Pharmacies Ordered to Shut Down after Inspections

STEVE LeBLANC,Associated Press

BOSTON (AP) — State officials have ordered 11 pharmacies to completely or partially shut down their operations after a series of unannounced inspections prompted by a deadly nationwide outbreak of fungal meningitis.

The Department of Public Health inspections were conducted across the state over the past several months at 40 sterile compounding pharmacies, which custom-mix solutions, creams and other medications in doses or forms that generally aren't commercially available.

The outbreak of meningitis, an inflammation of the lining of the brain and spinal cord, was discovered in Tennessee in September and has killed 45 people and sickened more than 600 nationwide. It was caused by a contaminated steroid, used mainly to treat back pain, that was linked to the Framingham-based New England Compounding Center, which has since closed. The inspections began last fall.

Besides the 11 cease-and-desist orders, public health inspectors said, another 21 pharmacies were cited for minor deficiencies that have since been corrected or are being addressed.

"While these results are troubling, this process has led to significant corrective measures and increased compliance," Public Health interim Commissioner Dr. Lauren Smith said Tuesday.

Pharmacies that have been shut down must submit plans, take corrective actions including renovations if necessary and then pass re-inspections before they can begin producing drugs again. Of the 11, eight have submitted corrective plans.

Inspectors said they found evidence one of the pharmacies was operating as a sterile compounding pharmacy despite an earlier statement saying it wasn't. The pharmacy was cited with having noncompliant clean room engineering controls and sterile compounding practices and insufficient personnel training and environmental monitoring.

Officials said another pharmacy was shut down for "issues with the storage of chemotherapy drugs" while a third was told to stop production of sildenafil citrate, which is sold as Viagra, after inspectors found it had produced the drug using improper components.

Another of the pharmacies ordered to stop sterile compounding, PharMerica, in Brockton, also has locations in Rhode Island and New Hampshire, and inspectors have notified the pharmacy boards in those states. The company had no comment

Tuesday, a spokesman said.

Compounding pharmacies traditionally fill special orders placed by doctors for individual patients, turning out small numbers of customized formulas each week. They typically are overseen by state pharmacy boards.

In the last two decades some compounders, like the NECC, have grown into large businesses that ship thousands of doses of drugs to multiple states.

U.S. Rep. Edward Markey, a Democrat who has been conducting a congressional investigation into compounding pharmacies, said he plans to reintroduce a bill designed to step up federal oversight of the industry.

"Even the strongest state standards will do little to solve the problem if Congress does not also hold compounding pharmacies everywhere to high safety and health standards," he said in a statement.

Smith said the results of the inspections show the need for more resources to ensure oversight of the facilities.

Gov. Deval Patrick, a Democrat, has proposed $1 million in new state spending to help the Board of Pharmacy hire more than 30 new full-time workers including inspectors.

The board has recently issued regulations requiring sterile compounding pharmacies to report their volume and distribution for the first time.

Patrick also has filed legislation that would mandate a special license for sterile compounding, set new fines and create whistleblower protections.

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