American Pharmacists Association

FDA Listening and Informational Session
Pharmacy, Consumer, and Industry Organizations
June 22, 2021
2:00PM-4:00PM (EST)

APhA appreciates the opportunity to attend today's compounding listening and information session for Pharmacy, Consumer, and Industry Organizations.

The American Pharmacists Association (APhA) is the largest association of pharmacists in the United States advancing the entire pharmacy profession. APhA represents pharmacists in all practice settings, including hospitals and health systems, community pharmacies, 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. Our Academy of Pharmacy Practice and Management (APhA-APPM) Compounding Pharmacy Special Interest Group or "SIG," consists of more than 4,700 members committed to meeting the individual needs of the patients they serve.

APhA applauds FDA's actions during the pandemic, in particular FDA's guidances aimed at easing drug shortages, which has permitted hospital and community compounding pharmacists to have more flexibility than ever before in meeting both providers' and patients' needs during the public health emergency (PHE). We are also grateful for FDA's use of enforcement discretion for pharmacy compounders who prepare alcohol-based hand sanitizers for consumer use during the PHE.

To assist FDA's efforts to meet providers' and patients' needs for compounded drugs, APhA offers the following comments:

Maintain and Enhance Compounding Flexibilities Under the PHE to Address Current and Future Drug Shortages

On April 20, 2020 (updated May 21st) FDA issued temporary guidance granting flexibility for pharmacists to compound certain necessary medications under 503A and 503B for hospitalized patients without patient-specific prescriptions to address COVID-19. In addition, FDA clarified that medications on the agency's drug shortage list are effectively considered to be "not commercially available," freeing 503A and 503B compounding facilities from limits on compounding drugs that are "essentially a copy" of a product already available on the market. Many of our hospital compounding pharmacist members have told us FDA's compounding flexibility is the only reason hospitals were able to keep up with patient demand. Accordingly, the recent flexibility to compound medications under both sections 503A and 503B are likely to be necessary for the foreseeable future. Compounding pharmacists stand ready to provide needed medications for COVID-19 treatment and drugs in shortage in the U.S. because of this global crisis. As FDA understands, compounding pharmacies can help meet the increased demands for these products to prevent and mitigate shortages. Accordingly, we urge FDA to continue to leverage the flexibility the agency has granted for pharmacists to compound

medications in shortage under 503A and 503B for hospitalized patients without patient-specific prescriptions to continue to address COVID-19 and beyond the PHE to ensure readiness to address future pandemics and public health needs. FDA should also expand this flexibility to any additional drugs in shortage for all medically necessary conditions. Permitting pharmacists to compound drugs for all drugs in shortage during and after the pandemic will help ensure our nation's hospitals and other providers have the medications they need without disruption and be able to focus their efforts on patient care.

Delay Enforcement of the Final Memorandum of Understanding (MOU)

In April 2021, APhA joined other pharmacy organizations representing thousands of pharmacy professionals and our patients in requesting FDA delay enforcement of the final MOU until at least October 26, 2023. We are concerned that multiple state boards of pharmacy, including but not limited to those in large states like Texas and Florida, have recently concluded that it will be necessary for their respective state legislatures to amend state law in order for the boards of pharmacy to be able to comply with the final MOU's requirements. To date, in some states the relevant laws have not been changed and it is unlikely that changes will be made and implemented before the October 26, 2021 enforcement date.

Similarly, the National Association of Board of Pharmacy (NABP) recently requested an enforcement delay until October 2022. NABP received similar comments "from multiple member boards of pharmacy that the timeline is too short for them to take the action needed to sign the MOU by October 2021."

NABP's comments state:

> "The majority of boards cite the burden that the coronavirus disease 2019 (COVID-19) pandemic has placed on them, causing a backlog in most, if not all, board activities and resulting in the need for boards to prioritize COVID-19-related actions above everything else.
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> Some boards also cite issues beyond those related to COVID-19. Several states have indicated that regulatory changes, which involve lengthy processes and require extensive public comment periods, are needed. Others have indicated that statutory amendments are necessary, and the legislatures are placing a great deal of focus on COVID-19-related legislation. In addition, states where legislatures only meet biennially, eg, Montana, Nevada, North Dakota, Texas, may not have appropriate changes in place until 2022 or even 2023.
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> *Additionally, the potential lack of access for patients who rely on pharmacies that are located in states that cannot sign the MOU is of great concern to NABP and its member boards. In fact, at least one state has no in-state compounding pharmacies and its patients rely exclusively on interstate shipment for their needed medications. As a result, an October 2021 enforcement date may cause an interruption in therapy for these and other patients nationwide [emphasis added]."*

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APhA thanks FDA for its work with stakeholders to construct a framework to ensure patients have access to safe and effective compounded medications. We look forward to continuing to serve as a resource for the agency on this topic to ensure our nation can meet the medication needs of our patients. If you have any questions or require additional information, please contact Michael Baxter, Senior Director, Regulatory Policy, at mbaxter@aphanet.org.