Compounding pharmacies, a multi-billion dollar industry, mix customized medicines based upon patients' unique needs. Such pharmacies have historically worked in response to physician-ordered prescriptions for specific patients. It has become increasingly common, however, for compounding pharmacies to produce large quantities of medicines that are shipped to patients and medical practitioners throughout the nation without patient-specific prescriptions.

The issue gained a lot of attention after an outbreak of fungal meningitis that killed dozens of people and sickened hundreds more in 2012 was traced to medicines distributed by a compounding pharmacy in Massachusetts. States, as the primary regulators of pharmacies, have enacted a number of laws designed to regulate compounding pharmacies. However, the changing nature of how such pharmacies work has led to a sometimes-confusing patchwork of laws. Recent federal regulations and guidelines by the Food and Drug Administration (FDA) have added another layer of complexity to the regulatory landscape as states determine how, or whether, to incorporate the federal rules and guidelines into their state laws.

Federal Action

Congress began regulating the compounding industry in 1997 when it amended the Food, Drug and Cosmetic Act by adding Section 503A, known as the Compounding Quality Act (CQA). In 2002, the Supreme Court found aspects of 503A unconstitutional. Those provisions were removed, and in 2013, the FDA defined a new category of compounding pharmacies known as “outsourcing facilities.” Pharmacies that choose to register with the FDA as outsourcing facilities are exempt from some of the requirements of conventional pharmaceutical manufacturers, such as obtaining FDA approval for the drugs they produce and distribute. They also are able to compound drugs without patient-specific prescriptions on a larger scale. However, outsourcing facilities must comply with a new set of rules intended to safeguard patients against contaminated pharmaceuticals. They must meet the same quality standards required of conventional drug manufacturers under the FDA’s Current Good Manufacturing Practices (CGMP).

Unlike conventional drug manufacturers, compounding pharmacies that choose not to register as outsourcing facilities are not held to federal CGMP standards. However, the FDA provides non-binding guidance to state regulators in the form of standards incorporated from the United States Pharmacopeial Convention (USP). The USP is “a scientific nonprofit that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed and consumed worldwide.” States are encouraged, but not mandated, under federal guidelines to adopt USP chapters on sterile compound-
ing (chapter 797), nonsterile compounding (chapter 795) and handling hazardous drugs in health care settings. Compounding pharmacies are also encouraged to adopt standards for pharmaceutical calculations, quality control and equipment. The USP has also published two “monographs” on the subject, which are standards for manufacturing or compounding specific drugs.

**State Action**

Most states have adopted at least a portion of the standards that address drugs that carry a heightened risk of harm if they are not compounded in a sterile environment. Twenty-five states have adopted the standards in their entirety.

States have also shown initiative in developing their own regulatory strategies. These strategies were identified in a 2016 assessment of state roles commissioned by The Pew Charitable Trusts Drug Safety Project. The assessment identified 11 states which require compounding pharmacies to obtain a separate license to perform sterile compounding activities. Ten states require additional training. For example, Alabama requires pharmacists to complete five hours of continuing education and to pass written and practical exams. Six states track regulatory violations in compounding pharmacies. Twenty-eight states indicated that they allow pharmacies to compound drugs without patient-specific prescriptions.

A companion report from Pew presents a series of recommended best practices that, if adopted throughout the nation, would produce a more uniform practice and regulatory framework for compounding pharmacies, and, the study claims, improve patient safety. It recommends that all compounding pharmacies comply with applicable USP standards, especially chapters 795 and 797, and cautions the pharmacies to be aware of and comply with changes to the USP hazardous drugs requirement (chapter 800) once it is finalized. The report also explains options for empowering states to implement additional quality standards, obtain the authority to seize and quarantine compounded pharmaceuticals, and shut down noncompliant compounding pharmacies.

Since 2014, NCSL has tracked 61 bills in state legislatures related to compounding pharmacies in a Prescription Drug Database. Seventeen bills have been signed into law, including Georgia HB 926, which requires, in part, that “All drug products compounded by a licensed outsourcing facility shall also be compounded in accordance with applicable current good manufacturing practices established by the federal Food and Drug Administration.”

**NCSL Contact and Resource**

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**Additional Resources**

Information on Compounding, FDA

National Assessment of State Oversight of Sterile Drug Compounding (2016), The Pew Charitable Trusts


The information contained in this LegisBrief does not necessarily reflect NCSL policy.