CNA HPSO

Pharmacist Liability Claim Report: 2nd Edition

Identifying and Addressing Professional Liability Exposures

The American Pharmacists Association (APhA) is proud to support the *Pharmacist Liability Claim Report: 2nd Edition*. APhA's contribution to the Report exhibits our commitment to the advancement of pharmacists' patient care activities that result in positive outcomes for patients and enhanced well-being for pharmacists. 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 for optimal health and well-being of the pharmacy team.

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Executive Vice President & CEO, American Pharmacists Association

APhA
AMERICAN PHARMACISTS ASSOCIATION

The Institute for Safe Medication Practices (ISMP) is pleased to have provided input into the development of the *Pharmacist Liability Claim Report: 2nd 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.

Michael R. Cohen, RPh, MS, ScD (hon.), DPS (hon.), FASHP
President, ISMP

ISMP
Institute for Safe Medication Practices

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Top 10 Findings from the Pharmacy Report

Average total incurred of professional liability pharmacy closed claims is **$124,407,** a **22.8** percent increase since the 2013 report. (See page 6.)

Hospital and **compounding specialty** locations have the highest average total incurred of all pharmacy types. (See page 7.)

Independent or individually owned and **compounding specialty** locations have the highest distribution of closed claims of all pharmacy types. (See page 8.)

Wrong drug and **wrong dose** continue to be the highest distribution of professional liability allegations closed claims. (See page 9.)

Eye injury/vision loss, as an injury, has an average total incurred more than four times the overall average total incurred of all professional liability closed claims. (See page 13.)

Gastrointestinal distress, infection/abscess, and **death,** as injuries, have the highest distribution of closed claims. (See page 14.)

Death, as an injury, has an average total incurred two and half times greater than the overall average total incurred of professional liability pharmacy closed claims. (See page 14.)

Average payment of license protection paid claim is **$5,349,** a **45.2** percent increase since the 2013 report. (See page 20.)

Reported license protection incidents have **increased 17.8** percent since the 2013 report. (See page 20.)

Drug diversion to others and **diversion to others resulting in criminal indictment** have an average license protection payment significantly higher than the overall average payment of $5,349 of license protection paid claim. (See page 23.)

PART 1: ANALYSIS OF PHARMACIST PROFESSIONAL LIABILITY CLOSED CLAIMS

Introduction

In collaboration with our partners at Healthcare Providers Service Organization (HPSO), we at CNA insure more than 80,000 pharmacists in a wide variety of pharmacy settings.

As part of our mission to educate our insureds and the healthcare field at large about risk-related issues, we are pleased to present our second pharmacist closed claims report. Our goal is to help pharmacists enhance patient safety and minimize liability exposure by providing up-to-date information on professional liability claim and licensure board complaint patterns and trends, as well as related risk management information and guidance. We believe that all pharmacists, pharmacy owners, and pharmacy professionals, regardless of practice setting, will find this detailed, fact-based report useful.

Summary of High Level Findings

- The two types of pharmacy locations with the highest average total incurred include **hospital** and **compounding specialty**. (See page 7.)

TOP FINDING

- The three types of pharmacy locations with the highest distribution of closed claims were **independent or individually owned, compounding specialty,** and **national/ regional chain**. (See page 8.)

TOP FINDING

- The overall average total incurred is $124,407. Seven allegations had an average total incurred higher than $124,407 and include **failure to identify overdosing, compounding calculation and/or preparation error, libel/slander, failure to provide instructions or wrong instructions, infection prevention error-contaminations of drugs/ container/equipment, failure to counsel patient,** and **scope of practice.** (See page 6.)

TOP FINDING

Database and Methodology

The professional liability dataset includes adverse claims that closed between the five-year period of January 1, 2012 through December 31, 2016, regardless of when the incident occurred or was reported. We reviewed professional liability closed claims that involve a CNA-insured pharmacist, pharmacy technician, or pharmacy entity, which resulted in a payment of at least $1 on behalf of the insured party.

These criteria, applied to the total number of reported pharmacy claims, create the 2018 claim dataset consisting of 184 closed claims available for review. For comparative purposes, any mention within this report to a prior CNA/HPSO pharmacy claim report will reference the 2013 claim dataset. The 2013 claim dataset was comprised of 162 closed claims over a 10-year period between January 1, 2002 and December 31, 2011. The average annual number of closed claims in the 2018 claim dataset has more than doubled compared to the 2013 claim dataset. Total incurred for professional liability closed claims, in the 2018 report, is in excess of $25 million. In the 2013 report, the total incurred for professional liability closed claims was in excess of $18 million.

As the inclusion criteria in this report may differ from those of prior CNA/HPSO pharmacy claim analyses and claim studies from other organizations, readers should exercise caution about comparing these findings with other reviews, unless the comparison is made within this report. Similarly, because of the fundamental 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.

Within the context of this report, the term **average total incurred** means the costs or financial obligations, including indemnity and expenses, resulting from the resolution of a claim, divided by the total number of closed claims.

PHARMACIST SPOTLIGHT

For risk control strategies related to:

- Scope of Practice
- Documentation
- Reporting an Incident
- Risk Control Self-assessment Checklist

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Data Analysis

Analysis of Claims by Licensure Type

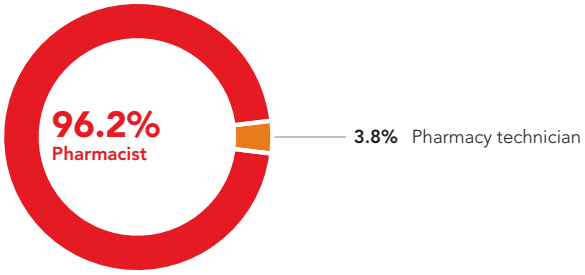
- The 2018 claim dataset includes closed claims which involve individual pharmacists, pharmacists employed by a corporate entity, as well as individual pharmacy technicians insured by CNA.
- The majority (96.2 percent) of closed claims arise from pharmacists with only 3.8 percent attributed to pharmacy technicians. This distribution is consistent with the comparative number of insured in-force pharmacists and pharmacy technicians in the CNA/HPSO program.
- Pharmacy technicians typically practice under the supervision of pharmacists; therefore, the lower severity of pharmacy technician claims is commensurate with the scope of their licensure.

A comparison of the 2018 claim dataset to the 2013 claim dataset indicates that the average total incurred has risen significantly from $101,269 to $124,407, a 22.8 percent increase.

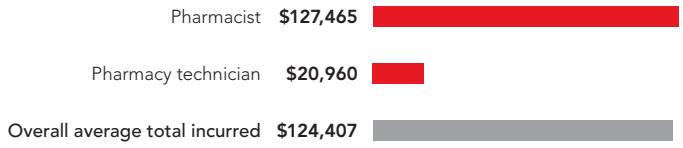
Comparison of Average Total Incurred: 2013 and 2018

- Of closed claims with total incurred of at least $1, 67.6 percent of claims resolve between $1 and $49,999, similar to the 2013 dataset.
- As shown below, there are 10 percent fewer claims closing with an average total incurred in the $1 to $9,999 range in 2018 compared with 2013.
- In 2018, there has been a shift to more claims closing in the $50,000 to $499,999 range when compared to 2013.
- There was a small, but significant increase in claims that closed with a total incurred amount of $1 million. This increase is largely due to the rise of claims against a pharmacist, which involved multiple patients. One example involves a pharmacist's failure to follow established procedures when compounding, which led to the contamination of medications or parenteral nutrition (PN) to multiple patients.

1 Distribution of Closed Claims by License Type

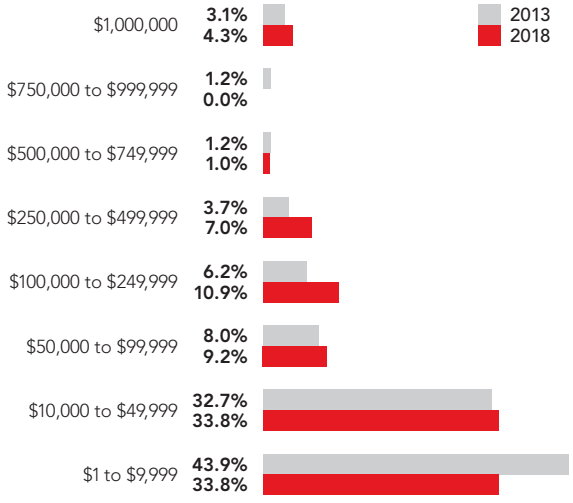


2 Severity of Closed Claims by License Type



3 Comparison of 2013 and 2018 Average Total Incurred

4 Comparison of Average Total Incurred: 2013 and 2018



Analysis of Pharmacy Closed Claims with Expense Payments Only

Claims may resolve without an indemnity payment to a plaintiff for various reasons. For example, such a claim may be:

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

Claims that resolve without an indemnity payment may nevertheless incur costs. Known as *paid expenses*, these expenditures can include attorney fees, expert witness fees, and costs involved in investigating the claim. Claim expenses can vary widely due to the unique circumstances of every case.

Expenses arising from claims with no indemnity payment have increased from the 2013 claim report. From the 2013 dataset, total expenses with no indemnity payments for the 10 years totaled $2.3 million. From the 2018 dataset total expenses with no indemnity payments were $2.3 million but based on five years of data.

Figure 5 displays average paid expenses per year for pharmacist claims that closed with no indemnity payment. While we promote efficient and focused defense of every claim, expense costs continue to rise. The reasons are varied, but include the escalating costs of defense counsel, as well as the need for skilled experts knowledgeable in the science and regulations relating to the practice of pharmacy. These expense costs are necessary to aggressively defend insured pharmacists against non-meritorious claims.

Analysis of Pharmacist Closed Claims by Pharmacy Type

Severity and Distribution by Pharmacy Type

- **Hospital pharmacies** have an average total incurred of $273,338, more than two times the overall average total incurred of $124,407. The main driver behind the higher average total incurred is due to significant injuries to already acutely ill patients. These injuries include loss of sight, loss of limb, and increase in patient injury or illness acuity requiring extensive hospital recovery.
- **Compounding specialty pharmacies** have undergone considerable regulatory changes over the past decade. The distribution and the severity of the average total incurred of compounding pharmacies may decline over time due to regulatory changes. However, since the process of resolving a professional liability claim can take many years this decline may not be noticeable for some time. The average total incurred of $256,381 is more than two times the overall average total incurred of $124,407.

