National Home Infusion Association
Providing solutions for the infusion therapy community

July 15, 2016

Ms. Leslie Kux
Associate Commissioner for Policy
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry (FDA-2016-D-0269)

Dear Ms. Kux:

The National Home Infusion Association (NHIA) submits these comments in response to the Draft Guidance for Industry announced in the Federal Register on April 18, 2016 entitled "Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act" (hereinafter referred to as "Draft Guidance).

NHIA continues to be concerned that the Food and Drug Administration's (FDA) policies regarding pharmacy drug compounding do not reflect the important distinction between the "dispensing" and "distributing" of drugs. This is a point of particular relevance to home infusion therapy providers, and one we made last year in our comments on the February 19, 2015 notice entitled "Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the States and the Food and Drug Administration; New Proposed Draft; Availability." This is not merely a semantic issue. Blurring those terms will result in traditional pharmacy compounders being subjected to rules and guidances that have been drafted, and intended, for facilities that engage in 503B-type activities. Such a result will unduly burden traditional pharmacy compounders and create a confusing web of contradictory rules between the FDA and the State regulatory authorities. As explained below, state definitions of pharmacy practice are tied to the term "dispensing". Deviating from the established meaning likely would have major adverse impacts on how pharmacy practice is defined today.

These comments illustrate that Congress, the FDA in other contexts, other federal agencies within the Department of Health and Human Services as well as the states recognize the meaningful difference between the definitions of "dispense" and "distribute." Specifically, it is widely accepted that the term "distribute" is used in connection with non-patient-specific drugs, while the term "dispense" refers to the delivery of a drug product upon a valid prescription. We believe that the FDA should be mindful of these broadly recognized, distinct definitions, and should ensure that its rules, guidances and the future Memorandum of Understanding use the terms consistent with these common definitions.

Congress clearly intended for "dispense" and "distribute" to have different meanings.

Congress has used the terms "dispense" and "distribute" in different subsections of Section 503A(b)(3) of the Federal Food, Drug and Cosmetic Act (FDCA). Section 503A(b)(3) provides that:

> *A drug product may be compounded under subsection (a) only if—...*
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> *(B) such drug product is compounded in a State—*
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> *(i)that has entered into a memorandum of understanding with the Secretary which 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; or*
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> *(ii)that has not entered into the memorandum of understanding described in clause (i) and 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. (Emphasis Added)*

Since Congress used both "distribute" and "dispense" in Section 503A(b)(3), it clearly intended that these terms are not synonymous or interchangeable.

The terms "dispense" or "distribute" are frequently used throughout the FDCA, even though the Act does not explicitly define the terms. Congress established clearly different definitions for "dispense" and "distribute" in a related context, which is indicative of Congress' intent for these terms to be distinct. Section 21 U.S.C. 802 defines the term "dispense" to mean "to deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term 'dispenser' means a practitioner who so delivers a controlled substance to an ultimate user or research subject."[1] In contrast, section 802 defines "distribute" to mean "to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term 'distributor' means a person who so delivers a controlled substance or a listed chemical."[2] Thus, Congress intended for the term "dispense" to refer to drugs administered to an individual patient, in contrast to the term "distribute," which is intended to refer to non-patient specific drugs.

FDA has adopted different definitions for "dispense" and "distribute."

The FDA has adopted definitions for "dispense" and "distribute" that are consistent with the definitions set forth by Congress in 21 U.S.C. 802. The FDA's definitions are currently codified in section 21 C.F.R. 208.3:

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[1] 21 U.S.C. 802(10).
[2] 21 U.S.C. 802(11).

(a) Authorized dispenser means an individual licensed, registered, or otherwise permitted by the jurisdiction in which the individual practices to provide drug products prescription in the course of professional practice.

(b)Dispense to patients means the act of delivering a prescription drug product to a patient or an agent of the patient either:

(1) By a licensed practitioner or an agent of a licensed practitioner, either directly or indirectly, for self-administration by the patient, or the patient's agent, or outside the licensed practitioner's direct supervision; or

(2) By an authorized dispenser or an agent of an authorized dispenser under a lawful prescription of a licensed practitioner.

