CNA HPSO

Pharmacist Professional Liability Exposure Claim Report: 3rd Edition

The American Pharmacists Association (APhA) leads the pharmacy profession by supporting pharmacists, student pharmacists, and pharmacy technicians in their role in optimizing medication use and patient health outcomes. APhA does this through advocacy, education, practice tools, and resources, for members to engage and learn from each other.

APhA is proud to contribute to and support the *Pharmacist Professional Liability Exposure Claim Report: 3nd Edition*. We thank CNA and Healthcare Providers Service Organization (HPSO) for their work, and believe this report will assist our members in enhancing their patient safety practices that advance the profession and helps pharmacists deliver the highest quality patient-centered care.

Michael Hogue, PharmD, FAPhA, FNAP, FFIP
Executive Vice-President and CEO, The American Pharmacists Association (APhA)

APhA
American Pharmacists Association
For Every Pharmacist. For All of Pharmacy.

The Institute for Safe Medication Practices (ISMP) is pleased to have provided input into the development of the *Pharmacist Professional Liability Exposure Claim Report: 3rd Edition*. ISMP's commitment to advancing medication safety means we recognize how essential collaboration within the healthcare community is for error prevention. Our collaboration with Healthcare Providers Service Organization (HPSO) provides valuable medication safety content designed to help healthcare professionals follow safe medication practices and keep patients safe. We thank HPSO for their work, and we believe that this report will assist pharmacists in enhancing their risk management practices.

Rita K. Jew, PharmD, MBA, BCPPS, FASHP
President, Institute for Safe Medication Practices (ISMP)

ISMP
Institute for Safe Medication Practices
An ECRI Affiliate

Top Ten Key Findings of the Pharmacist Professional Liability Exposure Claim Report

The average total incurred **increased** from $132,185 to **$136,000 (2.9 percent)** from the prior report. (See page 8.)

40%

The average total incurred for independent or individually owned pharmacies or pharmacy franchises has **increased almost 40 percent**, from $76,701 to $106,647 as shown in Figure 7. This increase was attributable to multiple large claims that resulted from **wrong drug errors**. (See page 10.)

Claims associated with **compounding pharmacies** tend to be some of the **most severe** as compared to other pharmacy types, with an average total incurred of $438,221. (See page 10.)

Wrong dose/strength claims remain the second highest percentage of all claims by allegation. The category also reflected a **46 percent increase** in average total incurred from $49,901 to $72,972 (Figure 9). Several high severity claims, including two cases of permanent organ injury and one patient death, contributed to this increase. (See page 13.)

3X

Although less common than other top allegations, **calculation and/or preparation errors** continue to be the allegation with some of the most severe claims, with an average total incurred that is more than **three times the overall average** of $136,000. (See page 13.)

19%

The average total incurred for **claims with harm, increased by 19 percent**, from $110,640 in the 2018 dataset to $132,155 in the 2023 dataset. (See page 25.)

Claims that resolve without an indemnity payment may nevertheless **incur expenses**. Such expenditures include **attorney fees, expert witness fees, and investigation costs**. These claims cost $11,336 on average, as demonstrated in Figure 16. (See page 26.)

The average defense payment of $7,650 for **license defense matters** in the 2023 dataset has **increased 43 percent** since the 2018 dataset ($5,349) and has **more than doubled** since the 2013 dataset of $3,685. (See page 30.)

$7,650

Allegations related to pharmacists' **professional conduct** comprise **41.1 percent** of all license defense closed matters. (See page 33.)

70%

Approximately **70 percent of license protection matters** led to some type of **Board action** against a pharmacist's license. (See page 38.)

Contents

Introduction **4**

Part 1: Pharmacist Professional Liability Exposures and Data Analysis. **5**

Dataset and Methodology 6

Limitations and Considerations. 7

Claim Analysis Overview 7

Comparison of Average Total Incurred and Claim Count Distributions 8

Closed Claims by Licensure and Type of Insured 9

Analysis of Claim Outcomes 10

Analysis of Pharmacy Type 10

Analysis of Allegations 12

Analysis of Injury 23

Analysis by National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Category. 25

Analysis of Claim Expenses 26

Risk Management and Medication Safety Resources 27

Part 2: Analysis of License Protection Matters with Defense Expense Payment . . . 29

Introduction. 29

Database and Methodology 29

Data Analysis. 30

Analysis of Matters by Allegation Class 30

Analysis of Allegation Class Sub-Categories 33

Allegations Related to Professional Conduct 33

Allegations Related to Medication Management 35

State Board of Pharmacy Outcomes. 38

Introduction

In collaboration with Healthcare Providers Service Organization (HPSO), CNA provides professional liability insurance to approximately 80,000 pharmacists and more than 3,500 pharmacies. As pharmacy practice continues to evolve and pharmacists' responsibilities expand, patients and healthcare providers increasingly rely upon the pharmacist's knowledge and experience to help ensure safe and effective patient care.

As part of our ongoing effort to provide informative and useful educational resources to our insureds and the healthcare industry, we are pleased to present this third edition of our Pharmacist Professional Liability Exposure Claim Report. It presents a unique perspective regarding professional liability closed claims, pharmacy board license protection matters, and associated allegations or injuries. Recognition and understanding of the types of medication errors and associated injuries that are most likely to occur will help inform and facilitate risk assessment and risk mitigation strategies that apply broadly to pharmacy practice settings. The summary of exposures and resources, reflected in this report, is designed to benefit our insureds and the pharmacy profession, irrespective of the practice setting. We hope that you will find this resource to be a useful tool for improving patient safety and pharmacy practice.

Terms

For the purposes of this report only, please refer to the following terms and explanations.

- **2013 dataset** – A reference to the prior CNA report, entitled *"2013 Pharmacist Liability: A Ten-Year Analysis"*, which included data from 2002 to 2011.
- **2018 dataset –** A reference to the prior CNA report, entitled *"Pharmacist Liability Claim Report: 2nd Edition"*, which included data from 2012 to 2016.
- **2023 dataset –** A reference to this CNA report, entitled *"Pharmacist Professional Liability Exposure Claim Report: 3rd Edition"*, which includes data from 2017 to 2022.
- **Distribution** – Refers to a specific group of closed claims with categories expressed as a percentage of the total.
- **Expense payment** – Monies paid in the investigation, management or defense of a claim, including, but not limited to, expert witness expenses, attorney fees, court costs and record duplication expenditures.
- **Total paid indemnity** – Monies paid on behalf of an insured pharmacist in the settlement or judgment of a claim.
- **Total incurred** – The sum of total paid indemnity and expense payments.
- **Average total incurred** – The costs of total paid indemnity and expense payments, divided by the total number of claims.

Part 1: Pharmacist Professional Liability Exposures and Data Analysis

Part 1 of the report provides selected findings from the 2023 dataset, including comparisons to prior claim reports. All professional liability claims included in this section result from a demand for money or services, in which an insured is named and professional malpractice is alleged. The demand may be asserted by a patient, a surviving family member or estate, or by an attorney representing the plaintiff.

The COVID-19 pandemic has affected the healthcare industry in a multitude of ways. With court system and pharmacy board closures, as well as delays during the pandemic, readers may contemplate the potential effect on the 2023 dataset and comparisons to past reports. A review of the 2018 and 2023 datasets revealed no notable impact on the 2020 to 2022 years compared to prior years. The variation in claims closed and average total incurred by year during the pandemic was similar to non-pandemic years overall. Errors and injuries specific to the pandemic, such as COVID-19 vaccine claims, represented a minimal effect on the 2023 dataset. This result may change in the upcoming months, or years, as additional claims are asserted and closed. Our goal is to help pharmacists enhance their practice and minimize professional liability exposures by identifying loss patterns and trends in the following categories:

- Pharmacy types
- Licensure types
- Allegations asserted against pharmacists or pharmacies
- Types of dispensing errors
- Injuries or adverse outcomes associated with claims
- Expenses associated with claims

Part 1 also includes a number of case studies highlighting potential risks, errors, and associated liability exposures encountered by pharmacists or pharmacies. Risk management resources are offered to help the reader identify opportunities and methods to mitigate these exposures.

Our goal is to **help pharmacists** enhance their practice and **minimize professional liability** exposures by identifying loss patterns and trends.

Spotlights on Risk Management

To supplement the ***Pharmacist Professional Liability Exposure Claim Report: 3rd Edition***, CNA and HPSO will publish seven Spotlight documents, which will highlight specific topics and provide greater detail on key risk management practices and medication/patient safety areas.

The following Pharmacist Spotlights include resources such as case studies, risk control considerations, and self-assessment checklists designed to help pharmacists evaluate and mitigate risk exposures associated with current practice:

- Defending Your License
- Documentation
- Vaccination Safety
- Safety Culture
- Policies and Procedures
- De-escalation and Crisis Management
- Workplace Issues and Well-being

Dataset and Methodology

There were 862 professional liability closed claims and incidents attributed to CNA-insured pharmacy professionals and entities in the HPSO program in the 2023 dataset. Part 1 of this report is comprised of 187 CNA professional liability claims that:

- Involved a pharmacist, pharmacy technician or pharmacy (business/corporate entity);
- Closed between January 1, 2017 and December 31, 2022, irrespective of when the claim was first reported or initiated; and
- Resulted in an indemnity payment of $1 or greater.

Because of the uniqueness of each individual claim, the average total incurred amounts displayed within this report may not necessarily be indicative of the severity attributed to any single claim.

Of note: an incident involving compounding of a sterile injectable product resulted in multiple patient injuries and claims that were reflected in both the 2018 and 2023 datasets. The injuries were originally treated as multiple claims in the 2018 dataset. However, these cases were combined into one claim in the 2023 dataset, as all injuries and losses for this case were associated with one incident and one insured, as summarized below:

- These cases resulted from alleged bacterial and fungal contamination of a compounded steroid medication. Following reports to the Food and Drug Administration (FDA) of multiple infections associated with the injection of sterile products distributed by a compounding pharmacy, the FDA recommended that healthcare providers discontinue use of the compounding pharmacy's products. The compounding pharmacy also issued a voluntary nationwide recall of all of its sterile compounded products. During its investigation, the FDA confirmed that unopened multi-dose, preservative-free vials supplied by the pharmacy contained both bacterial and fungal contamination. An FDA inspection of the pharmacy later resulted in numerous compliance observations, including, but not limited to:
    - failure to validate sterile product processing methods
    - failure to properly clean, maintain and sanitize equipment
    - failure to establish and document procedures designed to prevent contamination
    - failure to address batch potency specification failures
    - inadequate procedures and testing to ensure that products are sterile and pyrogen-free, as labeled.

Multiple lawsuits alleged that the plaintiffs' mild to severe infections and related sequelae resulted from injection of these contaminated products. Damages varied by case, but generally included medical expenses (some requiring hospitalization), pain and suffering and lost wages. After the settlement of all related cases, the total incurred for all claims arising from the incident exceeded $2,000,000, including in excess of $1,000,000 in expense payments.

Limitations and Considerations

- The data include only CNA-insured pharmacists, pharmacy technicians or pharmacy entities.
- Indemnity and expense payments include only monies paid by CNA on behalf of its insureds.
- Other possible sources of payment in response to the claim are not considered.
- The average total incurred includes only CNA indemnity payments and claim expenses. Numerous claims involve payments by co-defendants.
- The data reflect the "per claim" policy limits, which are typically $1,000,000 for CNA primary professional liability insurance.
- As some elements of the inclusion criteria in each dataset and in this report overall may differ from that of the previous CNA/HPSO pharmacist claim analyses and claim reports from other organizations, readers should exercise caution about comparing these findings with other reviews.

Claim Analysis Overview

Figure 1 provides a summary of total claim costs and average total incurred for the 187 claims included in the 2023 dataset. Higher expense payments related to claims involving pharmacists employed by a CNA-insured corporate entity can be attributed to two claims. The incidents resulted from claims involving sterile product repackaging and sterile compounding, leading to expense payments in the six and seven-figure range.

In the 2023 dataset, claims attributed to pharmacy technicians employed by a CNA-insured entity resulted in no expense payments. A review of the limited number of claims revealed that either negotiations led to co-defendants being responsible for all defense expenses, or early settlement was sought due to clear evidence of liability. An example includes a case in which the pharmacy technician pulled a correctly filled/bagged prescription medication and erroneously provided it to a patient with a similar last name. This error highlights the importance of confirming the "right patient" in every case, by using two or more patient identifiers. Acceptable identifiers include, but are not limited to, patient name, date of birth, home address and telephone number. Consider reviewing this resource from the Patient Safety Network (PSNet) for further information. Point-of-sale technology solutions that require electronic identity verification also should be considered. See the Institute for Safe Medication Practices (ISMP) 2023-2024 Targeted Medication Safety Best Practices for Community Pharmacy for this and other recommendations.

Additional detail by type of insured is presented in **Figures 4 and 5,** as well as within the associated narrative.

1 Summary of Total Claim Costs by Type of Insured
Closed Claims with Paid Indemnity of ≥ $1

Type of Insured	Total Indemnity	Total Expense	Average Total Incurred
Pharmacist employed by CNA-insured corporate entity	$10,538,390	$2,975,854	$139,322
Individually insured pharmacist	$10,021,480	$1,631,204	$132,417
Pharmacy technician employed by CNA-insured corporate entity	$265,000	$0	$132,500
Total	**$20,824,870**	**$4,607,058**	**$136,000**

Comparison of Average Total Incurred and Claim Count Distributions

- The average total incurred increased from $132,185 to $136,000 (2.9 percent) from the prior report, as reflected in **Figure 2**.
- Notably, claims settling in the $1 to $9,999 range *decreased* from 32.5 percent in the 2018 dataset to 23.6 percent of the total distribution in the 2023 dataset, while the percentage of claims in the $50,000 to $99,999 range *increased* from 7.8 percent to 13.9 percent, as indicated in **Figure 3**. This contributed to the overall increase in average total incurred.
- The percentage of claims with incurred losses above $750K has remained relatively stable between the 2018 and 2023 datasets at 4 to 5 percent of the total distribution.

