



Academy of
Managed Care
Pharmacy®

February 3, 2014

The Honorable Margaret Hamburg, MD
Administrator
Food and Drug Administration
Department of Health and Human Services
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville MD, 20852

Re: FDA-2013-D-1429; Draft Guidance; *Pharmacy Compounding of Human Drug Products under Section 503B of the “Federal Food, Drug, and Cosmetic Act”*

Dear Administrator Hamburg:

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide general comments to the Food and Drug Administration (FDA) regarding its guidance document: *Pharmacy Compounding of Human Drug Products under Section 503B of the “Federal Food, Drug, and Cosmetic Act”* (FDCA). AMCP is a national professional association of pharmacists with nearly 7,000 members who provide services on behalf of the more than 200 million Americans served by managed care organizations, including health plans and pharmacy benefit management companies. Our members are responsible for managing prescription drug benefits on behalf of clients of the managed care organizations that employ them. They are responsible for implementing a broad and diversified range of clinical, quality-oriented services and strategies whose objective is to assure that individual patients receive the appropriate drug at the right time in a convenient, cost-effective manner.

AMCP recognizes and has been supportive of legislative and regulatory efforts to address the unauthorized manufacturing of drug products. The 2012 fungal meningitis outbreak that occurred because of contaminated injectable products was the direct result of an entity engaging in the unauthorized manufacturing of drug products, not traditional pharmacy compounding. AMCP is sympathetic to the suffering and death of patients and the families affected by this tragedy and AMCP members work in a highly regulated environment in an effort to ensure that patients receive high quality medications that are safe and effective for their conditions. AMCP members are dedicated to ensuring patient safety and access to quality medications that meet patients' needs.

Compounding is a legitimate, long-established practice of the profession of pharmacy where the pharmacist combines drug products and excipient ingredients to produce medications in a form that may be more convenient or in a unique dosage form. Compounded medications, which must be prescribed by authorized medical practitioners and prepared by licensed pharmacists, allow physicians and pharmacists to customize drug therapy to a specific patient's unique needs when that patient is unable to utilize commercially

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available drug products. Compounded medications can range from making dosages more specific and palatable for a small child to combining several medications, such as chemotherapy agents for IVs for hospital patients. Compounding is integral to all aspects of pharmacy practice, including managed care pharmacy. Given the importance of compounding, AMCP's comments focus on recommendations to ensure that patients continue to receive access to safe and effective compounded medications.

When AMCP considers the impetus behind the *Drug Quality and Security Act of 2013* (DQSA) – to protect the public from the unauthorized manufacturing of drugs – these goals were not achieved by the creation of a new category of “outsourcing facility” that may or may not be a pharmacy, may *voluntarily* choose registration, and thus may evade meeting quality standards and investigation by the FDA. A company that is engaging in the unauthorized manufacturing of drugs is not going to volunteer to register with the FDA. Furthermore, FDA has recently noted in a “frequently asked question” that registration as an outsourcing facility means only that FDA has received the required information.

The registration process includes only basic requirements, such as name, address, facility location, and name of contact person – who may or may not be a pharmacist– and does not imply that the facility is compliant with current good manufacturing practices or is engaged in producing FDA-approved drugs.¹ The non-electronic registration requirement permits a contact phone number to be optional; AMCP believes a phone number must be required in the registration process. Further, AMCP opposes FDA registration of outsourcing facilities that are not licensed pharmacies without an identified licensed pharmacist or other state-registered provider supervising all activities. States have specific requirements for registration and standards for compounding practices that apply only to licensed pharmacies that meet the standards. At a minimum, FDA should review state board of pharmacy standards for compounding practices and require that outsourcing facilities provide that information as part of their registration.

FDA's guidance for registration of outsourcing facilities does not provide assurances to the public and would not have likely prevented the tragedies in 2012. According to the preliminary investigation findings (“the Findings”) of the Massachusetts Department of Health's report on the New England Compounding Center (NECC), “manufacturing and distributing sterile products in bulk was not allowed under the terms of its state pharmacy license. If NECC was appropriately licensed as a manufacturer with the FDA the company would have been subject to additional levels of scrutiny.”² The Findings also detailed many instances of failure to follow proper standards of sterilization, validation of equipment and a lack of clean facilities.

AMCP has consistently maintained that the FDA had the authority to address the fungal meningitis outbreak and that additional authority was not necessary. However, when some members of Congress decided that additional authority was necessary, AMCP wanted to be a part of the decision making process to shape the regulatory guidelines. The passage of DQSA created confusion by creating a new, unnecessary outsourcing facility that represents only an administrative registration requirement with no further assurances of safety and efficacy of compounded products. FDA will not physically inspect these facilities prior to granting a registration. There are guidelines calling for inspections years after the facility is registered.

¹ FDA Registered Outsourcing Facilities.

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm378645.htm#Questions>. Accessed January 28, 2014.

² New England Compounding Center (NECC) Preliminary Investigation Findings, Board of Registration in Pharmacy Report, October 23, 2012 (The Commonwealth of Massachusetts, Executive Office of Health and Human Services).

If there is another NECC-like incident and the responsible entity is not a FDA registered outsourcing facility, AMCP believes that FDA will again respond that it lacks authority to take action. Therefore, AMCP believes that the law and FDA guidance does not provide sufficient federal regulatory authority to prevent the unauthorized manufacturing of compounded drugs.

To further complicate the current regulatory scheme, the law states that an outsourcing facility may be a licensed pharmacy. State boards of pharmacy already have existing requirements concerning many of the practices regulated under DQSA and the guidance. DQSA creates a dual regulatory scheme. Some pharmacies will be licensed entities under state law and also registered under federal law. Other non-pharmacy entities may seek registration, but the public is not adequately informed of the company's business practices or pharmacy status. AMCP believes that this regulatory infrastructure will create complications in administration and that issues of responsibility and accountability will undoubtedly continue to occur.

AMCP thanks FDA for the opportunity to comment on this guidance related to the amended provisions of §503B under the FDCA. If you have any questions regarding these comments, please contact me at 703-883-8416 or erosato@amcp.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Edith A. Rosato". The signature is written in a cursive, flowing style.

Edith A. Rosato, R.Ph., IOM
Chief Executive Officer