

Food and Drug Law Alert

April 20, 2016

If you read one thing...

- FDA interprets the FDCA not to permit compounding for “office use” under Section 503A; compounding pharmacies must receive a valid prescription for an individually identified patient before distributing compounded drugs to a hospital, clinic or other health care facility.
- Hospitals and health care providers would generally be subject to the same limitations in Section 503A as compounding pharmacies, including restrictions on distributing products to other facilities and also on interstate distribution.
- FDA’s draft guidance proposes to refrain from enforcing the prescription requirement against hospital-based pharmacies if the compounded drug is distributed only to facilities under the same ownership and control within a one-mile radius of the pharmacy and administered within the facility pursuant to a patient-specific prescription or order.



FDA Issues Guidance for Hospitals and Health Systems Engaged in Drug Compounding

On Friday, April 15, 2016, the U.S. Food and Drug Administration (FDA) announced the availability of three new Draft Guidance documents relating to drug compounding under Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FDCA). These proposals are particularly relevant to hospitals and health systems operating under these sections of the law, and they would pose potential challenges to health systems using a “central-fill” pharmacy.

The [draft guidance](#) on **Hospital and Health System Compounding under the FDCA** explains how the sections of the FDCA pertaining to drug compounding, Sections 503A and 503B, apply to hospitals and health systems, and should be read in light of other guidance documents implementing the Drug Quality and Security Act (DQSA) of 2013. Under Section 503A of the FDCA, compounding pharmacies are required to obtain a valid prescription order prior to distributing any drug products, among other requirements.

The draft guidance makes clear that pharmacies that are part of a hospital or health system are treated the same under federal law as other compounding pharmacies and are required to comply with the requirements of Section 503A of the FDCA, unless they are registered as outsourcing facilities. However,

FDA proposes to refrain from enforcing the prescription requirement against hospital-based pharmacies if the drug product is **distributed to only facilities under the same ownership and control within a one-mile radius of the pharmacy and administered within the facility pursuant to a patient-specific prescription or order**. The draft explains that this proposal is intended to accommodate centralized drug compounding at a single hospital campus with multiple facilities, but not larger and more geographically diffuse health systems. FDA is concerned that centralizing and distributing compounded drugs across a larger health system is akin to drug manufacturing, but without the necessary standards to assure quality.

According to FDA, hospital pharmacies wishing to distribute compounded drugs outside of a one-mile radius without first receiving a valid prescription order should comply with Section 503B of the FDCA, including registering the facility with FDA, paying applicable fees, and compounding drugs according to Current Good Manufacturing Practices (CGMPs). Alternatively, hospitals may outsource production to FDA-registered outsourcing facilities or obtain compounded drugs based on an individual patient prescription.

On April 15, FDA also issued **draft guidance** on the **Prescription Requirement Under Section 503A** to clarify its views relating to the topic of “office use”—the practice of shipping compounded drugs to hospitals, clinics and physician offices in advance of, or without, obtaining a prescription for an individual patient. This draft guidance confirms that FDA interprets the statutory language of Section 503A as prohibiting the shipment of compounded drugs that are not the subject of a valid prescription order. It further specifies that a prescriber should notate that a patient’s clinical needs cannot be met by an approved drug and recommends the use of a statement: “*Per [type of communication] with [name of prescriber] on [date], [name of prescriber] has advised that compounded [name of drug] is necessary for the treatment of [name of patient].*”

FDA’s proposal does, however, recognize the statutory authority to engage in “anticipatory compounding”—the practice of compounding drugs in advance of receipt of a valid prescription order based on historical needs within an established relationship between a licensed pharmacist and the prescriber. FDA proposes that the statutory limitation restricting anticipatory compounding to “limited quantities” would be interpreted to apply a limit of a 30-day supply based on the history of the relationship. The draft guidance also emphasizes that **under no circumstances are pharmacies that are compounding drugs pursuant to the exceptions under Section 503A permitted to distribute drugs before receiving a prescription**. FDA acknowledges that hospitals and clinics have a valid need for “office stock” of certain compounded medications, but suggests that such products be compounded pursuant to the exceptions under Section 503B, which do not require a prescription.

A third **draft guidance** clarifies the definition of “Facility” under Section 503B. This guidance document explains that FDA will not allow outsourcing facilities to comingle activities governed under Sections 503B and 503A of the FDCA at a single geographic location.

FDA is accepting public comments on all three draft guidance documents until July 18, 2016.

Contact Information

If you have any questions regarding this alert, please contact:

Nathan A. Brown

202.887.4245

nabrown@akingump.com

Washington, D.C.

Eli Z. Tomar

202.887.4209

etomar@akingump.com

Washington, D.C.