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

September 2, 2014

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Draft Guidance "Current Good Manufacturing Practice – Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act" (Docket Number: FDA-2014-D-0779)

Dear Ms. Hamburg:

The National Home Infusion Association (NHIA) is pleased to submit these comments in response to the proposed rule published in the *Federal Register* on July 2, 2014 entitled, "Current Good Manufacturing Practice – Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act." This proposed rule sets forth the Food and Drug Administration's (FDA) expectations regarding compliance with Current Good Manufacturing Practice (CGMP) requirements for facilities that compound human drugs and register with the FDA as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

NHIA is a national membership association for clinicians, managers and organizations providing infusion therapy services for patients in home care and outpatient settings. Our members include independent local and regional home infusion pharmacies; national home infusion provider organizations; and hospital-based home infusion organizations. Generally, infusion pharmacies can be defined as pharmacy-based, decentralized patient care facilities that provide care in alternate sites to patients with either acute or chronic conditions.

As the FDA works to ensure compounded drug safety, NHIA believes it is important that the FDA fully understand and value the role 503A traditional compounding pharmacies play in the provision of infusion drug therapies. This Interim Guidance further underscores NHIA's stance that the FDA needs to ensure that 503A traditional compounding pharmacies can operate in a regulatory environment that allows for dispensing of drugs in all states where the pharmacies are licensed to dispense medications.

Infusion therapy (the administration of medications into the bloodstream via needle or

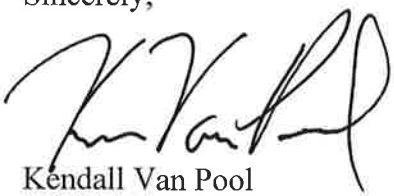
catheter) is the medically necessary treatment for many patients with cancer, serious infections and other conditions. Providing infusion therapy in a patient's home involves not only the delivery of medication, but also the specialized equipment, supplies, and professional services, including pharmacy compounding, necessary to ensure safe and effective administration of the therapy. Home infusion drugs are compounded on a patient-specific basis pursuant to prescriptions, often with the need to start administration of the drug on the same day as the physician's order.

The CGMP standards included in the Draft Guidance will effectively force home infusion pharmacies to remain 503A facilities. While NHIA expects that a majority of our members will be inclined to remain 503A facilities in at least the short-term, we would like for there to be a path to become 503B outsourcing facilities for those infusion pharmacies that choose that route. However, should the CGMP standards, specifically the sections regarding sterility standards become final as currently written, our members simply will not be able be able to operate as 503B facilities. While the FDA has included provisions allowing for limited batch compounding, the restrictions will be difficult, if not impossible, to meet for many of the drugs infusion pharmacies deliver to patients. Unless the FDA makes significant changes to CGMP sterility testing standards, these drugs will only be available from Section 503A regulated facilities, i.e., traditional compounding pharmacies. For that reason, it is essential that Section 503A continues to be a suitable regulatory niche for infusion pharmacies.

We also have longer term concerns about the 503B designation. The Centers for Medicare and Medicaid Services (CMS) and private payers may adopt policies in the future that require 503B status for the provision of compounded drugs. If such status precludes pharmacies from responding to patients' immediate medical needs due to sterility testing standards that do not permit the responsiveness that is required, then these patients may suffer serious consequences.

Please feel free to have your staff contact me, at (703) 838-2664-0308 or kendall.vanpool@nhia.org should you want to discuss our comments further. Thank you for your consideration of NHIA's comments.

Sincerely,



Kendall Van Pool
Vice President of Legislative Affairs
National Home Infusion Association