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January 5, 2016

Steven T. James
House Clerk
State House Room 145
Boston, MA 02133

William F. Welch
Senate Clerk
State House Room 335
Boston, MA 02133

Dear Mr. Clerk,

Pursuant to Section 25A of Chapter 112 of the Massachusetts General Laws, please find enclosed a report from the Department of Public Health entitled "*Investigatory and Disciplinary Actions Conducted by the Board of Registration in Pharmacy.*"

Sincerely,

Monica Bharel, MD, MPH
Commissioner
Department of Public Health

Charles D. Baker
Governor

Karyn Polito
Lieutenant Governor



Marylou Sudders
Secretary

Monica Bharel, MD, MPH
Commissioner

Board of Registration in Pharmacy

Annual Report on Investigations and Disciplinary Actions

December 2015



Legislative Mandate

The following report is hereby issued pursuant to Section 25A of Chapter 112 of the Massachusetts General Laws, which reads as follows:

Section 25A. The board shall submit an annual report to the department of public health, the joint committee on public health and the joint committee on health care financing on or before December 31. The report shall detail the investigatory and disciplinary actions conducted by the board and shall detail: (1) each complaint received by the board or initiated by the board; (2) the date of the complaint; (3) the violation alleged; (4) the name of any state or federal agency that collaborated with the investigation; (5) the summary of the final decision of the board to: (i) dismiss the complaint, (ii) impose an informal sanction or penalty, (iii) impose a formal sanction or penalty or (iv) amend a previously issued sanction or penalty; and (6) whether the board reported the result of its investigation to another state board, federal agency or external entity.

All relevant data collected and analyzed under subsections (b) to (e), inclusive, of section 39D shall be summarized and included in the report. The report shall be made available, including by electronic means, to the public and all hospitals, pharmacies and health care providers doing business in the commonwealth. Said report shall be posted on the department of public health's [website](#).

Executive Summary

The enactment of *Chapter 159 of the Acts of 2014, An Act Relative to Pharmacy Practice in the Commonwealth*, brought with it many new requirements and opportunities for the Board of Registration in Pharmacy (Board). This report, entitled “*Investigatory and Disciplinary Actions Conducted by the Board of Registration in Pharmacy*” is intended to track all complaints that moved through the Board from December 1, 2014 to December 1, 2015. This is the third annual report.

Each year the Board must track and report (1) each complaint received by the board or initiated by the board; (2) the date of the complaint; (3) the violation alleged; (4) the name of any state or federal agency that collaborated with the investigation; (5) the summary of the final decision of the board to: (i) dismiss the complaint, (ii) impose an informal sanction or penalty, (iii) impose a formal sanction or penalty or (iv) amend a previously issued sanction or penalty; and (6) whether the board reported the result of its investigation to another state board, federal agency or external entity.

The Board and staff have continued to work diligently to conduct investigations and process files expeditiously. In 2015, much progress has been made including the following:

- The continued expedited processing of complaints and staff assignments;
- The elimination of the backlog of completed investigations waiting to be heard by the Board;
- A rise in non-disciplinary dispositions with the continued implementation of Just Culture;
- A continued robust field presence uncovering regulatory violations and inspectional deficiency complaints;
- A decrease in patient complaints submitted to the Board;
- Continued monitoring of drug losses and other drug violations; and
- Focus on information-gathering at the investigation level prior to initiating formal complaints.

Since the first report in 2013, the processes put in place have allowed the Board staff to continue on a path of moving cases through the system at an accelerated pace. A thorough investigation and well-written report allows the Board to resolve these cases quickly. The goal is to fine-tune the Board’s processes and procedures and to ensure that quality improvement is monitored and continues in 2016 and beyond.

Introduction

Following the 2012 multi-state meningitis outbreak that was attributed to products from a Massachusetts-based pharmacy, legislation containing sweeping pharmacy practice reform was signed into law. Immediately after the outbreak, the Board began implementing regulatory and administrative reforms to improve oversight of the compounding pharmacy industry. Specifically, the 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. Additionally, Board staff developed new policies and procedures, including: managing communication about abnormal test results; managing above action limit¹ environmental monitoring results; pharmacy retail drug store closures; and handling incoming reports of theft or loss of controlled substances. These efforts helped the Board achieve its goal of enhanced oversight of the compounding pharmacy industry, as well as traditional retail pharmacies.

This Annual Report tracks all pharmacy complaints that were either pending, received, initiated, or opened during the period December 1, 2014-December 1, 2015.

Case Flow Overview

To provide context to the enclosed report, an overview of the Board's case flow is provided.² The Board *receives initial complaints* alleging regulatory violations or other misconduct against a licensee. At a weekly pharmacy *triage meeting*, Board staff determines 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*:

1. If they determine that the facts alleged, if true, would not constitute a violation, Board staff will *close* the matter.
2. 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*).
3. If further information is needed to make the determination, Board staff *open an Investigation*.

In the case of both Complaints and Investigations, Board staff conducts further investigation as necessary. If the evidence gathered in an Investigation clearly supports a violation, the Investigation may be immediately converted into a Complaint. If the Investigation does not yield clear evidence supporting a violation against a particular licensee, the Investigation is presented to the Board to determine if a complaint should be opened or the matter should be closed.

¹ The level which requires a pharmacy engaged in sterile compounding to take remedial measures.

² See Appendix A: *Case Flow Diagram*.

As part of the investigation, the investigator *contacts the licensee* for a response to the allegations. The investigators also *obtain evidence*, as available, from complainants³ and other witnesses. When the investigation is complete, the investigator writes a *report*. The report is then reviewed by the *Director of Compliance* to ensure accuracy and completeness.

Next, the Director of Pharmacy Compliance determines whether the Complaint will be presented to the *Board* or go to the *Board Delegated Complaint Review (BDCR) committee*.⁴ The BDCR has authority to dispose of Investigations or Complaints that fall under Board-specified criteria.

If the Complaint is outside of the BDCR criteria, the Complaint will be slated for review on a *Board meeting agenda* and subsequently presented to the Board. 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 data presented in Appendices B, C, and D, you will notice that the investigation and resolution of these cases may vary considerably. Various factors may contribute to the length of a case staying open including, complexity, availability of evidence or witnesses, concurrent criminal matters where board cases may be delayed or placed on hold, lengthy administrative hearings, appeal of final decisions, etc. Appendices E through M summarize relevant information captured in the overall data.

Data Structure

The data is separated into three (3) sections:

1. Formal Complaints;
2. Investigations; and
3. Preventable Medication Errors.

For all files listed, the report indicates the file number assigned to each file, the name and license number of the licensees involved, the violation alleged,⁵ 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:

³ Complainant: a person who makes a formal charge in an administrative proceeding or court saying that someone has done something wrong.

⁴ The BDCR consists of at least one Board member and at least the following Board staff: (1) the Executive Director or his/her designee; (2) Director of Compliance or his/her designee; and (3) Board Counsel.