Years from Occurrence to Closed Claim

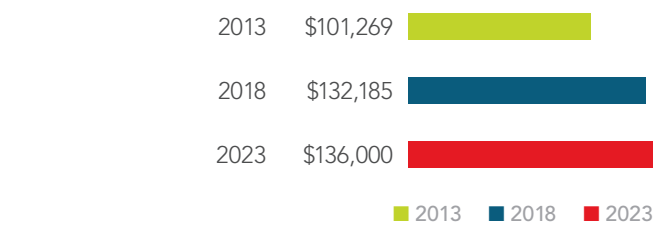
2.5 YEARS — Closed claims with paid indemnity of ≥ $10,000

1.4 YEARS — Closed claims with paid indemnity of < $10,000

2.9 YEARS — Closed claims with expense only

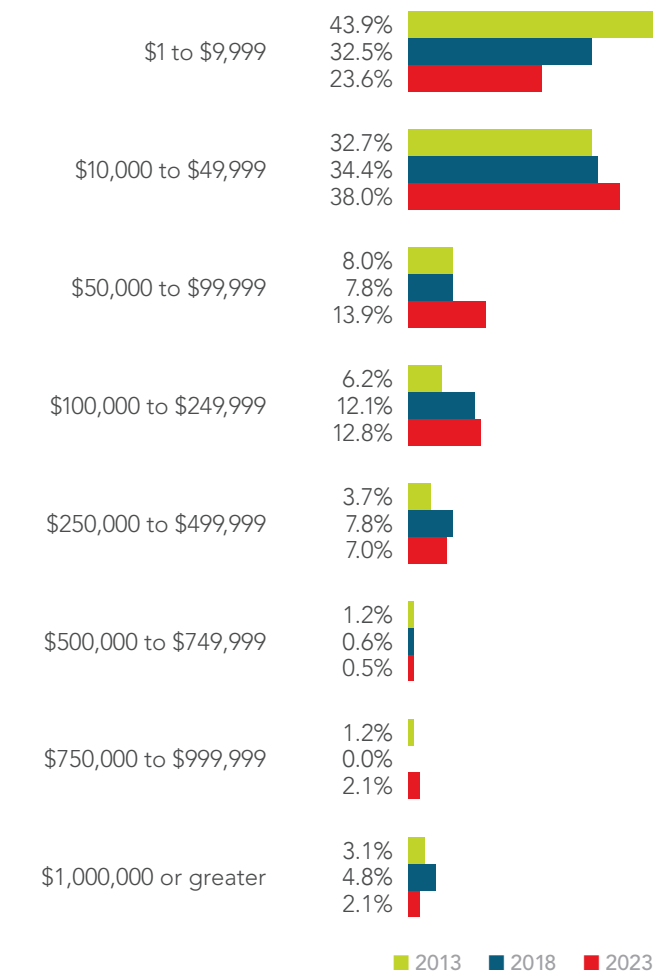
2 Comparison of Average Total Incurred

Closed Claims with Paid Indemnity of ≥ $1



3 Comparison of Closed Claim Count Distributions by Paid Indemnity Range

Closed Claims with Paid Indemnity of ≥ $1



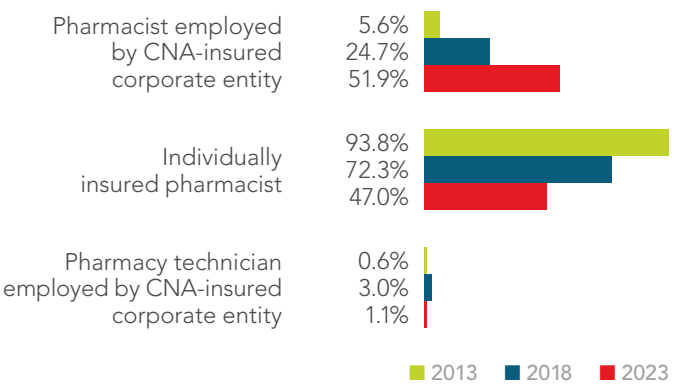
The average total incurred **increased** from $132,185 to **$136,000 (2.9 percent)** from the prior report.

Closed Claims by Licensure and Type of Insured

- Similar to the previous editions of this report, this dataset consists of closed claims that involved CNA-insured pharmacists, pharmacy technicians or pharmacies (business/corporate entity).
- As shown in **Figure 4**, the percentage of claims involving individually insured pharmacists has decreased significantly, while an increase in claims was noted for pharmacists employed by a CNA-insured corporate entity. A number of factors may be associated with this shift, such as evolving practices in pharmacy business management and employment practices.
- **Figure 5** demonstrates variability in the average total incurred within each of the three types of insured groups.
- Whether insured by an entity or possessing an individual policy, pharmacists encounter similar professional liability exposures. The differences in average total incurred reflected in **Figure 5** is primarily driven by the presence or absence of one or more severe claims. For example, individually insured pharmacists and pharmacists employed by a CNA-insured entity both experienced the same number of severe claims that settled at or near policy limits. In the 2023 dataset, higher defense expense payments for claims involving pharmacists employed by a CNA-insured entity resulted in the higher average total incurred for this group.
- Although the average total incurred has seen a significant increase for pharmacy technicians, as indicated in **Figure 5**, it should be noted that pharmacy technician claims represent a small number of closed claims.
  - Claim severity for pharmacy technicians is lower than for pharmacists on average, since they typically practice under a pharmacist's supervision. In most cases, the pharmacist and/or the pharmacy are named as the defendant or co-defendants.
  - The increase in the average total incurred for pharmacy technicians in the 2023 dataset was largely due to one claim involving a compounding pharmacy. The pharmacy technician erroneously prepared a compounded oral suspension for a minor patient using a concentrated form of the active ingredient. This resulted in an antispasmodic medication strength that was 50 times more than the prescribed level. The child became unresponsive and was hospitalized for more than a week before recovering. The total incurred for the insured pharmacy technician exceeded $200,000.

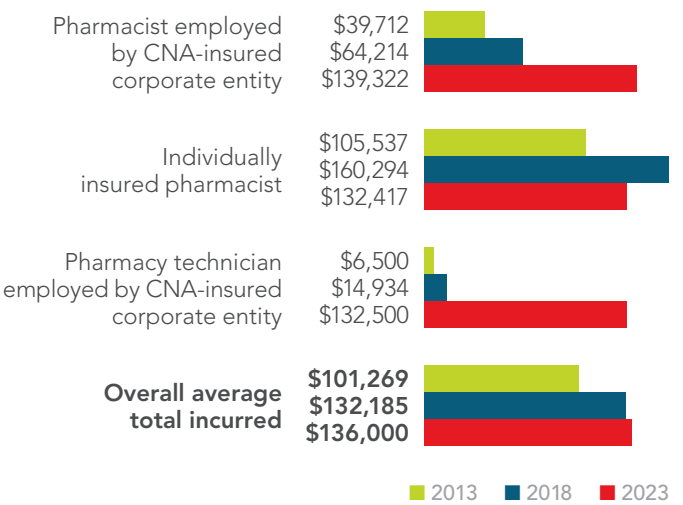
4 Distribution of Closed Claims by Licensure and Type of Insured

Closed Claims with Paid Indemnity of ≥ $1



5 Average Total Incurred of Closed Claims by Licensure and Type of Insured

Closed Claims with Paid Indemnity of ≥ $1



As noted by the American Society of Health-System Pharmacists (ASHP) in their "Standardize 4 Safety" initiative, no national consensus exists for concentrations of IV or oral liquid medications. Pharmacists should refer to the ASHP resources, as well as those issued by the University of Michigan, and use standard concentrations or commercially available products whenever possible to help mitigate such medication errors.

Analysis of Claim Outcomes

The following sections summarize professional liability claim distribution and average total incurred claim costs across various categories, including pharmacy type, allegation, injury, and National Coordinating Counsel for Medication Error Reporting and Prevention (NCC MERP) categories.

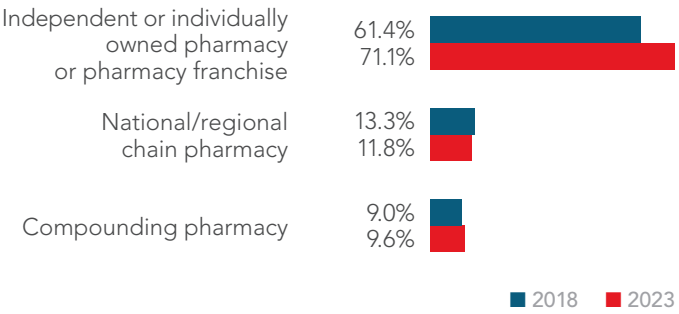
Analysis of Pharmacy Type

Figure 6 demonstrates a shift in the distribution of claims by pharmacy type, including an increase in independent or individually owned pharmacy or pharmacy franchise claims from 61.4 percent in the 2018 dataset to 71.1 percent in the 2023 dataset. In addition, the average total incurred for this pharmacy type has increased almost 40 percent from $76,701 to $106,647 as demonstrated in **Figure 7**. This increase was attributable to multiple large claims that resulted from **wrong drug** errors.

Claims associated with compounding pharmacies tend to be some of the most severe with the highest average total incurred for all pharmacy types. This category represents less than 10 percent of all claims. Therefore, the inclusion or absence of any large claims in this category can cause the average total incurred for compounding pharmacies to fluctuate significantly.

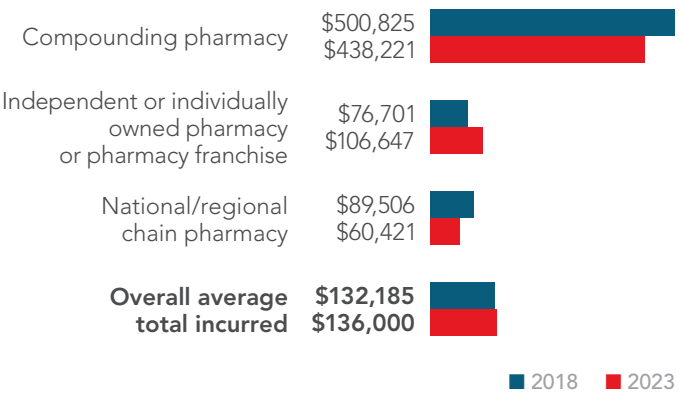
6 Distribution of Closed Claims by Top Pharmacy Type

Closed Claims with Paid Indemnity of ≥ $1
Only includes categories with the largest portion of the distribution.



7 Average Total Incurred by Top Pharmacy Type

Closed Claims with Paid Indemnity of ≥ $1
Only includes categories with the largest portion of the distribution.



The average total incurred for independent or individually owned pharmacies or pharmacy franchises has **increased almost 40 percent**, from $76,701 to $106,647 as shown in Figure 7. This increase was attributable to multiple large claims that resulted from **wrong drug errors**.

Compounding error claims in the dataset involved both sterile and non-sterile medications. High severity compounding claims primarily involved individual patient prescriptions, but also included compounded batch medications that involved multiple patients. The severity of these claims is a reflection of either the significance of the injury and/or the number of patients involved. The examples below provide additional perspective on compounding error claims.

Claims associated with **compounding pharmacies** tend to be some of the **most severe** as compared to other pharmacy types, with an average total incurred of $438,221.

- A 33-year-old patient with a history of chronic lymphocytic thyroiditis (Hashimoto thyroiditis) was prescribed thyroxine (T4). Finding the right dose for the patient had been challenging, leading the endocrinologist to prescribe a compounded product to facilitate dose flexibility. Soon after starting the new compounded medication, the patient experienced nausea, vomiting, chills and body aches. The patient initially suspected that they had influenza; however, the symptoms worsened. The patient then developed a rapid heart rate, severe headache and mental confusion. The patient sought medical care and was admitted to the hospital's intensive care unit (ICU). A definitive diagnosis initially eluded the treating providers. After further assessment, the ICU team established a diagnosis of thyrotoxicosis. They administered medications to induce a comatose state to help manage the condition. After the ICU team informed the endocrinologist of the patient's condition, he contacted the dispensing pharmacy. Analysis of the compounded capsules revealed an extraordinarily high active ingredient level, hundreds of times more than the desired level. A concentrated T4 had been used in compounding, instead of a 1:1000 T4 dilution. The patient asserted that chronic weakness and anxiety, as well as decreased cognitive function, had led to lost income and career opportunities. As part of a multi-defendant settlement, CNA contributed more than $350,000 on behalf of the insured pharmacist.
- The following claim resulted from a significant miscommunication concerning the nature of a compounded medication supplied to an otolaryngologist for office use. The compounding pharmacist filled the physician's order for dexamethasone 24 mg/mL, supplied in a vial. Although the pharmacy had compounded the solution previously, this was the first order from this physician. The physician intended to use the medication for injection into the middle ear. However, this was not clearly stated or documented in a medication order, prescription or other communications. The pharmacist intended the compounded product for external use only, and it was not compounded or labeled as a sterile product. Unfortunately, the product also was not labeled for external use only. Multiple patients alleged pain and injuries, with one patient suffering severe pain, tinnitus and hearing loss after multiple injections in both ears. Medical treatment included hearing aids and cochlear implant surgery. Both the physician and pharmacist participated in the settlement, resulting in a total incurred of more than $300,000 for the insured pharmacist.
- A compounding pharmacy received a lomustine prescription for a small-breed canine patient, a first-line medication to treat cutaneous lymphoma in dogs. The dog received one capsule of the compounded medication. Laboratory testing subsequently confirmed that the capsules contained six times the intended dose. The animal received supportive care for vomiting and other gastrointestinal (GI) symptoms. Due to previously compromised renal and liver function, the animal was euthanized soon after the overdose to prevent further suffering. This case resulted in a $10,000 payment, the limit of coverage for a veterinary claim under the policy.

