National Home Infusion Association

May 3, 2013

The Honorable Tom Harkin
Chair
US Senate Committee on Health, Education, Labor, and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Lamar Alexander
Ranking Member
US Senate Committee on Health, Education, Labor, and Pensions
428 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Harkin and Ranking Member Alexander:

On behalf of thousands of dedicated home infusion therapy pharmacists and nurses, as well as over a million patients that they serve each year, the National Home Infusion Association (NHIA) appreciates the opportunity to comment on your draft framework for Food and Drug Administration (FDA) oversight of certain types of drug compounding. NHIA commends your efforts to help ensure that the nation's drug supply is safe and can be trusted by patients nationwide.

NHIA believes that, while federal and state authority already exists over drug compounding, efforts should be made to strengthen the current regulatory structure. NHIA specifically believes that any additional oversight should be limited to drugs that are compounded in a manner that is defined in the United States Pharmacopeia (USP) General Chapter <797> as high-risk sterile preparations. Legislation and federal regulation should also be consistent with USP in terms and definitions and their application.

Any new regulation should strengthen current regulatory oversight, but not impose an undue cost and/or administrative burden to home infusion providers. In order to ensure patient safety in all sites of care, NHIA believes that any new regulation should extend to all entities that compound drugs.

NHIA has reviewed the draft legislation that the Committee distributed and has provided our comments in the attachment. NHIA has grave concerns that the legislation as proposed will define virtually all home infusion providers as "compounding manufacturers" because the definition includes entities that repackage a drug using sterile preservative-free single-dose vials or pool sterile drugs. As part of the preparation of many compounded drugs, including Total Parenteral Nutrition (TPN), sterile drugs are repackaged by pooling. Should the current provision stand as written, home infusion providers would lose their status as pharmacies and would not be able to provide the critical services they have provided for several decades. NHIA is looking forward to working with the Committee to ensure the legislative

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framework that has been proposed works and provides for a safe and cost-effective drug supply, while not eliminating or unduly hindering the practice of home infusion pharmacy.

NHIA also believes the legislative text needs to be very specific in nature when defining what activities a traditional compounder can and cannot do. Given the possible loss of an entity's pharmacy license and the ability to dispense and bill for patient-specific products and services, the stakes are high for traditional compounders under the proposed legislation, so there should be little room for interpretation that may lead to the loss of license when a pharmacy was acting in good faith.

Please feel free to have your staff contact Kendall Van Pool, NHIA Vice President of Legislative Affairs, at (703) 838-2664, (703) 725-2353 or kendallvanpool@nhia.org should you want to discuss our comments further.

Sincerely,

Russell Bodoff
President and CEO

NHIA, based in Alexandria, VA, represents and advances the interests of organizations that provide infusion and specialty pharmacy products and services to the entire spectrum of home-based patients. It is the leading voice in representing the interests of older and disabled Medicare patients denied home infusion coverage. For more information, visit: **www.nhia.org**

NHIA Comments to Senate HELP Committee Compounding Legislative Draft

Section 503A: Drug Compounding

(a) Definitions

NHIA has serious concerns with the definition of "compounding manufacturer," particularly the provisions in the draft Sec. 503A (a)(2)(A)(ii) that would include within the definition of a compounding manufacturer those entities that repackage a drug using sterile preservative-free single-dose vials or which pool sterile drugs. Pooling—in the context of patient specific prescriptions only—involves preparing a patient-specific single source container with multiple sterile ingredients, which is then used to add a specific volume to each of the patient-specific final compounded sterile preparation (CSP) containers. Pooling as a CSP technique is frequently used in home infusion pharmacies in the preparation of parenteral nutrition solutions when multiple doses (bags) are needed for a specific patient's dispense (typically 7 bags). This technique minimizes the number of individual additive manipulations, which further minimizes any potential breaches in sterile technique and supports accuracy of measurement by reducing the repetitive and different additives made into multiple final bags. The pooling is done as part of the continuous process of producing each patient's specific CSP prescription. Importantly, "pool bags" are not made up in advance nor stored for extended times or for multiple patients.

If Sec. 503A (a)(2)(A)(ii) is enacted into law as written, it will take traditional compounders out of the business of providing Parenteral Nutrition (PN), which they have been providing safely and effectively for over 40 years. Additionally, patient-specific CSPs that are commonly produced from multiple individual sterile preservative-free single-dose vials, such as deferoxamine therapy administered to patients suffering from sickle-cell anemia, would be prohibited. NHIA recommends that Sec. 503A (a)(2)(A)(ii) be stricken from the bill. We believe the definition of compounding manufacturer as stated in the draft Sec. 503A(a)(2)(A)(i) is sufficient to capture the range of activities that have led to the drafting of this legislation.

NHIA believes that Sec. 503A (a)(2)(A)(i) should only apply to high-risk sterile compounding as defined by USP <797>. This would ensure that sterile compounding that uses non-sterile products is the focus of the legislation rather than low-risk and medium-risk sterile preparations.

