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August 6th, 2026

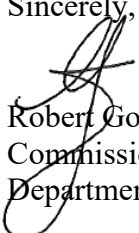
Timothy Carroll
House Clerk
State House Room 145
Boston, MA 02133

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,


Robert Goldstein, MD, PhD
Commissioner
Department of Public Health

MAURA T. HEALEY
GOVERNOR

KIMBERLEY DRISCOLL
LIEUTENANT GOVERNOR



KIAME MAHANIAH, MD, MBA
SECRETARY

ROBERT GOLDSTEIN, MD, PhD
COMMISSIONER

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

2023

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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 Chapter 112, 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

As directed by M.G.L. c 112, §25A, the Board of Registration in Pharmacy (Board) issues this report, entitled “*Investigatory & Disciplinary Actions Conducted by the Board of Registration in Pharmacy*” which is intended to track all complaints that have moved through the Board from December 1, 2022 to December 1, 2023. This is the tenth annual report to the legislature, and the ninth since 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 and, in 2023, have continued to focus on the following:

- Expedited processing of files;
- Heightened monitoring of drug losses and other drug violations;
- Compliance, prevention, and remediation rather than the issuance of discipline. Examples include:
 - the use of non-punitive remediation of unfulfilled continuing education credits and prescription filling errors;
 - educational field visits focused on general compliance, pharmacist manager of record responsibilities, controlled substances security, and controlled substance prescription validity;
- Educational outreach activities focused on pharmacy best practices, patient safety, and regulatory compliance;

- Customer service, including timely response to licensee inquiries and stakeholder engagement which has contributed to improved compliance;
- Collaboration with local, state and federal agencies;
- Robust field presence uncovering regulatory violations and inspectional deficiencies; and
- 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. Thorough investigations and well written reports allow the Board to resolve these cases quickly and efficiently. The Board's policy priorities include an emphasis on just culture remediation for quality-related events, controlled substances security and accountability, and the Pharmacy Substance Use Disorder (PSUD) program, all of which directly impact the number and nature of investigations and complaints. The goal is to continually improve the Board's processes and procedures continuing in 2023 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 out of specification 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 have helped the Board achieve its goal of enhanced oversight of traditional retail pharmacies as well as compounding pharmacies.

This annual report tracks all pharmacy complaints that were either pending, received, initiated, or opened during the period of December 1, 2022 through December 1, 2023.

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. 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

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

² See Appendix A: *Case Flow Diagram*.

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 that 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 the following Board-specified criteria:

- Confidentiality violations
- Practicing with an expired license
- Consumer grievances
- Continuing education deficiencies
- Failure to name an interim manager or to change manager of record
- Failure to submit a timely mandatory report
- Storage of controlled substances in licensed areas
- Loss of controlled substances
- Minor quality related events

[08]

If the complaint falls outside of the BDR criteria, the complaint will be slotted for review on a Board meeting agenda and subsequently presented to the Board. Following review of the case, 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 note 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 such as complexity; availability of evidence or witnesses; concurrent state or federal investigations where Board cases may be delayed or placed on hold; lengthy administrative hearings; and 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 investigation stage, the name of any

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 Pharmacy Compliance or their designee; and (3) Board Counsel.

⁵ Violations marked “Serious Reportable Event” pertain 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.

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, 2022 through December 1, 2023. 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 analyses of the information as well as charts to show a quick examination of the data to easily compare data sets and emphasize trends.

Conclusion

The systematic changes and improvements that have been put in place over the last ten 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 shows that the field presence of the pharmacy investigators and the implementation of the updated controlled substance loss policy, *2022-01: Loss of Theft of Controlled Substances*, 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.

