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Department of Public Health
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August 8, 2019

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

Michael D. Hurley
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

August 2019



Legislative Mandate

The following report is hereby issued pursuant to Section 25A of Chapter 112 of the Massachusetts General Laws, as inserted by Chapter 159 of the Acts of 2014, 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, 2017 to December 1, 2018. This is the sixth annual Report as directed by the Act.

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 Board staff have continued to work diligently to conduct Investigations and process cases expeditiously. In 2018, much progress has been made including the following:

- The continued expedited processing of files;
- The continued heightened monitoring of drug losses and other drug violations;

- An increase in dismissed Complaints due to the continued implementation of Just Culture through the use of voluntary anticipatory continuing education credits in lieu of discipline 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 continued 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 with accurate information at an accelerated pace. A thorough Investigation and well written report allows the Board to resolve these cases quickly and efficiently. The goal is to continue to fine-tune the Board's processes and procedures and ensure that quality improvement is monitored, continuing in 2019 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; reporting of defective drug preparations, 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 of December 1, 2017 through December 1, 2018.

Case Flow Overview

An overview of the Board's case flow is provided to offer context to this report.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 The level which requires a pharmacy engaged in sterile compounding to take remedial measures.

² See Appendix A: *Case Flow Diagram*.

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.

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 Pharmacy 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 Review (BDR) committee.⁴ The BDR has authority to dispose of Investigations or Complaints that fall under Board-specified criteria.

If the Complaint is outside of the BDR 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 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. 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

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

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

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 the case was closed are included.
 - If the case 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 was opened as a result of the Investigation are included. Associated Complaints that are related, but opened prior to the Investigation or in relation to the Investigation are also included in this report. 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, 2017 through December 1, 2018. 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 six 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.

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 in the licensure database. Each year, the files in this category are reviewed to determine if new categories need to be established.

This report shows that the field presence of the pharmacy investigators and the implementation of controlled substance loss policy 16-02 have contributed to increased compliance with statutes, regulations, and policies. This increased compliance, in conjunction with the completion of backlogged complaint volume from previous years and an efficient investigation process, has resulted in an overall decrease in case volume.

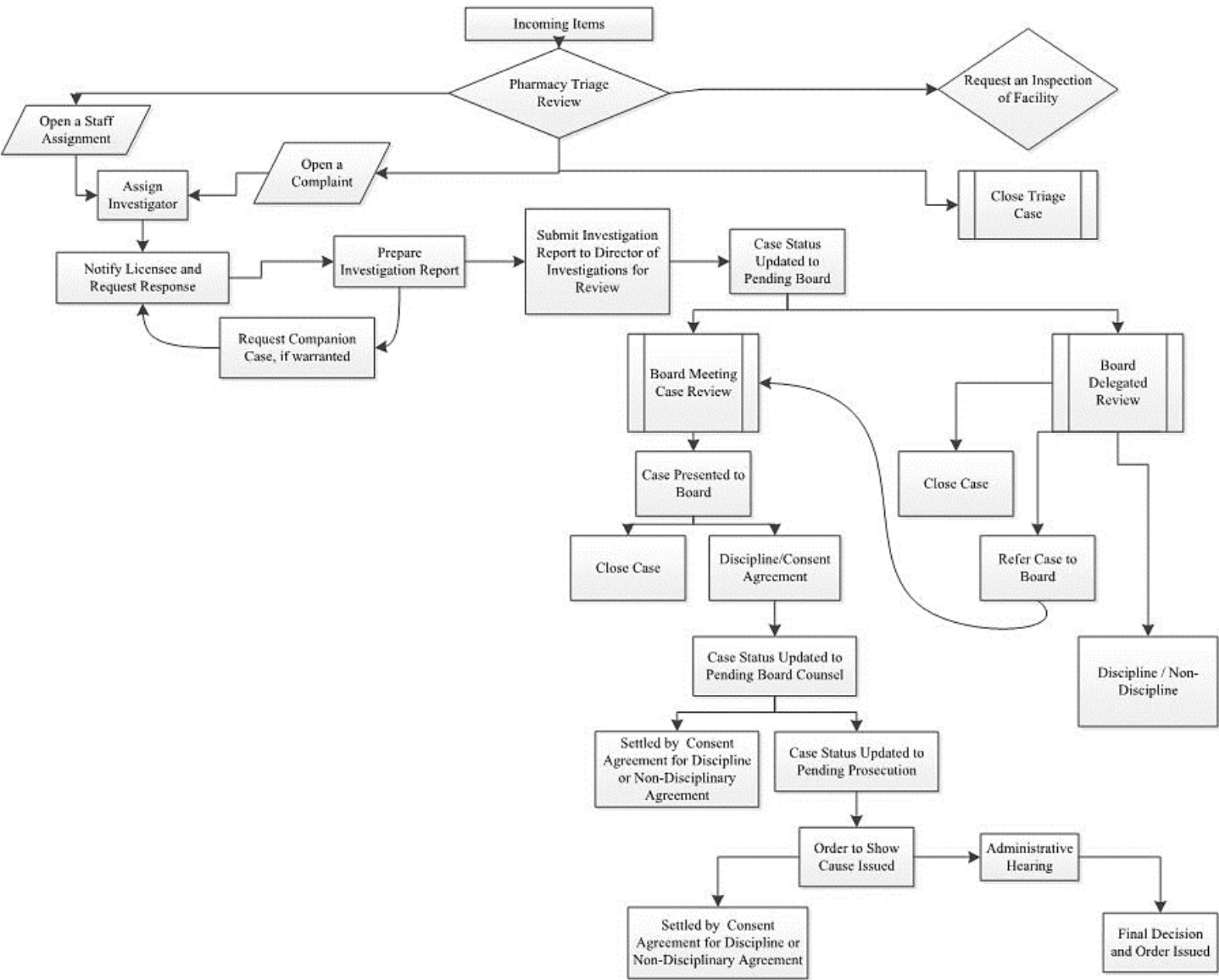
This report details all formal Complaints and Investigations that were pending, received, initiated, or opened by the Board during the period of December 1, 2017 through December 1, 2018. Significant progress has been made, including the following:

- In 2018, 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 2018.
- The Board continued to process cases expeditiously in 2018, resulting in a 49.8% increase in case closures since 2013.
- Board staff continued to encourage self-reports of continuing education deficiencies (classified as “Regulatory Violations”), resulting in an increase in Investigations related to these events.
- Investigators continue to pay close attention to the reports of drug losses, record keeping discrepancies and diversions, resulting in an increase of “Drug Violations” Complaints and surpassing the volume of the historical leader, “Failure to Fill RX Properly” Complaints.
- A continued field presence in 2018 uncovered regulatory violations and inspectional deficiencies resulting in formal Complaints.
- 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

Discipline/Consent Agreement



Appendix B: *Formal Complaint Data*

Please see separate Excel spreadsheet data.