PHARMACIST SPOTLIGHT

For risk control strategies related to compounding preparations see page 27 and visit:

- ISMP's Guidelines for Safe Preparation of Compounded Sterile Preparations

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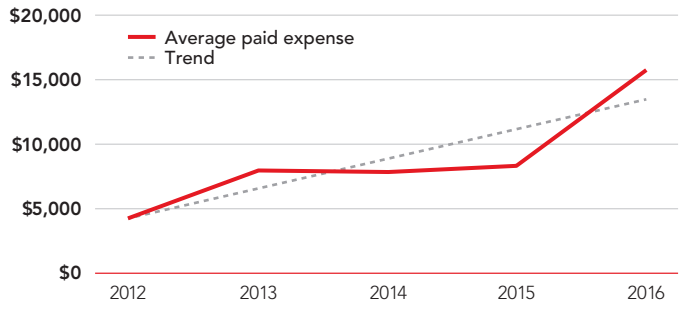
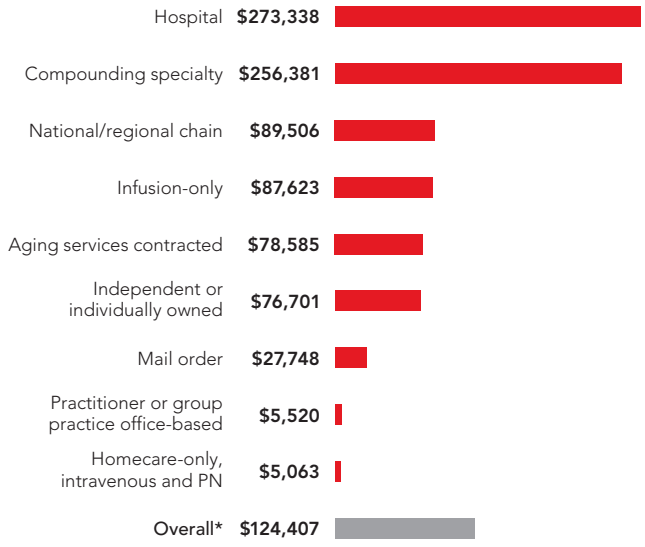
5 Average Paid Expense for Closed Claims with No Indemnity Payment, with Trend Line



6 Severity by Pharmacy Type

* Overall average total incurred for all claims.



Distribution of Closed Claims by Pharmacy Type

- The pharmacy types with the highest distribution of closed claims are **independent or individually owned, compounding specialty** and **national/regional chain.**
- **Compounding pharmacies** account for 17.9 percent of all closed claims and have an average total incurred of $256,381, which is twice the overall average total incurred of $124,407. Allegations frequently associated with compounding pharmacies include **failure to identify overdosing, calculation and/or preparation error,** and **improper/inadequate infection prevention technique/supervision.**

The **top four** pharmacy types account for **93.5 percent** of **all closed claims.**

Analysis of Allegations

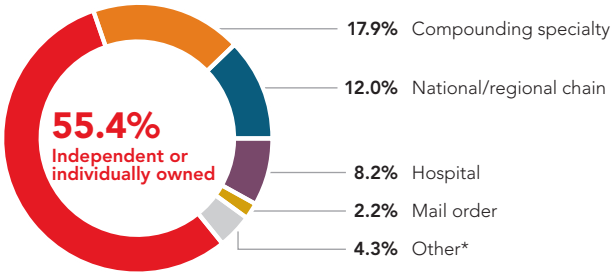
Severity by Allegation

- Figure 8 displays the seven allegation categories that resulted in an average total incurred higher than the overall average total incurred of $124,407.
- **Failure to identify overdosing** occurs the most infrequently of all closed claims in the analysis but has an average total incurred of $544,600, which is more than four times the overall average total incurred. An example of a claim in this category includes:
  - An insured, pharmacist-in-charge, filled a compounded Clonidine prescription for a seven-year-old patient, which was mistakenly prescribed at 1,000 times the prescribed dose. Upon ingesting the medication, the child immediately began experiencing seizure-type activity, became apneic, and unresponsive. The mother telephoned 911. During transport to the hospital, the patient suffered injury to his trachea due to multiple intubation attempts by the paramedics. The child remained hospitalized for 11 days and was diagnosed with toxic effects from the hypertensive agent.

7 Distribution by Pharmacy Type

This figure highlights the distribution of pharmacy types from the 2018 report.

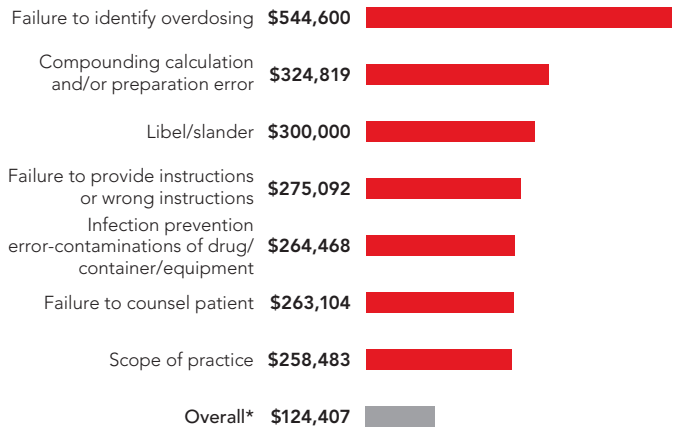
* Other includes aging service contracted, infusion-only, home care-only, intravenous and PN, practitioner or group practice office-based.



8 Severity of Allegations

This figure highlights the allegations with the highest average total incurred.

* Overall average total incurred for all claims.



- **Compounding calculation and/or preparation error** accounts for 5.0 percent of all closed claims in the analysis, with an average total incurred ($324,819) more than two and a half times the overall average total incurred. Examples of claims in this category include:
  - A pharmacist failed to properly calculate and convert a PN mix appropriately for a minor patient. The miscalculation and incorrect conversion resulted in a fatal overdose.
  - A patient with hypothyroidism was prescribed T-3 10 micrograms ER and was dispensed T-3 10 milligrams ER. The patient suffered a myocardial infarction and congestive heart failure.
- **Libel/slander** occurs infrequently in the analysis, but has an average total incurred of $300,000, which is more than twice as high as the overall average total incurred. One such allegation involves a pharmacist working at a national/regional pharmacy who refused to fill narcotic prescriptions from a certain prescriber. The prescriber alleged that the insured made defamatory statements about him to his patients, causing him to suffer financially and professionally.

Distribution of Closed Claims by Allegation

- **Infection prevention error-contaminations of drug/container/equipment** closed claims have increased from 0.6 percent in the 2013 report to 14.1 percent in 2018. The claims associated with this category involved pharmacists that failed to prevent microbiological contaminations in customized nutritional supplements, ophthalmic solutions, and intramuscular steroid medications. Failure to adhere to the standard of care, infection prevention protocols and processes, coupled with the severity of patient injuries, made these claims difficult to defend.

TOP FINDING

- **Wrong drug** (36.8 percent) and **wrong dose** (15.3 percent) continue to be the most common allegations at a combined 52.1 percent of all closed claims. This represents a decline from a combined 75.3 percent in the 2013 report. Wrong drug and wrong dose closed claims are discussed in more detail on pages 10-15.

TOP 3 ALLEGATIONS BY SEVERITY

1 **$544,600**
Failure to identify overdosing

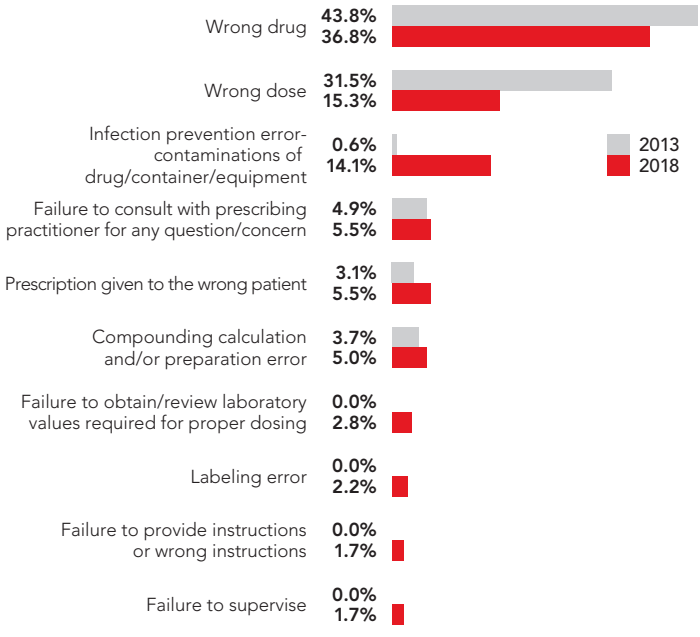
2 **$324,819**
Compounding calculation and/or preparation error

3 **$300,000**
Libel/slander

@#$%

9 Distribution by Allegations Errors

This figure highlights the allegations with the highest distribution of closed claims from the 2018 report and the 2013 report.



Factors Affecting Wrong Drug Dispensing Errors

Severity by Factors Affecting Wrong Drug Dispensing Errors

Many factors can contribute to dispensing a **wrong drug.** A major cause is the failure to take special precautions for **sound-alike** and **look-alike drugs**. Compromised safety checks may lead to a consequent error.

- **Other sources of errors include distractions during the dispensing process, failure to review prescriptions with the patient,** and **confusing drug names.** (See ISMP's List of Confused Drug Names for a listing of look-alike and sound-alike medications.)
- While relatively infrequent, the following risk factors are associated with closed claims arising from wrong drug dispensing errors that demonstrated a higher-than-average total incurred:
  - **Failure to separate look-alike drugs using color/ separation/tall man letters** has an average total incurred of $547,615, which is more than four times the total average total incurred of $124,407.
  - **Failure to question practitioner about an unusual prescription,** which led to the patient suffering a loss of organ function and is more than one and a half times the average total incurred at $229,873.
  - **Failure to specifically monitor and clarify anticoagulant prescription,** which led to a patient suffering from Coumadin toxicity and is more than one and a half times the average total incurred at $204,778.

