National Home Infusion Association
Providing solutions for the infusion therapy community

January 6, 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Re: Draft Guidance "Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act"

Docket Number: FDA–2013-D–1444

Dear Commissioner Hamburg:

The National Home Infusion Association (NHIA) submits these comments on the draft guidance entitled "Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug and Cosmetic Act" made available on December 4, 2013 by the Food & Drug Administration. NHIA is a national membership association for clinicians, managers and organizations providing infusion therapy services for patients in the home and outpatient settings.

This comment letter is limited to the FDA's planned issuance of a new standard Memorandum of Understanding (MOU) in accordance with Section 503A(b)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). NHIA will be submitting additional comments on other aspects of the draft guidance in a separate letter. We urge the FDA and the National Association of Boards of Pharmacy (NABP) to consider the unique nature of home infusion therapy and the well-established track record of home infusion pharmacies when developing the revised standard MOU.

Background on Home Infusion Therapy

Infusion therapy involves the administration of medication through a needle or catheter. The drug is generally administered intravenously, although it also may be provided through other non-oral routes such as via an intramuscular injection or epidural. Infusion therapy is indicated for patients with medical conditions that cannot be treated effectively with oral medications, such as patients diagnosed with infections that are unresponsive to oral antibiotics; cancer and cancer-related pain; and congestive heart failure.

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For the past four decades, infusion therapy has been provided safely and effectively in the home and outpatient settings. Home infusion therapy is furnished by specialized home infusion pharmacies that must meet state licensing and regulatory requirements as well as accreditation standards required by most third-party payers. Examples of common prescription drug therapies administered via home infusion include antibiotics, nutrition, chemotherapy and pain management. Importantly, home infusion pharmacies compound patient-specific medications in accordance with each patient's particular medical needs.

Home infusion pharmacies provide far more than the infusion drugs. They provide an array of professional services, including:

- Initial patient evaluation and assessment;
- Development and implementation of the patient care plan;
- Compounding and dispensing of infusion medications and equipment;
- Care coordination;
- Ongoing clinical monitoring and treatment plan oversight; and
- On-call services and patient discharge services.

Home Infusion Therapy Issues in the MOU

Home infusion pharmacies are regulated under Section 503A of the FD&C Act. Section 503A includes a requirement that drug products be compounded in a State that has entered into an MOU with the FDA that "addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State."[1] Congress did not include a statutory definition of "inordinate amounts of compounded drug products." However, the legislative history clearly indicates that "'inordinate' quantities means amounts typically associated with ordinary commercial drug manufacturing (emphasis added)."[2] 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 pharmacy.

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[1] FD&C Act, §503A(b)(3)(B)(i). Drug products may be compounded in a state that has not entered into such an MOU with FDA if "the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician." FD&C Act, §503A(b)(3)(B)(ii).

[2] U.S. Senate. Committee on Labor and Human Resources. *Food and Drug Administration Modernization and Accountability Act of 1997: Report Together with Minority Views (to accompany S. 830)* (S.Rpt. 105-43). Washington: Government Printing Office, 1997, p. 68.

Nonetheless, the FDA previously released a draft MOU on December 23, 1998 that specified that interstate distribution of an "inordinate amount of compounded drugs" occurs if the number of compounded prescriptions distributed interstate on an annual basis is equal to or greater than 20 percent of the total number of prescriptions dispensed or distributed by that pharmacy (including both intrastate and interstate prescriptions), or if prescriptions for one or more individual compounded drug products (including varying strengths of the same active ingredient) constitute more than 5 percent of the total number of prescriptions dispensed or distributed by the pharmacy.

We do not know the basis for these thresholds, but they appear to be arbitrary and inconsistent with Congress' intent that the "inordinate" language be limited to activities that are associated with manufacturing. More relevant to home infusion, however, we have two additional objections to this approach. The preparation and dispensing of an infusion drug subject to a patient-specific prescription is not an element of common manufacturing, regardless of whether the drug is delivered across a state border. In addition, the dispensing of an infusion drug to a specific patient is not a "distribution" of the drug, and thus is not a proper subject of the MOU.

NHIA encourages the FDA and the NABP to refrain from imposing such an arbitrary cap on the interstate dispensing of compounded drug products when drafting the new standard MOU. This type of limitation would not reflect advances in technology, current shipping techniques, quality controls and current practices by home infusion providers since 1999.

