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Department of Public Health
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February 1, 2017

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 & 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

Investigatory & Disciplinary Actions Conducted by the Board of Registration in Pharmacy

January 2016

Massachusetts Department of Public Health

Legislative Mandate

The following report is hereby issued pursuant to Section 25A of Chapter 112 of the Massachusetts General Laws 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 & Disciplinary Actions Conducted by the Board of Registration in Pharmacy"* is intended to track all complaints that moved through the Board from December 1, 2015 to December 1, 2016. This is the fourth 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 cases expeditiously. In 2016, much progress has been made including the following:

- The continued expedited processing of complaints and staff assignments;
- The heightened monitoring of drug losses and other drug violations;
- A decrease in non-disciplinary dispositions with the continued implementation of Just Culture through the use of voluntary anticipatory continuing education credits for specified complaint types;
- The continued collaboration with local, state and federal agencies;
- A continued robust field presence uncovering regulatory violations and inspectional deficiencies; and
- A focus on information gathering at the investigation level prior to initiating formal complaints.

Since the first annual report in 2013, the processes put in place have allowed the Board and Board staff to move 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 continue to fine-tune the Board's processes and procedures and ensure that quality improvement is monitored, continuing in 2017 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 limit[1] 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, 2015-December 1, 2016.

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*.

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 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 complainants[3] and other witnesses. When the investigation is complete, the investigator writes a *report*. The report is then reviewed by the *Director of Investigations* to ensure accuracy and completeness.

Next, the Director of Pharmacy Investigations 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 slotted 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 length of investigation and length of time until 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 Q 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 cases listed, the report indicates the number assigned to each case, the name and license number of the licensees involved, the violation alleged,[5] and if the case is beyond the investigation stage, the name of any local, state or federal agency that collaborated in the investigation. For each of the cases 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

[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 "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. Violations marked "Other" are instances that do not fall under typical categories the licensure database. Each year, the files in this category are reviewed to determine if new categories need to be established.

the case 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 externally reported. If a "not applicable (N/A)" is noted, it indicates that the Investigation or Complaint did not proceed to that 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 cases related to the same medication error, for all responsible licensees (pharmacy, pharmacist, pharmacy intern, pharmacy technician, etc.)

This Report is comprised primarily of data that has been collected and analyzed from December 1, 2015 through December 1, 2016. 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 Q 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.

Conclusion

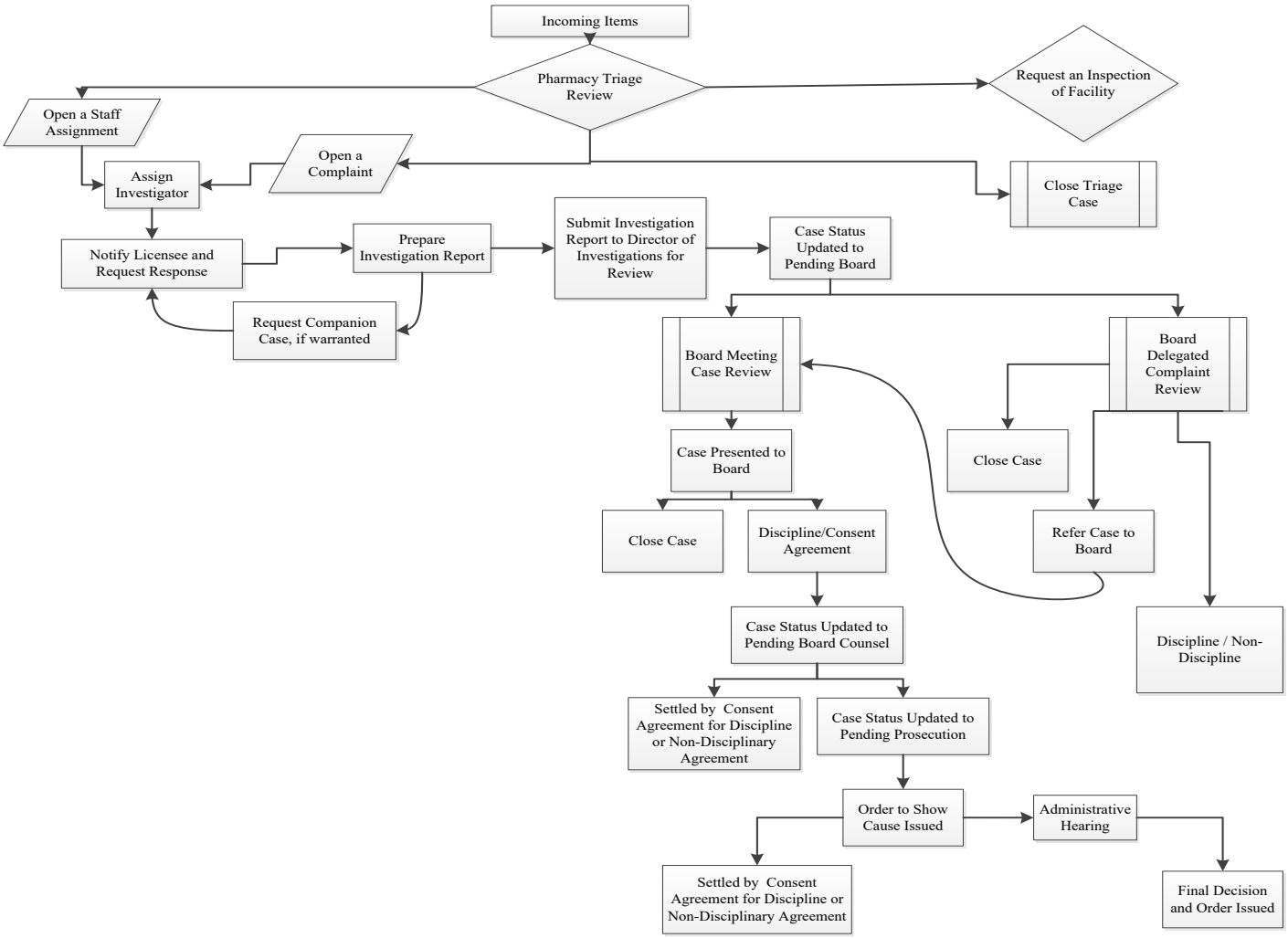
The systematic changes and improvements that have been put in place over the last four years reflect a Board that has policies and procedures that are clear, effective, and efficient. In addition, these changes also support a group of pharmacy investigators that continue to have a commanding field presence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

This report details all formal complaints and investigations that were pending, received, initiated, or opened by the Board during the period of December 1, 2015 through December 1, 2016. Significant progress has been made including the following:

- In 2016, Board staff continued the efficient processing system established in 2014. Overall, the data depicts that the high rate of case closures established in 2014 was maintained in 2016, despite the rise of opening volume.
- The Board continued to process cases expeditiously in 2016, resulting in an 86.7% increase in case closures since 2013.
- The total number of investigations that were opened in 2016 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 encourage self-reports of continuing education deficiencies, resulting in an increase in investigations related to these events.
- A continued and significant field presence in 2016 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 decrease as complaint volume stabilizes. 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.
- The Board and staff continue to forge strong relationships with our local, state and federal partners and will collaborate on cases where doing so is in the best interest of public health and safety.

As the Board and staff move forward they intend to continue monitoring and making quality improvements in the investigation and processing 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.

