



The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Department of Public Health
Division of Health Professions Licensure
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Joint Committee on Public Health
Chairman John F. Keenan
State House, Room 413B
Boston, MA 02133

Chairman Jeffrey Sánchez
State House, Room 130
Boston, MA 02133

Dear Chairmen Keenan and Sánchez:

The attached report details the investigatory and disciplinary actions conducted by the Massachusetts Board of Registration in Pharmacy (the Board), as required by Section 25 of Chapter 112 of the Massachusetts General Laws, and is responsive to the legislative reporting requirements of Chapter 38 of the Acts of 2013:

... provided, that the board shall submit a report to the joint committee on public health by December 31, 2013, and annually thereafter, detailing the investigatory and disciplinary actions conducted by the board; provided further, that the initial report shall detail the investigatory and disciplinary actions conducted by the board from September 1, 2012 through December 1, 2013, provided further, that the report shall detail a) each complaint received by the board or initiated by the board, b) the date of the complaint, c) the violation alleged, and d) whether or not a case file was opened and the complaint was referred to a board investigator; provided further, that the report shall further detail, for those complaints that resulted in an opened and docketed case file, a) the docket number, b) the name and license number of the licensees involved, c) a chronological account of the board actions taken during the investigation, d) the name of any state or federal agencies that collaborated with investigation, e) a summary of and rationale for the final decision of the board to dismiss the complaint, impose an informal sanction or penalty, impose a formal penalty or sanction, or amend a previously issued penalty or sanction, and f) whether or not the board reported the result of its investigation to another state board, federal agency or external entity; provided further, that

the board shall prepare a compilation of cases involving preventable medical error that resulted in harm to a patient or health care provider for the purpose of assisting health care providers, hospitals and pharmacies to modify their practices and techniques to avoid error; and provided further, that the board shall submit the compilation to the joint committee on public health and the commissioner of the department of public health by December 31, 2013, and annually thereafter, and shall make the compilation widely available, including by electronic means, to the public and to all hospitals, pharmacies and health care providers doing business in the commonwealth.

In response, the Board submits the enclosed report detailing all formal Complaints and Staff Assignments/Investigations that were pending, received, initiated, or opened by the Board during the period of September 2012 to December 1, 2013.

In the wake of the fungal meningitis outbreak in fall 2012, the Board implemented regulatory and administrative reforms to improve oversight of the compounding pharmacy industry. Specifically, Board staff instituted new or updated existing administrative procedures, including: priorities for complaint investigations; timelines and guidelines for standard investigation activities, guidelines for handling evidence and chain of custody logs; and processes for complaint intake and triage. The Board also established a sterile compounding pharmacy inspection log to supplement and enhance reporting capabilities of the Board; instituted a weekly critical incident report; and created a product recall checklist.

Further, Board staff developed new policies and procedures for managing communication about abnormal test results and pharmacy retail drug store closures, and for handling incoming reports of theft or loss of controlled substances from DEA.

These efforts helped the Board achieve its goal of enhanced oversight of the compounding pharmacy industry. Overall, in 2014, cases are pending investigation an average of 63 days sooner; and pending action by the board for an average of 33 days, down from 261 days just two years ago.

Case Flow Overview

To provide context to the enclosed report, we are providing you with an overview of the Board's case flow. The Board receives informal complaints alleging regulatory violations or other misconduct by licensees. At a weekly pharmacy triage meeting, Board Staff determine whether the allegations, if true, assert a violation of laws or regulations governing the practice of pharmacy by the particular licensee, and take one of three actions. If they determine that the facts alleged, if true, would not constitute a violation, Board staff will close the matter. If they determine that the facts alleged do constitute a violation and that there is clear evidence supporting the allegations, Board staff open a formal Disciplinary Complaint (Complaint). If further information is needed to make the determination, Board staff open a Staff Assignment. In the case of both Complaints and Staff Assignments, Board staff conduct further investigation as necessary. If the evidence gathered in a Staff Assignment clearly supports a violation, the Staff Assignment may be

converted into a Complaint. If the Staff Assignment does not yield clear evidence supporting a violation by a particular licensee, Board staff will close the Staff Assignment.

As part of the investigation, the investigator contacts the licensee for a response to the allegations. The investigators also obtain evidence, as available, from complainant and other witnesses. When the investigation is complete, the investigator writes a report. The Complaint is then slotted for review on a Board meeting agenda. Following the Board meeting review, the Board members may take the following actions: (1) dismiss the matter; (2) request further investigation; (3) authorize commencement of disciplinary proceedings; and/or (4) authorize terms for resolution of the Complaint by consent agreement.

