

2013 Pharmacist Liability

A TEN-YEAR ANALYSIS



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Healthcare Providers Service Organization

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Part 1

CNA ANALYSIS OF PHARMACIST
CLOSED PROFESSIONAL LIABILITY CLAIMS

2013

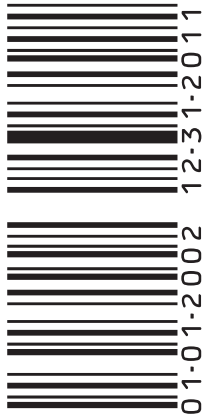
Risk Management Recommendations

Pharmacist Risk Management

Self-assessment Checklist

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INTRODUCTION

Through Healthcare Providers Service Organization (HPSO), CNA continues to be a leading underwriter of professional liability insurance for pharmacists, pharmacy technicians and entities that employ and/or contract with pharmacy professionals. To date, the HPSO program has focused on providing professional liability coverage for individual pharmacists and pharmacy technicians regardless of their employment status, as well as small community pharmacies and individually owned franchise pharmacies. As of 2012, there are approximately 70,000 pharmacist policies in force.

In collaboration with our partners at HPSO, we at CNA are dedicated to educating pharmacists and pharmacy technicians regarding their professional liability risk exposures.

PURPOSE

Our objective in this report is to utilize CNA's database of pharmacist and pharmacy technician closed claims from the HPSO program to identify liability patterns and trends. By limiting the study to closed claims resulting in a financial loss, we highlight the types of situations most likely to have serious adverse consequences for patients and create liability for pharmacy professionals. Using this report, pharmacists and pharmacy technicians can examine their current practices in relation to the claims and losses experienced by their peers, and better understand the risks and challenges they encounter on a daily basis.

This report contains several detailed case studies and high-level risk management recommendations, which, if implemented, can enhance medication safety and minimize the likelihood of patient injuries and pharmacist liability exposures. Additionally, a pharmacist self-assessment checklist is included on pages 53-55. It is intended to aid pharmacists in enhancing their risk awareness and safety practices.

EXECUTIVE SUMMARY

Analysis of CNA pharmacist closed claims data reveals that the most frequent allegations made against pharmacists involve dispensing errors. This report focuses on identifying the injuries and adverse outcomes most commonly associated with these claims, as well as the underlying causes of pharmacist error. Some of the salient findings are summarized below:

- **Pharmacy type:** The analysis reveals that pharmacists who experienced claims were more likely to work in an independent or individually owned franchise pharmacy, or a national or regional chain pharmacy practice setting. (See Figure 5: “Severity by Pharmacy Type” on page 15.)
- **Allegations:** Claims against pharmacists were most likely to involve allegations that the pharmacist dispensed the wrong drug or wrong dose. (See Figure 10: “Severity by Allegation Category” on page 21.)
- **Injury/illness/adverse effect:** Overdose was the most common patient injury for pharmacist closed claims, followed by unexpected death (i.e., death unrelated to the normal course of illness). (See Figure 19: “Severity by Drug-related Injury/Illness/Adverse Outcome” on page 38.)

Pharmacists who experienced claims were more likely to work in an independent or individually owned franchise pharmacy, or a national or regional chain pharmacy practice setting.

DATABASE AND METHODOLOGY

Over the 10-year period included in the study, there were 1,409 reported medication-related incidents, adverse patient outcomes and actual claims against pharmacists, pharmacy technicians, other pharmacy personnel and pharmacy entities insured through the CNA/HPSO program.

All reported pharmacist and pharmacy technician claims that closed between January 1, 2002 and December 31, 2011 were reviewed. Claims were included in the dataset for additional in-depth analysis if they

- involved a CNA-insured pharmacist or pharmacy technician
- closed during the defined 10-year period
- resulted in an indemnity payment of at least one dollar on behalf of the insured party

The application of these inclusion criteria resulted in a database of 162 closed pharmacist and pharmacy technician claims that qualified for the additional analysis found in this report. (Note that while the CNA/HPSO program insures pharmacist interns and pharmacist students, none had a reported claim during the 10-year time frame that met the inclusion criteria.)

TERMS

The following definitions apply within the context of this report:

- **Aging services** – Refers to specialized facilities or organizations that provide healthcare to a senior population. Sometimes also referred to as long term care facilities, aging services settings include, but are not limited to, nursing homes, skilled nursing facilities, assisted living centers and independent living facilities.
- **Aging services pharmacy** – A pharmacy that primarily provides drugs, pharmaceuticals and related equipment to residents in an aging services facility.
- **Community-based pharmacy** – A pharmacy not located in a hospital or other inpatient facility. This group represents the two location types that were involved in the majority of the analyzed closed claims:
 - independent and individually owned franchise pharmacies
 - national or regional chain pharmacies (e.g., mass merchandisers, supermarkets, etc.)
- **Compounding specialty pharmacy** – A pharmacy that primarily prepares and dispenses drugs requiring patient-specific formulation.
- **Expense payment** – Monies paid in the investigation, management and/or defense of a claim.
- **Home care-only pharmacy** – A pharmacy that exclusively dispenses drugs (all forms and routes) and related equipment for patients receiving home care.
- **Incurred** – The costs or financial obligations, including indemnity and expenses, resulting from the resolution of a claim.
- **Indemnity payment** – Monies paid on behalf of an insured in the settlement or judgment of a claim.
- **Infusion-only pharmacy** – A pharmacy that exclusively prepares and dispenses infusion therapy drugs/solutions and total parenteral nutrition.
- **Medication therapy management** – A distinct service or group of services that optimizes therapeutic outcomes for individual patients and which is independent of, but can occur in conjunction with, the provision of a medication product.
- **Mnemonic, Sig or speed codes** – Abbreviations that represent the name and dosage of a drug, and which can be rapidly entered into a pharmacy computer.
- **Patient** – Any person (or animal) who receives drugs dispensed by a pharmacist pursuant to a legal prescription.
- **Pharmacist in charge** – The designated pharmacist who is responsible for, along with other duties, ensuring compliance with the laws and regulations governing pharmacy operations.
- **Practitioner group practice office-based pharmacy** – A pharmacy owned by or under contract to a physician practice. (While in some such settings pharmacists may perform expanded clinical roles, such as medication therapy management, this was not a factor identified in any of the claims included in this report.)
- **Severity** – The average paid indemnity for those pharmacist claims that closed with an indemnity payment of one dollar or greater.

GENERAL DATA ANALYSIS

Analysis of Claims by Insurance Source and Licensure Type

Figure 1 reveals that 99.4 percent of the closed claims involved CNA-insured pharmacists. Of the CNA-insured pharmacists, 93.8 percent had individual professional liability policies, and 5.6 percent were employed by corporate entities that purchased professional liability coverage from CNA on behalf of their employed pharmacists. Only one closed claim (0.6 percent of the total) involved a lawsuit made against a pharmacy technician, who received coverage through his employment with a CNA-insured corporate entity. This distribution is similar to the pattern of insureds in the CNA/HPSO pharmacist program. Given these findings, the remainder of the report will refer to pharmacists, but pharmacy technicians are encouraged to utilize the findings herein that apply to their scope of practice.

It is important to note that this analysis factors in only those payments made by CNA on behalf of insureds. Pharmacists also may have received some amount of professional liability coverage through an employer or by agreement with a contracted staffing agency not insured by CNA. Payments made on behalf of the pharmacist by another insurer generally would represent a confidential part of a settlement agreement and thus are not included in this analysis.

FIGURE 1: Closed Claims by Insurance Source and License Type

(Includes closed claims with an indemnity payment of one dollar or greater.)

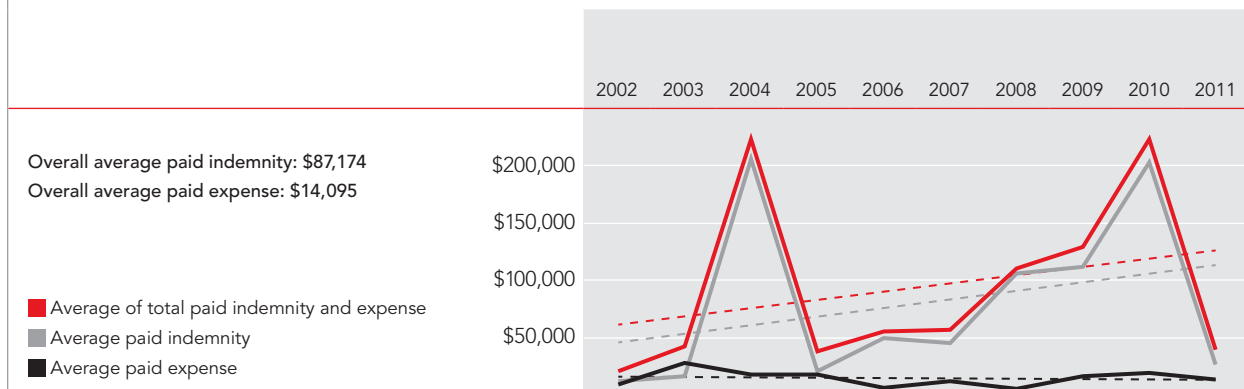
License type	Insurance source	Percentage of closed claims	Total paid indemnity	Total paid expense	Average paid indemnity	Average paid expense	Average total incurred
Pharmacist	Individually insured pharmacist	93.8%	\$13,837,154	\$2,204,495	\$91,034	\$14,503	\$105,537
Pharmacist	Pharmacist employed by CNA-insured corporate entity	5.6%	\$278,500	\$78,907	\$30,944	\$8,767	\$39,712
Pharmacy technician	Pharmacy technician employed by CNA-insured corporate entity	0.6%	\$6,500	\$0	\$6,500	\$0	\$6,500
Overall		100.0%	\$14,122,154	\$2,283,402	\$87,174	\$14,095	\$101,269

Analysis of Severity by Year

- There has been significant year-to-year variability in average paid indemnity over the defined 10-year period. However, the trend line reflects an overall development toward higher average indemnity payments, which were in the \$50,000 range in 2002 and now surpass \$100,000.
- The severity spike in 2004 was partially the result of one claim resolved at nearly the full policy limits. That claim involved the death of a child, who for six months received a thyroid medication instead of the chemotherapy ordered for her leukemia. Four other claims were resolved in the six-figure range and are described in the “Wrong Drug” and “Wrong Dose” sections of this report.
- The severity spike in 2010 resulted from three claims resolved at full policy limits:
 - The first claim involved multiple patients exposed to Hepatitis C. (See Case Study 2 on page 41.)
 - The second claim involved dispensing simultaneous wrong dosages of both Fentanyl and Phenergan, resulting in brain damage. (A description of the claim can be found in the “Wrong Dose” section of this report on pages 35 and 36.)
 - The third claim involved dispensing the wrong drug, resulting in premature labor and delivery of a brain-damaged infant. (See Case Study 1 on page 30.)
- It is interesting to note that there were significant dips in severity, as well as spikes. There is no single explanation for year-to-year variance. Because of this natural fluctuation in severity, it is necessary to observe the average paid indemnity for closed claims over a period of several years.

FIGURE 2: Average Paid Indemnity and Expense by Year the Claim Closed, with Trend Lines

(Includes closed claims with an indemnity payment of one dollar or greater.)



Pharmacist Closed Claims with Expense Payments Only

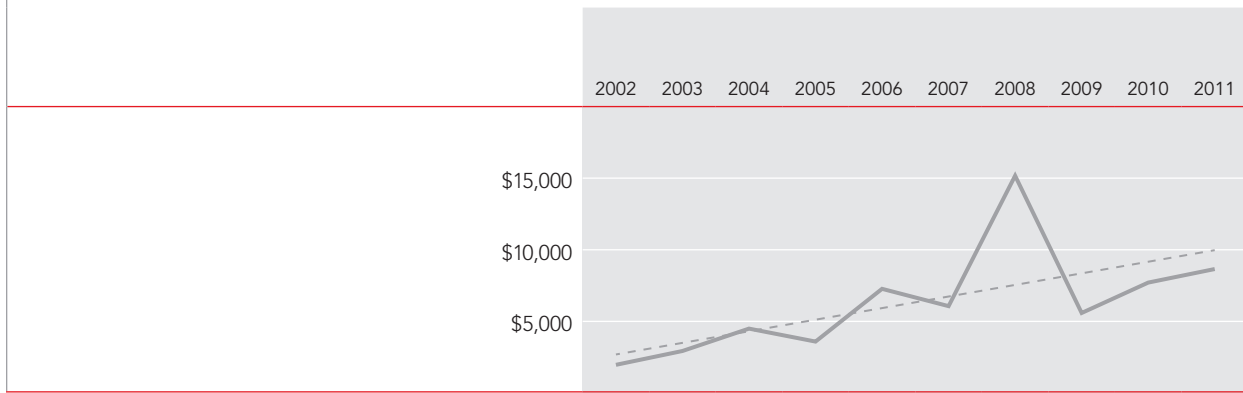
Figure 3 illustrates that during the period of the study, average paid expenses have been steadily increasing for those closed claims that were resolved with no indemnity payment, but which resulted in expense payments. Closed claims in this category included those that were

- successfully defended on behalf of the pharmacist
- resolved by the pharmacist's employer within the limits of the employer's insurance coverage
- investigated and prepared for trial prior to being settled by co-defendants with no indemnity paid on behalf of the pharmacist
- dismissed or abandoned by the patient at some point in the investigative or discovery process
- terminated in favor of the pharmacist by the court prior to trial

These claims were analyzed and revealed the following:

- Total expenses paid for this group of closed claims in the defined period were more than \$2.3 million.
- Average paid expenses for claims without an indemnity payment have steadily increased, rising from an average of \$1,967 in 2002 to \$8,645 in 2011.
- The 2008 increase in average paid expenses was due to three claims that were successfully defended and resulted in no indemnity payments. However, each of these three claims, described below, required extensive investigation and legal activity to achieve dismissal, resulting in expenses in the six-figure range:
 - The first claim alleged that an insured nuclear pharmacist breached his contractual confidentiality and noncompetition agreement with his employer by accepting employment with a competing company and improperly sharing information regarding a product he had developed at his original employer. There was no evidence that the insured breached any aspect of his employment agreement and the case was vigorously defended. During mediation, the claim was dismissed.
 - The second claim alleged that a pharmacist filled an improper prescription for controlled substances, resulting in a patient's death. The patient, who had a history of drug and alcohol abuse, overdosed and died after taking the dispensed Oxycodone, Alprazolam and Methadone. The investigation revealed that the pharmacist had acted within the scope of practice and complied with all applicable laws and regulations. An aggressive defense resulted in dismissal of the case against the insured pharmacist.
 - The third claim alleged that two pharmacists were negligent in dispensing a wrong dose of Fentanyl to a patient, resulting in permanent brain damage. Following extensive investigation, the CNA/HPSO-insured pharmacist was determined not to have made the error and was dismissed from the action.

FIGURE 3: Average Paid Expenses for Closed Claims with No Indemnity Payment, with Trend Line



Distribution of Closed Claims

Of the closed claims,

- 43.9 percent were resolved with indemnity payments of less than \$10,000.
- 32.7 percent were resolved for an amount between \$10,000 and \$49,999.
- 8.0 percent were resolved for an amount between \$50,000 and \$99,999.
- 6.2 percent were resolved for an amount between \$100,000 and \$249,999.
- 3.7 percent were resolved for an amount between \$250,000 and \$499,999.
- 5.5 percent were resolved for an amount between \$500,000 and the full policy limits of \$1 million.

Note that claim-specific information is provided in the allegation and injury sections of this report.

FIGURE 4: Distribution of Closed Claims by Paid Indemnity

(Includes closed claims with an indemnity payment of one dollar or greater.)

Paid indemnity	Percentage of closed claims
\$1 to \$9,999	43.9%
\$10,000 to \$49,999	32.7%
\$50,000 to \$99,999	8.0%
\$100,000 to \$249,999	6.2%
\$250,000 to \$499,999	3.7%
\$500,000 to \$749,999	1.2%
\$750,000 to \$999,999	1.2%
\$1,000,000	3.1%

Analysis of Pharmacist Closed Claims by Pharmacy Type

National/regional chain pharmacies (34.6 percent) and independent or individually owned pharmacies or pharmacy franchises (46.3 percent) collectively accounted for 80.9 percent of all the closed claims in the analysis. Both types experienced a similar average paid indemnity, which was lower than the overall average paid indemnity.

Six pharmacy types, described below, accounted for closed claims with an average paid indemnity higher than the overall average paid indemnity:

- **Practitioner or group practice office-based pharmacies comprised 1.2 percent of the closed claims in the analysis** and had the highest average paid indemnity at \$504,500. This category was primarily influenced by one claim with multiple claimants involving a physician endoscopy practice, which was resolved for full policy limits. See Case Study 2 on page 41 for the details of this claim.
- **Home care-only pharmacies represented 1.9 percent of closed claims in the analysis** and had an average paid indemnity higher than the overall average paid indemnity. This category was affected by one claim that was resolved for full policy limits.
- **Hospital inpatient pharmacies accounted for 4.3 percent of all the closed claims in the analysis**, with an average paid indemnity higher than the overall average paid indemnity. This category was influenced by one claim that was resolved for full policy limits.
- **Telemedicine-only (Internet) pharmacies represented 0.6 percent of the closed claims in the analysis.** This single claim had an indemnity payment higher than the overall average paid indemnity.
- **Infusion-only pharmacies experienced 1.2 percent of all the closed claims in the analysis** and had an average paid indemnity higher than the overall average paid indemnity.
- **Compounding specialty pharmacies accounted for 1.2 percent of closed claims in the analysis**, with an average paid indemnity higher than the overall average paid indemnity.

In 3.7 percent of the closed claims in the analysis, it was not possible to determine the pharmacy type. This lack of information may be due to the following reasons:

- The claim was primarily managed by another insurer.
- The claim was straightforward and quickly settled for a minimal indemnity payment and/or minor expenses.
- The claim was managed by co-defendants.

The significant claims in each type of pharmacy type are described in the allegation and injury sections of the report.

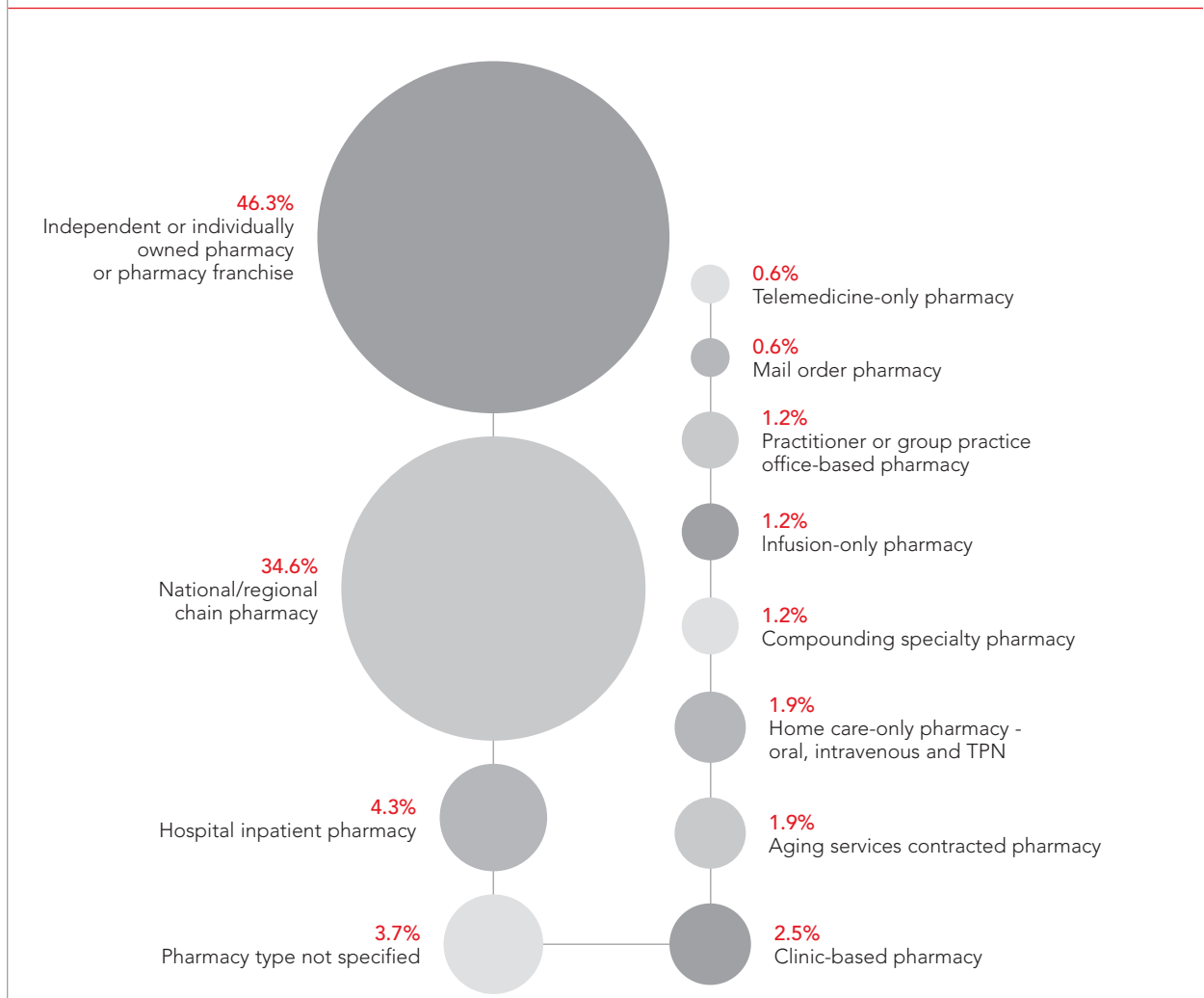
FIGURE 5: Severity by Pharmacy Type*

*(Includes closed claims with an indemnity payment of one dollar or greater.)
Refer to the listing of terms and definitions specific to this report on page 9.