Distribution of Wrong Drug Closed Claims by Factors Affecting Wrong Drug Dispensing Errors

As in the 2013 claim report, **failure to separate sound-alike drugs** continues to be the most common drug-dispensing risk factor at 15.1 percent in 2018 and 18.5 percent in 2013. An example includes the following claim:

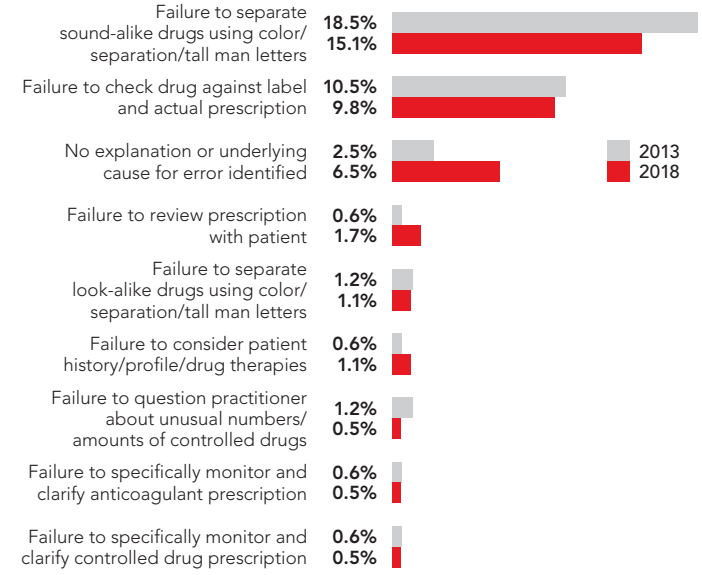
- A patient with no known history of cardiac illness was incorrectly dispensed Minoxidil instead of Methotrexate. The patient suffered cardiac tissue death, resulting in moderate congestive heart failure and permanent partial disability.

WAYS TO REDUCE DISPENSING THE WRONG DRUG

- ☐ Take extra precautions with **sound-a-like drugs**
- ☐ Take extra precautions with **look-a-like drugs**
- ☐ **Reduce distractions** during dispensing process
- ☐ **Review** prescription with patient
- ☐ **Clarify** confusing drug names

10 Distribution of Wrong Drug Closed Claims by Factors Affecting Wrong Drug Dispensing Errors

This figure highlights the factors affecting wrong drug dispensing errors with the highest distribution of closed claims from the 2018 report and the 2013 report.



11 Wrong Drug Closed Claims by Type of Drug Prescribed and Dispensed

- Claims that are **bolded in red** have an incurred cost higher than the overall average total incurred of $124,407.
- Claims **marked with one asterisk (*)** are those where the drug name and/or dose were not provided in the claim file.
- Claims **with a yellow 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 15 mg	Acyclovir 100 mg	Emotional distress, due to fear that wrong medication would cause further complications
Allopurinol 100 mg	Amitriptyline 100 mg	Syncope episode, requiring emergency treatment
Amitriptyline 10 mg	Amlodipine 10 mg	Dizziness, resulting in lost work days
Ammonul*	**Buphenyl***	**(Child) Seizures, necessitating hospitalization and resulting in permanent brain damage**
Atenolol 25 mg	Cetirizine 10 mg	Cardiac arrhythmia, experienced increased heart rate and physical discomfort
Atralin cream	Anthralin cream	Severe burn to the face, requiring hospitalization
Augmentin 500 mg twice a day	Prozac 40 mg twice a day	Vertigo, several emergency visits and ultimate diagnosis of serotonin syndrome
Carafate*	Carbamazepine*	Gastrointestinal distress, requiring emergency treatment
Carbamazepine*	Lithium*	(Child) Seizures and alleged permanent disability
Clarinex* (generic)	Clozapine 25 mg	Extreme light-headedness and dizziness, requiring hospitalization
Clomipramine*	Clomiphene*	Minor gastrointestinal distress
Clonazepam 1 mg	Clonidine 0.1 mg	Extreme hypotension, requiring hospitalization
Clonidine*	Glyburide*	(Child) Hypoglycemia crisis, requiring hospitalization
Dexilant 60 mg	Cymbalta 60 mg	Dizziness and light-headedness, resulting in loss of income
Dilantin*	Desyrel*	Gastrointestinal distress with nausea and vomiting, requiring emergency treatment
Diphenhydramine 50 mg (IV)	Dexamethasone 20 mg (IV)	Suffered minor sterile abscess
Doxycycline 100 mg	Doxepin 100 mg	(Child) Altered mental status, dizziness, pallor, and insomnia, requiring hospitalization
Drug name not provided*	Tramadol*	Anxiety over receiving wrong medication, leading to mild gastrointestinal distress
Drug name not provided *	Drug name not provided*	Psychological harm
Effexor XR 75 mg	Flagyl 500 mg	Mild gastrointestinal distress
Famotidine 1 mg	Methimazole 20 mg	(Dog) Hypothyroidism, requiring veterinary treatment
Fluoxetine 40 mg	Drug name not provided*	Hand tremors
Hydroxyzine HCL 25 mg	Hydralazine 25 mg	(Child) Mild gastrointestinal distress
Hydroxyzine HCL 25 mg	Hydralazine 25 mg	Several fainting episodes, requiring hospitalization
Labetalol 200 mg	Lamotrigine 200 mg	Exacerbation of high blood pressure, resulting hospitalization
Labetalol 200 mg	Lamotrigine 200 mg	Hypertension, requiring emergency treatment
Labetalol 200 mg	**Lamotrigine 200 mg**	**Dizziness and vertigo, requiring emergency treatment**
Lamisil*	Lamictal*	Dizziness, headaches and blurred vision
Lamotrigine 200 mg	Labetalol 200mg	Grand mal seizure, leading to dislocated shoulder and consequent surgery
Levofloxacin*	Levothyroxine*	Transient ischemic attack and memory loss
Lexapro 10 mg	Clozapine 100 mg	Syncopal episodes
Lexapro 20 mg	Levoxyl 150 mcg	Cardiac arrhythmia, requiring extensive cardiac evaluation
Lyrica 150 mg	**Lamictal 150 mg**	**Suicide**
Methadone*	Suboxone*	Pain and suffering, resulting from withdrawal symptoms
Methotrexate*	**Minoxidil***	**Severe cardiac tissue death, resulting in residual symptoms**

11 Wrong Drug Closed Claims by Type of Drug Prescribed and Dispensed (continued)

- Claims that are **bolded in red** have an incurred cost higher than the overall average total incurred of $124,407.
- Claims **marked with one asterisk (*)** are those where the drug name and/or dose were not provided in the claim file.
- Claims **with a yellow 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
Methylphenidate 10 mg	Methadone 10 mg	(Child) Severe fatigue, requiring emergency treatment
Methylphenidate*	Methadone*	(Child) Vertigo/dizziness
Metronidazole (liquid)*	Sotalol Hydrochloride (liquid)*	(Child) Cardiac arrhythmia, requiring emergency treatment
Minoxidil 2.5 mg	**Methotrexate 2.5 mg**	**Methotrexate poisoning, resulting in death**
Morphine*	Opana*	Mild gastrointestinal distress
Omeprazole and Bisoprolol hydrochlorothiazide*	Metoprolol* and Diltiazem*	Syncopal episodes, light-headedness and lethargy
Opana*	Morphine*	Emotional distress over wrong medication being dispensed
Oxycodone 30 ml immediate release	Oxycodone 30 ml extended release	Pain and suffering due to poor pain control
Pantoprazole 40 mg	Pravastatin 70 mg	Gastrointestinal distress, requiring hospitalization
Paxil 20 mg	Prozac 20 mg	Emotional distress over wrong medication being dispensed
Paxil 40 mg	Prozac 40 mg	Severe emotional distress
Phenobarbital 30 mg	Phentermine 37.5 mg	Angina, anxiety and restlessness
Pravastatin 80 mg	**Simvastatin 80 mg**	**Renal failure, requiring hospitalization for dialysis**
Pravastatin* and Verapamil 240 mg	Two prescriptions of Verapamil 240 mg and no Pravastatin	Renal failure, requiring hospitalization
Prednisone 5 mg	**Coumadin 5 mg**	**Gross hematuria and mucosal bleeding from Coumadin toxicity**
Prednisone 7.5 mg (1mg/1 ml liquid)	Risperidone 7.5 mg (1 mg/ml liquid)	(Child) Fatigue
Promethazine hydrochloride 25 mg	Hydrochlorothiazide 25 mg	Increase of gastrointestinal distress resulting in the inability to work and consequent loss of income
Propantheline 15 mg	Prolixin 5 mg	(Child) Neurological deficit, diagnosed with acute dystonic reaction
Q-dryl*	Miralax*	Increase of chemotherapy-related mouth ulcers
Ritalin 10 mg	Methadone 10 mg	Gastrointestinal distress, resulting in emergency treatment
Rivastigmine*	Risperidone*	Increase of dementia symptoms
Ropinirole 1 mg three times a day	**Risperdal 1 mg three times a day**	**Severe psychotic episode, resulting in involuntary psychiatric hospital admission**
Ropinirole 2 mg	**Risperidone***	**Dystonic drug reaction, requiring hospitalization**
Ropinirole 3 mg	Risperidone 3 mg	Mild episode of dizziness
Tacrolimus*	**Tamsulosin****	**Failed heart transplant, due to missed immunosuppressive medication**
Tamsulosin*	Tacrolimus*	Severe urinary retention, requiring hospitalization and disrupting chemotherapy treatment
Tizanidine* and Clonazepam*	**Two prescriptions of Clonazepam* and no Tizanidine**	**Ongoing joint pain and muscle weakness**
Tramadol*	Tizanidine*	Gastrointestinal distress, requiring emergency treatment
Trazodone*	Torsemide*	Dehydration, resulting in emergency treatment
Valium 2 mg	Xanax 2 mg	Two syncopal episodes, one causing a fall that resulted in a fracture and required surgery
Vyvanse*	Concerta*	(Child) Mild gastrointestinal distress
Warfarin 5 mg and Lisinopril 10 mg	Two prescriptions of Lisinopril 10 mg and no Warfarin 5 mg	Deep vein thrombosis, requiring hospitalization
Wellbutrin 150 mg	Effexor 150 mg	Emotional distress over wrong medication being dispensed

