

Chain Drug Review

Reporter for the Chain Drug Store Industry

Time of Change for Rx Compounding

NEW YORK — The compounding pharmacy profession of today bears little resemblance to the compounding pharmacy landscape in 2012, when a fungal meningitis outbreak was traced to the New England Compounding Center (NECC), a large-scale operation that was making thousands of purportedly sterile doses of injectable methylprednisolone acetate and shipping them across the nation.

In response to this tragedy, Congress passed the Drug Quality and Security Act in 2013, which gave the FDA oversight of a new category of high-volume sterile compounders, called outsourcing facilities, and gave state boards of pharmacy responsibility for traditional compounding pharmacies that produce patient-specific medications one prescription at a time.

“Our goal with this bill is to help put an end to health crises resulting from poorly regulated compounding manufacturers and make it clear who is on the flagpole — who is in charge and accountable for oversight of these compounding manufacturers and who is accountable for pharmacies,” Sen. Lamar Alexander (R., Tenn.) said at the time.

As the federal government prepared to oversee outsourcers, the states ratcheted up their oversight of the smaller-scale compounding pharmacies. Boards of pharmacy hired inspectors with experience in compounding and strengthened their regulations by incorporating United States Pharmacopeia (USP) chapters <795> and <797>. A new chapter governing hazardous substances and workplace safety, USP <800>, will take effect in

July 2018, and this will result in an even more rigorous inspection process.

“Compounding pharmacy today has changed significantly in recent years,” said Loyd Allen Jr., editor-in-chief of the International Journal of Pharmaceutical Compounding. “The technology and science supporting it continues to grow to help ensure safe and effective nonsterile and sterile compounding for patients. The need for individualized medications increases, and pharmacists must routinely learn new procedures and apply their scientific knowledge to meet individual patient needs.”

As a result of federal and state efforts, pharmacies using inferior equipment and processes have essentially been ordered out of the compounding business. Some states began inspecting not only the pharmacies within their borders but pharmacies shipping into their states. Retail pharmacies that did very low-volume compounding were forced to re-examine how committed they were to the practice.

In 2014, a year after Congress acted, Massachusetts, home of NECC, toughened state laws to ensure that the Commonwealth would not be the setting for any future outbreaks. “Massachusetts will now have among the most rigorous standards for compounding in the nation and can serve as a model for what other states can do to modernize their own pharmacy regulations,” said state Rep. Jeffrey Sanchez, chairman of the Joint Committee on Ways and Means, who authored the legislation, as it was signed into law.

The Massachusetts law called

for tougher inspections as well as new continuing education and training requirements for pharmacists. The measure also set new registration categories for sterile and “complex” nonsterile compounding practices.

On January 1, 2017, the state of California adopted new compounding pharmacy regulations that are believed to be even more rigorous than federal regulations. The new regulations require compounders who do not meet the standards to renovate or construct new facilities that are compliant, and out-of-state pharmacies that seek to ship to patients in California must meet the state’s standards.

In light of these regulatory developments, many chain drug stores in California, Massachusetts and elsewhere have assessed their clinical practice, business process, and layout and infrastructure and have opted to use compounding kits to meet the needs of patients, rather than manually compound medications in their pharmacy.

Compounding kits, such as those made by CutisPharma, provide a solution for chain pharmacies that is very high quality and fully compliant with regulations, and can be prepared without any substantial training or equipment. Pre-measured ingredients from FDA-registered manufacturers can be mixed according to the instructions in the package insert. The result is a safe, stable, high-quality nonsterile compounded medication that can be prepared on the bench.

Vancomycin oral solution, which are carried by all major retail chain pharmacies, many leading hospitals and long-term

care facilities, and independent pharmacies.

The California Board of Pharmacy’s Enforcement and Compounding Committee recently recommended a revision to state regulations that compounding kits not be included within their definition of compounding. That would mean that kits can be used to prepare topical or oral medications in the same way and under the same regulations as any other preparation in the pharmacy.

As a result of the regulatory overhaul in the compounding space, many hospitals have upgraded and expanded their compounding pharmacy capabilities. Where previously many hospitals would simply purchase sterile compounded medications from a compounding pharmacy, most now have either created the capacity in-house or entered into relationships with FDA-regulated sterile compounding outsourcing facilities. Whether in-house or outsourced, hospitals now have the confidence that the drugs in their inventory meet the rigorous cGMP (current Good Manufacturing Practices) standards that the FDA insists upon.

Compounded medications are vital for the health of patients who cannot tolerate certain ingredients, need a strength that is not manufactured, or have been prescribed a medication that is not commercially available.

The options available to chain pharmacies to meet these needs will ensure that patients can get what they need, when they need it, in a way that is compliant, transparent and, most important, safe.