National Home Infusion Association

NHIA Testimony to the Food and Drug Administration on Compounding MOU

Food and Drug Administration (FDA) Compounding Listening Session

June 6, 2016

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The MOU – A Provider's View

Thank you for your time today. I am a pharmacist by trade and Director of Health Ventures at Thomas Jefferson University Hospitals – Home Infusion Service. I also serve as Board Vice Chair for NHIA. Jefferson Home Infusion is located in Philadelphia and we serve a four state region that includes Maryland, Pennsylvania, Delaware and New Jersey. We are licensed in all four states to dispense home infusion medications.

Jefferson Home Infusion and the patients we serve would be negatively impacted by the MOU if it is implemented as drafted. The compounded products we provide to patients living within our four state service area are dispensed pursuant to an individual prescription and delivered directly to patients at their homes. The home infusion model of compounding pharmacy is different from most if not all other types of compounding pharmacies. Home infusion pharmacies compound and dispense their product directly to a patient pursuant to a prescription, and we also serve to coordinate the administration of the drug to the patient at their home. Most other compounding pharmacies compound and distribute products for other practitioners to administer.

The 503B Solution Fallacy

As a home infusion provider, becoming a 503B pharmacy would prohibit me from serving patients as I do today. Same day access to I.V. drugs commonly used in the home setting is needed to facilitate patient transitions from high acuity settings into the home. For example, release testing requires a pharmacy to hold product for days or weeks until validation for identity, strength and sterility is completed. This process is unnecessary when compounding a product for a single patient pursuant to a valid prescription. A delay in treatment of this nature would effectively prevent patients from receiving many infusion therapies we provide in the home setting today. Dispensing in increments of less than ten dosage units using three-day refrigeration stability also is unworkable, particularly for controlled substances where the law does not allow partial dispensing of a prescription except under specific circumstances. The 503B standards would prevent pharmacists from following physician orders to extend acute care treatments into the home, and thus would limit access to common home infusion

therapies. Further, patients living in rural areas and seniors would be disproportionally impacted if home infusion pharmacies were to be shoehorned into 503B status.

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As Tom noted, NHIA has serious concerns with the MOU, and if the draft MOU is finalized as proposed, patient access to patient-specific 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. We believe that Congress clearly did not intend to include dispensing of compounded drugs overstate lines within the scope of the MOU, and thus 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 patients served by these pharmacies, the ability of the pharmacy to provide infusion therapy across state lines is critical to ensuring patients have access to certain compounded sterile products.

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" which is included in the next subparagraph regarding the 5% cap if an MOU is not signed by a state. 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.

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." 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".

Lack of a Definition for a Unit of Compounded Product

Surprisingly, 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 actual 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 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.