Pharmacy type	Percentage of closed claims	Total paid indemnity	Average paid indemnity
Practitioner or group practice office-based pharmacy	1.2%	\$1,009,000	\$504,500
Home care-only pharmacy - oral, intravenous and TPN	1.9%	\$1,043,625	\$347,875
Hospital inpatient pharmacy	4.3%	\$2,124,667	\$303,524
Telemedicine-only pharmacy	0.6%	\$300,000	\$300,000
Infusion-only pharmacy	1.2%	\$587,500	\$293,750
Compounding specialty pharmacy	1.2%	\$402,500	\$201,250
Clinic-based pharmacy	2.5%	\$286,000	\$71,500
National/regional chain pharmacy	34.6%	\$3,623,565	\$64,707
Independent or individually owned pharmacy or pharmacy franchise	46.3%	\$4,545,595	\$60,608
Aging services contracted pharmacy	1.9%	\$147,500	\$49,167
Mail order pharmacy	0.6%	\$25,000	\$25,000
Pharmacy type not specified	3.7%	\$27,202	\$4,534
Overall	100.0%	\$14,122,154	\$87,174

FIGURE 6: Distribution of Closed Claims by Pharmacy Type

(Includes closed claims with an indemnity payment of one dollar or greater.)



Analysis of Closed Claims by Patient Age

- A claim involving multiple patients of varying ages was resolved for full policy limits and is described in detail as Case Study 2 on page 41.
- Medication dispensing errors involving patients who were minors comprised 15.4 percent of all the closed claims in the analysis and had the highest average paid indemnity of the defined age groups. This category was primarily affected by four closed claims involving children and/or adolescents, which were resolved at or near full policy limits. The category was also affected by a fifth claim resolved in the mid-six-figure range. These five claims are described below:
 - A wrong drug resulted in premature labor and delivery of a brain-damaged infant.
 - An improperly compounded Clonidine prescription led to the patient's death.
 - An improperly compounded prescription for total parenteral nutrition resulted in the patient suffering permanent brain damage.
 - A wrong form of Amphotericin caused acute multisystem failure, requiring extensive treatment for prolonged renal failure.
 - A wrong drug resulted in a leukemia patient's relapse and subsequent death.
- Medication dispensing errors involving adults aged 18 through 64 accounted for 52.5 percent of closed claims, the largest percentage in the analysis. The average paid indemnity for such claims was lower than the overall average paid indemnity. However, one claim – involving simultaneous overdoses of both Phenergan and Fentanyl, with the patient suffering permanent brain damage – closed at policy limits. In addition, several claims were resolved in the low-to-mid six-figure range. These claims included two patients who suffered permanent partial disability, three patient deaths, three patients who suffered loss of an organ or use of an organ, and one patient who suffered severe seizures.
- Medication dispensing errors involving senior adults aged 65 and older encompassed 29.6 percent of all the closed claims in the analysis and had a lower average paid indemnity than the overall average paid indemnity. However, several claims were resolved in the six-figure range, affecting the average paid indemnity. These included the following:
 - A wrong dose of Fentanyl was dispensed, resulting in respiratory arrest.
 - A wrong dose of Coumadin was dispensed, resulting in bleeding and hospital care.
 - A wrong drug was dispensed, causing permanent brain damage.
 - A patient's allergy to the prescribed drug was not identified, resulting in death.
 - A wrong drug was dispensed, resulting in seizures with brain damage.
- Medication errors involving animals represented 1.9 percent of all the closed claims in the analysis, with an average paid indemnity lower than the overall average paid indemnity. Age was not addressed in these claims. Animal closed claims are shown in Figure 13 on page 24.

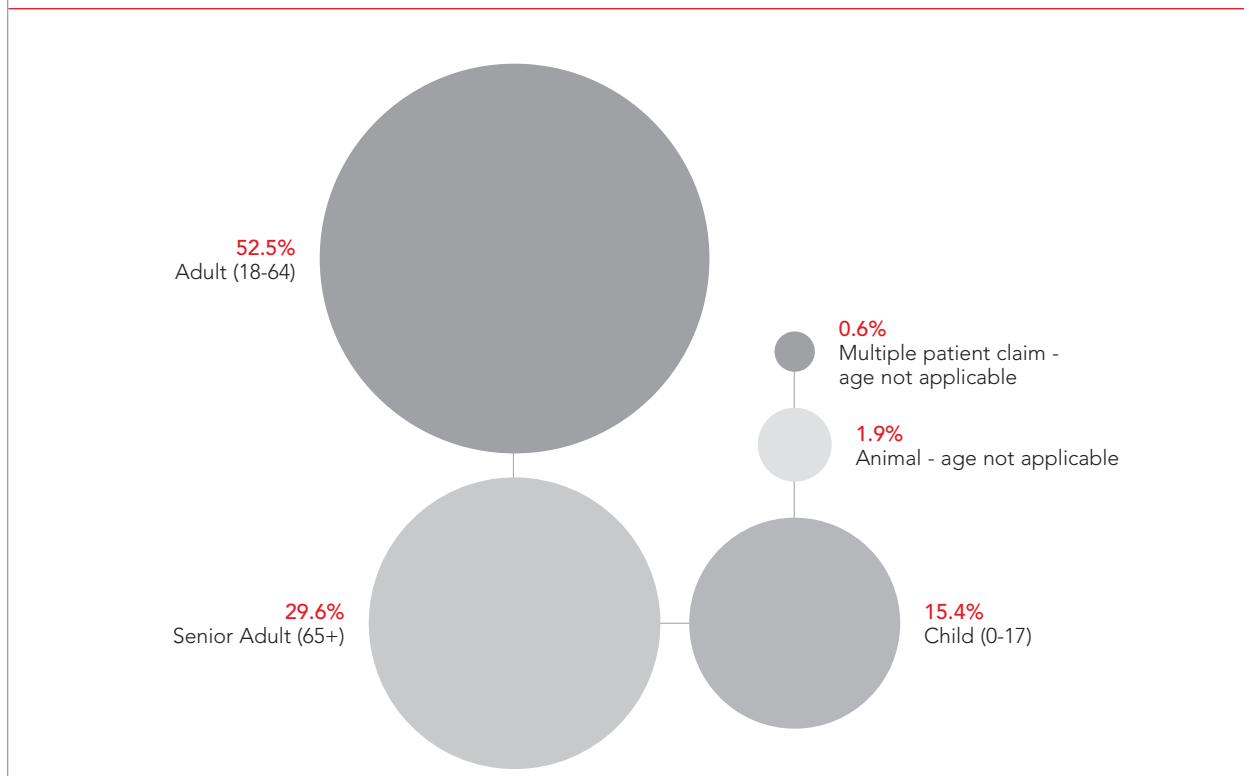
FIGURE 7: Severity by Patient Age

(Includes closed claims with an indemnity payment of one dollar or greater.)

Patient age	Percentage of closed claims	Total paid indemnity	Average paid indemnity
Minor patient (0-17)	15.4%	\$4,900,364	\$196,015
Adult (18-64)	52.5%	\$4,422,654	\$52,031
Senior adult (65+)	29.6%	\$3,759,398	\$78,321
Animal patient - age not applicable	1.9%	\$39,738	\$13,246
Multiple patient claim - age not applicable	0.6%	\$1,000,000	\$1,000,000
Overall	100.0%	\$14,122,154	\$87,174

FIGURE 8: Distribution of Closed Claims by Patient Age

(Includes closed claims with an indemnity payment of one dollar or greater.)



Analysis of Allegations

Wrong drug (43.8 percent) and wrong dose (31.5 percent) together represented 75.3 percent of all the closed claims in the sample. Wrong drug and wrong dose closed claims are discussed in more detail in separate sections of this report.

Six allegation categories resulted in an average paid indemnity higher than the overall average paid indemnity of \$87,174:

- **Infection/contamination of drug/drug vial/needle and/or syringe accounted for 0.6 percent of all closed claims in the analysis.** This single claim, which was resolved for full policy limits, involved multiple patients who were exposed to Hepatitis C. See Case Study 2 on page 41.
- **Compounding errors comprised 3.7 percent of all closed claims in the analysis** and had an average paid indemnity higher than the overall average paid indemnity. This category was primarily influenced by two claims, each of which was resolved at full policy limits:
 - A pediatric dose of Clonidine was improperly compounded by a pharmacy technician. The error was identified when the prescription was checked by the pharmacist, before it was dispensed. The pharmacist returned it to the technician with the correct compounding instructions. The technician provided the re-compounded drug to the pharmacist, who failed to recheck it before giving it to the father of the minor patient. The compounded dosage was still incorrect, resulting in the child's death.
 - Total parenteral nutrition for home care administration to a child was improperly compounded. The child suffered cardiac arrest and permanent brain damage.
- **Failure to counsel the patient accounted for 1.2 percent of all the closed claims in the analysis,** with an average paid indemnity higher than the overall average paid indemnity. This category was affected by the following two claims:
 - A closed claim that resolved in the mid-six-figure range involved the off-label use of oral Ketamine for pain and restless leg syndrome, resulting in the patient's death. It involved several breaches of the standard of care, including failure to
 - counsel the patient (and/or document any counseling discussion) regarding the experimental nature of the oral form of Ketamine and the potentially lethal risk associated with taking the experimental oral form of Ketamine in combination with other drugs
 - obtain a special written order, including the patient's medical and drug history, from the physician who prescribed this form of Ketamine for his patients, although pharmacy protocols required this for any patient who was to receive the oral form of Ketamine
 - provide the patient with written instructions and warnings
 - A closed claim that resolved in the low six-figure range involved a pharmacist who recommended an over-the-counter ointment for a patient who complained of a spider bite. The pharmacist allegedly failed to counsel the patient to seek medical assistance if the symptoms continued for more than 48 hours. The patient waited four days before seeking care, developed sepsis and necrotizing fasciitis, required multiple surgeries with skin grafting and suffered permanent disfigurement. The pharmacist disputed the allegation of failure to counsel, but there was no documentation to support the assertion that counseling had been performed.

- **Wrong form or route of drug comprised 2.5 percent of all the closed claims in the analysis,** with an average paid indemnity higher than the overall average paid indemnity. This category was primarily affected by the following claims:
 - A closed claim was resolved in the mid-six-figure range after intravenous Amphotericin B Lipid Complex was prescribed, but Amphotericin B was dispensed. The patient, a child, suffered acute multisystem failure and was transferred to a pediatric specialty hospital for extensive treatment of renal failure and hemodialysis.
 - The remaining wrong form or route of drug closed claims each involved an average paid indemnity lower than the overall average paid indemnity. They included two cases of eye drops being prescribed and the ear drop version of the drug dispensed, and also an instance of Depakote dispensed instead of the prescribed Depakote ER. The patients who received the erroneous prescriptions recovered.
- **Failure to identify a drug allergy accounted for 1.9 percent of all the closed claims in the analysis,** with an average paid indemnity higher than the overall average paid indemnity. All claims in this category involved allergic reactions to antibiotics. This category was primarily affected by one claim that was resolved in the mid-five-figure range. The patient had a known antibiotic allergy, but the pharmacist was unaware of potential cross-allergy with the antibiotic prescribed and dispensed. Another claim was resolved in the low six-figure range after the pharmacist stated that he was unaware of the meaning of a red or "warning" screen on the computer. The pharmacist bypassed the screen and dispensed the ordered antibiotic without further review or contact with the prescribing practitioner. The patient suffered an allergic reaction to the medication.
- **Failure to identify overdosing encompassed 3.1 percent of all the closed claims in the analysis,** with an average paid indemnity higher than the overall average paid indemnity. All claims in the category except one (an antineoplastic) involved opioids. This category was primarily influenced by a claim that was resolved in the mid-six-figure range, where intrathecal morphine 5 mg per ml at 0.5 cc per hour was prescribed. The pharmacist failed to identify this as an excessive dosage if administered by the intrathecal route. Although the pharmacist denied that intrathecal administration of the prescribed dose would constitute an overdose, the patient died and the cause of death was stated as morphine overdose.

FIGURE 9: Distribution of Closed Claims by Allegation Category

(Includes closed claims with an indemnity payment of one dollar or greater.)

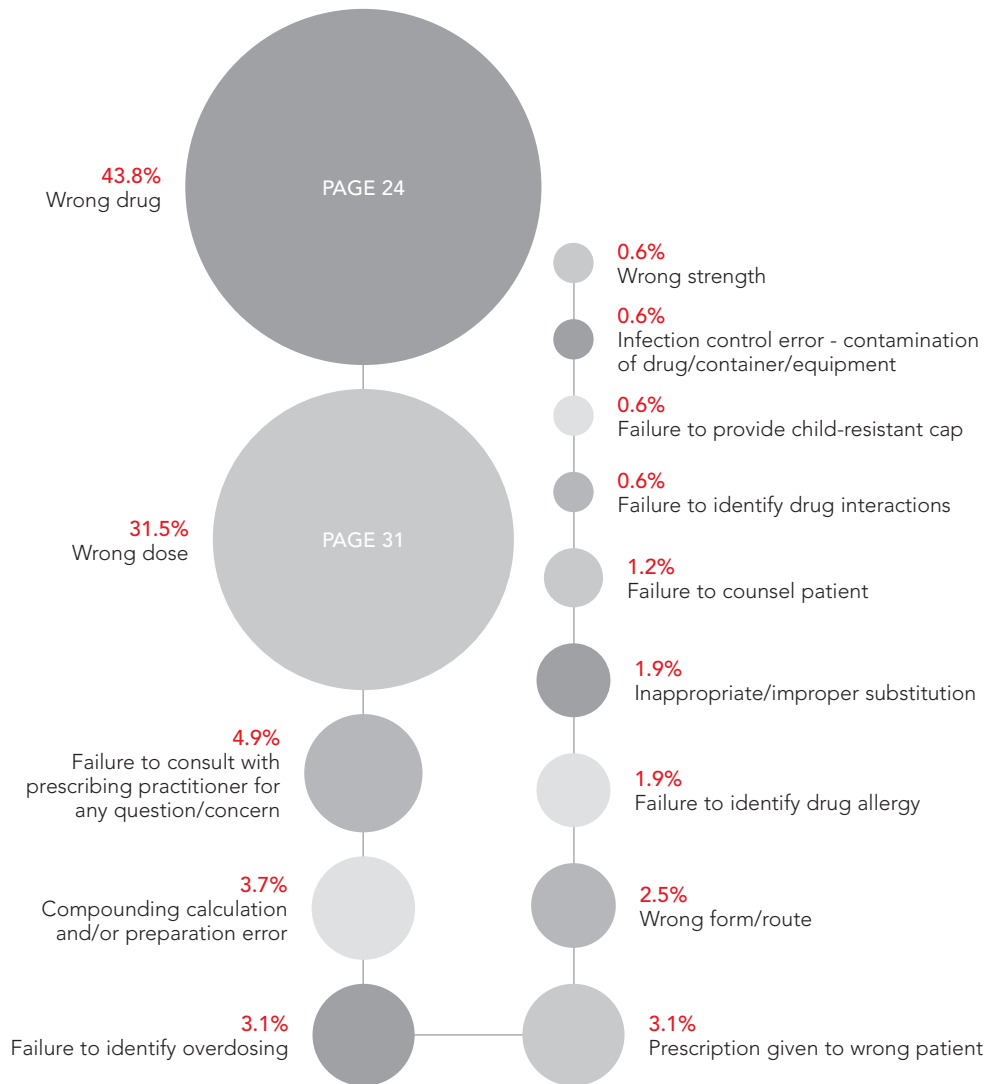


FIGURE 10: Severity by Allegation Category*(Includes closed claims with an indemnity payment of one dollar or greater.)*

Primary allegation	Percentage of closed claims	Total paid indemnity	Average paid indemnity
Infection control error - contamination of drug/container/equipment	0.6%	\$1,000,000	\$1,000,000
Compounding calculation and/or preparation error	3.7%	\$2,240,500	\$373,417
Failure to counsel patient	1.2%	\$524,500	\$262,250
Wrong form/route	2.5%	\$617,621	\$154,405
Failure to identify drug allergy	1.9%	\$372,500	\$124,167
Failure to identify overdosing	3.1%	\$567,399	\$113,480
Wrong strength	0.6%	\$79,167	\$79,167
Wrong dose	31.5%	\$3,791,807	\$74,349
Inappropriate/improper substitution	1.9%	\$216,250	\$72,083
Failure to consult with prescribing practitioner for any question/concern	4.9%	\$519,241	\$64,905
Wrong drug	43.8%	\$4,129,836	\$58,167
Failure to identify drug interactions	0.6%	\$30,833	\$30,833
Failure to provide child-resistant cap	0.6%	\$15,000	\$15,000
Prescription given to wrong patient	3.1%	\$17,500	\$3,500
Overall	100.0%	\$14,122,154	\$87,174

Wrong drug (43.8 percent) and wrong dose (31.5 percent) together represented 75.3 percent of all the closed claims in the sample.

Analysis of Disability by National Coordinating Counsel for Medication Error Reporting and Prevention (NCC MERP) Category

Three NCC MERP disability categories experienced an average paid indemnity higher than the overall average paid indemnity, accounting for 32.7 percent of all the closed claims in the analysis:

- **Error with permanent patient harm represented 11.7 percent of all the closed claims in the analysis**, with an average paid indemnity higher than the overall average paid indemnity. This finding is consistent with the fact that permanently disabled individuals may require significant medical and social support for the remainder of their lives. This category was affected primarily by three claims resolved at policy limits:
 - A child suffered permanent brain damage following infusion of improperly compounded total parenteral nutrition.
 - An adult suffered permanent brain damage following simultaneous overdoses of Phenergan and Fentanyl.
 - The premature birth of an infant with permanent brain damage resulted from the dispensing of a wrong drug. (Progesterone suppository was ordered and Prostin suppository dispensed and administered to the mother, inducing premature labor and delivery.)
- **Error resulting in the patient's death accounted for 11.7 percent of all closed claims in the analysis**, with an average paid indemnity higher than the overall average paid indemnity. This category was primarily affected by several claims that were resolved at or near policy limits. These included the deaths of two children, one from a Clonidine compounding error and the other from the dispensing of the wrong drug, which resulted in the child receiving no chemotherapy for leukemia. A third death involved an adult patient who received intrathecal morphine.
- **Error requiring an intervention to sustain the patient's life constituted 9.3 percent of all the closed claims in the analysis**, with an average paid indemnity higher than the overall average paid indemnity. This category was primarily affected by two claims. The first claim, which resolved near policy limits, involved a Fentanyl wrong dose, resulting in respiratory arrest, resuscitation and permanent brain damage. The second claim, which resolved in the mid-six-figure range, involved a wrong dose of Tacrolimus. This led to failure of the patient's transplanted liver, requiring the patient to undergo a second transplant operation.

