SPECIAL COMMISSION ON THE OVERSIGHT OF COMPOUNDING PHARMACIES

Recommendations on the Oversight of Compounding Pharmacies in the Commonwealth

January 2013

Governor Patrick convened the Special Commission to Make an Investigation into and Study of the Oversight of Compounding Pharmacies (the "Commission") in the Commonwealth in response to the tragic events of the multi-state meningitis outbreak that has been attributed to products from Massachusetts-based New England Compounding Center.

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. The findings and recommendations put forward by the Commission offer a framework within which policy changes should be contemplated and further studied.

The Commission was chaired by Christian A. Hartman, an expert in pharmacy practice and patient safety. Joining him in serving on the Commission were: Boston University Health Law Professor Kevin Outterson, Healthcare 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 on behalf of Interim Commissioner Dr. Lauren Smith, Health Care Financing Committee Chair Senator Richard R. Moore, Senate Minority Leader Bruce Tarr, and State Representative David Vieira. Additionally, the work of the Commission was supported by Iyah Romm, DPH Director of Policy and Planning for the Bureau of Health Care Safety and Quality and Dianne Morad, DPH Director of Government Affairs.

The Special Commission approached its charge with the following three principles in mind:

- Safety and quality is the foundation for all compounding activities.
- Compounding is a necessary service to meet the needs of patient care.
- Oversight of pharmacy practice must be just, transparent, and comprehensive.

The Commission identified a series of goals for completion in this process:

- Define "compounding" and "sterile compounding"
- Ensure the composition of the Board is appropriate
- Ensure appropriate transparency of the board
- Define knowledge and expertise required for the Board of Pharmacy and staff to carry out regulatory requirements
- Review whether the Board and Board staff have the ability and resources to proactively investigate and enforce compounding practices in accordance with USP 795 (non-sterile compounding) and USP 797 (sterile compounding)

- Review other states' practices related to regulatory oversight
- Identify the gaps between federal and state regulations
- Assess whether current state regulations provide adequate oversight of compounding pharmacies and pharmacists
- Review the extent of the Board of Pharmacy and related boards' reach into the hospital pharmacy setting
- Identify the extent to which the board should oversee compounding in other areas of healthcare, such as hospitals and physician practices
- Identify and, if necessary, strengthen whistleblower protection laws
- Identify what independent assessment and/or accreditation of compounding practices is available
- Offer recommendations for improving root-cause analysis and applying lessons learned from recent events

In five meetings held between November and December 2012, the Commission achieved consensus on the following statutory, regulatory, and operational recommendations.

Further study and continuous review

The pharmacy industry, especially as it pertains to compounding, continues to evolve as it adapts to a changing market. The following recommendations represent significant steps toward improving the safety and quality of compounding practices in Massachusetts. However, the Special Commission cautions that vigilance and ongoing, relevant training are essential to maintaining an environment in which compounded products remain safe and effective. Therefore, the Commission's first and highest recommendation is to require that the Board of Pharmacy actively and continuously monitor the practice of pharmacy compounding in Massachusetts to minimize risk and allow for a rapid response to any problems that do occur as soon as they are identified.

RECOMMENDATIONS

Board of Pharmacy Composition and Advisory Groups

1. The Board of Pharmacy's governing statute should be amended to reorganize the 11 seats of the Board of Registration in Pharmacy to be comprised of six pharmacists, one nurse, one physician, one pharmacy technician, one public member, and the Commissioner of Public Health or designee. Additionally, amended legislation should include the following provisions:
    a. Requiring that one of the Board of Pharmacy members possess qualifications in patient safety and quality, including training and professional experience.
    b. Basing the pharmacist seats on diverse qualifications and experiences in pharmacy practice, and not allowing more than two pharmacists from a single pharmacy practice setting to serve on the Board.

c. Removing the senate district provision for pharmacist appointed members of the Board of Registration in Pharmacy, and appointing at least one member from each public health district.
d. Limiting members of the Board of Registration in Pharmacy to three consecutive terms with eligibility to seek further appointment after standing down from the Board of Registration in Pharmacy for at least one term. Reducing term length should be reduced from five to three years.
e. Authorizing the Governor to extend a member's term until a successor is appointed, and prohibiting a member to serve in "holdover" by default.