(c)Distribute means the act of delivering, other than by dispensing, a drug product to any person.

(d) Distributor means a person who distributes a drug product.

Thus, both the United States Code and the FDA's own regulations explicitly provide that the term distribute does not include dispensing a drug. In fact, they make clear that the distribution of drugs does not include drugs that are dispensed. Both Congress and the FDA have limited the term "dispense" to the furnishing of a drug to a particular patient upon a prescription.

Other agencies within the Department of Health and Human Services recognize these same distinctions between the terms "dispense" and "distribute."

In addition to the FDA, other federal agencies recognize that "dispensing" a drug is a professional service performed for a particular patient, whereas "distributing" a drug relates to non-patient specific activities. For example, the Centers for Medicare & Medicaid Services' (CMS') Medicaid regulations establishing the reimbursement mechanism for covered outpatient drugs include a payment for a "professional dispensing fee." The regulations define "professional dispensing fee" as: "the professional fee which:

(1) Is incurred at the point of sale or service and pays for costs in excess of the ingredient cost of a covered outpatient drug each time a covered outpatient drug is dispensed;

(2) Includes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary. Pharmacy costs include, but are not limited to, reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing drug utilization review and preferred drug list review activities, measurement or mixing of the covered outpatient drug, filling the container, beneficiary counseling, physically providing the completed prescription to the Medicaid beneficiary, delivery, special packaging, and overhead associated with maintaining the facility and equipment necessary to operate the pharmacy; and

(3) Does not include administrative costs incurred by the State in the operation of the covered outpatient drug benefit including systems costs for interfacing with pharmacies.[3]

CMS issued a memo on February 11, 2016 to State Medicaid Directors regarding the implementation of this regulation in which it explained that the term "professional dispensing fee" is "designed to reinforce our position that the dispensing fee should reflect the pharmacist's professional services and costs to dispense a drug to a Medicaid beneficiary.... [S]tates need to ensure that pharmacy providers are reimbursed adequately for their professional services.... Pharmacy provider reimbursement rates should be consistent with efficiency, economy, and quality of care while assuring sufficient beneficiary access...."[4] Thus, similar to Congress and the FDA, CMS clearly contemplates that "dispensing" a drug is a professional service furnished to individual patients.

The definition of "professional dispensing fee" can be contrasted with CMS' definition for "bona fide service fee," which is set forth in the same regulation. "Bona fide service fee" is defined as:

"a fee paid by a manufacturer to an entity that represents fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that is not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug. The fee includes, but is not limited to, distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs).[5]

Thus, CMS recognizes that the distribution of a drug is not in connection with a particular patient, but rather is an action by or on behalf of a manufacturer.

States define "dispensing" a drug as an action related to administering a prescription drug to an individual patient, and differentiate the term from "distributing" a drug, which refers to non-patient-specific drugs.

Similar to the federal government, many states differentiate the terms "dispense" and "distribute." For instance, the definitions section of the Texas Pharmacy Act defines "dispense" to mean, "to prepare, package, compound, or label, in the course of professional practice, a prescription drug or device for delivery to an ultimate user or the user's agent under a practitioner's lawful order." It defines "distribute" to mean "to deliver a prescription drug or device other than by administering or dispensing."[6]

As another example, the definitions section of the Massachusetts Controlled Substances Act defines "dispense" as "to deliver a controlled substance to an ultimate user or research subject or to the agent

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[3] See 42 CFR 447.502.

[4] CMS Letter to State Medicaid Directors, SHO #16-001, RE: Implementation of the Covered Outpatient Drug Final Regulation Provisions Regarding Reimbursement for Covered Outpatient Drugs in the Medicaid Program, February 11, 2016, *available at* https://www.medicaid.gov/federal-policy-guidance/downloads/smd16001.pdf.

[5] See 42 CFR 447.502 (emphasis added).

