

MA Shuts Down Another Compounding Pharmacy

BOSTON (AP) — Massachusetts shut down another compounding pharmacy over sterility concerns after a surprise inspection prompted by the nationwide meningitis outbreak linked to a different company, state officials have said.

Dr. Madeleine Biondolillo of the state Department of Public Health said inspectors went to the Waltham location of Rhode Island-based Infusion Resource last week and found significant issues with the environment in which drugs were being mixed.

The company was inspected when it first opened in December 2009 and there had been no complaints since. She said the manager of record at the company was a former employee at Ameridose, which is owned by the same people who ran New England Compounding Center, the company linked to the meningitis outbreak.

She would not identify the drugs or say what specific issues investigators found at Infusion Resource, but she said they were concerned about sterility. The company mixes sterile injectable drugs for people who have been released from hospitals.

The company has agreed to contact its 40 patients and their doctors and ask them to return any unused medication. Biondolillo says there is no indication any medication the company compounded is unsafe. She said the company also had an area to administer intravenous drugs, which it was not licensed to do. She says the company voluntarily surrendered its pharmacy license this weekend.

Company Chief Executive Officer Bernard F. Lambrese said in a statement that the company will take immediate action to fix issues identified by Massachusetts investigators, including a crack in a window, the condition of flooring in a clean room and a leak in a refrigerator drain hose.

"No issues were cited relating to the integrity of our products nor to the quality of our compounding practices," Lambrese said. "I want to reassure our patients and the general public of the safety, purity and efficacy of our solutions produced at our Waltham pharmacy since we were first licensed in 2009. Patient safety is something we take very seriously."

Lambrese said in the meantime patient needs are being served out of the company's pharmacy in its main headquarters in East Providence, R.I.

The surprise inspections started in the wake of the nationwide outbreak of fungal meningitis, an inflammation of the lining of the brain and spinal cord, that has sickened more than 300 people, including 23 who have died, in 17 states. The outbreak has been linked to a steroid made by the NECC and taken mainly for back pain. Compounding pharmacies like NECC custom mix solutions in doses or forms generally not commercially available.

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Dr. Lauren Smith, interim commissioner of the state Department of Public Health, said Sunday that the department is adding five inspectors to help review all compounding pharmacies in the state by the end of the year. Previously pharmacies were inspected only when they opened or if they moved or were the subject of complaints.

Smith also said the state pharmacy board, which oversees compounding pharmacies, has asked member Sophia Pasedis to step down. Pasedis, a pharmacy manager for Ameridose, has been on the board since 2004. The state previously said she had recused herself from all matters related to Ameridose and the NECC, but Smith said minutes from pharmacy board meetings raise questions about whether that is true. She said Pasedis has so far declined to leave the board. Her term ends next month.

Tom Kiley, an attorney for Pasedis, said a resignation would be mostly symbolic because she doesn't have much time left in her term and the board will mostly be dealing with issues related to NECC, which she would not participate in.

"As a practical matter it doesn't make sense," Kiley said. "What she's going to do is whatever she can to contribute to the board and assist the board."

He said she always recused herself on issues related to NECC and Ameridose. He said meeting minutes may be vague because she may have been present at some point in a given meeting but not necessarily when NECC was discussed.

Smith said the Department of Public Health is taking other steps including proposing regulations to require frequent reports from compounding pharmacies and forming a commission to look at best practices in other states.

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