



December 10, 2018

The Honorable Scott Gottlieb, Commissioner  
Division of Dockets Management (HFA-305)  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

[Submitted electronically to [www.regulations.gov](http://www.regulations.gov)]

**Re: Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the States and the Food and Drug Administration; Revised Draft; Availability [Docket No. FDA-2018-N-3065-0001]**

Dear Commissioner Gottlieb:

APhA is pleased to submit these comments regarding the revised draft standard Memorandum of Understanding between FDA and the States Regarding Interstate Distribution of Compounded Human Drug Products (hereinafter, the “revised draft MOU”). Founded in 1852 as the American Pharmaceutical Association, APhA represents more than 62,000 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, managed care organizations, hospice settings, and the uniformed services.

APhA appreciates in the revised draft MOU, FDA, in response to our previous comments, made changes in what constitutes inordinate amounts and provides additional state flexibility. However, APhA continues to have concerns with language in the revised draft MOU we believe conflicts with previous FDA policy and Congress’s intent when it passed the Drug, Quality and Security Act (DQSA). Accordingly, below, we detail changes to the revised draft MOU necessary to safeguard both patient and provider access to compounded medications.

**I. Defining “Distribution” for the Purposes of the Revised Draft MOU**

APhA reiterates its concern that FDA continues to inappropriately redefine “distribution” to include “dispensing,” resulting in a significant expansion of FDA authority over pharmacy (and also medical) practice—an outcome Congress almost certainly did not intend or anticipate.

Existing statute directs FDA to develop an MOU that addresses “the distribution of inordinate amounts of compounded drug products interstate.”<sup>1</sup> While 21 U.S.C. § 353a(3)(B) does not explicitly define “distribution”, the statutory text differentiates between “distribution” and “dispensing” in a number of places—a clear indication that Congress ascribed different meanings to the two terms.<sup>2</sup> Historically, the terms “dispense” and “distribute” refer to two different activities. In both the Drug Supply Chain Security Act<sup>3</sup> and the Controlled Substances Act<sup>4</sup>, Congress and FDA expressly recognized the different usage of “dispense” and “distribute,” defining “dispensing” as something that is intrinsically clinical in nature, while defining “distribution” as the act of shipping or delivering a medication outside of the patient-provider relationship. In addition, multiple report language in sequential appropriations bills funding the FDA (FY16, FY17 and FY18) clearly states that re-defining these terms in a sample MOU represents an “overreach,” is “unprecedented” and inconsistent with the congressional intent of the statute.<sup>5</sup> To treat “distribution” and “dispensing” as interchangeable not only creates a very real possibility of confusion, it also requires FDA to intrude into clinical decision-making related to prescribing—an area meant to be governed by states. Thus, APhA believes the revised draft MOU should only address “distribution” of compounded medications across state lines and should have no effect of any kind on dispensing of prescriptions for identified patients by pharmacies dispensing compounded products pursuant to 503A.

Furthermore, APhA points to current law which states “The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States...” (21 USC 353a(b)(3)(B)(ii)).<sup>6</sup> Accordingly, APhA recommends FDA use and appropriately reference in its final MOU the following definitions of “dispense” vs. “distribute” recently adopted by the National Association of Boards of Pharmacy (NABP), which are also incorporated into the NABP Model State Pharmacy Act:<sup>7</sup>

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<sup>1</sup> 21 U.S.C. § 353a(3)(B). Available at: <https://www.law.cornell.edu/uscode/text/21/353a>.

<sup>2</sup> See e.g., *id.* at (3)(B)(ii) (differentiating the “dispensed” and “distributed” through the use of the disjunctive “or”, indicating that the terms are not interchangeable).

<sup>3</sup> Drug Supply Chain Security Act, §581(5) (2013) (defining distribute as “the sale, purchase, trade, delivery, handling, storage, or receipt of a product”, but stating that it “does not include the dispensing of a product pursuant to a prescription executed in accordance with section 503(b)(1) or the dispensing of a product approved under section 512(b)”).

<sup>4</sup> See 21 U.S.C. §802(10)-(11) (2013); See also 21 C.F.R. §208.3 (2013) (defining “distribute” as “the act of delivering, other than by dispensing, a drug product to any person”, thereby expressly excluding dispensing from the act of distribution).

