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Another Step Toward Finalizing the Compounding Memorandum of Understanding with States

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Once signed, the final MOU, will help to facilitate increased collaboration between the FDA and the states that sign it.

The FDA made available for public viewing a standard memorandum of understanding (MOU) between the agency and the states. This MOU is a huge step forward in the process of implementing more effective compounding policies, as well as proper training, collaboration and stakeholder engagement. The states are particularly import allies as, states play a vital role in reducing the risks associated with compounded drugs, while ensuring appropriate patient access.

Why are compounded drugs and compounding companies such a burning topic? Compounded drugs are not approved by the FDA, and as such have not been evaluated for quality, safety and effectiveness, making them a health risk to patients.

According to the FDA, “the compounding program is a priority for the agency and aims to develop policies that ensure appropriate access to lawfully-marketed compounded drugs for patients who have a medical need for them, while also protecting public health… one of the most crucial aspects of our work in this area has been to identify opportunities to partner with the states to address these important public health goals.”

This collaboration with states is the subject of the current MOU, which outlines the expectations for identification and reporting of adverse drug events, countrywide quality concerns, and the distribution of compounded drugs. Additionally, prescription drug limits for out of state distribution by a pharmacist, pharmacy or physician in states without a signed MOU. The law (section 503A of the FD&C Act) limits distribution of compounded drugs outside the state by a pharmacist, pharmacy, or physician located in a state that has not entered into the MOU to 5 percent of its total prescription orders dispensed or distributed.

The final MOU and the statutory 5 percent limit do not apply to drugs compounded by outsourcing facilities under section 503B of the FD&C Act and they do not apply to drugs that are compounded for animals. The states will have up to 365 days to review the MOU and return it with signature.

Read the whole announcement