⁵ 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" are not currently tracked, but the Board staff created two new investigation types – "Delay in Therapy" and "Abnormal Results" in FY15. These two types of investigations comprise a large majority of the investigations classified as "Other" in 2013. 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 **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, the result is provided. If the result was discipline on a license, the report indicates if the discipline was reported externally (outside reporting). If a “not applicable (N/A)” is noted, it denotes that the Investigation or Complaint did not proceed to that particular stage, or does not yet have a final decision.

For **Investigations**, the date the Investigation was opened, the date it was closed, and the date any Complaint docket was opened as a result of the Investigation are included. An Investigation cannot result in discipline because it would first have to be converted to a Complaint, and for that reason, no results of Investigations have been reported externally.

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

This Report is comprised primarily of data that has been collected and analyzed from December 1, 2014 through December 1, 2015. The data presented in the Excel spreadsheets in Appendices B, C, and D contain all of the information that has been collected. Appendices E through O contain an analysis of the information as well as charts to show a quick examination of the data, easily compare data sets and emphasize trends.

Improvements

The systematic changes and improvements that have been put in place over the last three years reflect a Board that has policies and procedures that are clear, effective, and efficient. In addition, these changes also support a group of pharmacy inspectors that continue to have a commanding field presence, which they utilize to educate the pharmacy community on compliance standards, and which ultimately leads to improved compliance with pharmacy laws and regulations.

Significant progress has been made including the following:

- In 2015, Board staff maintained the expedited formal complaint processing system established in 2014. Overall, the data depicts that the high rate of formal complaint closures established in 2014 was maintained in 2015. Most importantly, the data depicts an end to the backlog of complaints waiting to be heard by the Board.
- The Board processed more files in 2015, resulting in a maintained increase in file closures since 2013.
- The total number of investigations that were opened in 2015 increased from previous years. The increase is attributed to a focus during the intake process to refrain from opening formal complaints against licensees unless there is clear evidence of a violation.

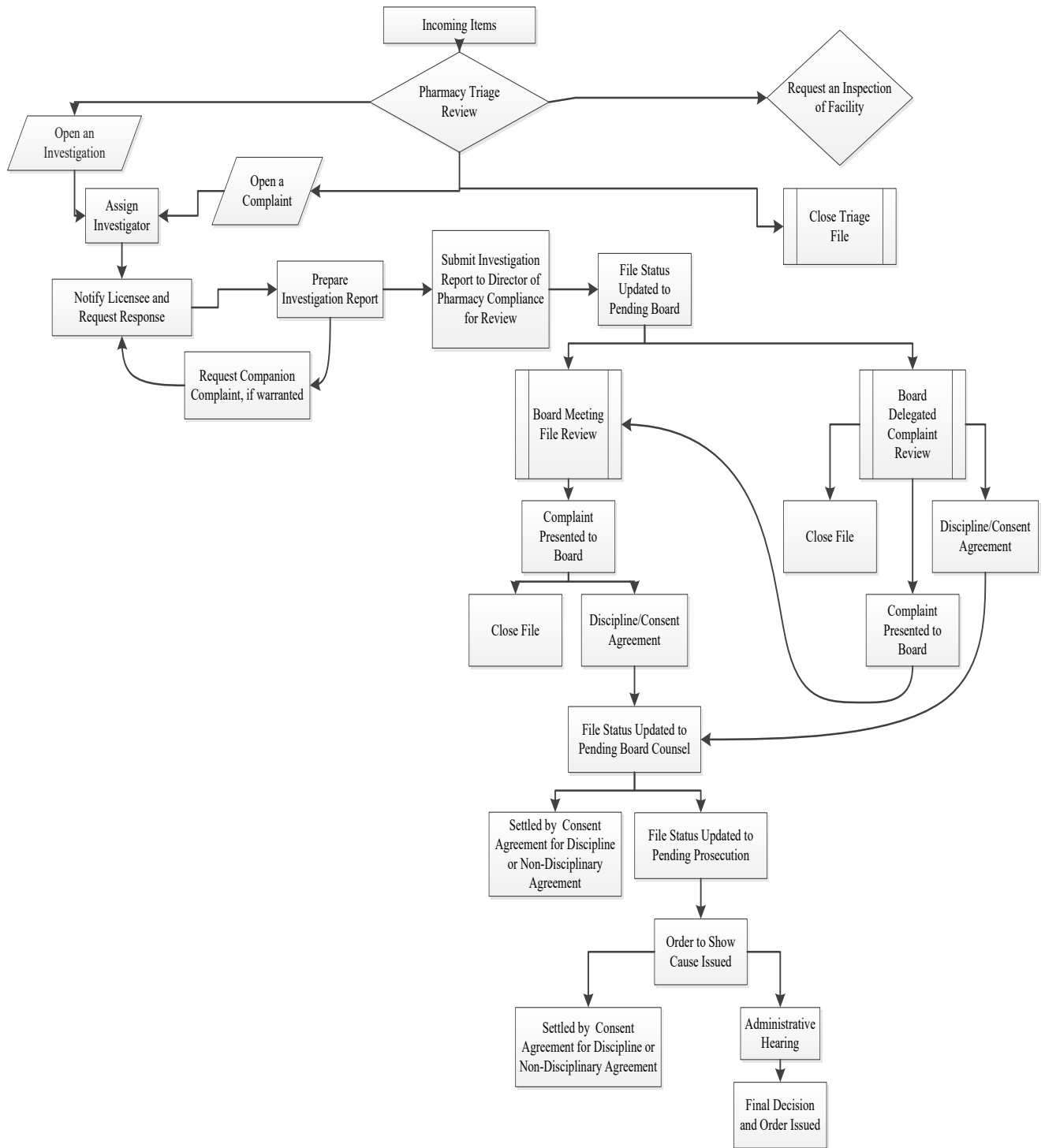
- Board staff continued to monitor controlled substance loss reports (classified as “Drug Violations”) and abnormal results related to sterile compounding, resulting in an increase in investigations related to these events.
- A continued and significant field presence in 2015 uncovered regulatory violations and inspectional deficiencies resulting in formal complaints. Investigators continue to pay close attention to the reports of drug losses and diversions, resulting in formal complaints for this type (classified as “Drug Violations”).
- The most common complaint type, “Failure to Fill RX Properly,” showed a significant statistical decrease. The high number of “Failure to Fill RX Properly” complaints in 2014 was an anomaly, as many of them were backlogged complaints from previous years with new companion complaints processed in 2014.
- There was a significant decrease in “Summary Actions” by the Board. With the recent focus on inspections of all pharmacies in Massachusetts in 2014 and 2015, instances of non-compliance that rise to a level of a “serious or immediate threat to public, health, safety and wellness” and necessitate summary Board action have not developed. In 2015, there were zero Summary Actions by the Board.
- The Board and staff continue to forge strong relationships with our state and federal partners and will collaborate on cases where doing so is in the best interest of public health and safety.

Conclusion

This report details all formal complaints and investigations that were pending, received, initiated, or opened by the Board during the period of December 1, 2014 through December 1, 2015.