Factors Affecting Wrong Dose Dispensing Errors

Both distribution and severity associated with wrong dose claims have decreased significantly since the 2013 closed claim report. This decrease may be due in part to the growing use of electronic prescribing and dispensing tools, such as computer physician order entry systems, health information exchange, and medication bar-coding. The following wrong dose claims are examples, which closed with higher than the overall average total incurred of $124,407:

- An elderly patient was prescribed Methotrexate for rheumatoid arthritis. Normal dose for this patient was one 25 mg tablet every seventh day. However, the insured pharmacist dispensed one 25 mg tablet daily for seven days. The overdose resulted in methotrexate toxicity causing permanent brain damage.
- A pharmacy technician dispensed an incorrect dosage of liquid morphine sulfate. The prescribing practitioner's order was for "20 mg/5 ml, give 5 mg every 4 hours." However the technician labeled the prescription incorrectly as "20 mg/5 ml, give 5 ml every 4 hours." The insured pharmacist signed off on the prescription without recognizing the error. After the third dose, the patient died from morphine toxicity.

Eight injuries have an average paid incurred **higher** than the overall average: **eye injury/vision loss, cardiopulmonary arrest, death, burn, seizure, congestive heart failure/ cardiac injury, ear injury/ hearing loss,** and **renal failure**.

PHARMACIST SPOTLIGHT

For risk control strategies related to safe methotrexate dispensing practices see:

- ISMP's Targeted Medication Safety Best Practices for Hospitals
- ISMP's Call to Action: Longstanding Strategies to Prevent Accidental Daily Methotrexate Dosing Must Be Implemented.

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Analysis of Injury/Illness/Adverse Outcome

Severity by Injury/Illness/Adverse Outcome

TOP FINDING

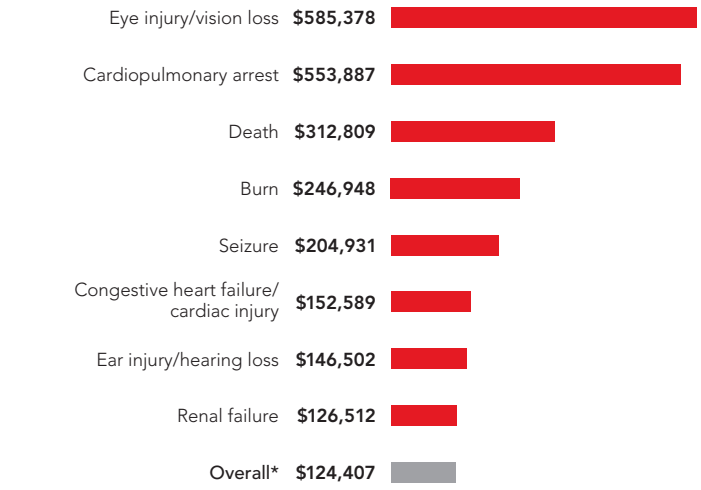
- **Eye injury/vision loss** injuries involve a pharmacist who incorrectly compounded eye medications for patients undergoing cataract surgery. The solution caused severe eye infections in which the patients suffered either partial or total loss of sight.

- **Cardiopulmonary arrest,** as an injury, has an average total incurred significantly higher than the overall average total incurred. This significantly higher average total incurred is affected by two claims involving separate and unrelated incidents where minor patients suffered overdose related cardiac arrest.
- **Burns** reflect a higher average total incurred compared to the overall average. While all claims in this category have higher incurred payments, the severity is most influenced by a closed claim involving a minor patient who suffered esophageal and gastrointestinal burns due to improper compounding of Omeprazole.
- **Seizure** had an average total incurred higher than the overall average total incurred. The severity was influenced by one closed claim related to a wrong drug being dispensed to a minor patient in which both the pharmacist and pharmacy technician were unfamiliar with the medication that was prescribed. The minor suffered from an increase in seizure activity due to Buphenyl being dispensed instead of the prescribed Ammonul.

12 Severity of Injury/Illness/Adverse Outcome by Injury/Adverse Outcome

This figure highlights the injury/illness/adverse outcome with the highest average total incurred.

* Overall average total incurred for all claims.



Distribution of Closed Claims by Injury/Illness/Adverse Outcome

- Ten injuries/illnesses account for 70.7 percent of all closed claims. These claims include **gastrointestinal distress, infection/abscess, death, emotional/psychological harm/distress, syncope/fainting, vertigo/dizziness/light-headedness, neurological deficit/damage, congestive heart failure/cardiac injury, eye injury/vision loss,** and **seizure**.

TOP FINDING

- **Gastrointestinal distress,** as an injury, demonstrates the highest distribution of closed claims. However, the majority of the patients suffered only temporary harm such as nausea, vomiting, constipation, and/or diarrhea.
- **Infection/abscess** injuries involve closed claims in which pharmacists failed to prevent microbiological contaminations in customized nutritional supplements, ophthalmic solutions, and intramuscular steroid medications.

- **Death,** as an injury, had a high distribution of closed claims and an average total incurred two and a half times greater than the overall average total incurred. Many of these claims involved Schedule II and Schedule III medications.

TOP FINDING

13 Distribution of Closed Claims by Injury/Illness/Adverse Outcome

This figure highlights the top 10 injuries/illnesses from the 2018 report.

Injury	Distribution of Closed Claims
Gastrointestinal distress	11.9%
Infection/abscess	11.9%
Death	10.3%
Emotional/psychological harm/distress	8.2%
Syncope/fainting	6.0%
Vertigo/dizziness/light-headedness	5.0%
Neurological deficit/damage	5.0%
Congestive heart failure/cardiac injury	4.3%
Eye injury/vision loss	4.3%
Seizure	3.8%
Total of the highest distribution of closed claims by injury/illness/adverse outcome	70.7%

Gastrointestinal distress, infection/abscess, and death have the highest distribution of professional liability closed claims.

TOP 5 CAUSES OF DEATH

1	Overdose	73.7%
2	Infection	10.4%
3	Increase of exacerbation of illness	5.3%
4	Glycemic event	5.3%
5	Loss of organ or organ function	5.3%

14 Wrong Dose Closed Claims by Dose Prescribed and Dispensed

- Claims that are **bolded in red** have an incurred cost higher than the overall average total incurred of $124,407.
- Claims **marked with one asterisk (*)** are those where the drug name and/or dose were not provided in the claim file.
- Claims **with a yellow background** indicate that the drug prescribed was involved in more than one wrong drug closed claim.

Drug prescribed	Dose prescribed	Dose dispensed	Resulting injury or adverse effect
Aldara	Three times a week for 16 weeks	Three times per day for 1 week	Severe skin burns, which includes blistering and scabbing
Amitriptyline	10 mg	100 mg	(Child) Several episodes of seizures, resulting in hospitalization
Amitriptyline	10 mg	100 mg	(Child) Syncopal episodes with vomiting and diarrhea, requiring hospitalization
Ativan	1.0 mg	2.0 mg	Addiction with unsuccessful attempts to wean patient off increased dose
Chlorambucil	1.9 mg	17.5 mg	(Dog) Gastrointestinal distress, requiring veterinary care
Coumadin	1 mg	5 mg	Abnormal International Normalized Ratio (INR), requiring hospitalization for vitamin K treatment
Coumadin	1 mg	5 mg	Abnormal INR, requiring hospitalization for vitamin K treatment
Digoxin	0.125 once a day	0.25 twice a day	Digoxin toxicity, resulting in death
Effexor	75 mg	150 mg	Severe psychosis
Fentanyl	25 mcg/hour	75 mcg/hour	Severe reaction to opioid overdose (including vomiting, dizziness and balance issue), requiring hospitalization
Flecainide	4 mg every 8 hours	8 mg every 8 hours	(Child) Cardiopulmonary arrest and successful resuscitation leading to prolonged hospitalization
Hydrochlorothiazide	50 mg once a day	100 mg once a day	Syncopal episodes due to hypotension, requiring emergency treatment
Keppra	750 mg twice a day	500 mg four times a day	Two seizure episodes, each requiring hospitalization
Klonopin	0.5 mg	1.0 mg	Increased anxiety, depression and suicidal thoughts
Lupron	Diluted to physician's order	Non-diluted	Emotional distress over the lost opportunity for in vitro fertilization
Lyrica	50 mg	150 mg	Fatigue and loss of work
Metformin	500 mg	1,000 mg	Acute renal failure, which resolved
Methotrexate	**25 mg every seventh day**	**25 mg for 7 days**	**Methotrexate toxicity, requiring hospitalization for more than one month**
Morphine sulfate oral solution	**20 mg/5 ml, 5 mg every 4 hours**	**20 mg/5 ml, 5 ml every 4 hours**	**Overdose and death**
Morphine sulfate oral solution	20 mg/5 ml, take 5 ml every 4 hours	20 mg/1 ml, take 5 ml every 4 hours	Fatigue and loss of work
Naltrexone	0.5 mg	50 mg	Medically induced coma, resulting from complications related to acute narcotic withdrawal
Oxycodone	15 mg	30 mg	Emotional distress
Prednisone	1 mg	10 mg	Abdominal cramping, requiring emergency treatment
Prednisone	1 mg	10 mg	Abdominal cramping
Ropinirole	3 mg	4 mg	Altered mental status with a three-day hospitalization
Synthroid	75 mcg	175 mcg	Thyrotoxicosis with psychiatric/neurologic effects, requiring hospitalization
Vitamin D	7,000 I.U. weekly	7,000 I.U. daily	Syncopal episode
Warfarin	1 mg	5 mg	(Child) Abnormal INR, requiring hospitalization for vitamin K treatment

Analysis of Disability for Categorizing Medication Errors

Severity by National Coordinating Counsel for Medication Error Reporting and Prevention (NCC MERP) Index Allegations

There are three NCC MERP Index for Categorizing Medication Errors that reflect an average total incurred higher than the overall average total incurred of $124,407 in the analysis.