Appendix C: *Investigation Data*

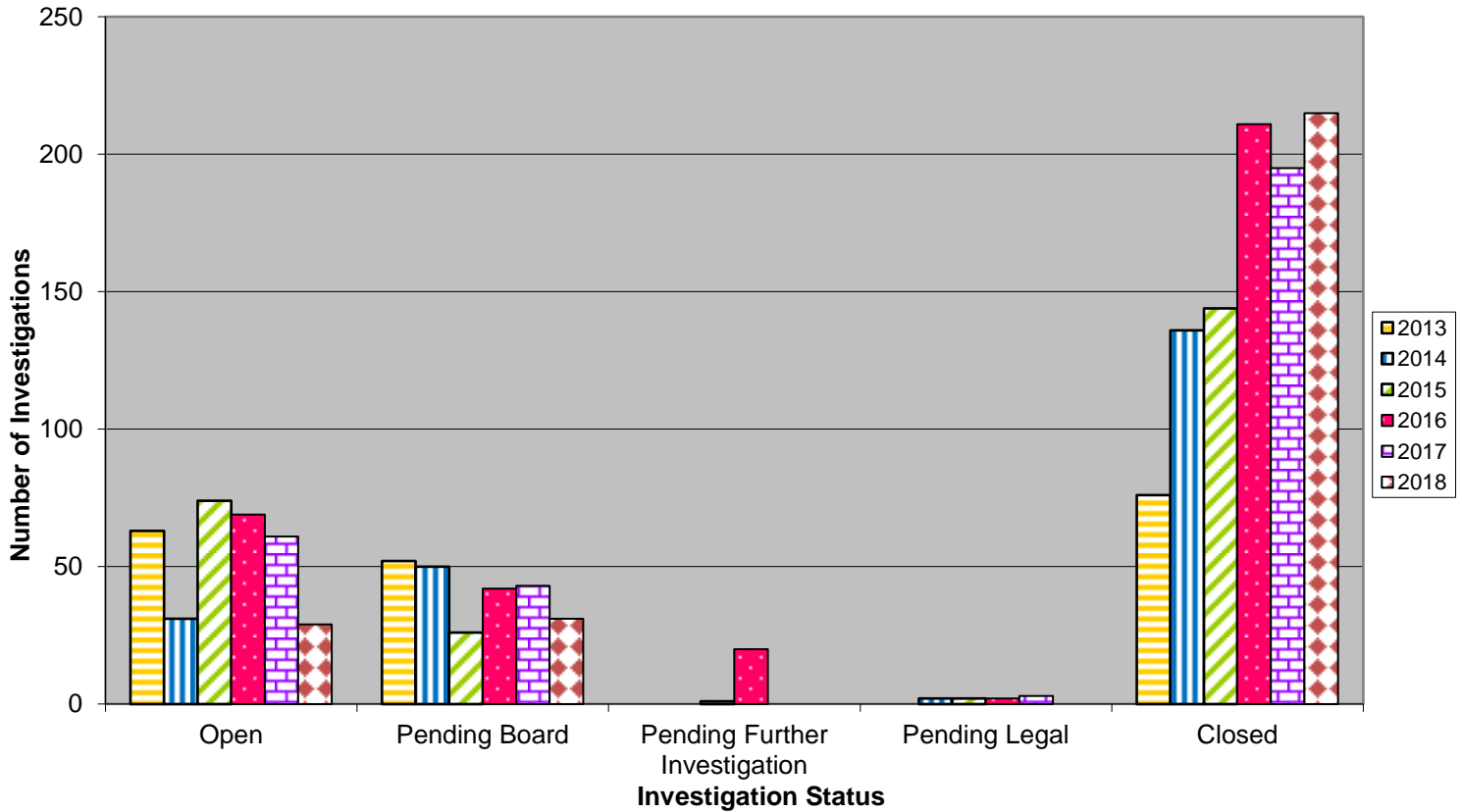
Please see separate Excel spreadsheet data.

Appendix D: *Medication Error Data*

Please see separate Excel spreadsheet data.

Appendix E: Investigation Status Types

Investigation Status

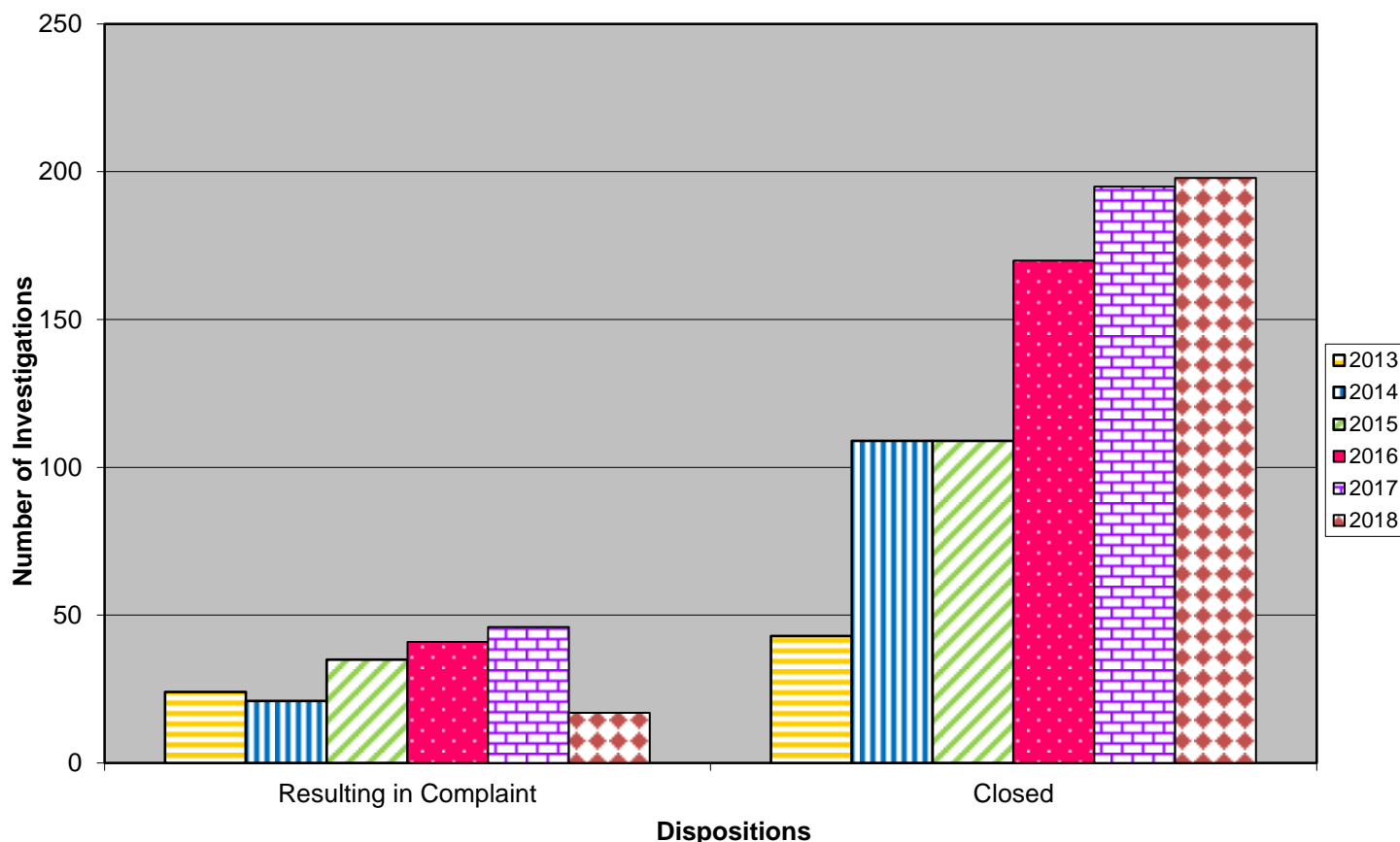


Status	2013	2014	2015	2016	2017	2018
Open	63	31	74	69	61	29
Pending Board	52	50	26	42	43	31
Pending Further Investigation	0	0	1	20	0	0
Pending Legal	0	2	2	2	3	0
Closed	76	136	144	211	195	215
Total	191	219	247	344	302	275

What this means: The total number of active Investigations in 2018 decreased since 2017. This is still an increase from prior years. Investigators work diligently to obtain evidence, statements, and write Investigation reports to get the information to the Board as quickly as possible, resulting in a decrease of pending Investigations. The Board continues to consistently hear most cases that are scheduled to be heard during each Board meeting.

