ISSUE BRIEF:

Compounding MOU: Urge States to Determine if They Can Sign

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BACKGROUND

When Congress added section 503A to the Food, Drug & Cosmetic Act in 1997, it directed the FDA to come to an agreement with the states — a memorandum of understanding — to help FDA "address … the distribution of inordinate amounts of compounded drug products interstate."

The legislation offered the states a choice: They could sign the MOU and report to FDA on inordinate amounts of compounded medications shipped by in-state compounding pharmacies to patients in other states. Or don't sign it, and pharmacies in that state would be limited to shipping out-of-state no more than five percent of all prescription orders, even those that are patient-specific.

Congress' expectation, communicated in committee testimony and in Appropriations Committee reports to FDA, was that FDA would structure the MOU in such a way that states would be motivated to sign it. That motivation was to be an administrative regime that was workable for state boards of pharmacy, the agencies that in most states are charged with regulating pharmacy compounding and whose funding comes not from the federal government but from the state legislature. In return, states would collect and report data on in-state pharmacies that shipped more than 50 percent of their compounded drugs out of state.

If the MOU was to be the carrot, the cap on out-of-state shipments was the stick. Impeding patients' access to compounded meds was not Congress' goal. The goal was to incentivize states to help FDA gather data on large shippers of compounded drugs – so that it could properly inspect and document patient safety in those pharmacies.

For patients served by compounding pharmacies based in states that don't sign the MOU (many of whose lives are sustained by the compounded medications that are shipped to them) the loss of access to those drugs – because of that five percent cap on shipments – would be significant. There will also be an economic cost to states, as compounding pharmacies limited by the five percent cap close or relocate to a state that did sign the MOU.

FDA had 23 years to create that MOU and get buy-in from the states. Unfortunately, the "final" MOU, released by FDA in May and set to take effect in October 2021, fails to address earlier concerns raised by states and pharmacy groups. Now several states are hinting that they won't sign it – or they've determined that they are prohibited by state law from doing so.

ACTION REQUESTED: Urge *your state board of pharmacy to take immediate action in determining if under state law it is authorized to sign FDA's Memorandum of Understanding Addressing Certain Distributions of Compounded Human Drug Products (MOU), and if it determines it cannot, contact FDA to urge that it extend the signing deadline from October 26, 2021 to October 26, 2023.*

Clearly, the MOU has serious flaws and is the subject of litigation that could result its being withdrawn – but that is an uncertain prospect. By taking action now, your board of pharmacy can avoid the severe curtailment of patient access to compounded medications in your state that will occur should your board not sign by the FDA's October 21, 2021 signing deadline.

Why do we urge that your board take action now? Recently, at least seven state boards – Alabama, Texas, Florida, Oregon, Nevada, Tennessee, and Alaska – have learned that their state laws prevent them from meeting the requirements of the MOU and therefore prohibit them from signing it. According to NABP, four of those states – Oregon, Nevada, Tennessee, and Alaska – have asked FDA if they may adopt the requirements of the MOU via regulation, rather than signing outright. They await a reply from FDA on that request. In the other three states,

action by the state legislature is required to correct conflicts between the MOU and state law governing the confidentiality of complaint information – legislative action that cannot be achieved by the October deadline. Should FDA not grant the request of those four states or extend the signing deadline for states that will require legislation to comply, a five percent cap will be implemented on out-of-state shipments of all compounded medications in those states.

Such a cap will be catastrophic for many patients who rely on compounded medications.

It's possible other states may discover similar constraints to signing. That's why it is important that every state board of pharmacy act now to analyze any legal restrictions that may exist under state law and take steps to remedy those restrictions as soon as possible – *including writing to make FDA aware of your state's concerns and asking the agency to extend the October 21, 2021 signing deadline.*

If FDA is unwilling to grant an extension of the deadline, and your state determines it has the authority sign the MOU by the deadline, we ask that your state sign the MOU. Doing so will prevent potential severe disruption to the ability of compounding pharmacies in your state to serve patients across state lines with critical compounded medications.

A QUICK MOU TUTORIAL

To assist your board in discussions of the MOU, following is a very brief tutorial on the effects of signing or not signing:

1. For states that DO sign:
    a. The MOU has serious flaws. It conflates definitions of 'distribute' and 'dispense' in a way Congress never anticipated. As a result, in states that sign the MOU, FDA will gain oversight of certain aspects of traditional dispensing, which has long been the purview of state boards of pharmacy, NOT a federal agency.
    b. FDA seriously underestimated the administrative burden on states that sign the MOU – the costs of staffing, reporting, etc., required of states in order to comply. The MOU creates, in effect, an unfunded mandate on states that sign.

2. For states that DON'T sign:
    a. If your state does not sign the MOU, compounding pharmacies in your state will be limited to shipping NO MORE THAN 5% of their compounded preparations out of state – even to areas just across the state line.
    b. For many, many compounders, that 5% cap could seriously hurt their business, and impede countless patients from getting their medications. It may even put some compounders out of business and create a loss of jobs (and tax revenue) in the state. (This 2020 op-ed by Virginia Congressman Morgan Griffith (VA-9) makes that point well.)

3. Clearly, there are negative implications for both signing and not signing. *But the implications for patient access to their medications are what matter most to us, and, we know, to the state board of pharmacy. That five percent cap, if implemented, will deprive patients of medication and your state of tax revenue and, potentially, jobs.*

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