



National Home Infusion Association
1600 Duke St. Suite 410
Alexandria VA 22314

February 1, 2021

Janet Woodcock, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Lemrey Carter, MS, PharmD, RPh
Executive Director
National Association of Boards of Pharmacy
1600 Feehanville Drive
Mount Prospect, IL 60056

RE: Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State Board of Pharmacy or Other Appropriate State Agency and the Food and Drug Administration

Dear Dr. Woodcock and Dr. Carter:

On behalf of the National Home Infusion Association (NHIA), I am writing regarding our suggestions to improve implementation of the Memorandum of Understanding (MOU) between the Food and Drug Administration (FDA) and State Boards of Pharmacy regarding distribution of compounded human drug products, which was issued last year. NHIA is a trade association that represents home infusion therapy providers, as well as companies that manufacture and supply infusion and specialty pharmacy products. As the leading voice for the home and specialty infusion community, we write to share our feedback on this important issue.

For more than 40 years, community-based, 503A home infusion pharmacies have safely and effectively coordinated services associated with administering intravenous medications to patients in their homes. Home infusion pharmacies are licensed and regulated by state boards of pharmacy in compliance with United States Pharmacopeia (USP) standards and FDA guidance related to sterile compounding. NHIA appreciates the efforts of the FDA to improve the safety of compounded sterile preparations and we agree that patients and prescribers must have confidence in the quality and safety practices of pharmacies engaged in these activities.

On October 27, 2020, the FDA published in the *Federal Register* the final MOU with the states establishing limits on how much interstate distribution of compounded drug products is allowed by pharmacies and physicians.¹ For states that do not enter into the MOU with the FDA, the cap on distribution of compounded products is set by federal statute at 5% of the total drug orders dispensed and distributed. Whether or not a state enters into the MOU with FDA has serious implications for home infusion providers that serve patients across state lines. While the vast majority of products prepared by home infusion pharmacies do not meet the definition of a compounded product per the federal statute that are exempt from the MOU, nearly all home infusion providers compound parenteral nutrition, which would need to be counted toward the 5% or 50% cap on interstate distribution.² Due to the potential administrative burden related to manually identifying and collecting data according to the definitions outlined in the final MOU, most home infusion providers will likely choose to avoid exceeding the limits for interstate distribution by modifying their service area.

State decisions regarding the MOU could have serious implications for patient access to parenteral nutrition, particularly when a pharmacy is located near a state border and serves patients in an adjacent state. NHIA understands that FDA intends to include patient-specific dispensing in its definition of interstate distribution, and enforce the limits in the MOU after giving states a 365-day period to decide whether to sign the MOU. NHIA is concerned that pharmacies may not have adequate time to evaluate the impact of the state decision on their operations. In some instances, pharmacies may choose to identify an alternative pharmacy, either within the same company or with a new provider, that is capable of meeting the needs of patients currently being served across state lines. NHIA wishes to ensure there are no interruptions in care for patients that may be impacted by this policy. Therefore, NHIA recommends the following to the National Association of Boards of Pharmacy (NABP) and State Boards of Pharmacy:

1. State boards of pharmacy should act expeditiously in determining whether or not they will enter into the MOU with FDA and make special efforts to communicate their intentions to pharmacies that will be impacted, including home infusion pharmacies.
2. NHIA recommends states give pharmacies at least 120 days' notice of the state's decision to allow time to plan for transitioning patients to an in-state provider if necessary. Compounding pharmacies will also need time to ensure their software systems are capable of determining whether or not interstate dispensing and distribution caps will be exceeded.
3. State Boards of Pharmacy and NABP should conduct regular stakeholder outreach to associations and providers regarding the plans for identifying compounding pharmacies, present plans for how data will be collected and reported to FDA, and solicit input from compounding pharmacies.

¹ 85 Fed. Reg. 68074 (Oct. 27, 2020).

² 21 U.S. Code 353a - As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

4. NHIA encourages NABP to create a compounding stakeholder information resource where information can be consolidated regarding the status of each state's participation in the FDA MOU and provide details about how data sharing is occurring between states, NABP, and FDA.

Again, NHIA supports the FDA's goal of ensuring compounded sterile products are safe and of high-quality, however we wish to be proactive in ensuring patient access to important therapies such as parenteral nutrition is not disrupted during the implementation of the MOU. Therefore, we appreciate your attention to this matter and welcome the opportunity to discuss the impacts of the MOU on access to home infusion products.

Respectfully,

A handwritten signature in black ink, appearing to read "Connie Sullivan".

Connie Sullivan, BSPharm
President and CEO