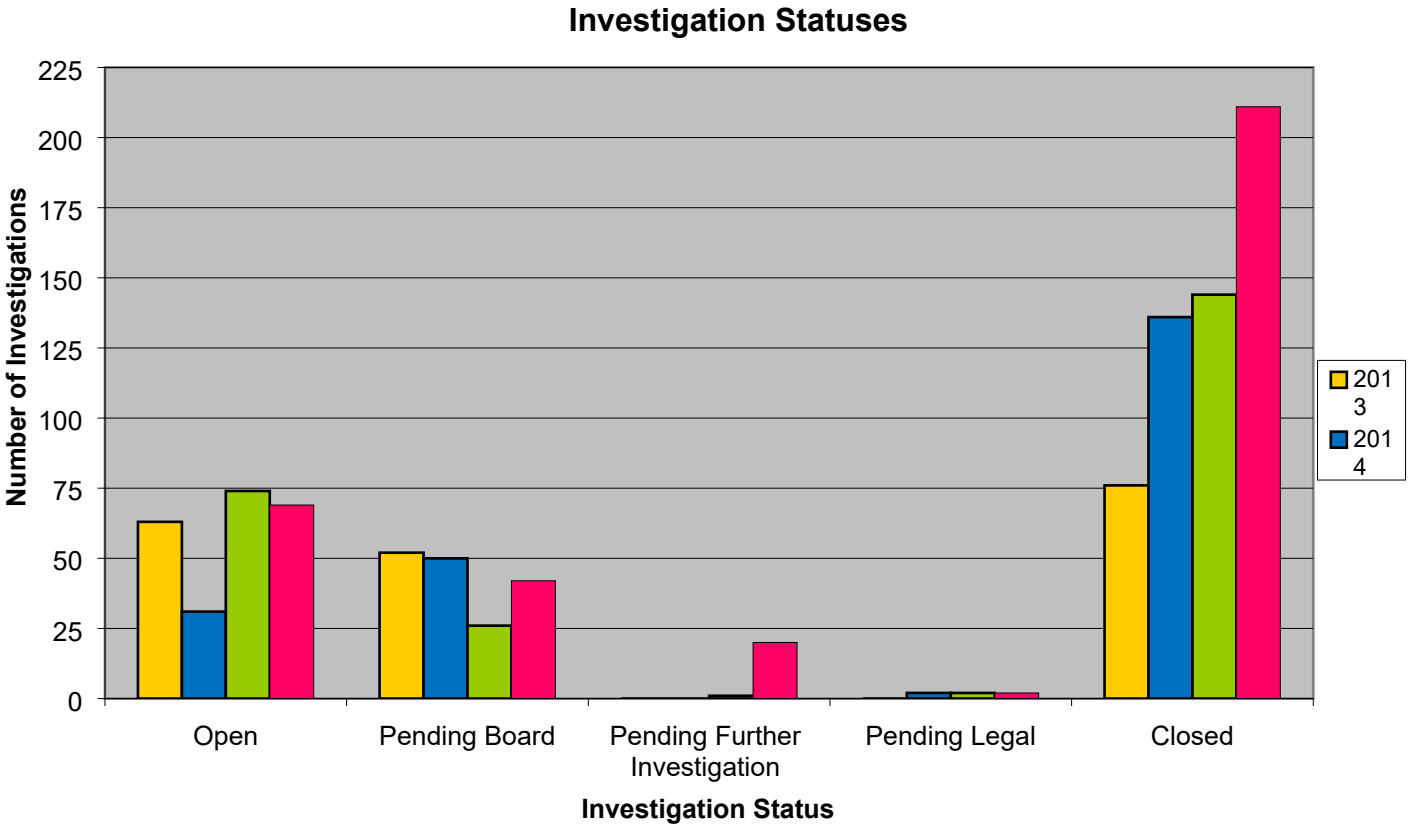
Appendix C: *Investigation Data*

Please see separate Excel spreadsheet data.

Appendix D: *Medication Error Data*

Please see separate Excel spreadsheet data.

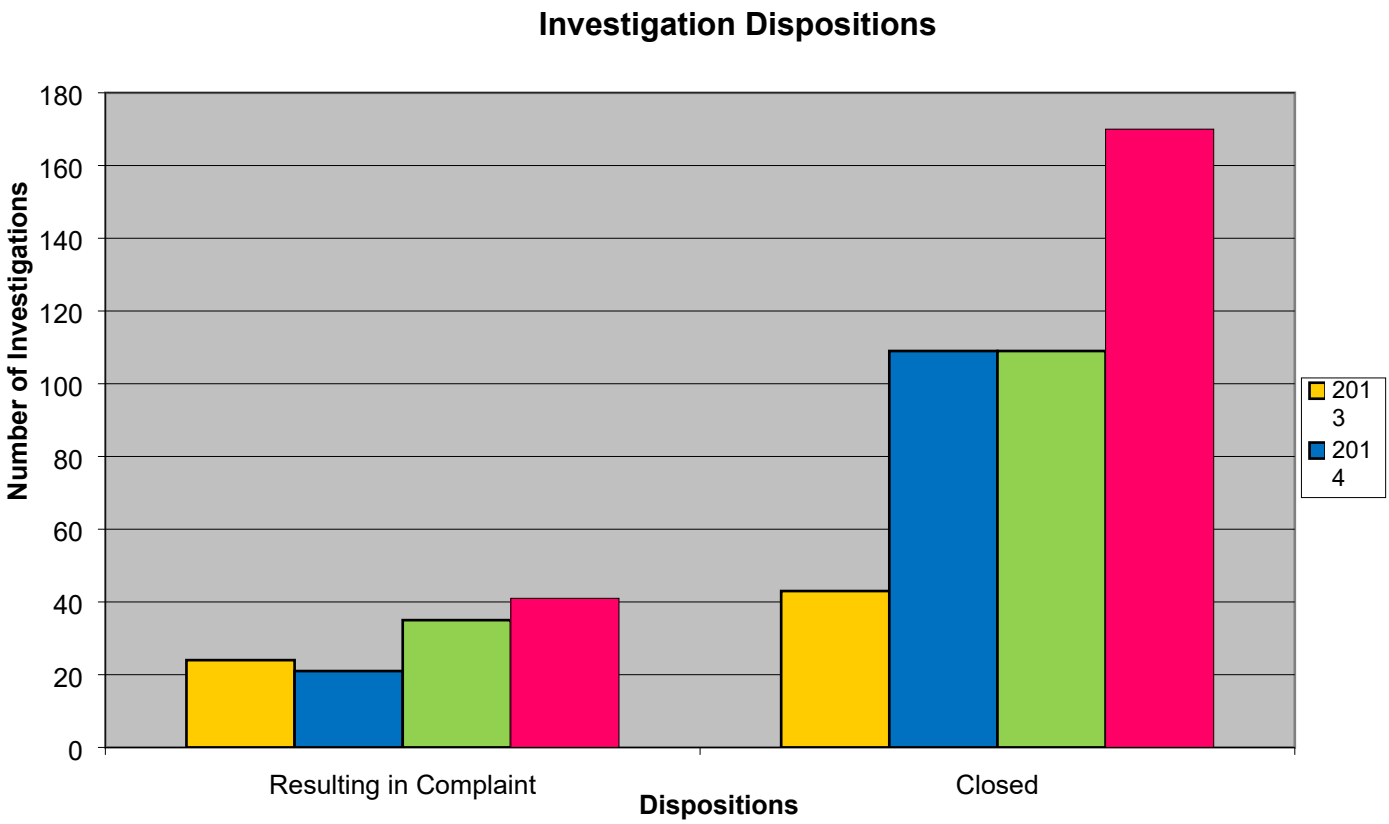
Appendix E: *Investigation Statuses*



Status	2013	2014	2015	2016
Open	63	31	74	69
Pending Board	52	50	26	42
Pending Further Investigation	0	0	1	20
Pending Legal	0	2	2	2
Closed	76	136	144	211
Total	**191**	**219**	**247**	**344**

What this means: The total number of active investigations in 2016 increased from previous years. The increase is attributed to a focus on evaluating the evidence available at the time of intake. If there is not clear evidence of a violation, Board staff will open an investigation to gather evidence in an attempt to substantiate the allegations. This practice has led to an increase in investigations. The total number of closed investigations in 2016 shows a continued increase in the efforts of the Board and staff to process cases expeditiously.