The remaining NCC MERP categories each had an average paid indemnity lower than the overall average paid indemnity.

FIGURE 11: NCC MERP* Category by Average Paid Indemnity

(Includes closed claims with an indemnity payment of one dollar or greater.)

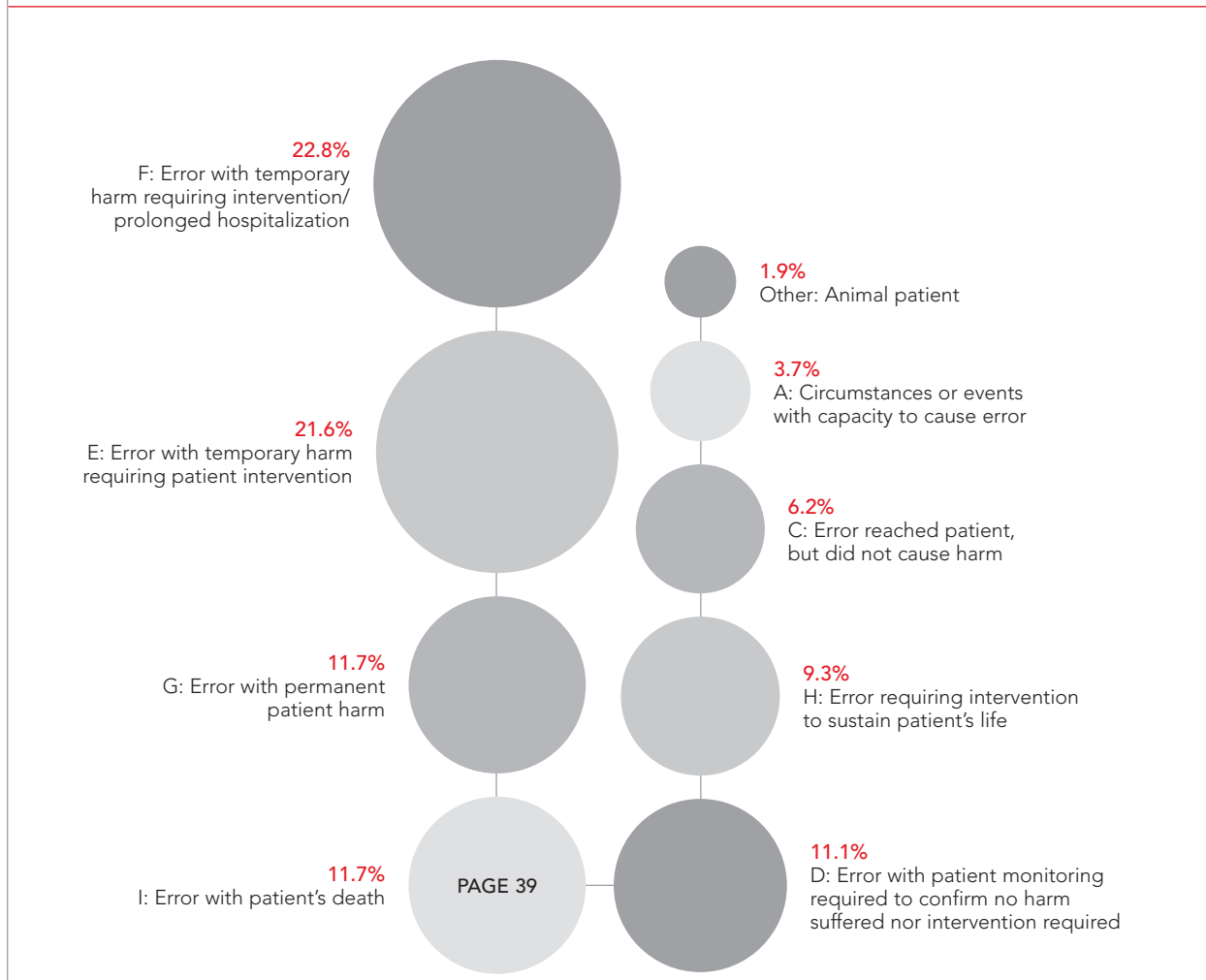
*National Coordinating Council for Medication Error Reporting and Prevention

NCC MERP category	Percentage of closed claims	Total paid indemnity	Average paid indemnity
G: Error with permanent patient harm	11.7%	\$5,808,875	\$305,730
I: Error with patient's death	11.7%	\$4,184,491	\$220,236
H: Error requiring intervention to sustain patient's life	9.3%	\$1,727,493	\$115,166
F: Error with temporary harm requiring intervention/prolonged hospitalization	22.8%	\$1,842,886	\$49,808
Other: Animal patient	1.9%	\$39,738	\$13,246
E: Error with temporary harm requiring patient intervention	21.6%	\$356,073	\$10,174
D: Error with patient monitoring required to confirm no harm suffered nor intervention required	11.1%	\$121,417	\$6,745
A: Circumstances or events with capacity to cause error	3.7%	\$23,000	\$3,833
C: Error reached patient, but did not cause harm	6.2%	\$18,181	\$1,818
B: Error occurred, but did not reach patient	0.0%	\$0	\$0
Overall	100.0%	\$14,122,154	\$87,174

FIGURE 12: Distribution of Closed Claims by NCC MERP* Category

(Includes closed claims with an indemnity payment of one dollar or greater.)

*There were no closed claims in NCC MERP Category B, "Error occurred, but did not reach patient."



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Analysis of Drug-related Animal Injuries

Pharmacist closed claims involving drugs prescribed for animals accounted for 1.9 percent of all the closed claims in the analysis. All claims involved dispensing of the wrong drug. While none of the animals died, they all became significantly ill and required veterinary intervention. The three animal-related claims are described below:

- A dog suffered severe vomiting, diarrhea and pancytopenia, requiring multiple transfusions. In addition, the sickened dog damaged the owner's furnishings and carpets, resulting in costly repairs/replacements.
- A dog developed gastritis and exacerbation of pancreatitis, requiring significant veterinary care.
- A cat suffered severe gastrointestinal symptoms, requiring significant veterinary care.

FIGURE 13: Animal Injuries

**Percentages are rounded.*

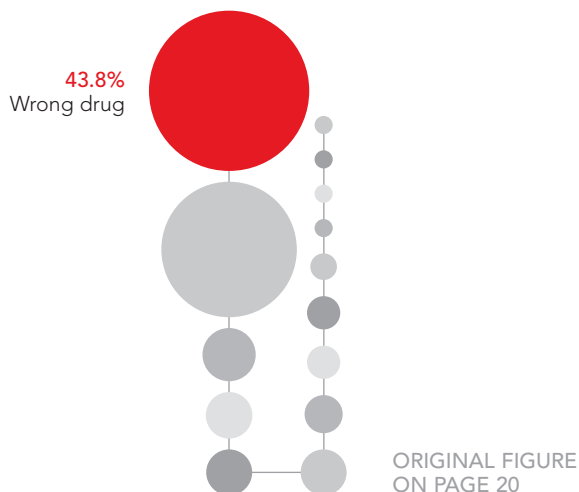
Selected injury	Percentage of closed claims	Total paid indemnity	Average paid indemnity
Poisoning	0.6%	\$35,000	\$35,000
Overdose	0.6%	\$2,738	\$2,738
Medication-related injury not defined	0.6%	\$2,000	\$2,000
Overall	1.9%*	\$39,738	\$13,246

Analysis of Wrong Drug Closed Claims

Figure 14 illustrates that of all the allegations in the analysis, 43.8 percent involved the pharmacist dispensing the wrong drug.

Wrong drug closed claims accounted for 43.8 percent of the claims in the analysis. Because the data were derived from review of the claim files rather than the patient's medical record, there were instances where the specific drug and/or dose prescribed and/or dispensed were not always identified in the claim file.

FIGURE 14: Distribution of Wrong Drug Closed Claims in Relation to All Allegation Categories



Ten closed claims where the patient received the wrong drug resulted in indemnity payments higher than the overall average paid indemnity of \$87,174. (Two of the claims involved the same Primidone incident, but both the dispensing pharmacist and owner were sued separately.)

- **Progesterone suppository prescribed and Prostaglandin suppository dispensed accounted for 0.6 percent of the wrong drug closed claims.** This wrong drug claim was resolved for full policy limits. It is described in detail as Case Study 1 on page 30.
- **Prescription of 6-Mercaptopurine and dispensing of Propylthiouracil comprised 0.6 percent of the wrong drug closed claims.** This wrong drug claim involved a child with leukemia who, over a six-month period, received thyroid medication rather than the prescribed chemotherapy. The patient suffered relapse and died. The claim was resolved at near policy limits.
- **Diamox prescribed and Diabinese dispensed represented 0.6 percent of the wrong drug closed claims.** The patient developed a rare series of adverse effects from taking the wrong drug and subsequently suffered permanent, significant loss of vision. The claim was resolved in the low six-figure range.
- **Primidone prescribed and Prednisone dispensed accounted for 1.2 percent of the wrong drug closed claims.** Although these claims involved only one patient, separate claims were made against the dispensing pharmacist and the pharmacy owner, both of whom were insured by CNA. The patient suffered permanent brain damage. Together, the two claims were resolved in the mid-six-figure range.
- **Tegretol was prescribed and Theophylline dispensed, accounting for 0.6 percent of the wrong drug closed claims.** (While two similar drug errors involving Tegretol occurred, only one claim, where Tegretol was prescribed and Theophylline was dispensed, resulted in the patient suffering grand mal seizures.) The claim was resolved in the low six-figure range.
- **Isosorbide prescribed and Glipizide dispensed accounted for 0.6 percent of the wrong drug closed claims.** The patient suffered a hypoglycemic crisis resulting in brain damage and ultimately death. The claim was resolved in the low six-figure range.
- **Klonopin and Tinzanidine prescribed and two prescriptions of Klonopin dispensed represented 0.6 percent of the wrong drug closed claims.** Although the labels indicated that the bottles contained two different drugs, in fact both bottles held identical Klonopin tablets. The patient did not question this and took twice the prescribed dosage of Klonopin, afterward becoming confused and unsteady, then falling and injuring his arm. The patient's arm injury required multiple surgical interventions and resulted in permanent disfigurement. The claim was resolved in the low six-figure range.
- **Tarceva prescribed and Tambocor dispensed accounted for 0.6 percent of the wrong drug closed claims.** The specific dose prescribed and dose dispensed is not available, but the claim identified that the patient received less than the prescribed dose. Because the patient did not receive the prescribed antineoplastic treatment, he was deemed to have lost the last and best chance for treatment of his lung cancer, which proved fatal. The claim was resolved in the low six-figure range.
- **Amaryl prescribed and Coumadin dispensed comprised 0.6 percent of the wrong drug closed claims.** The patient suffered gastrointestinal bleeding, requiring hospital care. The claim was resolved in the high five-figure range.

FIGURE 15: Severity of Wrong Drug Closed Claims by Name of Drug Prescribed and Name of Drug Dispensed

- Claims marked with an asterisk (*) are those where the drug name and/or dose were not provided.
- Claims with a gray background indicate that the drug prescribed was involved in more than one wrong drug closed claim.
- Indemnity payments marked in red are higher than the overall average paid indemnity of \$87,174.

Drug prescribed	Drug dispensed	Total paid indemnity	Resulting injury or adverse effect
6-Mercaptopurine*	Propylthiouracil*	\$900,000	(Child) Leukemia relapse and death
Aciphex*	Aricept*	\$1,000	Gastrointestinal bleeding, requiring emergency department treatment
Aciphex*	Aricept*	\$1,750	Gastrointestinal distress
Adipex*	Aciphex*	\$1,000	Emotional distress
Alprazolam*	Coumadin*	\$62	Abnormal International Normalized Ratio (INR), requiring administration of vitamin K
Amantadine*	Amitriptyline*	\$6,500	Sedation, lethargy and exacerbation of multiple sclerosis symptoms
Amaryl*	Detrol*	\$30,000	Multiple hypoglycemic events, requiring emergency department treatment
Amaryl*	Coumadin*	\$87,500	Gastrointestinal bleeding, requiring hospital treatment
Amidarone*	Warfarin*	\$5,500	Emotional distress, due to fear that the anticoagulant could affect an existing cardiac condition
Amitriptyline 50 mg	Hydrochlorothiazide 50 mg	\$17,096	Dehydration, twice requiring emergency department treatment
Axid*	Levothyroxine*	\$500	Stomach pain
Azithromycin*	Amoxicillin*	\$3,118	(Child) Allergic reaction with respiratory distress and emergency department treatment
Brethine*	Bromocriptine*	\$12,500	Severe nausea and vomiting, requiring hospital care
Carbamazepine*	Chlorpromazine*	\$42,500	Uncontrolled seizures and decreased mental status, requiring two episodes of hospital treatment
Celexa*	Atenolol*	\$2,750	Syncope, requiring emergency department treatment and observation
Celexa*	Zolpidem*	\$25,000	Dizziness and light-headedness, requiring emergency department treatment
Claritin*	Coumadin*	\$74,188	Hematuria, requiring hospital treatment
Claritin*	Ambien*	\$2,500	Dizziness and light-headedness, resulting in emergency department treatment
Clomiphene*	Clomipramine*	\$3,750	Dizziness, confusion and missed opportunity for fertility treatment, resulting in emotional distress
Clomiphene*	Clomipramine*	\$2,000	(Dog) Gastrointestinal symptoms and pancreatitis, requiring veterinary treatment
Clonidine*	Klonopin*	\$5,000	(Child) Dizziness and confusion, requiring emergency department treatment
Clonidine*	Clonazepam*	\$257	(Child) Emotional distress, requiring emergency department observation
Clonidine*	Glipizide*	\$25,000	(Child) Severe hypoglycemic event, resulting in hospitalization and alleged brain damage
Cyclosporine*	Cyclophosphamide*	\$35,000	(Dog) Gastrointestinal distress and pancytopenia, requiring transfusions and significant veterinary care, and resulting in property damage
Demerol suppository 100 mg	Dilaudid suppository 100 mg	\$50,000	"Near death" episode of hypotension and respiratory distress, requiring hospital treatment
Detrol*	Amaryl*	\$3,300	Three hypoglycemic events, each requiring emergency department treatment

continued...

FIGURE 15 (Continued): Severity of Wrong Drug Closed Claims by Name of Drug Prescribed and Name of Drug Dispensed

- Claims marked with an asterisk (*) are those where the drug name and/or dose were not provided.

- Claims with a gray background indicate that the drug prescribed was involved in more than one wrong drug closed claim.

- Indemnity payments marked in red are higher than the overall average paid indemnity of \$87,174.

Drug prescribed	Drug dispensed	Total paid indemnity	Resulting injury or adverse effect
Diamox*	Diabinese*	\$275,000	A rare series of adverse effects that were difficult to diagnose, resulting in permanent, significant vision loss
Doxazosin*	Glimepiride*	\$40,000	Two episodes of hypoglycemic shock, each requiring 911 assistance and hospital treatment
Drug not named	Drug not named	\$8,116	Dizziness, light-headedness and lethargy
Fertility drug*	Antidepressant drug*	\$12,000	Emotional distress over the lost opportunity for in vitro fertilization
Focolin XR*	Kadian*	\$6,500	(Child) Lethargy, dizziness and light-headedness, requiring charcoal gastric lavage in the emergency department
Furosemide*	Propranolol*	\$5,000	Exacerbation of congestive heart failure, requiring ventilator and ICU care with prolonged recovery
Hydralazine 50 mg	Hydroxyzine 50 mg	\$60,000	Cardiac arrhythmia, resulting in a "near death" experience and hospital intensive care
Hydrochlorothiazide and Atenolol*	Two prescriptions of Atenolol* and no Hydrochlorothiazide*	\$10,000	Severe edema, exacerbation of cardiac condition and emotional distress
Hydrocodone*	Fastin*	\$1,250	Anxiety, jitteriness and emotional distress
Hydroxyzine 25 mg	Hydralazine 25 mg	\$1,000	Vertigo, light-headedness and an episode of hypotension, requiring hospital treatment
Hydroxyzine*	Chloral Hydrate*	\$10,000	(Child) Severe exacerbation of psoriasis, requiring hospital treatment
Isosorbide*	Glipizide*	\$185,000	Hypoglycemic crisis, resulting in brain damage and ultimately in death
Keppra*	Cipro*	\$37,500	Seizures and alleged permanent disability
Klonopin and Tinzanidine*	Two prescriptions of Klonopin* and no Tinzanidine	\$137,500	Confusion, fall and arm injury, requiring multiple surgical interventions with permanent disfigurement
Klor-con*	Selegine*	\$1,200	Exacerbation of Parkinson-like symptoms
Lasix*	Lotensin*	\$2,999	Exacerbation of edema, requiring emergency department treatment
Lipitor*	Lotensin*	\$1,500	Racing pulse sensation, chills and diaphoresis, requiring emergency department treatment
Medrol pack*	Fosamax*	\$3,250	Esophageal burns with residual symptoms
Medroxyprogesterone 2.5 mg	Methotrexate 2.5 mg	\$30,000	Pain and emotional distress due to fear that the error could result in damage to previous liver transplant
Metalazone*	Methimazole*	\$8,500	Severe neuropathy of both feet and ankles and exacerbation of thyroid and diabetic conditions
Methotrexate*	Medroxyprogesterone*	\$3,500	Exacerbation of arthritic pain
Millipred*	Xanax*	\$26,000	(Child) Drowsiness and lethargy, requiring hospital treatment
Niacin*	Naprosyn*	\$250	Stomach discomfort, resulting in two lost work days
Norpramin*	Naproxen*	\$8,000	Gastrointestinal distress, requiring hospital treatment of a gastric ulcer
Paxil*	Alprazolam*	\$5,000	(Child) Major exacerbation of depression, including suicidal ideation, requiring prolonged hospitalization and follow-up care

continued...

FIGURE 15 (Continued): Severity of Wrong Drug Closed Claims by Name of Drug Prescribed and Name of Drug Dispensed

- Claims marked with an asterisk (*) are those where the drug name and/or dose were not provided.

- Claims with a gray background indicate that the drug prescribed was involved in more than one wrong drug closed claim.

- Indemnity payments marked in red are higher than the overall average paid indemnity of \$87,174.

Drug prescribed	Drug dispensed	Total paid indemnity	Resulting injury or adverse effect
Penicillin IV*	Morphine IV*	\$5,000	Respiratory arrest with anoxia, requiring resuscitation and resulting in permanent adverse effects
Pravastatin 40 mg	Paroxetine 40 mg	\$10,000	Gastrointestinal distress and vertigo, requiring emergency department treatment
Prevacid and Potassium Chloride*	Prevacid, Potassium Chloride and Zyprexa*	\$5,000	Vertigo and a fall, resulting in a spinal cord contusion that may require future surgery
Prevpac*	Prevacid*	\$25,000	Exacerbation of patient's existing infection and delay in restarting Celebrex, resulting in increased pain and suffering
Primidone*	Prednisone*	\$225,000	Permanent brain damage (The pharmacy owner was sued, as was the dispensing pharmacist.)
Primidone*	Prednisone*	\$225,000	Permanent brain damage (The pharmacist denied he made the error, but he was the only pharmacist on duty the day of the error. The pharmacy owner was also sued.)
Progesterone oil IM*	Human chorionic gonadotropin IM*	\$42,500	Non-implantation of the patient's last fertilized egg that was a genetic match with her living children, resulting in prolonged emotional distress
Progesterone suppository*	Prostaglandin suppository*	\$1,000,000	Premature labor and delivery of a 23-week infant who was both premature and severely neurologically impaired
Prozac*	Prolixin*	\$31,075	(Child) Seizures, necessitating hospital treatment with a prolonged recovery
Ritalin*	Reglan*	\$6,000	(Child) Glycemic event, requiring hospital treatment
Septra DS*	Darvocet N 100	\$8,927	Difficulty thinking, head pain, confusion and fatigue, requiring hospital treatment
Tarceva*	Tambocor*	\$100,000	Death, as the patient did not receive the prescribed antineoplastic treatment and lost the "last and best chance" for survival
Tegretol*	Toprol*	\$117	No severe acute symptoms, but patient required hospital monitoring
Tegretol*	Theophylline*	\$200,000	Grand mal seizures, requiring hospital treatment followed by extensive home care
Theophylline 450 mg	Lithium 450 mg	\$12,500	Severe allergic skin reaction, requiring hospital treatment
Topamax*	Toprol*	\$5,500	Two episodes of hypotension, resulting in call to Poison Control and emergency department care
Topamax*	Toprol*	\$6,000	Severe allergic reaction, necessitating hospital cardiac monitoring and steroid treatment
Wellbutrin and Cymbalta*	Two prescriptions of Wellbutrin and no Cymbalta*	\$2,500	Severe emotional distress
Zestril*	Zocor*	\$381	Exacerbation of hypertension from delay in restarting Zestril until Zocor had been stopped for a significant period of time
Zyrtec*	Zyprexa*	\$2,500	Vertigo, light-headedness and feelings of illness, requiring emergency department treatment
	Overall	\$4,129,836	

Factors Affecting Wrong Drug Dispensing Errors

Often, pharmacists cannot specify a reason for having dispensed the wrong drug. In reviewing the wrong drug closed claims, some elements emerged that appear to have contributed to the percentage and/or severity of such errors.