Appendix F: Investigation Dispositions

Investigation Dispositions



Disposition	2013	2014	2015	2016	2017	2018
Resulting in Complaint	24	21	35	41	46	17
Closed	43	109	109	170	195	198

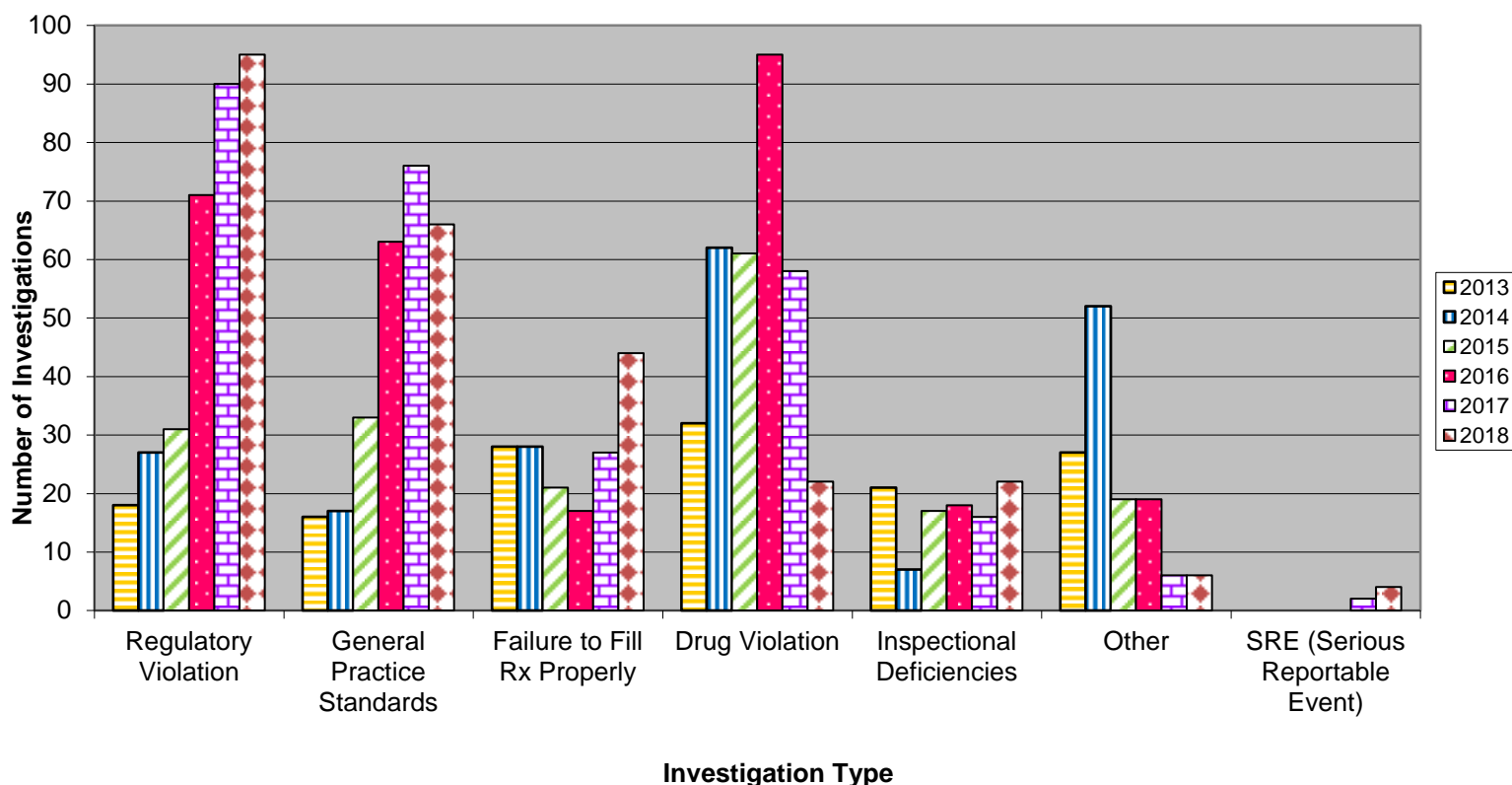
What this means: Due to the decreased volume of files processed in 2018 by investigators and the Board, the total number of Investigations resulting in, or associated with, a Complaint, decreased. This may be a result of the Board’s goal to continue implementation of a Just Culture.⁶ Investigations classified under the Investigation type “Failure to Fill Rx Properly” are increasingly sent to Board for review as Investigations rather than Complaints. This allows the Board to make the determination of whether or not a complaint is necessary.

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 G: Most Common Investigation Types

Most Common Investigation Types

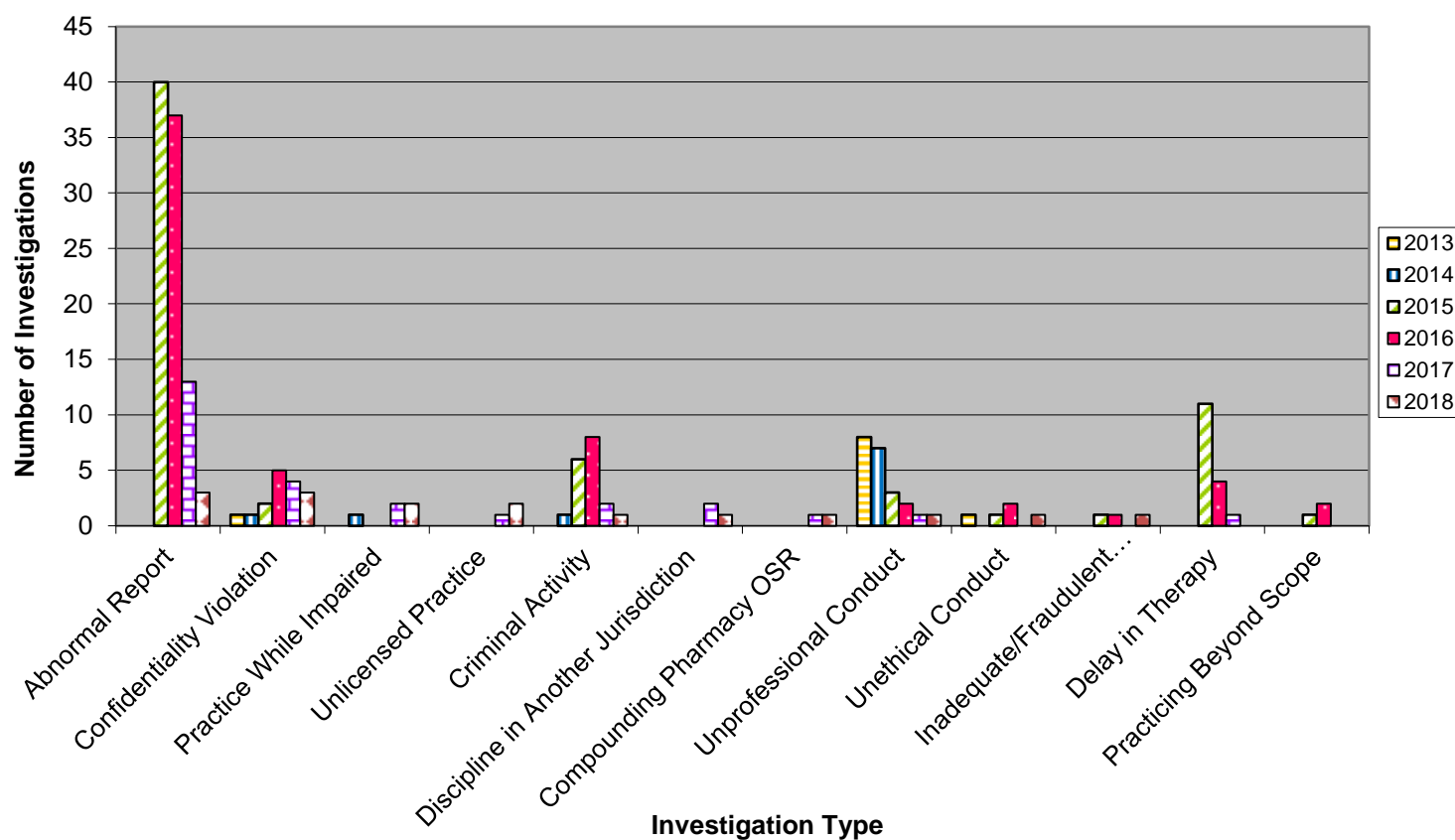


Investigation Type	2013	2014	2015	2016	2017	2018
Regulatory Violation	18	27	31	71	90	95
General Practice Standards	16	17	33	63	76	66
Failure to Fill Rx Properly	28	28	21	17	27	44
Drug Violation	32	62	61	95	58	22
Inspectional Deficiencies	21	7	17	18	16	22
Other	27	52	19	19	6	6
SRE (Serious Reportable Event)	0	0	0	0	2	4

What this means: The Board continued to see an increase in “Regulatory Violations” due to the self-reporting of continuing education deficiencies. The Board saw an increase in “Failure to Fill Rx Properly” (see Appendix F). Board staff also continued to monitor controlled substance loss reports, or “Drug Violations”. The implementation of [Policy 16-02](#) extended time to report a loss of controlled substances, so that a pharmacy may properly investigate circumstances prior to reporting. This resulted in a decrease of these Investigations.