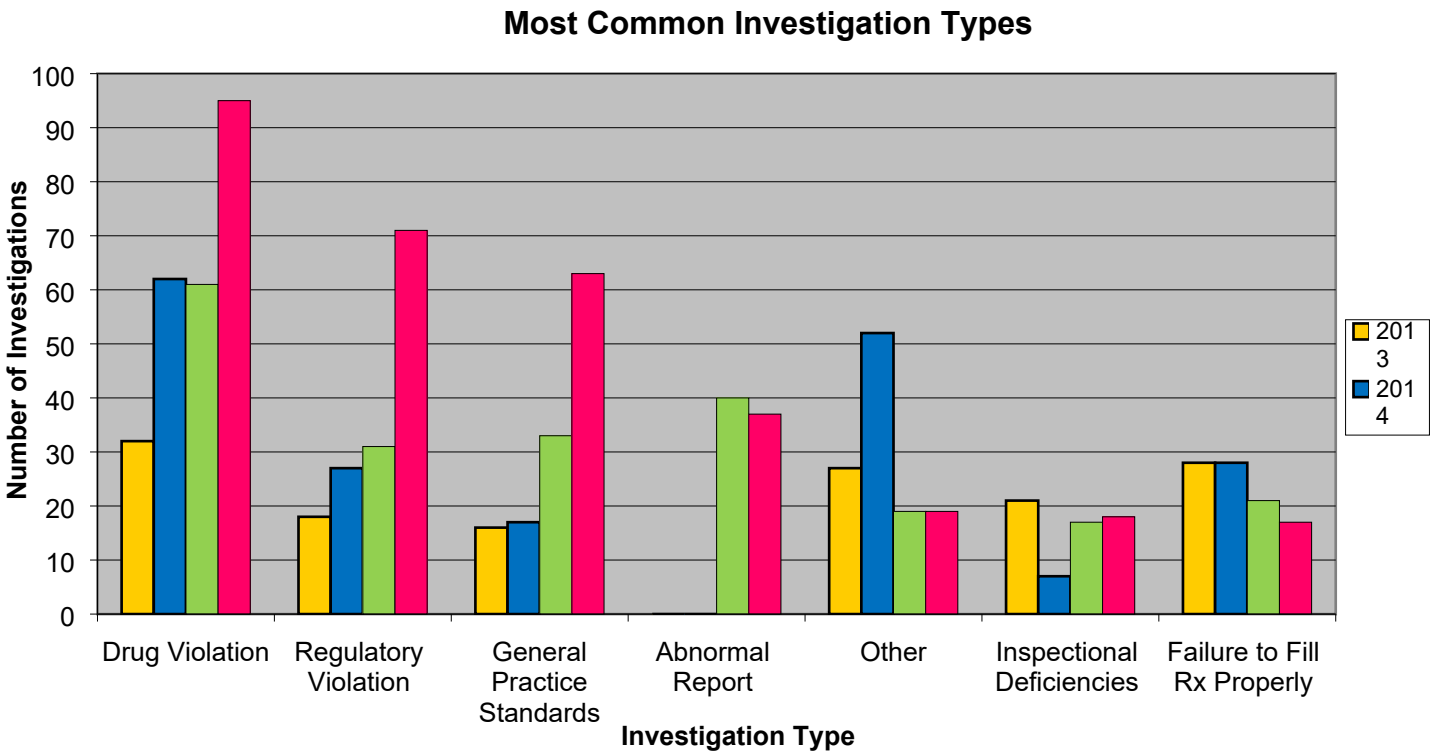
Appendix F: *Investigation Dispositions*



Disposition	2013	2014	2015	2016
Resulting in Complaint	24	21	35	41
Closed	43	109	109	170

What this means: As described in Appendix E, the Board and staff processed more cases in 2016, resulting in a maintained increase in case closures. Many of the investigations were closed and formal complaints were not opened because they did not rise to the level of a Board regulation or statutory violation or for the lack of evidence to substantiate that a violation occurred.

Appendix G: *Most Common Investigation Types*

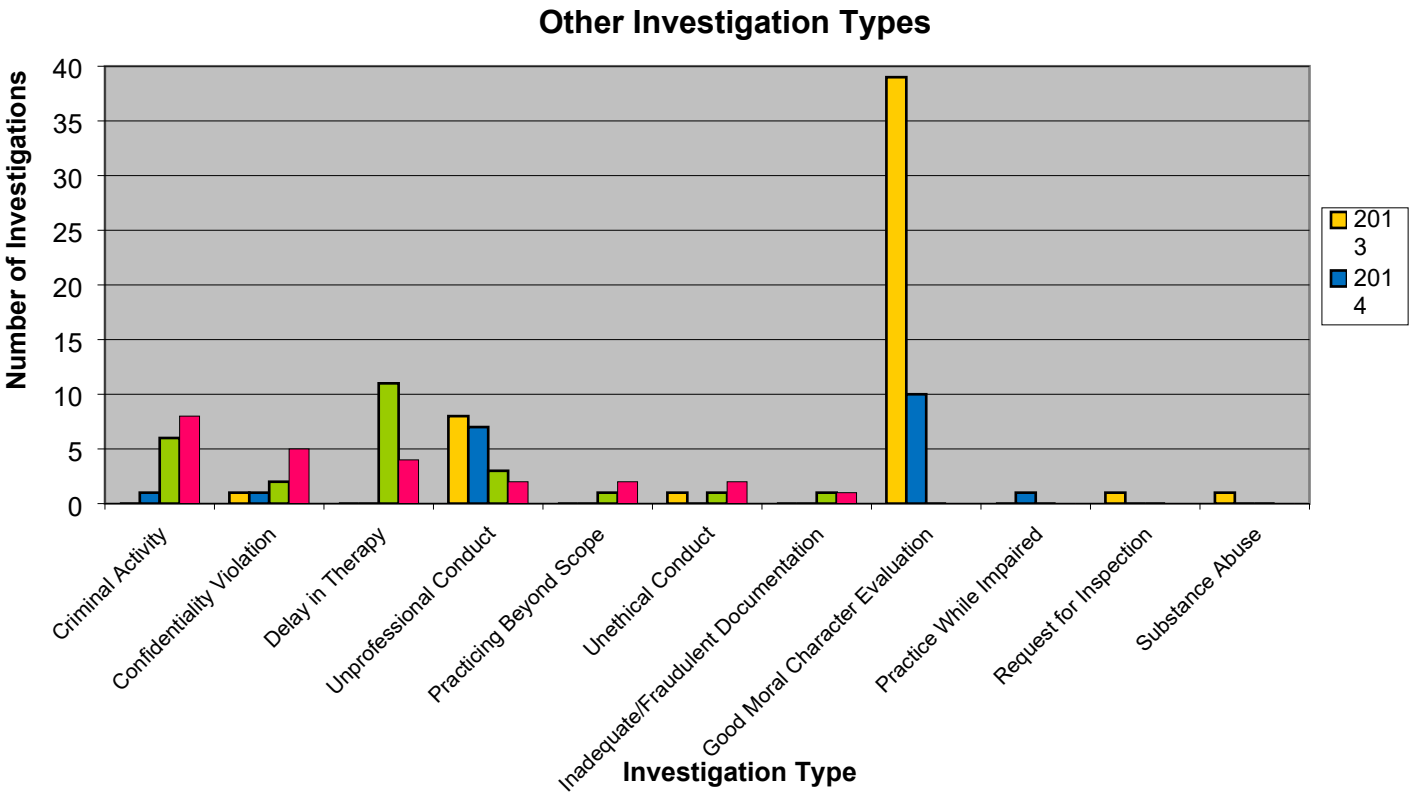


Investigation Type	2013	2014	2015	2016
Drug Violation	32	62	61	95
Regulatory Violation	18	27	31	71
General Practice Standards	16	17	33	63
Abnormal Report	n/a	n/a	40	37
Other	27	52	19	19
Inspectional Deficiencies	21	7	17	18
Failure to Fill Rx Properly	28	28	21	17

What this means: During 2016, Board staff continued to monitor controlled substance loss reports (classified as "Drug Violations") resulting in a significant increase in investigations related to these losses. In 2016, the Board instituted Policy 16-02 in an effort to expedite such investigations, informing all licensees of the information that is required for the most frequent controlled substance loss investigations. The Board continued to see an increase in the number of "Regulatory Violations" due to the encouragement of self-reporting continuing education deficiencies following the 2014 implementation of new continuing education requirements as required by law. Despite issuing an Alert shortly after the statute was signed into law, many of these self-reports were due to licensee confusion over the new requirements. To address this, the board issued in-depth Guidance, and 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. The Board will continue to take measures to increase awareness among licensees of the continuing education requirements.

