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FDA Alters Course on Definition of Compounding "Facility" in Final Guidance

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Businesses engaged in human drug compounding, both traditional pharmacies and the more recently created outsourcing facilities, have been on quite a rollercoaster ride since congressional enactment of the Drug Quality and Security Act (DQSA) approximately four-and-a-half years ago. Federal and State inspectional mandates have changed, FDA guidance documents (and a few regulations) have been churned out, and some entities have been the target of aggressive enforcement actions and even criminal prosecutions by the FDA/Department of Justice. Suffice it to say, this blog post cannot capture everything that compounders have been grappling with or how their compliance policies have been evolving. So today, we are sharing one important and positive bit of news for health systems and other entities that may be considering whether and how to set up an outsourcing facility under Section 503B of the Food, Drug, and Cosmetic Act (as amended by the DQSA).

We previously alerted interested parties in mid-2016 that FDA had issued three draft guidance documents with the potential to have significant ripple effects across the health care system (see **May 2016 post here**). On May 10, 2018, the Agency finalized one of those guidance documents, entitled "Facility Definition Under Section 503B of the Federal Food, Drug and Cosmetic Act," and completely changed course from the statutory interpretation and policy position it had laid out in the original draft guidance.

Specifically, under Section 503B, an outsourcing facility is defined as "a facility at one geographic location or address" that is engaged in the compounding of sterile drugs, has elected to register with FDA as an outsourcing facility, and otherwise complies with all of the statutory requirements set forth in Section 503B, such as compliance with applicable Good Manufacturing Practice regulations. The guidance at issue was intended to clarify the meaning of "a facility at one geographic location or address" and how the Agency would apply this definition in practice when it inspected and oversaw the operations of outsourcers. In short, the 2016 draft policy took the position that a single location under the same management could not engage in both "traditional compounding" and "outsourcing facility compounding" because those activities are subject to different drug quality standards – a strict interpretation of the Section 503B language that made it more difficult for experienced compounders to contemplate entry into the outsourcing facility business.

FDA received **24 written comments to the docket** regarding the 2016 draft guidance (one of which, in the interest of full disclosure, came from us), the majority of which urged a more flexible interpretation of the phrase "a facility at one geographic location or address" in order to support the growth of the outsourcing facility industry. Commenters pointed out unintended consequences of the proposed policy on issues as diverse as patient access, public health and safety, drug costs, and capital planning expenditures.

In its final guidance – **available here** – the Agency responded to these comments and concerns by recognizing that a 503B-registered outsourcing facility may be located adjacent to or even within the same building as a traditional compounding pharmacy (that is, one governed by Section 503A of the Act), providing that the two compounders and all their compounding activities are " ***completely segregated***" (emphasis in original). From a planning perspective, Management should determine how this complete segregation is put in place because it is going to be a case-by-case analysis, but a conservative approach may be warranted given the risks associated with non-segregation. For example, as FDA notes in the final guidance, "if an entity purporting to compound drugs under section 503A is located near an outsourcing facility and the entity's operations are not completely segregated from the outsourcing facility, FDA generally intends to consider that entity to be part of the outsourcing facility and subject to the conditions of section 503B."

In closing, this decision by FDA is welcome news to people who have been working to set up compliant outsourcing facilities and who may have faced significant operational difficulties trying to avoid the strict “single facility” interpretation communicated to industry in the 2016 draft guidance. The complete segregation of traditional compounding pharmacies and 503B outsourcing facilities makes legal, regulatory, and logistical sense for other reasons as well. But with this final policy statement from FDA, outsourcers can now have more confidence that they are not facing the prospect of an adverse inspectional finding due merely to their mailing addresses overlapping with the address of a traditional compounding pharmacy.

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