



Via Electronic Submission to: www.regulations.gov

December 3, 2021

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2021-N-0951: Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy in an Evolving Opioid Crisis; Public Workshop; Request for Comments

Dear Food and Drug Administration Staff:

The American Pharmacists Association (APhA) is pleased to submit our comments to the Food and Drug Administration (FDA) on “Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy in an Evolving Opioid Crisis; Public Workshop; Request for Comments.”¹ Founded in 1852, APhA is the largest association of pharmacists in the United States representing the entire pharmacy profession. APhA members practice in community pharmacies, hospitals, long-term care facilities, specialty pharmacies, community health centers, physician offices, ambulatory clinics, managed care organizations, hospice settings, and government facilities. Our members strive to improve medication use, advance patient care, and enhance public health.

While APhA shares FDA’s commitment to addressing the opioid crisis, we strongly oppose implementation of mandatory opioid prescriber education through a Risk Evaluation and Mitigation (REMS) strategy due to the immense burden it would place on pharmacists and pharmacies to verify that the required education has taken place. As you know, FDA had previously considered and rejected making mandatory education an opioid analgesic REMS requirement due to concerns about placing an undue burden on the healthcare delivery system. Rather than decreasing, these burdens would be even greater now given the intense focus of pharmacists and other health care providers on addressing the COVID-19 pandemic.

¹ FDA. Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy in an Evolving Opioid Crisis; Public Workshop; Request for Comments. 86 FR 50541. September 9, 2021. Available at: <https://www.govinfo.gov/content/pkg/FR-2021-09-09/pdf/2021-19437.pdf>

APhA offers the following specific comments on the proposal to require mandatory opioid prescriber education through a REMS:

Mandatory Opioid Prescriber Education through a REMS would place an Undue Burden on Pharmacists and Pharmacies

As noted above, APhA strongly opposes implementing mandatory opioid prescriber education through a REMS strategy because it would place an undue burden on pharmacists and pharmacies to verify the required prescriber education. Such a system would require pharmacists to query a database, website, or similar portal to verify education completion prior to dispensing each opioid analgesic prescription. **This inquiry would occur outside of the pharmacy workflow, requiring additional time on the part of already overburdened pharmacists.** APhA shares the sentiment expressed at the Public Workshop by pharmacist Mary Lynn McPherson of the University of Maryland Center to Advance Chronic Pain Research to “protect community pharmacists from losing their minds!” if they were required to verify mandatory opioid prescriber education for each opioid analgesic prescription.

As discussed at the Public Workshop, mandatory opioid prescriber education under a REMS would have a huge impact, affecting:

- 980,000 opioid prescribers
- 88,000 retail pharmacies
 - 144.3 million prescriptions
- 41.2 million patients²

In contrast, the next largest REMS for isotretinoin impacts:

- 20,000 prescribers
- 50,000 pharmacies
 - 2,050,000 prescriptions
- 530,000 patients³

Given the significant burden mandatory opioid prescriber education would have on pharmacists, pharmacies, and the health care system as a whole, APhA urges FDA not to move

² FDA/Duke Margolis Center for Health Policy. Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy (REMS) in an Evolving Crisis Public Workshop. Oct. 13-14, 2021. Slide 81. Available at: <https://healthpolicy.duke.edu/sites/default/files/2021-10/Opioid%20Prescriber%20Education%20Workshop%20Slide%20Deck.pdf>

³ Id.

forward with mandating opioid prescriber education through the REMS. Below, APhA details additional concerns with the proposal as well as other approaches to help address the opioid crisis.

Leverage Pharmacists in Addressing Substance Use Disorder/Opioid Use Disorder

The COVID-19 pandemic has highlighted how accessible pharmacists are and how they can be leveraged to improve the health of communities. Over 90% of Americans live within 5 miles of a community pharmacy.⁴ Rather than placing additional requirements on already overburdened pharmacists and pharmacies, the health care system should leverage pharmacists' services in addressing the substance use disorder (SUD)/opioid use disorder (OUD) crisis.

Pharmacists are important providers on the patient's health care team and play a critical role in caring for patients with acute and chronic pain and/or SUD/OUD including prescribing medications, as authorized; medication management; administering; dispensing; and educating patients about opioid and non-opioid pain medications, as well as talking to patients about nonpharmacologic therapies.

Pharmacists have more medication-related education and training than any other health care professional. As medication experts, pharmacists are uniquely qualified to provide opioid stewardship and medication management services including comprehensive medication management, dose optimization, appropriate tapering of opioids and other pain medications, and education on safe storage and disposal methods. In addition, pharmacists aid opioid overdose reversal efforts by furnishing naloxone and training patients and community members on its use.

Fully leveraging the full array of pharmacists' services would be a more effective way to address the SUD/OUD crisis than imposing mandatory education as part of the opioid analgesic REMS.

The Current System has been Effective in Reducing Opioid Analgesic Prescribing

In conjunction with other initiatives and efforts, the current system of making education available – but not mandatory -- for healthcare providers who prescribe opioids has been effective in reducing opioid analgesic prescribing per capita by almost 50%, from a peak of 84 prescriptions per 100 residents in 2012 to 43 prescriptions per 100 U.S. residents in 2020.⁵ During

⁴ NCPDP Pharmacy File, ArcGIS Census Tract File. NACDS Economics Department.