- **Error resulting in the patient's death (Category I)** accounts for 11.3 percent of all closed claims in the analysis, with an average total incurred $298,557, which is over twice the overall average total incurred.
- **Error requiring an intervention to sustain the patient's life (Category H)** represents 2.8 percent of all the closed claims in the analysis. However, the average total incurred is more than twice the overall average total incurred. One claim in this category involves a wrong dose of Clonidine, as discussed on page 8.
- **Error resulting in permanent patient harm (Category G)** has an average total incurred of $274,873 that is higher than the overall average total incurred of $124,407. The higher amount is due to the significant medical and social support needed to care for a permanently disabled patient for the rest of their life. This category reflects many compounding claims. An example of these claims includes the inappropriate compounding of medications resulting in microbiological contamination and consequent vision loss for multiple patients.
- **Error with temporary harm, requiring intervention/prolonged hospitalization (Category F)** represents 41.3 percent of all the closed claims in the analysis and has nearly doubled in distribution since the 2013 report. While the increase in distribution is multifactorial, more than half of these closed claims occurred due to patient receiving the wrong drug or wrong dose.
- **Error reached the patient, but did not cause harm (Category C)** represents 1.6 percent of all the closed claims in the analysis and is less than the average total incurred. However, the average total incurred is over $100,000. This category was influenced by closed claims involving libel/slander, as discussed on page 9.

15 Severity of NCC MERP Category by Average Total Incurred

* These claims involve inappropriate touching and invasion of privacy.

Allegations	NCC MERP Index	Percentage of closed claims	Average total incurred
Error resulting in patient's death	I	11.3%	$298,557
Error requiring intervention to sustain patient's life	H	2.8%	$291,615
Error resulting in permanent patient harm	G	17.4%	$274,873
Error reached patient, but did not cause harm	C	1.6%	$102,833
Error with temporary harm, requiring intervention/prolonged hospitalization	F	41.3%	$72,577
No medication error occurred*	N/A	1.1%	$28,750
Error with patient monitoring required to confirm no harm suffered nor intervention required	D	1.1%	$19,322
Error with temporary harm, requiring patient intervention	E	23.4%	$10,387
Overall		100%	$124,407

CASE SCENARIO: Successful Defense of a Pharmacist

An insured pharmacist-owner was alleged to have negligently dispensed a lithium carbonate dose that was highly toxic and dangerous to the health of a patient. The patient was a 40-year-old female under the care of a neuropsychiatrist for bipolar disorder and had been a customer of the pharmacy for several years.

The pharmacist received an electronic prescription from the neuropsychiatrist for 600 mg lithium carbonate, sustained release, including directions stating that four tablets were to be taken at bedtime. The insured recognized that this was a high dose and proceeded to check the pharmacy's computer to see if such a dosage form existed and determined that the maximum daily dose is 1,800 mg.

The pharmacist called the neuropsychiatrist's office and left a voicemail message for the doctor in an attempt to verify that the prescription and directions were correct.

A few hours later, the patient came into the pharmacy to pick up the prescription. The pharmacist informed the patient that he needed to verify the dosage with the prescriber. He asked the patient if she had taken lithium before and she confirmed that she had, but she did not remember the dose and did not have an old bottle. The pharmacist stated that he would call the patient when the medication was ready.

Later that day, the pharmacist spoke with the office nurse and relayed his concern regarding the high dose of the lithium carbonate and requested clarification from the doctor. The nurse said that she would give the message to the doctor and requested that the pharmacist fax a request for a second written prescription. Following the telephone call, the pharmacist electronically sent a prescription form to the attention of the prescriber's nurse, which included the patient and doctor's name, the date and the word "lithium."

The next day, the office sent back the completed prescription form, which was identical to the original. Since the pharmacist had received the same prescription twice, he dispensed the medication as written, although he had not been able to speak personally to the prescriber.

When the patient arrived to pick up the prescription, she was specifically told to double-check with the doctor before taking the medication, due to the high dosage. The pharmacist informed her that lithium did not come in 2,400 mg tablets and that this was a higher-than-ordinary dose. The written instructions were for her to take four 600 mg tablets by mouth at bedtime and to call her doctor immediately if any side effects occurred.

A detailed patient education form was provided, which listed the risks and benefits of taking the medication as well as the importance of having the correct amount of lithium in her body. The printed instructions indicated that the medication was to be taken by mouth as directed by the prescriber, usually two to three times daily.

A week later, the patient was admitted to the hospital as a result of lithium toxicity, leading to cardiac, neurological and renal complications. She remained hospitalized for more than three weeks. She further asserted that she suffered brain damage, cognitive impairment and other disabling conditions, which left her unable to make decisions for herself or function without assistance.

Resolution

A pharmacology expert was retained, who stated that he had no criticisms of the pharmacist who had filled the medication.

While the dosage was high, he believed that 2,400 mg of lithium a day could be an appropriate range for a particular patient. Although he had never seen a prescription for 2,400 mg of lithium to be taken all at once by a patient, he was confident that taking this quantity at one time presented no higher risk of lithium toxicity than spreading it out over the day. He further indicated that it was appropriate for a pharmacist to expect the prescribing neuropsychiatrist to know the patient better than the pharmacist does, and to rely on the prescriber's expertise. The expert was complimentary of the insured's documented efforts to verify and re-verify the dosage with the prescriber and warn the patient about the risks of such a dose.

Due to the positive expert review, the pharmacist's attorney aggressively defended the pharmacist's position and interests. The case was dismissed for both the pharmacist and the pharmacy with no indemnity paid. Expenses for this successfully resolved case were in the $50,000 range.

PHARMACIST SPOTLIGHT

For risk control strategies related to:

- Policies and Procedures
- Communication
- ISMP's Medication Safety Self-Assessment for Community/Ambulatory Pharmacy

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Risk Management Comments

The pharmacist practiced within the standard of care, and his own documentation supported his actions. The defense expert effectively countered the opinion offered by the patient's expert. Moreover, the pharmacist's attorneys aggressively defended the pharmacist's position and interests through the filing of appropriate court motions.

Risk Management Recommendations from the Case Scenario for the Pharmacist

- **Contact the prescribing practitioner for any questions related to the prescription and speak directly to him/her.** Prescription verification by a member of the practitioner's staff is not sufficiently reliable and may not absolve the pharmacist of liability in the event of an error.
- **If the prescription is unclear or questionable, and the prescribing practitioner is not available, inform the patient of the problem and explain that, for reasons of safety, the prescription cannot be filled until the question/issue is resolved.** Encourage the patient to contact the practitioner and facilitate contact between the practitioner and the pharmacist. If a delay in initiating drug therapy could pose a hazard to the patient, consider recommending that the patient seek emergency medical care.
- **Check that the patient is aware of the diagnosis,** and understands the prescribed drug's purpose, benefits and side effects and what actions should be taken in the event of a reaction.
- **Document all discussions with patients, parents/guardians, prescribing practitioners, or other parties,** and ensure that this documentation is included in both patient and pharmacy records. The following guidelines can help enhance documentation practices:
- **Document questions asked of the prescribing practitioner** regarding the submitted prescription, as well as the resulting response.
- **Document that patients are aware of and able to correctly teach-back the uses, potential side effects, and signs of an allergy or adverse effect of each prescribed drug,** as well as their awareness of especially dangerous reactions that require immediate medical attention.
- **Advise the patient of potential side effects and/or adverse effects that may occur** and actions that should be taken in the event of a reaction, including contacting the prescribing practitioner, calling the pharmacy or seeking emergency medical care.
- **Instruct the patient in the appropriate administration of the drug and any contraindications,** such as incompatible foods and potential adverse interactions with alcohol, other drugs or nonprescription remedies. As part of this process, point out the instructions included with each medication, and encourage the patient to read this information in full. If available, provide the patient and/or family with medication guides for reference.
- **If the patient's practitioner has prescribed a drug for an off-label use,** instruct the patient to discuss the drug's specific indications and expectations for results with the practitioner, as well as known side effects and signs of allergic or adverse reaction. As an additional safety measure, have the prescribing practitioner provide the purpose of the off-label drug on the prescription.

Risk Management Recommendations from the Case Scenario for the Pharmacy Owner

- **Perform, at a minimum, annual performance reviews for each employee,** including a review of errors, "near misses," document requirements compliance, existing skills and directly observed competencies.
- **Ensure that clinical practices comply with standards endorsed by pharmacy professional associations,** state practice acts and facility protocols.
- **Provide appropriate clinical support for pharmacists, in compliance with supervisory or employment agreements.** Encourage compliance with relevant legal, ethical and professional standards for clinical practice.
- **Provide pharmacy staff with coaching, mentoring, and clinical and system education** as needed to ensure that patient safety requirements are satisfied.
- **The pharmacy-owner should verify that the pharmacy computer system is tested and updated** at least twice annually to ensure that critical alerts are present (adapted from: ISMP's **Medication Safety Self Assessment® for Community/Ambulatory Pharmacy**).

PART 2: ANALYSIS OF PHARMACIST LICENSE PROTECTION DEFENSE PAID CLAIMS

Introduction

A board complaint can be filed against a pharmacist by a patient, colleague, employer, and/or regulatory agency. Complaints are subsequently investigated by the board, leading to results ranging from no action against the pharmacist to revocation of the pharmacist's license to practice. As stated in Part 1, CNA attempts to promote efficient and focused defense of claims.

Some of these complaints are unsubstantiated and the regulatory body closes the case without disciplinary action. However, regardless of the outcome, board investigations are serious matters, requiring legal assistance and a significant investment of time and effort on the pharmacist's part.

