

**Commonwealth of Massachusetts Executive Department  
Office of Governor Deval L. Patrick**

**Press Release**

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**GOVERNOR PATRICK ANNOUNCES LEGISLATION TO REFORM BOARD OF PHARMACY AND FILL GAPS IN COMPOUNDING INDUSTRY OVERSIGHT**

*Legislation draws on recommendations from Pharmacy Compounding Commission; Part of series of reforms Governor will announce to make government work better*

BOSTON – Friday, January 4, 2013 – Governor Deval Patrick today announced that he is filing legislation to reform the Board of Pharmacy and strengthen state oversight of the compounding pharmacy industry in Massachusetts. Governor Patrick’s legislation, along with related actions the Administration is taking, builds on recommendations released today by the Commission on Pharmacy Compounding.

The Governor established the Commission in October 2012 as part of the Administration’s comprehensive response to the national fungal meningitis outbreak linked to products manufactured at the New England Compounding Center (NECC) in Framingham.

“There is no action that we in government can take to prevent all abuses in all industries – but we must do what we can. This legislation makes patient safety paramount and will help fill the gaps in compounding pharmacy monitoring that allowed NECC to operate in the shadows,” said Governor Patrick. “Together these changes can ensure that the tragic events of last fall never happen again.”

This announcement comes as the first of several reforms the Governor will propose over the next week to address specific needs as part of the Administration’s continuing efforts to make government work better.

**Governor Patrick’s Legislation:**

1. Requires a special license for sterile compounding that will help regulators hold pharmacies accountable for their practices.

2. For the first time, authorizes the Board to assess fines against Massachusetts licensed pharmacies that violate Board of Pharmacy policies, regulations, or statute; and establishes whistleblower protections for pharmacists and pharmacy staff.
3. Requires licensure for out of state pharmacies that deliver and dispense medications in the Commonwealth.
4. Establishes a clear process to restructure and reorganize the composition of the Board of Pharmacy. The Board will include more members not practicing in the industry they are responsible for regulating. Under the legislation, the 11 member Board would be comprised of four pharmacists, one nurse, one physician, one pharmacy technician, one quality improvement expert, and three public members.

Today, the Governor also announced his support for a bill filed by Attorney General Coakley that updates the manslaughter criminal statute by raising the fine from \$1,000 to \$250,000 to help deter and sufficiently punish corporations when they are found guilty of criminal wrongdoing.

Governor Patrick will also direct DPH to increase inspection staff at the Board of Pharmacy and require that all inspectors be pharmacists with at least five years of clinical experience, with additional training requirements and specific expertise in sterile compounding for inspectors working in that area.

The Board of Pharmacy will continue its enhanced pharmacy inspection schedules that the Governor previously announced.

“The Governor’s legislation represents significant steps toward improving the safety and quality of compounding practices in Massachusetts,” said Interim DPH Commissioner Dr. Lauren Smith. “We look forward to working with the Legislature and other partners to make these changes happen as soon as possible.”

As part of these efforts, DPH will work with the U.S. Food and Drug Administration to increase communication surrounding investigations of pharmacies licensed by Massachusetts.

The Commission was chaired by Christian Hartman, an expert in pharmacy practice and patient safety; and was comprised of representatives from the Legislature, along with experts in pharmacy practice, regulatory affairs and patient safety.

The Commission undertook an intensive and focused study of compounding practices in Massachusetts, relying on perspectives from pharmacists, regulators, physicians, epidemiologists, health law practitioners and legislators to protect the public and to minimize the risk of drug shortages.

At Governor Patrick’s direction, DPH has already taken several steps to enhance monitoring of the compounding pharmacy industry, including advancing new regulations

that require sterile compounding pharmacies in Massachusetts to report volume and distribution to the state for the first time. This will alert the Board when a pharmacy like NECC is acting like a manufacturer, which requires an FDA license.

The regulations also require all licensed pharmacies and pharmacists to report to the Board when they are the subject of any disciplinary action by any state or federal agency. This allows the Board to know when issues are identified with Massachusetts pharmacies doing business in other states.