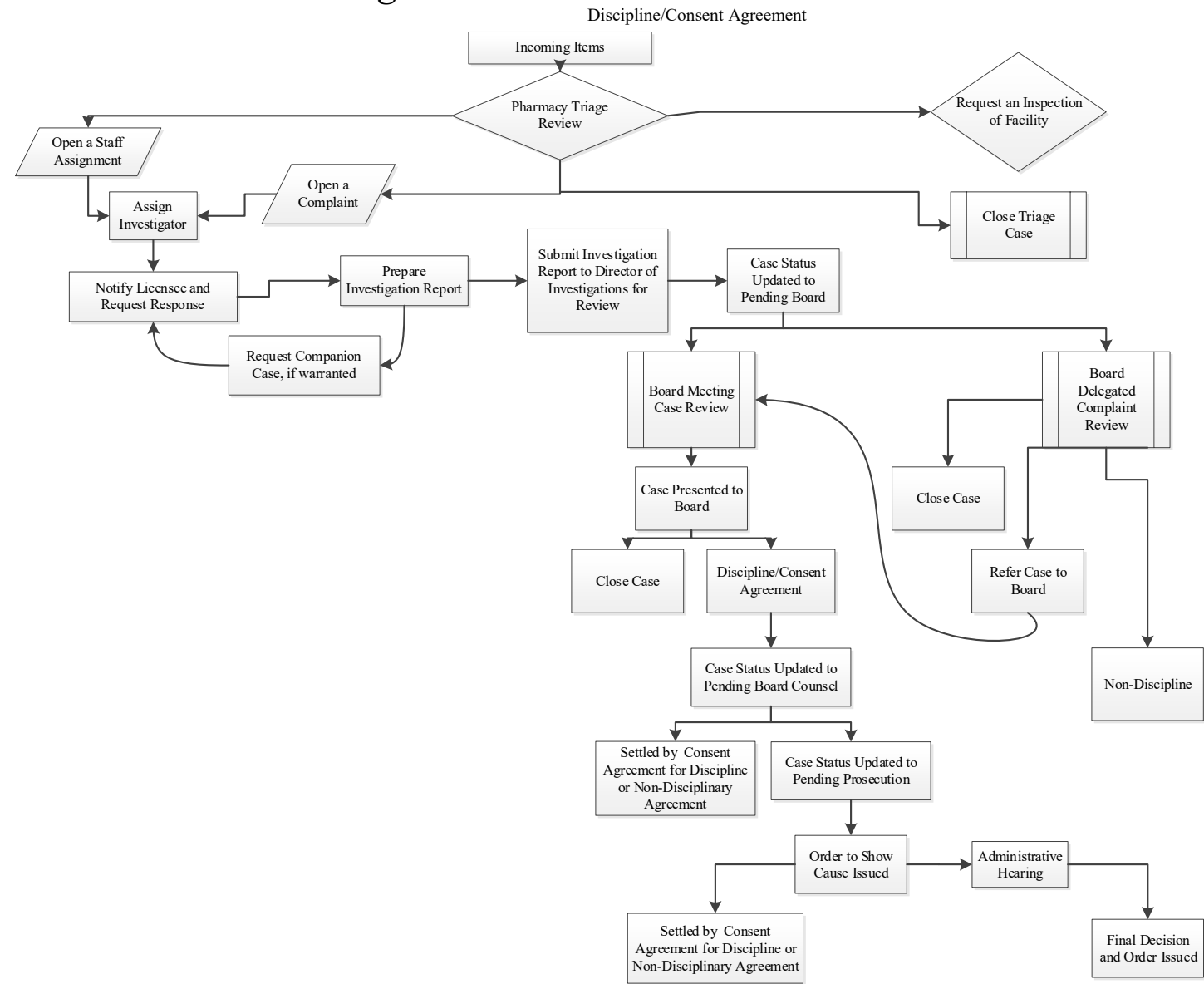
This report details all formal complaints and investigations that were pending, received, initiated, or opened by the Board during the period of December 1, 2022 through December 1, 2023. Areas of focus in the past year have included the following:

- Expeditious processing of cases in 2023.
- Encouragement of continuing education deficiency self-reports (classified as “regulatory violations”), resulting in increased compliance.

