



**American Pharmacists Association**<sup>®</sup>  
Improving medication use. Advancing patient care.

July 18, 2016

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

[Submitted electronically to [www.regulations.gov](http://www.regulations.gov)]

**Re: Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act; Draft Guidance for Industry (Docket ID: FDA-2016-D-0271P)**

Dear Sir/Madam:

APhA is pleased to submit these comments on FDA's draft guidance on Hospital and Health System Compounding under the Federal Food, Drug, and Cosmetic Act (the "Guidance"). Founded in 1852 as the American Pharmaceutical Association, APhA represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings, and the uniformed services.

APhA supports FDA's efforts to ensure drug quality and security as the provision of safe, effective medications, including compounded medications, is of paramount importance to our members. APhA is committed to working with FDA and other stakeholders to make certain that nothing like what occurred at the New England Compounding Center (NECC) happens again. As FDA is aware, compounding is an important part of pharmacy practice because it permits patients with unique medical needs to have access to vital medications when commercially available dosage forms do not exist. While APhA appreciates that the Guidance allows hospitals and health systems some flexibility in distributing compounded drug products prior to a patient-specific prescription,<sup>1</sup> APhA continues to have concerns that FDA's interpretation and

---

<sup>1</sup>Under the Guidance, hospital pharmacies may compound without a patient-specific prescription, as long as they comply with all FD&C Act and FDA regulations, under three conditions:

1. The pharmacy distributes the drugs only to health care facilities that are "owned and controlled" by the entity that owns the hospital pharmacy;
2. The health care facilities are within a 1-mile radius of the pharmacy; and
3. The drugs are used only within the health care facilities (i.e., no discharge prescriptions).

implementation of the Drug, Quality and Security Act (“DQSA”) is negatively impacting patients’ access to necessary compounded medications.

APhA appreciates FDA acknowledging in the Guidance the need for flexibility from the requirement that prior to compounding, there must be a patient-specific prescription. However, we disagree that this accommodation should be restricted to facilities owned and controlled by the same entity that owns and controls that hospital pharmacy. While APhA agrees such flexibility is critical in the hospital setting, many community pharmacies provide these same essential compounded products to hospitals and health systems, have well-established relationships with these facilities, and often encounter situations necessitating the timely compounding of products in advance of a patient-specific prescription.

APhA has also heard from members that limiting this hospital and health system exception to distribution within a 1-mile radius is problematic. Many health systems have specialty care units that, while meeting the common ownership criteria, are not within the 1-mile radius of the health system pharmacy. For example, if a health system’s neonatal intensive care units (NICUs) are not within a 1-mile radius of the health system’s pharmacy, that system’s pharmacy will no longer be able to supply lifesaving IV and umbilical specialty compounded fluids that are urgently needed by neonatologists, nurse practitioners and nurses for these very vulnerable patients because providing a patient-specific prescription prior to compounding is infeasible. Additionally, the arbitrary distance limitation could prevent the most qualified pharmacy/pharmacist from providing these medications. APhA recommends that FDA return to its previous interpretation and enforcement of section 503A(a)(2) of the FD&C Act and allow licensed pharmacists or licensed physicians in all practice settings to compound “limited quantities” in advance of a prescription when there is an existing relationship,<sup>2</sup> as long as it is allowed by state laws and regulations and in compliance with recognized professional standards and guidelines.

In a different draft compounding guidance, FDA states that hospitals, clinics, and health care facilities may rely on 503B facilities to obtain their office use compounded products.<sup>3</sup> While some hospitals and health systems obtain a portion of their products from 503B facilities, 503B facilities cannot supply all their compounding products because compliance with CGMP requirements makes it cost and/or time prohibitive to fulfill all the compounding needs of health care facilities, providers and patients, which is why many 503B facilities have defined formulary lists<sup>4</sup>. CGMP requirements include: procurement of bulk drug product(s) which meets CGMP; authoring procedures to compound the medication which meet CGMP; proper testing (validation, release testing, stability testing) and other requirements<sup>5</sup>. APhA members’ conversations with 503B facilities have confirmed the inability of these facilities to supply many small batch

---

<sup>2</sup> See 21 U.S. Code § 353a - Pharmacy compounding. Available at:  
<https://www.law.cornell.edu/uscode/text/21/353a>

<sup>3</sup> See FDA. Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry, Guidance for Industry. April 2016. Lines 375-377. Available at:  
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf>

<sup>4</sup> See SCA Pharmaceuticals. Product Catalog. 2016; Cantrell Drug Company. Product Catalog. 2016; and Leiter’s Compounding Product Catalog, 2016.

<sup>5</sup> See FDA. Guidance for Industry Current Good Manufacturing Practice — Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act. July 2014. Available at:  
<http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm403496.pdf>

medications commonly associated with office use (e.g., numbing creams/sprays, etc.). Therefore, rather than provide a very narrow exception for some hospitals and health systems, we strongly urge FDA to follow its previous long-standing policy, as well as the intent of Congress, and continue to allow 503A pharmacies to compound limited quantities without a patient-specific prescription and defer to states for statutory or regulatory authority over pharmacies' office use compounding.

APhA looks forward to continuing to work with the FDA and other stakeholders to construct a framework in accordance with current statutory authority and congressional intent that ensures patients have access to safe and effective medications. We hope to be a resource for FDA and are happy to be of assistance in any way possible. Thank you again for the opportunity to provide comments on this important issue. If you have any questions or require additional information, please contact Michael Baxter, Director of Regulatory Affairs, at [mbaxter@aphanet.org](mailto:mbaxter@aphanet.org) or by phone at (202) 429-7538.

Sincerely,



Thomas E. Menighan, BSP Pharm, MBA, ScD (Hon), FAPhA  
Executive Vice President and CEO

cc: Stacie S. Maass, RPh, JD, Senior Vice President, Pharmacy Practice and Government Affairs