2. The Board of Pharmacy should have the authority to establish content-specific expert advisory groups for topics including but not limited to specialized pharmacy practices, pharmacy technicians, and education. Such advisory groups should be convened to deliberate policy changes with regard to regulation and enforcement no less frequently than once per year. At a minimum, advisory groups should be tasked with:
    a. Evaluating certification for all Massachusetts registered pharmacy technicians, with recommendations provided to the Director of Health Care Safety and Quality and the Board President by December 31, 2013.
    b. Evaluating compounding accreditation processes, including but not limited to the Pharmacy Compounding Accreditation Board (PCAB), with recommendations provided to the Director of Health Care Safety and Quality and the Board President by December 31, 2013.
    c. Evaluating the policy and operational implications of establishing a single regulatory authority for all pharmacy practice in the Commonwealth, including oversight of freestanding (currently Board of Pharmacy), hospital (currently DPH), and physician-office (currently Board of Medicine) based pharmacies and pharmacists with recommendations provided to the Director of Health Care Safety and Quality and the Board President by December 31, 2013.
    d. Assessing the status of and making recommendations for amending policies and procedures regarding continuing education requirements in the Commonwealth with recommendations provided to the Director of Health Care Safety and Quality and the Board President by December 31, 2013.
    e. Assessing the potential requirement all pharmacists engaging in sterile compounding complete annual USP continuing education (0.1 CEU) with recommendations provided to the Director of Health Care Safety and Quality and the Board President by June 30, 2013.
    f. Developing a model to license all out-of-state pharmacies (non-compounding) with recommendations provided to the Director of Health Care Safety and Quality and the Board President by June 30, 2013.

3. The Board of Pharmacy, its staff, and advisory group members should be required to submit a conflict of interest statement annually to the Massachusetts State Ethics Commission, with the first statement submitted within 14 days of assuming such a role.
    a. The Governor should have the authority to remove an appointed member of the Board of Pharmacy or an Advisory Group if conflict of interest statements are not filed annually as required.
    b. Any ethics violations by Board of Pharmacy staff, Board members, and advisory group members should be noted on the Board's website and should be deemed sufficient cause for removal of an appointed member of the Board of Pharmacy or an Advisory Group.

Board of Pharmacy Staff Training

4. The Massachusetts Department of Public Health and the Board of Registration in Pharmacy should ensure access to ongoing training and education in compounding for inspectors.

5. The Massachusetts Department of Public Health and the Board of Pharmacy should ensure that as a minimum qualification for employment, all inspectors/investigators must be pharmacists with at least five years of clinical experience, must complete a certificate training program in investigative techniques within one year of employment, and for those inspecting sterile compounding pharmacies, specific expertise in that area, including United States Pharmacopeia General Chapter 797 is requisite.
    a. At least one of the aforementioned pharmacists on staff must have at least five years clinical experience in sterile compounding.

6. The Massachusetts Department of Public Health and the Board of Pharmacy should establish interdisciplinary relationships within the Department of Public Health Bureau of Infectious Disease, particularly in the area of epidemiology.

Statutory and Regulatory Changes

7. The Board of Pharmacy should create licensure categories for specific areas of pharmacy practices such as, but not limited to, retail, sterile compounding, long-term care, home infusion, nuclear, and specialty pharmacy.
    a. Regulations and inspection requirements for each license category should be consistent with USP 797 and USP 795.
    b. All pharmacy inspection schedules (and pursuant fee schedules) should be structured according to risk.

8. Statutory change should be pursued immediately to give the Board of Pharmacy authority to appropriately regulate and license out-of-state compounding pharmacies that distribute medications to Massachusetts

through the development of an out-of-state oversight process (see Recommendation 2f).

a. Out-of-state licensure should be separated into licensure categories as described for state licensure in Recommendation 7.
b. Fee schedules should be commensurate with risk stratification, and based upon national standards.

9. Statutory change should establish whistleblower protections for pharmacists, pharmacy technicians, pharmacy interns, clinical providers (physicians, nurses, physician assistants) and pharmacy support staff. The statutory change should establish whistleblower rewards similar to the False Claims Act.

10. The Board of Pharmacy should impose fines against Massachusetts licensed pharmacies that violate state law, regulations, and/or Board policies. Penalties should be commensurate with those in other states, and should specifically be levied only against organizations for violations.
    a. The Board should use the monetary penalties to establish a quality improvement fund to support patient safety and quality improvement programs for the Commonwealth, which should be administered by the Department of Public Health.

11. The Board of Pharmacy should impose fines to the extent allowed by law against out-of-state pharmacies, including unlicensed or licensed pharmacies that violate state law, regulations and/or Board policies.
    a. The Board should use the monetary penalties to establish a quality improvement fund to support patient safety and quality improvement programs for the Commonwealth, which should be administered by the Department of Public Health.

Board of Pharmacy Operational Policies

12. The Board of Pharmacy should make meeting minutes and actions publicly available on the Board of Pharmacy website. Disciplinary actions taken by the Board should be made publicly available no later than 30 days after final actions being completed. Suspension or revocation of licensure actions should be posted within five business days of the action. The intent is to make Board of Pharmacy activities transparent while maintaining effective investigations.

13. The Department of Public Health should make Board members' names, titles, and employers readily accessible on the Board of Pharmacy web page no later than January 15, 2013, and update this information within 30 days of notification of changes.

