Compounding pharmacies are facilities that mix customized formulations of medications for patients. A patient may need a compounded drug for a variety of reasons, including an allergy to an ingredient, a different dosage than is available in a manufactured drug, or a drug that is not widely produced. Compounders also can mix in flavorings to make medicines more palatable to children.

Traditionally, compounding pharmacies mixed medicines for individual patients with valid prescriptions whose particular needs could not be met by off-the-shelf prescription drugs. It has become common, however, for facilities to mix medicines on a large scale rather than for specific patients and prescriptions. This practice has drawn increasing concern, especially after the New England Compounding Center (NECC) in 2012 shipped injectable pain medication, some of which was tainted with fungal meningitis, to buyers around the country. More than 700 people in 20 states became infected, and 64 people died.

Compounding can be either sterile or non-sterile. Sterile compounded drugs require particular care in preparation due to the heightened risk of injury or death to the patient should an error occur. Drugs included in this category are “intravenously administered fluids and injectable drugs.” The NECC was accused of not properly testing its drugs for sterility. Non-sterile drugs include those such as “capsules, ointments, creams, gels, and suppositories” that do not require a sterile preparation environment, according to the U.S. Government Accountability Office.

Federal Action
Compounding pharmacies are not routinely inspected by the U.S. Food and Drug Administration (FDA), and compounded drugs are not inspected by the FDA for quality standards. Standards for mixing compounded drugs often are adopted from Sections 795 and 797 of the United States Pharmacopeia (USP), a commercial publication, rather than the Good Manufacturing Practice standards used by the FDA for manufactured drugs.

In an effort to provide some oversight, however, Congress passed the Drug Quality and Security Act in 2013, creating a new section (503B) of the Food Drug and Cosmetic Act (FDCA), under which a compounding pharmacy can become an “outsourcing facility.” These facilities must register with the FDA and comply with certain requirements. In exchange, they may compound drugs without patient-specific prescriptions.
Congress also reaffirmed section 503A of the FDCA on traditional patient-specific pharmacy compounding. As part of the 503A requirements, the FDA issued a draft Memorandum of Understanding (MOU) that the agency would sign with individual states to ensure that compounding pharmacies do not produce “inordinate” amounts of drugs for distribution across state lines. Under the current draft MOU, pharmacies located in a state with a signed MOU may ship compounded drugs out of state, but must limit the total amount of drugs compounded and shipped interstate to 30 percent of all drugs they prepare, regardless of where the drugs are distributed. Pharmacies located in a state without a signed MOU must limit the portion of compounded drugs they ship interstate to 5 percent of total prescription orders.

**State Action**

Although the FDA generally regulates pharmaceuticals and drug manufacturers and will be the primary regulator of outsourcing facilities, state boards of pharmacy typically are tasked with regulating compounding pharmacies. Most states have laws to regulate these pharmacies. Both the NECC tragedy and clarifications to federal statute have led some states to re-examine their laws and regulations on compounding and, in some cases, revise them.

**Office Stock.** Physicians or hospitals may need an “office stock” supply of compounded products to use with their patients. Per federal law, outsourcing facilities, not traditional pharmacies, may compound supplies of drugs without patient-specific prescriptions. Louisiana and Nebraska recently revised state policies to clarify that traditional pharmacies may compound drugs only pursuant to prescriptions.

**Recognizing Outsourcing Facilities.** Several states have updated policies to recognize outsourcing facilities. For example, Virginia enacted a law in 2015 that requires compounders to obtain permits from the state to be recognized as outsourcing facilities, and New York law now includes a registration category and specific application requirements for outsourcing facilities.

**Out-of-State Pharmacies.** States also can play a regulatory role for of out-of-state compounding pharmacies that ship compounded medicines into the state but may not meet state standards. California passed legislation in 2013 to address this issue by requiring out-of-state compounding pharmacies to submit to California Board of Pharmacy inspection and licensure requirements. Other states, such as Virginia, are using a program established by the National Association of Boards of Pharmacy to inspect nonresident pharmacies.

Compounding pharmacies continue to be an issue of interest in the states. NCSL has tracked 29 bills in 17 states related to compounding pharmacies in its 2015 Prescription Drug Database. Of these, five have been enacted in five states. Maryland passed a law requiring out-of-state compounding pharmacies to provide the state Board of Pharmacy a report documenting that the facility was inspected and operates under the standards of Section 797 of the USP. North Dakota and Virginia also have enacted legislation related to outsourcing facilities.

**NCSL Contact and Resource**

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**Additional Resources**

U.S. Government Accountability Office, *Drug Compounding: Clear Authority and More Reliable Data Needed to Strengthen FDA Oversight*


U.S. Food and Drug Administration, *Compounding and the FDA: Questions and Answers*