As the Board and staff move forward, they intend to continue monitoring and making quality improvements in the processing and expediting of formal complaints and investigations. This allows the Board to make informed and expeditious decisions on the numerous complaints that are received each year; all with the primary goal of protecting the health, safety and welfare of the public.

Appendix A: Case Flow Diagram



Appendix B: *Formal Complaint Data*

Please see separate Excel spreadsheet data.

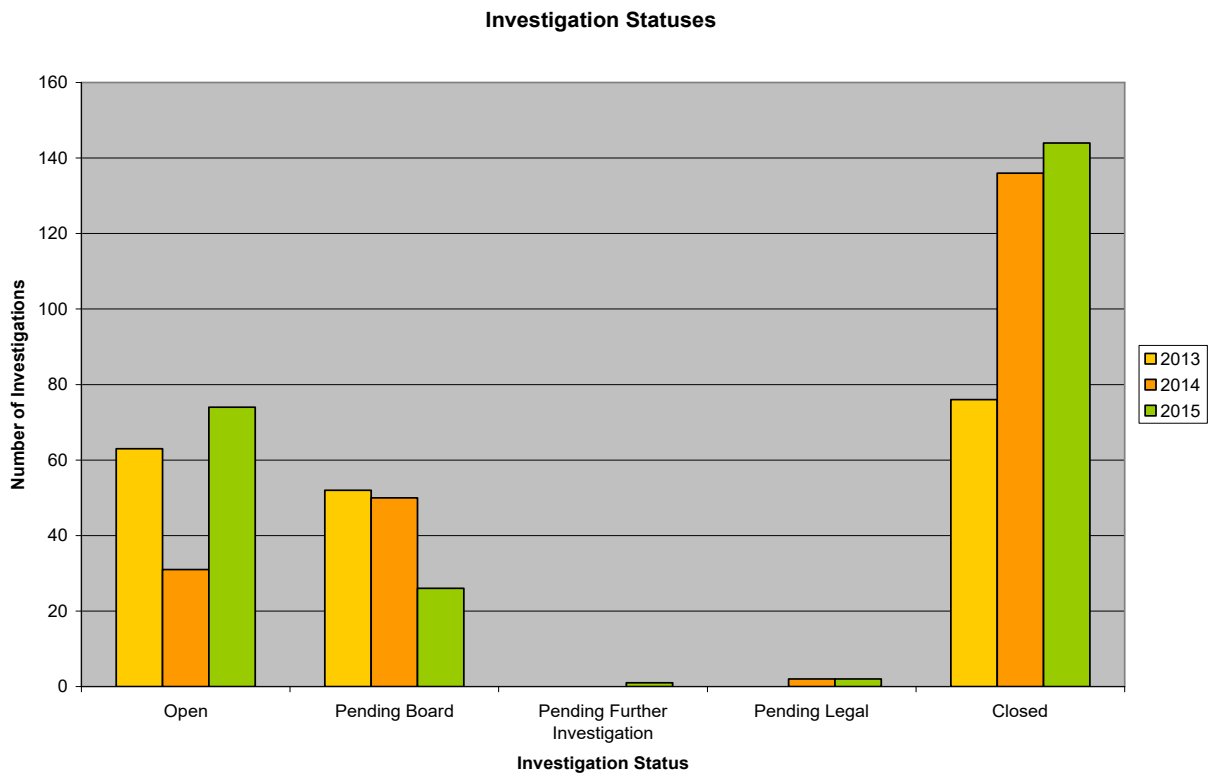
Appendix C: *Investigation Data*

Please see separate Excel spreadsheet data.

Appendix D: *Medication Error Data*

Please see separate Excel spreadsheet data.

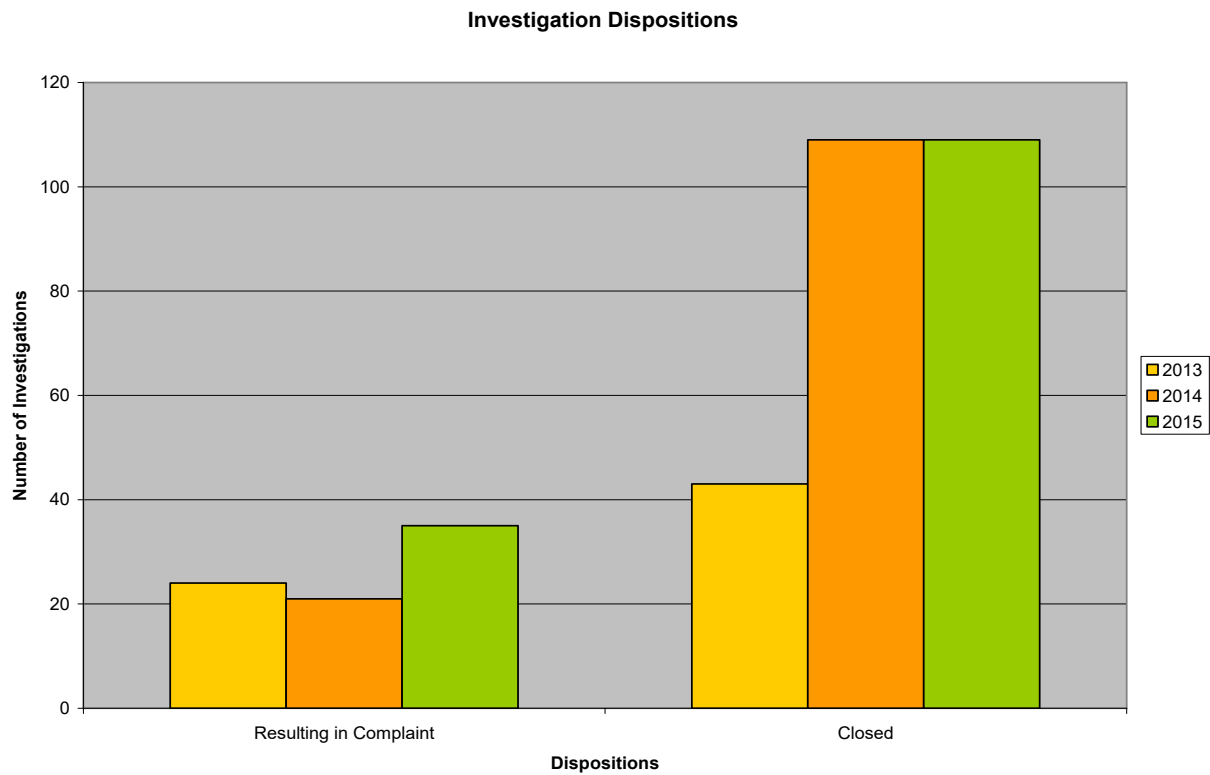
Appendix E: Investigation Statuses



Status	2013	2014	2015
Open	63	31	74
Pending Board	52	50	26
Pending Further Investigation	0	0	1
Pending Legal	0	2	2
Closed	76	136	144
Total	191	219	247

What this means: The total number of investigations that were opened in 2015 increased from previous years. The increase is attributed to a focus during the intake process to not open formal complaints unless there is clear evidence of a violation against the licensee. Rather, the board will open an investigation to collect additional evidence in an attempt to substantiate the allegations. This practice has led to an increase in investigations. The total number of closed investigations in 2015 shows a continued increase in the efforts of the Board to process files expeditiously.