License protection claims differ from professional liability claims in that they do not necessarily involve allegations directly related to a pharmacist's professional responsibilities, and may include allegations such as substance abuse or fraudulent billing. Another key difference is that the amounts paid for license protection defense claims represent only the legal fees and other costs involved in defending the pharmacist against the complaint, rather than indemnity or settlement payments to a plaintiff, or fines imposed by the state boards of pharmacy or health.

This section highlights the most common types of license protection claims. It is intended to assist pharmacists in identifying potential vulnerabilities and taking focused, proactive action to minimize risk.

Due to the fundamental uniqueness of each board matter, including the active participation of any state licensing and disciplinary board, the average payment displayed within this section of the report may not necessarily be indicative of the severity attributed to any single board matter.

Database and Methodology

The 2018 dataset examined in Part 2 represents a five-year period of 428 reported incidents or claims involving license protection defense for pharmacists who were insured through the CNA/HPSO insurance program. The final dataset includes claims that:

- Closed between January 1, 2012 and December 31, 2016.
- Resulted in a license protection defense expense payment.

These criteria, applied to the total number of reported pharmacist license protection defense claims, create a 2018 dataset consisting of 185 paid claims. Similar criteria produced a 2013 dataset comprised of 200 paid claims.

As noted in the introduction, two datasets are utilized in this report. The 2013 dataset used in Part 2 of this report reflected a 10-year period of 734 reported license protection incidents or claims affecting pharmacists insured through the CNA/HPSO insurance program that closed between January 1, 2002 and December 31, 2011.

Similar to Part 1, the average annual number of license protection defense paid claims in the 2018 claim dataset increased significantly compared to the 2013 claim dataset. Total incurred for license protection defense claims, in the 2018 report, is in excess of $980,000. In the 2013 report, the total incurred for license protection defense claims is in excess of $730,000. The reasons for the increase in license board defense claims vary, but they include, among others, the costs of defense counsel, as well as the individual nature and perspective of each state pharmacy board.

The **average number** of license protection **defense paid claims** per year **increased 85 percent** compared to the 2013 dataset.

Summary of High Level Findings

- Of the 428 total reported incidents, 185, or 43.2 percent, resulted in a payment.
- The average payment for license protection closed claims is $5,349, reflecting legal expenses and associated travel, food, lodging and wage loss costs reimbursable under the policy.
- The average payment amount may not be reflective of the total expense paid by the pharmacist for legal defense and does not represent any fines or penalties that may have resulted from the incident.

- The average number of incidents has increased 17.8 percent from an average of 73 per year over a 10-year period in the 2013 dataset to 86 per year over a five-year period in the 2018 dataset.

TOP FINDING

- The percentage of incidents that resulted in a paid claim increased from 27.2 percent of claims in the 2013 report to 43.2 percent of claims in the 2018 report.

- The average payment for license protection claims has increased 45.2 percent, from $3,685 in the 2013 report to $5,349 in the 2018 report.

TOP FINDING

- Allegations of **medication management** represent the majority (58.9 percent) of all license protection defense paid claims and the most frequent allegation within this class was **wrong drug** (17.4 percent).

- **Drug diversion to others** ($10,000) and **diversion to others resulting in criminal indictment** ($13,451) have an average payment significantly higher than the overall average payment of $5,349. (See page 23.)

TOP FINDING

Medication management, drug diversion and fraud are the three most frequent and highest severity allegations for license protection closed claims.

INCREASE IN INCIDENTS OVERALL

2013

73 per year
over a 10-year period
in the 2013 dataset

86 per year
over a five-year period
in the 2018 dataset

2018

16 Comparison of 2013 and 2018 License Defense Claim Data

	2013 report	2018 report
Number of years included in dataset	10	5
Total incidents	734	428
Average number of incidents per year	73	86
Paid claims	200	185
Paid claims as percentage of total incidents	27.2%	43.2%
Average payment	$3,685	$5,349

Data Analysis

The goal of this section of the report is to identify the actions or behaviors that most frequently lead to board complaints, as well as to suggest targeted risk management measures that can help minimize this risk. Note that while complaints can involve multiple allegations, the allegation classes selected here are based upon the primary reason for the complaint.

- The three allegation classes most frequently associated with board complaints, representing 81.6 percent of all complaints filed against pharmacists, are **medication management** (58.9 percent), **drug diversion** (11.9 percent), and **fraud** (10.8 percent).
- Allegation classes that exceed the overall average payment ($5,349) include **drug diversion** ($5,680), **documentation** ($6,166), **fraud** ($8,133), and **boundary** ($10,000).
- It is one of the pharmacist's primary professional responsibilities to maintain consistent documentation through record retention. Inadequate documentation may not only hinder the pharmacist's legal defense, it can lead to board complaints, as exemplified by the following claim:
  - The case involves a pharmacist-in-charge who failed to maintain current inventory and all records of sales, acquisitions, or dispositions of dangerous drugs, which was required in the state. The board investigated an alleged theft by the pharmacy technician where the pharmacist could not account for the lost inventory of promethazine with codeine.
- While not one of the most frequent complaints made against pharmacists, boundary issues can seriously affect the pharmacist's personal and professional reputation. These complaints represent a pharmacist's failure to respect a coworker's right to a work environment that is safe and free from harassment. An example of a boundary issue includes:
  - A female employee was working alone with an insured male pharmacist. After closing the pharmacy for the evening, the employee was in a back office doing paperwork when the pharmacist came up behind her, unbuttoned her shirt, and inappropriately touched her. The board's investigation included viewing video footage, which supported the employee's account of events. The board ordered the pharmacist's license to be indefinitely suspended and also levied a fine.

PHARMACIST SPOTLIGHT

For related risk control strategies see:

- License Protection
- Risk Recommendations

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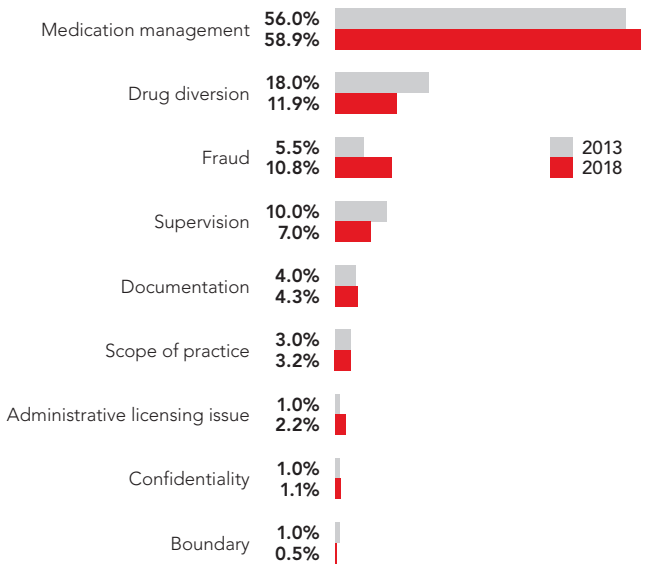
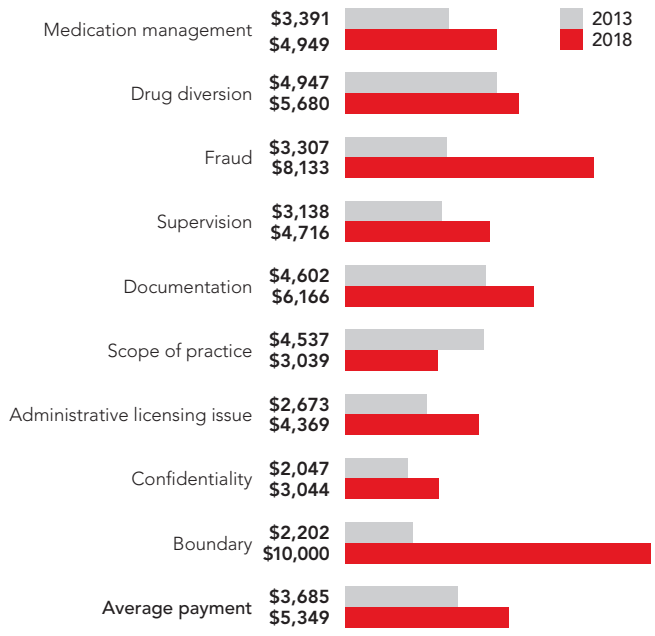
17 Comparison of 2013 and 2018 Claim Distribution by Primacy Allegation Class



18 Comparison of 2013 and 2018 Claim Severity by Primacy Allegation Class

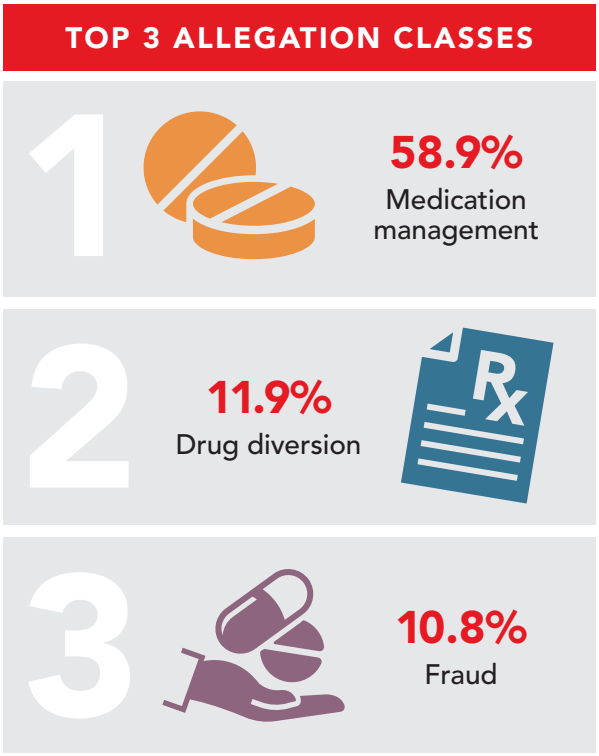


Most Frequent Allegations License Protection Defense Paid Claims

This section examines the three top allegation classes, **medication management** (58.9 percent), **drug diversion** (11.9 percent), and **fraud** (10.8 percent).

