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PRESCRIPTION DRUG COMPOUNDING PRACTICES FOR HOSPITALS, PHARMACIES AND OUTSOURCING FACILITIES – NEW FDA DRAFT GUIDANCE RELEASED

On April 15, 2016, the Food and Drug Administration ("FDA") issued three important draft guidance documents that clarify the standards under Sections 503A and 503B of the federal Food Drug & Cosmetic Act ("the Act") applicable to compounding activities carried out by prescription drug compounders. These compounders include hospital pharmacies, non-hospital pharmacies (including retail pharmacies) and facilities known as "outsourcing facilities" that compound drugs but need not be licensed pharmacies. At a high level, the draft guidance serves to: (i) detail that valid prescription orders for compounded drugs must clearly list the individual patient, whether or not required by state law, and clearly indicate that a compounded preparation is required; (ii) recommend a clarification regarding permitted anticipatory compounding to provide that hospital or health system pharmacies may compound and distribute any quantity of compounded drug product to related health care facilities within a one-mile radius of the hospital pharmacy, provided such drugs are only administered to patients within such health care facilities (i.e., no dispensing for self-administration off the premises); (iii) indicate that the FDA intends to further define "limited quantities" for purposes of anticipatory compounding as a 30-day supply of a particular compounded drug based on historical purchases over the past year; and (iv) clarify that outsourcing facilities may not be co-located with non-outsourcing facility pharmacies that perform traditional pharmacy compounding.Although issued in draft form, the guidance offers important insight into the FDA's current thinking on these topics. As a result, we recommend that pharmacies, hospitals, health systems, outsourcing facilities and other interested entities respond to the FDA's request for comments and suggestions on the draft guidance and either request clarifications, offer support or recommend changes. These comments must be submitted within 90 days or before **July 14, 2016**.

BACKGROUND

Compounded drug products are created by taking an FDA-approved drug and changing the dosage, administration method and/or composition by combining the drug with additional substances. For example, compounding could include the alteration of a pill into liquid oral form or creating a specialty intravenous therapy for a cancer patient that includes multiple drug therapies. Compounded drug products do not undergo any premarket review for safety, effectiveness or quality and are therefore not approved by the FDA. Furthermore, unlike FDA-approved drugs, drugs compounded by pharmacies are not subject to the FDA's current good manufacturing practices ("CGMP") requirements. Drugs compounded by outsourcing facilities, while exempt for other important FDA manufacturing requirements, remain subject to CGMP compliance.

ANALYSIS OF DRAFT GUIDANCE

Prescription Requirement for Compounded Drugs Under Section 503A. The Act describes two situations in which a drug may be compounded by a licensed pharmacy or physician: (i) based on the receipt of a valid prescription order for an identified individual patient; or (ii) in limited quantities before the receipt of a valid prescription order for an identified individual patient ("anticipatory compounding"). Under current guidance, in order to comply with the FDA's anticipatory compounding rules, the compounding: (i) must be based on a history of receiving valid prescription orders for the compounding of a particular drug product; and (ii) these orders must be generated solely within an established relationship between either the compounder and the patient or the compounder and the prescriber. These limitations on anticipatory compounding - specifically, that compounding must be pursuant to a "valid prescription order" in "limited quantities" and based on an "established relationship" - have long been wanting for more well-defined standards. The FDA's Section 503A draft guidance therefore provides useful insight into the FDA's interpretation of these standards.First, the FDA stated that a "valid prescription order" for a compounded drug product includes both a valid standalone prescription written by an authorized prescriber and an order or notation written by an authorized prescriber in a patient's chart. To be valid, a prescription or order must clearly document the prescriber's determination that a compounded drug is necessary for the identified patient. If it is unclear whether the order is for a compounded drug product, the FDA recommends that the pharmacist consult with the prescriber to clarify and then make an appropriate notation on the prescription order. Additionally, to be valid, a prescription for a compounded drug must clearly identify the patient for whom the drug has been prescribed. If the patient's identity is not clear from the prescription, whether or not permissible under state law, the compounding pharmacy should not compound the drug until the patient's identity is verified by the prescriber.Second, the FDA clarified the definition of "limited quantities" for purposes of anticipatory compounding requirements. Under the draft guidance, the FDA will consider a compounder to have met the "limited