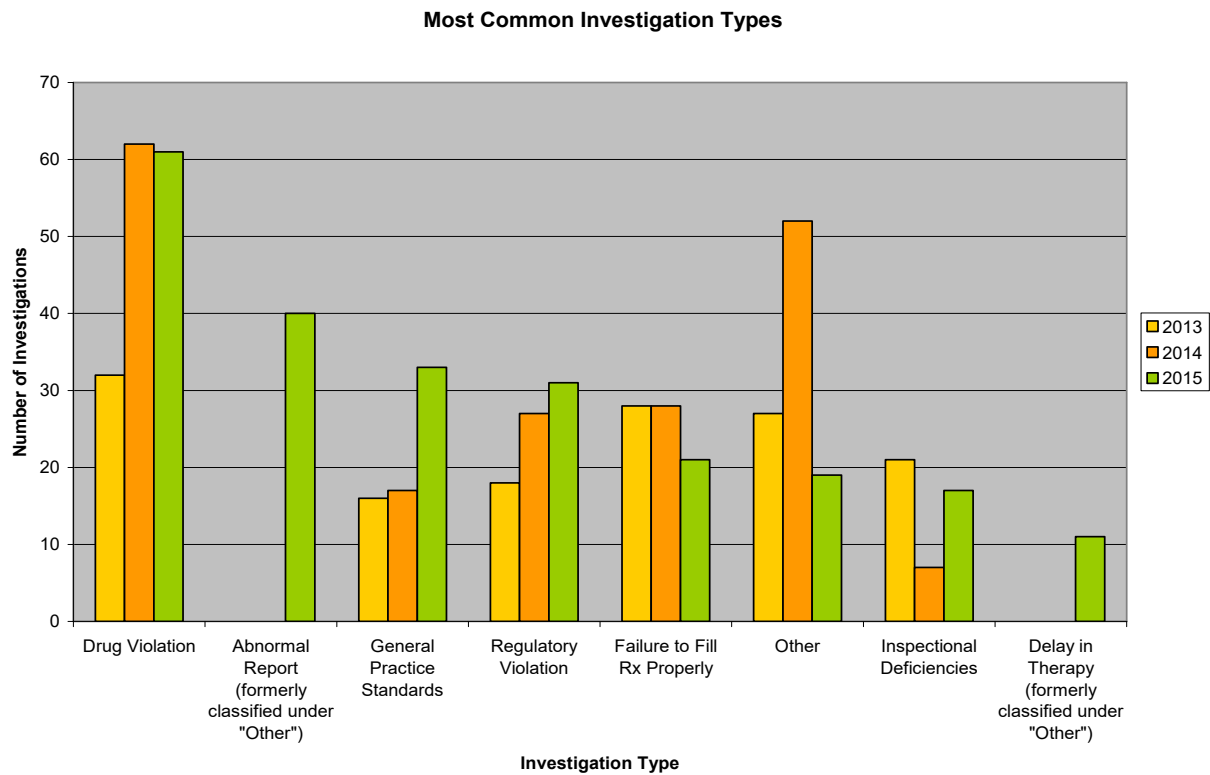
Appendix F: Investigation Dispositions



Disposition	2013	2014	2015
Resulting in Complaint	24	21	35
Closed	43	109	109

What this means: As described above, the Board processed more files in 2015, resulting in a maintained increase in file closures. Many of the investigations were closed and formal complaints were not opened because they lacked Board jurisdiction or did not rise to the level of a Board regulation or statutory violation.

Appendix G: Most Common Investigation Types

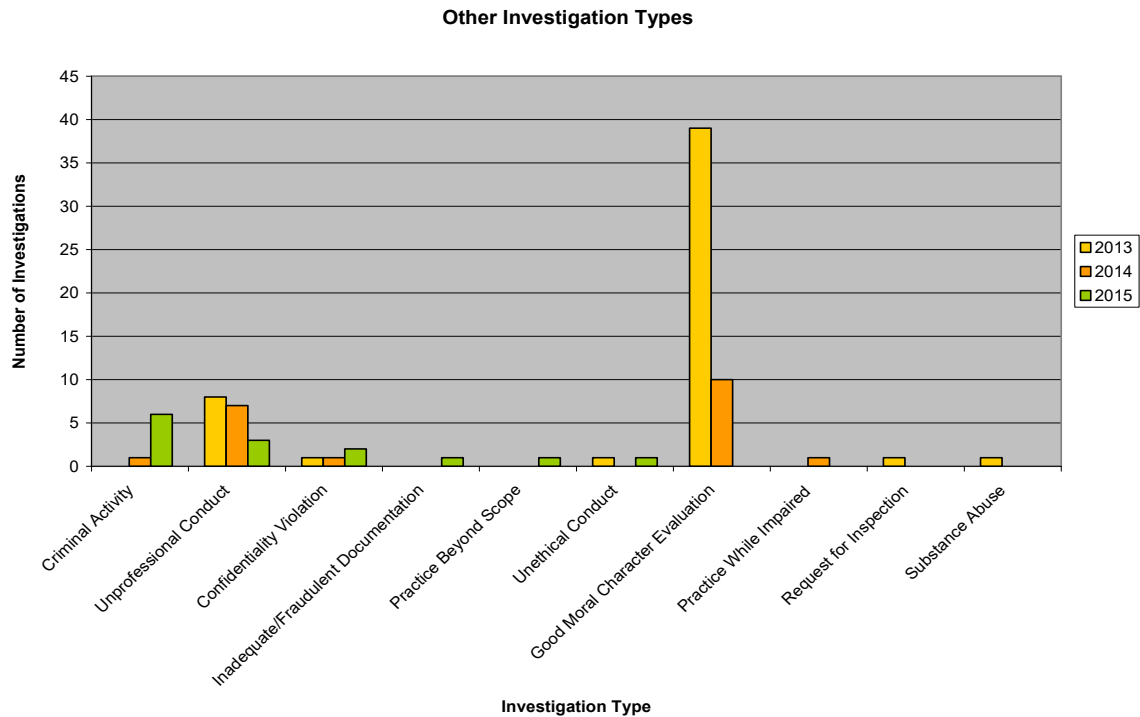


Investigation Type	2013	2014	2015
Drug Violation	32	62	61
Abnormal Report (formerly classified under "Other")	N/A	N/A	40
General Practice Standards	16	17	33
Regulatory Violation	18	27	31
Failure to Fill Rx Properly	28	28	21
Other	27	52	19
Inspectional Deficiencies	21	7	17
Delay in Therapy (formerly classified under "Other")	N/A	N/A	11

What this means: During 2015, Board staff continued to monitor controlled substance loss reports (classified as “Drug Violations”) and abnormal results related to sterile compounding, resulting in an increase in investigations related to these events. With the creation of the new investigation and complaint types “Abnormal Results” and “Delay in Therapy,” the Board saw a decrease in the number of investigations classified as “Other”. The Board saw a slight increase in the number of “Regulatory Violations” due to the encouragement of self-reporting continuing education deficiencies. Licensees who self-reported continuing education deficiencies were given the opportunity to correct the deficiency prior to the investigation being presented to the

Board, rather than a formal complaint opened against their license with non-disciplinary stayed probation effective until the deficiency was corrected.

