



December 7, 2018

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane; Room 1061
Rockville, MD 20852

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

To Whom It May Concern:

The National Home Infusion Association (NHIA) submits these comments on the Food and Drug Administration’s (FDA) revised draft standard memorandum of understanding (MOU) entitled “Memorandum of Understanding Addressing Certain Distributions of Compounded Drug Products Between the State of [insert State] and the U.S. Food and Drug Administration” (draft MOU). NHIA is a national membership association for clinicians, managers and organizations providing infusion therapy services for patients in the home and outpatient settings.

NHIA and its members are strongly committed to maintaining the highest standards for compounding quality, promoting patient safety, and assuring patient access to safe and effective infusion therapies in the home and outpatient settings. We were pleased to see modifications to the draft MOU that address issues raised in our comments dated July 20, 2015. Specifically, we commend the FDA for redefining the threshold for “inordinate use” to 50 percent. We also support FDA’s decision to allow states more flexibility in determining whether to take action when a pharmacy exceeds the inordinate use threshold. We also applaud FDA for abandoning the ill-defined term “unit” in its calculation of compounded drug products distributed interstate.

However, we continue to have serious concerns that the draft MOU will have significant unintended consequences for home infusion patients and providers. Our concerns, outlined in greater detail below, focus on four key issues:

- Recent recommendations and edits by the National Association of Boards of Pharmacy could create significant confusion regarding whether the draft published September 7, 2018 reflects the most recent thinking of FDA
- The MOU includes dispensed products in the calculation of interstate distribution

- The MOU relies on inappropriate and inconsistent methodologies for calculating interstate distribution
- States do not have the capacity to comply with requirements of the MOU

Recent Comments by National Association of Boards of Pharmacy

It is our understanding that National Association of Boards of Pharmacy (NABP) has submitted a “redlined” version of the MOU that makes a number of significant and substantive changes. Of particular concern is a footnote in NABP’s redline that recommends that “The definition of *distribution* in this MOU is separate and distinct from and should not be used in relation to the term *distribution* as it is used in Section 503A(b)(3)(B)(i) of the Food Drug and Cosmetic Act.”

NHIA and its members strongly object to this recommendation, which extends far beyond the authority of FDA under the FDC&A, and would create confusion, inconsistency, and administrative burdens for boards of pharmacy and providers alike. Several boards of pharmacy are already on record regarding their concerns about the conflation of *dispensing* and *distributing*.

Further, we are deeply troubled by this effort by NABP to “move the goalposts.” NABP had significant input into the crafting of the MOU prior to its initial release. These late recommendations represent a significant change and warrant additional review. We call on FDA to issue a 90-day extension to the comment period, and to engage with stakeholders to address the modifications recommended in NABP’s comments.

Inclusion of Dispensed Products in Definition of Distribution

Consistent with our comments dated July 20, 2015, NHIA reiterates its concerns about the inclusion of dispensed products in the definition of distribution. Many home infusion providers are located near state borders and fill prescriptions for individualized compounded drugs to patients who reside in a neighboring state. For these pharmacies, the provision of infusion therapy across state lines to individual patients has become routine practice. Patients with highly specialized therapies for rare disorders and patients in rural areas near state lines may not have access to an in-state home infusion provider who can meet their needs. As many new biologic therapies are restricted to a small number of home infusion providers, there may simply be no option for patients to access these medications from an in-state providers. These patients would be substantially harmed by this draft MOU.

Unfortunately, the MOU states that a “distribution” occurs when a compounded human drug product leaves the facility in which the drug was compounded, including dispensing to an agent of a patient or to a patient for his or her own use. As an example, home infusion providers compound pain management sterile preparations for patients on hospice care and these preparations are sometimes dispensed to an agent of the patient, such as a hospice nurse. We

believe this definition of distribution exceeds FDA’s authority and that Congress did not intend to include dispensing of compounded drugs over state lines within the scope of the MOU.