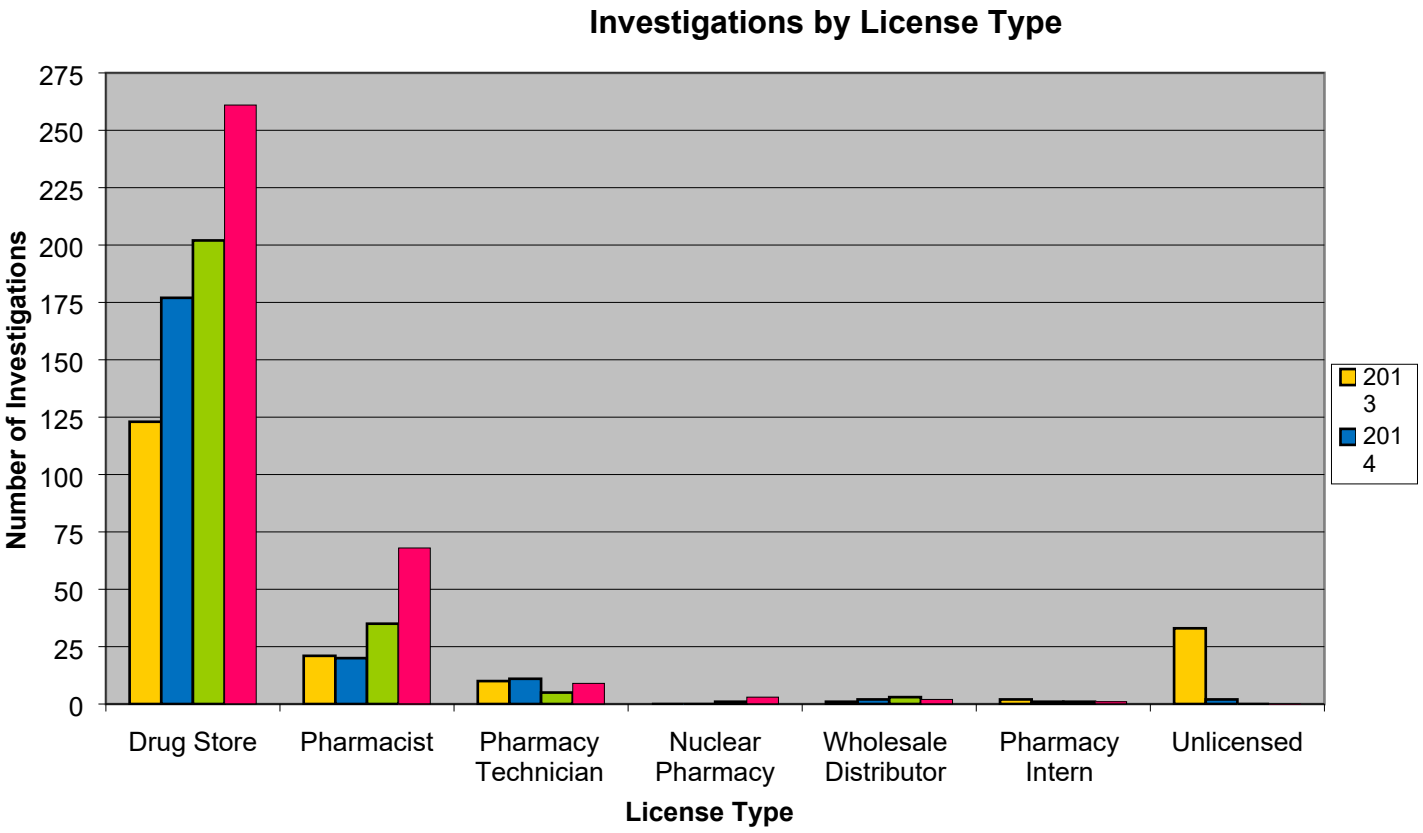
Appendix H: *Other Investigation Types*



Investigation Type	2013	2014	2015	2016
Criminal Activity	0	1	6	8
Confidentiality Violation	1	1	2	5
Delay in Therapy	0	0	11	4
Unprofessional Conduct	8	7	3	2
Practicing Beyond Scope	0	0	1	2
Unethical Conduct	1	0	1	2
Inadequate/Fraudulent Documentation	0	0	1	1
Good Moral Character Evaluation	39	10	0	0
Practice While Impaired	0	1	0	0
Request for Inspection	1	0	0	0
Substance Abuse	1	0	0	0

What this means: In 2016, the Board saw a slight increase in the number of criminal activity investigations. This is the result of the encouragement of self-reporting of criminal arrests, as required by 247 CMR 10.00. Those licensees that reported criminal arrests which 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 is still "Good Moral Character Evaluation," which was removed from investigations entirely and shifted to an administrative process conducted by Board staff in 2014.

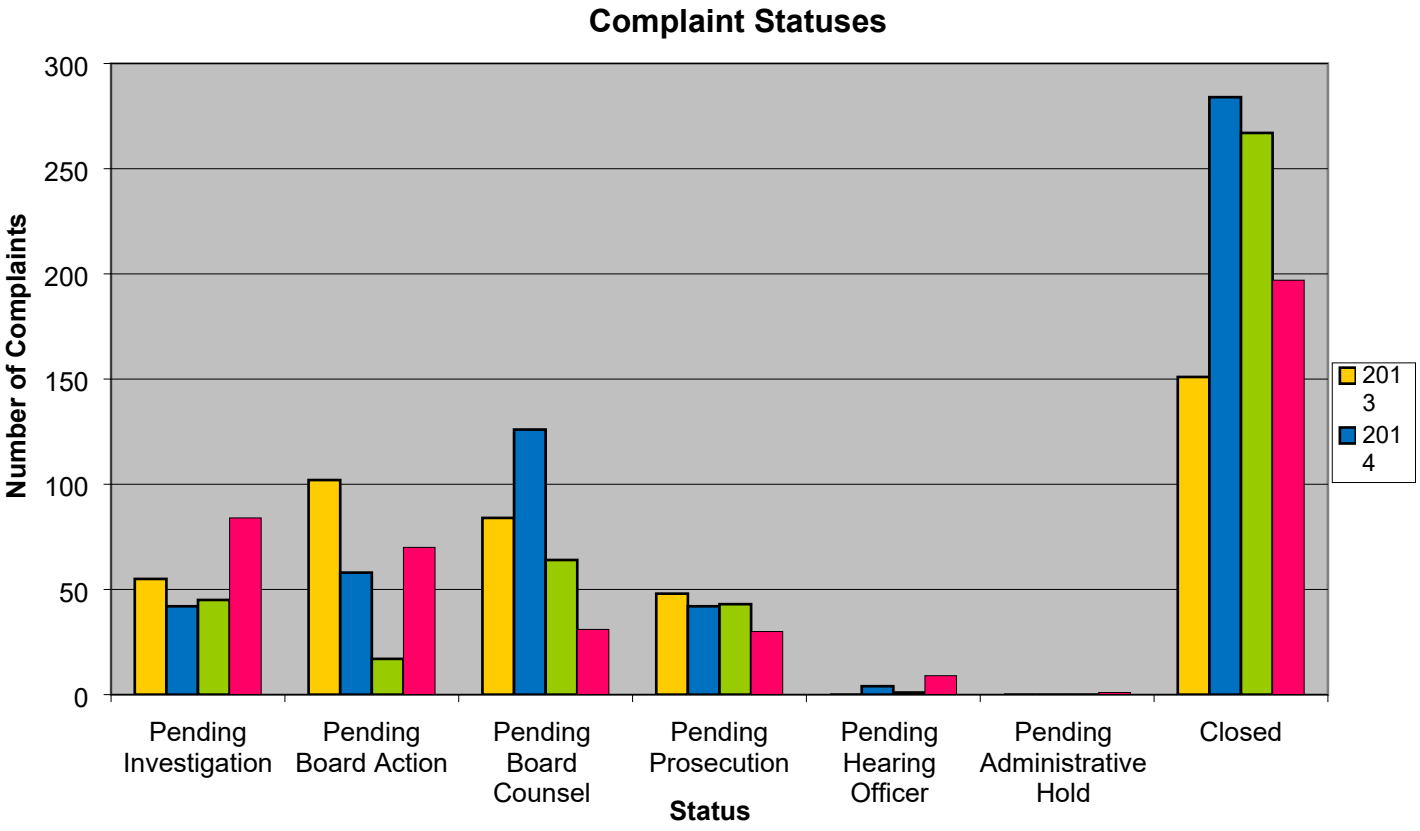
Appendix I: *Investigations by License Type*