Medication Management

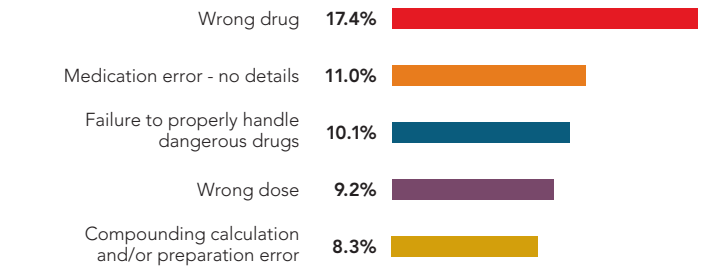
- Allegations of **medication management** represent the majority (58.9 percent) of all license protection defense paid claims. While complaints ranged widely within this allegation class, the most frequent allegation (17.4 percent) was **wrong drug.**
- Other frequent allegations within this class also include **failure to properly handle dangerous drugs** (10.1 percent), **wrong dose** (9.2 percent), and **compounding calculation and/or preparation error** (8.3 percent).
  - An example of a wrong dose claim involved a pharmacist who dispensed Chlorpromazine 100 mg, one tablet daily (30-day supply) for a patient who was prescribed Chlorpromazine 10 mg, one tablet daily (30-day supply). The pharmacist performed a final check of the prescription before it was dispensed to the patient. Subsequent to the discovery of the error, the pharmacist made no entry of this error in the quality improvement log, which violated facility policy and procedure.



19 Distribution of the Top Five Medication Management Allegations

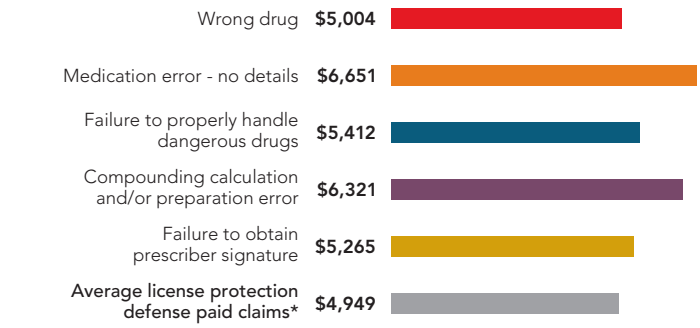
(58.9 percent of total license protection defense paid claims)

* Total percentage is calculated within the allegation class, and percentages are rounded.



20 Top Five Medication Management Allegations by Severity

* For all Medication Management allegations.



Drug Diversion

- **Drug diversion** to self and others represents 11.9 percent of the total license protection defense paid claims.
- **Diversion to others** ($10,000) and **diversion to others resulting in criminal indictment** ($13,451) demonstrated an average payment higher than the overall average payment of $5,349.
  - One board complaint involved a pharmacist who knowingly filled false prescriptions for a self-medicating friend, a physician, for hydrocodone and diazepam.
  - Another complaint involved a pharmacist who wrote a fake prescription to test a patient's insurance for the corresponding copay amount. After filling the first prescription, the pharmacist then handwrote a second prescription with a note that read, "To replace lost Rx." The second prescription was billed to the pharmacist's family member. The pharmacist was seen taking the prescriptions by not only the facility's surveillance video, but by other pharmacy staff.

Fraud

- **Fraud** allegations, including acts such as **theft,** filling **fraudulent prescriptions, practicing without a license** and **falsifying records,** comprise 10.8 percent of license protection defense paid claims.
- Claims involving allegations of fraudulent actions are the most frequent within this class (80.0 percent) and also have the highest average payment associated with the claims ($8,262).
  - One complaint involved a pharmacist who presented a forged prescription for Valium to a local pharmacy. The prescription was filled by the pharmacy and picked up by the pharmacist. The board ordered the pharmacist's license to be placed on probation.

PHARMACIST SPOTLIGHT

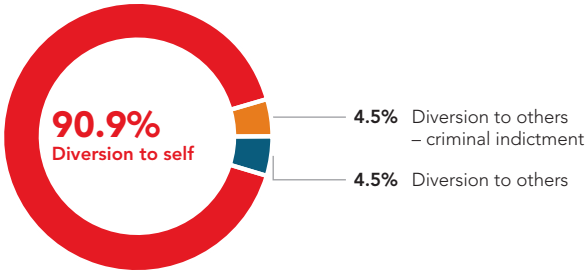
A source of support for substance abuse issues:

- Substance Abuse and Mental Health Services Administration's (SAMHSA's) National Helpline, also known as the Treatment Referral Routing Service, at 1-800-662-HELP (4357).

21 Distribution of Drug Diversion Allegations

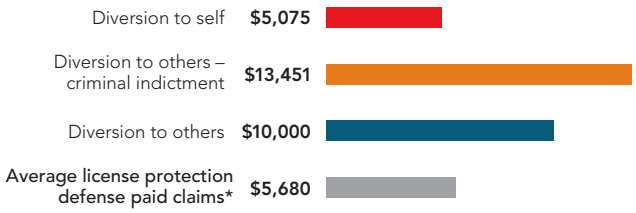
(11.9 percent of total license protection defense paid claims)

* Total percentage is calculated within the allegation class, and percentages are rounded.



22 Severity by Drug Diversion Allegations

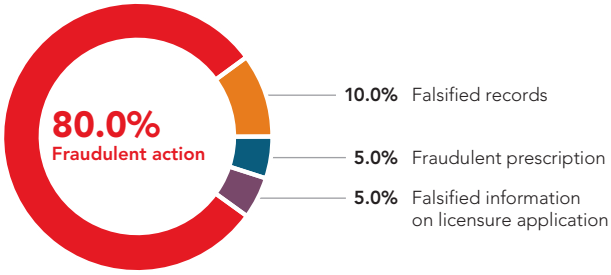
* For all drug diversion allegations.



23 Distribution of Fraud Allegations

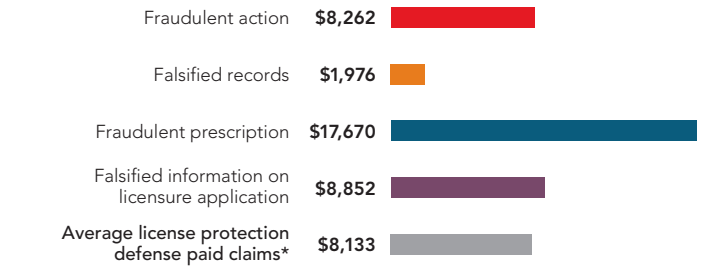
(10.8 percent of total license protection defense paid claims)

* Total percentage is calculated within the allegation class, and percentages are rounded.



24 Severity by Fraud Allegations

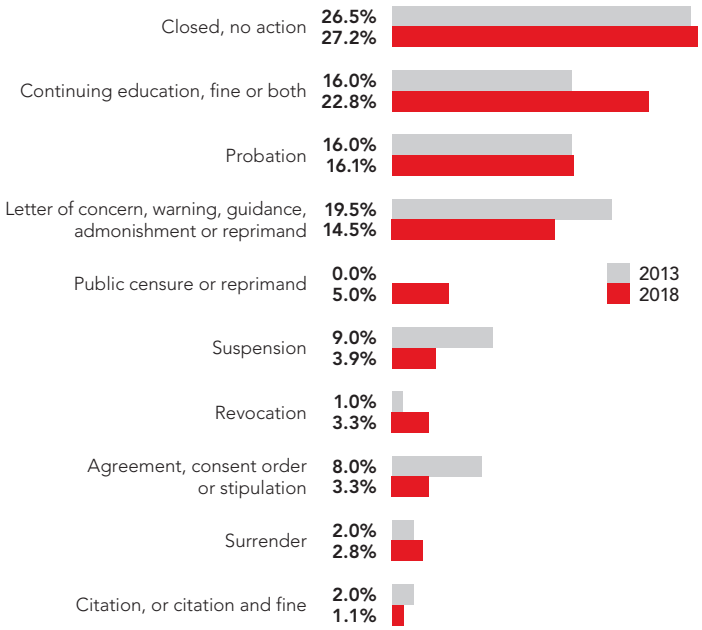
* For all fraud allegations.



Licensing Board Actions

- Figure 25 compares the distribution of licensing board actions between 2013 and 2018 claim reports and in both reports the majority of paid license protection defense claims **closed with no action** taken by the board. A decision by the board not to impose discipline represents a successful defense of the insured pharmacist. Paid license protection defense claims resulting in no action by the board increased slightly from 26.5 percent in 2013 to 27.2 percent in 2018.
- The more serious board decisions in the 2018 report, license **surrender** at 2.8 percent and **revocation** at 3.3 percent, are less common, but can have a career-altering or even career-ending disposition. However, complaints resulting in less serious decisions may have a significant impact on the pharmacist, as defense of a board complaint can require a considerable amount of time to prepare for defense.
- Licensing board actions resulting in a **letter of concern, warning** and **admonishment** decreased from 19.5 percent in the 2013 report to 14.5 percent in 2018.
- **Continuing education, fine** or **both** increased from 16.0 percent in 2013 to 22.8 percent in 2018.

25 Comparison of 2013 and 2018 Licensing Board Actions



Risk Management Recommendations

The following risk control strategies are designed to serve as a starting point for pharmacists seeking to assess and enhance risk control practices. They complement the recommendations that follow the detailed closed claim analysis. Other valuable resources and tools can be utilized and may be accessed at HPSO, the Agency for Healthcare Research and Quality (AHRQ) and ISMP.

Alert Fatigue

According to the Agency for Healthcare Research and Quality (AHRQ), the term "alert fatigue" describes how busy healthcare providers become desensitized to safety alerts, and, as a result, may bypass, override, ignore or otherwise fail to respond appropriately to warnings, potentially leading to patient harm. Alert fatigue is caused by an excess of alerts and/or warnings in the clinical environment, most but not all of which are less than urgent. This unintended consequence of the computerization of healthcare has become a significant hazard in many healthcare settings.

The AHRQ Patient Safety Network online resource Alert Fatigue discusses this phenomenon in detail. The following steps, adapted from the AHRQ resource, can help pharmacists avoid medication errors, as well as foster a working environment that places patient safety a top priority.