The practice of pharmacy compounding has changed significantly since the original MOU language was proposed in 1998. The practice of sterile compounding by licensed pharmacies in the late 1990s was based on published recommendations that lacked regulatory enforcement—a practice that was fundamentally changed with the adoption of enforceable sterile compounding standards in Chapter <797> by the United States Pharmacopeia (USP) in 2004. Organizations such as the American Society of Health-System Pharmacists and USP had issued pharmacy compounding practice recommendations in the late 1990s that centered on the pharmacist's responsibility for ensuring proper preparation, labeling, storage, dispensing, and delivery of compounded sterile products. While the published recommendations addressed many of the concerns of the profession, formal accountability to regulatory agencies for compliance with these recommendations was lacking.

Efforts to remedy the enforcement of sterile compounding standards continued, and culminated on January 1, 2004, when the first official and enforceable sterile preparation compounding standard in the United States was published as USP Chapter <797>. The expert committee responsible for writing USP Chapter <797> received considerable feedback and comments after the chapter was published. Based on many of these comments, the committee proposed revisions to USP Chapter <797> in the *Pharmacopeial Forum* 32(3), May–June 2006. The revision process included a call for public comments on the proposed revisions, and the response was overwhelming with

more than 500 individuals, hospitals, pharmaceutical companies, and professional organizations responding. USP posted a commentary document that provides insight and background on the comments and the subsequent revision process. After careful deliberation and consideration of these comments, a revised standard was developed and released in December 2007. The revised standard became official on June 1, 2008. It is important to note that USP <797> is not a static document. The USP Sterile Products Expert Committee is continuously monitoring research and practice to suggest improvements to chapter <797> and revised chapters are periodically issued by the USP.

With that as background, many home infusion providers are located in multistate regions and furnish quality, individualized compounded infusion drugs and related services to patients in multiple states. In other words, the provision of infusion therapy across state lines to individual patients has become routine practice of infusion pharmacies.

In addition, imposing an arbitrary cap on the interstate dispensing of compounded products may unnecessarily 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 shortage of home infusion drugs and a lack of competition among providers in certain areas of the country.

For these reasons, NHIA believes the FDA and the NABP should define "inordinate amounts of compounded drug products interstate" in a manner that is consistent with Congressional intent and which reflects the developments and progress that have occurred since 1999. Specifically, the MOU should address the distribution of products that are "typically associated with ordinary commercial drug manufacturing." It should not restrict the activities of home infusion pharmacies, which dispense compounded drug products and provide professional services to specific patients.

It is important to note that during the lengthy Congressional consideration of legislation this year that ultimately became the Drug Quality and Safety Act of 2013, Congress clearly sought to avoid disrupting the traditional practices of home infusion pharmacies The early drafts of both the House and Senate bills contained provisions to ensure that certain practices common to home infusion pharmacies would be exempted from federal regulation. Furthermore, the Senate HELP Committee's Manager's Amendment specifically exempted home infusion pharmacies from the elements of federal regulation that would have been problematic for infusion pharmacies. Nothing in the Drug Quality and Safety Act is inconsistent with Congress' intent on infusion pharmacy issues. An MOU that echoes the provisions of the draft MOU from 1999 would very much disrupt infusion pharmacy practices and would be contrary to Congress' clear intent in 2013. The FDA should consider a similar exemption for infusion pharmacies in its MOU.

MOU Implementation

The FDA noted in the guidance that it does not intend to enforce the 5% limit on interstate distribution until 90 days after the FDA has finalized the MOU and made it available to the States for their consideration and signature. NHIA has concerns with this limited window for States to consider and negotiate with the FDA on provisions within their MOU. Each State may have specific needs that differ from other States, and the FDA should be prepared to be flexible and work with states to resolve State specific matters.

States and their Boards of Pharmacy all have different oversight structures, and in some cases States may be required by their own sunshine laws to take longer than 90 days to sign the MOU. Also, it is quite possible that some Boards of Pharmacy may lack the authority to sign the MOU. This issue was apparent during the comment period on the 1998 MOU. The Alaska Board of Pharmacy commented that "the board has determined that they do not have the authority to comply with the Memorandum of Understanding as presently written." Several other States submitted their own draft memorandums for consideration with the FDA. The FDA should be responsive to the needs of the States and should reconsider a hard 90 day enforcement timeline for the 5% limit on interstate distribution.

We look forward to working with the FDA and NABP in a collaborative way to ensure the MOU is drafted to encourage coordination between state boards and FDA. Please feel free to have your staff contact Kendall Van Pool, NHIA Vice President of Legislative Affairs, at (703) 838-2664 or kendallvanpool@nhia.org should you want to discuss our comments further. Thank you for your consideration of this NHIA's comments.

Sincerely,

Russell Bodoff
President & CEO
National Home Infusion Association

CC: The National Association of Boards of Pharmacy