ISSUE BRIEF:

Pharmacy Compounding Reporting Act of 2023

Proposal would eliminate a 1997 directive made obsolete by DQSA in 2013 and would replace it with:

1. *Mandatory reporting by compounding pharmacies that ship more than 50% of production out-of-state.*
2. *A mandatory adverse events reporting requirement for* all *compounding pharmacies.*

In 1997, as part of revisions made to the Food, Drug & Cosmetic Act, Congress directed FDA to execute a memorandum of understanding (MOU) under which state boards of pharmacy would report to the agency certain information about state-licensed compounding pharmacies that *distributed* a large percentage of their compounded drugs across state lines. In pharmacy law, *distribution* refers to providing batches of compounded drugs to a hospital/clinic for in-hospital/in-clinic administration without a patient-specific prescription; in that way, *distribution* is distinctly different from the patient-specific *dispensing* done by traditional compounding pharmacies.

Passage of DQSA in 2013 made obsolete the need for such an MOU by creating a new category of compounding facility, 503B outsourcing facilities, which operate under current good manufacturing practices (cGMP) and are authorized to *distribute* batches of compounded drugs to hospitals/clinics without a prescription. With that action – and subsequent FDA guidance – traditional compounders were effectively prohibited from *distributing* compounded drugs and limited to *dispensing* pursuant to a patient-specific prescription. In other words, compounders could no longer do what the MOU with states was intended to provide reporting on.

Unfortunately, DQSA failed to repeal that obsolete 1997 MOU requirement, and so in 2020 (after 23 years), FDA finalized an MOU. It was soon challenged in federal court (*Wellness Pharmacy, Inc. et. Al. v Xavier Becerra)*, and as a result, in early 2021 FDA acknowledged to the court that it:

- Failed to conduct formal notice-and-comment rulemaking as required.
- Failed to properly assess the economic impact of the MOU as required.
- Would begin again the process of promulgating an MOU, following the proper protocols as required by the 1997 congressional directive.

But why should FDA be forced to pursue a path toward creating an MOU that is widely viewed as obsolete and unnecessary – especially since several states have indicated formally that they cannot sign it (because of state law) or will not sign it (because of the administrative burden)?

Our proposal would implement in law two important requirements for providing reporting on compounded drugs to FDA:

1. It would repeal the 1997 MOU requirement in the Food, Drug & Cosmetic Act – and the burden of FDA having to cajole states sign an MOU – and replace it with a requirement for reporting to state boards of pharmacy by all traditional compounding pharmacies that ship more than 50 percent of their compounded drugs out-of-state. This goes well beyond the reporting required under the 1997 MOU directive, to include reporting on compounded drugs dispensed pursuant to a patient specific prescription.
2. It would create a framework for mandatory reporting of adverse events by traditional compounding pharmacies – a requirement long sought by FDA.

Mandatory reporting by pharmacies that ship more than 50% of preparations out-of-state

As stated, DQSA rendered the MOU as unnecessary. The agency persists in its efforts to promulgate an MOU because the 1997 directive remains in the Food, Drug & Cosmetic Act. DQSA failed to repeal it. And yet despite its obsolescence, *there are serious implications even for a revamped MOU – implications for states and implications for patient access to compounded medications that, in the judgment of their physician, they need.*

For states that DO sign, the MOU creates an administrative burden – the costs of staffing, inspecting, reporting, etc. The MOU creates, in effect, an unfunded mandate.

For states that DON'T sign, the 1997 law says compounding pharmacies based in that state will be limited to shipping NO MORE THAN 5% of their compounded preparations out of state. That 5% cap could seriously impede access to needed drugs for countless patients. It could put some compounders out of business and create a loss of jobs (and tax revenue) in the state.

As many as 10 states have indicated that they either cannot or will not sign an MOU.

The Pharmacy Compounding Reporting Act of 2023 eliminates that uncertainty – and much of the administrative burden on states – by repealing the 1997 directive and replacing it with reporting to state boards of pharmacy (and by state boards of pharmacy to FDA) by pharmacies that ship more than 50% of patient-specific compounded drugs out-of-state. That reporting is through an NABP-developed portal that already exists. FDA gets the reporting it has long sought, and patient access to essential compounded drugs is preserved.

Mandatory adverse events reporting framework
FDA has long lamented in its public statements the absence of mandatory adverse events reporting by traditional compounding pharmacies. This proposal would enact such a requirement.

The proposed adverse events framework, developed by an industry work group, would require reporting by pharmacies of "serious" adverse events (as defined in CFR 310.305) related to compounded drugs. That reporting would occur via the same National Association of Boards of Pharmacy portal, funded by an FDA grant, that has been developed for reporting of interstate shipments under the MOU. The proposed framework would require pharmacies to report adverse events within no more than __ days, and it would shield pharmacies from disciplinary action based *solely* on the reporting of an adverse event. It would require that the pharmacy conduct and document reasonable investigation of the reported adverse event – something not currently required of outsourcing facilities or drug manufacturers. It would also prohibit entities from denying certification or accreditation based solely on the reporting of adverse events by a pharmacy.

THE ASK:
The 1997 MOU directive is obsolete and must be repealed. This proposal does that, while implementing reporting by compounding pharmacies that FDA has long sought. It deserves your support.

House Members: FILL HERE

Senators: FILL HERE

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