Although the average total incurred is considerably lower for other pharmacy types when compared to compounding pharmacies, claims associated with other pharmacy types also may be severe. The following scenario provides an example of a claim involving an individually owned pharmacy:

- An elderly, hypertensive patient in an assisted living facility received a new prescription for metolazone 2.5 mg. A local pharmacy that supplied most medications for residents of the facility received and filled the order. The assisted living facility staff administered the medication for approximately three weeks. During this time, the patient began to feel ill and became increasingly weak. Complaints of GI distress, nausea, vomiting, and, later, GI bleeding followed. The patient was hospitalized, and blood tests revealed severe pancytopenia. The hospital staff contacted the pharmacy to investigate the patient's pre-admission medications, and discovered that the prescription was written correctly as metolazone 2.5 mg. However, the dispensed medication was methotrexate 2.5 mg. The patient's condition continued to decline, and they expired soon after admission to the hospital. The total incurred for the insured pharmacy in this case was more than $1,000,000.

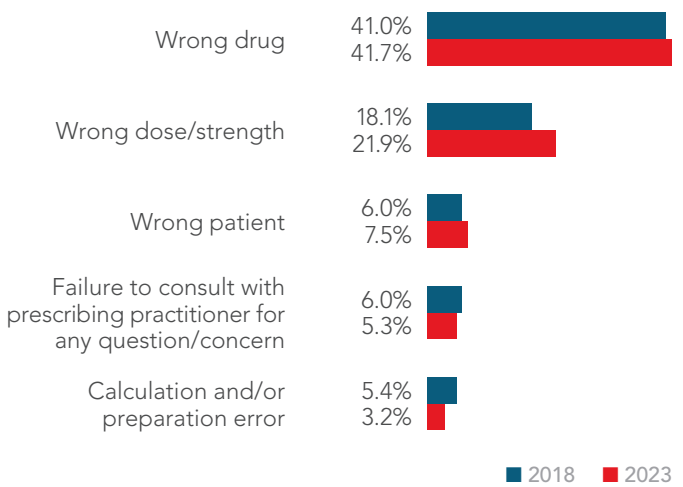
This specific error, and similar errors, are not new. Although the latest technology may help to reduce errors, mistakes may still occur. For example, entering a few medication letters into the pharmacy medication database may lead to a selection error with similarly spelled medication names and dosage strengths displayed on the screen. A minimum of five letters is recommended. However, five letters may still result in a list displaying more than just the desired medication. The ISMP resource entitled "Guidelines for Safe Electronic Communication of Medication Information," as referenced in this article, may help to minimize or eliminate medication errors.

Analysis of Allegations

- Claims asserting that the **wrong drug** was dispensed have remained the top allegation asserted against pharmacists in the two most recent editions of the claim report, as depicted in **Figure 8**.
- While only increasing slightly as a portion of total claims from 18.1 percent in the 2018 dataset to 21.9 percent in the 2023 dataset, **wrong dose/strength** claims remain the second highest percentage of all claims by allegation. The average total incurred for this category also has increased by 46 percent from $49,901 to $72,972 (**Figure 9**). Several high severity claims, including two cases of permanent organ injury and one patient death, contributed to this increase.

8 Distribution of Closed Claims by Top 5 Most Common Allegations

Closed Claims with Paid Indemnity of ≥ $1



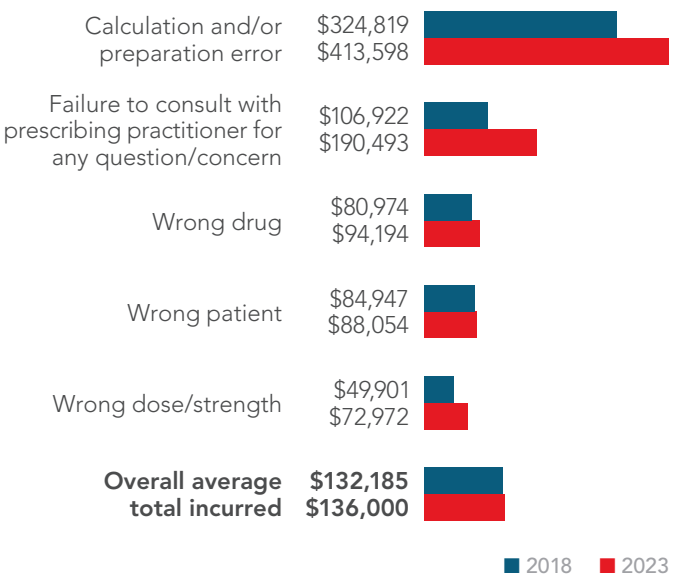
Wrong dose/strength claims remain the second highest percentage of all claims by allegation. The category also reflected a **46 percent increase** in average total incurred from $49,901 to $72,972 (Figure 9). Several high severity claims, including two cases of permanent organ injury and one patient death, contributed to this increase.

- The increase in the average total incurred for the **failure to consult with prescribing practitioner** was affected by claims associated with opioid prescriptions dispensed by an independent or an individually owned pharmacy or pharmacy franchise that resulted in death.

Although less common than other top allegations, **calculation and/or preparation errors** continue to be the allegation with some of the most severe claims, with an average total incurred that is more than three times the overall average of $136,000. Calculation errors often involved a misplaced decimal point or use of an incorrect conversion factor. Claims involving preparation errors also have resulted from using the concentrated form of an active ingredient rather than a specified diluted form. Prescriptions also may be misinterpreted when a "leading zero" is missing before a decimal point, or when a "trailing zero" appears with a whole number after a decimal point. These errors may lead to an active ingredient in the compounded product that is greater than intended. Adherence to compounding methods and practices, published by the official compendia of standards for drugs marketed in the United States, will help to prevent these and other compounding errors. Access the U.S. Pharmacopeia (USP) Compounding Compendium for further information. General Chapter <795> addresses non-sterile compounding specifically. This article from ISMP identifies a number of factors that may lead to an increased potential for error, including failure to include a verification step, visually similar labeling or ingredient appearance, and confirmation bias.

9 Average Total Incurred by Top 5 Most Common Allegations

Closed Claims with Paid Indemnity of ≥ $1



Although less common than other top allegations, **calculation and/or preparation errors** continue to be the allegation with some of the most severe claims, with an average total incurred that is more than **three times the overall average** of $136,000.

Pharmacist Spotlight

See additional resources to improve compounding practice:

- USP Compounding Compendium. Quality assurance resource for compounding methods, preparations and practices across healthcare settings.
- ISMP 2022 Guidelines for Sterile Compounding and the Safe Use of Compounding Technology.
- American Pharmacists Association compounding resources page.

The following cases involve errors related to **calculation and/or preparation**, as well as **wrong dose/strength:**

- A 50-year-old patient sought care from an ophthalmologist for blurry vision in the left eye. After a difficult diagnostic process and referral to a nearby university medical center, the cause was determined to be ocular toxoplasmosis. After unsuccessful treatment with other drug combinations, intravitreal clindamycin and dexamethasone proved to be beneficial. As treatment continued, a new prescription for clindamycin 150 mcg/0.1 mL with dexamethasone 0.8mg/0.2 mL was filled by a local compounding pharmacy to continue the therapy. Upon receiving the first injection from the new prescription, the patient immediately experienced a severe and painful burning sensation, with vision quickly fading to near blindness in the left eye. Although some vision returned over time, the patient alleged that the medication caused significant vision loss. The patient subsequently sued the ophthalmologist and the compounding pharmacist. The claim investigation revealed that, although the sterile product was labeled as prescribed, a calculation error resulted in a clindamycin concentration 100 times greater than prescribed. The compounding pharmacist was working alone during this timeframe, resulting in the lack of an independent review of the calculations. The physician was later dismissed from the lawsuit, as it would not have been possible to detect any problem with the properly labeled product at the time of injection. The defense pursued mediation before trial, resulting in a settlement with a total incurred of more than $450,000.

A double check of the critical calculation step may have prevented this error. Although double checks are beneficial and may have prevented this error, they are not a panacea. Read more about when to recommend and use double checks in your practice in this ISMP article.

- A 45-year-old patient suffered from cystic fibrosis and renal insufficiency. As their condition worsened, lung transplantation surgery was recommended as the best option to extend and improve the patient's quality of life. The patient received tacrolimus to prevent organ rejection following surgery. Approximately three months post-surgery, the patient presented to the pharmacy with a new tacrolimus prescription. The order called for 0.5 mg capsules, with directions to take five capsules every 12 hours. The insured pharmacist erroneously filled the prescription with tacrolimus 5 mg capsules, with the same directions to take five (5) capsules every 12 hours. The resulting dose totaled 50 mg per day, ten times the prescribed dose. Approximately two months later, the error was discovered, in part due to increasing kidney problems. The patient filed suit soon after learning of the medication error, alleging permanent kidney injury, incurred and future medical expenses, lost wages, pain and suffering, and loss of consortium. At the deposition, defense experts testified effectively and questioned whether the kidney damage was due to the patient's pre-existing kidney condition or other factors, rather than solely due to the medication error. At mediation, the case was settled for well below the initial demand, which was in excess of policy limits. Total incurred for the insured pharmacist was approximately $500,000.

Tacrolimus has been involved in many drug errors reported to the FDA Adverse Event Reporting System (FAERS) and the ISMP National Medication Errors Reporting Program (ISMP MERP). Consult this article for recommended safe practices to prevent tacrolimus-related errors. Potential errors may include, but are not limited to, a missing "leading zero" (0.5 mg strength), mix-ups with extended and regular-release products, as well as errors during compounding of tacrolimus oral liquid formulations.

Wrong Drug Dispensing Errors

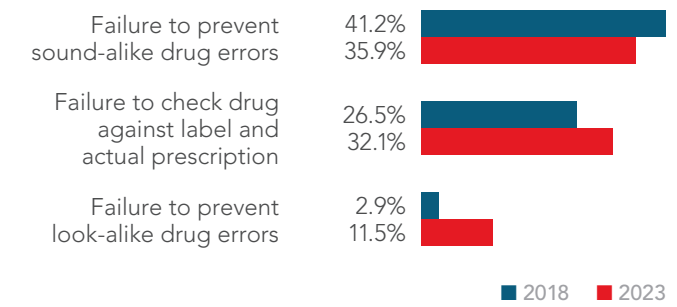
An array of possible error types or contributing factors may lead to a **wrong drug** allegation and patient injury. **Figures 10 and 11** reflect those contributing factors with the highest percentage of claims and their associated average total incurred in the 2023 dataset, with comparisons to the prior report.

- The 2023 dataset demonstrates a shift in cases involving look-alike and sound-alike (LASA) drug errors. These mix-ups, also known as confused drug errors, comprised the most common type of **wrong drug dispensing error** claims, accounting for a combined total of approximately 45 percent of claims across both datasets (**Figure 10**).
- Claims arising from sound-alike drugs represented the only **wrong drug** subcategory with an average total incurred ($161,914) that was more than the overall average total incurred of $136,000. (**Figure 11**)
- The average total incurred for cases involving the LASA claims was affected by several large claims. One error led to a patient's death, resulting in an outcome in excess of $1,000,000. Two other large claims, in which both the pharmacy and the pharmacist were named as co-defendants, involved patient organ failure. Each claim paid in excess of $750,000.
- The notable decrease in the average total incurred for the look-alike drug category from the 2018 dataset to the 2023 dataset can be attributed to a large claim involving a minor patient in the 2018 dataset. The error resulted in the patient suffering permanent harm from increased seizure activity.

Due to the high percentage of claims associated with LASA medications, strategies to manage and reduce risks associated with medication name mix-ups should be implemented. The ISMP also updated its list of drug names with Tall Man (mixed case) letters in 2023. The **Risk Management and Medication Safety Resources** section includes further information and resources.

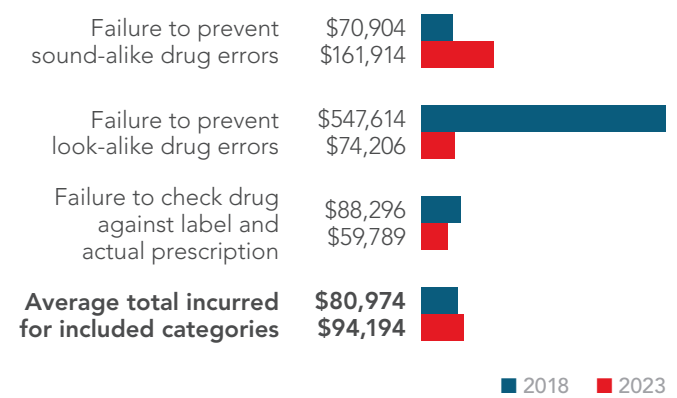
10 Distribution of Closed Claims by Wrong Drug Dispensing Errors

Closed Claims with Paid Indemnity of ≥ $1
Only includes categories with the largest portion of the distribution.



11 Average Total Incurred by Wrong Drug Dispensing Errors

Closed Claims with Paid Indemnity of ≥ $1
Only includes categories with the largest portion of the distribution.



Tall Man (Mixed Case) Lettering

hydrALAZINE or hydrOXYzine

Highlights differences between similar drug names by capitalizing dissimilar letters.

Can be used with color or bolding to draw attention to dissimilarities between look-alike drug names.

Alerts pharmacists and other healthcare providers that the drug name can be confused with another drug name.

Examples of claims involving wrong drug errors include the following:

- After nearly two years of medical evaluation and testing, a seven-year-old's diagnosis was confirmed as Wilson's disease. The physician prescribed penicill**AMINE** 250 mg to bind with and remove excess copper from the body. The pharmacist was not familiar with the medication, and, a search for the drug name in the available database, returned several similarly spelled products. The pharmacist selected and dispensed penicillin VK 250 mg in error. Two months later, a new prescription for penicill**AMINE** was presented to another pharmacist at the same pharmacy, and was again erroneously filled based upon the recorded medication history. The refills of the wrong medication continued for approximately one year before it was discovered when current medications were reviewed due to the patient being hospitalized. A lawsuit alleged negligence by the physician (delayed diagnosis), as well as the insured pharmacist (original **wrong drug** error) and the pharmacy (ongoing medication errors). Although some experts questioned the medical decision to prescribe penicill**AMINE** rather than other alternatives for this patient, a valid prescription was filled with the wrong medication. Allegations included the progression of liver damage, worsening behavioral problems, learning difficulties and neurological symptoms. Before trial, a settlement was sought and reached, resulting in a total incurred for the insured pharmacist of more than $250,000.

