



April 16, 2021

Dockets Management Staff: Docket No. [FDA-2015-N-0030]
Food and Drug Administration 5630
Fishers Lane, Room 106
Rockville, MD 20852

Submitted Electronically to FDA Docket No. [FDA-2015-N-0030]

The undersigned organizations represent thousands of pharmacy compounding professionals. We write today regarding the FDA's final [Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products](#) (MOU) with the states regarding interstate distributions of compounded drugs. For the reasons discussed below, we respectfully request that the 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. Specifically, both Texas and Florida have state laws that protect the confidentiality of complaint information submitted to their state boards of pharmacy, and both boards have received legal opinions that those laws would need to be changed before the board could attest to the ability to comply with the final MOU.

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. Some states have biennial or part-time legislative sessions that do not align with the FDA's deadline for states to sign the final MOU. Florida is in the final two weeks of their legislative session, with no legislation pending to address the final MOU, and the next legislative session there does not begin until January 2022. Likewise, Texas is in the final six weeks of their biennial legislative session and the next legislative session in that state does not convene until January 2023.

According to the [National Association of Boards of Pharmacy's FDA Compounding MOU Project](#) data, Alabama, New Mexico, Wyoming, Idaho, and Tennessee have also indicated they are unable or unwilling to sign the final MOU. We understand that multiple other states are facing similar legal hurdles and budgetary concerns and are preoccupied with the COVID-19 pandemic as well. Therefore, these states will not likely be able to meet the FDA's deadline to sign the final MOU. States' boards have also expressed concerns about how many additional inspectors and/or other full-time employees will be needed to meet the final MOU's requirements.

Enforcement of a five percent cap beginning in October of this year will result in an unnecessary disruption of health care for thousands of patients and will put an enormous strain on the pharmacies that serve them. Patients who rely on compounded medications from pharmacies in states that cannot, or do not sign the final MOU by the October 26, 2021 deadline will be penalized by disruption of care and inability to receive therapy from their pharmacy of choice.

States should be given more time to amend their laws and budget the necessary funds so they can sign and comply with the final MOU.

For these reasons, we respectfully request FDA delay its enforcement of the final MOU until, at least, October 26, 2023.

Thank you in advance for your consideration of this request.

If you have questions or would like to discuss the matter, please contact APC's Scott Brunner at scott@a4pc.org or at (404) 844-8607.

Sincerely,

Alliance for Pharmacy Compounding
American Pharmacists Association
National Alliance of State Pharmacy Associations
National Community Pharmacists Association

CC: National Association of Boards of Pharmacy