Pharmacist failures to separate or otherwise distinguish among sound-alike drugs (18.5 percent), as well as failure to check the drug against the label and the actual prescription (10.5 percent), were the most common explanations for wrong drug dispensing errors.

Three factors were identified for those wrong drug closed claims that experienced an average paid indemnity higher than the overall average paid indemnity:

- Failure to obtain the patient history/profile/drug therapies accounted for 0.6 percent of the wrong drug closed claims and had a paid indemnity near policy limits.
- Failure to question the prescribing practitioner about any unusual prescription comprised 1.9 percent of the wrong drug closed claims, with an average paid indemnity much higher than the overall average paid indemnity.
- Failure to question the practitioner about unusual numbers/amounts of controlled drugs accounted for 1.2 percent of the wrong drug closed claims. These claims represented an average paid indemnity higher than the overall average paid indemnity.

In addition, claims with no identified explanation or specific underlying cause for the error accounted for 2.5 percent of the wrong drug closed claims. These claims experience an average paid indemnity higher than the overall average paid indemnity.

FIGURE 16: Factors Affecting Wrong Drug Dispensing Errors

Factors	Percentage of closed claims	Total paid indemnity	Average paid indemnity
Failure to obtain patient history/profile/drug therapies and make appropriate recommendations	0.6%	\$900,000	\$900,000
Failure to question prescribing practitioner about an unusual prescription	1.9%	\$1,137,500	\$379,167
No explanation or underlying cause for error identified	2.5%	\$480,116	\$120,029
Failure to question practitioner about unusual numbers/amounts of controlled drugs	1.2%	\$187,500	\$93,750
Failure to specifically monitor and clarify anticoagulant prescriptions	0.6%	\$74,188	\$74,188
Failure to separate sound-alike drugs using color/separation/tall man letters, etc.	18.5%	\$952,197	\$31,740
Failure to separate look-alike drugs using color/separation/tall man letters, etc.	1.2%	\$43,250	\$21,625
Failure to verify generic equivalency prior to legal substitution	1.9%	\$56,000	\$18,667
Failure to review and check prescription for error/discrepancy/illegibility	2.5%	\$68,362	\$17,091
Failure to check drug against label and actual prescription	10.5%	\$209,223	\$12,307
Pharmacy technician acted outside the state-defined scope of practice	0.6%	\$6,500	\$6,500
Failure to specifically monitor and clarify controlled drug prescriptions	0.6%	\$5,000	\$5,000
Failure to review prescriptions with patient	0.6%	\$5,000	\$5,000
Failure to consider patient history/profile/drug therapies	0.6%	\$5,000	\$5,000
Overall	43.8%	\$4,129,836	\$58,167

Case Study 1: Wrong Drug Error

The patient was a 23-year-old woman who was 23 weeks pregnant and had been experiencing slight vaginal bleeding with a suspected inadequate cervix. She was admitted to the hospital inpatient obstetrical unit for observation and bed rest. Her physician prescribed a progesterone suppository in an effort to prevent premature labor and delivery.

Feeling ill, the pharmacist had asked to be relieved and was told she could leave. As it was a very busy day, she decided instead to wait until the relieving pharmacist came on duty. The relieving pharmacist did not arrive for two more hours, and the order for the progesterone suppository was received and handled by the pharmacist during that time. The pharmacist was unfamiliar with this drug, and it was later confirmed that the hospital pharmacy had not carried the progesterone suppository for many years. She entered what she believed to be the correct mnemonic for progesterone into the computerized system and the drug Prostin appeared. The pharmacist did not question the different name and dispensed Prostin suppositories, believing it was the same drug.

Tragically, Prostin is a cervical ripening agent sometimes used for abortion procedures, which provides the opposite clinical effect of the prescribed drug. The labor and delivery nurse did not identify the error and administered the Prostin suppository. The patient went into active labor and prematurely delivered a 23-week-gestation male infant. The baby was born severely impaired, requiring intubation and ventilator support, and was transferred to a specialized hospital where he remains, receiving total care.

The error was discovered the following day and was disclosed to the parents and to the pharmacist. The pharmacist agreed she should have investigated the prescribed drug since she was unfamiliar with it. She further agreed that when entering the drug into the computer, she failed to question whether the two drugs were the same, research the drug names or call the physician to clarify the order. Both the hospital and the involved nurse were named as co-defendants in the subsequent litigation.

Resolution

The incident was reported to the state department of health. The pharmacist was devastated by the injury. She was unable to explain why she had failed to follow facility and pharmacy safety policies and acknowledged her negligence. Due to the infant's need for lifelong, around-the-clock care, the full limits of the pharmacist's policy were tendered. Expenses were in excess of \$50,000.

Risk Management Comments

The pharmacist attempted to protect the pharmacy from possible dispensing errors related to understaffing by staying until her replacement arrived. However, her illness and the busy pace of the pharmacy may have been factors in her lack of judgment and the resulting medication dispensing error. Regardless, the pharmacist failed to utilize appropriate pharmacy procedures and safeguards to minimize the likelihood of preventable errors.

Risk Management Recommendations

Dispensing of any medication involves potential risk, and every possible safeguard should be undertaken to prevent errors. The following strategies can help reduce the likelihood of error:

1. Do not dispense any unfamiliar drug without performing appropriate research regarding its uses, contraindications and hazards.
2. Ensure that each pharmacy computer is programmed to offer comprehensive, current drug research, which is automatically updated or otherwise regularly provided for each pharmacy staff member.
3. Once the drug is researched and understood, clarify the patient's clinical history, diagnosis and drug history to ensure that the prescribed drug is appropriate for the clinical effect desired.
4. Follow pharmacy protocols when entering the drug order into the pharmacy computer, using only approved Sig codes or mnemonics.
5. Consider any override of a computerized warning to be an incident, and regularly review all overrides to identify system errors, incomplete formulary, inadequate or improper Sig codes, practitioner ordering issues, or pharmacist and pharmacy technician competency issues.
6. Never assume similar sounding names are equivalents. Sound-alike names are one of the major factors in pharmacy errors. Effective measures should be taken to separate and clearly identify sound-alike drugs, including use of conspicuous warning labels.
7. Contact the prescribing practitioner regarding any question related to the prescribed drug, including contraindications and potential interactions, and consult with the supervising pharmacist or pharmacy director, as needed.
8. Ensure that all prescriptions are checked prior to dispensing, preferably by a second pharmacist, for additional safety. In a single-pharmacist setting, the pharmacist must check each prescription against the original order; verify that the proper drug, dosage and quantity are dispensed; and confirm that the label, patient instructions and any warnings are correct.

Analysis of Wrong Dose Closed Claims

Figure 17 illustrates that 31.5 percent of all the closed claims in the analysis involved the pharmacist dispensing a wrong dose of the prescribed drug. These claims had an average paid indemnity of \$74,349, which is lower than the overall average paid indemnity of \$87,174.

Wrong dose closed claims (31.5 percent) accounted for the second highest percentage of all the closed claims in the analysis. Because the data were derived from review of the claim files, rather than the patient's medical record, there were instances where the specific doses prescribed and/or dispensed were not included in the claim file.

FIGURE 17: Distribution of Wrong Dose Closed Claims in Relation to All Allegation Categories

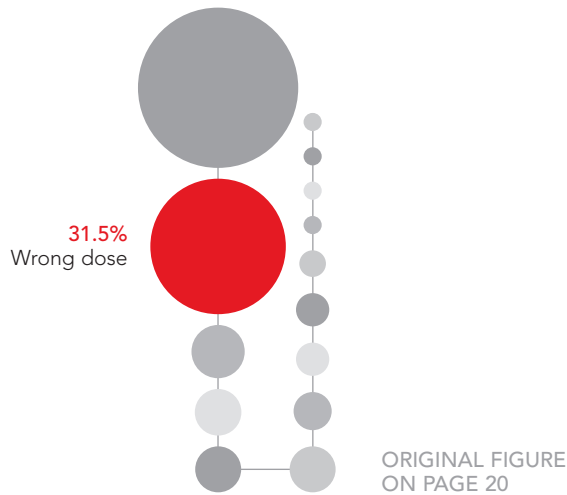


FIGURE 18: Wrong Dose by Drug and Dose Prescribed and Dose Dispensed

- Claims marked with an asterisk (*) are those where the drug name and/or dose were not provided.
- Claims with a gray background indicate that the drug prescribed was involved in more than one wrong dose closed claim.
- Indemnity payments marked in red are higher than the overall average paid indemnity of \$87,174.
- Claims marked with a plus sign (+) are those where the pharmacist believed the prescribed dose of the drug was dispensed, but the patient suffered symptoms of overdose of one or more of the drugs dispensed and required medical treatment.

Drug prescribed	Dose prescribed	Dose dispensed	Total paid indemnity	Resulting injury or adverse effect
Alprazolam	2 mg	0.25 mg	\$3,750	Symptoms of withdrawal from the medication and emotional distress
Amitriptyline	10 mg	100 mg	\$2,738	(Cat) Gastrointestinal distress, requiring veterinary care
Amitriptyline	10 mg	100 mg	\$187,500	Sedation, confusion and fall, resulting in facial fractures, subdural bleeding and death
Amitriptyline	10 mg	100 mg	\$15,000	Shortness of breath, headache, nausea and vomiting
Amitriptyline	10 mg	50 mg	\$10,500	Sedation, dizziness, and fall with muscle and tendon arm injuries, requiring hospital treatment
Augmentin	1 tsp	3 tsp	\$40,000	(Child) Gastrointestinal symptoms with permanent partial disability
Chloral Hydrate	300 mg	3,000 mg	\$18,000	(Child) Over-sedation, resulting in hospital admission and allegation by parents of permanent brain damage
Cipro, Flagyl and Prednisone	Cipro 500 mg, Flagyl 500 mg, Prednisone 20mg	Cipro 100 mg, Flagyl 250 mg, Prednisone 5mg	\$10,000	Severe exacerbation of Crohn's disease symptoms
Ciprofloxacin and Hydrocodone with Acetaminophen*	Not available*	Not available*	\$4,100	Gastrointestinal distress, pain, suffering and lost work hours
Clindamycin*	Not available*	Not available*	\$10,000	Temporary loss of vision and emotional distress
Clonidine	0.1 mg	0.4 mg	\$20,000	(Child) Vertigo and fall, resulting in a concussion and requiring emergency department treatment
Clonidine	0.2 mg	2 mg	\$45,000	Arrhythmia and hypotension, requiring hospital intensive care treatment
Coumadin	0.1 mg	10 mg	\$82,500	Stroke with permanent adverse effects (Patient asked why medication looked different and was told it was generic equivalent.)
Coumadin	1 mg	10 mg	\$27,500	Bleeding under the skin on both arms, face, mouth and around both eyes, requiring hospital treatment and monitoring
Coumadin	1 mg	10 mg	\$15,000	Bruising and contusions with possible gastrointestinal bleeding
Coumadin	1 mg	5 mg	\$3,500	Abnormal International Normalized Ratio (INR) following total knee replacement, requiring readmission and vitamin K treatment
Coumadin	2 mg	10 mg	\$500,000	Exacerbation of unstable International Normalized Ratio (INR), increased bleeding risk and endocarditis, requiring prolonged hospitalization
Coumadin	2 mg	5 mg	\$10,000	Lethargy and loss of consciousness, requiring hospitalization and subsequent prolonged home care
Coumadin	5 mg	10 mg	\$4,750	Gastrointestinal bleeding, requiring hospital care
Cozaar*	Not available*	Not available*	\$10,000	Weakness, lethargy, dizziness and loss of one month's work

continued...

FIGURE 18 (Continued): Wrong Dose by Drug and Dose Prescribed and Dose Dispensed

- Claims marked with an asterisk (*) are those where the drug name and/or dose were not provided.
- Claims with a gray background indicate that the drug prescribed was involved in more than one wrong dose closed claim.
- Indemnity payments marked in red are higher than the overall average paid indemnity of \$87,174.
- Claims marked with a plus sign (+) are those where the pharmacist believed the prescribed dose of the drug was dispensed, but the patient suffered symptoms of overdose of one or more of the drugs dispensed and required medical treatment.

Drug prescribed	Dose prescribed	Dose dispensed	Total paid indemnity	Resulting injury or adverse effect
Decadron	1 mg	4 mg	\$25,000	Exacerbation of Cushing's syndrome symptoms
Dilantin	100 mg	30 mg	\$8,560	Two seizure episodes, each requiring hospital treatment
Fentanyl patch	50 mcg	100 mcg	\$975,000	Permanent brain damage
Haldol	1 mg	10 mg	\$35,000	Confusion, agitation and hallucinations with uncontrolled blinking and muscle twitching, requiring hospital-supervised tapering off from the Haldol
Haloperidol	20 mg	1 mg	\$7,500	Several psychotic episodes and deterioration of patient's psychiatric condition
Humulin*	Not available*	Not available*	\$4,500	Glycemic events with permanent exacerbation of the patient's diabetes mellitus, due to dispensing of expired Insulin
Insulin (type not noted)	2 units	20 units	\$15,000	Major hypoglycemic episode requiring hospital treatment
J-Max	3cc	3 tsp	\$20,000	(Child) Severe respiratory distress, requiring life-flight to a pediatric hospital with cardiac intensive care
Lanoxin	0.125 mg	0.25 mg	\$21,500	Cardiac arrhythmia, requiring inpatient hospital care
Lanoxin	0.25 mg	0.025 mg	\$31,000	Cardiac arrhythmia, requiring life-flight to a hospital providing cardiac intensive care
Levoxyl	50 mg	150 mg	\$10,000	Severe pain and headaches, preventing patient from completing college courses
Lorazepam	5mg(+)	5mg(+)	\$9,000	Dizziness, light-headedness and unsteady gait with marked fatigue [(+)Pharmacist was unable to identify any error based on pharmacy records and believed the proper dose was dispensed. The patient was adamant that the drug dispensed was not the same as his usual prescription, and he required emergency department care for his symptoms.]
Mercaptopurine	100 mg	200 mg bid	\$35,000	Liver failure and death (Abnormal liver test results were reported to physician but not addressed, and pharmacist provided refills.)
Methadone	10 mg	40 mg	\$14,160	Cardiac arrest, successful resuscitation and prolonged hospital care
Methadone	10 mg	40 mg	\$12,275	Weakness, light-headedness and consequent fall, resulting in broken teeth and a leg injury
Methotrexate	7.5 mg once per week	0.25 mg three times per day for 30 days	\$12,500	Pain and acute renal failure
Morphine	100 mg	200 mg	\$25,000	Sedation and confusion with a known brain lesion, resulting in impaired cognition

continued...

FIGURE 18 (Continued): Wrong Dose by Drug and Dose Prescribed and Dose Dispensed

- Claims marked with an asterisk (*) are those where the drug name and/or dose were not provided.
- Claims with a gray background indicate that the drug prescribed was involved in more than one wrong dose closed claim.
- Indemnity payments marked in red are higher than the overall average paid indemnity of \$87,174.
- Claims marked with a plus sign (+) are those where the pharmacist believed the prescribed dose of the drug was dispensed, but the patient suffered symptoms of overdose of one or more of the drugs dispensed and required medical treatment.

Drug prescribed	Dose prescribed	Dose dispensed	Total paid indemnity	Resulting injury or adverse effect
Oxycontin	10 mg, one to two tablets every 4 hours (+)	10 mg, one to two tablets every 4 hours (+)	\$1,000	Patient alleged overdose with dizziness, vertigo and emotional distress, requiring emergency department treatment. [(+) The patient had previously been prescribed Hydrocodone 10 mg. The pharmacist questioned the change in the drug, as well as the high dose and frequency, and called the physician's office to clarify the prescription. The pharmacist was told by a member of the physician's office staff that the prescription was correct, but did not insist on speaking directly with the prescribing physician. The physician later stated that he had wanted the patient to receive Oxycontin 10 mg, one tablet every 6-8 hours prn. The pharmacist did not document any of these events.]
Permax	0.05 mg	Permax 0.5 mg	\$3,750	Gastrointestinal distress, necessitating emergency department treatment
Phenergan and Fentanyl	Phenergan 12.5 mg, Fentanyl 12.5 mcg	Phenergan 25 mg, Fentanyl 75 mcg	\$1,000,000	Simultaneous overdoses of both drugs, causing permanent brain damage
Prednisone	20 mg one tablet daily	20 mg three tablets, three times daily	\$750	General complaints of feeling very ill, resulting in emergency department treatment
Synthroid	0.25 mg	0.025 mg	\$5,250	Severe muscle and back pain, requiring emergency department treatment (Patient also experienced hair loss.)
Synthroid*	Not available*	Not available*	\$3,500	Chest pain, necessitating physician treatment
Tacrolimus*	Not available*	Not available*	\$362,500	Rejection of prior transplanted liver, requiring a second liver transplant
Thioridazine	10 mg	100 mg	\$8,000	Vertigo, syncope and fall with head injury, necessitating a CT scan and hospital observation
Trileptal	300 mg	600 mg	\$3,224	(Child) Severe nausea and vomiting, requiring emergency department treatment
Tylenol with codeine	#4	#3	\$500	Pain in patient's back and feet, resulting in lost work time
Warfarin	1 mg	5 mg	\$45,000	Gastrointestinal bleeding, requiring hospital treatment
Warfarin	2.5 mg	25 mg	\$5,000	Gastrointestinal and nasal bleeding, requiring hospital treatment
Warfarin	3 mg	5 mg	\$47,500	Rectal bleeding, requiring hospital treatment
Warfarin	5 mg	10 mg	\$25,000	Bleeding in the spine, resulting in severe pain and multiple hospitalizations
Overall			\$3,791,807	

The following information relates to the five wrong dose closed claims with a paid indemnity higher than the overall average paid indemnity of \$87,174:

- **Phenergan 12.5 mg and Fentanyl 12.5 mcg patch prescribed in combination and Phenergan 25 mg and Fentanyl 75 mcg patch dispensed in combination, accounted for 0.6 percent of the wrong dose closed claims.** The patient received simultaneous overdoses of both drugs and suffered permanent brain damage. The claim was resolved at full policy limits.
- **Fentanyl 50 mcg patch prescribed and Fentanyl 100 mcg patch dispensed represented 0.6 percent of the wrong dose closed claims.** The patient suffered permanent brain damage and the claim was resolved at nearly full policy limits.
- **Coumadin 2 mg prescribed and Coumadin 10 mg dispensed accounted for 0.6 percent of the wrong dose closed claims.** The patient suffered exacerbation of her unstable INR. This increased her risk for hemorrhage and required extensive hospital care, where she later developed endocarditis, resulting in further prolonged hospitalization. The claim was resolved in the mid-six-figure range.
- **Tacrolimus dispensed in less than the prescribed dosage comprised 0.6 percent of the wrong dose closed claims.** Neither the specific prescribed dosage nor the actual amount dispensed was noted in the claim file, which reflected only that the dispensed dosage was less than the prescribed dosage. The patient had undergone a liver transplant, and the dispensing of less than the prescribed dosage of Tacrolimus resulted in rejection of the transplanted liver. A second liver transplant was subsequently required and performed. The claim was resolved in the low six-figure range.
- **Amitriptyline 10 mg prescribed and Amitriptyline 100 mg dispensed accounted for 1.9 percent of the wrong dose closed claims.** In one of these claims, the patient experienced dizziness and fell, resulting in cranial and facial fractures, a subdural hematoma and subsequent death. The claim was resolved in the low six-figure range.