Appendix H: Other Investigation Types

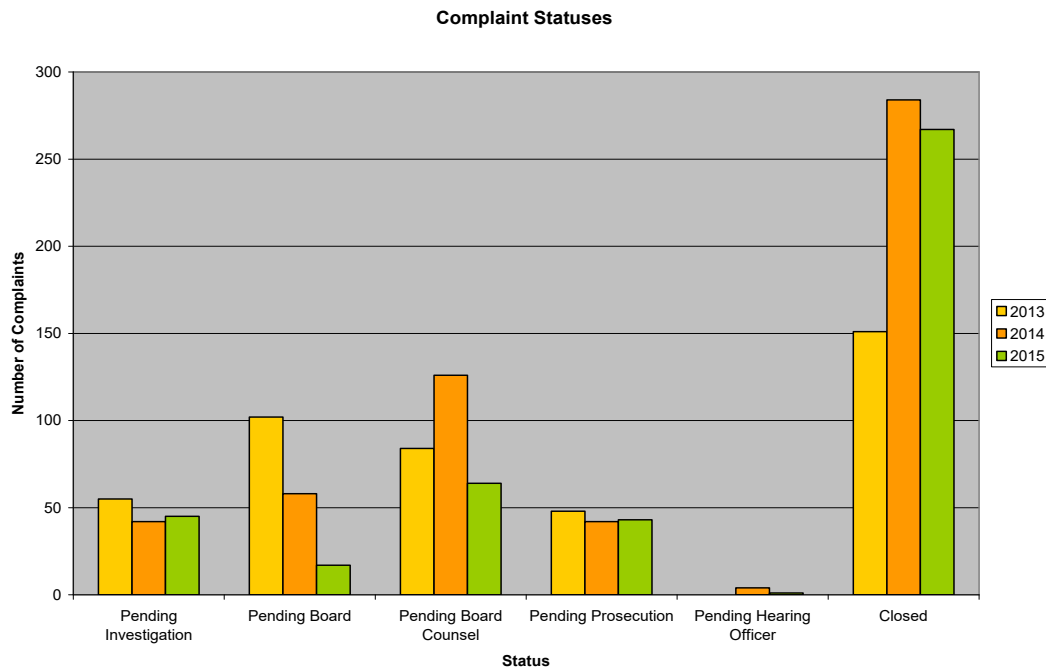


Investigation Type	2013	2014	2015
Criminal Activity	0	1	6
Unprofessional Conduct	8	7	3
Confidentiality Violation	1	1	2
Inadequate/Fraudulent Documentation	0	0	1
Practice Beyond Scope	0	0	1
Unethical Conduct	1	0	1
Good Moral Character Evaluation	39	10	0
Practice While Impaired	0	1	0
Request for Inspection	1	0	0
Substance Abuse	1	0	0

What this means: In 2015, the Board saw an increase in the number of criminal activity investigations. This is the result of the encouragement of self-reporting. Those licensees that reported less serious crimes that were not related to the practice of pharmacy were investigated and presented to the Board, but formal complaints were not opened. The largest decrease in investigations was “Good Moral Character Evaluation,” which was removed from investigations entirely and shifted to an administrative process conducted by Board staff, as it is part of the

initial licensure process. Investigations conducted by the Office of Public Protection are limited to licensed individuals and entities.

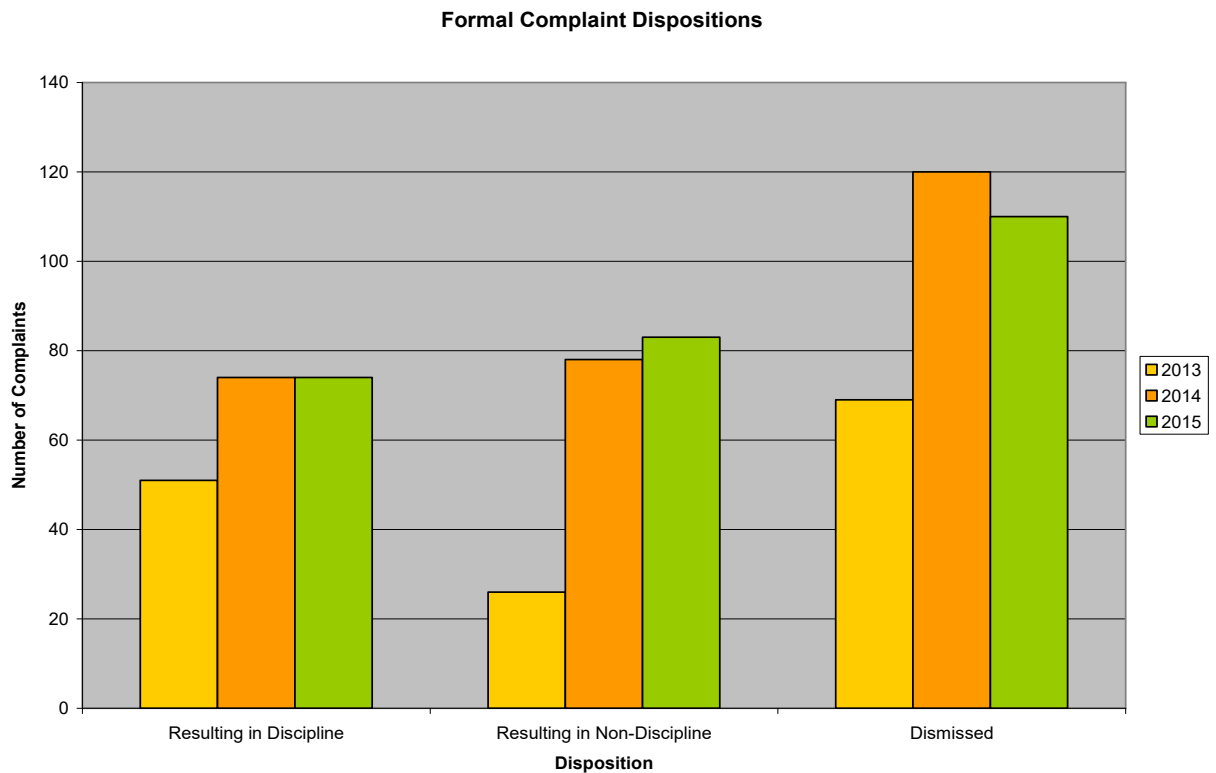
Appendix I: Formal Complaint Statuses



Status	2013	2014	2015
Pending Investigation	55	42	45
Pending Board	102	58	17
Pending Board Counsel	84	126	64
Pending Prosecution	48	42	43
Pending Hearing Officer	0	4	1
Closed	151	284	267
Total	440	556	437

What this means: In 2015, Board staff maintained the expedited formal complaint processing system established in 2014. Overall, the data depicts that the high rate of formal complaint closures established in 2014 was maintained in 2015. Most importantly, the data depicts an end to the backlog of complaints waiting to be heard by the Board. At the end of 2015, complaints that are updated to Pending Board are routinely heard at the next scheduled Board meeting.