- Licensee education and improved controlled substance security and accountability in pharmacies have contributed to a lower number of “drug violations” complaints.
- Investigator field presence has continued to be robust in 2023 allowing for investigators to promote regulatory compliance and assist with remediation.
- Strong relationships with our local, state and federal partners have been developed.
- Improved customer service through timely responses to inquiries/questions in order to promote compliance.

As the Board and Board 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.

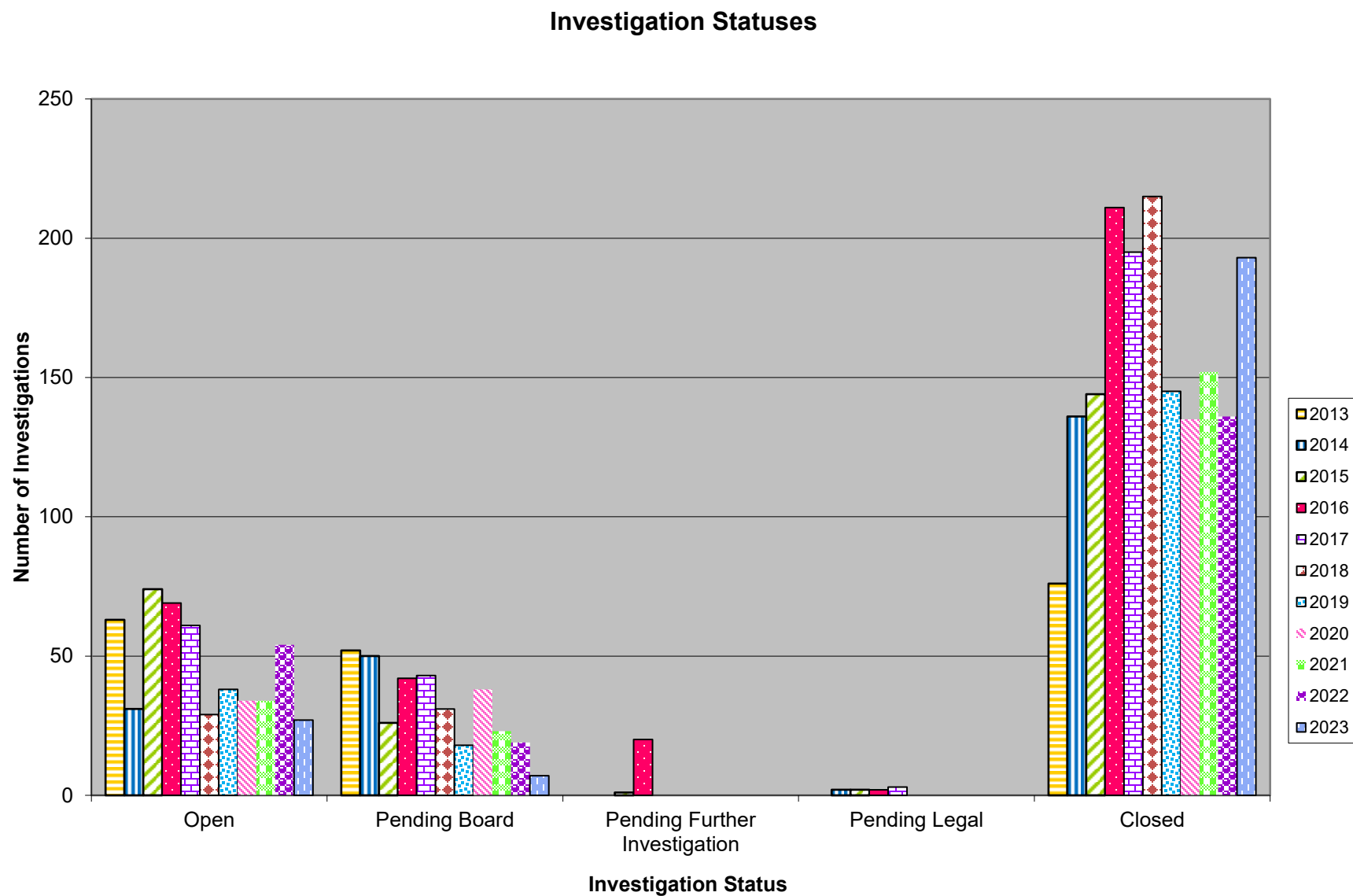
Appendix C: *Investigation Data*

Please see separate Excel spreadsheet data.