Investigations by License Type	2013	2014	2015	2016
Drug Store	123	177	202	261
Pharmacist	21	20	35	68
Pharmacy Technician	10	11	5	9
Nuclear Pharmacy	0	0	1	3
Wholesale Distributor	1	2	3	2
Pharmacy Intern	2	1	1	1
Unlicensed	33	2	0	0

What this means: In keeping with historical figures, Drug Stores had the highest number of investigations of all license types. Investigations typically start against Drug Stores, as the Drug Store maintains and holds the records surrounding the alleged incidents. Once information is obtained from Drug Stores and reviewed, related companion cases are opened against any individual licensees involved in the alleged incidents whose conduct constitutes a violation of applicable regulation or statute.

Appendix J: *Formal Complaint Statuses*

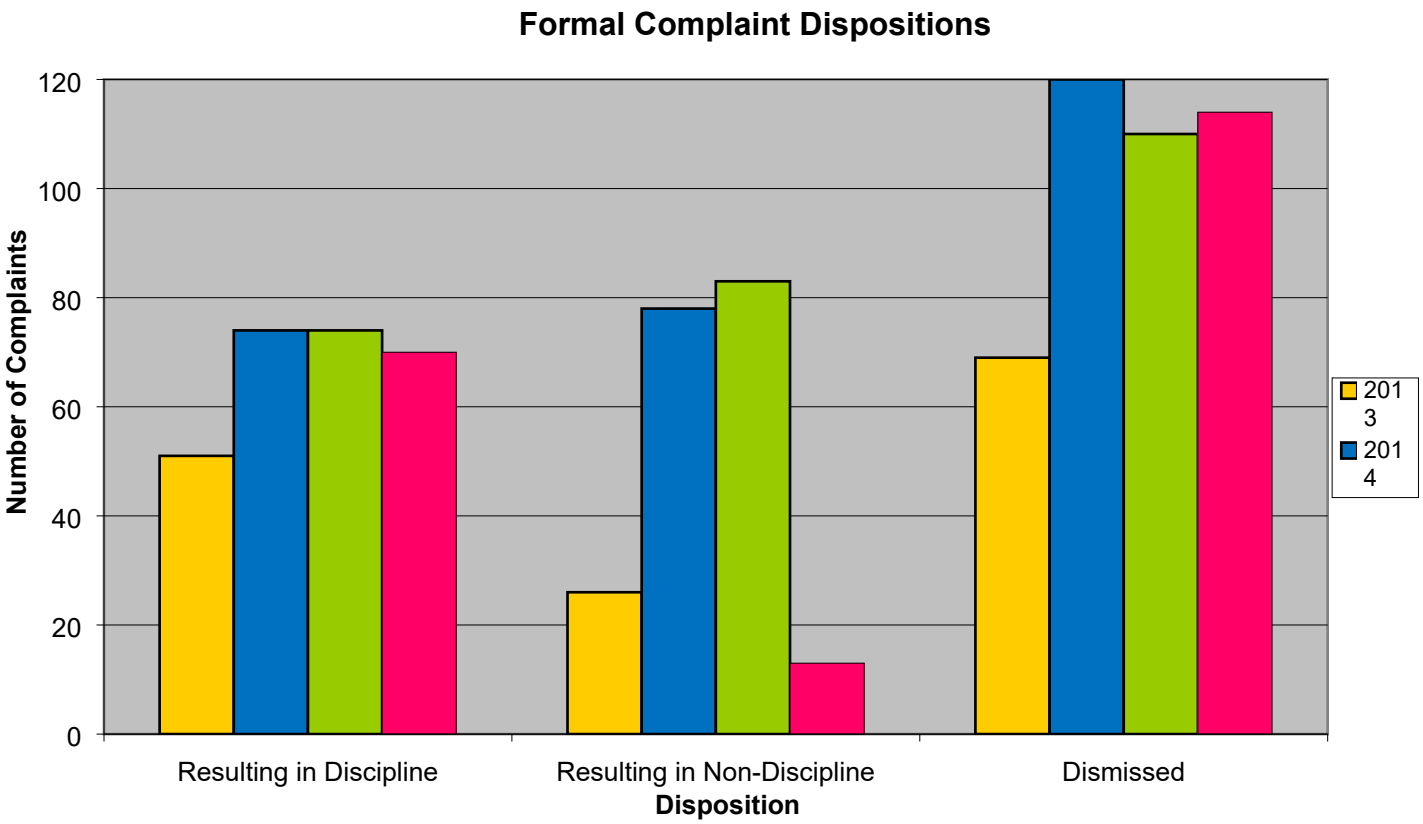


Status	2013	2014	2015	2016
Pending Investigation	55	42	45	84
Pending Board Action	102	58	17	70
Pending Board Counsel	84	126	64	31
Pending Prosecution	48	42	43	30
Pending Hearing Officer	0	4	1	9
Pending Administrative Hold	0	0	0	1
Closed	151	284	267	197
Total	**440**	**556**	**437**	**422**

What this means: In 2016, Board staff maintained the expedited formal complaint processing system established in 2014. Most importantly, the data depicts that the Board continued to process all complaints that were waiting to be heard by the Board. At the end of 2016, complaints that are updated to Pending Board are routinely heard at the next scheduled Board meeting. The data additionally shows a rise in new complaint volume during 2016. To accommodate the rising volume, field-based investigators that handle inspections are training to investigate complaints. The cross-training of all investigators will allow the Director of

Pharmacy Investigations to allocate field-based and office-based staff based on operational needs.