Appendix J: Formal Complaint Dispositions

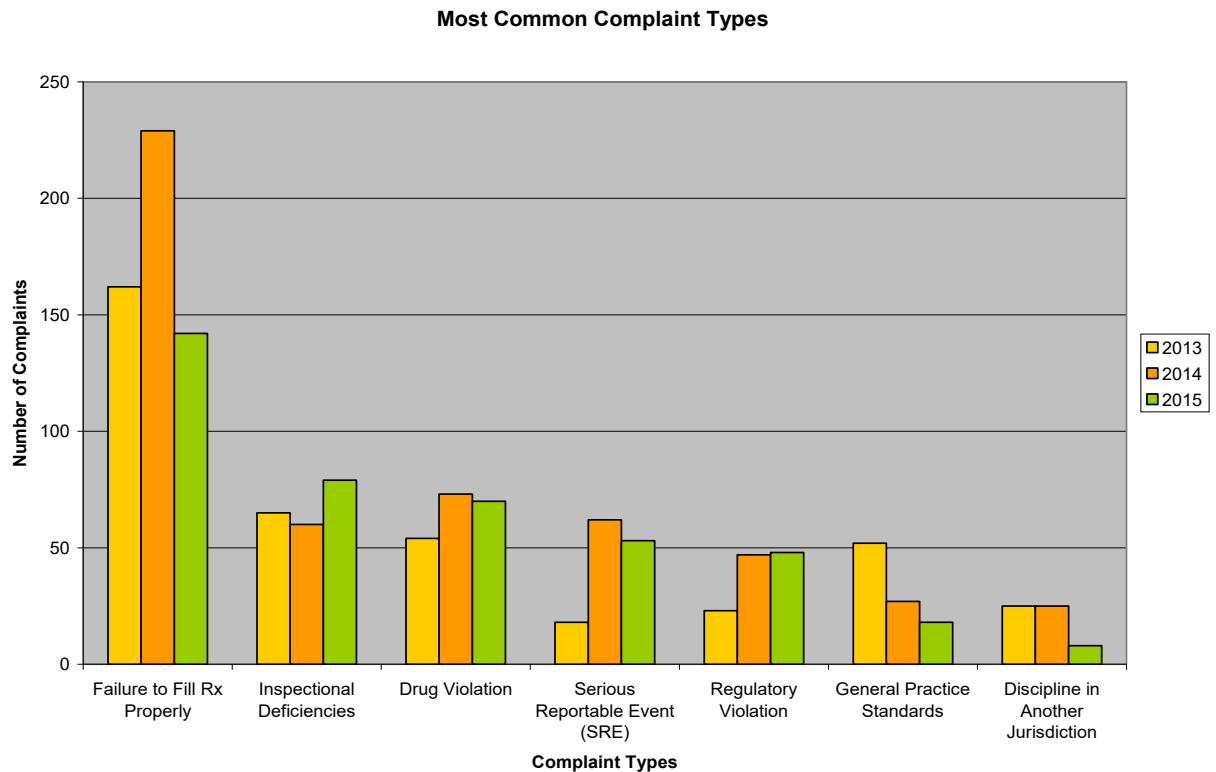


Disposition	2013	2014	2015
Resulting in Discipline	51	74	74
Resulting in Non-Discipline	26	78	83
Dismissed	69	120	110

What this means: As described above, the Board continued to process complaints expeditiously in 2015, resulting in a marked increase in all formal complaint dispositions since 2013. Furthermore, the continued implementation of a Just Culture⁶ has contributed to the increase in non-disciplinary dispositions (i.e., stayed probation with required continuing education requirements) and dismissals for formal complaints after careful consideration by the Board.

⁶ A *Just Culture* recognizes that individual practitioners should not be held accountable for system failings over which they have no control. A *Just Culture* also recognizes many individual or “active” errors represent predictable interactions between human operators and the systems in which they work. However, in contrast to a culture that touts “no blame” as its governing principle, a *Just Culture* does not tolerate conscious disregard of clear risks to patients or gross misconduct (e.g., falsifying a record, performing professional duties while intoxicated). Excerpted from: Marx D. Patient Safety and the “*Just Culture*”: A Primer for Health Care Executives. New York, NY: Columbia University; 2001. Available at: <http://www.safer.healthcare.ucla.edu/safer/archive/ahrq/FinalPrimerDoc.pdf>