Appendix D: *Medication Error Data*

Please see separate Excel spreadsheet data.

Appendix E: *Investigation Status Types*



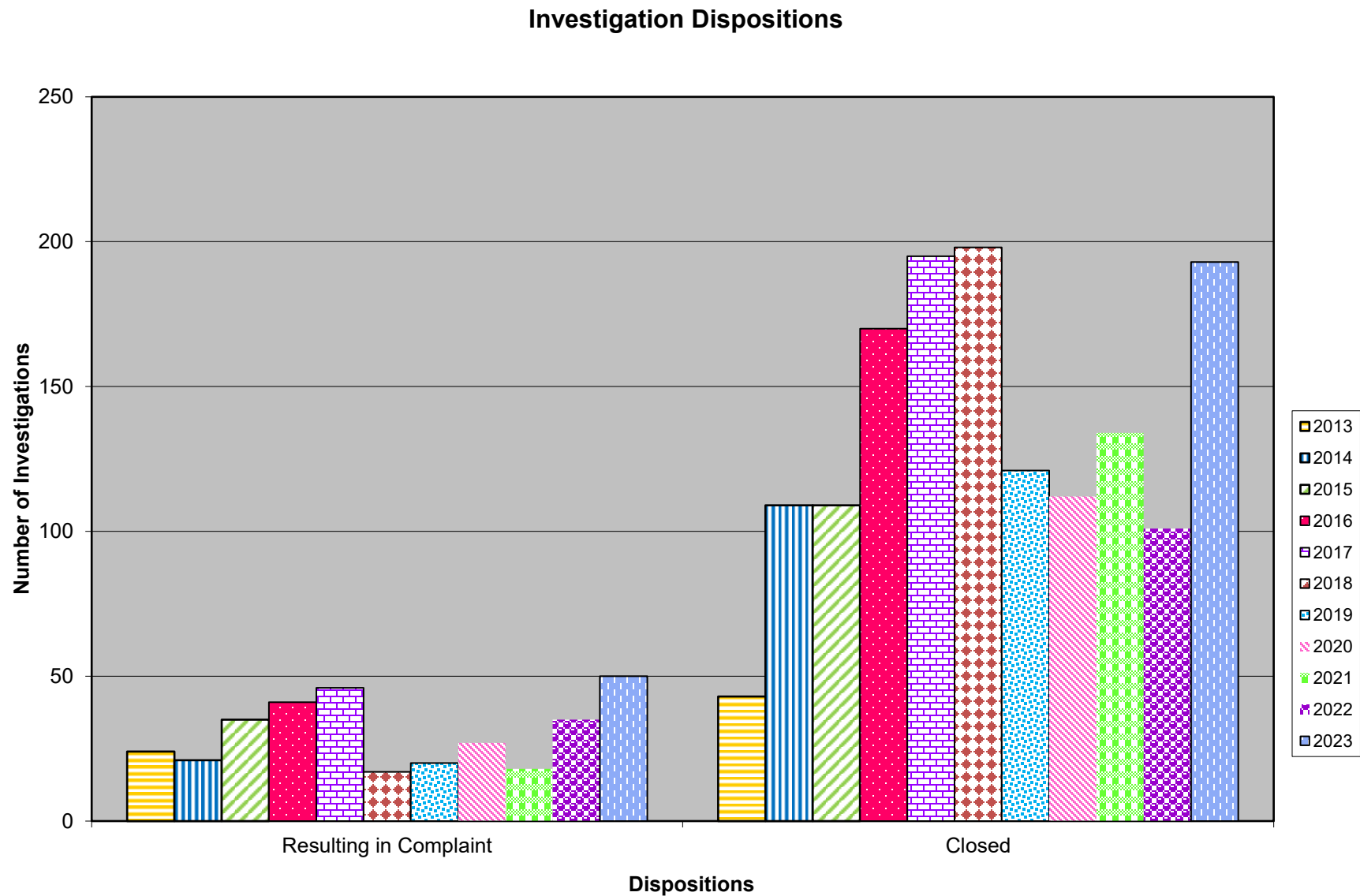
*What
this
means:*

Status	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Open	63	31	74	69	61	29	38	34	34	54	27
Pending Board	52	50	26	42	43	31	18	38	23	19	7
Pending Further Investigation	0	0	1	20	0	0	0	0	0	0	0
Pending Legal	0	2	2	2	3	0	0	0	0	0	0
Closed	76	136	144	211	195	215	145	135	152	136	193
Total	191	219	247	344	302	275	201	207	209	209	227

Investigators work diligently to obtain evidence, statements, and write investigation reports to get complete and accurate information to the Board as quickly as possible. This allows the Board to consistently hear cases as scheduled during each Board meeting. Additionally, many investigations involve continuing education deficiencies that are quickly disposed of through the BDR process.

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Appendix F: *Investigation Dispositions*



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Disposition	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Resulting in Complaint	24	21	35	41	46	17	20	27	18	35	50
Closed	43	109	109	170	195	198	121	112	134	101	193

What this means: The total number of investigations resulting in, or associated with, a complaint has increased since last year. The triage process continues to include preliminary follow up, providing additional information to determine if an actual violation has occurred. Investigations classified under the investigation type “Failure to Fill Rx Properly” are increasingly sent to Board for review as investigations rather than complaints. The Board then votes whether additional companion investigations or complaints need to be opened on individual licensees. As indicated in Appendix E, investigations of continuing education deficiencies are also presented as investigations. This allows the Board to make the determination of whether or not a complaint is necessary.

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Appendix G: Most Common Investigation Types

OBJ

Investigation Type	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Regulatory Violation	18	27	31	71	90	95	78	67	55	56	68