<sup>5</sup> See, Omnibus Appropriations Act: House Report 114-205, FY2016; Omnibus Appropriations Act: House Report 114-531, FY 2017; Omnibus Appropriations Act: House Report 115-232: FY 2018.

<sup>6</sup> See, §353a. Pharmacy compounding. Available at: <http://uscode.house.gov/view.xhtml?req=granuleid:USC-prelim-title21-section353a&num=0&edition=prelim>

<sup>7</sup> See, Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy. August 2018. Available at: <https://nabp.pharmacy/publications-reports/resource-documents/model-pharmacy-act-rules/> - which states (s2) “Distribute” or “Distribution” means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a Drug, whether by passage of title, physical movement, or both. The term does not include: (1) To Dispense or Administer; (2) Delivering or offering to deliver a Drug by a common carrier in the usual course of business as a common carrier; or (3) Providing a Drug sample to a patient by a Practitioner licensed to prescribe such Drug; a health care professional acting at the direction and under the supervision of a Practitioner; or the Pharmacy of a hospital or of another health care entity that is acting at the direction of such a Practitioner and that received such sample in accordance with the Act and regulations to administer or dispense.”

*“WHEREAS the Food and Drug Administration, as required by the Drug Quality and Security Act, has released a draft standard Memorandum of Understanding for individual states to enter into with FDA that addresses the **distribution** of inordinate amounts of compounded drug products interstate. And*

*WHEREAS the long standing, generally accepted definition of **distribution** does not include the act of patient specific **dispensing**. And*

*WHEREAS in the current draft MOU, the Food and Drug Administration has deviated from the long standing, generally accepted definition of **distribution** by including the act of patient specific dispensing. And*

*WHEREAS the **Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy, August 2018** states:*

*“Distribute” or “Distribution” means to sell, offer to sell, deliver, offer to deliver, broker, give away, or transfer a Drug, whether by passage of title, physical movement, or both. The term does not include to Dispense or Administer. Therefore,*

***BE IT RESOLVED THAT** the National Association of Boards of Pharmacy will not support a Memorandum of Understanding in which the term **distribution** includes the act of **dispensing**.”*

APhA recently submitted comments with other pharmacy organizations to FDA requesting the comment period for the revised draft MOU be extended for an additional 90 days to give state BOPs, pharmacy organizations, medical providers, patient organizations and other stakeholders a chance to review and comment on the NABP revisions to the revised draft MOU. We believe the need for additional time is supported by the results of a recent survey to all state Boards of Pharmacy (BOPs) by APhA and other pharmacy organizations.<sup>8</sup>

## **II. Clarification Needed**

*Modify: “If the State of [insert State] receives a complaint involving an adverse experience or product quality issue relating to a drug compounded by a physician and distributed outside the State, the State will notify the appropriate regulator of physician compounding within the State. If the complaint involves a serious adverse drug experience or serious product quality issue, the State will also notify FDA by sending an email to [StateMOU@fda.hhs.gov](mailto:StateMOU@fda.hhs.gov) with the information in section III.c.1.a of this MOU as soon as possible, but no later than 3 business days, after receiving the complaint.”*

If certain procedures are determined to be necessary for the safety and quality of compounded drug products, APhA recommends these requirements be similarly applied to all compounders. For example, APhA recommends adding the following provision “After this notification, the State will share with FDA the results of the investigation that it conducted,” to the section on physician compounding.

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<sup>8</sup> Of the nine completing the survey question on whether the “...state would sign the revised draft MOU as currently drafted and without changes,” five states and one territory (Puerto Rico) indicated they were “very unlikely” (Mississippi, Montana, New Mexico, North Dakota, and Vermont) or three “somewhat unlikely” (Minnesota, South Carolina, Utah) to sign the MOU in its current format, with one (California) skipping the question.

APhA looks forward to continuing to work with the FDA and other stakeholders to construct a framework that enhances safety and quality without compromising patient access to vital medications. We hope to be a resource for FDA and are happy to be of assistance in any way possible. Thank you again for the opportunity to provide comments on this important issue. If you have any questions or require additional information, please contact Michael Baxter, Director of Regulatory Affairs, at [mbaxter@aphanet.org](mailto:mbaxter@aphanet.org) or by phone at (202) 429-7538.

Sincerely,

A handwritten signature in black ink that reads "Thomas E. Menighan". The signature is written in a cursive style with a prominent initial 'T'.

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

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs