Pharmacy Blames Cleaning Company for Meningitis Outbreak

STEVE LeBLANC,Associated Press

BOSTON (AP) — Gov. Deval Patrick on Friday proposed tighter regulations on sterile compounding pharmacies following a deadly nationwide meningitis outbreak linked to a Massachusetts company.

The proposal comes as the New England Compounding Center is trying to place blame for the outbreak on a cleaning contractor that provided once-a-month services to NECC's cleanroom facilities.

The outbreak linked to NECC has been blamed for 39 deaths and hundreds of illnesses nationwide.

Patrick said he's filing a bill that would require compounding pharmacies to obtain a special state license that he said would make it easier for regulators to hold them accountable. The bill would also create whistleblower protections for pharmacy workers and enforce new fines and penalties for compounding pharmacies that break the rules.

"There is, of course, no action that we in government can take to prevent all abuses in all industries, but we must do what we can," Patrick said.

Patrick's bill would also require that out-of-state pharmacies that deliver and dispense medications in Massachusetts also obtain a state license.

Pharmacies and pharmacists would also have to report to an overhauled 11-member state oversight board whenever they are the subject of any disciplinary action by other state or federal agency, under the bill.

The Colorado pharmacy board had complained about the New England Compounding Center in July, before the third of three batches of tainted steroids tied to the outbreak was shipped in August, but the Massachusetts pharmacy board's director and attorney didn't notify leadership at the Department of Public Health.

Patrick said the change would enable the oversight board "to know when issues arise with Massachusetts' pharmacies doing business outside of our state." Patrick also wants to hire more inspectors to keep an eye on the industry.

Patrick's recommendation came as NECC sent a letter to UniFirst Corp., demanding it take legal responsibility for claims against the compounding center related to the outbreak.

The letter was referenced in a Thursday filing by UniFirst to the Securities and Exchange Commission. In the filing, UniFirst wrote that the demand relates to the once-a-month cleaning services they provided to NECC.

UniFirst said it believes the claims are without merit.

UniFirst spokesman Adam Soreff said in a statement the company's UniClean business sent two technicians to NECC monthly for 90 minutes each. He said the cleaners used the NECC's own cleaning solution.

"UniClean was not in any way responsible for NECC's day-to-day operations, its overall facility cleanliness, or the integrity of the products they produced," he said.

A tainted steroid produced by Framingham-based NECC, and given mainly for back pain, has been tied to the fungal meningitis outbreak, which was discovered in Tennessee in September.

The company has shut down and recalled its products. Inspections at NECC's facility found various potential contaminants, including standing water and mold. Last month, the company declared Chapter 11 bankruptcy and said it was seeking to set up a fund to pay victims.

Messages were left for the attorney for NECC's insurance company requesting comment, including on whether letters similar to the one sent to UniFirst have or will be sent to other companies.

Patrick said the state needs to take other steps. He said he supports a bill proposed by Attorney General Martha Coakley that would raise the maximum fine for corporate manslaughter from $1,000 to $250,000.

The $1,000 penalty hasn't been updated since it was first established in state law nearly 200 years ago.

In November, Massachusetts also began requiring sterile compounding pharmacies to report the volume and distribution of their medications to state regulators for the first time. Patrick said the new rule will help alert the state when a pharmacy like NECC is acting like a manufacturer and should obtain a license from the federal Food and Drug Administration.

Compounding pharmacies custom-mix drugs in doses or forms that generally aren't commercially available.

"Taken together, these changes can ensure that the significant harms that we've seen from substandard compounding never happen again," Patrick said.

___

Associated Press reporter Jay Lindsay contributed to this report.

Copyright 2013 The Associated Press.

Source URL (retrieved on *09/16/2014 - 6:44am*):
http://www.chem.info/news/2013/01/pharmacy-blames-cleaning-company-meningitis-outbreak