Appendix H: *Other Investigation Types*⁷

Other Investigation Types



Investigation Type	2013	2014	2015	2016	2017	2018
Abnormal Report	0	0	40	37	13	3
Confidentiality Violation	1	1	2	5	4	3
Practice While Impaired	0	1	0	0	2	2
Unlicensed Practice	0	0	0	0	1	2
Criminal Activity	0	1	6	8	2	1
Discipline in Another Jurisdiction	0	0	0	0	2	1
Compounding Pharmacy OSR ⁸	0	0	0	0	1	1
Unprofessional Conduct	8	7	3	2	1	1
Unethical Conduct	1	0	1	2	0	1
Inadequate/Fraudulent Documentation	0	0	1	1	0	1

⁷ The following complaint types have been removed from this report as they have not been used since 2015 or earlier: Good Moral Character Evaluation, Request for Inspection, and Substance Abuse.

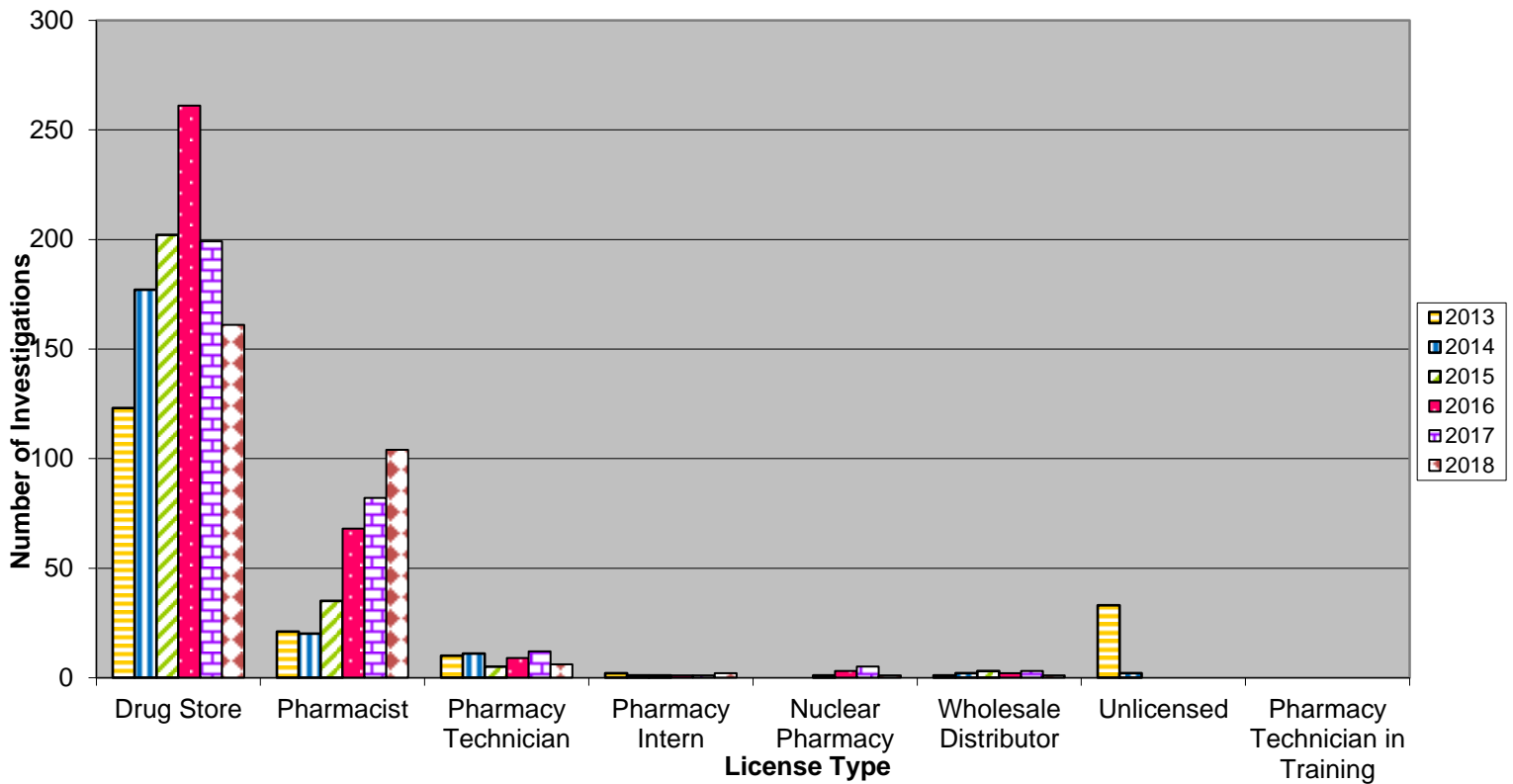
⁸ Compounding Pharmacy Out of Specification Report (OSR)

Delay in Therapy	0	0	11	4	1	0
Practicing Beyond Scope	0	0	1	2	0	0

What this means: The Board conducted a limited number of Investigations classified in the categories on the chart above. Most matters that are characterized in these categories are opened as Complaints, but these Investigations were opened to collect further information to determine if a Complaint is warranted. The decrease in investigations classified as “Abnormal Reports” is attributed to the implementation of staff action policy 16-04, which allows for Above Action Level reports to be resolved at the triage level. This policy includes a requirement for Board Staff to submit a report of above action level statistics to the Board on a monthly basis.

