National Home Infusion Association

NHIA Testimony Food and Drug Administration Compounding Listening Session

June 5, 2017

Thank you for the opportunity to attend today's listening session. The National Home Infusion Association (NHIA) has had the opportunity to attend and present at past listening sessions and are grateful for the opportunity to present our views on compounding pharmacy regulation. NHIA is the trade association representing 503A home infusion pharmacies that provide sterile intravenous (IV) medications, a limited number of subcutaneous medications, and services to patients able to be treated at home.

NHIA is committed to ensuring patients receive high quality, sterile medications and supports efforts to eliminate the potential for patient harm from contaminated compounds. The majority of compounding activities performed by home infusion pharmacies involves the preparation of a commercially available sterile product into a final form that is conducive to self-administration by patients and/or their caregivers in the home setting. Examples of common medications administered at home include: anti-infectives, immunoglobulin, parenteral nutrition, analgesics and various biologics.

Today NHIA will focus our comments on issues that remain a concern for home infusion providers – the draft Memorandum of Understanding (MOU) pertaining to the distribution of compounded product over state lines, inspection standards and the definition of compounding.

The Memorandum of Understanding

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 MOU specific 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. Lastly, we will discuss a common fallacy that is often levied in discussions regarding implementation of the MOU.

The MOU's Scope Should Not Include Dispensing

Section 503A clearly distinguishes between "distribution" and "dispensing" for the purposes of the MOU. Congress clearly did not intend to include dispensing of compounded drugs overstate lines within the scope of the MOU and has stated this as part of Appropriations Report Language on multiple occasions. Thus, the FDA's draft MOU should respect congressional intent and 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 to adjacent states, where the pharmacy is licensed, 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 following 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 the 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.

The 503B Solution Fallacy

It is often stated that if implementation of MOU is unworkable for home infusion providers providers could always option to become a 503B outsourcing facility. In fact the opposite is true becoming a 503B pharmacy would prohibit home infusion providers from serving patients that they serve 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.

Inspection Standards and Insanitary Conditions

NHIA is heartened by the FDA's released guidance on insanitary conditions at compounding facilities after the last listening session. The FDA's effort regarding this issue is encouraging and NHIA welcomes this opportunity to restate our comments that we submitted to the open docket on compounding.

In general, NHIA reiterates that the FDA should not apply manufacturing standards to 503A pharmacies. As written, the Draft Guidance lists facility designs not currently required under the standards used by authorities that regulate, license, accredit and inspect 503A home infusion pharmacies. Several conditions cited in the document are sourced from the manufacturing sector and will create undue barriers to providing individual patients with sterile home infusion products. Few 503A pharmacies across the healthcare spectrum today could meet the facility requirements identified in this document, and as a result, nearly every hospital, home infusion pharmacy and physician clinic meeting 503A criteria would likely be cited for insanitary conditions by FDA inspectors. NHIA believes the application of the several requirements in the guidance would impede a 503A pharmacy's ability to fulfill a patient specific order for a compounded sterile product. NHIA strongly urges the FDA to consult with state boards of pharmacy and the United States Pharmacopeial Convention (USP) regarding appropriate facility designs for 503A pharmacies, and not refer to manufacturing standards when defining insanitary conditions.

Definition of Compounding

NHIA requests the FDA consider working with congress to revise the current definition of compounding as currently stated in the Food, Drug and Cosmetic Act. The existing language is problematic because, 1) it is exclusionary rather than inclusionary, and 2) relies on the product labeling to define whether or not a product is classified as a compound. Few product labels consider risk factors such as the length of the infusion, number of doses being made at one time, or the product sterility. NHIA supports revising the definition of compounding to ensure a level playing field for all pharmacies that engage in preparing sterile products and asks that FDA work with USP on a definition of compounding that considers additional risk factors that might expose a patient to a contaminated product.

In Summation

NHIA is pleased that the FDA continues to host these compounding pharmacy listening sessions and we welcome the opportunity to partner with you on your efforts to ensure compounding pharmacy is safe and effective for the patients our members serve. While not addressed in this session we want to alert you to forthcoming comments regarding pharmacy procedures similar in nature to traditional compounding being included in manufacturer labeling that NHIA is preparing. Please feel free to have your staff contact Kendall Van Pool, at Kendall.vanpool@nhia.org or 703-838-2264 should you want to discuss our comments further. Thank you for your consideration of NHIA's comments.