Appendix K: *Formal Complaint Dispositions*

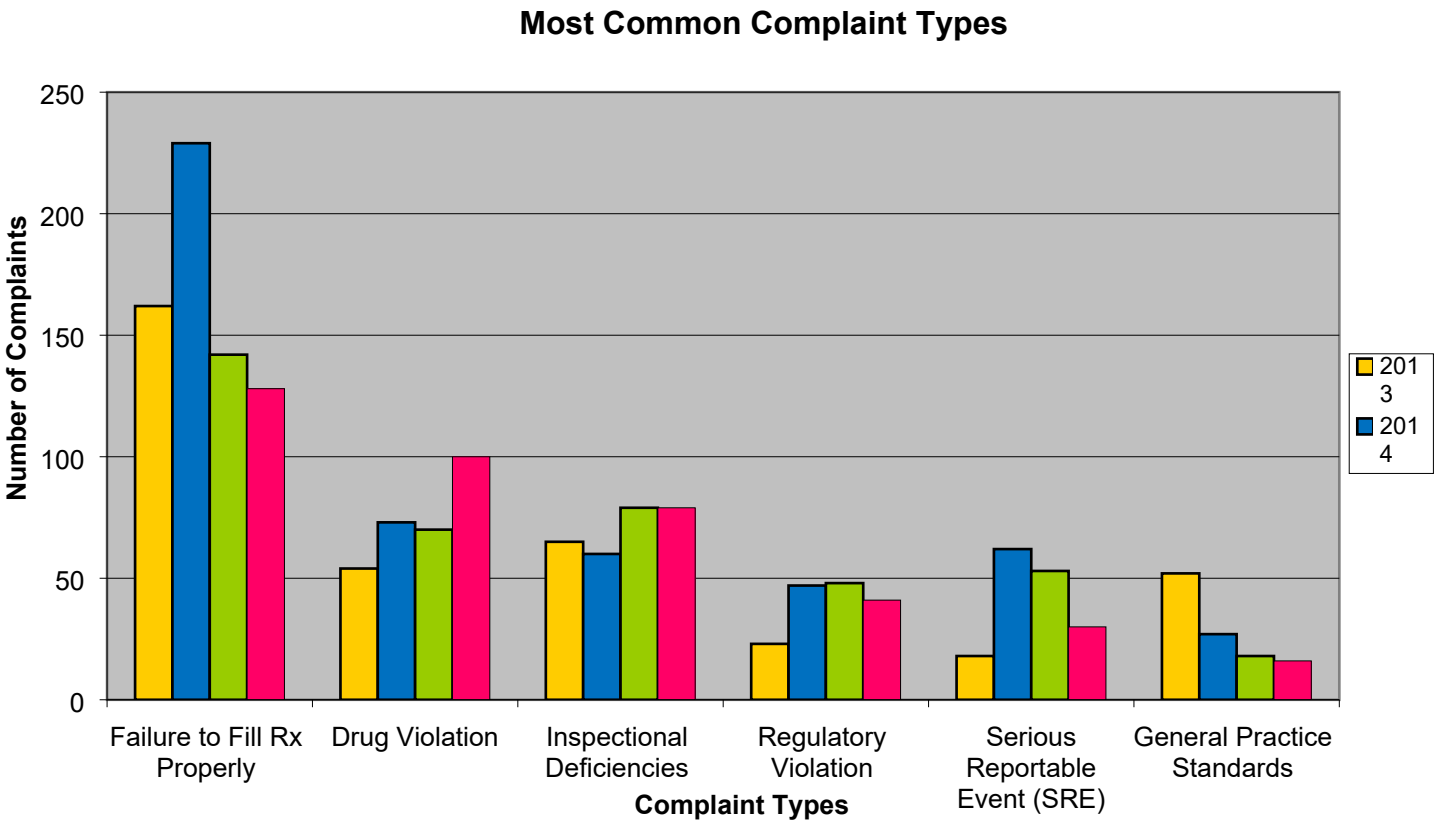


Disposition	2013	2014	2015	2016
Resulting in Discipline	51	74	74	70
Resulting in Non-Discipline	26	78	83	13
Dismissed	69	120	110	114

What this means: In keeping with the continued implementation of a Just Culture[6], beginning in 2016, licensees were given the opportunity to self-remediate complaints related to medication errors by completing continuing education credits in anticipation of the Board hearing their respective complaint. This new opportunity has resulted in many of the complaints being dismissed for discipline not warranted, and a significant decrease in complaints resulting in non-discipline.

[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

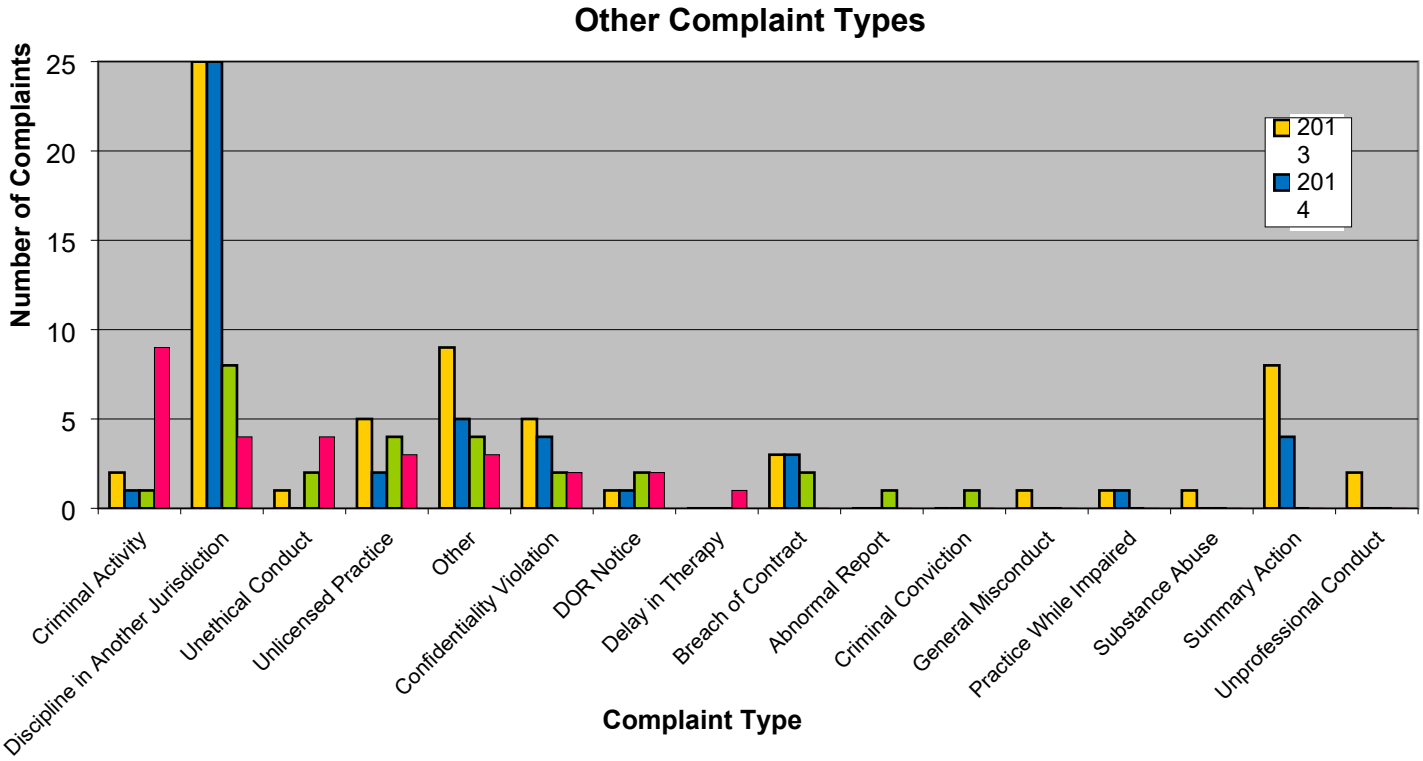
Appendix L: *Most Common Complaint Types*



Complaint Type	2013	2014	2015	2016
Failure to Fill Rx Properly	162	229	142	128
Drug Violation	54	73	70	100
Inspectional Deficiencies	65	60	79	79
Regulatory Violation	23	47	48	41
Serious Reportable Event (SRE)	18	62	53	30
General Practice Standards	52	27	18	16

What this means: The most common complaint type, "Failure to Fill RX Properly," showed a significant decrease again this year. 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. A continued and significant field presence in 2016 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").