NHIA commends and supports the allowance for limited advanced compounding as outlined in the draft Sec. 503A (a)(3)(A)(ii)(II). NHIA is encouraged by the inclusion of this provision as traditional compounding pharmacies may encounter situations in which it is prudent to prepare products in advance when a need has been identified. However, NHIA requests clarification of what constitutes "a history" under this provision to ensure that a practitioner is not discouraged from appropriately compounding drugs so as to remain a traditional compounding pharmacy. NHIA also recommends that

the legislation should allow for compounding on the anticipation of a need communicated through a discharge planner, perhaps as follows after line 2 on page 5 of the draft bill:

> (III) compounds a drug in limited quantities before the receipt of a prescription order for an identified individual patient if such compounding is based on information received from a discharge planner that such drug will be required by a patient anticipating discharge from a hospital or other inpatient setting.

In many cases, home infusion providers begin to compound a product in anticipation of need, based on historical referral patterns for the particular patient or due to the particular diagnosis. This advance compounding is performed to facilitate timely initiation of infusion therapy, often involving the transition of patients between the hospital site of care, and the home where the prescribed infusion therapy will be administered. Medications compounded in advance are not dispensed until the patient-specific prescription is received.

NHIA believes that the new Sec. 503A (a)(3)(B) of the bill that addresses the health-system exemption should be expanded to allow non-hospital health systems, including pharmacies that are within a group of pharmacies owned and operated by the same legal entity, to ship drugs for dispensing purposes within the system. NHIA recommends the following legislative text to achieve this goal:

> (B) EXCEPTION - A pharmacy within a health system (as defined in section 506F) or a pharmacy within a group of pharmacies that are owned and operated by the same legal entity and that share access to databases with drug order information for their patients shall be considered a traditional compounder if such pharmacy compounds a drug and ships such drug for dispensing within such system or group of pharmacies and otherwise meets the definition under subparagraph (A).

(b) Exemptions From Certain New Drug Requirements

Sec. 503A (b)(2) would provide that a compounding manufacturer cannot be licensed as a pharmacy in any state. This extreme limitation on the practice of pharmacy would have dire consequences for traditional compounders who may inadvertently cross the line into compounding manufacturing (e.g., those who repackage a drug using sterile preservative-free single-dose vials or by pooling sterile drugs)—a line we believe has been inappropriately drawn, as described above. Traditional compounders provide a vital service in the provision of admixed and compounded infusion therapies for home-based patients. Without a pharmacy license, home infusion providers could not obtain the accreditation necessary to dispense and bill Medicare, Medicaid or commercial insurers for infusion services provided directly to patients in their home. NHIA has no specific edits to Sec. 503A (b)(2), but we call attention to the extreme consequences that this particular section would have for the majority of home infusion providers should the criteria delineating compounding manufacturers in Sec. 503A(a)(2)(ii) remain as currently written.

(c)Drugs That May Not Be Compounded

While developing a list of drugs that may not be compounded makes senses conceptually to ensure a safe drug supply, NHIA has concerns that the provisions included in this section provide literally unlimited authority to the Secretary with insufficient guidance and direction. The process of designating a product as a drug that cannot be compounded should be open and transparent, consultative in nature, and inclusive of all relevant stakeholders. In addition, the process should be based on statutorily defined criteria that includes records of safety in traditional compounding.

Draft Sec 503A (c)(3)(C)(i)(I) appropriately limits a traditional compounding pharmacy from producing a copy of a marketed drug, while providing exemptions in which such compounding is justifiable. However, NHIA believes the exemption for producing a copy of marketed drug in the case of human drug on the drug shortage list under section 506E is not consistent with the reality of drug shortages as experienced by home infusion providers. In many cases drug shortages emerge for individual pharmacies before they are formally recognized by the FDA. There have been instances in which home infusion providers have had to compound a product because it was unavailable, yet the shortage was resolved before it could be formally recognized on the FDA list. There have also been times when a marketed drug product is listed on the ASHP drug shortage website, but never appears on the FDA Shortage List. NHIA believes the language exempting compounding a copy of a marketed drug should allow for these drug shortage realities, in order for home infusion providers to ensure there is no interruption in patient care.

(d)Bulk Ingredient Qualifications and Restriction on Wholesaling

Similar to section (c) above, NHIA has concerns that the provisions included in this section provide overly broad authority to the Secretary with insufficient guidance and limits. The process of designating a bulk substance to the list of bulk substances that cannot be compounded should be open and transparent, consultative in nature, and inclusive of all relevant stakeholders. In addition, the process should be based on statutorily defined criteria that reflect, at minimum, a pharmacy's record of safety in traditional compounding. The Committee should consider adding this process as part of the legislation to ensure there is adequate oversight of the Secretaries discretion in this section.