Appendix I: Investigations by License Type

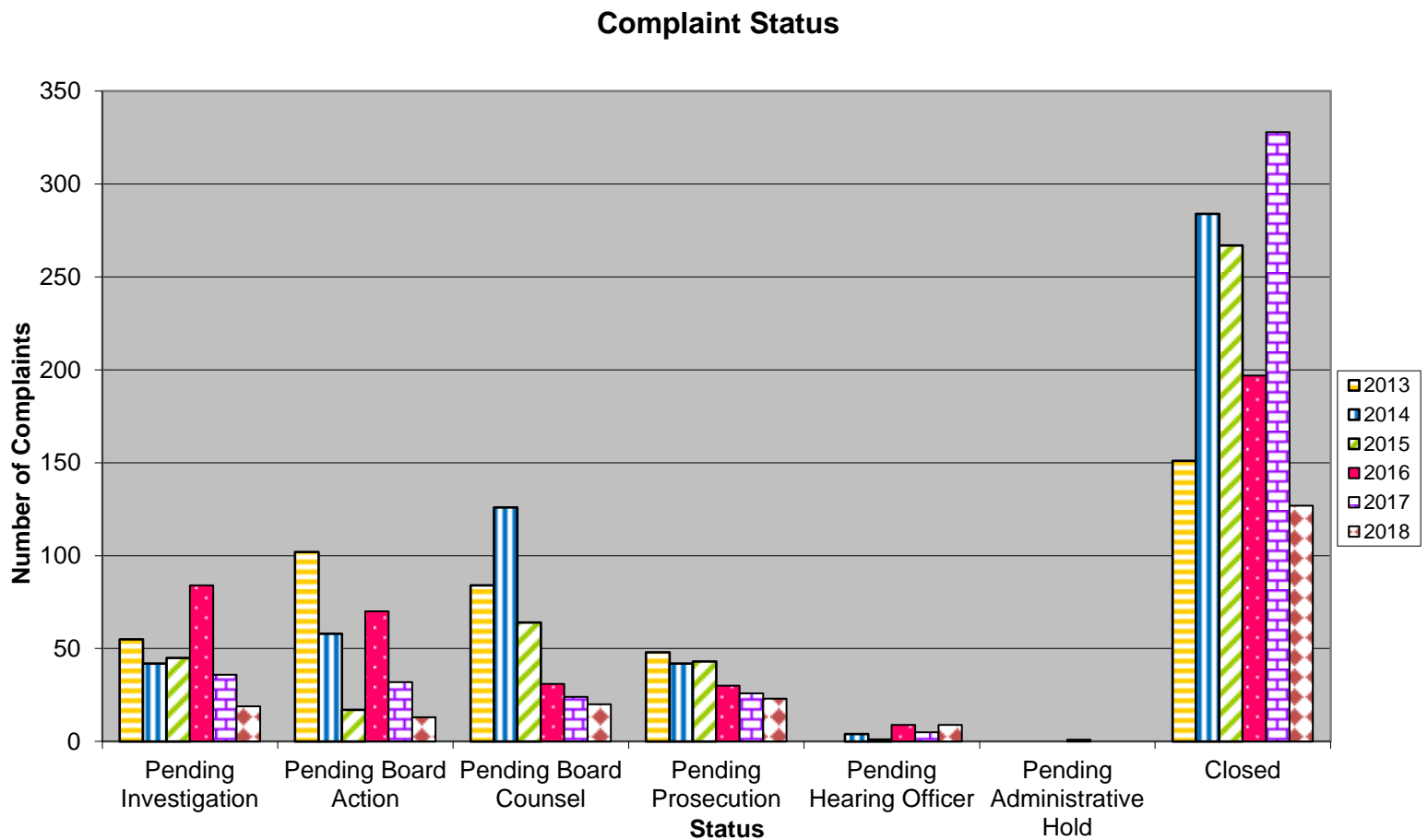
Investigations by License Type



Investigations by License Type	2013	2014	2015	2016	2017	2018
Drug Store	123	177	202	261	199	161
Pharmacist	21	20	35	68	82	104
Pharmacy Technician	10	11	5	9	12	6
Pharmacy Intern	2	1	1	1	1	2
Nuclear Pharmacy	0	0	1	3	5	1
Wholesale Distributor	1	2	3	2	3	1
Unlicensed	33	2	0	0	0	0
Pharmacy Technician in Training	0	0	0	0	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 the drug store in question 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. The rise in pharmacist Investigations is attributed to continuing education deficiency self-disclosures, as mentioned in Appendix G.

Appendix J: Formal Complaint Status Types



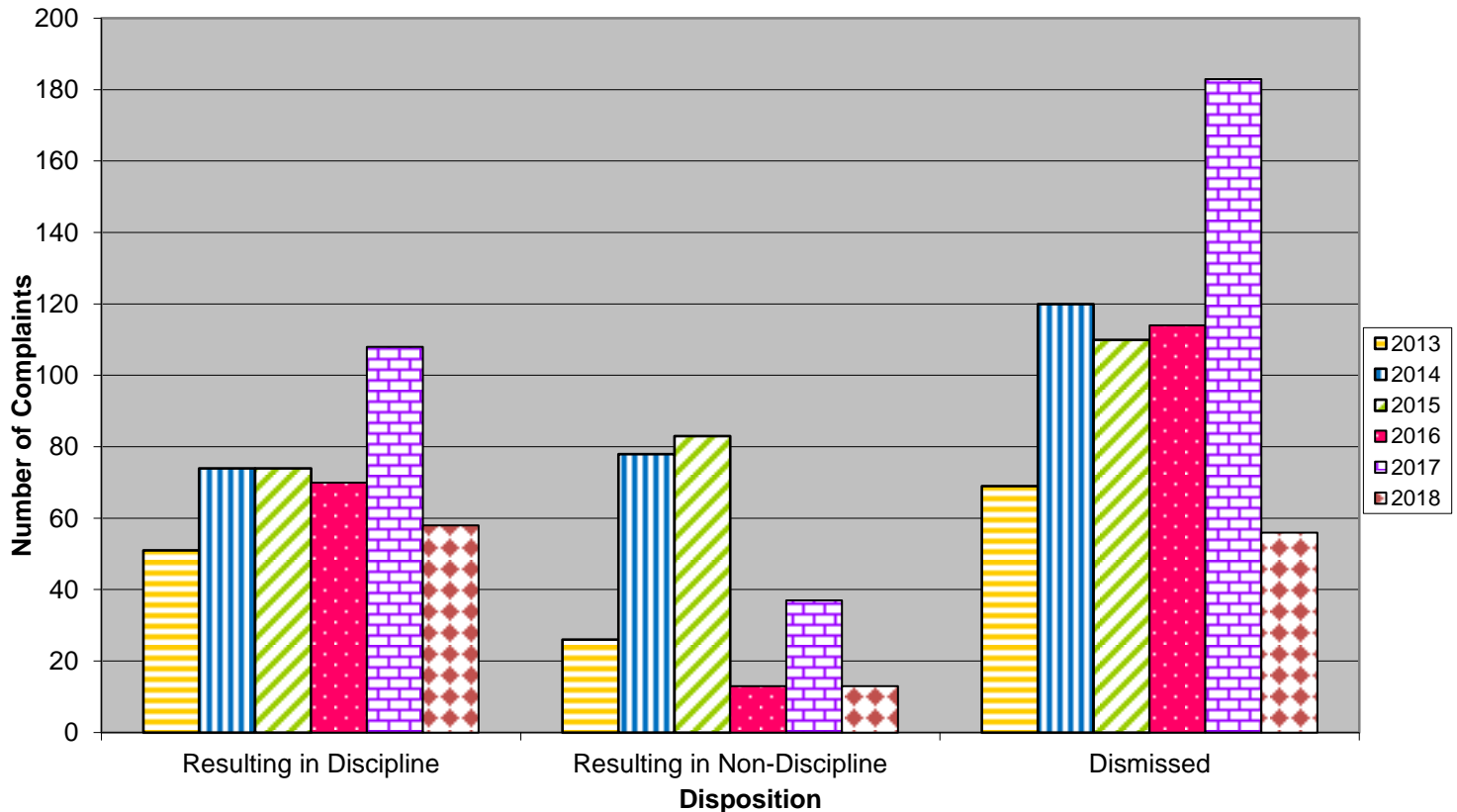
Status	2013	2014	2015	2016	2017	2018
Pending Investigation	55	42	45	84	36	19
Pending Board Action	102	58	17	70	32	13
Pending Board Counsel	84	126	64	31	24	20
Pending Prosecution	48	42	43	30	26	23
Pending Hearing Officer	0	4	1	9	5	9
Pending Administrative Hold	0	0	0	1	0	0
Closed	151	284	267	197	328	127
Total	440	556	437	422	451	211

What this means: Most importantly, the 2018 data shows that the Board continued to process all Complaints that were waiting to be heard by the Board. At the end of 2018, Complaints that are updated to Pending Board Action are routinely heard at the next scheduled Board meeting, unless they are delayed by extenuating circumstances beyond Board or staff control. For example, many of the Complaints that have been Pending Board Action for longer than a month have not been heard due to lack of quorum caused by recusals. In 2018, while Complaint closure volume decreased due to overall decreased volume, the closure rate is consistent with the closure rate of prior years.⁹ Complaints are processed in the expedited formal Complaint processing system established in 2014.

