LAS VEGAS, NV—The National Association of Boards of Pharmacy (NABP) in December launched a nationwide program to identify and inspect compounding pharmacies.

NABP Executive Director Carmen Catizone, speaking December 5 at ASHP’s Midyear Clinical Meeting in Las Vegas, said critical information about the pharmacies, including disciplinary actions taken against them, will be collected in a database.

The database will allow state boards of pharmacy to better regulate nonresident pharmacies that want to do business in the state, he said.

"Before a state decides to renew a license for a nonresident pharmacy, or issue a license for a nonresident pharmacy, they will have access to this database so they can really see what’s going on," Catizone said.

Ultimately, he said, NABP will have a list "of every pharmacy in the United States, whether it's involved in compounding, sterile compounding," or so-called nontraditional compounding.

The undertaking is part of NABP’s response to the outbreak of fungal meningitis and other infections in patients treated with methylprednisolone acetate made by the New England Compounding Center (NECC) of Framingham, Massachusetts. As of December 17, more than 600 people had been sickened during the outbreak and 39 had died.

"Every single one of us was responsible for this tragedy," Catizone said. "The regulatory system broke down, the pharmacy compounding system broke down, the collaboration between the FDA and the states broke down, the purchasing of the products broke down."

Catizone said NABP will first inspect "nonresident" pharmacies identified by the Iowa Board of Pharmacy that sell products to entities in the state. NABP will serve as the designated agent of the Iowa pharmacy board and will work in cooperation with pharmacy boards in states that are home to the compounding pharmacies.

Catizone said the Iowa Board of Pharmacy has provided NABP with an initial list of 582 nonresident pharmacies.

The first wave of inspections will run through February and involve pharmacies whose compounding activities seem to be of a scope or scale that go beyond traditional practice, Catizone said.

A second round of inspections, scheduled for March through June, will focus on other nonresident pharmacies, including those that engage in sterile and nonsterile compounding.

Catizone called drug shortages the driving force behind increased reliance on compounding and compounding pharmacies. He said conflicts exist between hospitals that need critical drugs for patient care and regulatory bodies that oversee the practice of compounding.

According to FDA, hospitals aren’t the only entities that purchased compounded drugs from NECC. The agency’s list of customers included hospitals, ambulatory surgery centers, eye clinics, pain clinics, and plastic surgery centers.

State regulators aren’t able to reliably ensure that compounding pharmacies are operating in compliance...
with the law, Catizone said.

"The primary problem is resources. The states don't have the resources, in many cases, to inspect pharmacies on a regular basis," he said. "That's unacceptable."

He urged pharmacists to demand that the licensing fees that they pay to their state be used to support pharmacy boards so that they can adequately oversee compounding pharmacies.

The Massachusetts Board of Registration in Pharmacy in November approved rules that allow the state to track the volume and distribution of products made by compounding pharmacies. The rule is intended to help the state determine whether a compounding pharmacy is acting as a manufacturer and should thus be subject to federal oversight.

During congressional hearings last November, NECC was said to have behaved as a manufacturer.

According to FDA, 14,000 patients throughout the country may have been treated with NECC-compounded methylprednisolone acetate that was prepared and then recalled last year. At least two recalled lots have tested positive for fungal contamination, and FDA has confirmed the presence of microorganisms in other compounded products made by the company.

Over the years, NECC has been investigated for allegedly preparing compounded drugs in the absence of a patient-specific prescription. The Colorado State Board of Pharmacy in 2011 issued a cease-and-desist order to NECC for engaging in this practice and determined last year that the company was violating the order.

Catizone emphasized that, for liability purposes, hospitals need to know the location of any compounding pharmacy they purchase from and whether the pharmacy follows its own state pharmacy regulations.

"If any of your institutions purchased medications from NECC, and they were not on a per-prescription basis, or if they were for office use or clinic use, you broke the law. Because that's against the law in Massachusetts," Catizone said.

Federal regulation of pharmacy compounding has been hindered by conflicting court opinions over a law enacted in 1997. FDA officials say this lack of legal clarity prevents the agency from exercising its authority against pharmacies like NECC or even defining precisely when a compounder is, in reality, a drug manufacturer.

Catizone said that situation will soon change, and he said pharmacists need to work with other stakeholders and be a responsible part of the process.

"We can't sit back, we can't argue . . . for 20 more years about the definition of compounders," Catizone said. "We have to act."

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