



American Pharmacists Association[®]
Improving medication use. Advancing patient care.

July 10, 2017

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

RE: Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics – Exploring the Path Forward (Docket ID: FDA-2017-D-2497)

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the opportunity to provide FDA input on the Training Health Care Providers on Pain Management and Safe Use of Opioid Analgesics—Exploring the Path Forward; Public Workshop (hereinafter, “May 2017 Public Meeting”). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 64,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, physician office practices, managed care organizations, hospice settings, and the uniformed services.

APhA supports legislative, regulatory, and private sector efforts that include pharmacists addressing our Nation’s substance use disorder epidemic as long as those efforts appropriately balance those efforts with the legitimate needs of the millions of patients living with pain. At the May 2017 Public Meeting, FDA signaled its interest in mandating education for prescribers of all opioids, including immediate release (IR) formulations, possibly through a REMS program. While APhA supports education as an important component of a multipronged approach to addressing use, abuse and misuse of opioid medications, APhA cautions that new requirements on health care professionals need to be effective and meaningful. APhA is committed to working with the Food & Drug Administration (FDA), and other federal agencies, Congress, state agencies and officials, health professionals and other stakeholders to identify methods and tools that help curb opioid misuse and abuse and provide accessible and appropriate treatment options for patients with acute and chronic pain.

A. Effectiveness

As previously noted, FDA has expressed interest in imposing mandatory prescriber education regarding pain management, opposed to product-specific education, to help address the opioid crisis. APhA and its members are supportive of efforts to combat prescription drug abuse

and misuse, including comprehensive education for health care providers on chronic pain and substance use disorder treatments, like the education outlined in the Draft Revisions to the Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids.¹ However, we believe new requirements need to be tested for effectiveness and their benefit should outweigh their burden. In addition to REMS programs' education requirements, FDA can evaluate the impact of state-level mandatory education as several states have required the completion of pain- and opioid-related education as a condition of licensure for health care professionals, including pharmacists. Therefore, APhA recommends that FDA research the effectiveness of mandatory prescriber education before implementing such a policy. If research confirms the benefit of opioid-related prescriber education outweighs the burden, APhA recommends that FDA work with states on implementation to avoid duplication, minimize burden and maximize the intended goal.

On its face, mandatory opioid education may not seem like an overly onerous requirement given its goal is to address a serious public health problem in the United States. However, in the current health care environment, providers have limited time and many competing priorities, all with a goal of improving patient care and safety. Changing state, federal, and payor requirements add to provider burden. Consequently, any new educational requirement should be considered carefully as it may detract from patient care or a provider's ability to seek education critical to their patient population.

B. Implementation Timeframe

APhA encourages FDA to carefully analyze the time necessary to implement mandatory education. For example, if there is not an effective implementation plan, which would include communication to prescribers and an adequate time for them to receive training, patient care will be negatively impacted. Delays in prescriber education, verification, and renewal processes could result in unintended consequences that are at odds with the goal of the policy and further fragment patient care. Without a clear process and time for prescribers to comply, patient access to needed medication will be impeded or patients will be forced to switch between prescribers or be driven to illegal alternatives.

C. Verification

APhA is concerned that the burden of verifying a prescriber's education mandate could fall on the pharmacist. While there are a multitude of mechanisms that may be used to mandate opioid-related education, any method to verify prescriber education should be seamless and not become the responsibility of the dispensing pharmacist. Requiring pharmacists to check multiple systems or different computers, as currently occurs for checks and reporting in prescription drug monitoring programs (PDMPs), detracts from pharmacist-patient interactions and patient care. Furthermore, the pharmacist is the likely health care professional to find a solution for a patient whose prescriber failed to satisfy the mandatory education requirement. Adequate mechanisms will need to be in place to assure that patients with legitimate pain needs are not prevented from receiving appropriate treatment in a timely manner.

¹ Food and Drug Administration (May 2017). Draft Revisions to the Food and Drug Administration Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids, available at: <https://www.fda.gov/downloads/Drugs/NewsEvents/UCM557071.pdf>, last accessed: June 29, 2017.

D. Variability of Prescribers and Practices

When considering any requirement on prescribers of opioids, it is important to remember there are a wide-variety of health care professionals who prescribe. While many view pharmacists strictly in a dispensing role, APhA notes that pharmacists may also prescribe opioids in certain states.² Consequently, APhA suggests FDA consider the impact and logistics of mandatory education for all the different types of prescribers of opioids, including pharmacists, before developing and implementing mandatory education.

E. REMS Programs as a Possible Mechanism for Mandatory Education

FDA has indicated an interest in expanding the ER/LA REMS program to include a mandatory prescriber education element in response to the opioid epidemic, a recommendation supported by an FDA advisory panel. FDA has used the REMS program to limit risks to patients. As FDA considers expanding or modifying a REMS program, such as the extended-release/long-acting (ER/LA) REMS program, APhA recommends that FDA study the effectiveness of elements currently in place and pilot new ones being considered. Without such research, APhA believes the benefits of mandatory prescriber education through a REMS program will be limited and may not meaningfully enhance care and safety. Therefore, before implementing mandatory education, modifications or other REMS-like programs, APhA recommends studying the effectiveness of such elements to limit waste and improve their impact on patients.

In addition, APhA believes that the ongoing reassessment of REMS programs, including specific elements, is vital to both patients and providers. From a patient safety standpoint, assessment measures should be designed to create an iterative feedback loop. Using the same efficacy assessment tools year after year may not provide substantive, actionable insight into poor outcomes and/or adverse events. This is consistent with the discussion at the May 2017 Public Meeting where panelists discussed the difficulty in evaluating the effectiveness of mandatory education as an intervention. Therefore, we urge the FDA to require assessment tools that generate usable data and build on information gleaned from previous assessments. Further, each REMS program's assessment process should involve input and guidance from prescribers, pharmacists, and patients and assessment results should be shared with clinicians. In addition, to provide manufacturers with the flexibility to create these assessment tools and to respond appropriately to findings, we recommend FDA streamline the process for making changes based on assessment data.

As FDA uses solutions to limit risks associated with a drug or class of drugs, APhA reiterates its past recommendation that FDA standardize REMS program elements to enhance REMS programs and make them less burdensome. Currently, there are hundreds of REMS programs, each with its own unique administrative nuances and components. This variability can make compliance daunting for health care professionals and patients. Although flexibility in

² See Centers for Disease Control and Prevention. *Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team*. Atlanta, GA: Centers for Disease Control and Prevention, U.S. Department of Health and Human Services; 2017.

program design is necessary and even desirable, introducing some level of consistency around the REMS elements would reduce compliance burdens without compromising program effectiveness.

Thank you for the opportunity to provide comments regarding health care provider training on pain management and safe use of opioid analgesics. APhA believes it is imperative that a proper balance be maintained in delivering appropriate pain management for the millions of patients with legitimate needs for opioids while taking steps to minimize and prevent misuse and abuse. As you move forward, please do not hesitate to use APhA as resource. APhA is committed to identifying and implementing solutions to curb the nation's opioid epidemic and utilizing the pharmacist's expertise to help improve pain management and the lives of patients. If you have any questions or require additional information, please contact Jenna Ventresca, Associate Director, Health Policy, at jventresca@aphanet.org or by phone at (202) 558-2727.

Sincerely,

A handwritten signature in black ink that reads "Thomas E. Menighan". The signature is written in a cursive, flowing style.

Thomas E. Menighan, BSP Pharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

cc: Stacie Maass, BSP Pharm, JD, Senior Vice President, Pharmacy Practice and Government Affairs