Five wrong dose closed claims resulted in a paid indemnity higher than the overall average paid indemnity of \$87,174.

Analysis of Injury/Illness/Adverse Outcome

Nine injuries had an average paid indemnity higher than the overall average paid indemnity of \$87,174. The top nine injuries are as follows:

- **Fetal birth-related brain damage accounted for 0.6 percent of all the closed claims in the analysis**, with an indemnity payment at the full policy limit. The injury resulted from a wrong drug error, when Prostaglandin suppository was prescribed for a woman who was 23 weeks pregnant. However, a Prostin suppository was mistakenly dispensed and administered instead. The patient delivered prematurely, and the infant was born with brain damage and multiple disabilities.
- **Brain injury other than birth-related accounted for 2.5 percent of all the closed claims in the analysis**, and had an average indemnity payment higher than the overall average paid indemnity. While all claims in this category had high indemnity payments, the category was primarily influenced by two claims that were resolved at full policy limits, and another two claims that were resolved in the low six-figure range:
 - A claim involving improperly compounded TPN potassium dosage resulted in cardiac arrest and profound brain damage in a young child.
 - A claim involving simultaneous overdoses of both Phenergan and Fentanyl resulted in profound brain damage. Claim severity was negatively affected by the pharmacy manager, who attempted to alter records without the pharmacist's knowledge.
 - Two claims (against both the pharmacist owner and the dispensing pharmacist) related to a wrong drug error for a single patient, which involved a prescription for Primidone and the dispensing of Prednisone. The patient suffered brain damage and emotional distress. Each claim was resolved in the low six-figure range.
- **Multisystem failure represented 0.6 percent of all the closed claims in the analysis**, and had an indemnity payment higher than the overall average paid indemnity. The single claim involved dispensing of Amphotericin B instead of the prescribed Amphotericin B Lipid Complex. The wrong form of the drug was infused for approximately an hour before being identified by the nurse. The patient, who was a minor, suffered acute multisystem organ failure with chronic renal damage. The claim was resolved in the mid-six-figure range.
- **Infection/abscess/sepsis accounted for 1.2 percent of all the closed claims in the analysis**, and had an average paid indemnity higher than the overall average paid indemnity. One claim involved multiple patients who were exposed to Hepatitis C. This claim, which was resolved for policy limits, is described in Case Study 2 on page 41. The second claim involved a pharmacist's recommendation for a nonprescription ointment for a spider bite. The pharmacist stated that he counseled the patient to see his physician if he did not improve within 48 hours, but the patient denied that this advice had been given. The patient waited four days before seeing his physician and subsequently suffered sepsis and necrotizing fasciitis, resulting in multiple surgical procedures, skin grafting and disfigurement of his leg. The claim was resolved in the low six-figure range.

- **Respiratory arrest accounted for 1.9 percent of all the closed claims in the analysis**, with an average paid indemnity higher than the overall average paid indemnity. It was primarily influenced by two claims:
 - The first claim, which was resolved for nearly full policy limits, involved a patient who suffered a respiratory arrest following application of a Fentanyl patch. The pharmacist disputed the allegation that an incorrect dosage was dispensed, but the patient responded when given Narcan and suffered permanent brain damage.
 - Another claim involved respiratory arrest after the pharmacist failed to consult with the prescribing practitioner over a difficult-to-read prescription (Fentanyl 12 mg). Not knowing that Fentanyl 12 mg was available, the pharmacist assumed the prescription was for Fentanyl 112 mg and dispensed Fentanyl 100 mg, which she believed to be the “closest dose” to the amount ordered. The patient suffered respiratory depression leading to respiratory arrest, and was successfully resuscitated. The claim was resolved in the high five-figure range.
- **Death (unexpected and unrelated to the patient’s expected course of illness) encompassed 11.7 percent of all the closed claims in the analysis**, with an average paid indemnity higher than the overall average paid indemnity. This category was affected by several claims – discussed in the Allegation, Wrong Drug, Wrong Dose and Cause of Death sections of this report – with paid indemnity higher than the overall average paid indemnity, including the following cases:
 - A dose of intrathecal morphine was dispensed. It was later alleged to be an overdose, resulting in death.
 - An incorrect dosage of Clonidine was compounded by the pharmacy technician and was not checked by the pharmacist before being dispensed and administered to a child.
 - The pharmacist dispensed a six-month prescription of a drug for a thyroid condition instead of the prescribed chemotherapy for a child’s leukemia.
 - In collusion with two physicians, the pharmacist illegally dispensed Phentermine to an Internet patient, knowing that there would be no physician oversight.
 - The pharmacist dispensed oral Ketamine without counseling the patient regarding the risks of taking the drug off-label or with other drugs, and without following pharmacy protocols related to reviewing the medical history of the patient.
- **Loss of organ or organ function accounted for 1.2 percent of all the closed claims in the analysis**, and had an average paid indemnity higher than the overall average paid indemnity. This category included a claim involving a patient who had received a liver transplant. Because the wrong drug was dispensed, the patient did not receive the prescribed anti-rejection medication and suffered rejection of the transplanted liver. A second transplant was required and subsequently performed.
- **Renal/kidney failure accounted for 1.9 percent of all the closed claims in the analysis**, reflecting an average paid indemnity higher than the overall average paid indemnity. This category was primarily affected by a claim where the pharmacist dispensed Oxycodone instead of the prescribed Roxicodone, and the patient suffered renal failure with unconsciousness, hematuria and encephalopathy.
- **Eye injury/vision loss comprised 1.9 percent of all the closed claims in the analysis**, and had an average paid indemnity higher than the overall average paid indemnity. This category was primarily affected by a claim where the patient suffered permanent loss of vision due to a rare response to the wrong drug, resulting in Behcet’s disease. The claim was resolved in the low six-figure range.

FIGURE 19: Severity by Drug-related Injury/Illness/Adverse Outcome

(Includes closed claims with an indemnity payment of one dollar or greater.)

*Death-related claims are described in detail on pages 39-43.

Injury	Percentage of closed claims	Total paid indemnity	Average paid indemnity
Fetal/infant birth-related brain damage	0.6%	\$1,000,000	\$1,000,000
Brain injury other than birth-related brain injury	2.5%	\$2,450,000	\$612,500
Multisystem failure	0.6%	\$610,500	\$610,500
Infection/abscess/sepsis	1.2%	\$1,125,000	\$562,500
Respiratory arrest	1.9%	\$1,055,000	\$351,667
Death*	11.7%	\$4,184,491	\$220,236
Loss of organ or organ function	1.2%	\$372,500	\$186,250
Renal/kidney failure	1.9%	\$285,021	\$95,007
Eye injury/vision loss	1.9%	\$281,821	\$93,940
Cerebrovascular accident (CVA)/stroke	0.6%	\$82,500	\$82,500
Seizure	3.1%	\$319,635	\$63,927
Increase or exacerbation of illness	8.6%	\$660,200	\$47,157
Cardiac arrhythmia	1.9%	\$126,500	\$42,167
Burn	1.2%	\$82,417	\$41,209
Ear injury/hearing loss	0.6%	\$38,625	\$38,625
Coma	0.6%	\$31,000	\$31,000
Bleeding/hemorrhage	5.6%	\$253,250	\$28,139
Overdose	13.6%	\$613,124	\$27,869
Syncope/fainting	0.6%	\$25,000	\$25,000
Gastrointestinal distress	1.9%	\$55,000	\$18,333
Dehydration/malnutrition	0.6%	\$17,096	\$17,096
Glycemic event	4.9%	\$131,300	\$16,413
Fall	1.2%	\$32,275	\$16,138
Bruise/contusion	0.6%	\$15,000	\$15,000
Cardiopulmonary arrest	0.6%	\$14,160	\$14,160
Neurological deficit/damage	0.6%	\$8,500	\$8,500
Allergic reaction/anaphylaxis	3.7%	\$48,045	\$8,008
Inflammation/inflammatory response	0.6%	\$8,000	\$8,000
Swelling/edema	1.9%	\$17,999	\$6,000
Emotional/psychological harm/distress	9.3%	\$84,555	\$5,637
Vertigo/dizziness/light-headedness	6.8%	\$56,616	\$5,147
Congestive heart failure	0.6%	\$5,000	\$5,000
Chest pain/angina	0.6%	\$3,500	\$3,500
Pain and suffering	4.9%	\$23,000	\$2,875
Addiction	1.2%	\$5,524	\$2,762
Overall	100.0%	\$14,122,154	\$87,174

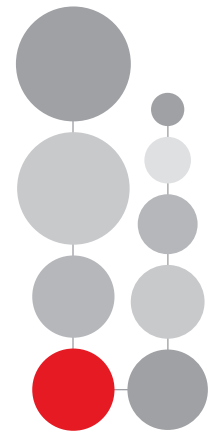
Analysis of Closed Claims Resulting in Death

A total of 11.7 percent of all the closed claim injuries in the analysis were medication-related patient deaths. Figures 20 and 21 provide further analysis of the causes of those deaths. Figure 20 depicts the distribution (i.e., percentage of total deaths) of the identified causes of death. Figure 21 lists the identified causes of death by severity.

Death-related closed claims comprised 11.7 percent of all the closed claims in the analysis and had an average paid indemnity more than twice as high as the overall average paid indemnity of \$87,174.

There were seven identified causes of death:

- **Overdose (wrong dose) of the prescribed drug(s) accounted for 57.9 percent of the death closed claims**, and resulted in an average paid indemnity greater than the average paid indemnity. These claims are included with all the wrong dose closed claims described in Figure 18, on pages 32-34.
- **Cancer accounted for 10.5 percent of the death closed claims**, resulting in an average paid indemnity that was the highest for any cause of death. One cancer death resulted when 6-Mercaptopurine was prescribed and Propylthiouracil was dispensed, causing the patient (a child) to suffer a fatal relapse of leukemia. Another cancer death occurred when Tarceva was prescribed, but Tambocor was dispensed, and the patient died of lung cancer.
- **Glycemic events comprised 5.3 percent of the death closed claims**, resulting in an average indemnity payment higher than the overall average paid indemnity. One death resulted when the patient received Glipizide instead of the prescribed Isosorbide.
- **Allergic reaction/anaphylaxis accounted for 10.5 percent of the death closed claims**, with an average paid indemnity higher than the overall average paid indemnity. In one claim, a death resulted when the pharmacist did not know the meaning of a computer red warning screen identifying the patient's allergy to Levaquin, and bypassed the screen without further investigation. In another claim, death was caused by an allergic reaction to Rocephin, where the pharmacist knew the patient was allergic to penicillin but was not aware of the potential for a cross-allergy to Rocephin.
- **Increase or exacerbation of an existing condition represented 5.3 percent of the death closed claims** and had an average paid indemnity lower than the overall average paid indemnity. One death occurred when the consultant pharmacist at an aging services facility failed to review the resident's medical and drug history. The primary care provider had discontinued the resident's Synthroid. Because the pharmacist did not review the resident's medical history, he failed to notice that the resident had had a prior thyroidectomy and to notify the primary care practitioner that it would be unsafe to discontinue the patient's Synthroid.
- **Loss of organ function accounted for 5.3 percent of the death closed claims**, resulting in an average paid indemnity lower than the overall average paid indemnity. The claim involved failure to monitor laboratory results for a patient with severe Crohn's disease who received 6-Mercaptopurine and whose laboratory results were significantly abnormal. The patient suffered liver failure and died.
- **Inflammation or inflammatory response comprised 5.3 percent of the death closed claims**, with an average paid indemnity lower than the overall average paid indemnity. Death occurred when a child developed Stevens-Johnson syndrome after receiving both Lamictal and Depakote, a combination contraindicated for use in children.



11.7%

I: Error with patient's death

ORIGINAL FIGURE
ON PAGE 23

FIGURE 20: Distribution of Fatal Injuries by Cause of Death

Including all of the closed claims that involved death (11.7 percent of all the closed claims in the analysis), and that resulted in an indemnity payment of one dollar or greater.

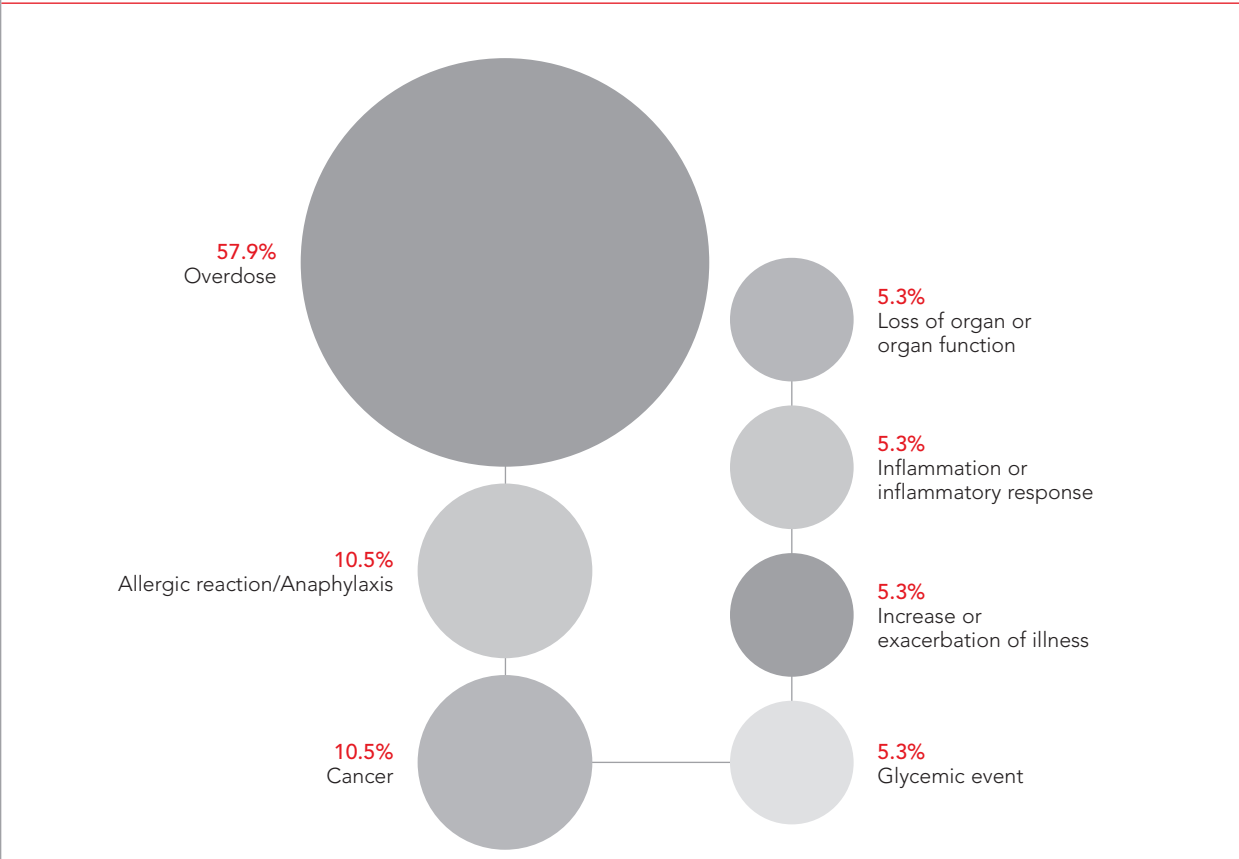


FIGURE 21: Severity by Cause of Death for Closed Claims with Fatality

Including all of the closed claims where death was the identified injury and that had an indemnity payment of one dollar or greater.

* Percentages are rounded.

Cause of Death	Percentage of death closed claims	Total paid indemnity	Average paid indemnity
Cancer	10.5%	\$1,000,000	\$500,000
Overdose	57.9%	\$2,532,825	\$230,257
Glycemic event	5.3%	\$185,000	\$185,000
Allergic reaction/anaphylaxis	10.5%	\$360,000	\$180,000
Increase or exacerbation of illness	5.3%	\$55,000	\$55,000
Loss of organ or organ function	5.3%	\$35,000	\$35,000
Inflammation or inflammatory response	5.3%	\$16,666	\$16,666
Overall	100.0%*	\$4,184,491	\$220,236

Case Study 2: Hepatitis C Exposure – Infection Control and Contractual Risks

The claim was made against a consultant pharmacist employed by an endoscopy center to monitor the management of drugs in the center's pharmacy. Allegations against the consultant pharmacist included failure to follow proper sterile technique, resulting in multiple patients being exposed to and/or contracting Hepatitis C. Additional allegations included negligent hiring, training and supervision of center staff.

The consultant pharmacist was employed by the physician owner of the endoscopy center. The scope of the pharmacist's responsibilities included verifying that drugs in the pharmacy were stored properly and at the correct temperature. Her duties also entailed ensuring that Class II narcotics were properly double-locked, logged and tracked; removing outdated drugs from stock; and appropriately disposing of expired drugs. The pharmacist offered to lead inservice educational sessions for the staff regarding clinical pharmaceutical issues, but the center declined this proposal.

The consultant pharmacist was aware that Propofol in both 20cc and 50cc single-dose vials was purchased and maintained in the facility for patients requiring anesthesia. The pharmacist had no further knowledge regarding Propofol use in the facility. Since Propofol is not a Class II drug, tracking amounts used and monitoring daily practices were not within the consultant pharmacist's defined duties and responsibilities. The center's policies and protocols specifically indicated that the physician and director of nursing were directly responsible for

- hiring, supervising and evaluating all clinical staff
- developing, implementing and monitoring compliance with facility clinical and administrative policies, procedures and protocols
- overseeing clinical management and tracking of all drugs
- complying with the facility's infection control policies and procedures

As noted, Propofol was available in 20cc and 50cc single-dose vials. Since many patients require Propofol in dosages other than 20cc or 50cc, the physician owner improperly required the nursing and anesthetist staffs to draw up the unused amount of Propofol after injection for subsequent use, even though the vials were designed for single patient use. Some nurses retrieved a new syringe and attached it to the needle left in the Propofol vial – the same needle that had been used to withdraw the drug for the prior patient. Other nurses were said to have drawn the full 50cc into one syringe, dispensed the amount needed for the first patient and then simply used the drug remaining in the syringe for

the next patient. Both techniques breached the accepted standard of care for single-dose vials and violated infection control standards. However, the consulting pharmacist had no knowledge of these practices.

Regarding the other allegations against her, the consultant pharmacist likewise had no responsibility for the hiring, training and supervision of staff as alleged in the lawsuit. Initially, it was believed that the case should be taken to trial and fully defended. Subsequently, several additional factors were identified, altering the initial decision:

- The pharmacist had no defined responsibility to directly monitor the staff's use of Propofol. However, the pharmacist's contract with the center contained a provision stating that she was "responsible for all matters pertaining to the use of drugs in the center." This provision greatly expanded the consulting pharmacist's scope of responsibility.
- The use of the same needle or syringe to withdraw the Propofol from single-dose vials for use in multiple patients violated infection control standards of care, resulting in the potential exposure of thousands of patients to disease. Several hundred lawsuits were filed. Many settled for significant payments, and 43 patients instituted allegations against the consultant pharmacist.
- The state where the consulting pharmacist was employed had enacted medical professional liability reform laws that protected physicians and nurses from noneconomic damages of more than \$350,000 for any individual claimant. Pharmacists were excluded from this protection. The center's physician, nurse anesthetists and others settled their portion of the claims quickly and subsequently filed for bankruptcy protection. In addition, the physician and two nurse anesthetists have been indicted on criminal charges with trials pending. Numerous staff members have been called to testify before a grand jury and the state medical licensing board.
- The state where the pharmacist was employed had "joint and several" liability responsibility for all named parties. As a result, once the physicians, nurses and other protected codefendants had settled their claims, the consultant pharmacist could theoretically be held liable for any unpaid verdict amount if the jury apportioned a percentage of the liability to her.
- Because the physician, the center and several of the nurse anesthetists had declared bankruptcy, patients and their attorneys sought out other potential defendants, including the consulting pharmacist.

