July 20, 2015

Stephen Ostroff, MD, Acting Commissioner
Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-N-1459: Draft Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products Between the State of [Insert State] and the U.S. Food and Drug Administration

Dear Dr. Ostroff:

Innovatix appreciates the opportunity to comment on the U.S. Food and Drug Administration (FDA) draft memorandum of understanding (MOU) that addresses certain distributions of compounded human drug products. Innovatix is one of the nation's largest non-acute care group purchasing organizations, with a national membership of over 23,000 non-acute care providers, including approximately 2,900 infusion providers. Prior to submitting these comments, Innovatix held an Advisory Group meeting with its members, composed primarily of infusion and long-term care providers, and has participated in several stakeholder meetings to better understand the implications of this draft guidance.

While Innovatix applauds the agency's efforts to bring increased scrutiny to those pharmacies crossing the line from compounding to manufacturing, we understand that some of the language in the proposal will negatively affect the ability of our members to serve patients with specific needs across state lines. Specifically, the MOU inappropriately treats "dispensing" and "distribution" as interchangeable terms and asserts that if 30% or more of a pharmacy's compounded drugs are distributed across state lines, the FDA will consider the distribution an "inordinate amount." Ultimately, Innovatix recommends that the FDA

- clearly define the terms dispensing and distribution, and keep them completely separate as maintained by federal precedent; and
- eliminate the arbitrary 30% benchmark as it applies to interstate distribution of compounded drug products. If the FDA insists on providing a subjective cap, then the term "unit" should be clearly defined and easily calculated so that it is understood by all affected entities (as drafted, it is unclear if 30% applies to all prescriptions or a single day's supply).

Below, we provide detail on why each of these recommendations is crucial to the ability of our members to provide excellent patient care, and to avoid quality and access issues.

Dispense and distribute should remain two separate terms

When Congress added Section 503A to the Food, Drug & Cosmetic Act in 1997, policymakers intended the words distribute and dispense to be distinct and separate.[1] This section requires states to enter into an MOU with the FDA to address the distribution of inordinate amounts of compounded drug products. In the appendix to the MOU, the definition of distribution inappropriately includes the act of dispensing to a patient's agent or to a patient for the patient's own use. By interchanging the words dispense and distribute, such a policy blatantly exceeds the scope of congressional intent. The MOU requirement in Section 503A was intended to prevent traditional compounders from entering into the practice of mass manufacturing, but the terms dispense and distribute need to remain separate in order to make this distinction. Dispensing should continue to apply to pharmacies that compound patient-specific infusion drugs, and distribute should apply to entities that manufacture drug products.

The ability of pharmacies to provide home infusion therapy would be hampered by the FDA's proposed definitions. Infusion pharmacies compound patient-specific medications for patients whose medical conditions cannot be treated with oral medications. Not only is home infusion therapy more cost-effective than inpatient treatment in a hospital or skilled nursing facility, but it can allow a patient to resume a normal lifestyle and work activities while recovering from their illness, and in doing so, provide a patient with the opportunity for a better quality of life. By including dispensing in the definition of distribute, the MOU would potentially interfere with the ability of infusion pharmacies to dispense medically needed drugs to patients across state lines. It is not uncommon for the catchment areas of home infusion providers to include patients in neighboring states, due simply to their proximity. Depending on location, it may actually be faster for a provider located in a neighboring state to serve a patient than for a provider in the same state (but perhaps at a greater distance) to send the medication. Furthermore, though this distinction is not explicitly made in the MOU, its underlying purpose is understood: dispensing is the professional service provided by a

[1] Section 503A provides that a drug product may be compounded in compliance with this section only if the drug product is compounded in a State that has: (i) 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 (ii) 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.

pharmacist pursuant to a prescription, with the end-user being the patient. Dispensing is not an element of mass manufacturing nor should it be considered distribution of a drug.

The FDA Should Not Apply Inordinate Amount Limits

The draft MOU proposes that an entity has distributed (and dispensed) an inordinate amount of compounded drugs if the number of units distributed interstate is equal to or greater than 30% of the total number of compounded and non-compounded drug products distributed or dispensed during a calendar month. Since the FDA does not explain why or how 30% is now deemed the appropriate threshold amount nor does it appear to tie to quality concerns, such a policy appears arbitrary and capricious. If a pharmacy meets the strict regulations of its state board of pharmacy and the FDA, the reason why it could distribute 30% of the number of units compounded by that entity in a given month as opposed to 32%, for example, is not clear. Therefore, no cap should be mandated in the final MOU. Implementing a set cap of any size on interstate compounded drug shipments may prevent some patients from obtaining the specific or specialized medicines that they need, which would create troubling access issues for beneficiaries. Furthermore, the FDA does not include the definition of a unit in the MOU, which makes the policy and the full extent of its impact even more unclear for stakeholders.

We urge the FDA to continue to recognize the differences between compounding and manufacturing practices when using the terms distribute and dispense in the final MOU; distribution is reflective of a manufacturing or factory shipping process whereas dispensing is the professional service provided by a pharmacist, performed by a pharmacy pursuant to a patient prescription. The FDA should also remove the 30% cap, since this limit could harm patient access to certain necessary medications, and the proposed cap does not tie to the quality of drug products themselves.

Thank you in advance for considering our concerns. We hope that you will review our recommendations, which were shaped with the input of our infusion and long-term care providers who understand how harmful the proposed language may be for patient care.

Sincerely,

John P. Sganga, FACHE
Executive Vice President, GNYHA Ventures
President & CEO, Innovatix
President & CEO, Essensa