

01.04.13 Compounding Pharmacy Legislation Announcement

AS PREPARED:

Governor Deval L. Patrick
Compounding Pharmacy Legislation Announcement
State House, Room 360
Friday, January 4, 2013

Good afternoon, everyone. Thank you for coming. I have a couple brief announcements.

First, I want to announce that we are filing legislation this afternoon to make several reforms to the Board of Pharmacy.

As you know, the Board has responsibility for oversight of pharmacy operations across the state. The tragic meningitis outbreak has shown us all that the Board's governing authority has not kept up with an industry that has evolved from corner drug stores to the types of large manufacturers that have been at the center of so much trouble.

So today, we are proposing that the Legislature change the governing statutes to reform the Board of Pharmacy and its functions.

Under our bill, the Board would include more members from outside the industry they are asked to regulate. 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. This will bring a greater range of professional perspective to the Board.

This builds on the appointment of three new members to the Board recently who work across diverse health care fields.

Second, our legislation will also require a special license for sterile compounding that will help regulators hold pharmacies accountable for their practices.

Third, the bill would authorize the Board to assess fines against Massachusetts pharmacies that break the rules, and establishes whistleblower protections for pharmacists and pharmacy staff who bring infractions to the attention of authorities.

Finally, this bill would require licensure for out of state pharmacies that deliver and dispense medications in the Commonwealth.

These changes in statute are in addition to the changes in practice we have already instituted. In November, we issued 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 new 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 enables the Board to know when issues arise with Massachusetts pharmacies doing business in other states.

I think you also know that we have begun random, unannounced inspections of compounding pharmacies as well. To increase the Board's ability to closely monitor pharmacies, I will direct DPH to increase the number of inspection staff and raise inspector training requirements. New staff resources will allow the Board to continue its enhanced pharmacy inspection schedules.

There is no action that we in government can take to prevent all abuses in the industry. But we must do what we can and continue to work with our federal partners to fill the regulatory gaps that we have identified. Together these changes can ensure that the significant harms we have seen from substandard compounding are never allowed to happen again.

Let me add that I support the Attorney General's bill that updates the manslaughter criminal statute by raising the fine from \$1,000 to \$250,000. This is a long overdue deterrent.

Now that the Legislature is back in session, I want to say that today's announcement is one of several reform proposals we will be filing over the next week to address several needs. Each is a part of this Administration's continuing effort to make government work better.

That brings me to my second quick announcement -- which has to do with transportation financing. I have been briefed on the MassDOT board's draft report, and I have sent them back to do a little more work. I see this report as not just a plan for what to do to maintain the status quo for the T and our existing Boston-area system, but how to drive business growth and economic opportunity throughout the Commonwealth. The report needs a little more work in that regard. It should be ready in another week, and submitted to me and the Legislature on Monday, January 14th instead of Monday, January 7th.

That's all. Happy to take any questions you may have.