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quantities" standard if: (i) the compounder holds for immediate distribution no more than a 30-day supply of a particular compounded drug product to fill valid prescriptions it has not yet received; and (ii) the amount of the supply is based on the number of valid prescriptions that the compounder has received for identified individual patients in a 30-day period over the past year that the compounder selected. As an example, if the highest number of units of a particular compounded drug for which a pharmacy received patient-specific prescriptions for in a 30-day period in the last year was 500 units, the pharmacy could compound up to 500 units of the drug in anticipation of new patient-specific prescriptions.Finally, the draft guidance now explicitly advises licensed pharmacies or physicians seeking to compound drug products to maintain records demonstrating compliance with the anticipatory compounding prescription requirements. This includes maintaining documentation of both valid prescription orders (as described above) and records of calculations performed to determine permissible "limited quantities" of compounded drugs.*Hospital and Health System Compounding.* Hospital pharmacies and standalone pharmacies that are part of a health system often provide compounded drug products for administration to the hospital's or health system's patients. The FDA in the draft guidance reiterates its support generally for these practices when carried out consistent with applicable legal requirements. Historically, however, it has been unclear how the FDA interprets these standards in the health system context. It is therefore significant that the FDA has proposed in the hospital and health system compounding draft guidance that it will view as compliant hospital pharmacy compounding in the absence of a patient-specific prescription irrespective of amounts compounded if the following criteria are met:

- The compounded drugs are distributed only to health care facilities that are: (i) owned and controlled by the same entity that owns and controls the hospital facility; and (ii) located within a one-mile radius of the compounding pharmacy;
- The compounded drugs are administered within the health care facilities to patients within the health care facilities, pursuant to a patient-specific prescription or order; and
- The compounded drugs are compounded in accordance with all other provisions of Section 503A and any other applicable requirements of the Act and FDA regulations.

We note that the draft guidance is unclear regarding whether this guidance applies to any facility that is under common ownership (same corporate entity) as the hospital pharmacy or if it applies only to hospital departments of the same Medicare or state certified/licensed hospital. As such, interested parties may consider submitting a request for clarification to the FDA within the draft guidance comment period noted above.*Facility Definition Under Section 503B.* Registered outsourcing facilities are not required to be licensed pharmacies and are permitted to compound drugs in greater than "limited quantities" provided they comply with CGMP requirements. Since many outsourcing facilities have expressed an interest in being able to engage in traditional, patient-specific compounding under Section 503A, they have requested guidance clarifying what constitutes the "facility" and whether traditional compounding and outsourcing services may be co-located.In addressing this issue, the FDA Section 503B draft guidance interprets the term "facility" to include any activities occurring at a geographic location or address (including multiple buildings in proximity) and under the direct or indirect control of an entity. In its draft guidance, the FDA explicitly states that it intends to interpret "facility" in this way in order to prevent commingling of pharmacy compounding and outsourcing activities for patient safety purposes. According to the FDA, the goal is to avoid confusion regarding what standards a compounded drug must meet and to limit the risk that outsourcing that does not meet CGMP standards could occur.

PRACTICAL TAKEAWAYS

Although the recent FDA guidance is still in draft form, it offers important insight into likely FDA interpretations of the Act's compounding and outsourcing requirements. While the guidance offers important clarifications for compounding pharmacies and outsourcing facilities alike, it also warrants further clarity on some issues. As a result, hospitals, health systems, pharmacies, other compounders and outsourcing facilities should consider submitting comments on the draft guidance by **July 14, 2016**. For example, health systems may want to request that FDA clarify that the one mile radius exception be expanded to a reasonable radius (e.g., five miles) to comport with state and federal drug distribution laws applicable to commonly owned facilities. Outsourcing facilities may want to request that FDA adopt Medicare standards governing the separation of licensed facilities. Finally, while the draft guidance addresses federal requirements only, note that all pharmacies must still comply with applicable state pharmacy laws when compounding prescription drugs.If you have questions regarding the FDA's draft guidance or other pharmaceutical compounding matters, please contact:

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