Failure to Fill Rx Properly	28	28	21	17	27	44	45	40	36	39	57
General Practice Standards	16	17	33	63	76	66	31	38	38	40	41
Failure to Fill Rx Properly	28	28	21	17	27	44	45	40	36	39	
Delay in Therapy	0	0	11	4	1	0	1	10	14	20	20
Inspectional Deficiencies	21	7	17	18	16	22	12	9	9	8	12
Drug Violation	32	62	61	95	58	22	10	12	13	10	10
SRE (Serious Reportable Event)	0	0	0	0	2	4	6	10	12	11	5

What this means: The Board continued to investigate a significant number of regulatory violations in 2023. Controlled substance loss reports, or “Drug Violations” remain steady as a result of increased compliance and [Policy 2022-01 updates](#), which allow pharmacies ample time to properly investigate the circumstances of a controlled substance loss prior to reporting, resulting in an overall downward trend since its implementation in 2018. “Delay in Therapy” investigations have remained steady as there has been more information gathering at the triage level to determine if an actual delay in therapy has occurred. Failure to Fill Rx Properly increased significantly from 2022 to 2023.

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Appendix H: *Other Investigation Types*

OBJ

Investigation Type	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Discipline in Another Jurisdiction	0	0	0	0	2	1	3	6	23	18	4
Practice Beyond Scope	0	0	1	2	0	0	0	0	0	0	3
Criminal Activity	0	1	6	8	2	1	3	5	5	1	2
Compounding Pharmacy OSR	0	0	0	0	1	1	1	2	1	2	1
Unlicensed Practice	0	0	0	0	1	2	2	1	0	1	1
Practice While Impaired	0	1	0	0	2	2	1	3	0	0	1
Other	27	52	19	19	6	6	4	0	0	0	1
Confidentiality Violation	1	1	2	5	4	3	2	0	0	1	1
Unethical Conduct	1	0	1	2	0	1	1	2	3	1	0
Substance Abuse	1	0	0	0	0	0	0	0	0	1	0
Dishonest or Deceptive Conduct	0	0	0	0	0	0	0	2	0	0	0
Inadequate/Fraudulent Documentation	0	0	1	1	0	1	1	0	0	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 was warranted. Although “Discipline in Another Jurisdiction” has decreased, Board staff continues to review the National Association of Boards of Pharmacy (NABP) Clearinghouse. The NABP Clearinghouse captures discipline from other jurisdictions and makes this information available to the Board.