The use of Tall Man letters (e.g., penicill**AMINE**) and the addition of a medication alert in the pharmacy medication database would highlight this LASA medication risk. Including the brand name "Cuprimine" with the generic name in the system would further differentiate the drug from penicillin products. Prescribers also may mitigate medication error risks by including the indication for use in the prescription order. Review additional risk reduction methods in the PSNet medication error case study, and consult the "Confused Medications" resources at the end of Part 1.

- A failure to check the medication selected/dispensed against the prescription led to a metastatic breast cancer patient receiving the antihypertensive drug losartan instead of the hypnotic drug zolpidem. Syncope and a fall led to hospitalization and other sequelae, allegedly resulting in early death. Total incurred was more than $200,000.

Although checking the medication against the prescription may have prevented this error, other error prevention strategies also may have averted this outcome. Such techniques should include ensuring sufficient staffing levels and implementation of bar code scanning systems. From the pharmacist's perspective, offering and conducting patient counseling represents a sound professional practice. Each of these strategies may play an important role in preventing medication mix-ups.

- In another case involving confused medications, an elderly patient received a prescription for risperi**DONE** instead of the intended medication, r**OPINIR**ole, for Parkinson's disease. The patient sought care in the emergency department for nausea, vomiting and other GI symptoms. The patient was hospitalized to treat dehydration and for further observation. A settlement was reached involving the pharmacy and the insured pharmacist, with the pharmacist's total incurred of more than $100,000.

Multiple strategies may be pursued by the pharmacy and pharmacist to prevent LASA medication errors. Nevertheless, engaging the patient through education plays an important role. As described in this ISMP article, patients and/or caregivers should be advised about the risk of LASA medication mix-ups and steps for avoidance. Pharmacists should reiterate to patients that all questions about their medication therapy are welcome, especially questions that may prevent an error and/or injury.

Wrong Drug Closed Claims by Drug Prescribed/Dispensed

Claims that are **bolded in red** have an incurred cost that is higher than the overall average total incurred of $136,000. Claims with a **gray background** indicate that the drug prescribed was involved in more than one **wrong drug** closed claim.

Drug Prescribed	Drug Dispensed	Resulting Injury or Adverse Effect
Abilify (aripiprazole) 5 mg	Lexapro (escitalopram) 5 mg	Dizziness, anxiety, paranoia, headache, fatigue, nausea
Allopurinol 100 mg	Amitriptyline 100 mg	Dysarthria, gait instability, weakness, dizziness, hospital admission for observation
Anagrelide 1 mg	Anastrozole 1 mg	Respiratory arrest, requiring hospitalization
Aricept (donepezil) 10 mg	**Aripiprazole 10 mg**	**Emotional/psychological distress**
Aricept (donepezil) 10 mg	Abilify (aripiprazole) 10 mg	Vertigo, dizziness
Atenolol 25 mg	Amitriptyline 25mg	Dyspnea, chest pain
Buprenorphine 2 mg	Phenobarbital (strength not available)	Opioid withdrawal including irritability, insomnia and anxiety
Celexa (citalopram) 20 mg	Celebrex (celecoxib) 200 mg	Upper GI bleeding, requiring hospitalization
Cephalexin 500 mg	Desmopressin 0.2 mg	Hypotension, alleged renal damage, hospital admission for observation
Chlorothiazide (strength not available)	Diazoxide (strength not available)	Edema, electrolyte imbalance, vomiting (minor patient)
Chlorthalidone 50 mg	**Clozapine 50 mg**	**Syncope, lightheadedness, tachycardia, hospital admission for observation**
Clopidogrel; montelukast (strengths not available)	Valproic acid; Fioricet (APAP, butalbital, caffeine)	Falls, head injury, requiring hospitalization
Colace (docusate sodium) 100 mg	Doxycycline 100 mg	Rhabdomyolysis, diarrhea, weight loss, kidney failure, requiring hospitalization
Cyanocobalamin 1000 mcg/mL	Ketorolac 30 mg/mL	Injection site swelling, GI distress
Dexilant (dexlansoprazole) 30 mg	Cymbalta (duloxetine) 30 mg	GI distress, hospital admission for observation
Dexilant (dexlansoprazole) 60 mg	Duloxetine 60 mg	Chest pain
Dexilant (dexlansoprazole) 60 mg	Cymbalta (duloxetine) 60 mg	Dizziness, blurry vision
Duloxetine 20 mg	Doxycycline 50 mg	Syncope
Fluoxetine (strength not available)	Amantadine (strength not available)	GI distress
Geodon (ziprasidone) 40 mg	Celexa (citalopram) 40 mg	Insomnia, GI distress, emotional distress, hospital admission for observation (minor patient)
Hydralazine 25 mg	Hydroxyzine 25 mg	Tachycardia, anxiety
Hydroxyzine 25 mg	Hydralazine 25 mg	Headache, hypotension
Ibuprofen 200 mg	Morphine ER 200 mg	Toxic metabolic encephalopathy, respiratory arrest, hospitalization, death
Ibuprofen 800 mg	Gabapentin 600 mg	Increased heart rate, chest pain
Influenza vaccine	**NovoLog (insulin aspart) 100 Units/mL (U-100)**	**Hypoglycemia, diaphoresis, hospital admission for observation**
Keppra (levetiracetam) 500 mg	**Keflex (cephalexin) 500 mg**	**Nausea, vomiting**

Drug Prescribed	Drug Dispensed	Resulting Injury or Adverse Effect
Keppra (levetiracetam) 750 mg	**Levaquin (levofloxacin) 750 mg**	**Bilateral hearing loss**
Klonopin (clonazepam) 2.5 mg/mL (0.1 mg/drop)	Clonidine 0.1 mg/5 mL	Hyperkalemia, emotional/psychological distress
Labetalol 200 mg	**Lamotrigine 200 mg**	**Hypertension, burning/tingling, weakness**
Labetalol 200mg	Lamotrigine 200 mg	Dizziness, syncope, hypertension, requiring hospitalization
Lexapro (escitalopram) 10 mg	**Ambien (zolpidem) 5 mg**	**Vertigo, dizziness**
Lipitor (atorvastatin) 20 mg	Crestor (rosuvastatin) 20 mg	GI distress
Metformin 500 mg	Methocarbamol 500 mg	Hyperglycemia, dizziness, fall, requiring hospitalization
Methadone (strength not available)	Hydromorphone (strength not available)	Chest pain, fatigue
Methadone 10 mg	Dextroamphetamine sulfate 10 mg	Vertigo, dizziness
Methimazole 5 mg	Metolazone 5 mg	Dehydration
Methocarbamol 750 mg	Metformin ER 750 mg	Hypoglycemia, anxiety, irritability
Methylphenidate 10 mg	Methadone 10 mg	Vertigo, dizziness
Metolazone 2.5 mg	**Methotrexate 2.5 mg**	**Pancytopenia, hospitalization, death**
Metronidazole 500 mg	Ciprofloxacin 500 mg	Nausea, anorexia, mental confusion
Multiple	Prescribed meds, plus spironolactone 15 mg	Allergic reaction/rash
Multiple	Prescribed meds, plus Xanax (alprazolam) 1 mg	Dizziness, lethargy, fall, requiring hospitalization
Multiple	Tizanidine 4 mg Gabapentin 300 mg	Weakness, fall
None	Synthroid (levothyroxine) 75 mcg (0.075 mg)	Chest pain, tachycardia, hospital admission for observation
Norethindrone 0.35 mg	Norgestimate 0.25 mg/ethinyl estradiol 35 mcg (Sprintec)	Vomiting
Not available	Metformin, glipizide, levothyroxine sodium (strengths not available)	Hypoglycemia, hospital admission for observation
Omeprazole 20 mg	Fluoxetine 20 mg	Fatigue, headache, insomnia, confusion, GI distress
Ondansetron 4 mg/5 mL	Risperidone 1 mg/mL	Vomiting, drooling, tachycardia, hospital admission for observation (minor patient)
Oxaprozin 600 mg	Oxcarbazepine 600 mg (extended release)	Falls, urinary retention, nausea, vomiting, requiring hospitalization
Oxcarbazepine 600 mg	**Oxaprozin 600 mg**	**Seizure, cardiac arrest, renal failure, requiring hospitalization**
Oxybutynin (strength not available)	Glyburide (strength not available)	Nausea, diaphoresis, hypoglycemia, hospital admission for observation
Pantoprazole 40 mg	Pravastatin (strength not available)	Muscle pain, weakness

Drug Prescribed	Drug Dispensed	Resulting Injury or Adverse Effect
Paxil (paroxetine) 20 mg	Wellbutrin XL (bupropion) 150 mg	Weakness, fatigue
Penicillamine 250 mg	**Penicillin 250 mg**	**Fatigue, GI pain (minor patient)**
Phenobarbital suspension 15 mg/mL	Azathioprine 6.7 mg/mL	Seizures, death (feline patient)
Pioglitazone 30 mg	Remeron (mirtazapine) 30 mg	Drowsiness, confusion
Potassium citrate 10 mEq	**Potassium chloride 10 mEq**	**Kidney stones, pain, requiring hospitalization**
Prednisone 20 mg	Levodopa/carbidopa 25-250 and 50-200	Nausea, dizziness, fall, hospital admission for observation
Probenecid-colchicine 500 mg-0.5 mg	Probenecid 500 mg	Gout exacerbation
Protonix (pantoprazole) (strength not available)	Paxil (paroxetine HCl) (strength not available)	Vertigo, dizziness
Renvela (sevelamer carbonate) 800 mg	Gabapentin 800 mg	Tremors, nausea, depression
Requip (ropinirole HCl) 0.5 mg	Risperidone 0.5 mg	Nausea, vomiting, heartburn, hospital admission for observation
Simvastatin (strength not available)	Suboxone (buprenorphine/ naloxone) (strength not available)	Nausea, vomiting
Spironolactone 25 mg	Carvedilol 25 mg	Bradycardia, chest pain, hospital admission for observation
Spironolactone 25 mg	Olanzapine 15 mg	Involuntary muscle movement, confusion, vision impairment
Suboxone (buprenorphine/ naloxone) 8 mg/2 mg	Zolpidem 10 mg	Fall, head injury, avulsed teeth
Testosterone (strength not available)	Ketamine (strength not available)	Dizziness, hallucinations, headache, hospital admission for observation
Timolol 0.5% ophthalmic solution	Tobramycin 0.3% ophthalmic solution	Eye irritation
TobraDex (tobramycin-dexamethasone ophthalmic drops)	Neomycin-polymyxin B-hydrocortisone otic drops (ear drops)	Eye injury, vision loss
Topiramate 100 mg (extended release)	Torsemide 100 mg	Dizziness, excessive urination
Tramadol (strength not available)	Trazodone 50 mg	Vertigo, dizziness
Zoloft (sertraline HCl) 50 mg	Zocor (simvastatin) (strength not available)	Decreased control of psychotic episodes
Zolpidem 10 mg	**Losartan 50 mg**	**Dizziness, low blood pressure**

* All trademarks of the pharmaceuticals listed in the *Pharmacist Liability Claim Report: 3rd Edition* are the property of their respective owners, and Continental Casualty Company has no affiliation with them.

Wrong Dose/Strength Dispensing Errors

Errors involving the **wrong dose/strength**, including the dosing frequency, may be associated with one or more human errors and environmental factors such as: workplace distractions, illegible prescriptions, and/or misinterpretation of a written prescription. Use of certain error-prone abbreviations, symbols and dose designations may contribute to **wrong dose/strength** errors, whether used in written, verbal or electronic communications. Selection errors may occur, such as when the pharmacist or pharmacy technician pulls the incorrect medication strength from the shelf or selects the wrong strength in the computer system. A prescriber also may provide the pharmacy with an incorrect strength or dose frequency order in the prescription. Although this type of error may not originate with the pharmacist, it may lead to allegations against the pharmacist, such as a failure to confirm an unusual medication dose/strength with a prescriber. Examples of **wrong dose/strength** claims for which claim costs exceeded the overall average total incurred of $136,000 include:

- A 90-year-old patient required long-term anticoagulation therapy. Following a request for a refill for warfarin 2 mg, the pharmacist dispensed warfarin 5 mg in error. Approximately two weeks after receiving the medication, the patient suffered a brain hemorrhage and was hospitalized for two weeks. The patient was discharged to a rehabilitation facility for physical/speech therapy. One month after admission to rehab, the patient was found unresponsive and later pronounced dead. The defense team was able to demonstrate a well-documented history of patient non-adherence to recommended prothrombin time testing, which supported the defense of the lawsuit. As a result, the total incurred for this case of $180,000 was well below the plaintiff's demand.

Warfarin, and other anticoagulant medications, are included on the ISMP List of High-Alert Medications in Community/Ambulatory Care Settings. Errors involving a number of high-alert medications in the 2023 dataset have resulted in severe patient injuries. These medications include, but are not limited to, opioids, methotrexate, insulin products, oral hypoglycemic agents and immunosuppressant agents. Errors may or may not be more common with high-alert medications, but the potential consequences are significant and often devastating. See the resources at the end of Part 1 for links to high-alert medications lists focusing on different healthcare settings. The lists are effective only when paired with implementation of risk reduction strategies. These efforts may include a range of actions that will vary based upon the pharmacy type/facility. Examples include standardization of prescribing, storage, preparation and administration, use of clinical decision support and automated alerts, use of auxiliary labels and limiting access to the medications.

- A 50-year-old patient's Zocor (simvastatin) dose of 40 mg was prescribed by the physician. The pharmacist on duty received the prescription and completed the process, dispensing Zocor 80 mg daily. The investigation of the error revealed that the pharmacist received a computer system warning regarding specific restrictions on the 80 mg/day dose. Discussions with the pharmacist and other pharmacy personnel indicated that workloads and staffing levels may have contributed to the error, including a failure to check the labeled container against the prescription before dispensing. The patient was hospitalized for more than a month with muscle weakness, rhabdomyolysis, muscle atrophy and residual paresthesia of the lower extremities. The total incurred for the insured pharmacist was more than $350,000.
- An 83-year-old cancer patient in hospice care received a prescription for morphine oral solution 20 mg/5 mL. However, the medication dispensed was a higher strength, morphine 100 mg/5 mL. The error resulted in a five-day hospitalization and allegedly contributed to the patient's death. Based upon the investigation, the prescription was received and filled by the pharmacy technician. Although the medication underwent review by the pharmacist, the error was not identified before dispensing. The case settled at mediation, resulting in a total incurred of more than $250,000.