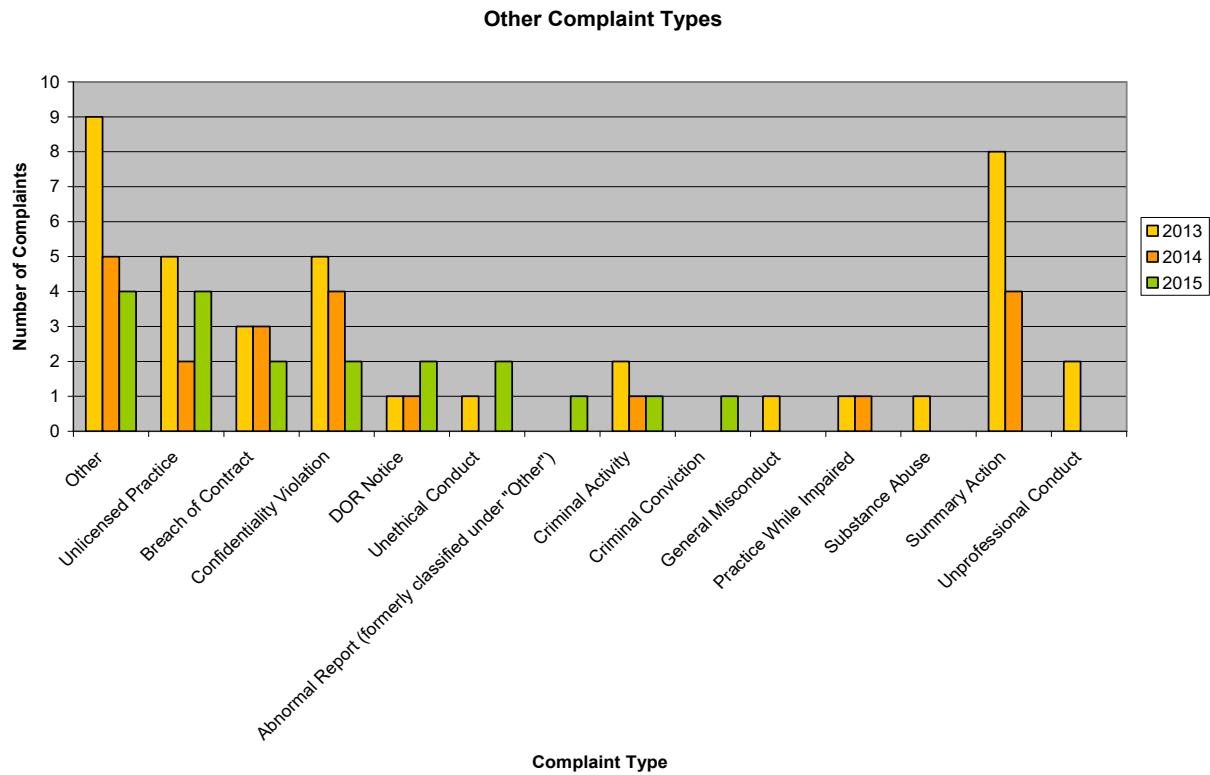
Appendix K: Most Common Complaint Types



Complaint Type	2013	2014	2015
Failure to Fill Rx Properly	162	229	142
Inspectional Deficiencies	65	60	79
Drug Violation	54	73	70
Serious Reportable Event (SRE)	18	62	53
Regulatory Violation	23	47	48
General Practice Standards	52	27	18
Discipline in Another Jurisdiction	25	25	8

What this means: A continued and significant field presence in 2015 uncovered regulatory violations and inspectional deficiencies resulting in formal complaints. Investigators continue to pay close attention to the reports of drug losses and diversions, resulting in formal complaints for this type (drug violations). The most common complaint type, “Failure to Fill RX Properly,” showed a significant statistical decrease. However on closer examination, the high number of “Failure to Fill RX Properly” complaints in 2014 was an anomaly, as many of them were backlogged complaints from previous years with new companion complaints processed in 2014.

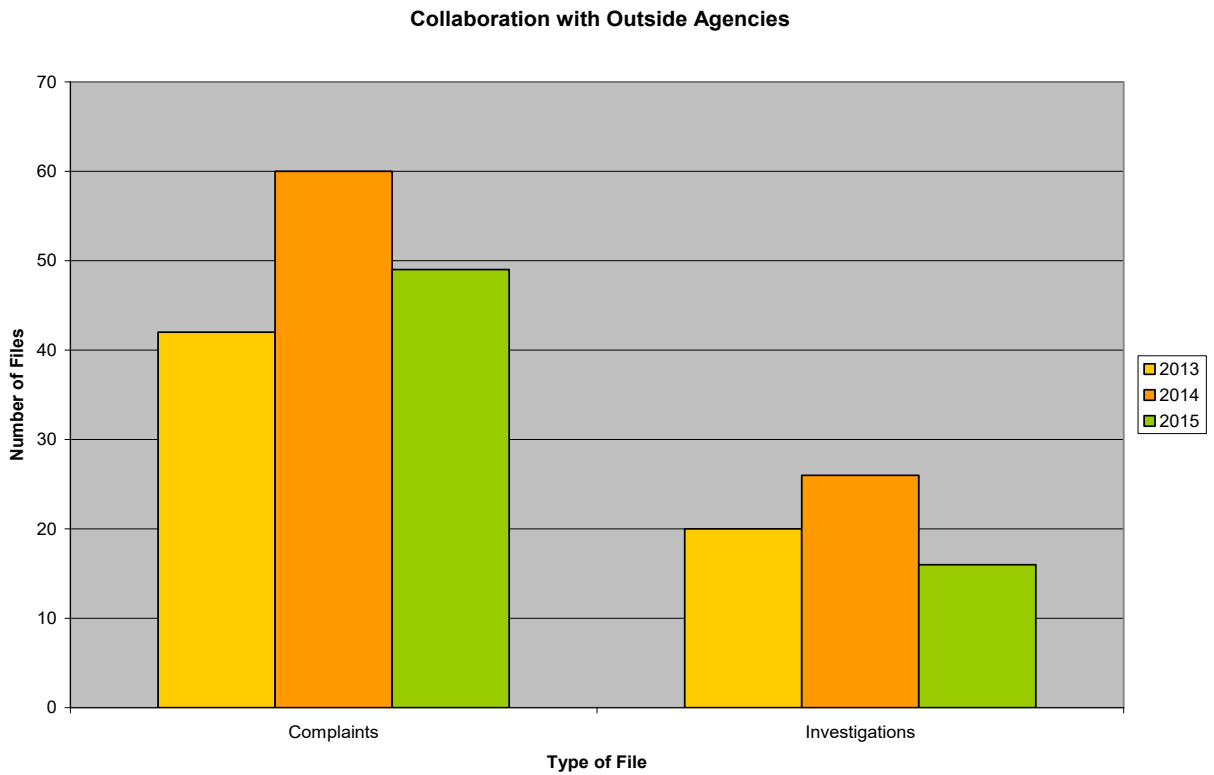
Appendix L: Other Complaint Types



Complaint Type	2013	2014	2015
Other	9	5	4
Unlicensed Practice	5	2	4
Breach of Contract	3	3	2
Confidentiality Violation	5	4	2
DOR Notice	1	1	2
Unethical Conduct	1	0	2
Abnormal Report (formerly classified under "Other")	n/a	n/a	1
Criminal Activity	2	1	1
Criminal Conviction	0	0	1
General Misconduct	1	0	0
Practice While Impaired	1	1	0
Substance Abuse	1	0	0
Summary Action	8	4	0
Unprofessional Conduct	2	0	0

What this means: The most significant change since 2013 was the decrease in “Summary Action” by the Board. In 2015, the Board took no Summary Action on any licensees. With the recent focus on inspections of all pharmacies in Massachusetts in 2014 and 2015, instances of non-compliance that rise to a level of a serious or immediate threat to public, health, safety and wellness and necessitate Board action have not developed. The next largest decrease since 2013 was complaints classified as “Other.” The decrease is attributed to the creation of a new complaint type, “Abnormal Results,” which also decreased in 2015. Pharmacies engaged in sterile compounding have adjusted to these new reporting requirements and Board staff has educated sterile compounding pharmacies concerning appropriate responses to “Abnormal Results.”