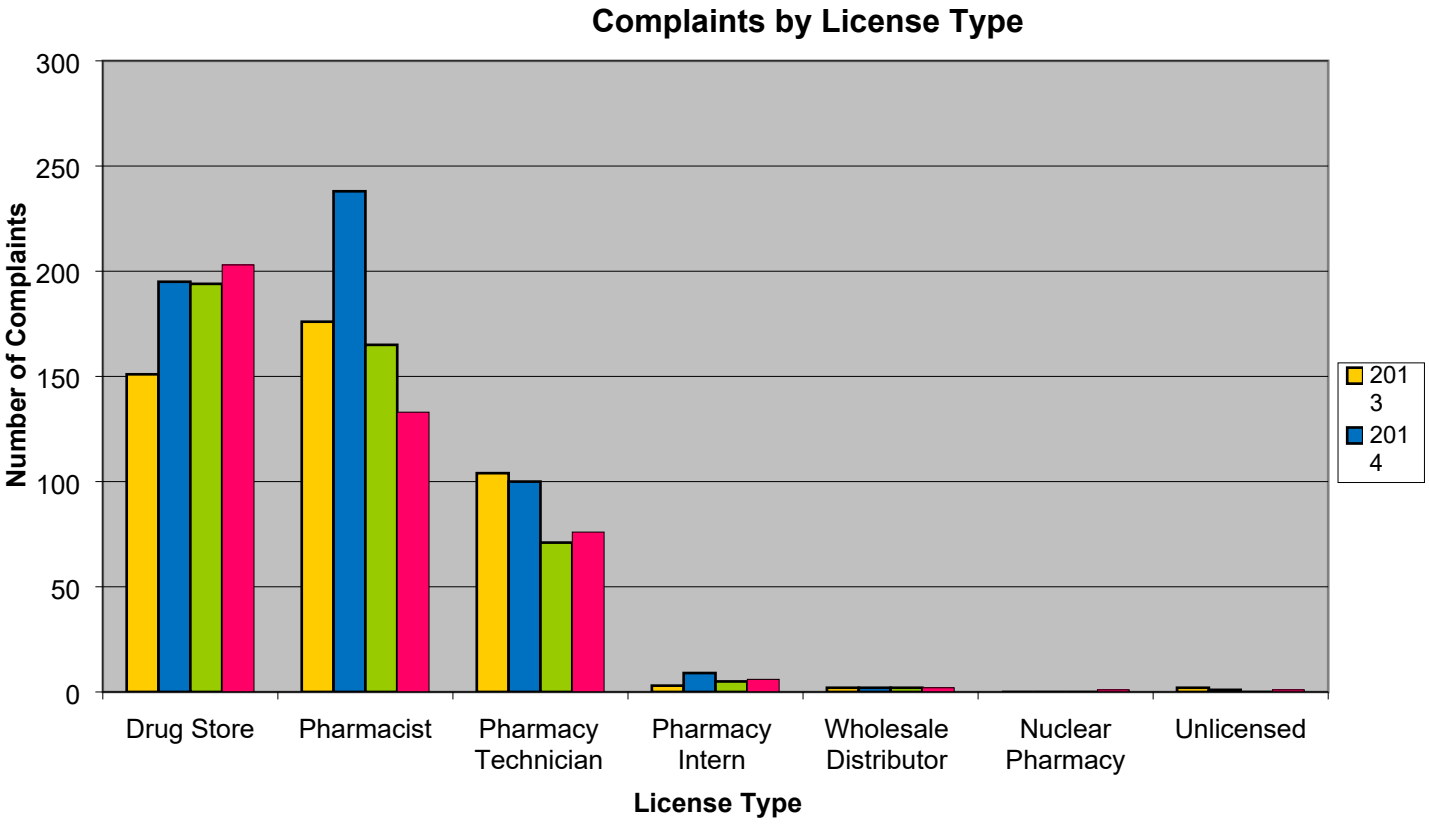
Appendix M: *Other Complaint Types*



Complaint Type	2013	2014	2015	2016
Criminal Activity	2	1	1	9
Discipline in Another Jurisdiction	25	25	8	4
Unethical Conduct	1	0	2	4
Unlicensed Practice	5	2	4	3
Other	9	5	4	3
Confidentiality Violation	5	4	2	2
DOR Notice	1	1	2	2
Delay in Therapy	0	0	0	1
Breach of Contract	3	3	2	0
Abnormal Report	0	0	1	0
Criminal Conviction	0	0	1	0
General Misconduct	1	0	0	0
Practice While Impaired	1	1	0	0
Substance Abuse	1	0	0	0
Summary Action	8	4	0	0
Unprofessional Conduct	2	0	0	0

What this means: The most significant change in 2016 was the rise in "Criminal Activity" complaints. The rise is attributed to Board outreach efforts that have focused on reminding licensees of mandatory reporting requirements of any pending criminal charges or convictions. The Board has had cases where circumstances caused immediate threat to health and safety; however, Board staff quickly identified these cases and worked with pharmacy staff who voluntarily ceased unsafe practices. Without voluntary action the Board would have taken summary action.

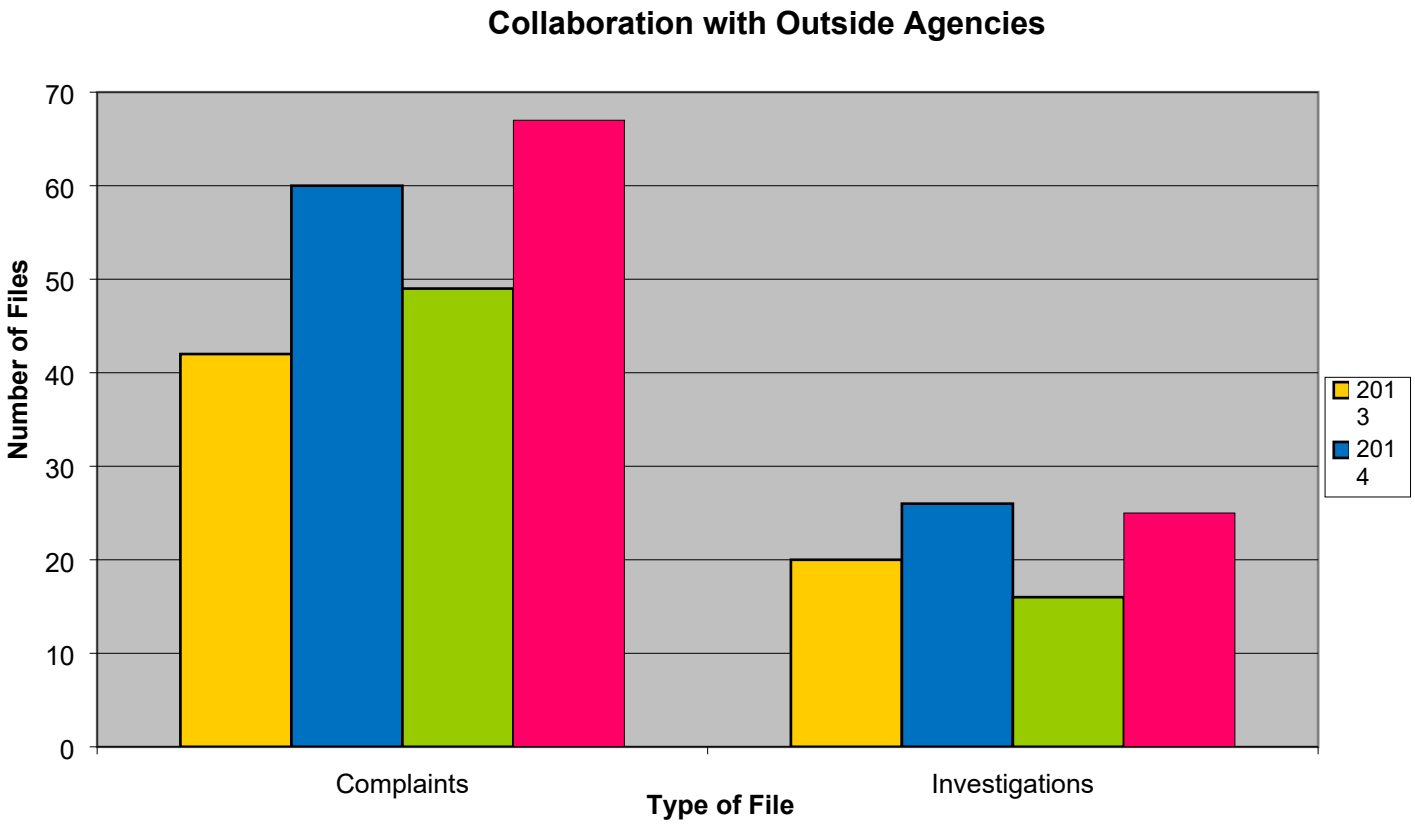
Appendix N: *Complaints by License Type*