Wrong Dose/Strength Closed Claims by Dose/Strength Prescribed/Dispensed

Claims that are **bolded in red** have an incurred cost that is higher than the overall average total incurred of $136,000. Claims with a **gray background** indicate that the drug prescribed was involved in more than one **wrong dose/strength** closed claim.

Drug	Dose Prescribed	Dose Dispensed	Resulting Injury or Adverse Effect
Abilify (aripiprazole)	2 mg, 1 daily	20 mg, 1 daily	Emotional/psychological distress
Abilify (aripiprazole)	2 mg, 1 daily	20 mg, 1 daily	Tremors, tardive dyskinesia
Abilify (aripiprazole)	5 mg, 1 daily	30 mg, 1 daily	Altered mental status, hospital admission for observation
Amitriptyline	10 mg	100 mg	Lethargy, dizziness
Amitriptyline	10 mg	100 mg	Lethargy, dizziness, syncope, requiring hospitalization
Amitriptyline	25 mg	100 mg	Lethargy, dizziness, vertigo
Atropine ophthalmic drops	0.01%, 1 drop from 1 to 3 times a day	1%, 1 drop from 1 to 3 times a day	Ocular irritation, burning, blurred vision (minor patient)
Bystolic (nebivolol)	2.5 mg, 1 daily	10 mg, 1 daily	Vertigo, dizziness, decreased blood pressure, requiring hospitalization
CellCept (mycophenolate mofetil)	250 mg, 3 twice a day	500 mg, 3 twice a day	Decreased kidney function, damage to transplanted heart, requiring hospitalization
Ciprofloxacin	500 mg, 1 twice a day, every 12 hours	500 mg, 1 daily	Increased pain (related to existing infection)
Concerta (methylphenidate)	36 mg, 1 tab twice a day	36 mg, 1 tab daily	Agitation, emotional distress (minor patient)
Estradiol	4 mg daily	14 mg daily	Vaginal bleeding
Gentamicin	Not Available	Not Available	Emotional/psychological distress (minor patient)
Hydralazine	25 mg, 1 daily	100 mg, 1 daily	Decreased blood pressure
Imiquimod cream 5%	Apply 3 times per week to affected areas	Apply 3 times a day to affected areas	Skin blistering, burning, irritation
Lipitor (atorvastatin)	20 mg, 1 daily	40 mg, 1 daily	Muscle and joint pain, lethargy
Lomustine	10 mg	60 mg	Kidney and liver issues, animal euthanized (canine patient)
Losartan	25 mg, 1 tab daily	100 mg, 1 tab daily	Nausea, vomiting, vertigo
Metformin	1,000 mg, 1 tablet daily	1000 mg, 1 tablet twice a day	Nausea
Methotrexate	**2.5 mg, once daily (prescribing error, intended dose: once weekly)**	**2.5 mg, once daily (failure to recognize prescribing error)**	**Nausea, vomiting, diarrhea, myelosuppression, renal failure, hospitalization**
Morphine	**20 mg/5 mL every 4 hours as needed**	**100 mg/5 mL every 4 hours as needed**	**Drowsiness, altered respirations, hospital admission for observation**
Morphine	20 mg/mL, 0.5 mL every 6 hours, prn	20 mg/mL, 1/2 tsp (2.5 mL) every 6 hours, prn	Drowsiness, altered respirations, hospital admission for observation

Drug	Dose Prescribed	Dose Dispensed	Resulting Injury or Adverse Effect
Morphine (extended release)	30 mg	60 mg	Drowsiness, GI distress
Oxycodone	5 mg, 1 every 4-6 hours, as needed for pain	30 mg, 1 every 4-6 hours, as needed for pain	Drowsiness, GI distress, altered breathing, requiring hospitalization
Pain medication via pump (unknown opioid)	42 mL (strength unknown)	22 mL (strength unknown)	Drowsiness, GI distress, hospital admission for observation
Praluent (alirocumab)	50 mg injection every 2 weeks	75 mg injection every 2 weeks	High blood pressure
Pregabalin	75 mg, 1 twice a day	150 mg, 1 twice a day	Fall, broken tooth
Primidone	50 mg, 2 tabs in the morning, 3 tabs in evening daily	250 mg, 2 tabs in the morning, 3 tabs in evening daily	Falls, fibula fracture, requiring hospitalization
Pristiq (desvenlafaxine)	100 mg, 1 daily	25 mg, 1 daily	Worsening depression
Risperidone	1 mg/10 mL, 2.5 mL twice a day (total of 0.5 mg/day)	1 mg/mL, 2.5 mL twice a day (total of 5 mg/day)	Dystonia of jaw/facial muscles, mental anguish (minor patient)
Suboxone (buprenorphine-naloxone)	2 mg/0.5 mg, 3 tabs per day	8 mg/2 mg, 3 tabs per day	Emotional/psychological distress
Tacrolimus	5 mg, 1 every 12 hours	0.5 mg, 1 every 12 hours	Swelling, kidney rejection symptoms, requiring hospitalization (minor patient)
Tacrolimus	**0.5 mg, take 5 capsules every 12 hours**	**5 mg, take 5 capsules every 12 hours**	**Renal failure**
Testosterone	2 mg dose to skin	20 mg dose to skin	Extensive hair growth
Venlafaxine	75 mg, twice a day	37.5 mg, twice a day	Anxiety, depression, suicidal ideations
Vitamin D	1,000 Units daily	50,000 Units daily	Emotional/psychological distress
Vitamin D	50,000 Units, take 1 per week X 4 weeks	50,000 Units, take 1 per day X 4 weeks	Emotional/psychological distress
Vyvanse (lisdexamfetamine dimesylate)	30 mg, 1 daily	70 mg, 1 daily	Nausea, dizziness (minor patient)
Warfarin	1 mg, take 5 daily	5 mg, take 5 daily	Prolonged clotting time
Warfarin	**2 mg, 1 tablet on M-W-F. Take 2 tabs on other days.**	**5 mg, 1 tablet on M-W-F. Take 2 tabs on other days.**	**Brain hemorrhage, hospitalization, death**
Zocor (simvastatin)	**40 mg, 1 daily**	**80 mg, 1 daily**	**Weakness, leg pain, rhabdomyolysis, requiring hospitalization**

* All trademarks of the pharmaceuticals listed in the *Pharmacist Liability Claim Report: 3rd Edition* are the property of their respective owners, and Continental Casualty Company has no affiliation with them.

Analysis of Injury

- As evidenced in **Figure 12**, the change in the distribution of injuries demonstrates the wide range of possible adverse outcomes between reports. In general, this change does not indicate any trends in the claim data and results solely from changes in claim circumstances, such as the scope and severity of a patient's existing medical conditions, or the nature of the medication or dosage error involved. For example, the 2018 dataset included three injury types in the top 10 (cardiac arrhythmia, seizure and neurological deficit/damage) that ranged from three to five percent of the distribution in the 2018 dataset. None of these injuries were in the top 10 of the 2023 dataset.

Top Causes of Death

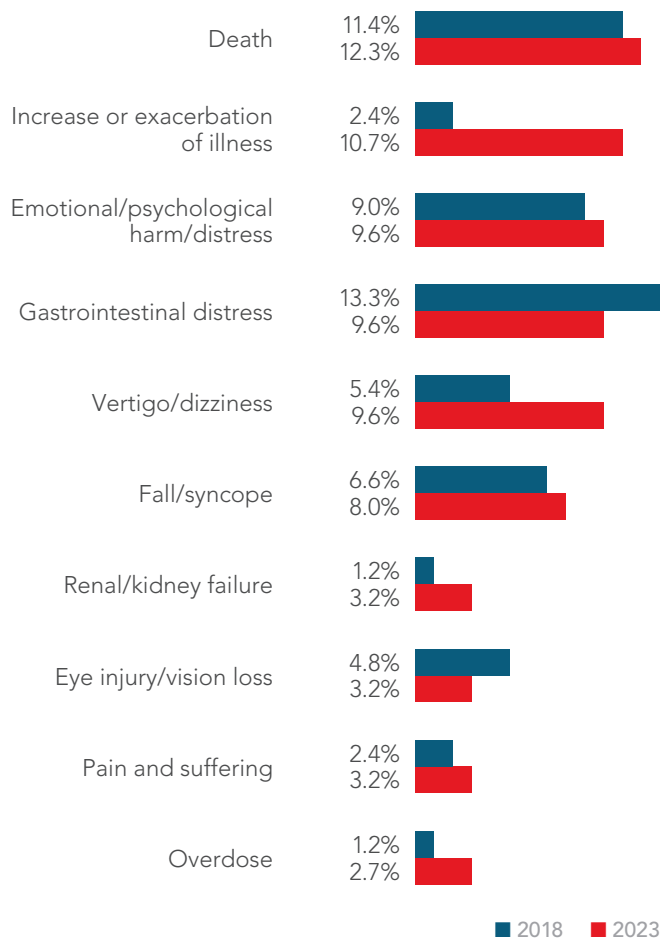
61% Overdose

Increase or exacerbation of illness **26%**

9% Loss of organ or organ function

12 Distribution of Closed Claims by Top 10 Most Common Injuries

Closed Claims with Paid Indemnity of ≥ $1



How Courts Define Malpractice

Four elements must exist for an incident to be considered malpractice:

1 Duty	2 Breach	3 Cause	4 Harm
A pharmacist-patient relationship must exist.	Standard of care was not met.	Injury was caused by the pharmacist's error.	Injury resulted in damages.

Similarly, **Figure 13** reflects the potential volatility within and across several injury categories. One example is the **increase or exacerbation of illness** category, which can represent a range of conditions from gastrointestinal distress to cardiovascular disease, to severe infection/sepsis – all with highly diverse incurred amounts. Another example is the **emotional/psychological harm/distress** category. Several claims in the 2018 dataset were associated with severe outcomes (two related to controlled substance misuse and one **wrong drug** allegation) compared to one severe claim in the 2023 dataset (**wrong drug** allegation).

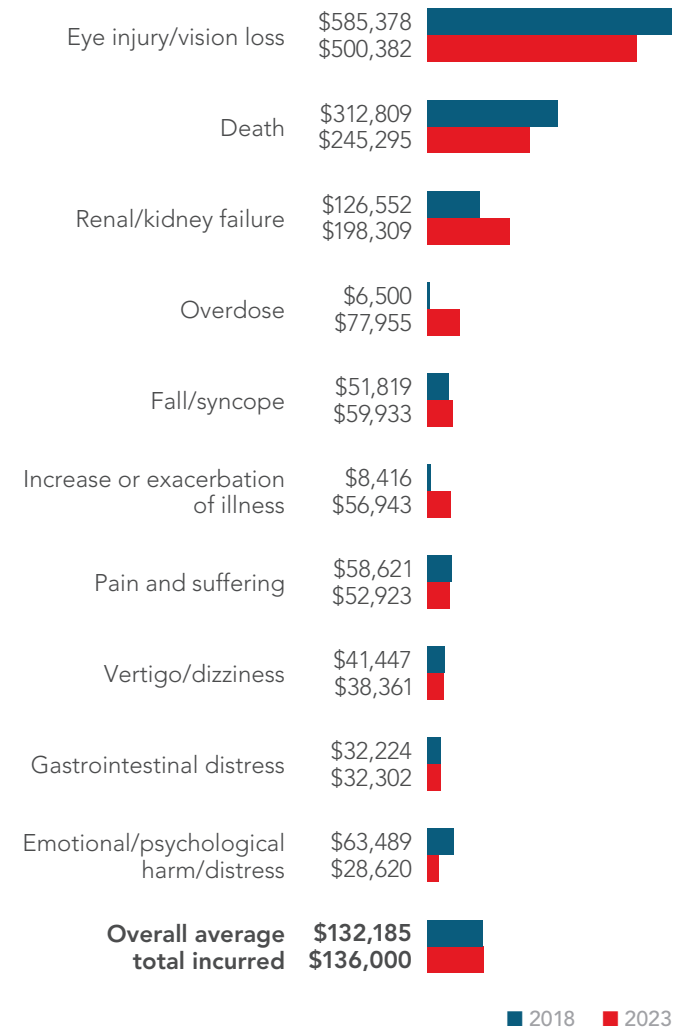
In contrast, injuries such as **eye injury/vision loss** or **death** consistently resulted in higher total incurred amounts as illustrated in the examples below:

- A compounding pharmacy failed to employ appropriate sterile techniques when repackaging a medication for ophthalmic injection from single-use vials to pre-filled syringes. The claim resulted in multiple injuries, including partial or complete loss of vision. The total incurred for the insured pharmacy and pharmacist was more than $2,000,000.
- A paraplegic patient (sports injury) with ongoing pain and muscle spasticity received medications to manage symptoms via an implanted pump. A compounding error involving the morphine component of the mixture resulted in an opioid strength of six times the prescribed concentration. The error resulted in the patient's death and a total incurred for the insured pharmacist of approximately $500,000.

The significant increase in severity of overdose injuries is primarily attributed to two opioid **wrong dose/strength** claims involving morphine oral solution and oxycodone tablets. In each claim, the patients received approximately five times the prescribed dose, requiring hospitalization. The elderly patient who received the morphine overdose died, while the adult patient who received oxycodone recovered with no permanent injuries.

13 Average Total Incurred by Top 10 Most Common Injuries

Closed Claims with Paid Indemnity of ≥ $1



The significant **increase in severity of overdose injuries** is primarily attributed to **two opioid wrong dose/strength claims** involving morphine oral solution and oxycodone tablets. The patients received approximately **five times the prescribed dose**.

Analysis by National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) Category

According to an excerpt from the organization's mission, the NCC MERP strives to "maximize the safe use of medications and increase awareness of medication errors". In the graphic below, the NCC MERP category details are listed, grouped by error/no error, and level of harm. These groupings are consistent with those presented on the NCC Website.