In reviewing the enclosed report, you are likely to notice that investigation and resolution of these cases can take a great deal of time and effort. Board staff, including the investigators, must not only gather information about complaints and establish their legitimacy, but carefully prepare evidence of a violation in the event that administrative action is warranted. You may observe that some complaints can take anywhere from several months to several years to investigate, review, prosecute, and close.

Report Structure

The report is separated into three (3) sections:

1. Complaints
2. Staff Assignments/Investigations
3. Preventable Medical Errors

For all files listed, the report indicates the Complaint numbers assigned to each file, the name and license number of the licensees involved, the violation alleged¹, and the name of any state or federal agency that collaborated in the investigation.

For each of the files handled by the Board during the above-listed time frame, a chronological account of the Board actions taken is indicated as follows:

For **Complaints**, the date the investigation was opened, the date it was sent to the Board for Board action, the date it went to Board Counsel, the date it was sent to Prosecution, and the date the docket was closed. If the docket is closed, a summary of the result is provided. If the result was formal discipline on a license, the report indicates if the discipline was reported externally (outside reporting). If an NA (not applicable) is noted, it denotes that the Investigation or Complaint did not proceed to that particular stage, or does not yet have a final decision.

¹ Violations marked "Other" are instances that do not fall under typical categories or are not included in our tracking database complaint type list. For example, "contaminated sterile compounds", "abnormal result reports from sterile compounders", or "delay in therapy," are not currently tracked, but the Board plans to update its tracking during FY15. Violations marked "Serious Reportable Event" pertains to a pharmacy's requirement to report to the Board any improper dispensing of a prescription drug that results in serious injury or death.

For **Staff Assignments/Investigations**, the date the Staff Assignment/Investigation was opened, the date it was closed, and the date any complaint docket was opened as a result of the Staff Assignment/Investigation. A Staff Assignment/Investigation cannot result in discipline, and for that reason, no results of Staff Assignments/Investigations have been reported externally.²

Preventable Medical Errors:

The report of Preventable Medical Errors details all available information for Complaints and Staff Assignments/Investigations where the alleged violation was related to a medical error. For each medical error, the report indicates a synopsis of the medical error. Redundant errors are typically companion files related to the same medical error, for all responsible licensees (pharmacy, pharmacist, technician, manager of record, etc.)

To further assist in your review, we have also enclosed a summary of the actions taken by the Board from September 2012 to December 1, 2013, on formal Complaints and Staff Assignments/Investigations.

If you have any questions, please contact Jay Youmans, Director of Government Affairs, at 617-624-5059.

Sincerely,



James G. Lavery
Director, Division of Health Professions Licensure

² The handling of all cases not related to compounding was largely put on hold in the fall of 2012 throughout the winter and spring as the fungal meningitis crisis demanded the board staff's full attention during that time. By mid-2013, board staff returned to focus on outstanding complaints but had to recreate paper trails caused by staffing changes. In some instances, existing board authorization to take further action on these cases was either lacking or required revisiting due to concerns about enforceability.

Formal Complaint Dockets:

Pending Investigation	55
Pending Board	102
Pending Board Counsel	84
Pending Prosecution	48
Closed	151
Total	440
Collaboration with Outside Agencies	42

Closed Complaint Dockets:

Resulting in Discipline	51
Resulting in Non-Discipline	26
Dismissed	69
Opened in Error	5

Complaint Dockets by Type:

Failure to Fill Rx Properly	162
Inspectional Deficiencies	65
Drug Violation	54
General Practice Standards	52
Discipline in Another Jurisdiction	25
Regulatory Violation	23
Serious Reportable Event (SRE)	18
Other	9
Summary Action	8
Confidentiality Violation	5
Unlicensed Practice	5
Breach of Contract	3
Criminal Activity	2
None (Opened in Error)	2
Unprofessional Conduct	2
General Misconduct	1
Practice While Impaired	1
Substance Abuse	1
Unethical Conduct	1
DOR Notice	1

Staff Assignments/Investigations:

Open	121
Closed	70
Total	191

Staff Assignments/Closed Investigations:

Resulting in Complaint	24
Opened in Error	3
Dismissed	43

Investigations by Type:

Good Moral Character Evaluation	39
Drug Violation	32
Failure to Fill Rx Properly	28
Other	27
Inspectional Deficiencies	21
Regulatory Violation	18
General Practice Standards	16
Unprofessional Conduct	8
Error	2
Confidentiality Violation	1
Request for Inspection	1
Substance Abuse	1
Unethical Conduct	1