

## **FDA Releases Revised Memorandum of Understanding That Would Ease Restrictions on Interstate Shipment of Compounded Drugs**

September 10, 2018

### **Key Points**

- FDA has put out a new draft MOU for stakeholders to review and provide comments over the next 90 days.
- If a state enters into the proposed MOU, pharmacies within its borders would be allowed to distribute up to 50 percent of their compounded drugs out of state. The state would be obligated to provide certain information to FDA on pharmacies that exceed this threshold.
- By law, pharmacies in states that do not enter into an MOU with FDA are limited—by default—to distributing no more than 5 percent of their compounded prescriptions across state lines.

On Friday, September 7, 2018, the U.S. Food and Drug Administration (FDA) issued a lengthy press release detailing the agency's plans to collaborate with states in the oversight of traditional pharmacies engaged in drug compounding. In conjunction, FDA published a revised draft memorandum of understanding (MOU) into which states could enter with the agency to facilitate greater information-sharing about the interstate activities of these compounding pharmacies in their respective states.

Section 503A of the Food, Drug, and Cosmetic Act (FDCA) prohibits compounding pharmacies and physicians from distributing "inordinate amounts" of compounded drugs across state lines. Specifically, the law restricts interstate distribution to 5 percent of a pharmacy's compounded drugs, unless the state has entered into an MOU with FDA. This default limit could complicate distribution for pharmacies near state borders and others with a more diffuse customer base.

FDA had issued an earlier draft MOU in 2015—which this revised draft replaces—that would have allowed "503A" pharmacies to distribute up to 30 percent of their total compounded prescriptions interstate. This was perceived as unworkable by some advocates who pushed a congressional amendment to FDA's FY 2018 budget that

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would have prohibited the agency from finalizing and implementing the MOU. Although the amendment was resoundingly defeated, advocates lost the battle, but may have won the war with the issuance of a less restrictive MOU.

The revised draft would allow pharmacies and physicians relying on the exemptions under Section 503A to distribute **up to half of all compounded prescriptions** out of state. Unlike the prior draft, the number of compounded prescription orders distributed interstate would be divided by the number of prescription orders dispensed or distributed both intrastate and interstate **for compounded drug products**, rather than for all drug products.

Even if pharmacies exceed this limit, the state would be required to only notify FDA rather than take action against the pharmacy. It would then presumably fall to FDA to enforce Section 503A's prohibition on distributing inordinate amounts of compounded drugs across state lines. In exchange for these more lenient standards, FDA is seeking to foster greater ongoing federal-state coordination in the oversight of traditional pharmacies. For example, states signing the MOU would agree to notify FDA of complaints against compounders within three business days.

Despite relaxing the geographic restrictions on distribution, the agency did double—or triple—down on Section 503A's prescription requirement. Some advocates had been pressing FDA to reinterpret the law's reference to "distribution" to allow pharmacies to ship compounded drugs without first receiving an individual patient prescription. Although FDA has re-defined "distribution" as sending the drug out of the facility, thereby excluding orders that patients pick up, the agency held firm that compounders wanting to distribute drugs for "office use" must register with the agency under Section 503B of the FDCA. Pharmacies relying on Section 503A's exemptions **must always receive a prescription before shipping the drug.**

Comments on the revised draft MOU are due on December 10, 2018. Thus, the MOU will not be available for states to enter into until sometime in 2019 at the earliest. Once a final standard MOU is available to states, FDA would wait an additional 180 days before taking action against 503A pharmacies that exceed the default 5 percent limit.