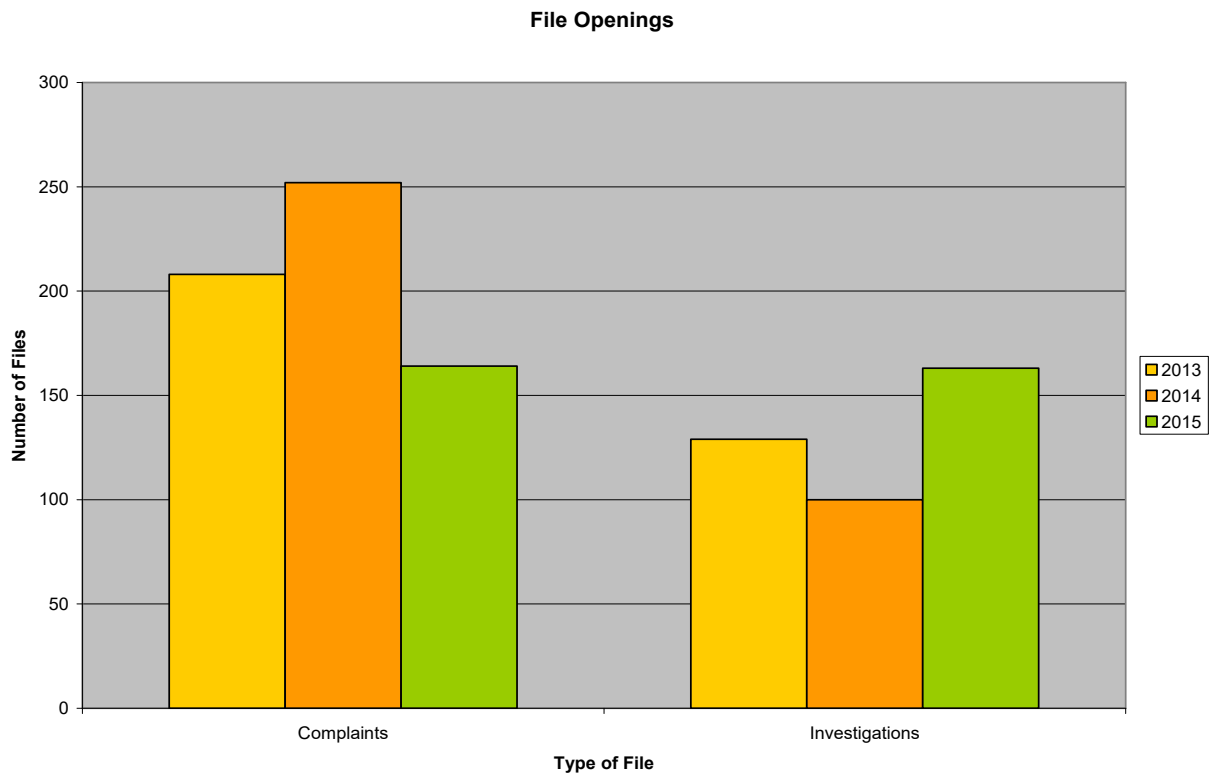
Appendix M: Collaboration with Outside Agencies



Collaboration with Outside Agencies	2013	2014	2015
Complaints	42	60	49
Investigations	20	26	16

What this means: In 2015, the investigators continued to collaborate with outside agencies, including federal, state and local law enforcement agencies. Statistically, this number appears to decrease. However on closer examination, the high number of cases involving collaboration with outside agencies in 2014 also includes backlogged cases from previous years, many of which were closed in 2014. The Board and Board Staff continue to forge strong relationships with our state and federal partners and will collaborate on cases where doing so is in the best interest of public health and safety.

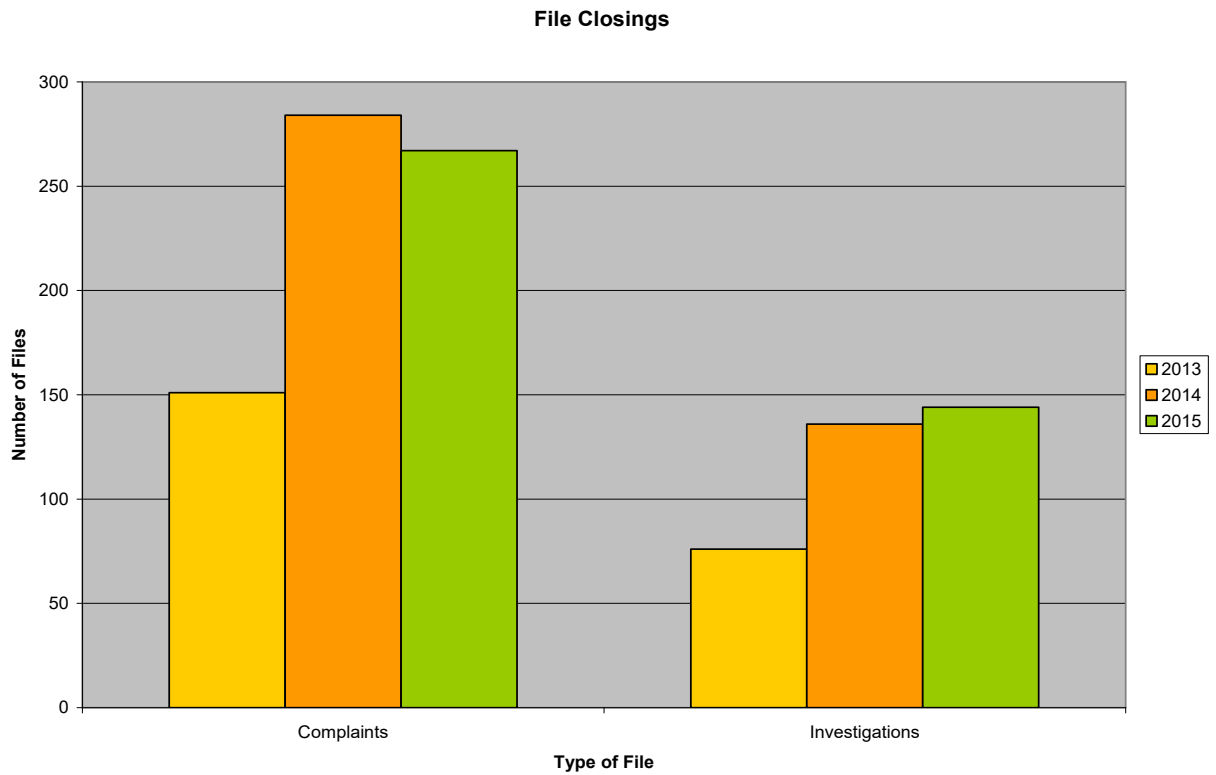
Appendix N: *File Openings*



Openings	2013	2014	2015
Complaints	208	252	164
Investigations	129	100	163

What this means: In 2014, there was a distinct rise in formal complaints due to an increase in prescription related complaints and also a concerted effort to address the backload of cases that began in 2013. Even accounting for the unusually high number of complaints in 2014, a statistical comparison of years shows a significant decrease in the opening of formal complaints in 2015. The rise in staff assignments in 2015 is also directly related to the decrease in complaints. As described in Appendix E, staff has focused on opening investigations to establish the facts and review evidence prior to determining whether a violation may have occurred and refrain from opening formal complaints unless there is clear evidence of a violation against the licensee.

Appendix O: *File Closings*



Closings	2013	2014	2015
Complaints	151	284	267
Investigations	76	136	144

What this means: In 2015, the Board closed a total of 411 files, a slight decrease from files closed in 2014, but an almost eighty percent increase over 2013. Investigators and Board staff continue to work diligently to conduct investigations and process files expeditiously.