National Home Infusion Association

NHIA Testimony Food and Drug Administration Listening Session on the Draft MOU

June 20, 2019

Thank you for the opportunity to attend today's listening session on the draft "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).

The National Home Infusion Association (NHIA) is a national membership association for clinicians, managers and organizations providing infusion therapy services for patients in the home and alternative sites of care. Our members provide sterile intravenous (IV) medications, a limited number of subcutaneous medications, and services to patients able to be treated at home.

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 alternative sites of care. NHIA members and staff have advised the US Pharmacopeia in the development and maintenance of healthcare quality standards, notably the recently released update to its "General Chapter <797> Pharmaceutical Compounding – Sterile Preparations." Further, NHIA has submitted comments and participated in ongoing dialogue with the Food and Drug Administration (FDA) about the draft MOU, its *Insanitary Conditions at Compounding Facilities Guidance for Industry*, and other policy considerations that affect the safety and availability of compounded medications.

We have appreciated the opportunity to bring our unique perspective to FDA and to work toward meaningful, achievable policy that assures both the safety and availability of compounded sterile products. In that spirit, during today's session, NHIA would like to focus on elements within the draft MOU that continue to raise concerns for the home infusion community. Specifically, we remain concerned about the following key issues:

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

The Memorandum of Understanding

Inclusion of Dispensed Products in Definition of Distribution

The draft MOU currently states that a "distribution" occurs when any compounded human drug product leaves the facility in which the drug was compounded, including drugs that are *dispensed pursuant to a prescription*. This definition is at odds with the National Association of Boards of Pharmacy (NABP) Model State Pharmacy Act (used by many states), which 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. We believe that this definition 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.

Moreover, by including dispensed products in the definition of distribution, and by limiting the amount of compounded products that can be distributed across state lines, the draft MOU could create significant access issues for home infusion patients. For example, many home infusion providers routinely fill prescriptions for patients who reside in a neighboring state. 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.

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 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 required of states, 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:

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

$$\text{Inordinate Amounts: } 50\% >$$

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.

Summary

NHIA is pleased that the FDA continues to host these 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. If you have questions, comments, or need additional information about our position, please feel free to contact Connie Sullivan, NHIA's President and CEO at Connie.Sullivan@nhia.org or Sharon Pearce, NHIA Vice President of Government Affairs at Sharon.pearce@nhia.org.