In December, the Governor announced the appointment of three new members to the Board of Pharmacy who work across diverse health care fields, to bring greater balance to the Board. Finally, DPH has been collaborating with its federal partners and has urged Congress to act to address the regulatory grey area between state and federal oversight.

In addition to Hartman, other members who served on the Commission were: Boston University Health Law Professor Kevin Outtersen, health care education and training expert Eric Kastango, Brigham & Women's Hospital Pharmacy Director Michael Cotugno, Department of Public Health Director of Health Care Safety and Quality Dr. Madeleine Biondolillo, Health Care Financing Committee Chair Senator Richard T. Moore, Senate Minority Leader Bruce Tarr, and state Representative David Vieira.

#### **STATEMENTS OF SUPPORT:**

"Governor Patrick's new legislative package builds upon his aggressive state-wide emergency actions taken in the wake of the fungal meningitis outbreak. This proposal will ensure that Massachusetts has the strongest state pharmacy regulations on the books, helping to prevent another drug compounding disaster from happening in Massachusetts again. Because compounding pharmacies do not limit their sales within the borders of any one state, patients in Massachusetts and throughout the country are still vulnerable to safety failures by pharmacies located in states with weaker laws. This is a nationwide problem, that is why I have introduced federal legislation that will protect patients in Massachusetts and around the country from ever enduring this kind of tragedy again. I will work closely with Governor Patrick and anyone in Congress to turn the lessons we have learned from this tragedy into law."

--Congressman Ed Markey

"The tragedy that was traced to the New England Compounding Center in Framingham had a human face in the more than 600 people who were infected and the 39 who died from the meningitis outbreak and their loved families. But it was also about the important need for government to take on greater oversight responsibility through these recommendations which honor that suffering and those tragic deaths and to make sure that this does not happen again to anyone else."

-- Senator Richard T. Moore, the Senate President's designee on the Pharmacy Compounding Commission

"The Governor's proposal today is an important first step in ensuring public safety and health in the wake of recent tragic events. I am honored to have played a role in the development of the Commission's recommendations and look forward to continuing the dialogue particularly around centralizing pharmacy regulations for hospital and physician's offices under the Board of Pharmacy."

-- Representative David Vieira, member of the Pharmacy Compounding Commission

"The only way to protect people from tainted drugs and industry insiders that put profit over safety is through strict regulation of the pharmaceutical industry. This will never happen when the government allows an industry or special interest to police itself. The Board of Pharmacy must be made up of impartial members that have no conflict of interest and must have the power to act quickly to sanction compounding pharmacies that fail to follow the rules and endanger the lives of our citizens."

-- Senator Mark Montigny, Chairman of the Senate Post Audit and Oversight Committee.  
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“The Governor’s legislation offers sensible options to improve the safety and quality of pharmacy practice in Massachusetts. I will continue working with the Governor’s office to pursue any new policy that strengthens patient protections and prevents any future tragedies such as we saw with the tainted drugs produced by the New England Compounding Center.”

-- Representative Jeffrey Sánchez, House chairman of the Legislature’s Joint Committee on Public Health.

“I am pleased the administration is taking the initial steps to move forward in rectifying the serious safety concerns surrounding compounding pharmacies in the Commonwealth. I look forward to working with the Governor and my colleagues to ensure these critical changes occur to prevent tragedies such as the meningitis outbreak from ever occurring again.”

--Representative Harold Naughton, House chairman of the Committee on Public Safety and Homeland Security

“As hospitals continue to work with the Department of Public Health to find strategies to address the national and local drug shortage concerns, we commend the Administration and the Commission on Pharmacy Compounding for proposing thoughtful ways to ensure that providers and patients are able to access a safe supply of drugs and medications.”

-- Anuj K. Goel, vice president of legal and regulatory affairs, Massachusetts Hospital Association

"The Governor's proposal will improve essential public health functions that residents of Massachusetts absolutely rely on. This clarified authority and improved staffing to provide

oversight of the compounding industry is the right and necessary thing to do. We applaud the Governor for taking this action today."

-- Toby Fisher, executive director of the Massachusetts Public Health Association.

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