NHIA
National Home Infusion Association
Providing solutions for the infusion therapy community

July 20, 2015

Dr. Stephen Ostroff, M.D.
Acting Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Notice "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the States and the Food and Drug Administration; New Proposed Draft; Availability" (Docket Number: FDA-2014-N-1459)

Dear Acting Commissioner Ostroff:

The National Home Infusion Association (NHIA) submits these comments on the FDA's February 19, 2015 notice entitled "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the States and the Food and Drug Administration; New Proposed Draft; Availability."

NHIA has serious concerns with the Memorandum of Understanding (MOU), and if the draft MOU is finalized as currently written, patient access to home infusion will be unduly harmed. We focus our comments on three issues – (1) the inclusion of "dispensing" in the definition of distribution, (2) the arbitrary nature of the definition of "inordinate amounts", and (3) the lack of a definition of a "unit" of compounded product.

The MOU's Scope Should Not Include Dispensing

Section 503A clearly distinguishes between "distribution" and "dispensing" for the purposes of the MOU. As explained below, it is clear that Congress did not intend to include dispensing of compounded drugs overstate lines within the scope of the MOU. The MOU should not address dispensing of compounded drugs to a patient over state lines if all other requirements of 503A are met. Many home infusion providers are located near state borders and furnish quality, individualized compounded infusion drugs and related services to patients across state lines. For these pharmacies, the provision of infusion therapy across state lines to individual patients has become routine practice.

Section 503A provides that a drug product may be compounded in compliance with this section only if the drug product is compounded in a State:

> *(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of*

> *complaints relating to compounded drug products distributed outside such State; or*
>
> *(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician. (emphasis added)*

Importantly, the statute explicitly uses the term "distributed" as part of the subparagraph that triggers the MOU requirement, and does not include the term "dispense" that is included in the next sub paragraph regarding the 5% cap. The most logical interpretation of this language is that Congress recognizes the difference between dispensing and distributing drug products, and limits the MOU provision to addressing only the distribution of drug products across state lines.

Additionally, the FDA *has* adopted clear definitions for "dispense" and "distribute". The FDA explicitly defines the terms in 21 C.F.R. 208.3, which provides:

> *(a) Authorized dispenser means an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to provide drug products prescription in the course of professional practice.*
>
> *(b)Dispense to patients means the act of delivering a prescription drug product to a patient or an agent of the patient either:*
>
> > *(1) By a licensed practitioner or an agent of a licensed practitioner, either directly or indirectly, for self-administration by the patient, or the patient's agent, or outside the licensed practitioner's direct supervision; or*
> >
> > *(2) By an authorized dispenser or an agent of an authorized dispenser under a lawful prescription of a licensed practitioner.*
>
> *(c)Distribute means the act of delivering, other than by dispensing, a drug product to any person.*
>
> *(d) Distributor means a person who distributes a drug product.*

Thus, the FDA consistently and explicitly provided that the term distribute does not include dispensing a drug. Unfortunately, the recently released MOU failed to reflect this difference in the statute and has redefined these terms for the purposes of the MOU. The MOU's definition of distribution includes dispensing as part of distribution, despite Congress' clear separation of the two terms in Section 503A. In addition other laws, such as the Controlled Substances Act, distinguish drug dispensing from drug distribution. These laws and FDA's own regulations should guide the FDA's definition of dispense and distribute for the purposes of the MOU. If

wholly separate definitions be needed for the MOU, NHIA recommends the FDA consider the following definitions:

> *Distribute - to deliver (other than by administering or dispensing) a compounded drug product.*
>
> *Dispense - to deliver a compounded drug product directly to an individual patient, or their agent, based on the receipt of a valid prescription order.*

Inordinate Amount of Compounded Drug Product Definition Needs To Be Refined

Congress did not include a statutory definition of "inordinate amounts of compounded drug products" for the purposes of the MOU. However, the legislative history indicates that "'inordinate' quantities means amounts typically associated with ordinary commercial drug manufacturing (emphasis added)."[1] Thus, it is clear that Congress did not intend for the MOU to adversely affect the practice of home infusion therapy where drugs are compounded for individual patients or otherwise apply to practices commonly associated with traditional pharmacy.

Nonetheless, the draft MOU specifies that interstate distribution of an "inordinate amount of compounded drugs" occurs if the number of compounded prescriptions distributed interstate on a monthly basis is equal to or greater than 30 percent of the total number of units distributed by that pharmacy. Additionally, the FDA has not provided an explanation of how 30 percent or more was determined to be the trigger for "inordinate". It appears to be an arbitrary calculation, and as stated above, it also is inconsistent with Congress' intent that the "inordinate" language be limited to activities that are associated with manufacturing and not traditional pharmacy practice.

Imposing an arbitrary cap on the interstate dispensing of compounded products may unnecessarily 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. Should the FDA consider a definition for inordinate amounts of compounded product that relies on a percent threshold the FDA should consider 50 percent because that is the point when a pharmacy is sending more compounded product interstate than intrastate.

Lack of a Definition for a Unit of Compounded Product

The draft MOU did not include a definition of a "unit" for the purposes of defining inordinate amounts of compounded products, despite the critical importance of that term to the calculation of inordinate amounts of compounded products. The lack of a definition of a "unit" prevents stakeholders from being able to determine the effect of this provision on patients and providers. The FDA should provide stakeholders with a proposed definition of a "unit" and allow for comment on that definition so stakeholders can appropriately evaluate the MOU during the comment period. In our view, to do otherwise would violate the Administrative Procedures

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[1] U.S. Senate. Committee on Labor and Human Resources. *Food and Drug Administration Modernization and Accountability Act of 1997: Report Together with Minority Views (to accompany S. 830)* (S.Rpt. 105-43). Washington: Government Printing Office, 1997, p. 68.

Act's requirements for meaningful public participation in the federal rule-making process. The public should see the FDA's definition of "unit" before it appears in the final MOU.

NHIA recommends that the FDA consider using the following definition:

> *"For the purposes of the definition of "inordinate amount of compounded human drug products" a unit is defined as a drug product finished in its deliverable form (e.g. one tablet, one syringe, or one compounded sterile product (e.g. bag or cassette)), as required to carry out a prescribed therapy."*

This definition is consistent with the definition of "individual saleable unit" in Title II of the Drug Quality and Security Act.

Please feel free to have your staff contact Kendall Van Pool, NHIA Vice President of Legislative Affairs, at (703) 838-2664 or kendallvanpool@nhia.org should you want to discuss our comments further. Thank you for your consideration of NHIA's comments.

Sincerely,

Russell Bodoff

Russell Bodoff
President & CEO
National Home Infusion Association