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Appendix I: *Investigations by License Type*

OBJ

Investigations by License Type	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Drug Store	123	177	202	261	199	161	113	125	120	117	120
Pharmacist	21	20	35	68	82	104	81	76	85	85	89
Pharmacy Technician	10	11	5	9	12	6	6	4	2	1	9
Nuclear Pharmacy	0	0	1	3	5	1	0	2	1	1	4
Pharmacy Technician in Training	0	0	0	0	0	0	0	0	0	1	2
Wholesale Distributor	1	2	3	2	3	1	1	0	1	2	1
Pharmacy Intern	2	1	1	1	1	2	0	0	0	1	1
Non-Resident Outsourcer	0	0	0	0	0	0	0	0	0	1	1
Unlicensed	33	2	0	0	0	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 with drug stores, as the drug store maintains and holds the records surrounding the alleged incidents. Once information is obtained from the drug store and reviewed, related companion cases are opened against any individual licensees involved in the alleged incidents whose alleged conduct constitutes a violation of applicable regulation or statute.

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Appendix J: Formal Complaint Status Types

[OBJ]

Status	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Pending Investigation	55	42	45	84	36	19	21	22	43	45	74
Pending Board Action	102	58	17	70	32	13	8	12	5	39	41
Pending Board Counsel	84	126	64	31	24	20	31	20	58	164	211
Pending Prosecution	48	42	43	30	26	23	9	7	1	0	98
Pending Hearing Officer	0	4	1	9	5	9	8	2	1	0	0
Pending Administrative Hold	0	0	0	1	0	0	0	0	0	0	0
Closed	151	284	267	197	328	127	116	106	67	73	104
Total	440	556	437	422	451	211	193	169	175	321	528

What this means: This chart captures a snapshot of the complaint status of active complaints at the end of the reporting period for each year indicated. The reporting period covers December 2 of the prior year to December 1 of the year indicated in each column heading. Active complaints for the reporting period are those that were already open at the start of the reporting period as well as those opened during the reporting period. Complaints that are updated to pending board action are routinely heard at the next scheduled Board meeting, unless they are delayed by extenuating circumstances. Many of the complaints that have been pending board action for longer than a month have not been heard due to scheduling of an investigative conference, pending external agency investigations, or holding a case due to other pending investigations for the same licensee.

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Appendix K: *Formal Complaint Dispositions*

[OBJ]

Disposition	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Resulting in Discipline	51	74	74	70	108	58	72	57	38	35	53
Resulting in Non-Discipline	26	78	83	13	37	13	11	18	16	17	3
Dismissed	69	120	110	114	183	56	33	31	13	22	40

What this means: The complaints resulting in discipline are largely 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. Non-disciplinary dispositions may involve stayed probations that include terms and conditions to be completed by the licensees. Many complaints are dismissed due to licensees having completed proactive remediation as part of a corrective action plan.

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Appendix L: Most Common Complaint Types

OBJ

Complaint Type	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Inspectional Deficiencies	65	60	79	79	53	32	32	17	30	92	193
Drug Violation	54	73	70	100	153	93	93	86	91	153	181
General Practice Standards	52	27	18	16	16	14	12	12	8	23	47
Regulatory Violation	23	47	48	41	49	23	18	15	8	7	27
Discipline in Another Jurisdiction	25	25	8	4	1	1	2	5	14	19	20
Failure to Fill Rx Properly	162	229	142	128	140	27	7	5	2	6	18

What this means: In 2023, the most common complaint type was “Inspectional Deficiencies”. “Inspectional Deficiencies” increased greatly from 2022 to 2023. Complaints in this category often are the result of a violation observed by pharmacy investigators during an inspection. The number of “Discipline in Another Jurisdiction” cases increased due to the continued review of the National Association of Boards of Pharmacy (NABP) Clearinghouse. The Clearinghouse captures discipline from other jurisdictions and makes this information available to the Board.