Figures 14 and 15 summarize the distribution and average total incurred for the 2018 and 2023 datasets by NCC MERP category groups.

- Although the percentage of claims involving a patient's **death** has increased in the 2023 dataset **(as seen in Figure 12),** the NCC MERP data as indicated in **Figure 14** indicates a decrease in death-related claims. This result is due to the inclusion of two animal death cases (included in the NCC MERP "Other" category), as well as several other claims in which a patient death occurred, but the outcome could not be attributed to a medication error.
- Although the percentage of claims with harm has decreased, this group continues to represent the highest percentage in the distribution at 78.1 percent. The average total incurred for claims with harm increased by 19 percent from $110,640 in the 2018 dataset to $132,155 in the 2023 dataset.

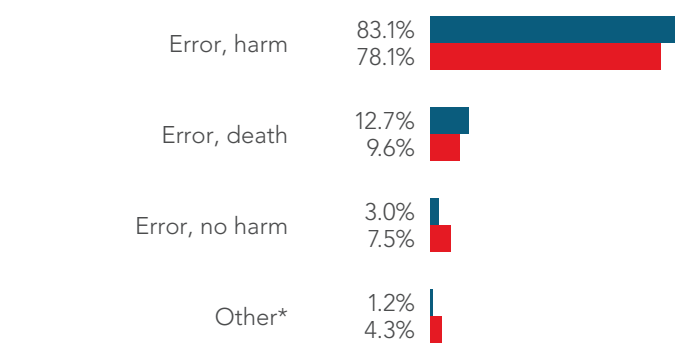
The average total incurred for **claims with harm increased by 19 percent**, from $110,640 in the 2018 dataset to $132,155 in the 2023 dataset.

NCC MERP

NCC MERP Category	NCC MERP Group
A. Circumstances or events that have the capacity to cause error	No Error
B. An error occurred, but the error did not reach the patient (An "error of omission" does reach the patient)	Error, No Harm
C. Error reached patient, but did not cause harm	
D. Error with patient monitoring required to confirm no harm suffered nor intervention required	
E. Error with temporary harm requiring patient intervention	Error, Harm
F. Error with temporary harm requiring intervention/prolonged hospitalization	
G. Error with permanent patient harm	
H. Error requiring intervention to sustain patient's life	
I. Error with patient's death	Error, Death

14 Distribution of Closed Claims by NCC MERP Category Groups

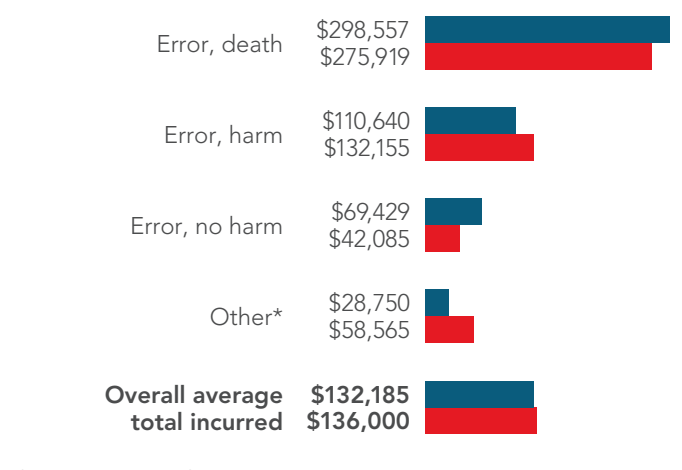
Closed Claims with Paid Indemnity of ≥ $1



* Claims not consistent with NCC MERP categories

15 Average Total Incurred by NCC MERP Category Groups

Closed Claims with Paid Indemnity of ≥ $1



* Claims not consistent with NCC MERP categories

Analysis of Claim Expenses

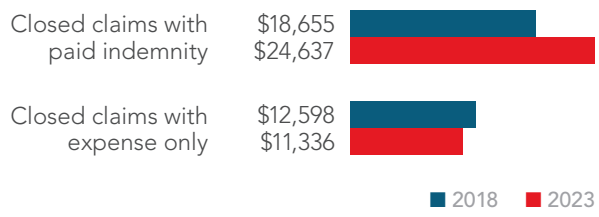
The preceding sections of Part 1 include total incurred losses – defined as indemnity and paid expenses combined. This section focuses on the paid expense portion of a claim. Claims may resolve with or without an indemnity payment to a claimant for various reasons. Examples of claims that close without an indemnity payment include claims that were:

- Successfully defended on behalf of the pharmacist, pharmacy technician or pharmacy entities, resulting in a favorable jury verdict.
- Withdrawn by the plaintiff during the investigation or discovery process.
- Dismissed in favor of the defendant pharmacist, pharmacy technician or pharmacy entity by the court prior to trial.

Claims that resolve without an indemnity payment may nevertheless incur expenses. These expenditures can include attorney fees, expert witness fees, and investigation costs. Such claims cost $11,336 on average, as reflected in **Figure 16**. The expense costs associated with claims with paid indemnity are higher due to the increased time and activity level necessary to build a defense to support settlement or mediation negotiations, or to prepare for trial. Cases resulting in a defense judgment will result in no indemnity payment, but may result in significant expenses. The average cost for closed claims with expense only, and no indemnity, is reduced significantly by claims that are not pursued, are withdrawn or dismissed.

Figure 16 demonstrates the differences in average paid expense costs for closed claims with paid indemnity and those that closed with expense only.

16 Comparison of Closed Claim Expense Costs



Claims that resolve without an indemnity payment may nevertheless **incur expenses**. Such expenditures include **attorney fees, expert witness fees, and investigation costs**. These claims cost $11,336 on average, as demonstrated in Figure 16.

Risk Management and Medication Safety Resources

Awareness *and implementation* of guidelines and recommendations from professional and safety organizations, governmental agencies, liability insurers and other recognized sources serve as guidelines to continuous improvement and the goal of safer practice. The following resources may be considered as a starting point. Pharmacy professionals should explore the appropriate tools and information specific to their scope and place of practice in order to prevent medication errors and improve patient safety.

General Medication and Patient Safety Resources

- Healthcare Providers Service Organization – Resources. Articles, case studies, claim reports and more for pharmacists and other healthcare professionals.
- U.S. FDA Drug Safety Information. Resources such as alerts/statements, safety podcasts, MedWatch adverse event reporting and post-market safety information.
- American Pharmacists Association. The website includes medication safety resources, medication safety news, educational resources and more.
- Institute for Safe Medication Practices (ISMP). Available resources include medication safety education, online resource library, including guidelines, self-assessments, safety tools, newsletters, consumer information, and more.
- Agency for Healthcare Research and Quality and associated Patient Safety Network (PSNet). A broad array of patient safety information and resources for professionals and the public.
- ISMP's List of Error-Prone Abbreviations, Symbols, and Dose Designations.

Targeted Best Practices

- First ISMP Targeted Medication Safety Best Practices for Community Pharmacy released.
- ISMP 2023-2024 Targeted Medication Safety Best Practices for Community Pharmacy. Five consensus-based best practices, focused on preventing serious and fatal medication errors.
- ISMP 2022-2023 Targeted Medication Safety Best Practices for Hospitals. Three new recommendations in 2022, focused on hospital and health system pharmacists.

Compounding and Repackaging

The 2023 dataset closed claim analysis and the case studies in this document support the importance of risk mitigation in medication compounding. The following resources may aid pharmacists who provide compounding services:

- U.S. FDA – Human Drug Compounding. Compounding progress report, laws and policies, outsourcing facility information, oversight and compliance information, and more.
- U.S. FDA – Compounding Questions and Answers.
- American Society of Health-System Pharmacists. Compounding Frequently Asked Questions.
- USP Compounding Compendium. Quality assurance resource for compounding methods, preparations and practices across healthcare settings.
- National Association of Boards of Pharmacy – Verified Pharmacy Program® (NABP – VPP®). Compounding pharmacies may pursue accreditation to USP nonsterile (<795>) and/or sterile (<797>) compounding standards.
- Pharmacy Compounding Accreditation Board.
- Board Certified Sterile Compounding Pharmacist (BCSCP) credential.
- ISMP 2022 Guidelines for Sterile Compounding and the Safe Use of Compounding Technology.
- American Pharmacists Association compounding resources page.

High-Alert Medications

Pharmacy professionals and their patients will benefit through awareness of the following resources and implementing action to mitigate the risk of high-alert medication errors.

- High-Alert Medications in Community/Ambulatory Care Settings (ISMP, 2021).
- High-Alert Medication Learning Guides for Consumers will help counsel and educate patients.
- High-Alert Medication List-Relatively Useless Without Associated Risk-Reductions Strategies focuses on the hospital setting, but is also relevant to other pharmacy practitioners.
- High-Alert Medications in Long-Term Care (LTC) Settings (ISMP, 2021).

Confused Medications

These resources provide current methodologies and drug name pairs to assist pharmacists with identifying medications that may require special safeguards.

- FDA and ISMP Lists of Look-Alike Drug Names with Recommended Tall Man (Mixed Case) Letters (2023).
- List of Confused Drug Names (2019) includes look-alike and sound-alike medication name pairs.
- Adopt Strategies to Manage Look-Alike and/or Sound-Alike Medication Name Mix-ups. (2022)

Key Risk Management Principles*

- ☐ Implement policies and procedures to support patient safety
- ☐ Verify patient identity (right patient)
- ☐ Confirm medication (right drug, right dose, right route)
- ☐ Conduct patient counseling and education
- ☐ Complete thorough documentation

* For more recommendations, safety considerations and actions, see this article on the PSNet website.

Part 2: Analysis of License Protection Matters with Defense Expense Payment

Introduction

A regulatory board complaint may be filed against a pharmacist by a patient, colleague, employer, and/or a regulatory agency, such as the State Department of Health. Complaints are subsequently investigated by the Board of Pharmacy ("the Board") to ensure that licensed pharmacists are practicing safely, professionally, and ethically. Board investigations may lead to outcomes ranging from no action against the pharmacist to revocation of the pharmacist's license to practice.

Board investigations are serious matters, often requiring legal assistance as well as significant investment of time and effort by the pharmacist before resolution. Expenses associated with license defense matters include reimbursement for the cost of legal representation to defend the CNA/HPSO insured pharmacist during the investigation, rather than indemnity or settlement payments to a plaintiff, or fines imposed by a regulatory agency. Therefore, the average defense expense referenced within this section of the report is limited to license defense matters and is not necessarily indicative of the severity of the underlying allegation that is the subject of the Board investigation. In addition, regulatory or Board actions against a pharmacist's license to practice differ from professional liability claims as they may or may not involve allegations directly related to patient care and treatment. For example, Board matters may include allegations such as unprofessional conduct, substance use, fraudulent billing, or failure to comply with pharmacy regulations. This section highlights the most common types of license defense matters. It is intended to assist pharmacists in identifying potential vulnerabilities and instituting focused, proactive action to minimize risk. For more information on license defense and Board matters, see the Pharmacist Spotlight: Defending Your License.

Database and Methodology

As noted in the introduction to Part 1, three datasets are referenced in this report. The 2023 claim report dataset discussed in this section is comprised of license defense matters involving an insured pharmacy professional (pharmacist, pharmacy technician, or pharmacist working for an insured pharmacy business/corporate entity) that closed between January 1, 2017, and December 31, 2022, and resulted in a defense expense/payment of at least one dollar. These criteria applied to the total number of reported pharmacist license defense matters resulted in a 2023 dataset comprised of 280 closed matters. Similar criteria produced a 2018 dataset consisting of 185 closed matters, and a 2013 dataset consisting of 200 closed matters. Defense payments for license defense matters include legal expenses and associated travel, food, lodging, and lost wages reimbursable under the policy.

Data Analysis

Figure 17 reveals that the average defense payment for license defense matters in the 2023 dataset has increased 43 percent since the 2018 dataset and has more than doubled since the 2013 dataset. The reasons for the rising Board defense payments include escalating costs of defense counsel, inflation, the individual nature of each Board disciplinary investigation, and the length of time to resolve matters. In addition, the COVID-19 pandemic resulted in delays in Board business, which may have contributed further to rising defense costs observed in license defense matters in the 2023 dataset.

17 License Defense Data Comparison of 2013, 2018, and 2023 Claim Reports

	2013 Dataset	2018 Dataset	2023 Dataset
Number of years in dataset	10	5	6
Total number of matters with payment in dataset	200	185	280
Total paid	$737,073	$989,565	$2,142,130
Average defense payment	**$3,685**	**$5,349**	**$7,650**

The average defense payment of $7,650 for **license defense matters** in the 2023 dataset has **increased 43 percent** since the 2018 dataset ($5,349) and has **more than doubled** since the 2013 dataset of $3,685.

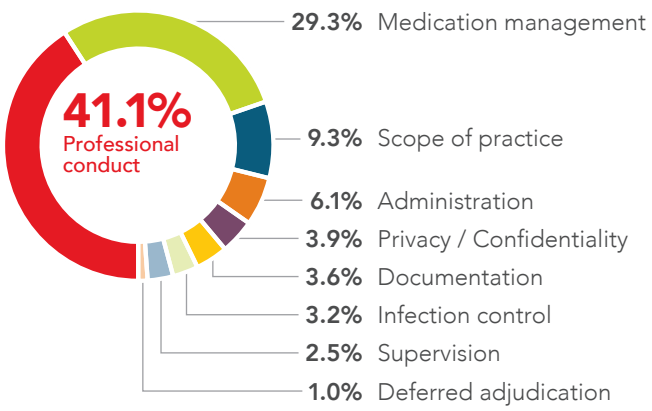
Analysis of Matters by Allegation Class

This section of the report highlights the most common licensing board allegations asserted against pharmacy professionals. Although complaints against a pharmacist's license to practice often involve multiple allegations, this analysis classified matters based upon the primary reason for the complaint.

Professional conduct complaints represent the highest percentage of all license defense matters in the 2023 dataset, at 41.1 percent. As indicated in **Figure 18**, combined with **medication management** complaints, these two categories represent 70.4 percent of all license defense matters. These top two allegation categories will be discussed in greater depth later within this section of the report.