⁵ 86 FR 50541, p. 50542.

this same time period, total opioid analgesic prescriptions declined from a high of 263 million to 144 million.⁶

In addition, total morphine milligram equivalents (MMEs) per prescription decreased from 246 billion in 2011 to 110 billion in 2020, while average MMEs per prescription decreased from 946 to 764 during the same time period.⁷ New outpatient starts on opioid analgesics also declined from 47.4 million in 2011 to 31.7 million in 2019, with steeper declines in patients with more than one prescription a year.⁸ These statistics demonstrate that implementing mandatory education as part of the opioid analgesic REMS is not necessary to meet the goal of reducing inappropriate opioid prescribing.

Mandatory One-Size-Fits-All Opioid Education is Not the Right Approach to Reducing Inappropriate Opioid Prescribing: A Variety of Educational Programs are Necessary

As discussed at the Public Workshop by numerous commenters, education is not one-size-fits-all. As Kathy Chappell of the American Nurses Credentialing Center stated, there is a need to address outliers who are not in compliance with opioid clinical practice guidelines. Family physician Blake Fagan of Mountain Area Health Education Center agreed that the focus should be on the group of practitioners that prescribe high amounts of opioids. Lisa Robin of the Federation of State Medical Boards echoed this advice, recommending that State Medical Boards pay particular attention to practitioners who need individualized education and/or attention. Effectively reaching outliers will not be accomplished with a one-size-fits all educational program mandated through the REMS. Rather, as Kathy Chappell stated, the challenge is how to best individualize education within the health care system to help individual prescribers and members of the health care team gain the competencies they need.

As an accredited continuing pharmacy education (CPE) provider, APhA offers a variety of SUD/ODU programs and resources designed to meet the needs of our diverse membership. Offerings include live and on-demand webinars, such as our recent “Reducing the Stigma of Substance Use Disorders: Words Matter” webinar; home-study activities; workshops and seminars; Annual Meeting sessions; podcasts; journal articles; fact sheets, tools, and guides; and other resources on SUD/ODU issues.⁹ APhA also sponsors our Pain, Palliative Care, and

⁶ FDA/Duke Margolis Center for Health Policy. Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy (REMS) in an Evolving Crisis Public Workshop. Oct. 13-14, 2021. Slide 93. Available at:

<https://healthpolicy.duke.edu/sites/default/files/2021-10/Opioid%20Prescriber%20Education%20Workshop%20Slide%20Deck.pdf>

⁷ Id at Slide 95.

⁸ Id at Slide 96.

⁹ APhA. Opioid Use and Misuse Resource Center. Available at: <https://www.pharmacist.com/Practice/Patient-Care-Services/Opioid-Use-Misuse>

Addiction Special Interest Group (PPCA SIG), which serves as a forum for the sharing of information among pharmacists and student pharmacists who care for individuals with all types of acute and chronic pain, SUD/ODU, and those patients with life-limiting illnesses who have pain and other symptoms.¹⁰

Mandated Education Does Not Necessarily Lead to Desired Changes in Behavior, and Might Discourage Providers from Prescribing Opioids, thus Threatening Patient Access to Needed Medications

As Dr. Graham McMahon, President and CEO of the Accreditation Council for Continuing Medical Education (ACCME) explained at the Public Meeting: “While general mandates will create compliance, such mandates generate counterproductive psychological resistance and cynicism, and would not be expected to create learning, skill development or a change in behavior.”¹¹ Steve Singer of ACCME agreed, stating that mandated education can be a disincentive, especially if it fails to meet the relevance principle. David Fiellin of the Yale School of Medicine echoed Drs. McMahon and Singer, stating that mandatory does not mean effective or high quality. Bobby Mukkamala, Chair of the American Medical Association’s Substance Use and Pain Care Task Force pointed out that CME mandates do not remove administrative barriers to treating mental health and SUD, which is the real problem we are trying to address.

In addition, many presenters at the Public Workshop also expressed concerns about patient access to opioids if the prescriber had not taken mandatory REMS education. For example, Kate Nicholson, President of the National Pain Advocacy Center, said that one more mandatory requirement may drive health care providers from medication management and impede access to care.

Conclusion

For the reasons stated above, especially the undue burden verification of mandatory opioid prescriber education would place on pharmacists, APhA urges FDA not to move forward with this proposal. APhA looks forward to continuing to collaborate with FDA and its federal agency partners, Congress, health care provider organizations, patient groups, and other stakeholders to address the SUD/ODU crisis and provide needed care to our patients. If you have any

¹⁰ APhA. Pain, Palliative Care, and Addiction SIG. Available at:

<https://engage.pharmacist.com/communities?CommunityKey=6ffff6f38-ee7b-4c50-83fe-161a52b427e5>

¹¹ FDA/Duke Margolis Center for Health Policy. Reconsidering Mandatory Opioid Prescriber Education Through a Risk Evaluation and Mitigation Strategy (REMS) in an Evolving Crisis Public Workshop. Oct. 13-14, 2021. Slide 144. Available at:

<https://healthpolicy.duke.edu/sites/default/files/2021-10/Opioid%20Prescriber%20Education%20Workshop%20Slide%20Deck.pdf>



questions or need additional information, please feel free to contact Karin Bolte, Director, Health Policy at (202) 558-2727.

Sincerely,

A handwritten signature in black ink, reading 'Ilisa BG Bernstein', is positioned below the word 'Sincerely,'.

Ilisa BG Bernstein, PharmD, JD, FAPhA
Senior Vice President, Pharmacy Practice and Government Affairs