This combination of factors made it necessary to settle the claim on behalf of the consultant pharmacist, despite multiple expert opinions supporting the pharmacist's actions.

Resolution

Settlement on behalf of the consultant pharmacist was achieved by tendering the full limit of the pharmacist's insurance policy, which was divided among the 43 patients. Expenses incurred as a result of the pharmacist's defense were in excess of \$90,000.

Risk Management Comments

The pharmacist's duties and responsibilities did not include supervision of staff while handling Propofol. Thus, it would have been impossible for the pharmacist to discern whether sterile technique was being correctly implemented in the administration of the drug. However, the pharmacist's contract was worded differently from the actual scope of services requested by, and being provided to, her employer.

Risk Management Recommendations

Providing contracted consultant services to an organization involves specialized risks, which can be mitigated by the following strategies:

1. Understand and comply with state regulations relevant to the consultant role within the particular healthcare delivery model.
2. Ensure that the description of the position accurately reflects the scope of practice, as well as the scope of services and specific job duties to be performed.
3. Engage an attorney to review all contracts involving consulting services for a clinical facility prior to signing and executing such contracts.
4. Read the employment contract carefully to determine the full extent of responsibility being assumed, and request that legal counsel negotiate the removal of inappropriate, overly broad or undesirable descriptions of duties and responsibilities.
5. Review facility infection control and medication administration manuals to determine if policies and procedures comply with required standards of care.
6. If agreeing to a contract that includes overall responsibility for supervising the use of drugs in the facility, ensure that the contract provides for the following:
 - mandatory education regarding all aspects of medication management, including infection control techniques
 - policies and protocols related to proper medication management, including infection control
 - a requirement that unused portions of medications in single-dose packaging be disposed of in the proper manner
 - direct, frequent observation of the preparation and administration of drugs within the facility
 - immediate training for staff who are not performing within standards and/or complying with protocol
7. Document all actions taken to ensure the safe and appropriate dispensing, administration, storage and disposal of drugs within the facility.

Engage an attorney to review all contracts involving consulting services for a clinical facility prior to signing and executing such contracts.

Case Study 3: Successful Defense of a Pharmacist

The claim involved a pharmacist-owner. Allegations against him included wrongful death due to failure to counsel the patient on the dangers of concurrently taking Flomax, Diltiazem and Lexapro.

The patient was a 48-year-old man, who had been a customer of the pharmacy for many years. He was a smoker with a history of diabetes, obesity and hypertension, and he had been taking Diltiazem for hypertension and Lexapro for anxiety and depression. He presented with a prescription for Flomax to treat newly diagnosed urinary symptoms related to prostate enlargement.

The pharmacist entered the patient's Flomax prescription into the computerized system and saw no warnings regarding interactions among the patient's drugs or contraindications to dispensing the Flomax as ordered. He provided the patient with printed information regarding the medication, including warnings and potential side effects. When offered additional discussion and explanation by the pharmacist, the patient indicated he had no questions regarding his medications.

One week after starting the Flomax medication, the patient suffered a fatal myocardial infarction. The patient's wife, as the representative of his estate, filed suit against the pharmacy and the pharmacist, alleging wrongful death, pain and suffering, loss of consortium, medical and funeral expenses, and loss of earnings. The wife's counsel offered an expert opinion that the drugs dispensed by the pharmacist represented a risk of adverse enzymatic interaction and that the pharmacist should have warned the patient of an increased risk of cardiac injury.

Resolution

A pharmacology expert was retained, who stated there was no credible evidence of an interaction among the drugs already being taken and the Flomax. The enzymatic reaction cited by the wife's expert could occur. However, such a reaction would not cause adverse interactions among the medications the patient was taking. The determination was that the pharmacist had acted in accordance with the standard of care.

A motion for final summary judgment was filed with the court. Pending the court's hearing of the motion, the claimant's attorney requested a settlement offer. The pharmacist and his attorney declined to offer a settlement and the decision was made to await the results of the motion.

The wife's attorney subsequently filed a Notice of Voluntary Dismissal without Prejudice for both the pharmacist and the pharmacy and no indemnity was paid. Expenses were in the \$20,000 range, representing a successful outcome for the pharmacist.

Risk Management Comments

The pharmacist had 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, and the pharmacist's attorneys aggressively defended the pharmacist's position and interests through the filing of appropriate court motions and declination of the claimant's settlement offer.

Risk Management Recommendations

The managing and dispensing of drugs has inherent risks. Automated systems, processes and protocols are necessary to minimize the possibility of human error. Nevertheless, consistent adherence to the standard of care by a trained and experienced pharmacist, supported by appropriate documentation practices, can provide the basis for a successful defense. The following measures can help minimize the risk of drug interactions and other adverse events:

1. Maintain and consistently adhere to appropriate policies, protocols and systems to identify potential problems caused by new drugs, including possible interactions between a newly prescribed drug and other drugs or nonprescription remedies also used by the patient.
2. Maintain current patient history and drug information, updating the information at each encounter.
3. If electronic applications are used to identify potential interactions, ensure that all drugs are entered and medical information is regularly updated, and also that warning systems conspicuously address hazardous situations.

4. If no electronic tracking system is used, ensure that the pharmacist has immediate access to computerized resources, including the United States Pharmacopeia, the American Hospital Formulary Service and other reputable sources of current drug information.
5. Ensure that prescription bottles or other containers include all relevant information, especially any warnings or special patient instructions.
6. Provide written patient instructions and counsel the patient regarding medication regimens.
7. Offer each patient the opportunity to ask questions during and after medication counseling, and document the patient's response to this offer.
8. Document all written drug information, instructions and warnings that are provided to the patient.

ADDITIONAL RISKS

Emerging risks include drug shortages, counterfeit or defective drugs in the international distribution system, inadequately regulated Internet access to medications, widespread overprescribing of opioids, shortages of trained and competent pharmacy technicians and pharmacists, increasing numbers of new drugs entering the marketplace, consumer pressure for new drugs and inadequate procedures for naming new drugs, to cite just a few. Additionally, increasing numbers of individuals with prescription benefits are expected to enter the healthcare system, creating new pressures and demands on pharmacies and pharmacists. Pharmacists are urged to remain cognizant of risks and adapt their custom and practice as needed to ensure patient safety.

How could I possibly have made such an obvious dispensing error? This is a question often asked by and about highly competent, conscientious and experienced pharmacists who nevertheless make a significant dispensing error, resulting in a patient injury.

Many factors contributing to loss of focus or attention have been cited by pharmacists and others who study pharmacy errors. The following are just some of the error factors identified in articles and on pharmacist-related Web sites:

- the absence (in some pharmacies) of high-quality systems to support patient safety and minimize errors, or conversely, over-reliance on electronic systems to identify potential drug interactions and dispensing errors
- confirmation bias and inattentional or perceptual bias (see pages 45-46)
- continuous changes in computer systems
- drug shortages and supply delays
- frequent telephone calls and other interruptions
- inadequate workspace
- interruptions for administration of vaccinations
- lack of adequate break or rest time
- overwhelming work volume and pace
- physical health problems and stress-related issues
- poor pharmacy design with high noise levels and excessive visual stimulation

CONFIRMATION BIAS AND INATTENTIONAL OR PERCEPTUAL BLINDNESS

One interesting area of error investigation involves examining the effects of *confirmation bias* and *inattentional/perceptual blindness*. These terms refer to the human tendency to inadvertently seek confirmation of our beliefs, and to ignore what contradicts our beliefs. We tend to interpret evidence in ways that incorporate our underlying beliefs and expectations. Rather than seeing what is actually in front of us, we see what we believe we *should* be seeing. As a result, pharmacists are often at a loss to explain how they could have made an error in filling and dispensing a drug that they believe they checked carefully.

This phenomenon is discussed in detail in *"Inattentional Blindness: What Captures Your Attention,"* a monograph available from the Institute of Safe Medical Practices (ISMP) Web site at www.ismp.org. This type of error is believed to occur when a portion of the pharmacist's attention is diverted and the mind unconsciously, and sometimes incorrectly, "fills in the gaps." Such lapses can lead to drug errors with devastating patient outcomes.

The following steps can help avoid confirmation bias or inattentional/perceptual blindness, as well as foster uninterrupted and intense concentration on the drug-dispensing process:

- **Create an environment where high-risk and error-prone drugs are highly conspicuous.** Brightness or shininess, alarms, unusual shapes and vivid color cues serve as reminders to remain attentive and mindful. Also, sequestering high-risk or error-prone drugs adds additional physical steps to the dispensing process, further alerting the pharmacist of the need for attention to detail.
- **Challenge expectations.** Routine can produce an "automatic pilot" phenomenon, impairing an individual's ability to notice important information. For example, if a particular medication is *usually* in a particular position on the shelf, the pharmacist may assume it is *always* there, failing to recognize that it has been replaced by a new drug or different dose.
- **Prevent over-dependence on technology.** This can lead pharmacy staff to expect that any problem or inconsistency will be identified by automated systems and to assume that the computer has generated a correct label. Each step in the processing of a prescription (prescription review, order entry, drug selection, compounding, filling, labeling, verification and dispensing) requires the pharmacist to *challenge* the expectation that the process will be error-free.
- **Maintain appropriate mental and physical workloads and limit task interference.** Multiple events, tasks, demands and stresses may compete for the pharmacist's attention, leading to loss of focus and consequent carelessness. For example, calculating the doses of compounded prescriptions while feeling ill is a formula for eventual error. Conversely, a quiet work shift with very low work volume may lead to boredom or complacency, which can also impede necessary concentration.
- **Recognize individual capabilities and limitations.** Pharmacy professionals have a responsibility to learn their individual tolerances in regard to workload and interruptions, to take appropriate steps to select appropriate employment, and to ensure that their work environment and job demands reflect their strengths and weaknesses. Pharmacists must collaborate with employers to ensure appropriate workloads, adequate rest and nutrition breaks, neat and well-organized work areas, well-defined job responsibilities and a work atmosphere conducive to concentration.
- **Know what tends to impair attentiveness.** Each person's ability to concentrate and focus is different and can vary throughout the workday. It can be influenced by many factors, including aging, illness, fatigue and mental aptitude. Drug and/or alcohol use can significantly affect anyone's ability to focus and make decisions. Therefore, screening protocols should be implemented for prospective and current employees who exhibit signs of impairment. Pharmacists must seek to understand their individual capacities and select an appropriate work environment.

To summarize, because inattentive blindness is involuntary and most often unnoticed, it is important to consistently utilize effective alerts and flags, sequester high-risk and error-prone drugs, minimize distractions and diversions, and maintain an appropriate workload. In addition, it may be helpful to place work areas away from other activities and distractions, such as in-store music, radios and frequent telephone calls. Many pharmacies are exploring new pharmacy designs and incorporating support personnel to enhance pharmacist focus and minimize distractions. For more information, consult the following resources:

- Angier, N. "Blind to Change, Even as It Stares Us in the Face." *New York Times*, April 1, 2008. Available at www.nytimes.com/2008/04/01/science/01angi.htm?_r=2&ex=1207713600&en=204&oref=slogin.
- Arons, B. "A Review of the Cocktail Party Effect." MIT Media Lab, 1992. Available at www.media.mit.edu/speech/papers/1992/arons_AVIOSJ92_cocktail_party_effect.pdf.
- Federal Aviation Administration, *FAA Human Factors Awareness Course*. Available at www.hf.faa.gov/webtraining/Intro/Intro1.htm.
- Green, M. "'Inattentive Blindness' & Conspicuity." *Visual Expert*, 2004. Available at www.visualexpert.com/Resources/inattentiveblindness.html.

It is important to consistently utilize effective alerts and flags, sequester high-risk and error-prone drugs, minimize distractions and diversions, and maintain an appropriate workload.

RISK MANAGEMENT RECOMMENDATIONS

Many of the risk management recommendations provided after the preceding case studies are widely applicable. The following additional strategies are intended to support pharmacists' efforts to evaluate and enhance their patient safety and risk management practices:

Medication Safety Assessments

CNA and HPSO recommend that pharmacists collaborate with their pharmacies and colleagues at least annually to assess workplace safety practices, using the following tools, among others:

- **The Institute for Safe Medication Practices' (ISMP's) Medication Safety Self Assessments®.** Versions are available for both inpatient and community/ambulatory pharmacies at <http://www.ismp.org/selfassessments/default.asp>. Assessment results can be confidentially submitted to the ISMP to support ongoing research related to medication safety practices.
- **The Agency for Healthcare Research and Quality's (AHRQ's) Pharmacy Survey on Patient Safety Culture.** The survey instrument and accompanying free toolkit of materials were developed to assist community pharmacies in assessing their patient safety culture. The program can be downloaded for use by visiting the AHRQ Web site at <http://www.ahrq.gov/qual/patientsafetyculture/pharmsurvindex.htm>.

Regular use of these or other pharmacy safety assessment tools – including consideration of the findings in this report, participation in professional association safety programs, enhanced quality improvement programs, continuing clinical education, and implementation of appropriate systems and processes – will assist pharmacists in recognizing, evaluating and correcting gaps in their medication safety practices.

Scope of Practice

There is essentially no defense for working outside the state-established scope of practice. Being less than fully cognizant of regulations and standards related to pharmacist practice represents a substantial risk. The following measures can serve to lessen these exposures:

- **Annually review the state scope of practice, state pharmacy practice act, and workplace policies and procedures,** and modify workplace protocols and/or one's own actions accordingly. Practice only within these parameters, keeping in mind that the most stringent of the regulations, standards or policies must be followed.
- **Notify employers or partners of any improper or outdated policies and protocols,** and work only within the legal scope of practice and the standard of care.
- **Evaluate whether workplace practices or conditions represent an unacceptable risk for dispensing errors,** and take appropriate corrective actions – up to and including seeking alternative employment/partnerships.

Professional Liability Coverage

Ensure that collaborating and supervising professionals, practice partners, and employing or contracting entities maintain appropriate professional liability insurance limits, as required by the practice setting, state law and/or regulations. In addition, if insurance is provided through the employer, review the policy and employment contract/agreement to determine if employment-based coverage is adequate, or whether it is advisable to obtain individual coverage. Finally, determine the steps needed to ensure continued coverage if employment status changes or the employer changes insurers.

Proactive Medication Safety Activities

Regardless of the type or location of the pharmacy, the following proactive steps can help minimize pharmacy medication errors:

1. **Perform a pharmacy safety assessment at least annually**, or following the occurrence of errors or “near misses.” Several assessment processes (including those of the ISMP and the AHRQ) are available, and are listed on page 47. Ensure that all levels of pharmacy staff are involved in the process, including owners/partners, leadership, pharmacists, pharmacy technicians and pharmacy support staff. In addition, establish rapid plans of correction for identified areas of potential risk. If necessary, contact the ISMP for assistance in using its self-assessment tool and/or submitting and analyzing self-assessment results.
2. **Ensure that pharmacy policies, procedures and protocols are consistent with the state scope of practice and standard of care**, reviewing and revising them at least annually and after any unusual event, identified error or “near miss.”
3. **Implement electronic pharmacy practice systems that support patient safety by documenting prescriptions, dietary supplements, over-the-counter preparations, laboratory values, diagnoses and other relevant patient information in the patient’s pharmacy record.** The following guidelines can enhance system performance:
 - Insist upon ongoing education for pharmacy staff members in the use of all aspects of electronic systems.
 - Periodically require dispensing staff to dispense medications without utilizing the electronic systems. Monitor their actions to protect against over-reliance on electronic decision-making algorithms and to ensure that staff maintain high-level dispensing and documentation skills in the event electronic systems are interrupted or inaccessible for any reason.
 - Ensure that electronic systems allow for continuous improvements, include clinical decision support systems, present “hot links” to drug resources, and provide for regular and automatic resource updating. Systems also should provide ready access to primary resources; protocols to identify nonstandard dosages; and triggers to warn against drug duplication, allergies, potential cross-allergies, drug interactions and contraindicated drugs.
 - Back up all systems at least daily and store backup records in an easily retrievable off-site location in case of fire or other disaster.

4. **Implement bar-coding technology, robotics and other tools as appropriate** to further protect against human error and to enhance patient safety. In addition, implement systems that allow for and encourage e-prescribing.
5. **Protect against dispensing errors related to look-alike and sound-alike drugs and drug names** by including visual warnings, such as brightly colored warning labels and/or "Tall Man" letters, and by storing high-risk and commonly confused drugs in a separate area of the pharmacy. Refer to the ISMP's "List of Confused Drug Names," available at www.ismp.org/Tools/confuseddrugnames.pdf.
6. **Contact the prescribing practitioner for any question related to the prescription and speak directly to the prescribing practitioner.** Prescription verification by a member of the prescribing practitioner's staff is not sufficiently reliable.
7. **When feasible, select systems that allow for integration with patient electronic medical records,** in order to facilitate access to important clinical data related to the dispensing of prescribed medications.
8. **Require that systems provide regular quality assurance reports, as well as usage data to assist in maintaining appropriate inventory.** Review the data to anticipate drug shortages before they occur and establish alternative manufacturer/distributor arrangements.
9. **Manage and review all warning screen overrides as an "incident."** Review and analyze the pharmacist's judgment in each such incident and provide coaching, counseling and reeducation as necessary. Incorporate disciplinary action if such efforts do not immediately lead to improved medication safety practices.
10. **Utilize pharmacy errors or "near misses" as teaching opportunities** for pharmacy staff to learn how to prevent similar future events.
11. **Maintain a quality assurance program that monitors the effectiveness of pharmacy systems, policies, procedures and protocols.** Additionally, there should be timely, regular and accurate quality reports, including reviews of all dispensing errors and "near misses."
12. **Perform at least annual performance reviews for each employee, including a review of errors, "near misses," medication safety breaches, documentation requirement compliance, existing skills and directly observed competencies.** Provide pharmacy staff with coaching, mentoring, and clinical and systems education as needed to ensure that medication safety requirements are satisfied.
13. **Regularly distribute customer satisfaction surveys,** in order to continually evaluate and improve customer service.

Patient Education and Counseling

1. **Develop, maintain and practice professional written and spoken communication skills.** Consider what information is essential to share, when to share it, how to share it (i.e., in writing, face to face, or by telephone), and with whom it should be shared. This is essential to ensuring effective communication, while also protecting the patient's privacy. Ideally, every pharmacy should have an area where the pharmacist can speak confidentially to a patient.
2. **Ensure that the patient is aware of the diagnosis,** and assist the patient in establishing realistic expectations regarding the prescribed drug and its benefits and effects.
3. **Advise the patient of potential side effects and/or adverse effects that may occur** and what actions should be taken in the event of a reaction, including contacting the prescribing practitioner, calling the pharmacy or seeking emergency medical care.
4. **Instruct the patient in the appropriate administration of the drug and any contraindications for specific lifestyle issues,** such as incompatible foods and potential adverse interactions with alcohol, other drugs or nonprescription remedies. Furthermore, point out the special labeling included with each drug, and encourage the patient to read this information.
5. **To avoid errors when dispensing generic equivalents, carefully investigate any patient assertion that the drug differs from the usual generic equivalent** in terms of appearance, dosage or method of administration.
6. **Discuss the risks, common side effects and dangers of taking more or less than the prescribed dose,** as well as the risks of taking the medication with other prescribed or self-administered drugs, supplements or nonprescription remedies.
7. **Require patients to provide written refusal of counseling, including signature and date,** if they choose not to discuss their medications with the pharmacist.
8. **Utilize child-safe packaging for each prescription.** If patients request alternative packaging, obtain and retain their written consent for the use of the requested non-protective packaging.
9. **Place each drug in the patient's bag as it is explained.** When the counseling and discussion session is complete, it may be a safe practice to staple or otherwise seal the bag closed, depending on pharmacy protocol. Alternatively, during patient counseling, advise patients to ensure that they store all their medications in a safe and protected manner.
10. **Inform patients without insurance coverage or the ability to pay for their prescribed drugs that there may be lower-cost alternatives and/or manufacturer assistance programs available,** and encourage them to contact their prescribing practitioner for more information and assistance.