[6] TEX. OCC CODE ANN. §551.003.

of an ultimate user or research subject by a practitioner or pursuant to the order of a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary for such delivery."[7] Similarly, the definitions section of the Massachusetts Board of Pharmacy regulations define "dispensing" to mean "the physical act of delivering a drug, chemical, device or combination thereof to an ultimate user pursuant to the lawful order of a practitioner, as defined in M.G.L. c. 94C, § 1, including the utilization of the professional judgment of the pharmacist and the packaging, labeling, or compounding necessary to prepare the drug, chemical, or device for delivery."[8] These definitions can be contrasted with the Massachusetts Controlled Substances Act's definition of "distribute," which means to "deliver other than by administering or dispensing a controlled substance."[9]

FDA's Draft Guidance should be revised to use the terms "dispense" and "distribute" consistent with their generally accepted definitions.

Despite these commonly recognized clear differences, FDA's Draft Guidance (FDA -2016-D-0269) obscures the terms "dispense" and "distribute." Section III.A. of the Draft Guidance describes FDA's policy regarding the receipt of a valid prescription order or a notation approved by the prescriber under Section 503A, and provides that "if the identity of the patient who will receive the drug is not clear from the prescription, the compounder should contact the prescriber for clarification and must not distribute the drug unless the identity of the patient is clarified." However, in accordance with the statutory and regulatory definitions noted above, the drugs would be dispensed under a prescription, not distributed.

Likewise, FDA's draft policy on when a drug can be compounded before receipt of a valid prescription (section III.B.2) erroneously refers to distributing rather than dispensing drugs. The policy provides that a compounder can conduct anticipatory compounding under section 503A if it is done in limited quantities, which is satisfied if:

- The compounder holds for distribution no more than a 30-day supply of a particular compounded drug product (i.e., units of a compounded drug product that the compounder believes it will distribute over a 30-day period) to fill valid prescriptions it has not yet received; and
- The amount of the supply is based on the number of valid prescriptions that the compounder has received for identified patients in a 30-day period over the past year that the compounder selected.

FDA defines "for distribution" to mean a "drug product that is available for immediate distribution and does not include drug product that is being held pending receipt of the results of release testing such as sterility." Since FDA acknowledges that the compounder will use the drugs to fill valid prescriptions, the compounder will be holding the drugs "for dispensing" – not "for distribution" - and will "dispense" the drugs – not distribute the drugs - in accordance with the statutory and regulatory definition. In fact, in this same subsection, FDA provides an example to illustrate its policy on anticipatory compounding under section 503A in which it correctly refers to a physician holding and dispensing or administering a compounded drug to patients.

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[7] MASS. GEN LAWS ch.94C, § 1.
[8] Mass. Regs. Code tit 247, § 2.00.
[9] MASS. GEN LAWS ch.94C, § 1.

Subsection III.C. is entitled "When a Compounded Drug Product Can Be Distributed Under Section 503A," but describes that "for each drug compounded under section 503A, the compounder must obtain a patient-specific prescription order." Thus, we believe that the title should be revised to "When a Compounded Drug Product Can Be Dispensed Under Section 503A," to be consistent with the terminology used in the statute and FDA's regulations.

In contrast, subsection III.D. addresses compounded drug products that are kept in stock by hospitals, clinics or health care practitioners, and correctly indicates that outsourcing facilities may engage in the distribution of these non-patient-specific drugs without obtaining prescriptions for identified patients. FDA correctly indicates in a footnote that "an outsourcing facility cannot dispense a prescription drug to a patient without a prescription."

NHIA believes that the FDA's Draft Guidance should be consistent with Congressional intent as well as the Agency's related regulations by consistently using the term "distribute" when referring to non-patient-specific compounded drugs and the term "dispense" when referring to the delivery of a drug product upon a valid prescription. Neither Congress nor the FDA previously intended for the terms to be used synonymously. We are concerned that FDA's inconsistent and erroneous use of the term "distribute" in the Draft Guidance may have unintended consequences that extend beyond the scope of the guidance.

Please feel free to contact me at (703) 838-2664 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