In response to the COVID-19 pandemic, many jurisdictions expanded pharmacists' **scope of practice** to include administering vaccinations, prescribing specified medications, and administering certain diagnostic tests. These changes were often subject to rapidly changing guidelines, and pharmacies struggled to adapt to the challenges of the pandemic and provide adequate staffing to meet the needs of their patients and customers. Pharmacies and other organizations that employ

18 License Defense Matters by Primary Allegation Class



pharmacists are responsible for providing a safe, supportive environment in which pharmacists can practice according to professional standards and regulations. The licensed professional pharmacist, in turn, bears the responsibility for practicing within the parameters of the state scope of practice laws with respect to their license. In the 2023 dataset, **scope of practice**-related allegations represent 9.3 percent of all license defense matters (**Figure 18**). This category includes allegations of practicing outside the parameters of pharmacist licensure and dispensing medications without a valid prescription, as in the following example:

- The insured pharmacist was working for a large retail pharmacy chain, which was about to close, and its e-prescription system was experiencing technical difficulties. Rather than ask two customers to return another day for their prescriptions, the pharmacist dispensed atenolol to one customer and dispensed 60 tablets of metformin 1000 mg to another customer, both without a written prescription or authorization from a provider. The pharmacist rang up these prescriptions on the pharmacy register as general pharmacy merchandise in order to enter the unauthorized prescriptions into the register system. However, this meant that the prescriptions were not recorded or dispensed in the pharmacy's prescription dispensing computer system. Following an investigation into the unauthorized dispensing, the pharmacist was terminated by their employer, who reported the pharmacist to the Board. The Board concluded that the pharmacist's conduct violated state law by knowingly dispensing medication without proper authorization. The Board issued a letter of reprimand against the pharmacist, which remains a public record. The total cost incurred to defend the pharmacist in this matter exceeded $1,200.

Pharmacy administration-related allegations, which consist of 6.1 percent of license defense matters (**Figure 18**), include failure to report suspicious or excessive prescribing/prescription practices, failure to provide proper instructions to a patient, and failure to counsel a patient, as in the following example:

- The insured pharmacist was acting as pharmacist-in-charge (PIC) of a community pharmacy, which was experiencing a rush of patients picking up prescriptions, including a patient who was picking up a new prescription for 15 amoxicillin 500 mg capsules. The pharmacist permitted a pharmacy technician to instruct the patient, which was outside of the scope of practice for a pharmacy technician. The pharmacy technician told the patient to take one capsule three times daily with food. The pharmacist then falsely indicated in the pharmacy's prescription dispensing record that the patient refused patient counseling. The patient later informed his physician that he took one amoxicillin capsule daily with food for three days. The physician reported the pharmacist to the Board, which investigated the incident and discovered that the pharmacist failed to provide verbal patient counseling or written instructions to a patient. The Board ordered the pharmacist to pay a $2,500 fine and issued a reprimand. The total cost incurred to defend the insured pharmacist in this matter exceeded $7,200.

License Protection vs. Professional Liability. What's the difference?

License Protection	Professional Liability
Inquiry by the State Board of Pharmacy, arising from a complaint.	**Civil lawsuit** arising from a patient's malpractice claim.
Allegation can be directly related to a pharmacist's clinical responsibilities and professional services, and/or they may be of a nonclinical nature (i.e., substance abuse, unprofessional conduct or billing fraud).	**Allegations are related to clinical practice** and professional responsibilities.
The State Board of Pharmacy is authorized to suspend or revoke a license. Its primary mission is to protect the public from unsafe practice of the professional.	**The civil justice system cannot suspend or revoke your license to practice.** Rather, professional liability lawsuits serve to fairly compensate patients who assert that they have suffered injury or damage as the result of professional negligence.

- Allegations related to **privacy/confidentiality**, which comprise 3.9 percent of license defense matters (**Figure 18**), include allegations of failure to maintain the confidentiality or security of protected health information. Some matters involved pharmacists improperly accessing confidential patient information for an unethical or illegal purpose, other than to provide patient care or service. With the implementation of electronic health records, and the metadata associated with those programs, it is now easier to determine when a provider has improperly accessed patient data. The example below arose due to an alleged failure to keep the pharmacy area secure from non-pharmacy personnel.

- The insured pharmacist was working for a large retail pharmacy chain. On the day in question, she was working as a "floater" for another store in her area. The pharmacy technician who was scheduled to work with the pharmacist did not report to work, so the pharmacist was working independently. During a rush of customers, the pharmacist requested assistance, and two retail employees came to help work the cash registers in the pharmacy. A few days later, an area pharmacy manager informed the pharmacist that she may have breached HIPAA regulations by allowing non-pharmacy personnel into the pharmacy area. The pharmacist's employer reported the incident to the Board and removed her from pharmacy duties until an investigation could be completed. The Board investigated the incident and dismissed the matter without taking any disciplinary action against the pharmacist. However, the investigation took nine months to resolve, and the total cost incurred to defend the insured pharmacist in this matter exceeded $1,500.

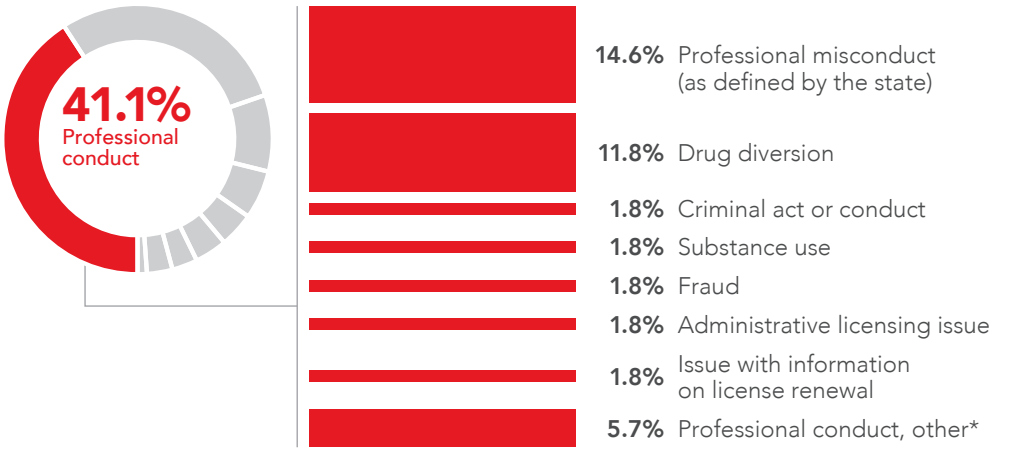
Documentation is an essential tool for patient service, communication among providers, and demonstrating compliance with federal, state, and third-party payer requirements. It also serves as an important element of a pharmacist's professional responsibilities. **Documentation**-related allegations against pharmacists are relatively uncommon at 3.6 percent of license defense matters (**Figure 18**). Documentation-related allegations include failure to document care/treatment as required by law, regulation or agency/institution procedures, as well as fraudulent or falsified patient care or billing records, as in the following example involving falsified records related to vaccine administration:

- While working in the pharmacy of a regional chain grocery store, the insured pharmacist filled a birth control prescription for a patient. After the patient left the store, the pharmacist processed and entered immunization prescriptions for a hepatitis A vaccine, a hepatitis B vaccine, and a pneumococcal vaccine for the patient – none of which were administered to the patient. Over the course of the next month, the pharmacist processed and entered immunization prescriptions into the pharmacy records system for at least six other patients who later denied being administered those immunizations. These actions were presumed to benefit the pharmacy financially. A co-worker reported the pharmacist's actions to their employer, who reported the pharmacist's actions to the Board. The Board concluded that the pharmacist made deceptive, untrue, or fraudulent representations in the practice of pharmacy, fined the pharmacist $3,500, and required him to complete 12 hours of continuing education on state laws and regulations. The total cost incurred to defend the insured pharmacist in this matter exceeded $7,100.
- For risk control recommendations related to pharmacist charting, refer to the Pharmacist Spotlight: Documentation.

Analysis of Allegation Class Sub-Categories

Figures 19 and **20** provide additional information regarding the two most frequent and severe allegation sub-categories. Note that percentages are calculated based upon the total matters with defense expense payments for pharmacy professionals.

19 Allegations Related to Professional Conduct



* Other allegations in the professional conduct category, which comprise <2% of all license defense matters in the 2023 dataset, include failure to maintain current inventory, failure to report theft of controlled substances, failure to maintain security of pharmacy and/or drugs, closing pharmacy without proper notice, action in another jurisdiction, and wastage errors.

Allegations Related to Professional Conduct

As licensed professionals, pharmacists are expected to conduct themselves in an ethical manner as a representative of the profession and in accordance with their professional status. Allegations related to pharmacists' professional conduct comprise 41.1 percent of all license defense closed matters with payment in the 2023 dataset. Matters involving allegations of **professional misconduct, as defined by state laws, regulations and professional association guidelines,** comprise the highest distribution of all license defense closed matters in the 2023 dataset, at 14.6 percent of all pharmacist license defense matters (**Figure 19**). This broad allegation category includes assertions that the pharmacist was not acting in a manner expected of a licensed professional, or in circumstances that may or may not have been directly related to the pharmacist's clinical responsibilities. This category includes matters such as those where the pharmacist allegedly failed to comply with pharmacy regulations and engaged in unprofessional conduct towards coworkers and/or patients, as in the following examples:

- While working in a hospital pharmacy, the insured pharmacist received a STAT order from a facility physician for FEIBA (factor eight inhibitor bypassing activity). The pharmacist did not have sufficient medication available to fill the order. Instead of procuring sufficient medication, the pharmacist supplied what was available and informed a facility nurse that she would have to "call around" to other pharmacies to procure the additional medication on her own. The facility clinical coordinator reported the pharmacist's unprofessionalism to the Board, and the Board issued a formal reprimand. The total cost incurred to defend the insured pharmacist in this matter exceeded $3,300.
- After assisting a patient at the customer service desk of a grocery store pharmacy, the insured pharmacist muttered a derogatory term regarding the patient's sexual orientation as the patient walked away. The pharmacist said the slur loudly and clearly, such that coworkers and other customers near the service desk were able to hear what she said. Following an internal investigation into the incident, the pharmacist's supervisor reported

Allegations related to pharmacists' **professional conduct** comprise **41.1 percent** of all license defense closed matters.

her conduct to the Board. The Board concluded that the pharmacist violated the State Pharmacy Act by engaging in unprofessional conduct. The Board issued a formal reprimand against the pharmacist, ordered her to pay a $1,000 civil monetary penalty, as well as complete three hours of continuing education on ethics. The matter took more than a year to resolve, and the expenses incurred to defend the insured pharmacist totaled more than $6,200.

- While working in a national chain pharmacy, the insured pharmacist surreptitiously approached a coworker from behind and injected Naloxone into the coworker's arm. The pharmacist's coworker did not experience any adverse effects due to the injection; however, he had no apparent need to receive the medication and had not consented to the administration of this medication. The pharmacy terminated the pharmacist's employment and reported his conduct to the Board. Although the pharmacist had been practicing for more than eight years without any prior discipline, given the egregious unprofessionalism of his conduct, the Board placed the pharmacist on probation for two years. This matter took more than a year to resolve, and the expenses incurred to defend the insured pharmacist totaled over $12,000.

Similar to the 2018 dataset, allegations related to **drug diversion** remained one of the top allegations for pharmacists, representing 11.8 percent of all pharmacist license defense matters (**Figure 18**). Examples include diverting medications to oneself or furnishing dangerous drugs with the potential for abuse to others. Most, if not all, pharmacists will confront the problem of substance use disorders firsthand during their career, either through their own experience, that of a colleague, or a patient. Drug diversion and unaddressed substance use issues cause harm to pharmacies and pharmacy colleagues and can also compromise patient safety. Pharmacies should establish an anonymous reporting system for staff to report concerns, including a standard, confidential process for investigating alleged drug diversion. The Institute for Safe Medication Practices (ISMP) has several resources that address the topic of drug diversion, including webinars and several newsletters.

Pharmacists, technicians, and other pharmacy staff can play an important role in early detection of substance use disorders and drug diversion by being aware of common signs and symptoms. Healthcare providers are often reluctant to report a coworker's suspected substance use for a variety of reasons. Nevertheless, pharmacists should be aware that they may have legal and ethical responsibilities to identify and report suspected substance use and drug diversion through the appropriate professional channels. Some Boards and employers can hold providers responsible for harm to patients for failure to alert when they become aware of a colleague with a suspected substance use disorder. In addition, the Drug Enforcement Administration (DEA) also has issued its own reporting requirements. Federal regulations state that reports of drug diversion by fellow employees serves the public interest, stating that an employee with knowledge of such drug diversion is obligated to report such information to a responsible security official of the employer (212 CFR § 1301.91). The agencies that should be notified for suspected drug diversion may differ by jurisdiction, but typically include:

- State Board of Pharmacy;
- Local law enforcement and local fraud alert networks; and
- The DEA Office of Diversion Control.

Pharmacist Spotlight

The Substance Abuse and Mental Health Services Administration's (SAMHSA's) National Helpline, also known as the Treatment Referral Routing Service, is a source of support for substance abuse issues and is available to provide free, confidential assistance at 1-800-662-HELP (4357) or via FindTreatment.gov.