Documentation

1. **Document all drugs and prescribed supplements dispensed** in the patient's pharmacy record.
2. **In compliance with pharmacy and regulatory requirements, document all discussions with patients, parents/guardians, prescribing practitioners, mentors, managers 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, and also the resulting response.
 - Document that patients are aware of and able to correctly repeat back to the pharmacist each prescribed drug's uses, potential side effects, and signs of an allergy or adverse effect. Also ensure that they understand which possible adverse reactions are especially dangerous and require immediate medical attention.
 - 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 prescribing practitioner, including information regarding known side effects of the drug and the signs of allergic or adverse reaction.
 - 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. Note that receiving clarification from a non-prescribing member of the practitioner's staff does not absolve the pharmacist of liability in the event of an error leading to patient injury.
3. **Document all counseling sessions with patients or parents/guardians and ensure that they are able to correctly repeat back instructions, as well as warning signs when they should seek medical attention.** In addition, require patients to sign a form attesting that they have received counseling, or in the case of refusal, that they have refused counseling and are aware that there may be risks associated with their medications.
4. **Carefully examine and review each medication or preparation with the patient before placing it into the patient's bag, in order to ensure that the correct medications have been prepared and dispensed.** Document this discussion and review, as well as any questions the patient may have regarding a change in the shape or color of a medication, noting how questions were resolved. While the change may be the result of a proper substitution, it is important that the patient be aware of both the brand and generic names of medications, as well as the correct appearance of all drugs taken.
5. **Document any patient requests for non-childproof packaging,** and require the patient to sign for any non-safety bottle caps dispensed.

Competencies

As noted above, annual performance of the ISMP self-assessment process may be helpful in identifying gaps in staff competency. A robust quality improvement program, effective peer review, regular performance assessments, and a process for reviewing errors and “near misses” will assist in identifying areas where additional skills or enhanced competencies are needed. The following measures are also essential to maintaining professional competencies and protecting patients from harm:

1. **Regularly review professional association Web sites for known and emerging risks**, as well as for educational and self-assessment tools.
2. **Fulfill continuing education requirements for ongoing licensure**. Select a range of topics in order to maintain current knowledge, as well as to explore cutting-edge pharmaceutical products, research initiatives and risk warnings.
3. **Work in the setting most aligned with your individual skills and competencies**, one that is suited to your unique tolerances regarding work volume, workplace environment and design, staffing patterns and work hours.

CONCLUSION

The critical first step in the process of protecting patients and reducing liability exposure is to learn about the risks that confront today's pharmacists. The claims data, analysis and risk management recommendations contained in this resource are intended to inspire pharmacists nationwide to carefully examine their practices, dedicate themselves to patient safety, develop effective risk prevention programs, and direct their risk management efforts toward areas of demonstrated error and loss.

RISK MANAGEMENT SELF-ASSESSMENT CHECKLIST FOR PHARMACISTS (AND PHARMACY TECHNICIANS WHEN APPLICABLE)

The checklist that follows is designed to assist pharmacists (and other pharmacy professionals where appropriate) in evaluating and modifying their current customs and practices, in order to enhance medication and patient safety.

The checklist is designed to be easily detached from the rest of the document for use by our readers. Additional copies of the checklist may be downloaded at Healthcare Providers Service Organization (www.hpsso.com) or CNA Healthcare (www.cna.com).

Self-assessment Topic	Yes	No	Action(s) I need to take to reduce risks
Scope of Practice and Standard of Care			
I select a work environment that is consistent with my licensure, specialty certification, training, experience and personal workload tolerances.			
I know my competencies – including experience, training, education and skills – are consistent with the scope of work requested of me by my pharmacy and/or clinical setting.			
I ensure that my competencies and experience are appropriate before accepting an assignment to provide coverage for another pharmacist during breaks or unscheduled absences.			
I am provided with (or request and obtain) orientation whenever I work in a new or different location or setting.			
I obtain continuing education and training, as needed, to maintain my license and refresh and expand my competencies.			
I review my state’s specific regulations regarding the scope of practice for pharmacists at least annually, in order to ensure that I understand and am in compliance with the legal scope of practice and standards of care for pharmacists in my state.			
I comply with the requirements of my state regarding other regulatory bodies, such as the board of medicine (if applicable).			
I prepare and dispense medications pursuant to a legal prescription from a licensed practitioner as defined and regulated in my state.			
I consult the prescribing practitioner if I am not provided with an appropriate, legible prescription or if I have any questions regarding the safety or efficacy of the prescribed medication.			
If my state permits pharmacists to prescribe certain medications as part of a defined prescriptive protocol or collaborative drug therapy agreement with a physician or nurse practitioner, I know exactly what medications I may prescribe and under what conditions I may do so, and I adhere to all regulations, protocols and agreements involving the prescribing of the defined drugs.			
If my state permits pharmacists to administer some immunizations and drugs within specific guidelines and pursuant to a legal prescription, I know exactly which immunizations and drugs I may administer and under what conditions I may do so, and I adhere to all regulations, protocols and pharmacy policies and procedures involving administration of immunizations and drugs.			
I decline to perform any requested action/service if it is outside of my legal scope of practice.			
I decline to perform any requested action/service if it is outside the accepted standard of care.			

Self-assessment Topic	Yes	No	Action(s) I need to take to reduce risks
Proactive Patient Safety Actions			
I inform my pharmacy of the existence of self-assessment tools – such as the Institute for Safe Medication Practices’ “Medication Safety Self Assessments®” (www.ismp.org) or the Agency for Healthcare Research and Quality’s “Pharmacy Survey on Patient Safety Culture” (www.ahrq.gov) – and assess my own safety practices at least annually.			
I actively participate in the review of pharmacy policies and procedures to ensure they are in compliance with state scope of practice and standards of care, and I make necessary changes when gaps appear in needed policies, information is outdated, or policies do not fully comply with regulations and standards.			
I obtain drug-related patient laboratory values, document them in the pharmacy system, alert the patient’s practitioner of abnormal findings, and document the practitioner contact and any changes in the patient’s prescription(s).			
I utilize electronic systems effectively by			
<ul style="list-style-type: none"> ▪ insisting upon ongoing education for all pharmacy staff in the proper use of all aspects of the system, especially after any upgrade or change in the electronic process or equipment 			
<ul style="list-style-type: none"> ▪ periodically requiring all dispensing staff to record, prepare and dispense prescriptions without using the electronic system, in order to evaluate current skills and avoid developing an over-dependence on the system 			
<ul style="list-style-type: none"> ▪ regularly updating clinical decision support systems and “hot links” to drug-related informational resources 			
<ul style="list-style-type: none"> ▪ ensuring that the system includes flagging and/or warning screens for nonstandard dosages, medication duplication, allergy or cross-allergy, potential/known drug interactions and contraindicated drugs based on the patient’s profile 			
<ul style="list-style-type: none"> ▪ addressing the cause(s) of any system flag or warning screen and taking proper measures to protect the patient’s safety before proceeding 			
I strongly recommend that pharmacy management institute a daily off-site data backup process to secure patient records in case of pharmacy fire or other damage.			
I encourage the use of bar-coding and (if appropriate in my pharmacy) robotics and other tools, in order to decrease the possibility of human error.			
I encourage implementation of electronic systems that support e-prescribing.			
I actively participate in discussions regarding shelf placement and flagging of sound-alike drugs, including implementation of multiple visual flags such as colored warning labels, “Tall Man” letters and sequestering of some medications.			
I encourage storage of high-risk and commonly confused drugs in a locked, sequestered place in the pharmacy, which alerts pharmacists and requires them to actively pass through the protections in order to dispense high-risk drugs.			
I maintain a copy of the “ISMP’s List of Confused Drug Names” (www.ismp.org/Tools/confuseddrugnames.pdf) at my workstation or on a “hot link” on my computer terminal, and/or post the list in a visible area for all pharmacy staff to observe.			
I integrate the patient’s pharmacy and electronic medical records, when appropriate and feasible.			

Self-assessment Topic	Yes	No	Action(s) I need to take to reduce risks
Proactive Patient Safety Actions (Continued)			
I participate in the pharmacy's quality assurance program, which involves monitoring the effectiveness of pharmacy systems, policies, procedures and protocols, as well as reviewing system-produced reports.			
I ensure that my pharmacy considers any override of a warning screen to be an incident, which is reviewed for appropriateness.			
I ensure that there is a system to counsel and educate pharmacy staff involved in any incidents deemed improper.			
I encourage my pharmacy to utilize "near misses" as safety improvement educational opportunities.			
I encourage my pharmacy to perform at least annual criteria-based performance reviews of each staff member as part of the quality and medication safety program.			
I encourage my pharmacy to regularly distribute customer satisfaction surveys, in order to continually improve the quality of patient services and identify opportunities to enhance medication safety.			
Patient Education and Counseling			
I counsel each patient regarding his/her medications and document the process, including patient refusals of counseling.			
I encourage patients to ask questions regarding their medications. I respond to all such questions until they are able to correctly repeat back the information, and I document this in their pharmacy record.			
I ensure that patients know both the brand and generic names for their medications, as well as the expected appearance of each form of the drugs they are taking.			
I counsel patients to keep drugs in a safe place and require them to sign for non-safety caps.			
I instruct patients to discuss their expectations regarding any off-label drug use with the prescribing practitioner, and I document this request.			
Documentation			
I document all drugs and prescribed supplements in the patient's pharmacy record.			
I document all counseling sessions and/or refusals of counseling in the patient's pharmacy record.			
I document the patient's ability to correctly repeat back the information provided regarding the drug's name, dosage, expected results and common side effects.			
I perform and document patient counseling regarding all high-risk drugs, including signs of an adverse response, contraindications for use with other prescribed and nonprescribed drugs or remedies, risks of not taking the medication exactly as prescribed and symptoms that necessitate immediate medical intervention.			
For those drugs where it is clinically required, I review and document relevant laboratory test results. I consult with the prescribing practitioner to modify the patient's prescription as needed based on the test results, and document those actions.			
I document all discussions with the patient, family members, the prescribing practitioner and appropriate healthcare personnel.			

For additional pharmacist-oriented risk management tools and information, visit www.cna.com and www.hpsso.com.

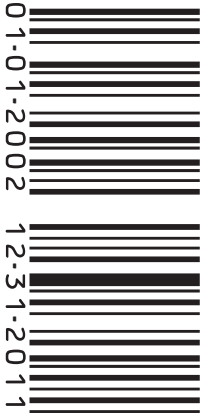
Part 2

HEALTHCARE PROVIDERS SERVICE ORGANIZATION
(HPSO) ANALYSIS OF PHARMACIST LICENSE PROTECTION
DEFENSE PAID CLAIMS

2013

Risk Management Recommendations
pages 56-64

Made in USA



INTRODUCTION: REVIEW OF LICENSE PROTECTION DEFENSE PAID CLAIMS

An action taken against a pharmacist's license to practice differs from a professional liability claim in that it does not necessarily involve allegations directly related to his or her professional responsibilities. Such an action may involve allegations of substance abuse or other personal issues that could potentially have an impact on the ability to perform professional duties. Another difference is that the amounts paid for license protection defense claims represent legal fees and other costs involved in defending the pharmacist against the complaint, rather than indemnity payments to a plaintiff.

A board complaint can be filed against a pharmacist by a patient, a patient's family member, a colleague or an employer. Understanding the most common allegations can help pharmacists identify situations where they may be vulnerable and take steps to minimize board complaints.

DATABASE AND METHODOLOGY

During the study period, there were 734 reported incidents or claims involving license protection defense for pharmacists who were insured through the CNA/HPSO insurance program. The final dataset included 200 license protection defense paid claims that

- closed between January 1, 2002 and December 31, 2011
- concerned a pharmacist or a pharmacy owned by a pharmacist
- resulted in a license protection defense expense payment

Of the 734 total reported incidents, 200 or 27.2 percent resulted in a payment, totaling \$737,073. The average payment for this group was \$3,685, 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 his or her license defense.

FIGURE 1: License Protection Defense Claim Payment

(Closed January 1, 2002 through December 31, 2011)

Payment status	Count	Percentage of total reported incidents	Total paid	Average payment
Paid claims	200	27.2%	\$737,073	\$3,685
Closed without payment	534	72.8%		
Total	734	100.0%		

LICENSE PROTECTION DEFENSE PAID CLAIMS

Paid claims for license protection defense involved both medical and non-medical regulatory board complaints against pharmacists. All but one paid claim involved pharmacists who were individually insured in the CNA/HPSO program. The exception was a pharmacist who owned the pharmacy where the event occurred, which was insured through the HPSO program.

The pharmacists with a license protection defense paid claim most often worked in a pharmacy setting (98.0 percent), followed by hospitals (1.0 percent) and aging services facilities (1.0 percent). The average paid for pharmacy claims (\$3,689) and hospital claims (\$3,694) was slightly higher than the overall average payment (\$3,685).

FIGURE 2: Severity by Practice Location

(Closed January 1, 2002 through December 31, 2011)

Location	Percentage of total paid claims	Total paid	Average payment
Pharmacy	98.0%	\$723,135	\$3,689
Hospital	1.0%	\$7,389	\$3,694
Aging services facility	1.0%	\$6,549	\$3,275
Total	100.0%	737,073	\$3,685

Drug diversion is one of the three most frequent allegations. It also has the highest severity, with an average payment of \$4,947.

ANALYSIS OF ALLEGATIONS

This section examines the frequency and severity of the license protection defense paid claims by allegation class. Primary allegation classifications utilized by the various state boards of pharmacy include misconduct, unprofessional conduct and incompetent practice, to name a few. The goal of this report, however, is to provide insight into the *action(s)* or *behavior(s)* that led to the board complaint. Therefore, the allegation classes selected here are based on the primary reason for the complaint.

In considering the total paid claims for license protection defense, certain trends appear in the data, which in turn suggest risk management measures that pharmacists can implement to minimize the likelihood of a board complaint. The most frequent board complaint involves medication mismanagement (56.0 percent). For the purposes of this report, medication mismanagement encompasses a wide range of alleged infractions, including wrong drug, wrong dose and failure to obtain the prescriber's signature. The next most frequent board complaint is drug diversion (18.0 percent), followed by failure to supervise (10 percent).

Drug diversion is one of the three most frequent allegations. It also has the highest severity, with an average payment of \$4,947.

FIGURE 3: Severity by Primary Allegation Class

Allegation	Percentage of total paid claims	Total paid	Average payment
Drug diversion and/or use on duty	18.0%	\$178,076	\$4,947
Documentation error	4.0%	\$36,814	\$4,602
Beyond scope of license	3.0%	\$27,221	\$4,537
Medication mismanagement	56.0%	\$379,790	\$3,391
Fraud and/or deceit	5.5%	\$36,375	\$3,307
Failure to supervise	10.0%	\$62,752	\$3,138
Administration error	1.0%	\$5,345	\$2,673
Boundary violation	1.5%	\$6,606	\$ 2,202
Breach of confidentiality	1.0%	\$4,094	\$2,047
Total	100.0%	\$737,073	\$3,685

Medication Mismanagement

The most frequent allegation in the medication mismanagement allegation class was wrong drug at 31.0 percent. Wrong dose was the second most frequent at 21.0 percent. A total of four deaths resulted from wrong dose allegations. There was nothing unique about wrong drug license protection claims, as compared with wrong drug professional liability claims. Complaints and allegations were similar, as are appropriate risk management measures

The costliest allegations were not the most frequent. Failure to follow wastage procedures for expired medications had the highest payment (\$10,000). Prevention of such complaints requires implementation of and consistent adherence to established procedures and protocols.

Complaints ranged widely in this allegation class. Many medication mismanagement events could be prevented by following the risk management recommendations on page 64, as well as those set forth in Part 1 of this report.

FIGURE 4: Detailed View of Allegation Class – Medication Mismanagement

(56.0 percent of total license protection defense paid claims)

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

Allegation detail	Percentage of total paid claims*	Total paid	Average payment
Failure to follow wastage procedures for expired medications	1.0%	\$10,000	\$10,000
Filling prescriptions across state lines	2.0%	\$18,329	\$9,165
Failure to obtain/review laboratory values required for proper dosing	1.0%	\$ 8,480	\$8,480
Failure to identify overdosing	2.0%	\$12,006	\$6,003
Failure to report theft of controlled substances	3.0%	\$16,205	\$5,402
Failure to obtain prescriber's signature	6.0%	\$36,596	\$5,228
Equipment error	1.0%	\$ 5,000	\$5,000
Dispensing without legal prescription	1.0%	\$5,000	\$5,000
Failure to provide instructions to patient or provision of wrong instructions	3.0%	\$13,599	\$ 4,533
Failure to consult with prescriber regarding any questions/concerns	1.0%	\$3,939	\$3,939
Wrong strength	4.0%	\$19,426	\$ 3,885
Fraudulent actions	6.0%	\$27,132	\$ 3,876
Labeling error	3.0%	\$11,157	\$3,719
Dispensing expired medications	2.0%	\$7,003	\$3,502
Wrong patient	4.0%	\$13,987	\$3,497
Infection control error (contamination)	1.0%	\$3,000	\$3,000
Wrong drug	31.0%	\$94,453	\$2,699
Failure to properly handle dangerous drugs	3.0%	\$8,008	\$2,669
Wrong dose	21.0%	\$57,701	\$2,509
Did not fill prescription	2.0%	\$3,951	\$1,976
Failure to inform patient of change to generic form of drug	3.0%	\$3,299	\$1,100
Failure to counsel patient	1.0%	\$1,055	\$1,055
Improper repackaging and/or relabeling of drug	1.0%	\$465	\$465
Total within allegation class	100.0%	\$379,791	\$3,391

Case Study: Wrong Dose

This license protection defense paid claim involved a pharmacist working in a hospital pharmacy. The pharmacist incorrectly calculated a zinc concentrate for a premature newborn, who weighed slightly over one pound at birth. The written order was for zinc concentrate at 330 mcg/100ml, prescribed in quantity per volume rather than in quantity per patient weight. Using an electronic compounding device to prepare the zinc concentrate, the pharmacist recalculated for quantity by

weight but incorrectly entered mg rather than mcg, and dispensed 330 mg/100ml. Although the nursing staff stopped administration to the baby immediately upon discovering that the dosage was incorrect, attempts at providing an antidote failed and the baby died.

The board suspended the pharmacist's license for 30 days and required the pharmacist to participate in a retraining program. Payment made for this license protection defense was \$3,495.

Drug Diversion

Drug diversion to self and others, together with pharmacist use while on duty, represented 18.0 percent of the total license protection defense paid claims. While diversion to self was the most frequent complaint (52.8 percent), diversion to others resulted in the highest average payment (\$6,288) and accounted for 25.0 percent of the paid claims in this allegation class. The remaining 22.2 percent of the complaints in this category centered on use while on duty, which had the second highest average payment (\$5,919).

FIGURE 5: Detailed View of Allegation Class – Drug Diversion

(18.0 percent of total license protection defense paid claims)

*Total percentage is calculated within the allegation class.

Allegation detail	Percentage of total paid claims*	Total paid	Average payment
Diversion to others	25.0%	\$56,594	\$6,288
Use while on duty	22.2%	\$47,352	\$5,919
Diversion to self	52.8%	\$74,130	\$3,902
Total within allegation class	100.0%	\$178,076	\$4,957

Failure to Supervise

Failure to supervise accounted for 10.0 percent of the total license protection defense paid claims. The three most frequent situations grouped under this allegation were failure to report theft of controlled substances by staff (45.0 percent), improper utilization of unlicensed assistive personnel (UAP) (35.0 percent) and failure to restrict access to the pharmacy (20.0 percent). The highest average payment (\$3,487) was related to improper utilization of UAP.

Various inappropriate tasks were performed by UAP, including signing for deliveries of controlled substances, accepting and recording prescriptions over the telephone, and being put in charge while the pharmacist left the premises.