⁹ Year – Closure Rate: 2015 – 61%; 2016 – 46%; 2017 – 72%; 2018 – 60%

Appendix K: Formal Complaint Dispositions

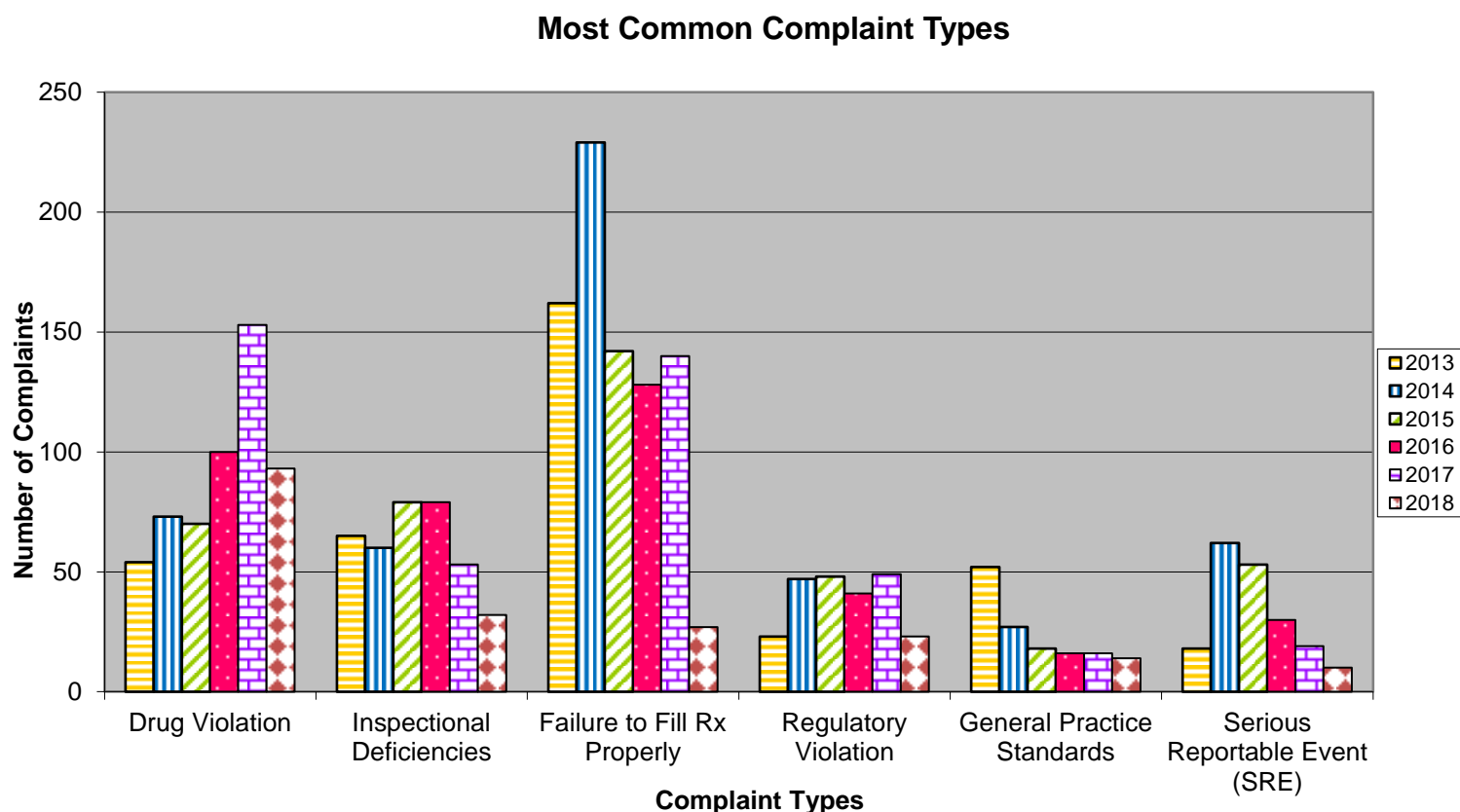
Complaint Dispositions



Disposition	2013	2014	2015	2016	2017	2018
Resulting in Discipline	51	74	74	70	108	58
Resulting in Non-Discipline	26	78	83	13	37	13
Dismissed	69	120	110	114	183	56

What this means: In keeping with the continued implementation of a Just Culture (see Appendix F), in 2018, licensees were given the opportunity to respond to Complaints related to medication errors by completing continuing education credits in anticipation of the Board hearing their respective Complaint. This opportunity has resulted in many of the Complaints being dismissed for discipline not warranted, and a significant decrease in Complaints resulting in non-disciplinary action. The Complaints resulting in discipline are attributed to Complaints for inspectional deficiencies and drug violations resulting from record keeping discrepancies or diversion, which are areas that the Board is monitoring closely.

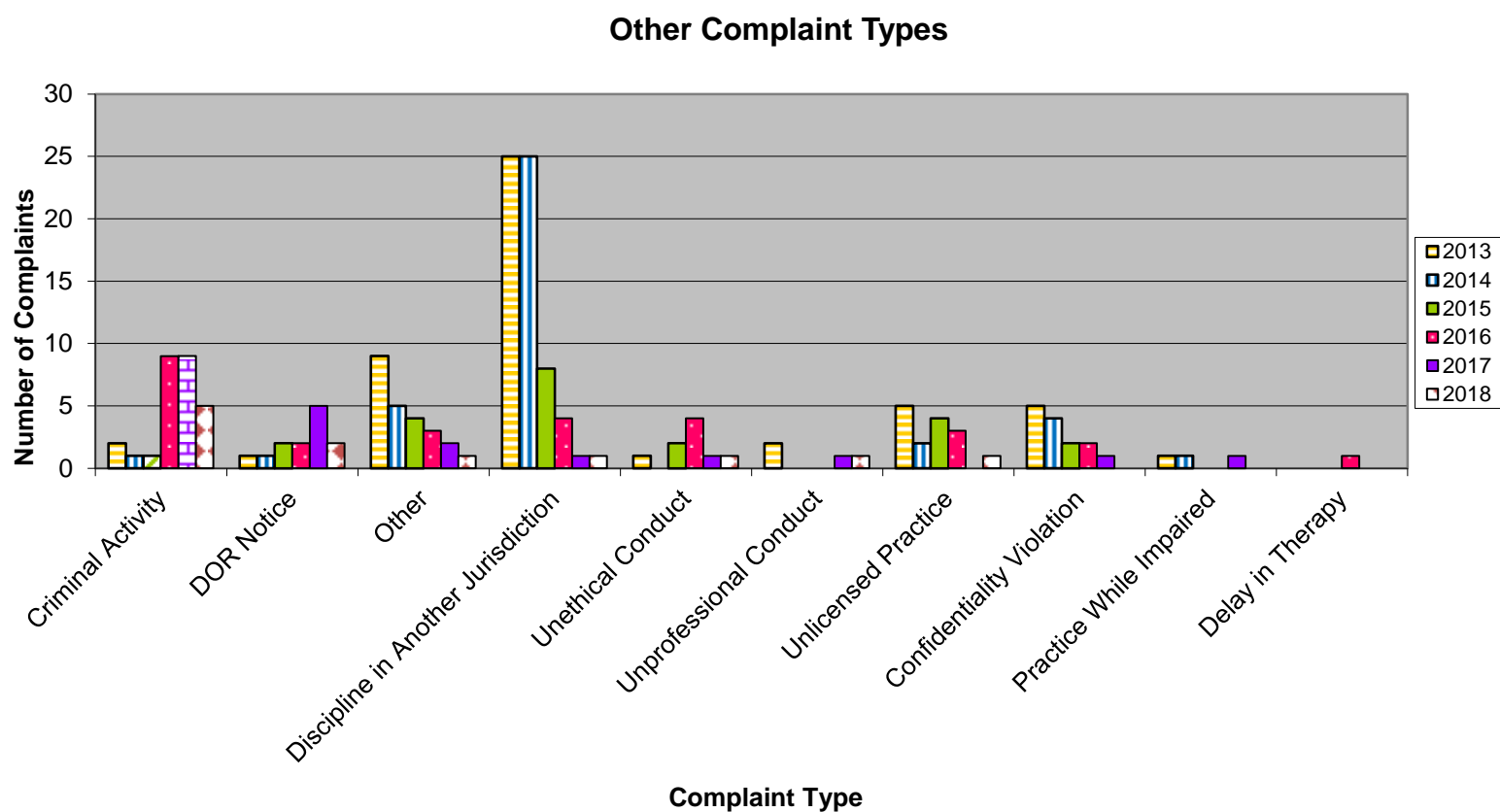
Appendix L: Most Common Complaint Types



Complaint Type	2013	2014	2015	2016	2017	2018
Drug Violation	54	73	70	100	153	93
Inspectional Deficiencies	65	60	79	79	53	32
Failure to Fill Rx Properly	162	229	142	128	140	27
Regulatory Violation	23	47	48	41	49	23
General Practice Standards	52	27	18	16	16	14
Serious Reportable Event (SRE)	18	62	53	30	19	10

What this means: In 2018, the most common Complaint type was “Drug Violation”. Cases in this category often are the result of a reported loss of controlled substances, diversions or record keeping deficiencies. In 2018, the Board opened Complaints on pharmacies that had reportable confirmed losses of controlled substances. . Complaints for “Failure to Fill RX Properly,” showed a decrease. This is the result of this complaint type increasingly being handled as an investigation (see appendix G). A continued and significant field presence in 2018 uncovered inspectional deficiencies and regulatory violations resulting in formal Complaints.