The National Association of Boards of Pharmacy (NABP) Model State Pharmacy Act contains distinct and specific definitions for dispensing and distributing. This model – which many states use in their pharmacy regulations, rules, and oversight – explicitly states that the terms “distributed or distribution” does not include “to dispense or administer.” Further, section 503A of the Food Drug and Cosmetic Act (FDCA) explicitly uses the term “distributed to trigger the MOU requirement, but does not use the term “dispense” as it relates to the 5 % cap. FDA has adopted clear definitions for “distribute” that explicitly preclude the act of dispensing.

Methodologies for Calculating Interstate Distribution

The MOU requires states to monitor the number of compounded products being distributed across state lines both for the purposes of determining whether a compounder exceeds the 5 percent cap imposed in states that do not enter into the MOU, and also for determining whether a compounder has distributed an inordinate amount of compounded drug products interstate. Further complicating this requirement, the MOU uses different formulas to determine both of these thresholds. In both cases, NHIA has concerns about states’ abilities to comply with the draft MOU.

Cap on Interstate Distribution:

$$5\% < = \frac{\text{Compounded drug products distributed out of the state}}{\text{Total prescription orders dispensed or distributed by such pharmacy or physician}}$$

Inordinate Amounts:

$$50\% < = \frac{\text{Compounded drug products distributed out of the state per month}}{\text{Number of prescription orders for compounded drugs distributed or dispensed intrastate and interstate per month}}$$

To minimize the amount of data collection necessary, and to minimize confusion and potential errors, NHIA recommends that the FDA utilize a single metric for determining the cap on the amount of compounded orders that pharmacists, pharmacies or physicians can distribute interstate in states that do not sign an MOU, as well as in the calculation for inordinate use. Specifically, we urge FDA to use the following definition for calculating both the cap in states that do not sign the MOU, and for calculating inordinate amounts:

$$\begin{array}{l}
 \text{Interstate} \\
 \text{Cap} \\
 5\% > \\
 \\
 \text{AND} = \frac{\text{Compound Orders Distributed Over State Lines}}{\text{Total prescription orders (compounded and non-compounded) distributed and dispensed by such pharmacy or physician}} \\
 \\
 \text{Inordinate} \\
 \text{Amounts:} \\
 50\% >
 \end{array}$$

Finally, NHIA is concerned about FDA’s requirement that states monitor interstate distribution on a monthly basis. This would pose a significant administrative burden both to the pharmacies reporting this information, and to state boards of pharmacy to collect that information. We recommend that states collect distribution data on an annual basis.

State Capacity

As drafted, the MOU imposes several requirements on state boards of pharmacy. Upon signing the MOU, states are required to investigate complaints related to drug products compounded and distributed outside of the state. States are required to investigate adverse reactions or product quality issues, assess the public health risk associated with complaints, and take appropriate action. States will have to develop systems for identifying and calculating the amount of drug products that are distributed interstate and will have to submit detailed reports to the FDA.

Many state boards of pharmacy will be unable to fulfill these obligations with existing resources. Rather than take on new, unfunded mandates, many states will simply not enter into the MOU and compounding pharmacies in those states would be restricted from distributing more than 5 percent of total prescription orders across state lines. This arbitrary cap may restrict patients’ access to home infusion therapy, since an infusion pharmacy could only furnish compounded prescriptions to a limited percentage of out-of-state patients. It could also result in a lack of competition among providers in certain areas of the country.

In closing, NHIA encourages the FDA to continue working with stakeholders to refine the draft MOU to assure that patients can continue to access safe, effective, and high quality infusion therapies. Please feel free to contact Sharon Pearce, NHIA Vice President of Government Affairs at Sharon.pearce@nhia.org, or myself at Connie.Sullivan@nhia.org.

Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'Connie Sullivan', with a stylized flourish at the end.

Connie Sullivan, BS Pharm.
President & CEO
National Home Infusion Association