14. The Board of Pharmacy should adopt a "Just Culture" when evaluating

medication incidents. This should include associated trainings for Board of Pharmacy members, investigators, and pertinent legal staff within one year of this recommendation. Additionally, the Department of Public Health should consider adoption of "Just Culture" throughout the Department and Health Professions Licensure Boards as determined to be necessary and appropriate by the Commissioner of Public Health.

15. The Department of Public Health should provide timely and transparent posting of pharmacy inspections and the results of those inspections including environmental and product testing. Inspections resulting in a summary action or cease and desist notice should be posted within five business days, and all other actions, including routine inspections, should be posted within 30 days of the action.

16. The Department of Public Health should enhance inspection schedules of all pharmacies licensed by the Board of Pharmacy.
    a. The Commission endorses that the Board of Pharmacy has authority for unannounced, proactive investigations, and encourages these actions.
    b. Pharmacies engaged in medium and high-risk compounding, as defined by the United States Pharmacopeia, should be inspected no less frequently than annually.
    c. The Board of Pharmacy should develop an aggressive inspection schedule for other licensed entities no later than June 30, 2013.
    d. The Commission endorses the inclusion of a bi-annual (every six months) attestation in current Board of Pharmacy regulations, and recommends requiring Manager of Record and Senior Executive signatures.
    e. The Board of Pharmacy should notify all licensees of the establishment of whistleblower protections.
    f. The Board of Pharmacy should develop attestation requirements for licensed registered pharmacists and registered technicians of compliance with Board regulations to coincide with license renewal deadlines.
    g. The Commission endorses the Board of Pharmacy's regulation provisions requiring quality and volume data reporting from sterile compounding pharmacies.
    h. The Commonwealth should appropriately resource the Board of Pharmacy to support comprehensive and proactive investigations of compounding pharmacies, including ongoing training of investigators, and all other aforementioned activities. Inspector/investigator staff should be increased accordingly.

17. The Department of Public Health and Board of Pharmacy should publish a list of medications developed and maintained by the FDA and National Association of Boards of Pharmacy that may not be compounded in

Massachusetts without prior approval of the Board. This should include consideration of market availability/shortage, risk, patent rights, and cost. This list should be published coincidental with the promulgation of new licensure regulations.

Regulations and USP Standards

18. No later than June 30, 2013, the Board of Pharmacy should define in regulation 'sterile compounding' pursuant to USP 797, 'non-sterile compounding' pursuant to USP 795, and manufacturing.
    a. The Massachusetts Department of Public Health and the Board of Pharmacy should review and modify all existing regulations to align all definitions of compounding in the regulations.
    b. The Commission notes that "sterile compounding" has been defined under emergency regulations to 247 CMR promulgated on November 1, 2012.

19. No later than June 30, 2013, the Board of Pharmacy should permit United States Pharmacopeia (USP) continuing education inclusion under current 0.2 Continuing Education Units (CEU) annual law requirements.

20. No later than June 30, 2013, the Board of Pharmacy should require all licensed pharmacists complete 0.2 continuing education units (2 hours) annually focused on patient safety.

21. No later than June 30, 2013, the Board of Pharmacy should promulgate regulatory language to define physician office and hospital-based compounding for the purposes of citation in the regulations of the Board of Registration in Medicine and Division of Health Care Quality (see out-of-state licensure requirements).
    a. The Massachusetts Department of Public Health should adopt regulations paralleling those at 247 CMR requiring adherence to identical compounding regulations in the hospital, clinic, long term care, and ambulatory surgery settings.
    b. The Massachusetts Board of Registration in Medicine and Board of Registration in Nursing should adopt regulations paralleling those at 247 CMR requiring adherence to identical compounding regulations in physician office practices.

22. The Board of Pharmacy should require certification for all Massachusetts registered pharmacy technicians engaged in sterile compounding activities. The Board of Pharmacy should assess the rate of certification among all Massachusetts registered technicians, and determine an effective date for this requirement by June 30, 2013. That implementation date should be no later than December 31, 2014.

23. The Massachusetts Board of Registration in Medicine, Board of Registration in Nursing, Department of Public Health, and any other regulatory entities with licensees handling compounded medications should amend existing regulations to ban use among licensed providers of products from unlicensed pharmacies. Responsibility through the regulations should be conferred to facilities where appropriate, or in practice settings, such as to individuals responsible for purchasing such medications.

Other Recommendations

24. The Massachusetts Department of Public Health and associated boards should seek to establish a formal communication mechanism with the United States Food and Drug Administration, including but not limited to the development of memoranda of understanding guiding sharing of information and joint or several investigations of entities licensed by Massachusetts.

25. The Commonwealth of Massachusetts should advocate for the FDA to exert its current authorities under federal regulation. The Board of Pharmacy should exert authority where the FDA does not.