



**American Pharmacists Association**<sup>®</sup>  
Improving medication use. Advancing patient care.

**APhA**

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

**RE: Draft Revisions to the Food and Drug Administration Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids (Docket ID: FDA-2017-D-2497)**

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the opportunity to provide input on the *Draft Revisions to the Food and Drug Administration Blueprint for Prescriber Education for Extended-Release and Long-Acting Opioids* (hereinafter “Draft Blueprint”). APhA, founded in 1852 as the American Pharmaceutical Association, represents 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 offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

APhA has served as a strong advocate for legislative, regulatory, and private sector efforts to address our Nation’s substance use disorder epidemic, however, it is important to balance those efforts with the legitimate needs of the millions of patients living with pain. APhA is committed to working with the Food & Drug Administration (FDA), and other federal agencies, Congress, state agencies and officials, health professionals and stakeholders to identify ways to maximize the role of the pharmacists in curbing opioid misuse and providing treatment options. Education is an important component of a multipronged approach in addressing use and misuse of opioid medications. APhA is generally supportive of the Draft Blueprint and its broad focus on pain management and substance use disorder treatment. We believe solutions to this epidemic will require the unified and coordinated efforts of many diverse stakeholders, including health care professionals, patients and caregivers, community-based organizations, and federal, state, and local governments.

Pharmacists are often an underutilized health care resource despite their medication expertise and accessibility. Pharmacists today graduate with a Doctorate of Pharmacy (PharmD) degree, which requires six to eight years to complete, and have more medication-related training than any other health care professional. While many view pharmacists strictly in a dispensing role

with regard to opioids, APhA notes pharmacists may also prescribe opioids in certain states and have a role in substance misuse treatment as well.<sup>1</sup> APhA encourages FDA to include and support in its policies the role of the pharmacist in treating patients in pain. APhA offers the following recommendations to further this goal and enhance the impact of a final blueprint.

## **A. Overarching Concerns and Suggestions**

### **a. Application Competency**

Several of the requirements in the Draft Blueprint make statements regarding knowledge requirements, but do not reference how to apply the knowledge in practice. Providing education regarding the different kinds of pain and related treatments may not benefit patients if providers do not actively apply that information in their practices. For example, APhA is aware that health care practitioners can have difficulty interpreting prescription drug monitoring program (PDMPs) reports or are unaware of algorithms used in clinical decision support tools. Thus, APhA highly recommends FDA emphasize both knowledge and practical application in FDA's final blueprint.

### **b. Team-Based Care**

While APhA applauds FDA's leadership for initiating broader pain management education for HCPs, APhA would like to see the final blueprint better incorporate the May 2016 Advisory Committee Meeting recommendation to include non-prescribing health care team members into an updated blueprint.<sup>2</sup> APhA appreciates the Draft Blueprint's use of the term "health care provider" (HCP) to more broadly capture a variety of practitioners. Unfortunately, the Draft Blueprint fails to fully consider the functions and expertise of other members of the care team, such as pharmacists, or the importance of team-based care.

The benefits of better utilizing members of the care team are lost when their range of services, skill set and expertise are not adequately recognized. For example, research has demonstrated that pharmacists can improve or stabilize pain in patients after a single visit and resolve different adverse events within three visits.<sup>3</sup> In addition, in a systematic review of 298 published studies, pharmacist-provided medication therapy management (MTM) services resulted in significantly improved outcomes in disease management, cost savings, or quality of life measures.<sup>4</sup> Consequently, APhA encourages FDA to better account for pharmacists and other members of the care team who help improve outcomes for patients in pain in a final blueprint.

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<sup>1</sup> 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. Available at: <https://www.cdc.gov/dhds/pubs/docs/CPA-Team-Based-Care.pdf>

<sup>2</sup> See, FDA. Joint Meeting of the Drug Safety and Risk Management Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee Meeting Announcement. May 3-4, 2016. Available at: <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/AnestheticAndAnalgesicDrugProductsAdvisoryCommittee/UCM497290.pdf>

<sup>3</sup> Ma JD, Tran V, Chan C, Mitchell WM, Atayee RS. Retrospective analysis of pharmacist interventions in an ambulatory palliative care practice. *J Oncol Pharm Pract* 2016; 22:757-65. DOI: 10.1177/1078155212607089. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/26428283>

<sup>4</sup> Chisholm-Burns MA, Kim Lee J, Spivey CA, et al. US pharmacists' effect as team members on patient care: systematic review and meta-analysis. *Med Care* 2010;48(10):923-33. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/20720510>

APhA is concerned that without emphasizing a team-based approach to care, including effective communication strategies with patients and other providers, prescribers of pain medication may not appreciate the importance of collaborating with other providers or the benefits of coordinated care.

