AMCP 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Re: FDA-2013-D-1444; Draft Guidance; *Pharmacy Compounding of Human Drug Products under Section 503A of the "Federal Food, Drug, and Cosmetic Act"; Withdrawal of Guidance's*

Dear Administrator Hamburg:

The Academy of Managed Care Pharmacy (AMCP) is pleased to provide general comments and recommendations to the Food and Drug Administration (FDA) regarding its guidance document: *Pharmacy Compounding of Human Drug Products under Section 503A 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 condition. 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.

Requirements for Compounded Products (§III.A)

AMCP supports the draft policy provisions identified in §III.A that define the requirements for compounding a medication. AMCP supports the ability of state licensed pharmacies that employ licensed pharmacists or physicians to compound products ordered by a state-licensed prescriber for patient specific use or in limited quantities before receipt of a prescription order when the requirements listed in §III.A.2 have been met. AMCP also supports the requirements listed in §III.A that ensure product integrity and accessibility of compounded products.

Limitations on Compounding Certain Products (§III.B)

AMCP recommends that FDA:

- Carefully select medications defined as having "demonstrable difficulties" for compounding as outlined in §III.B.3 to ensure that patients continue to receive access to high quality medications that are not essentially copies of currently manufactured products and that may be compounded safely by licensed pharmacies or other appropriate practitioners.
- Limit access to compounded products that are not FDA approved or that contain non-FDA approved ingredients, such as vitamin or food supplements. FDA must also provide an organized and timely list of bulk products that have been withdrawn or removed from the market.
- Update the products withdrawn or removed from the market list at least annually.

AMCP will submit separate comments and recommendations for compounding bulk products and those presenting demonstrable difficulties for compounding pursuant to docket FDA–2013–N–1523 issued in the *Federal Register* on December 4, 2013.

Memorandum of Understanding between States and FDA for Certain Interstate Distributions (§III.B.4)

AMCP has several concerns with FDA's proposed guidance on the implementation of the memorandum of understanding (MOU) between FDA and the states for interstate distribution of compounded products for quantities in excess of 5% of total orders distributed or dispensed as described in §III.B.4.

- AMCP seeks FDA assurances that this entire provision apply only to distribution of inordinate amounts of compounded products that are not provided pursuant to a patient-specific prescription or in limited quantities in anticipation of a prescription.
- The regulation of dispensing compounded products should remain in the purview of the states. This interpretation is consistent with the language adopted by §503A of the FDCA which states that the MOU is to consider "the distribution of inordinate amounts of compounded products interstate." Given this statement and the history of pharmacy compounding for dispensing purposes, FDA must not intervene in the legitimate compounding practices by state-licensed pharmacies.

- AMCP also seeks clarity on the timeframe applicable to determining the 5% distribution rule. The guidance does not provide the clarity necessary to ensure proper compliance. AMCP recommends that the timeframe be based on a calendar year.

In regard to the implementation of the provisions of the MOU, AMCP is concerned that without further guidance, states may inadvertently be required to adhere to the 5% distribution rule without being afforded proper time and process to adopt the provisions. To alleviate these concerns, AMCP recommends the following steps prior to full MOU implementation:

- Ensure that the public, including affected states, has appropriate opportunity to comment on the MOU before the 90 day implementation timeframe begins. FDA should not present the MOU to states until after the public has been presented with at least a 60 day period to comment on the draft document. Then, the states may be presented with the MOU for initial review.
- FDA should then allow for states to formally adopt the MOU according to a timeframe necessary and unique to the state. The process might require administrative hearings, notice and comment period, or other state-specific procedures. Given this variability within the states, a strict 90-day timeframe established by the FDA may not be sufficient to allow certain states to complete review processes. Rather, FDA should allow states input on the steps necessary to implement the MOU and then set a 90-day timeframe for adoption.

Guidance on Regulatory Actions by FDA (§IV)

- AMCP recommends that FDA reserve its regulatory authority to actions involving unauthorized manufacturing ***after*** a proper determination that the entity is engaged in activity outside of the state definition of traditional compounding. The determination of whether an activity is outside of traditional compounding pursuant to §503A should be made by the state board of pharmacy, not by FDA.

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

Sincerely,

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