount of prescription medications entering sewage systems, lakes and rivers.

ASA encourages the exploration of policies that can increasingly expand drug take-back programs. However, ASA also recognizes that there is a lack of empirical evidence on the impact of ongoing drug take-back programs. We believe it is imperative that this report highlight the effectiveness of drug take-back programs or call for a study on such, which could assess effective messaging to patients about these options to dispose of unused medications and inform on how to make patients more aware of existing and/or new programs. The report should highlight successful programs, as well as take-back programs that fell short of goals. This will help in future implementation of take-back programs and ensure lessons learned are incorporated.

It is also essential for the Food and Drug Administration to support initiatives to increase education and awareness on safe storage and disposal among physicians, patients, caregivers, and family members. The ASA believes these efforts are an essential tool to help curb misuse and abuse of opioid analgesics. Further examination of multiple disposal options is warranted. For example, the ability for patients to send back through the mail, utilize drop-off boxes at pharmacies or other public places like police and fire stations, and participate in take-back prescription drug days already in place.

Educating the Workforce

Effective physician education is reinforced throughout the continuum of medical education, including residency training, clinical experiences, and continuing education for practicing physicians. ASA supports vigorous efforts to improve education across the health care professions in both pain management and substance abuse prevention and treatment. Professional education and training must assure clinical competence in pain care, including, but certainly not limited to, the prescribing of controlled substances. Clinicians must be trained and demonstrate competencies in pain management, controlled substance prescribing and substance abuse prevention.

Additionally, we believe that any educational initiative should be targeted at all prescribers, not just opioid prescribers. Initiatives focused only on opioid prescribing or only on Schedule II drugs, and that permit prescribers to avoid education simply by opting out of prescribing certain drugs, would likely lead to prescribing other controlled substances that also have abuse potential. Furthermore, as health care becomes more collaborative, it is imperative that all clinicians (physicians, nurses, and physician assistants) receive adequate and appropriate training on controlled substances.

As a result, the Report to Congress should document the number and types of clinical education programs that are training physicians, nurses, and physician assistants on controlled substances. We also believe that the report should examine how many and what types of clinical education programs

(including physicians, nurses, physician assistants) provide information on safe storage and disposal and encourage discussing the risks of misuse, abuse and addiction associated with opioid analgesics with patients. This data can inform the topics and breadth of information that should be integrated into educational efforts.

Prescription Drug Monitoring Programs

ASA members have seen the benefits of select state-based prescription drug monitoring programs (PDMP). The current variance across state programs remain a challenge. As such, implementation of a national PDMP should be examined. Such a program, if properly designed, could reduce unnecessary or inappropriate opioid prescribing as well as facilitate consistent reporting and tracking across the country. Almost every state has its own PDMP, but those programs tend to differ significantly from one state to another, and there are marked differences in how states set up agreements with other states to share the data. Another significant problem is a lack of physician access to information about what prescriptions patients have filled in other states. A national PDMP, perhaps beginning with providers participating in the Medicare and/or Medicaid programs, could address many of the shortcomings of inconsistent state PDMPs and eventually create a uniform resource that reduces gaps in care or information that enables prescription drug abuse and hinders effective monitoring.

ASA is confident that clear benefits can be derived from national PDMP. If a national PDMP were to be implemented, ASA recommends that it include the following features:

- It should be designed so providers can easily access information (such as allowing authorized delegates);
- It should have the capacity to integrate with the major electronic health IT systems used by physicians and other providers;
- It should provide timely and reliable data in an easily digestible format; and
- It should be integrated with education, prescription monitoring and enforcement efforts.

If properly designed and implemented, a national PDMP can be an effective tool in curbing inappropriate prescribing and can help address the opioid epidemic. Encouraging consistent use is a critical part of its implementation.

As a result, we believe the Report to Congress should examine the benefits and limitations of a national PDMP. The Report should also examine the design elements outlined above to determine what is needed to implement an effective national PDMP.

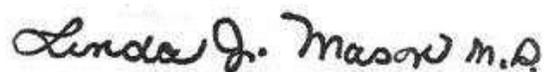
Improving Reporting Requirements

ASA supports improved transparency and reporting so that the public and Congress have more information regarding prescription opioids. A national database or reporting system can help determine trends in prescribing, find outliers, and address gaps in knowledge when patients receives multiple prescriptions across state lines. Additionally, improved transparency and reporting could allow for data-driven utilization and performance reports. The access to this data would also provide the ability to carefully study outliers. We caution, however, that any examination of outliers should also weigh population differences and needs of a given practice area. This will ensure that any comparisons that are made incorporate all needed data to make informed decisions on prescribing practices. The Report to Congress should examine the utility and effectiveness of both a national database and individual provider

reports, as well as steps for appropriately documenting outliers and incorporating all necessary data elements.

Thank you for your leadership in addressing the opioid epidemic in communities across the nation. We appreciate the opportunity to provide our comments to the RFI for the Report to Congress. We look forward to reading the report. Please do not hesitate to contact Ashley Walton, J.D., Senior Pain Medicine and Federal Affairs Manager, via email at a.walton@asahq.org or by telephone at (202) 289-2222, if we can be of further assistance.

Sincerely,

A handwritten signature in black ink that reads "Linda J. Mason M.D." The signature is written in a cursive style.

Linda Mason, M.D., FASA
President
American Society of Anesthesiologists (ASA)

American Society of **Anesthesiologists**[®]