**c. Consistent Terminology**

APhA requests the final blueprint address the need to better differentiate between terms such as substance use disorder, addiction, abuse and misuse, among others. Often these terms are conflated or may be used variably by different HCPs. Consequently, APhA suggests the final blueprint acknowledge the need for consistent terminology to improve care and communication and provide clarity of their use where possible.

**d. Pain Management and Comorbidities**

A significant gap in the Draft Blueprint exists regarding pain management for patients suffering from comorbidities. Thus, APhA encourages modifying the Draft Blueprint to better educate HCPs on treating patients in pain suffering from other comorbidities.

**e. Reconciling Blueprint Versions**

APhA appreciates FDA’s efforts to revise the education blueprint. However, it is not clear from the Federal Register notice whether FDA means for the Draft Blueprint to replace the current blueprint in its entirety, or whether FDA will combine the two documents. For example, the current blueprint includes several tables, “Drug Information Common to the Class of Extended-Release and Long-Acting Opioids Analgesics (ER/LA opioid analgesics)” and “Specific Drug Information for Extended-Release and Long-Acting Opioid Analgesics (ER/LA opioid analgesics).” It is not clear whether these sections will be included in the blueprint going forward. If the aforementioned tables are not included, APhA recommends FDA include such information as an appendix to a final blueprint.

**B. Topic Specific Concerns and Suggestions**

**a. Assessing Patients in Pain**

APhA suggests specifically including PDMPs in “II. Assessing Patients in Pain,” as an example of a screening tool that should be used to evaluate the known risk factors for opioid use disorder. This will help clarify that PDMPs are in fact a screening tool. In addition, APhA has concerns regarding the effectiveness and use of patient provider agreements (PPAs), more commonly referred to as a “pain contract” mentioned in the Draft Blueprint. We believe a blueprint should reference and show preference to information, tools, and resources on which HCPs can rely. Accordingly, APhA recommends the final blueprint include evidence-based treatments and tools where possible and in cases where such information is not supported by evidence, note the treatment or tool should continue to be evaluated.

**b. Naloxone**

APhA appreciates FDA’s effort to increase naloxone prescribing by its inclusion in the Draft Blueprint. Although, by stating, “HCPs should prescribe and discuss the use of naloxone products as a means of avoiding death due to overdose,” in the Draft Blueprint, APhA is concerned the use of “should” may set the expectation that naloxone should be prescribed for all patients using opioids for chronic pain. APhA suggests modifying the sentence to better reflect the provider’s judgement regarding the decision to prescribe naloxone, and using a broader term than “prescribe” as there are various mechanisms for patients to receive naloxone (e.g., standing order).

**c. PDMPs**

“Section IV. Managing Patients on Opioid Analgesics” states “HCPs should review the patient’s refill history and refer to the state PDMP(s) available at each visit...” Patients may see a HCP for a variety of conditions unrelated to pain management. Therefore, APhA recommends modifying this section to encourage checks at each pain management visit.

**d. Adverse Events**

The Draft Blueprint mentions monitoring and reporting of adverse events multiple times. APhA believes a final blueprint should include the importance of adverse event reporting and the mechanisms to report. A final blueprint should highlight HCP reporting options and the need to discuss adverse event reporting with patients.

Thank you for the opportunity to provide comments on the Draft Blueprint. APhA is committed to working collaboratively to reduce substance use disorders and improve the safe use of opioids. We appreciate FDA’s work on this important issue and encourage the Agency to use APhA as resource. If you have any questions or require additional information, please contact Jenna Ventresca, Associate Director, Health Policy, at [jventresca@aphanet.org](mailto:jventresca@aphanet.org) or by phone at (202) 558-2727.

Sincerely,



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

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