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Appendix M: Other Complaint Types

OBJ

Complaint Type	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Unlicensed Practice	5	2	4	3	0	1	5	3	4	3	14
Delay in Therapy	0	0	0	1	0	0	1	1	2	5	10
Criminal Activity	2	1	1	9	9	5	10	9	7	5	5
DOR Notice	1	1	2	2	5	2	4	2	1	1	4
Practice Beyond Scope	0	0	0	0	0	0	0	0	0	0	3
Practice While Impaired	1	1	0	0	1	0	1	0	0	1	2
Substance Abuse	1	0	0	0	0	0	0	0	0	2	1
Other	9	5	4	3	2	1	0	4	3	1	1
Unprofessional Conduct	2	0	0	0	1	1	1	1	1	1	1
Serious Reportable Event (SRE)	18	62	53	30	19	10	3	3	0	1	1
Criminal Conviction	0	0	1	0	0	0	0	3	3	0	0
Unethical Conduct	1	0	2	4	1	1	1	0	0	1	0

What this means: In 2023, the Board saw an increase in complaints for “Unlicensed Practice” some of which were self-reported. The Board also saw an increase in complaints for “Delay in Therapy” as there was an increase in consumer allegations submitted to the Board often due to unanticipated temporary store closures. “Practice Beyond Scope” was included as a complaint category for the first time in 2023.

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Appendix N: Complaints by License Type

OBJ

Complaints by License Type	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Drug Store	151	195	194	203	237	137	131	106	118	247	403
Pharmacist	176	238	165	133	133	48	36	35	34	39	68
Pharmacy Technician	104	100	71	76	72	19	24	17	12	12	26
Pharmacy Technician in Training	0	0	0	0	0	1	3	8	9	13	16
Wholesale Distributor	2	2	2	2	4	3	3	3	2	5	7
Nuclear Pharmacy	0	0	0	1	1	0	0	0	0	0	3
Resident Outsourcer	0	0	0	0	0	0	0	0	0	0	2
Non-Resident Outsourcer	0	0	0	0	0	0	0	0	0	1	2
Pharmacy Intern	3	9	5	6	4	3	0	0	0	1	1
Unlicensed	2	1	0	1	0	0	0	0	0	0	0

What this means: In 2023, most complaints opened by the Board were against drug stores. Many of the drug store complaints involve unknown losses of controlled substances and inspectional deficiencies. In 2023, the overall complaint volume has increased due in large part to the inspectional deficiencies observed by pharmacy investigators while conducting inspections.

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Appendix O: *Collaboration with Outside Agencies*

OBJ

Collaboration with Outside Agencies	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Complaints	42	60	49	67	77	41	38	49	36	46	73
Investigations	20	26	16	25	38	18	8	42	28	12	13

What this means: The Board and Board staff continue to forge strong relationships with our local, state and federal partners.

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Appendix P: Case Openings

OBJ

Openings	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Complaints	208	252	164	226	226	77	114	83	113	198	279
Investigations	129	100	163	211	170	155	140	132	141	139	153

What this means: In 2023, complaint and investigation openings have both increased. This may be attributed to the increasing field presence since the COVID-19 pandemic began. Additionally, the triage process often includes preliminary investigation of allegations, providing a more accurate assessment as to whether a complaint or an investigation should be opened.

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Appendix Q: Case Closings

OBJ

Closings	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Complaints	151	284	267	197	328	119	113	106	67	71	104
Investigations	76	136	144	227	195	221	130	127	152	127	193

What this means: The number of complaints and investigations closed by the Board has increased in comparison to that of previous years. Investigators and Board staff continue to work diligently to conduct investigations and process cases expeditiously.

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