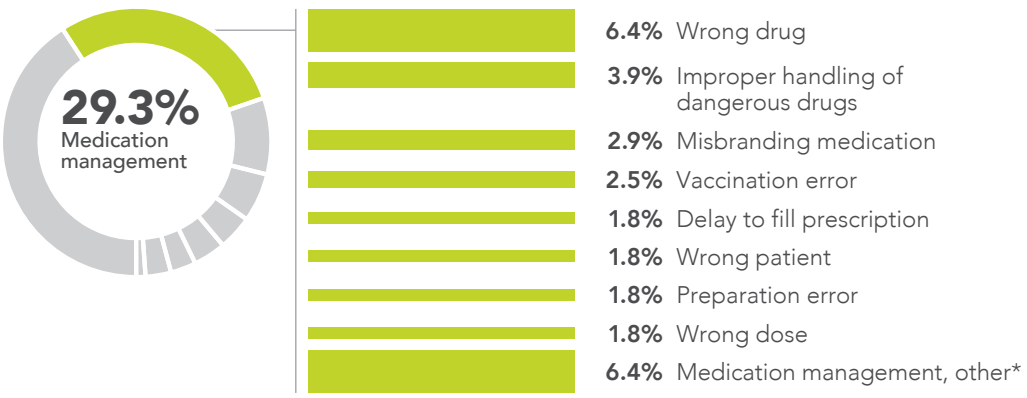
For resources related to substance use in pharmacy, you can also visit:

- USA Pharmacists Recovery Network (State-specific resources)
- APhA Opioid Resource Center
- APhA-ASP Operation Substance Use Disorders
- APhA Institute on Substance Use Disorders

Allegations Related to Medication Management

Medication safety and access are critical elements of the broad range of healthcare services provided by pharmacy professionals. Pharmacists occupy an essential role in the medication administration pathway that begins with a provider prescribing a medication and ends with patient consumption of the medication. During the medication dispensing phase, pharmacists have the opportunity to prevent medication errors such as identifying wrong drug and wrong dose errors, as well as patient allergies and contraindications. Pharmacists also have a legal and ethical duty to ensure that medications are stored safely and securely in the pharmacy, and to identify loss or diversion of controlled substances.

20 Allegations Related to Medication Management



* Other allegations in the medication management category, which comprise <2% of all license defense matters in the 2023 dataset, include labeling error, administration error, dispensing expired medications, failure to identify allergy, failure to communicate change to generic drug, equipment use error, failure to report medication error as required by policy or law, and other/unknown prescription filling errors.

Wrong drug errors, which account for 6.4 percent of all pharmacist license defense matters (**Figure 20**), can occur due to various reasons during the medication dispensing process, and not solely due to human error on the part of the pharmacist. While some medication errors can be attributed to human error, human error is often the result of poorly designed systems. Pharmacies must not only implement systems and procedures that support safe medication dispensing, but they also must proactively identify and address any barriers or system problems that may encourage staff to deviate from accepted practices. In their role, pharmacists are accountable for their actions and the medications that they dispense. Therefore, they must apply safety practices appropriately and consistently. The following example illustrates how technological interventions such as medication bar code scanning and electronic prescribing may *help* to eliminate *some* sources of medication dispensing errors. However, pharmacists must remain vigilant for errors as no system is infallible:

- The insured pharmacist was reviewing prescription orders, filled by a pharmacy technician, when he questioned the high dosage of a prescription for levofloxacin 750 mg. The pharmacist asked the technician to look up the patient in the pharmacy system to verify the medication. The technician informed the pharmacist that the medication was correct and that the patient had filled prescriptions for this medication previously. Since the information in the computer system matched the medication being dispensed, the pharmacist approved the medication but nevertheless asked to talk to the patient when he arrived to pick up his prescription. However, when the patient came to the pharmacy, staff provided the prescription to the patient and failed to alert the pharmacist. It was later discovered that, when the patient's physician had called the re-fill order into the pharmacy, the name of the drug on the patient's prescription was erroneously changed in the pharmacy system by clerical staff. The patient was prescribed levetiracetam 750 mg for management of his seizure disorder, not levofloxacin. After taking the incorrect medication for several days, the patient developed a tremor, experienced a seizure, and was admitted to the hospital,

where it was determined that he had been taking the wrong medication. The patient then reported the pharmacist to the Board. Although the Board recognized that the error did not originate with the pharmacist, the pharmacist was responsible for the actions of the pharmacy personnel he supervised and the medications he dispensed. The Board ordered the pharmacist to comply with a consent agreement, which required completion of several continuing education courses and payment of a fine. The total cost incurred to defend the pharmacist exceeded $3,100.

In the 2023 dataset, allegations of **failure to properly handle dangerous drugs** comprise 3.9 percent of all pharmacist license defense matters (**Figure 20**). Pharmacies are responsible for designing safe and secure environments for their staff, properly securing dangerous drugs, and taking steps to prevent the theft or diversion of drugs. If a pharmacist, especially a pharmacist acting as the pharmacist in charge (PIC), fails to follow policies and procedures to prevent theft or diversion, or if a pharmacist fails to report theft or diversion, the pharmacist may be investigated and disciplined by the Board. In the following example, a PIC faces discipline for failing to account for all the controlled substances stolen from the pharmacy where he worked:

- The insured pharmacist was the PIC for a community pharmacy, when he noticed that, while the pharmacy had recently ordered three bottles of alprazolam 2 mg, there was no alprazolam 2 mg in stock. Documentation also failed to indicate that the medication had been dispensed. Surveillance video demonstrated that another pharmacist had taken all three bottles of alprazolam from the shelves, placed them into the trash, and later took the trash and placed it in his car, which was parked next to the pharmacy's dumpster. The PIC reported the theft of controlled substances to local authorities, and the offending pharmacist was later convicted. Following the pharmacist's conviction, a Board inspector conducted an audit of the pharmacy's acquisition and disposition records for alprazolam over the prior three-year period. Comparing these records to the PIC's police report, the inspector determined that the pharmacy's shortage of alprazolam during that time period was about 25 percent more than what the PIC reported. The Board concluded that the PIC failed to provide effective controls against the theft or diversion of dangerous drugs, failed to maintain records of the inventory of dangerous drugs, and failed to secure the prescription department of the pharmacy. The Board placed the insured pharmacist on probation for three years, during which time he was prohibited from acting as the PIC or supervising other pharmacy personnel. The expenses incurred to defend the pharmacist in this matter totaled more than $6,700.

Pharmacies are responsible for designing **safe and secure environments for their staff,** properly securing dangerous drugs, and taking steps to prevent the theft or diversion of drugs.

Section 502(a) of the Federal Food, Drug and Cosmetic Act (FFDCA) declares that a drug or device is misbranded if its labeling proves false or misleading. In the 2023 dataset, allegations of **misbranding medication, or unauthorized off-label usage of medications** account for 2.9 percent of all pharmacist license defense matters (**Figure 20**). These matters included allegations of selling misbranded and adulterated medications, as well as other deficiencies related to the quality and safety of medications and compounded substances that were dispensed and sold to patients and customers, such as the following example:

- The insured pharmacist was a PIC of a community pharmacy that engaged in drug compounding for human and veterinary patients. During a routine state inspection, it was discovered that some compounded drug labels lacked drug names and strengths, a violation of state statute. Several compounded drugs examined by inspectors were labeled with names such as "Formula #12" or "Magic Ointment." These violations resulted in an enforcement inspection. The investigation revealed that, after becoming the PIC, the pharmacist personally dispensed thyroid medications that were compounded using substances not approved for human or veterinary use. Ivermectin labeled "for veterinary use only" was also used to compound Ivermectin 4.5% cream for several human patients. Based upon the number of violations that Board investigators identified, the Board proposed revocation of the pharmacist's license. However, negotiations with the Board resulted in placing the pharmacist's license on probation for three years. The incurred expenses to defend the pharmacist in this Board investigation totaled more than $11,000.

Pharmacy roles and services evolved in response to the COVID-19 pandemic, as community pharmacists were permitted to perform COVID-19 screening tests and administer vaccinations. Allegations related to **vaccination errors** constituted 2.5 percent of all pharmacist license defense matters (**Figure 20**). Although not all of these incidents involved COVID-19 vaccine errors, most of these allegations involved pharmacists mistakenly administering the wrong brand of COVID-19 vaccine or administering COVID-19 vaccines that had expired. A few vaccination errors involved the pharmacist administering the wrong vaccine, or using an improper or unsafe technique while administering a vaccine, as highlighted in the following example:

- A teenage patient and her mother presented to a large chain pharmacy to obtain flu shots. The insured pharmacist was the only pharmacist on duty, and the pharmacy was busy with patients and other pharmacy customers. As she was about to administer the vaccine to the teenage patient, the pharmacist was momentarily distracted by another customer and accidentally poked the teenager twice with the syringe. This angered the mother, who promptly left the pharmacy with her daughter without receiving their vaccines. The mother reported the pharmacist to the Board. The Board ultimately issued a private warning letter against the pharmacist. The expenses incurred to defend the pharmacist in this matter were less than $1,000.
- For risk control recommendations related to vaccine administration, refer to resources such as the APhA COVID-19 resource center and the Pharmacist Spotlight: Vaccination Safety.

A drug or device is misbranded if its **labeling proves false or misleading**. In the 2023 dataset, these matters included allegations of **selling** misbranded and **adulterated medications**.

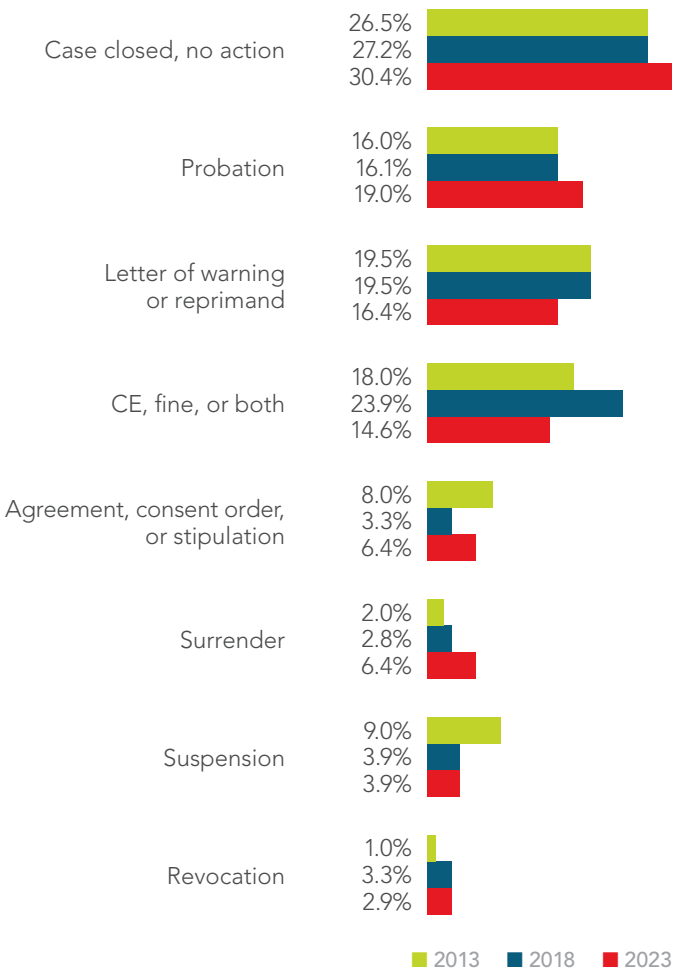
State Board of Pharmacy Outcomes

While the terminology used to describe the types of disciplinary actions Boards impose may differ between states and jurisdictions, disciplinary action taken by all Boards can affect a pharmacist's ability to practice. Any complaint filed against, and potentially implicating the license/certification of a pharmacist, can have career-altering consequences, ranging from reprimands or fines to surrender or revocation of license, resulting in career termination. **Figure 21** compares the distribution of Board licensing actions between the 2013, 2018 and 2023 datasets. In the 2023 dataset, the greatest percentage of license protection matters, 30.4 percent, **closed with no action** taken by the Board. A Board's decision to refrain from imposing disciplinary action represents a positive outcome for the insured pharmacist.

Approximately 70 percent of license protection matters led to some type of Board action against a pharmacist's license. Even complaints resulting in less severe decisions by the Board, such as **probation**, **consent agreements** or stipulations, **fines**, mandated **continuing education**, or **letters of warning or reprimand**, may have a significant emotional and professional impact on the pharmacist. Board investigations are serious matters, requiring legal assistance, as well as a substantial investment of time and effort by the pharmacist until they are resolved.

Although it may be difficult to prevent complaints from being filed, following basic risk management principles, including consistent adherence to state practice acts and organizational policies and procedures, proactively obtaining professional education and training to maintain clinical competencies, and accurate documentation, increase the likelihood of a "no action" decision by the board.

21 Comparison of 2013, 2018, and 2023 Distribution of State Board of Pharmacy Actions



Approximately **70 percent of license protection matters** led to some type of **Board action** against a pharmacist's license.

151 North Franklin Street
Chicago, IL 60606
1.866.262.0540
www.cna.com

1100 Virginia Drive, Suite 250
Fort Washington, PA 19034
1.800.982.9491
www.hpso.com

In addition to this publication, CNA and Healthcare Providers Service Organization (HPSO) have produced numerous studies and articles that provide useful risk control information on topics relevant to pharmacists, as well as information relating to pharmacist insurance, at www.hpso.com. These publications are also available by contacting CNA at 1-866-262-0540 or at www.cna.com.

The information, examples and suggestions presented in this material have been developed from sources believed to be reliable, but they should not be construed as legal or other professional advice. CNA accepts no responsibility for the accuracy or completeness of this material and recommends the consultation with competent legal counsel and/or other professional advisors before applying this material in any particular factual situations. This material is for illustrative purposes and is not intended to constitute a contract. Please remember that only the relevant insurance policy can provide the actual terms, coverages, amounts, conditions and exclusions for an insured. All products and services may not be available in all states and may be subject to change without notice. "CNA" is a registered trademark of CNA Financial Corporation. Certain CNA Financial Corporation subsidiaries use the "CNA" trademark in connection with insurance underwriting and claims activities. Copyright © 2023 CNA. All rights reserved.

Healthcare Providers Service Organization is a registered trade name of Affinity Insurance Services, Inc.; (TX 13695); (AR 100106022); in CA, MN, AIS Affinity Insurance Agency, Inc. (CA 0795465); in OK, AIS Affinity Insurance Services, Inc.; in CA, Aon Affinity Insurance Services, Inc., (CA 0G94493), Aon Direct Insurance Administrators and Berkely Insurance Agency and in NY, AIS Affinity Insurance Agency.

Healthcare Providers Service Organization is a registered trade name of Affinity Insurance Services, Inc., an affiliate of Aon Corporation. For more information about HPSO, or to inquire about professional liability insurance for allied healthcare professionals, please contact HPSO at 1-800-982-9491 or visit HPSO online at www.hpso.com.

Published 6/2023.