



Alliance for
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Compounding

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**Statement of the Alliance for Pharmacy Compounding's CEO Scott Brunner, CAE, on
The MEMORANDUM OF UNDERSTANDING ADDRESSING CERTAIN DISTRIBUTIONS OF COMPOUNDED
HUMAN DRUG PRODUCTS, formally released today by the U.S Food & Drug Administration**

Today the FDA made available the long-awaited final memorandum of understanding with states on the interstate distribution of inordinate quantities of compounded drugs. This version of the MOU is the fourth iteration – but the first “final” version – in the 20-plus years since its creation was mandated in amendments to the Food, Drug & Cosmetics Act.

In states that sign the MOU, pharmacies that ship more than 50 percent of their compounded drugs out of state will trigger state investigation and reporting requirements and the state board of pharmacy will be required to report adverse events to the FDA. Pharmacies in states that don't sign the MOU will be prohibited from distributing more than five percent of their compounded drugs out of state.

Obviously, a five percent cap on out-of-state shipment of compounded preparations would have a profound chilling effect on patient access to certain compounded drugs. That's why, over the past two decades, APC has been diligent – dogged, even – in urging FDA to make essential changes to the previous drafts of the MOU. Our aim has been twofold: to assure, first, that the lawful and proper provision of compounded meds to patients, *pursuant to a prescription and regardless of their state of residence*, is preserved; and second, that the final MOU is one that states can live with and will actually sign.

We are pleased that this latest version of the MOU incorporates some of the suggestions APC and other stakeholders made in relation to the requirements on states, including increasing the reporting time of adverse events from three to five days and increased the time for states to consider signing the MOU from 180 days to 365 days. And we support FDA's coordination with NABP on development of information-sharing software intended to lessen the burden on state boards of pharmacy.

We think those changes can serve as helpful inducements for states to sign the MOU, and we're grateful to FDA for responding to those concerns.

However, we are gravely concerned that the final MOU still redefines the key term “distribution” to include the patient-specific dispensing of compounded drugs – *in other words, applying the term distribution to include traditional dispensing of medications pursuant to a patient-specific prescription, an area appropriately regulated by state boards of pharmacy under state law*. This redefining of a key

term is inconsistent not only with the plain statutory language of the Food, Drug & Cosmetic Act, but with the definition of the term “distribution” in every other appertaining federal law. Concern about that inconsistency has been raised in multiple letters from members of Congress to the FDA, statements in the congressional record, appropriations report language directives, and the overwhelming consensus of stakeholder input to the agency on this issue.

Here’s why it matters: In states that choose for whatever reason not to sign the MOU, pharmacies will be limited to shipping no more than five percent of ALL compounded drugs (*including* those dispensed with a prescription) out of state. Because compounding pharmacies often specialize in compounding preparations for specific conditions – autism, ENT, men’s or women’s health, etc. – it’s not unusual for a patient in Alabama to get a compounded medication from a pharmacy based in New Jersey or Utah that is also licensed in Alabama. Enforcement of a five percent cap on that kind of traditional, patient-specific dispensing – as opposed to applying the cap only to distributions of drugs in larger quantities without a prescription – could deprive patients of needed medications. Moreover, it’s simply not supported by the statute and will undoubtedly trigger lengthy and expensive litigation, tying up the issue in the courts for a long time.

It’s particularly disappointing given the lengths APC and other stakeholders went to in providing FDA suggestions for a very narrow, limited definition of “distribution” for the purposes of the MOU that would meet the statute’s intent, satisfy FDA’s information needs, and avoid legal action.

That said, the timing of the release of this final MOU is curious given recent temporary guidance from FDA that allows 503A pharmacies to actually *distribute* (without a patient-specific prescription) certain compounded COVID-19 treatment drugs to hospitals when those drugs are unavailable commercially or from 503B outsourcing facilities.

This concept in the temporary guidance is quite similar to the extremely limited definition of “distribution” that APC, the National Community Pharmacists Association and American Pharmacists Association suggested as a permanent path in a joint comment to FDA last summer (for administration to patients in emergency clinical situations).

It’s unfortunate that in this final MOU, FDA has ignored the statute, Congress and stakeholder concern by creating from nothing a definition of “distribution” different from the way term is commonly understood in pharmacy and medical practice and is used throughout state and federal law.

We will continue working with our allies in Congress and other pharmacy stakeholders and organizations representing providers who rely on compounded drugs to treat their patients to effect policy outcomes that are both safe and protect patient access to the medicines they need.

Compounding pharmacists have stepped up to safely provide a critical service by compounding COVID-19 drugs in shortage through distributions to hospitals to treat their patients. Under this MOU, that would be expressly prohibited – which just doesn’t make sense. APC will be considering how best to proceed in light of this flawed final MOU.

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing compounding pharmacists, technicians, educators, students, researchers and suppliers. Compounding

exists for patients and animals who are not served by traditional pharmaceutical manufacturers. Every day, APC members play a critical, often life-or-death role in patients' lives, creating essential medications unavailable elsewhere for a range of issues, including autism, oncology, dermatology, ophthalmology, pediatrics, women's health, and others. Learn more at www.a4pc.org.