



August 28, 2019

Brenda Destro, Deputy Assistant Secretary for Planning and Evaluation  
U.S. Department of Health and Human Services  
Office of the Assistant Secretary for Planning and Evaluation  
Office of Science and Data Policy  
Attn: EPAEDEA Report Feedback  
200 Independence Avenue SW, Room 434E  
Washington, DC 20201

Dear Deputy Secretary Destro:

On behalf of the American Academy of Family Physicians (AAFP), which represents 134,600 family physicians and medical students across the country, I write in response [request for information](#) titled, "Ensuring Patient Access and Effective Drug Enforcement" as published by the Office of the Assistant Secretary for Planning and Evaluation in the July 26, 2019 *Federal Register*.

The AAFP appreciates that HHS seeks comment on ensuring legitimate access to controlled substances, including opioids, while also preventing diversion and abuse. The AAFP's [position](#) on chronic pain management and opioid misuse recognizes the intertwined public health issues of chronic pain management and the risks of opioid use and misuse continue to receive national attention. Family physicians find themselves at the crux of the issue, balancing care of people who have chronic pain with the challenges of managing opioid misuse and abuse. Pain is one of the oldest challenges for medicine. Despite advances in evidence and understanding of its pathophysiology, chronic pain continues to burden patients in a medical system that is not designed to care for them effectively. Opioids have been used in the treatment of pain for centuries, despite limited evidence and knowledge about their long-term benefits, but there is a growing body of clear evidence regarding their risks. As a result of limited science, external pressures, physician behavior, and pharmacologic development, we have seen the significant consequences of opioid overprescribing, misuse, diversion, and dependence.

In the face of this growing crisis, family physicians have a unique opportunity to be part of the solution. Both pain management and dependence therapy require patient-centered, compassionate care as the foundation of treatment. These are attributes that family physicians readily bring to their relationships with patients. While our currently fragmented health care system is not well-prepared to address these interrelated issues, the specialty of family medicine is suited for this task. The AAFP is actively engaged in the national discussion on pain management and opioid misuse. Committed to ensuring that our specialty remains part of the solution to these public health crises, the AAFP challenges itself and its members at the physician, practice, community, education, and advocacy levels to address the needs of a population struggling with chronic pain and/or opioid dependence.

#### STRONG MEDICINE FOR AMERICA

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We offer the following feedback to the HHS identified issues:

Obstacles to legitimate patient access to controlled substances

- Lack of adjustments in payment models to enable physicians to provide patient-centered, compassionate care in the treatment of chronic pain and opioid dependence and to appropriately compensate them for providing such care.
- Narrow and limited governmental and private insurance coverage of MAT in the primary care setting, with adequate reimbursement for the increased time, staff, and regulatory commitments associated with MAT.
- Limited role of advanced practice nurses (APNs) and physician assistants (PAs) in providing MAT as part of a team supervised by a DATA 2000-waivered primary care physician.
- The lack of some health professionals collaborating with primary care physicians to deliver the multidisciplinary care that patients struggling with chronic pain and/or opioid dependence need.
- The time-consuming need to consider obtaining a Drug Addiction Treatment Act of 2000 (DATA 2000) waiver to deliver office-based opioid treatment (OBOT).
- The stigma perceived of providing access to and information about appropriate antidotes (e.g. naloxone) for patients who are at highest risk of an intentional or unintentional overdose.
- The lack of a nonjudgmental and culturally proficient environment for patients struggling with chronic pain and/or opioid dependence.
- That some plans do not encourage and enable physicians to use protocols for medication-assisted treatment (MAT) to address opioid dependence within the clinic population.
- Arbitrary limits on prescribed pain medications.
- Pharmacy protocols that result in refusing a legitimate prescription or rationing medications that are dispensed based on the misapplication of the U.S. Centers for Disease Control and Prevention's Guidelines for Prescribing Opioids for Chronic Pain.
- Incarcerated individuals have challenges accessing MAT substance use disorder programs do not align with state or federal prescribing limit laws.
- Lack of mental health professionals needed to provide the behavior therapy necessary for MAT program requirements.
- Patients' social determinants may impact access, such lack of insurance, transportation, financial insecurity, and geographical proximity to health care.

Issues with diversion of controlled substances

- State PDMPs should be better used as these electronic databases are used to track prescribing and dispensing of controlled prescription drugs; they can be used to obtain information on suspected abuse or diversion and to help identify patients at risk so they can benefit from early intervention.

How collaboration between Federal, State, local, and tribal law enforcement agencies and the pharmaceutical industry can benefit patients and prevent diversion and abuse of controlled substances:

- Review current practice patterns and protocols, considering the Federation of State Medical Boards (FSMB) and Centers for Disease Control and Prevention (CDC) guidelines for the treatment of chronic pain.

- Work with local, regional, and/or national practice-based research networks to develop science that will best inform the care of patients who have chronic pain and the appropriate management of opioid use, especially in vulnerable populations.
- In states that lack appropriate laws, advocate for better access to naloxone, and appropriate Good Samaritan protections for prescribers and lay rescuers.
- Work with state and federal licensing boards, the Drug Enforcement Administration (DEA), and the Substance Abuse and Mental Health Services Administration (SAMHSA) to destigmatize MAT, particularly in the setting of the community provider.
- Work with state and national partners to improve the functionality, utility, and interoperability of PDMPs, and develop best practices for their use and implementation.
- Expand governmental and private support of research into the management of chronic pain, as well as methods to better identify and manage opioid misuse. Particular attention should be paid to vulnerable populations who are at higher risk for undertreatment of pain and/or for opioid misuse.

The availability of medical education, training opportunities, and comprehensive clinical guidance for pain management and opioid prescribing, and any gaps that should be addressed.

- Align residency program training to deliver evidence-based information on best practices in the management of chronic pain and opioid dependence.
- Expand current continuing medical education (CME) offerings to deliver evidence-based information on best practices in the management of chronic pain and opioid dependence, including the appropriate use of naloxone.
- Expand the opportunities for DATA 2000 waiver training during residency. For mentoring and training purposes, this will ideally include faculty members at each residency site who are trained in MAT. Sites where waivered family medicine faculty members are not available should utilize collaborative teaching and mentoring arrangements with other providers.
- Expand the availability of waivered training courses at national, state, and regional CME meetings, as well as the availability of online and other alternative models of waiver training.
- Develop a list of DATA 2000-waivered family physicians across the United States who are willing to provide mentorship for newly waivered family physicians and residents, ideally with some form of reimbursement for their mentorship activities.

Steps to improve reporting requirements so that the public and Congress have more information regarding prescription opioids, such as the volume and formulation of prescription opioids prescribed annually, the dispensing of such prescription opioids, and outliers and trends within large data sets.

- Inform, educate, and facilitate development of overdose education and naloxone distribution (OEND) programs in the community.
- Increase collaboration among community behavioral health services, nurse care management services, other psychosocial support services, and primary care in order to support community providers of MAT.
- Expand cross-coverage opportunities for solo, waivered family physicians working in rural and underserved areas, including the possible short-term use of nonwaived physicians to provide coverage.
- Increase reporting about the association between pain management and chronic disease.

Deputy Secretary Destro

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We appreciate the opportunity to comment. Please contact Robert Bennett, Federal Regulatory Manager, at 202-655-4908 [rbennett@aafp.org](mailto:rbennett@aafp.org) with any questions.

Sincerely,

A handwritten signature in black ink that reads "Michael Munger MD". The signature is fluid and cursive, with "Michael" and "Munger" connected, and "MD" written in a smaller, more formal script to the right.

Michael Munger, MD, FAAFP  
Board Chair