Failure to report theft of controlled substances by staff is an indication of inadequate supervision and insufficient controls for handling controlled substances. It also reveals a failure on the part of the pharmacist in charge to ensure that procedures and protocols are being correctly followed by staff, or to enact such procedures in the first place.

Complaints related to failure to restrict access to the pharmacy included not securing the pharmacy and/or pharmacy area to prevent unauthorized staff from entering.

The pharmacist in charge is ultimately responsible for the activities of the staff under his or her supervision. Proper oversight, effective controls for theft prevention and regular review of pharmacy procedures with the staff will reduce the likelihood of finding oneself before a board of pharmacy, defending one's license because of the negligence or misdeeds of others.

FIGURE 6: Detailed View of Allegation Class – Failure to Supervise

(10.0 percent of total license protection defense paid claims)

*Total percentage is calculated within the allegation class.

Allegation detail	Percentage of paid claims*	Total paid	Average payment
Improper utilization of unlicensed assistive personnel (UAP) for pharmacy tasks	35.0%	\$24,407	\$3,487
Failure to report theft of controlled substances by staff	45.0%	\$30,291	\$3,366
Failure to restrict access to pharmacy	20.0%	\$8,054	\$2,014
Total within allegation class	100.0%	\$62,752	\$3,138

LICENSING BOARD ACTIONS

More than a quarter – 26.5 percent – of paid license protection defense claims resulted in no action by the board. Another 70.5 percent resulted in monitoring, continuing education requirements or the issuing of a caution to the pharmacist. Career-ending decisions included license surrender (2.0 percent) and revocation (1.0 percent).

FIGURE 7: Analysis of Board Outcomes for Paid Claims

Outcome	Percentage of total paid claims
Closed, no action	26.5%
Continuing education or fine or both	16.0%
Citation	2.0%
Agreement/consent order/stipulation	8.0%
Letter of concern/warning/guidance	19.5%
Revocation	1.0%
Suspension	9.0%
Surrender	2.0%
Probation	16.0%
Total	100.0%

EXPLANATION OF TERMS

- **Consent agreement** – a stipulated condition or conditions that must be met for the pharmacist to continue to practice
- **Letter of concern** – a communication from the board expressing concern that the pharmacist may have engaged in questionable conduct
- **Citation** – a communication from the board noting that a violation has occurred and cautioning the pharmacist not to engage in the same action(s) in the future

RISK MANAGEMENT RECOMMENDATIONS

The following risk management strategies for pharmacists can help improve safety and reduce the likelihood of a board complaint:

- **Maintain consistent documentation, follow established procedures, and deliver clear and timely patient consultations.** Each is essential to minimize allegations against a pharmacist.
- **Recognize the stressors that may lead to substance abuse and allegations of unprofessional conduct.** Be proactive in seeking support to manage the situations or circumstances that can make a pharmacist vulnerable to substance abuse.
- **Be certain that patients understand the drug name, the reason for its use, and the prescribed dosage and frequency** at the time of purchase.
- **Use a “repeat back” technique** to ensure that the patient knows what the drug is called, what it does, and when and how it should be taken.
- **Allow new patients additional time to ask questions** during the first consultation.
- **Be aware of cultural and linguistic differences.** For example, the word “once” in English indicates one time, but in Spanish it denotes the number eleven.
- **Consider providing patients with a date and time form** they can use to remind themselves when their medications should be taken, and also to record what they have taken and when.
- **Always encourage patients to take medications exactly as prescribed** and to call with questions, documenting the discussion and instructions provided to the patient.
- **Know the state pharmacist scope of practice** and manage and dispense medications only within that defined scope of practice.
- **Consult with another practitioner when appropriate** to mitigate the risk of dispensing the wrong medication or dosage.
- **The pharmacist in charge should review with the manager/owner any outstanding compliance issues on a regular basis.** Remember that the pharmacist in charge will be held accountable by the board for failure to follow regulations, procedures and directions, and is also responsible for reporting any violations of the controls mandated by the board.
- **Never assign pharmacy personnel to tasks beyond the scope of their license, certification or job description.** Similarly, never use unlicensed assistive personnel for tasks that require a licensed professional.
- **Maintain security procedures** to prevent access to the pharmacy area by unauthorized staff.

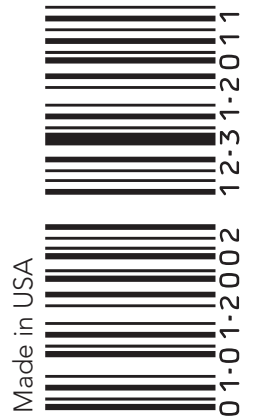
Additional risk management recommendations can be found in Part 1 of this report.

Part 3

HIGHLIGHTS FROM HEALTHCARE PROVIDERS
SERVICE ORGANIZATION'S 2012 QUALITATIVE
PHARMACIST WORK PROFILE SURVEY

2013

Summary of Findings
pages 65-75



INTRODUCTION

In 2012, CNA and HPSO conducted three separate studies, designed to analyze pharmacist closed professional liability claims (Part 1), review pharmacist license protection closed claims (Part 2), and survey insured pharmacists about a range of professional and risk issues (Part 3).

Part 3 differs significantly from the closed claims analyses in Parts 1 and 2, as it presents selected highlights from the Healthcare Providers Service Organization's 2012 Qualitative Pharmacist Work Profile Survey. (The complete results of the survey may be accessed on the HPSO Web site at www.hpso.com/PharmClaimReport2013.*) It reflects direct feedback from two subsets of our insured pharmacists: those who have had a claim filed against them, and a demographically similar group with no claims. Both groups of respondents electively opted to complete the 2012 HPSO survey tool. In this survey, the term *respondent* refers to those HPSO-insured pharmacists who voluntarily replied to the HPSO survey.

This survey was performed at the request of insureds and others interested in issues that are not addressed by the analysis of closed claims. It should be noted that the findings in Part 3 are derived only from those pharmacists who responded to the 2012 HPSO pharmacist survey, and do not reflect all HPSO-insured pharmacists or all pharmacists in general.

The survey approach permitted the comparison of several variables that influence professional liability exposure, including

- experience and specialty certification
- the effect of annual continuing education requirements on average paid indemnity
- characteristics of the incident, such as day of the week and time
- the effect of robotics and automation on average paid indemnity
- presence of adequate staffing and risk management policies

HPSO engaged Wolters Kluwer Health, Lippincott Williams & Wilkins to survey pharmacists on these and associated issues. The survey participants included pharmacists who participated in the HPSO insurance program between January 1, 2002 and December 31, 2011.

**Note that the numbering of the figures in Part 3 is not sequential, as they have been excerpted from the full survey results posted on the HPSO Web site in a somewhat different order.*

SURVEY BACKGROUND AND METHODOLOGY

The purpose of this survey was to examine the relationship between professional liability exposure and a variety of demographic and workplace factors. To that end, the responding pharmacists were divided into two groups: those who had experienced a professional liability claim resulting in loss that had closed between 2002 and 2011, and those who had never experienced a claim.

The sample for the group that experienced claims consisted of 378 pharmacists who have submitted a professional liability claim within the past 10 years. This claim group sample had two subgroups: 188 pharmacists with an indemnity payment made on their behalf and 190 with an expense payment but no indemnity payment. The non-claims sample was produced from a randomized sample of 5,000 current CNA/HPSO customers that approximately matched the geographic distribution of the claims group.

A hybrid methodology was used, consisting of a printed mail survey along with an e-mailed invitation to complete an online version of the survey. To ensure that no one could take the survey twice, each participant was sent the print version and, if an e-mail address was available, the online invitation as well. Those receiving the print version were invited to take the online survey via a generic link. Each survey was labeled with a unique identifier to ensure against duplicate respondents. To encourage study participation, respondents were eligible to receive a prize.

Within Part 3 of the report, results are reported on overall responses for both the claims and non-claims groups, as well as expense-only and indemnity data for the group with claims. The margin of error at the 95 percent confidence level for the claims portion of the study was ± 6.1 percent, and the corresponding margin for the non-claims version was ± 2.8 percent. In either case, 95 percent of the time we can be confident that percentages in the total population would not vary by more than these percentages in either direction.

SURVEY RESPONSE RATES SUMMARY

	Claims		Non-claims
	Print	Online	
Initial deployment	9/3/2012	9/15/2012	9/15/2012
Reminder #1 sent		10/1/2012	
Reminder #2 sent		11/1/2012	
Field closed			11/16/2012
Initial sample size		378	5,000
Undeliverable/opt out		19	103
Usable sample		359	4,897
Number of respondents		113	989
Response rate		32%	20%

Please note that the survey findings are based on self-reported information and thus may be skewed due to the respondents' personal perceptions and recollections of the requested information.

The qualitative HPSO survey results are not comparable to the quantitative CNA pharmacist closed claims data in Part 1 or the pharmacist license protection closed claims data in Part 2. Some figures and narrative findings in Part 3 include a reference to the average total paid amount of the respondents' closed claims. It is important to remember, first of all, that the average total paid amount combines average paid indemnity and expense-only payments. Secondly, in this section, this figure reflects only those payments made on behalf of HPSO-insured pharmacists who had a closed claim and who responded to the survey. Therefore, average total paid findings in Part 3 should not be compared with average paid indemnity findings in Part 1.

SUMMARY OF FINDINGS

- Most respondents, both those who experienced claims and those who did not, have not participated in a residency program. However, the effect of such a program on average payments appears to be positive.
- All of the respondents surveyed said they are required to obtain a certain number of continuing education credits per year, with a majority (64.5 percent) needing up to 15 credits annually. This group saw the overall highest average total payment (\$71,487).
- Having experience as a pharmacy tech or paid intern for at least two years before becoming a licensed pharmacist corresponded to significantly lower average total payments.
- Respondents who did not have a mentorship experience were more likely to experience a claim. Non-mentored pharmacists also had a higher average total payment (\$91,759), compared with those who had a mentor (\$29,434).
- While more pharmacists are expected to fill a prescription within 15 minutes, higher average total payments were made on behalf of those without a fill-time limit. Payments made on behalf of those with time limits were consistently lower, no matter the length of their time limit.
- Bar-coding was used less frequently by respondents who experienced a claim (66.0 percent), compared with the non-claims group (76.7 percent). The use of bar-coding resulted in lower average total payments.
- The use of automation and robotics appeared to result in lower average total payments. While only a third of respondents who experienced a claim benefited from this technology, their average total payments were approximately \$15,000 less.
- Most respondents do clarify a prescription with the prescribing practitioner before making any substitutions. Clarifying prescriptions before making a drug substitution appeared to result in lower average total payments.
- Pharmacy technicians served as the main source of assistance for most respondents surveyed. However, higher average total payments were made when the pharmacist was working with another pharmacist (\$77,647) or when the pharmacist worked alone (\$69,589).

TOPIC 1: RESPONDENT DEMOGRAPHICS

Gender

The proportions of male and female respondents within the claims and non-claims samples were mirror images of one another, with a majority of male participants having experienced a claim. Despite this, overall average payment on behalf of female respondents was more than twice that of their male counterparts.

TABLE 1: Pharmacist Gender

Q: What is your gender?

	Non-claims	Claims	Average total paid
Female	60.2%	39.1%	\$77,571
Male	39.8%	60.9%	\$35,314

Age

The majority of respondents having experienced a claim were over the age of 50, with 33.9 percent falling between 51 and 60 years of age. This is in contrast to the non-claims respondents, who were primarily under the age of 40. The highest average total payments were made on behalf of pharmacists over 46 years of age.

TABLE 2: Age

Q: What is your age?

	Non-claims	Claims	Average total paid
30 years or younger	29.6%	0.9%	\$2,640
31 to 35 years	15.6%	4.6%	\$27,475
36 to 40 years	13.2%	6.4%	\$8,115
41 to 45 years	9.6%	15.6%	\$16,263
46 to 50 years	7.0%	13.7%	\$81,361
51 to 60 years	17.0%	33.9%	\$42,018
61 years or older	8.0%	24.7%	\$55,473

Highest Level of Education

A large percentage of respondents who experienced a claim were practicing with their bachelor's degree, which can be correlated to the age demographic of this sample. With the recent emergence of doctorate programs in pharmacy, it is not surprising to see more of these degrees in the non-claims data, which was dominated by younger pharmacists.

The highest average total payment was seen for pharmacists with an entry-level doctorate degree (\$88,402), an increase of nearly \$40,000 over those holding a bachelor's degree alone.

Those with the most comprehensive education history (i.e., post-BS doctorate) had the overall lowest average total payments.

TABLE 3: Highest Level of Education

Q: What is your highest level of education completed?

	Non-claims	Claims	Average total paid
Bachelor of Pharmacy	38.1%	73.2%	\$51,657
Doctor of Pharmacy (entry-level)	34.7%	13.9%	\$88,402
Doctor of Pharmacy (post-BS)	27.2%	12.9%	\$18,405

Location

The overall distribution of practice location was consistent between the claims and non-claims groups. Respondents in the suburbs, the most common setting (48.1 percent), had the lowest average total payment (\$14,157). Urban-based pharmacists had the highest average total payment (\$112,294).

TABLE 4: Location

Q: Which of the following best describes the location of your practice?

	Non-claims	Claims	Average total paid
Rural	15.0%	22.2%	\$58,508
Suburban	50.8%	48.1%	\$14,157
Urban	34.3%	28.7%	\$112,294

Years in Practice

Nearly all respondents (90.7 percent) who experienced a claim had been in practice for at least 11 years. The highest average payments (\$69,013) were made on behalf of those practicing at least 15 years. The likelihood of experiencing a claim increases with the number of years in practice.

TABLE 5: Years in Practice

Q: How many years have you been practicing as a pharmacist?

	Non-claims	Claims	Average total paid
Less than 2 years	13.2%	2.1%	\$1,374
2 to 5 years	23.1%	0.0%	\$0
6 to 10 years	12.7%	7.3%	\$15,233
11 to 15 years	11.3%	11.5%	\$12,148
More than 15 years	39.8%	79.2%	\$69,013

TOPIC 2: PRACTICE PROFILE

Completing a Residency Program

Most respondents, both those who experienced claims and those who did not, have not participated in a residency program. However, participation in such a program appears to have a positive effect on average payments.

TABLE 6: Having Completed a Residency

Q: Did you complete a residency program?

	Non-claims	Claims	Average total paid
Yes	11.7%	5.9%	\$33,405
No	88.3%	94.1%	\$56,923

Number of Annual Continuing Education (CE) Credits Required

All of the respondents surveyed said they are required to obtain a certain number of continuing education credits per year, with a majority (64.5 percent) needing up to 15 credits annually. This group saw the overall highest average total payment (\$71,487). Payments for those respondents in states requiring more than 15 hours per year were fairly consistent.

TABLE 11: Number of Annual CE Credits Required

Q: According to your state licensing board, how many CE credits are you required to complete annually to maintain your pharmacist licensure?

	Non-claims	Claims	Average total paid
None	0.3%	0.0%	\$0
1-15	51.2%	64.5%	\$71,487
16-30	40.1%	31.8%	\$18,877
31-60	8.4%	3.7%	\$22,057

Years Working Before Pharmacist Certification

Having experience as a pharmacy tech or paid intern for at least two years before becoming a licensed pharmacist corresponded to significantly lower average total payments.

TABLE 12: Years Working Before Certification

Q: According to your state licensing board, how many CE credits are you required to complete annually to maintain your pharmacist licensure?

Pharmacy technician	Non-claims	Claims	Average total paid
None/NA	44.6%	40.3%	\$87,031
Less than 2 years	19.5%	18.2%	\$92,679
2 to 5 years	28.9%	37.7%	\$37,885
6 to 10 years	6.4%	2.6%	\$6,969
11 to 15 years	0.8%	1.3%	\$36,645
More than 15 years	0.3%	0.0%	\$0

Paid intern	Non-claims	Claims	Average total paid
None/NA	13.4%	18.6%	\$115,972
Less than 2 years	33.8%	51.5%	\$60,753
2 to 5 years	52.2%	32.0%	\$13,926
6 to 10 years	0.8%	0.0%	\$0
11 to 15 years	0.0%	0.0%	\$0
More than 15 years	0.0%	0.0%	\$0

TOPIC 3: PHARMACY DETAILS

Mentorship During Initial Work Experience

Respondents who did not have a mentorship experience were more likely to experience a claim. A correlation can be made to indemnity payments, as this group had a higher average total payment (\$91,759) than did those who had a mentor (\$29,434).

TABLE 18: Mentorship

Q: During your first two years of working, did you have a mentor that you could go to when you had questions?

	Non-claims	Claims	Average total paid
Yes	71.6%	59.4%	\$29,434
No	27.0%	38.7%	\$91,759
Don't know	1.4%	1.9%	\$4,783

Time Limit for Filling Prescriptions

While more pharmacists are expected to fill a prescription within 15 minutes, higher average total payments were made on behalf of those without a fill-time limit. Payments made on behalf of those with time limits were consistently lower, no matter the length of their time limit.

TABLE 22: Time Limit for Prescriptions

Q: What is the time limit or expectation for filling prescriptions?

	Non-claims	Claims	Average total paid
No limit/expectation	19.2%	11.8%	\$88,588
Within 15 minutes or less	62.5%	70.6%	\$9,661
20 minutes or less	9.4%	5.9%	\$238
25 minutes or less	3.1%	5.9%	\$1,650
30 minutes or less	2.7%	0.0%	\$0
More than 30 minutes	3.1%	5.9%	\$5,000

Bar-coding Usage

Bar-coding was used less frequently by respondents who experienced a claim (66.0 percent), compared with the non-claims group (76.7 percent). The use of bar-coding resulted in lower average total payments.

TABLE 24: Bar-coding Usage

Q: Does your pharmacy utilize bar-coding to scan for correct drug products?

	Non-claims	Claims	Average total paid
Yes	76.7%	66.0%	\$28,062
No	23.3%	34.0%	\$102,453

Use of Robotics/Automation

The use of robotics and/or automation appeared to result in lower average total payments. While only a third of respondents who experienced a claim benefited from this technology, their average total payments were approximately \$15,000 less.

TABLE 25: Robotics and/or Automation Usage

Q: Does your pharmacy utilize robotics/automation?

	Non-claims	Claims	Average total paid
Yes	42.1%	32.1%	\$43,146
No	57.9%	67.9%	\$58,135

Clarification of Drug Substitutions

Most respondents do clarify a prescription with the prescribing practitioner before making any substitutions. There appears to be a positive correlation between clarifying prescriptions before making a drug substitution and average total payments, which totaled \$53,481 for those who do clarify, compared with \$172,512 for those who do not.

TABLE 31: Clarifying Drug Substitutions

Q: Do you clarify with the prescribing practitioner before making substitutions?

	Non-claims	Claims	Average total paid
Yes	92.8%	93.4%	\$53,481
No	7.2%	6.6%	\$172,512

TOPIC 4: ABOUT THE CLAIM SUBMITTED

Assistance in the Pharmacy

Pharmacy technicians served as the main source of assistance for most respondents surveyed. However, higher average total payments were made when the pharmacist was working with another pharmacist (\$77,647) or when the pharmacist worked alone (\$69,589).

TABLE 35: Staff Assistance in the Pharmacy

Q: At the time of the incident, who was assisting you in the pharmacy? (Note: Respondents were asked to "check all that apply.")

	Non-claims	Claims	Average total paid
Pharmacy tech	86.9%	67.0%	\$43,948
Self/no one	13.9%	20.6%	\$69,589
Other pharmacist	60.9%	20.6%	\$77,647
Clerical	15.6%	8.2%	\$10,389
Pharmacy owner	3.2%	6.2%	\$9,803
Other	4.1%	4.1%	\$13,398
Registered pharmacist intern	25.9%	2.1%	\$5,250
Assistant	7.9%	0.0%	\$0

In addition to this publication, CNA has produced numerous studies and articles that provide useful risk control information on topics relevant to healthcare professionals. These publications are available by contacting CNA at 1-888-600-4776 or at www.cna.com. Healthcare Providers Service Organization (HPSO) also maintains a variety of online materials for pharmacists, including newsletters, articles and useful clinical and risk control resources, as well as information relating to pharmacist professional liability insurance, at www.hpso.com.

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