Alliance for Pharmacy Compounding

Compounding the Joy of Living

Role of 503A Compounding Pharmacies in Drug Shortages
Current Reality vs. HR 167

Currently	**Under HR 167**
SHORTAGES • *Under FDA guidance (not federal law),* 503A compounding pharmacies may compound drugs on the FDA shortage list – pursuant to a prescription – without violating the prohibition on compounding drugs that are essentially copies of FDA-approved drugs.	SHORTAGES • *Under federal law,* 503A compounding pharmacies may compound drugs on the FDA shortage list *as well as on the ASHP shortage list* – pursuant to a prescription – without violating the prohibition on compounding drugs that are essentially copies of FDA-approved drugs.
• 503A compounding pharmacies are prohibited from *distributing* shortage drugs to hospitals or clinics (meaning supplying batches of a drug without a patient -specific prescription). 503As can only *dispense* compounded drugs to patients pursuant to a patient-specific prescription.	• 503A compounding pharmacies may *distribute* small batches of compounded drugs to hospitals or clinics (without a patient-specific prescription), including drugs on the FDA Drug Shortage List or the ASHP Drug Shortage List, provided these additional actions are taken: • The physician must certify that the drug is unavailable from the manufacturer or from an outsourcing facility. • Drug must be labelled with text indicating it is for urgent in-hospital/-clinic administration. • Patient-specific information must be matched to the medication once administered to the patient. • The compounded drug must be labeled with a BUD compliant with USP. • Adverse events must be reported to the FDA via MedWatch ASAP but not later than 15 days.
• FDA has authority to relax the prescription requirement and, urged by APC, did so during the pandemic under a temporary Guidance for Industry that allowed 503As to distribute 13 urgently needed COVID drugs to hospitals under tight regulatory guardrails, including oversight by state boards of pharmacy. That temporary GFI expired in May 2023.	
• Current FDA guidance provides an exception to the prohibition on compounding drugs that are essentially a copy of an FDA approved product for drugs that are FDA's shortage list. However, this guidance does not have the weight of law, and the FDA shortage list at times lags the market and does not reflect *regional* drug shortages.	• No need for special temporary guidance from FDA, which can cause delays or lag in getting essential drugs to hospitalized patients.

URGENT USE: • 503A compounding pharmacies are prohibited from *distributing* urgently needed drugs, including copies of FDA-approved drugs, that are in shortage, to prescribers for in-clinic administration to patients without a patient-specific prescription. 503As can only *dispense* compounded drugs pursuant to a patient-specific prescription. • During the pandemic, FDA's temporary guidance only allowed distributions of compounded shortage drugs to hospitals. It did not allow distributions for in-clnic administration, resulting in many delays in in-clinic procedures for many patients.	URGENT USE: • 503A compounding pharmacies can *distribute* small quantities of urgently needed compounded drugs, both copies of FDA-approved drugs and those compounded from bulk substances, that are in shortage to prescribers for in-clinic administration to patients without a patient-specific prescription, provided these guidelines are met: • If essentially a copy of an FDA-approved drug, the drug must appear as "currently in shortage" on the FDA Drug Shortage List or the ASHP Drug Shortage List. • The physician must certify that the drug is unavailable from the manufacturer or from an outsourcing facility. • Drug must be labelled with text indicating it is for urgent in-hospital/-clinic administration. • Patient-specific information must be matched to the medication once administered to the patient. • The compounded drug must be labeled with a BUD compliant with USP. • Adverse events must be reported to the FDA via MedWatch ASAP but not later than 15 days.

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