



# American Pharmacists Association<sup>®</sup>

Improving medication use. Advancing patient care.

**FDA LISTENING SESSION:  
Hospital Organizations  
June 20, 2017  
9:00AM - 12:00PM**

**Statement of the American Pharmacists Association  
Michael Baxter  
Director, Regulatory Affairs**

Good afternoon, I am Michael Baxter, Director, Regulatory Affairs for the American Pharmacists Association (APhA). APhA, founded in 1852 as the American Pharmaceutical Association, represents 64,000 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, physician offices, ambulatory clinics, managed care organizations, hospice settings, and the uniformed services.

I would like to thank the FDA for holding a listening session to gather stakeholder input on hospital and health system compounding under the federal Food, Drug, and Cosmetic Act (FD&C). As FDA is aware, compounding is an important part of pharmacy practice at hospitals and other sites of care because it permits patients with unique medical needs to have access to vital medications when commercially available dosage forms do not exist. APhA appreciates FDA granting some flexibility to hospitals and health systems, through enforcement discretion, in distributing compounded drug products prior to a patient-specific prescription in the recent *Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act, Guidance for Industry, DRAFT GUIDANCE*<sup>1</sup> (hereinafter, the “Guidance”).<sup>2</sup> However, APhA continues to have concerns that FDA’s interpretation and implementation of the Drug, Quality and Security Act (DQSA) is negatively impacting patients’ access to necessary compounded medications.

Currently, FDA is interpreting section 503A’s “identified individual patient” requirement to equate to a specifically named patient on the prescription or order, which we do not believe was intended by Congress. In addition, FDA’s general prohibition of office use is at odds with congressional intent and its own previous and longstanding interpretation of 503A to allow “limited quantities” of medications to be compounded “before” the receipt of a prescription for an “individual patient.” In section II.B of the Guidance, FDA notes hospitals and health systems have certain characteristics distinguishing them from conventional manufacturers. We agree, and believe the same is true for community-based

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<sup>1</sup> FDA. Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act. Guidance for industry. Draft Guidance. April 2016. Available at:

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496287.pdf>

<sup>2</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).

pharmacies as well. Community pharmacies provide 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 an “identified individual patient” prescription. Based on the language used in section 503A, it is clear Congress used the “identified individual patient” and “limited quantities” to delineate traditional compounding from manufacturing. Therefore, consistent with congressional intent, APhA recommends that FDA allow licensed pharmacists and physicians, regardless of practice settings, to compound “limited quantities” for office use when there is an existing relationship<sup>3</sup> in order to meet patients’ compounding needs.

We would also like to note while the 1-mile flexibility helps negate many scenarios which would hurt patient access to needed compounded medications in hospitals and health systems, APhA heard from members that limiting this hospital and health system exception to distribution within a 1-mile radius is still problematic for health systems. While meeting the common ownership criteria, many health systems have specialty care units outside of 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 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 FDA return to its previous interpretation and enforcement of section 503A(a)(2) of the FD&C Act and allow licensed pharmacists or physicians in all practice settings to compound “limited quantities” in advance of a prescription when there is an existing relationship, as long as it is allowed by state laws and regulations and in compliance with recognized professional standards and guidelines.

In another compounding guidance,<sup>4</sup> FDA offered that hospitals, clinics, and health care facilities can rely on 503B facilities to obtain their office use compounded products. However, while hospitals and health systems can 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 and why many 503B facilities have defined formulary lists.<sup>5</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>6</sup> As stated in the June 5, 2017 listening session for pharmacy organizations, APhA members’ conversations with 503B facilities have confirmed the inability of these facilities to supply many small batch medications commonly associated with office use (e.g., numbing creams/ sprays, etc.). Therefore, rather than provide a narrow exception for some hospitals and health systems, APhA, again strongly urges FDA to follow its previous long-standing policy, as

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<sup>3</sup> See 21 U.S. Code § 353a - Pharmacy compounding. Available at: <https://www.law.cornell.edu/uscode/text/21/353a>

<sup>4</sup> FDA. Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act. December 29, 2016. Final Guidance. Available at:

<https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM496286.pdf>

<sup>5</sup> See SCA Pharmaceuticals. Product Catalog. 2016; Cantrell Drug Company. Product Catalog. 2016; and Leiter’s Compounding Product Catalog, 2016.

<sup>6</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>

well as the clear intent of Congress,<sup>7</sup> to 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 ongoing efforts by 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 compounded medications. We hope to be a resource for FDA and are happy to be of assistance in any way possible.

Thank you.

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<sup>7</sup> See, H. Rept. 114-531 - AGRICULTURE, RURAL DEVELOPMENT, FOOD AND DRUG ADMINISTRATION, AND RELATED AGENCIES APPROPRIATIONS BILL, 2017. Available at: <https://www.congress.gov/congressional-report/114th-congress/house-report/531/1?q=%7B%22search%22%3A%5B%22H.+Rept.+114-531%22%5D%7D&r=1>