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July 1, 2015

Stephen Ostroff, M.D.
Acting Commissioner of Food and Drugs
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: Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products between the States and the Food and Drug Administration; Extension of Comment Period.

Dear Dr. Ostroff:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, and our 43,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the draft memorandum of understanding (MOU) addressing certain distributions of compounded drug products between the states and the Food and Drug Administration (FDA). **The AHA urges the FDA to clarify how it defines “distribution” and how it will determine whether “inordinate” amounts of compounded drug products have been distributed interstate. Doing so will help to ensure the continued safety and availability of compounded medications prepared in-house by hospital and health care system pharmacies for the treatment of patients.**

The ability to continue to repackage drugs and mix, dilute and repackage biologicals and to deliver these products in a safe and timely manner to patient care sites is a fundamental part of pharmacy practice in hospitals and health care systems. Among other things, hospitals and health systems repackage drugs and biological products to meet the needs of pediatric patients requiring smaller doses of approved sterile drug products that may not be available commercially. Their use also reduces the risk of medication errors that are associated with drawing up a dose from a vial at the point of patient care.

Section 503A of the Federal Food, Drug, and Cosmetic (FD&C) Act describes the conditions that must be satisfied by pharmacies that prepare compounded drug products in order to be exempted from certain requirements of the act that apply to drug manufacturers, such as requirements for labeling, premarket approval and good manufacturing practices. The FDA proposes to use the MOU as a template for determining exemption.



One of the conditions to qualify for this exemption is that the drug product must be compounded in a state that has entered into an MOU with the FDA. Such an MOU must address the distribution of “inordinate” amounts of compounded drug products interstate and provide for appropriate investigation by the state of complaints relating to these compounded drug products. The draft MOU proposes that a pharmacy would be deemed to have distributed an “inordinate” amount of compounded drugs interstate if the number of units of compounded drugs it distributes interstate during any calendar month is greater than or equal to 30 percent of the number of units of compounded and non-compounded drugs distributed both intrastate and interstate during that month. Thus, a pharmacy which meets or exceeds this 30 percent “inordinate amount” threshold would be out of compliance with Section 503A and, therefore, not exempt from certain FD&C Act requirements that apply to manufacturers.

Definition of “distributed.” **The AHA believes that a pharmacy within a health care system should not be considered to have “distributed” compounded drugs interstate if the pharmacy is merely moving drugs between facilities that are part of the same health care system, even if the movement occurs between facilities located across state lines.** Many health care systems have facilities that are geographically close but located across state borders. The movement of compounded drugs between the facilities of such a health care system is analogous to moving them from the pharmacy on one floor to a patient care area to another floor in the same building, or to a clinic on the same campus. Health care system pharmacies and clinical services operate under system-wide policies and procedures, and utilize common data systems intended to ensure high-quality and safe patient care. This oversight ensures that compounded drug products are appropriately and safely prepared, transferred and dispensed according to an overall plan of care for the benefit of the health care system’s patients. This activity should not be equated with the commercial transactions that occur when independent pharmacies distribute compounded drug products interstate to unaffiliated health care providers.

If the FDA is not willing to define “distribution” so as to exclude the movement of compounded products between health care system facilities, we recommend that the agency instead reinstate its previous exception, contained in the 1999 draft MOU. This exception excludes from the calculation of “inordinate” amounts any compounded drug products that are distributed interstate, but within 50 miles of the pharmacy or physician’s office. The application of such an exception would preserve the ability of health care systems to routinely and safely move compounded drug products from a centralized pharmacy to system facilities and clinics that are located across state borders.

Calculation of “inordinate” amounts. As noted, the FDA proposes that a pharmacy would be deemed to have distributed an “inordinate” amount of compounded drugs interstate if the number of units of compounded drugs it distributes interstate in a month is greater than or equal to 30 percent of the number of units of compounded and non-compounded drugs distributed both intrastate and interstate during that month. However, neither the draft MOU nor the discussion in the *Federal Register* notice announcing the draft MOU discuss how repackaged drugs and mixed, diluted or repackaged biologicals would be treated in this calculation. **The AHA urges the FDA to clarify that the number of units of repackaged drug products and mixed, diluted or repackaged biologicals shipped across state lines by a pharmacy should not be included in the numerator of its proposed calculation of whether the pharmacy has**

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exceeded the “inordinate amounts” threshold. However, they should be included in the denominator of the calculation as non-compounded drugs.

The FDA does not consider these repackaged drug and biological products to be compounded products covered under Section 503A of the FD&C. The FDA’s own definitions make it clear that repackaging of drugs is not the same as compounding. For instance, in “Compounding and the FDA: Questions and Answers,” the agency defines compounding as “a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.” By contrast, in draft guidance, the FDA defines repackaging as “the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug.” Further, in other agency documents, including the two draft guidance documents on repackaging of drug products and on the mixing, diluting or repackaging of biological products, the FDA indicates that these products fall outside the scope of section 503A of the FD&C Act. Specifically the FDA states, “Drugs that are repackaged are not subject to sections 503A and 503B of the FD&C Act” and “sections 503A and 503B of the FD&C Act do not provide exemptions for mixing, diluting, or repackaging of biological products.”

Thank you again for the opportunity to comment. If you have any questions, please contact me or Roslyne Schulman, director of policy development, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

/s/

Linda E. Fishman
Senior Vice President
Public Policy Analysis and Development