Appendix M: *Other Complaint Types*¹⁰



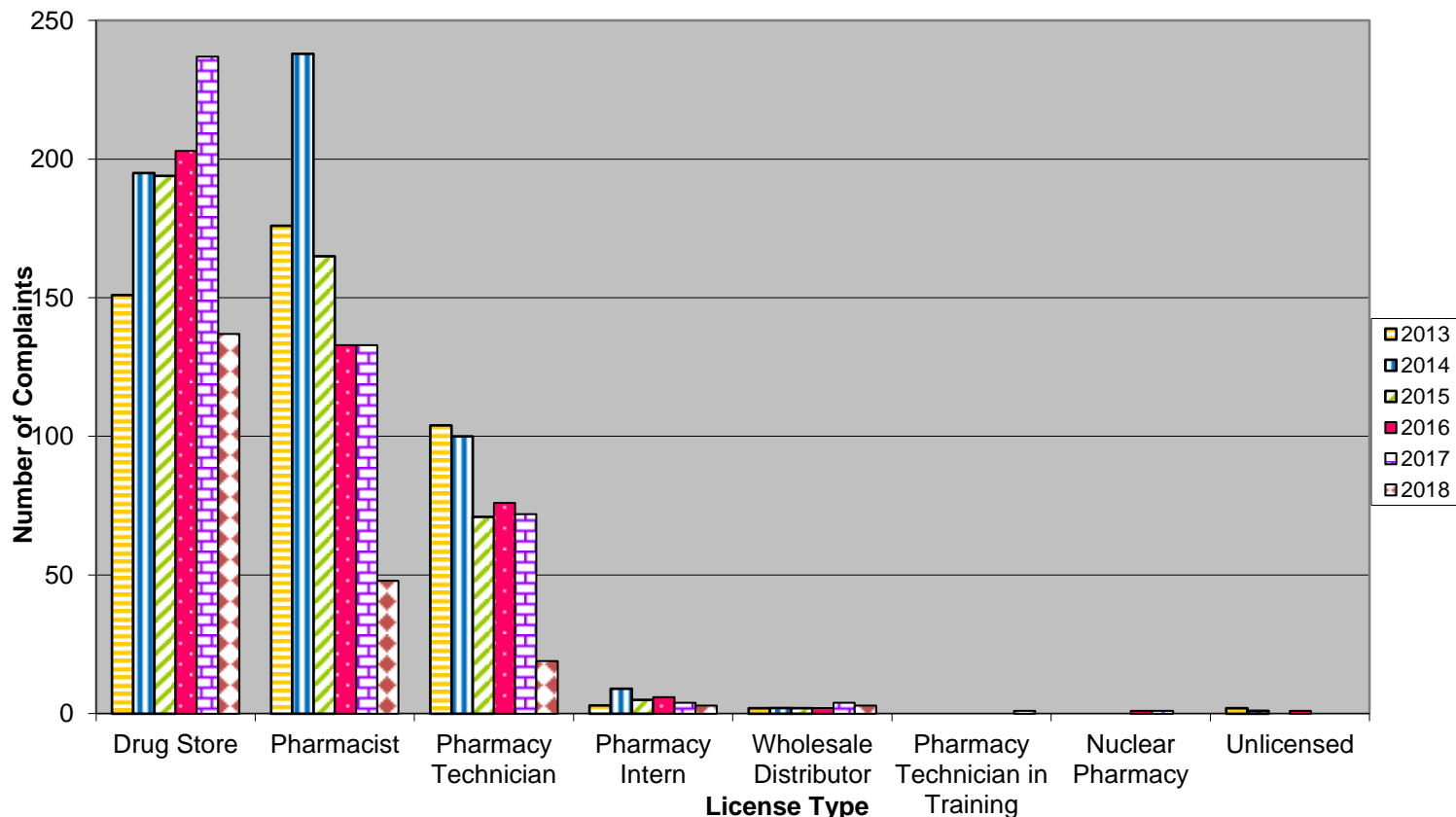
Complaint Type	2013	2014	2015	2016	2017	2018
Criminal Activity	2	1	1	9	9	5
DOR Notice	1	1	2	2	5	2
Other	9	5	4	3	2	1
Discipline in Another Jurisdiction	25	25	8	4	1	1
Unethical Conduct	1	0	2	4	1	1
Unprofessional Conduct	2	0	0	0	1	1
Unlicensed Practice	5	2	4	3	0	1
Confidentiality Violation	5	4	2	2	1	0
Practice While Impaired	1	1	0	0	1	0
Delay in Therapy	0	0	0	1	0	0

¹⁰ The following complaint types have been removed from this report as they have not been used since 2015 or earlier: Breach of Contract, Abnormal Report, Criminal Conviction, General Misconduct, and Substance Abuse.

What this means: In 2018, the total number of “Criminal Activity” Complaints decreased. The Board saw suspension notices from the Department of Revenue decrease since 2017, which remains equivalent to prior years. By law, the Board is required to suspend the license of the individual named after receiving such a notice from the Department of Revenue. These Complaints are handled through an administrative process overseen by the Board’s Counsel.