Complaints by License Type	2013	2014	2015	2016
Drug Store	151	195	194	203
Pharmacist	176	238	165	133
Pharmacy Technician	104	100	71	76
Pharmacy Intern	3	9	5	6
Wholesale Distributor	2	2	2	2
Nuclear Pharmacy	0	0	0	1
Unlicensed	2	1	0	1

What this means: In 2016, the Board opened the most complaints against Drug Stores. As described in Appendix I for investigations, complaints also typically begin with Drug Stores and after additional information is received, related companion cases are opened against individual licensees involved in the alleged incidents. Although the largest groups, Drug Stores and Pharmacists, appear to decrease in volume in 2016, the higher totals in previous years are an anomaly, as many of them were backlogged complaints from previous years. These decreases are also attributed to the focus on gathering evidence through investigations rather than complaints, as described in Appendix E.

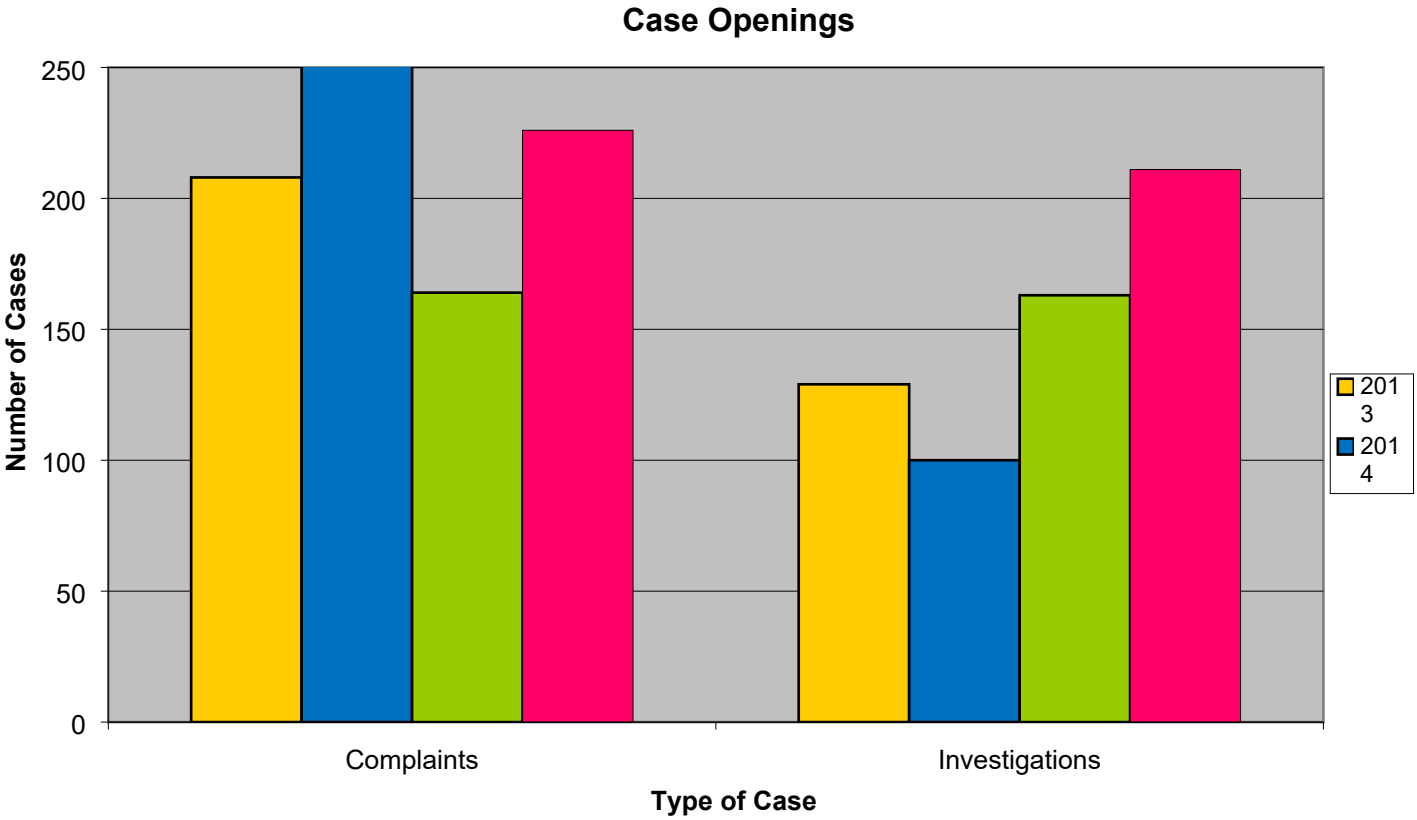
Appendix O: *Collaboration with Outside Agencies*



Collaboration with Outside Agencies	2013	2014	2015	2016
Complaints	42	60	49	67
Investigations	20	26	16	25

What this means: In 2016, the investigators continued to collaborate with outside agencies. Statistically, this number appears to increase. The Board and Board staff continue to forge strong relationships with our local, state and federal partners and will collaborate on cases where doing so is in the best interest of public health and safety. Board staff attributes the increases in files with collaborating agencies to the increase in volume of files of specific types. Board staff often collaborates with outside agencies on alleged Drug Violations, Criminal Activity, Regulatory Violations, General Practice Standards and Inspectional Deficiencies cases, all of which increased or maintained their volume in 2016.

Appendix P: *Case Openings*



Openings	2013	2014	2015	2016
Complaints	208	252	164	226
Investigations	129	100	163	211

What this means: In 2016, there was an increase in the number of openings, corresponding to both Complaints and Investigations. Staff attributes these increases in case volume to the increased number of investigators on hand to inspect pharmacies, resulting in increases in inspectional deficiency and regulatory/code violation cases. In addition, increased monitoring of reported drug losses has resulted in increased drug violation cases and increased continuing education requirements for all pharmacists and compounding continuing education requirements for compounding staff has also resulted in increased continuing education related regulatory/code violation cases.

Appendix Q: *Case Closings*

Closings	2013	2014	2015	2016
Complaints	151	284	267	197
Investigations	76	136	144	227

What this means: In 2016, the Board closed a total of 424 cases, a slight increase from cases closed in 2014 and 2015, and a 86.7% increase over closings in 2013. Investigators and Board staff continue to work diligently to conduct investigations and process cases expeditiously.