- **Reduce or eliminate clinically inconsequential alerts.** Removing/deleting insignificant alarms should be performed using a structured review process and individual pharmacist should not be allowed to make these changes without organizational review/approval.
- **Tailor alerts to patient characteristics and critical integrated clusters of physiologic indicators.** For example, incorporate renal function laboratory results into the alert system so that alerts for nephrotoxic medications are triggered only for patients at high risk.
- **Tier alerts according to severity.** Warnings may be presented in different forms, in order to key clinicians to alerts that are more clinically consequential.
- **Apply human factors principles when designing alerts,** carefully choosing the format, content, legibility and color of alerts.

- **Periodically, evaluate the pharmacy computer system for clinically insignificant and false positive alerts,** and take action to minimize alert fatigue (Medication Errors Involving Overrides of Healthcare Technology).
- **Review all system reports on alerts** to determine which alerts are overridden and the reasons for the overrides.
- **Require that pharmacists document rationale when overriding a serious alert,** such as exceeding a maximum dose, or a serious drug interaction (Medication Safety Self Assessment® for Community/Ambulatory Pharmacy).

Pharmacy technicians and office staff should be excluded from bypassing clinically significant alerts. The pharmacist on-duty should review and approve the bypassed alerts when checking the final product. A daily report of bypassed alerts for a pharmacist or prescriber should be reviewed and any outliers should be addressed. Reviews can take place when workload has slowed or staffing has improved, or a pharmacist or prescriber is scheduled for this task. (ISMP Medication Safety Alert! Community/Ambulatory Care edition. August 2015;14(8): 2-4.)

High-alert Medications

ISMP defines high-alert medications as "Drugs that bear a heightened risk of causing significant patient harm when used in error" (High-Alert Medications in Community/Ambulatory Settings). In this report, many of the medications that caused significant patient injury are on the ISMP's *High-Alert Medications* list for acute care, community and ambulatory healthcare and long-term care settings. It is, therefore, valuable for a pharmacist and/or pharmacy owner to be cognizant of the classes/categories of medications, as well as the specific medications that if given in error can cause significant patient injury. Included are a few risk control strategies developed by ISMP that can prevent significant patient injury related to high-alert medications. Refer to High Alert Medication List-Relatively Useless Without Associated Risk-Reductions Strategies for additional information. The majority of the strategies are directed toward the pharmacy-owner. However, pharmacists may find themselves in a position that requires they know, recommend, and/or implement such strategies.

- **Have easy access to updated medication information,** and check these sources whenever a question arises.
- **Use a secondary labeling system for high-alert medications,** as well as automated alerts.
- **Standardize the process of ordering high-alert medications,** as well as storing, preparing and administering them.
- **Limit access to high-alert medications** to staff that are appropriately trained.
- **Implement verification redundancies,** such as manual independent and automated double-checks, as appropriate.
- **ISMP presents the following recommendations** in Medication Safety Self Assessment® for Community/Ambulatory Pharmacy:
  - **Ensure that electronic hard stops are in place at the point of sale** to restrict completion of the sale until patient education has occurred for selected high-alert medications or high-risk patient populations.
  - **Update and test the pharmacy computer system at least twice annually** to ensure that critical alerts are present for narrow therapeutic index and high-alert medications.
  - **Ensure that the pharmacy computer system performs dose range checks** and warns pharmacy staff about overdoses and under doses for narrow therapeutic index and high-alert medications.
  - **Establish criteria for selected high-alert medications or high-risk patient populations to trigger required medication counseling,** and a system is in place to alert the pharmacist of this need when the patient comes in to pick up the prescription (e.g., bold alert on the bag, pharmacy computer system alert).
  - **Establish a process to include** an independent double check of prescriptions for selected high-alert medications before they are dispensed.
  - **Provide pharmacy, at a minimum, annual staff education** on ways to avoid errors with high-alert medications, narrow therapeutic index medications, and other error-prone medications or devices.

Unanticipated Adverse Events

Every medical professional is exposed to the risk of a patient experiencing an unanticipated outcome due to a procedure, treatment, test, or medication. Care must be taken to minimize the likelihood of such outcomes and to prepare staff to respond appropriately if an adverse event occurs. A pharmacist or pharmacy business owner can effectively reduce the impact of unanticipated occurrences by:

- Defining and identifying the potential for adverse events.
- Recognizing an adverse event when it occurs.
- Providing appropriate post-event intervention, including tracking, trending and analyzing incidents, as well as making necessary policy changes in response.

Thorough preparation and ongoing training of staff are critical to loss reduction, especially in the following areas:

- How to reduce the risk of events.
- To whom events should be reported.
- How events should be reported, and how quickly.
- Who is responsible for communicating with the patient regarding the facts of the event.

Responding to adverse events. The first priority is to assure that the patient has received immediate medical care, as necessary, and notify the prescriber. The following risk management measures should be implemented following the adverse event:

- Secure any equipment, medications or supplies involved in the event.
- Document all actions taken in the patient's pharmacy information record. Do not document any conclusions in the incident report or record that are not based on objective, factual information.

Reporting incidents and adverse events. Incident report forms assist in the uniform reporting of unanticipated events. Forms should be designed to record only objective, factual information. The reporting process is not about placing blame on any individual, operating system or medical device.

Incident report forms are most effective when completed by the individual who witnesses or first becomes aware of the event. They should be completed in a legible, objective and thorough manner, with all witnesses to the event interviewed promptly. In addition, no lines in the form should be left blank. If anyone other than the pharmacist is completing the incident report, the form should be reviewed and approved by the pharmacy business owner or the designated supervisor upon completion.

Pharmacists must exercise care when documenting an event in the patient pharmacy information record. The occurrence itself should be recorded in a factual and objective manner, incorporating any steps that were taken to minimize negative consequences to the patient. The incident report itself, however, should never be filed or mentioned in the patient pharmacy information record.

As part of the quality/performance improvement process, incidents should be investigated as soon as possible, with a focus on why the event occurred and what, if anything, could have been done to prevent it. Findings should be documented on a separate form and should not be noted in the patient pharmacy information record. Incident/event reporting should be performed under the auspices of the performance/quality improvement plan, which may help protect against discovery and/or admissibility in a court of law, depending upon jurisdiction.

If a life-threatening or permanently disabling event occurs, notify the insurer either directly or through the insurance agent or broker pursuant to the terms and conditions of the professional liability policy.

Under state and federal healthcare quality improvement regulations/requirements, notification of the adverse patient event must be made to various regulatory agencies (e.g. FDA, Health Department, The Joint Commission, and/or ISMP). The regulations/requirements have mandated timeframes for reporting the event, so it is imperative to know those requirements/regulations and respond accordingly.

Communicating with patients and families. To ensure continuity, the patient's primary care provider and/or the treating/prescribing provider should be contacted in regard to any needed follow-up after an adverse event has occurred. Another individual may be designated as the primary contact with the family.

If possible, communicate in person, preferably in a quiet, comfortable setting. Every effort should be made to accommodate the patient and family regarding place and time. When additional information becomes available schedule a follow-up meeting with the patient and/or family.

Emphasize facts during the discussion, focusing on what happened and how it may affect the patient's prognosis, if this is known. Be honest with the patient and do not speculate about the causes of the event. Express empathy without assigning blame or criticizing the care or response of others. Be prepared to answer questions about what steps will be taken to prevent such events in the future.

The pharmacist should consider the full breadth of the patient's/family's needs after an unanticipated event and offer empathy, comfort and support. Patients and their families deserve to know what happened, feel the pharmacist's concern and learn what the practice is doing to prevent the event from recurring.

Consult with legal counsel regarding the provisions of the state's disclosure law, as well as any laws addressing apologies to patients and admission of liability. The professional liability insurer also may offer risk control materials in this area.

Compounding

- Designate a compounding area that is separate from other pharmacy activities.
- Assess the availability of ready-made product formulations.
- Verify selection of the correct compounding formula and the identity of all ingredients and their measured quantities through an independent double check prior to preparation.
- Ensure only personnel who are adequately qualified perform sterile compounding activities.
- Properly store and label sterile medication vials.
- Assess, at a minimum, quarterly, active pharmaceutical ingredients and bulk chemicals used in the pharmacy for compounding and that those that are not regularly used are eliminated from stock.
- Verify that active pharmaceutical ingredients and bulk chemicals used in the pharmacy for compounding are clearly labeled with their contents, the date the product was first opened, and the manufacturer's expiration date, if applicable. (If an expiration date is unavailable from the manufacturer, a one-year expiration date from the date the product was first opened is assigned.)
- Verify, for selected patient groups (e.g., pediatric patients and patients receiving medications dosed according to age or weight), the prescriber's calculated dose is made before preparing and dispensing the medication.

Infection Prevention

- Establish policies and procedures for routine cleaning and disinfection of environmental surfaces in the facility.
- Follow aseptic practices, including following proper hand hygiene standards, wearing gloves and other personal protective equipment, and equipment disposal to minimize the risks of contamination when preparing medications or when handling individual loose oral solid products.
- Select EPA-registered disinfectants or detergents/disinfectants with label claims for use in healthcare, and follow manufacturer's recommendations for use (e.g., amount, dilution, contact time, safe use, and disposal).
- Dispensing devices are appropriately cleaned after being used to prepare any medications that may leave a residue.

For more information on these topics, see: Medication Safety Self Assessment® for Community/Ambulatory Pharmacy, Guidelines for Safe Preparation of Compound Sterile Preparations and Centers for Disease Control and Prevention: Infection Control Assessment Tools. For more risk control recommendations, please see the HPSO website for the Risk-Control Self-assessment Checklist and the Pharmacist Spotlights on the following topics:

- Communication
- Documentation
- Policies and Procedures
- Scope of Practice
- License Protection
- Reporting an Incident
- Risk Control Self-assessment Checklist

REVIEW THESE RISK CONTROL AREAS OF CONCERN

- ☐ High-alert Medications
- ☐ Alert Fatigue
- ☐ Unanticipated Adverse Events
- ☐ Compounding
- ☐ Infection Prevention

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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**.

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