Appendix N: Complaints by License Type

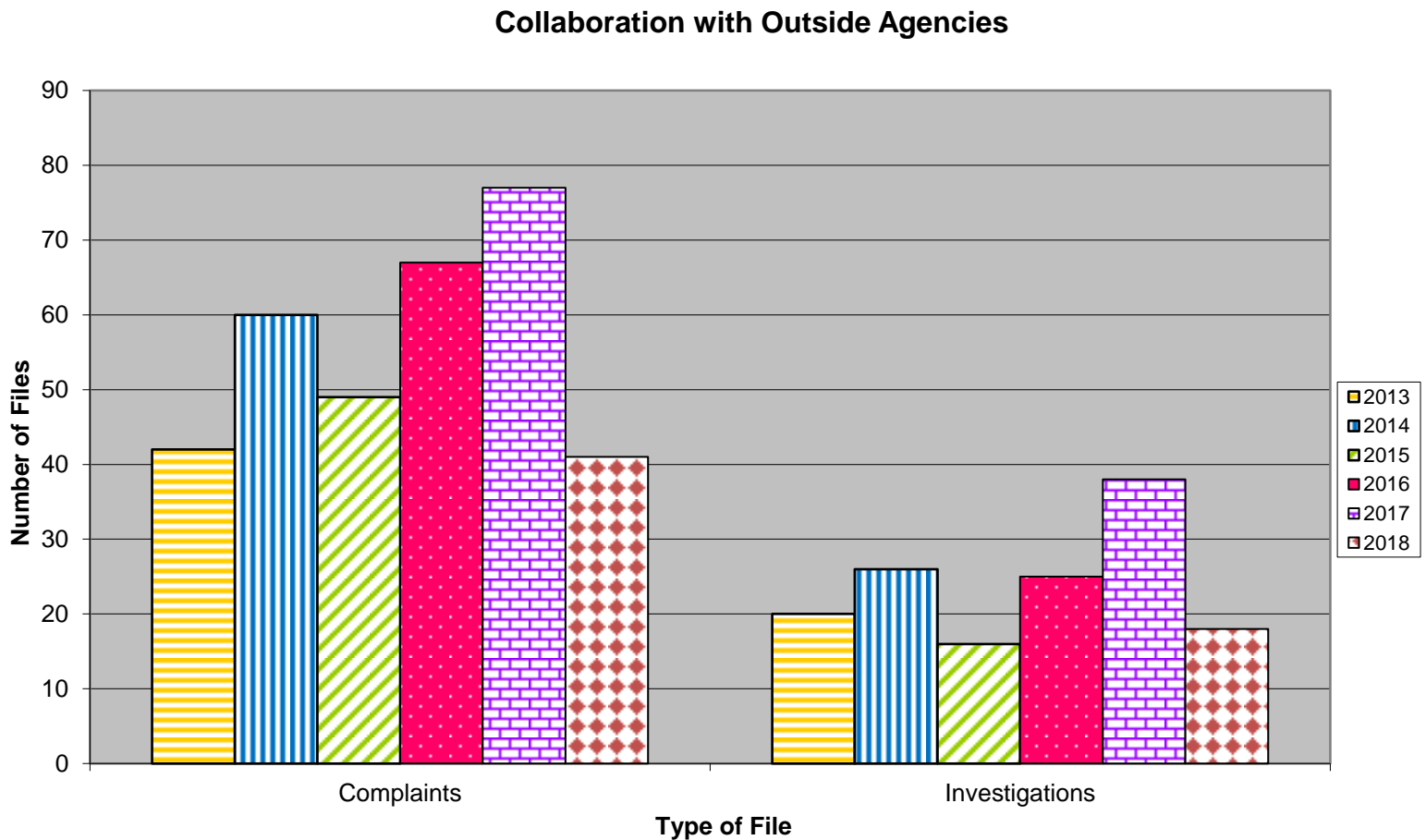
Complaints by License Type



Complaints by License Type	2013	2014	2015	2016	2017	2018
Drug Store	151	195	194	203	237	137
Pharmacist	176	238	165	133	133	48
Pharmacy Technician	104	100	71	76	72	19
Pharmacy Intern	3	9	5	6	4	3
Wholesale Distributor	2	2	2	2	4	3
Pharmacy Technician in Training	0	0	0	0	0	1
Nuclear Pharmacy	0	0	0	1	1	0
Unlicensed	2	1	0	1	0	0

What this means: In 2018, most Complaints opened by the Board were 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 may be opened against individual licensees involved in the alleged incident(s). 2018 marked the commencement of licensure for Pharmacy Technicians in Training, and the first complaint of this type was opened. Complaint volume for all other license types, decreased in 2018.

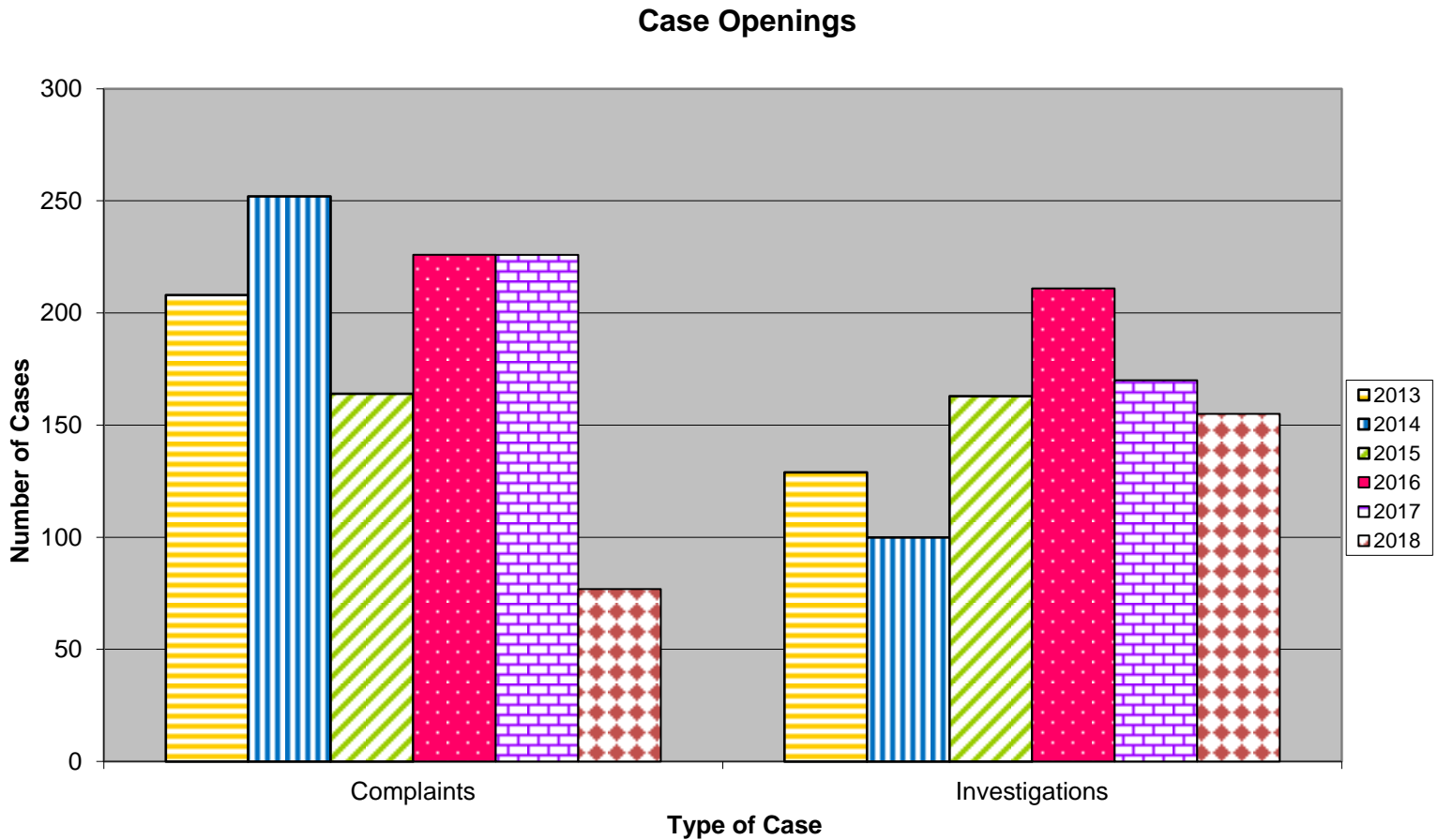
Appendix O: *Collaboration with Outside Agencies*



Collaboration with Outside Agencies	2013	2014	2015	2016	2017	2018
Complaints	42	60	49	67	77	41
Investigations	20	26	16	25	38	18

What this means: In 2018, the data demonstrates a continued effort of staff to collaborate with outside agencies in Complaints and Investigations. 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.

Appendix P: Case Openings



Openings	2013	2014	2015	2016	2017	2018
Complaints	208	252	164	226	226	77
Investigations	129	100	163	211	170	155

What this means: In 2018, Complaint openings have decreased, while Investigation openings maintained a similar average with prior years. This is attributed to increased licensee understanding of statutes, regulations, and policies, resulting from an increased field presence by Board Investigators. The decrease may also be attributed to the implementation of [Policy 16-02](#), which extended time to report a loss of controlled substances, resulting in these matters remaining triage files until the loss is confirmed or located prior to the close of the reporting timeframe.

Appendix Q: Case Closings



Closings	2013	2014	2015	2016	2017	2018
Complaints	151	284	267	197	328	119
Investigations	76	136	144	227	195	221

What this means: In 2018, the Board achieved a 49.8% increase since 2013 in Complaint and Investigation closings. Furthermore, in 2018, the Board closed 183 fewer cases than in 2017. This is attributed to the completion of backlogged Complaint volume from previous years and the expedited processing of new cases since 2014. Investigators and Board staff continue to work diligently to conduct Investigations and process cases expeditiously.