AMERICAN ACADEMY OF FAMILY PHYSICIANS

December 2, 2021

Janet Woodcock, M.D.
Acting Commissioner
U.S. Food and Drug Administration
5630 Fishers Lane
Rockville, MD 20852

Dear Acting Administrator Woodcock:

On behalf of the American Academy of Family Physicians (AAFP), which represents 133,500 family physicians and medical students across the country, I write in response to the notice, *Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy (REMS) in an Evolving Opioid Crisis*, as requested by the September 9, 2021, Federal Register. The FDA convened a public workshop on October 13-14, 2021 to consider the effects of mandatory prescriber education on the current opioid crisis as part of a Risk Evaluation and Mitigation Strategy (REMS).

In 2012, the number of opioid prescriptions written (259 million) equaled the adult population of the United States.[i] Despite the increase in opioid prescribing, similar increases have not been observed with other analgesics, including nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen, or other adjunctive nonopioid therapies, nor has there been a concomitant change in the amount of pain that Americans report. Given these concerning trends in opioid prescribing and use, the FDA and other stakeholders increased scrutiny and monitoring of prescribing trends. The AAFP's position paper on Chronic Pain Management and Opioid Misuse acknowledged that family physicians played a role in this rising trend; primary care providers are responsible for about half of the opioid pain relievers dispensed and called on family physicians to take a number of steps to improve appropriate prescribing and address the growing burden of opioid dependence.[ii]

In 2012, the FDA approved the Extended Release/Long Acting (ER/LA) REMS, which required ER/LA opioid analgesic companies to make an education program available for clinicians who prescribe ER/LA opioid analgesics. In response to concerns of burdensome requirements, the FDA did not make this education program mandatory for prescribers and required the program be free or low cost. This was expanded in 2018 to include companies that make instant release (IR) opioid analgesics (OA).

Since the FDA's requirement that OA companies provide optional educational programs for clinicians and the creation of additional private and public training opportunities, opioid prescription rates have declined steadily. From 2016 to 2020, the opioid prescription per capita rate fell from 0.84 to 0.44.[iii] Despite this positive step in prescribing practices, the overdose death rate in the U.S. has continued to rise. A majority of the deaths involve illicit substances like heroin, fentanyl, and fentanyl analogues, but it is widely believed that many of these substance use disorder (SUD) instances began with opioids as a result of continued over prescribing.



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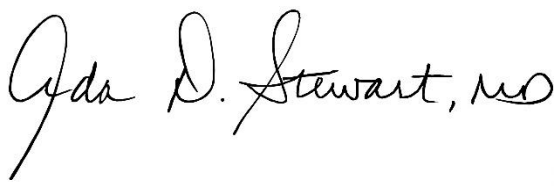
**The AAFP strongly supports prescriber education programs to address over prescribing concerns but urges the FDA not to implement a mandatory training requirement for prescribers.** Physicians have improved prescribing practices through optional trainings over the last six years and are seeking training to improve screening, diagnosis, and treatment of SUD involving opioids and other legal or illicit drugs. Additionally, private and public organizations, medical schools, and residencies have increased training on appropriate prescribing and pain management. Adding mandatory requirements for training would be burdensome to physicians, many of whom have already sought additional training on pain management practices. These added burdens, such as the mandatory education requirement for physicians to obtain the X-waiver to provide SUD treatment, have been shown to worsen access to evidence-based, appropriate care.[iv] Additionally, resources for mandated training could be better used for implementation and use of prescription drug monitoring programs (PDMPs) or the implementation of payment that supports more time-intensive, whole-person care for pain management.

The AAFP is committed to addressing the dual public health crises of undertreated pain and opioid misuse/abuse at both the national and local levels. To this end, the AAFP has formed a cross-commission advisory committee to address the multiple issues involved. Through its efforts with other physician and medical organizations, as well as governmental entities, the AAFP is committed to being a leader in promoting the advancement of safe pain management and opioid prescribing, and in addressing the growing burden of opioid dependence. The AAFP is also an accredited continuing medical education (CME) provider and has offered several courses for family physicians on, appropriate prescribing, REMS, and pain management. Additionally, as of 2018, the average family medicine residency devotes about 33 hours to education about pain management topics including 5.4 hours on chronic pain assessment, 16.2 hours on therapy, and 11.4 hours on risk assessment.[v] This additional training in medical school, family medicine residencies, and through continuing education opportunities facilitates appropriate prescribing of opioids without restricting access to chronic pain management.

The AAFP shares the FDA's concern about rising overdose rates across the U.S. The COVID-19 pandemic has exacerbated mental health challenges and made accessing care more difficult for many individuals. More accessible SUD treatment is critically important to reducing the overdose death rates. Physicians continue to face barriers to prescribing evidence-based treatment like buprenorphine and other medication-assisted treatment (MAT). Previous caps on patient volume for MAT administration have hindered the expansion and accessibility of MAT. Documentation, counseling, and inspection requirements are important to ensuring practices follow recommended guidelines but often make it difficult for small or rural practices to provide MAT given geographical and financial challenges. The AAFP applauded the new route to becoming a qualified physician via the DATA-waiver and the increased cap on the number of patients that a physician or other clinician can treat.

Thank you again for the opportunity to provide comments on this important topic. For additional questions, please contact Meredith Yinger, Senior Regulatory Strategist, at myinger@aafp.org.

Sincerely,



Ada D. Stewart, MD, FAAFP
Board Chair, American Academy of Family Physicians

[i] Substance Abuse and Mental Health Services Administration. Results from the 2012 national survey on drug use and health: summary of national findings. Rockville, MD: Substance Abuse and Mental Health Services Administration; 2013.

[ii] Daubresse M, Chang HY, Yu Y, et al. Ambulatory diagnosis and treatment of nonmalignant pain in the United States, 2000-2010*. Med Care*. 2013;51(10):870-878.

[iii] IQVIA Institute, "National Prescription Audit" extracted March 2021, U.S. Census Bureau

[iv] Kleinman, R. A., & Morris, N. P. (2020). Federal Barriers to Addressing the Opioid Epidemic. *Journal of General Internal Medicine 2020 35:4*, *35*(4), 1304–1306. https://doi.org/10.1007/S11606-020-05721-5

[v] Zoberi, K., & Everard, K. M. (2018). Teaching Chronic Pain in the Family Medicine Residency. *Family Medicine*, *50*(1), 22–27. https://doi.org/10.22454/FAMMED.2018.134727