



## Compounding – special risk management concerns

by **Kenneth R. Baker, R.Ph., J.D., Senior Vice President, General Counsel, Pharmacists Mutual Insurance Company**

Every pharmacist understands the fear of learning that he or she has made a mistake and the patient received a prescription with an error. We all know that terrible feeling when the realization hits that a patient could have been – or even worse – was injured. It seems so simple; we get a prescription, enter the information into the computer, pull the package from the shelf, count and package the prescription. So simple, and yet, every pharmacist and every technician has made mistakes.

For those of us who practice compounding pharmacy, however, there are special risks and special fears. There are extra steps and more ways we can make an error. True, there is more time; the volume is not even close to that faced by the pharmacist in the high volume operation. However, because of the nature of compounding, the error is potentially even more dramatic.

Compounding pharmacists must calculate, weigh, mix and formulate. At each step, there exists the possibility for

error. In some ways, it is surprising that compounding pharmacists do not make more errors, but in fact they make very few, judging from the number of claims received at Pharmacists Mutual.

The problem with compounding is not the number of errors; it is the potential severity of the error. Example - a pharmacist compounded a prescription that required a preservative, Benzalkonium Chloride, to be added. The amount of Benzalkonium was small, a 1 to 750 concentration. The final product that was applied to the patient, however, was a 1 to 7.5 concentration of Benzalkonium. The result was severe burns.

A packaged, manufactured drug involved in a wrong strength mistake can result in a five-fold increase in the dosage of the drug given to the patient compared to what was prescribed. That could

end up as a serious error, but it is seldom that a pharmacist in a typical pharmacy would make a mistake that was one hundred times the amount prescribed. This is one of the special risks associated with compounding.

*... because of the nature of compounding, the error is potentially even more dramatic.*

There is one other special risk that compounding pharmacists face. When one of us dispensing in a typical pharmacy makes a mistake and fills a prescription with the wrong drug or wrong strength, it can be serious,

but the effects are limited by the fact that it was one patient. We take no solace in that, but if the drug we were pulling from the shelf was to fill not one prescription, but fifteen prescriptions for fifteen patients, the risk exposure multiplies.

Compounding pharmacists will receive several prescriptions during a week from the same physician for the exact same dosage. The law in Iowa, like most

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## Prompt reporting important to control loss costs

By **Vic Garman, Vice President of Claims, Pharmacists Mutual Insurance Company**

Ever wondered what you could do to help control insurance costs? You can **promptly notify your insurance carrier** of all losses or potential losses. Losses should be reported **within 24 hours** of becoming aware of the loss.

Any delay in the reporting of losses can drive up claim loss costs. An insurance company's opportunity to manage the claim and ultimately control the loss is directly impacted by how soon we are made aware of the loss.

Here are some examples of how timely or untimely reporting of losses can affect claim costs:

**Scenario 1: Automobile glass loss** – an insured person sustains damage to a

vehicle's windshield. A few weeks later they take their car to the repair facility to have repairs made. The repair facility sends the insurance company a bill of \$750 for the glass replacement. The insurance company's first notice of the loss was receipt of the glass facility's invoice.

**Potential control factors** - The insurance company in this instance may have potentially negotiated a better cost on the replacement windshield; comparing the quoted cost of replacement to other local/national glass vendors. Glass or vehicle repair facilities replacement quotes on the price of a windshield can vary significantly. Also, initially, it may

have been a viable option to repair versus replace the windshield.

**Scenario 2: Automobile accident** – an accident occurs between an insured vehicle and another vehicle resulting in significant damages. There is a dispute over who is responsible/liable for the loss. The loss occurred in a construction zone. The loss is reported to the insurance carrier three days after the accident with an indication of no injuries. An assignment is made to an adjuster that same day, and the adjuster is able to respond immediately to begin the investigation.

The accident scene as it existed at the  
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## Compounding -- continued

states, allows for the compounding of prescriptions in batches. The definition of compounding in Iowa is taken from the National Association of Boards of Pharmacy Model Practice Act and reads:

*“Compounding” means preparing, mixing, assembling, packaging, and labeling a drug or device for an identified individual patient as a result of a practitioner’s prescription drug order or initiative based on the prescriber/patient/pharmacist relationship in the course of professional practice or for the purpose of, or incident to, research, teaching, or chemical analysis, and not for sale or dispensing. All compounding, regardless of the type of product, is to be done pursuant to a prescription. Compounding also includes the preparation of drugs or devices in which all bulk drug substances and components are nonprescription or in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns . . . 657 IAC 20.2. (emphasis added).*

Not only is batching a time saving procedure, but it may actually be safer. When weighing in larger quantities, the resultant mixture is likely more accurate. Compounding in batches also allows for more checks and increases the amount of time that can be devoted to each step; it also means, that greater steps must be taken to safeguard the final product. Special risks call for special risk management steps.


In a regular dispensing practice we use a structured workflow, such as the Sentinel System<sup>SM</sup><sup>1</sup>, so that we fill each prescription in the same manner each

time. This allows for the development of quality habits, which insures each best practice is used each time. We use best practices to catch an error before the mistake occurs or to prevent the mistake from reaching the patient. If we do make a mistake, and we eventually will, we investigate the mistake and learn from it. We use that knowledge to further improve our system.

It needs to work the same way in compounding, but there are differences. Compounding is much more process driven, and the steps are less standard because the prescriptions are less standard. Still, there are processes, and there are workflows that can be employed in each process. Compounding best practices may be different from those used in a more typical pharmacy, but they are no less useful. Compounding pharmacists need to develop a set of protocols and make certain they are used each time a prescription is compounded. The first place to look for these protocols is a policy and procedures manual, but a manual is only effective if its use is enforced.

<sup>1</sup> The Sentinel System<sup>SM</sup> is a service mark of PMC Quality Commitment, Inc., a Pharmacists Mutual Company.

Training is a large part of any risk management program, and is particularly important in compounding. Most technicians and pharmacists engaged in compounding have received excellent training, but training should be continuous throughout the person’s career.

The concern of Pharmacists Mutual is the potential size of compounding pharmacy claims, not the volume. Compounding pharmacists do a very good job, and patients benefit greatly from their expertise and vigilance. However, Pharmacists Mutual knows that in order to protect the majority of good compounders from increasing insurance costs, we must also be vigilant in our underwriting. Compounders have seen an increase in the number of questions asked and the information requested. We hope it does not inconvenience you too much, and ask that you understand the need. Our insistence on quality compounding operations and risk management procedures protects you and is the only fiscally sound course for a mutual, policyholder-owned, insurance company like ours. 

## Fraud alert

Many of you pharmacy owners and managers are aware of this **scam** already, but in case some are not, this is what’s been happening:


Pharmacies are getting calls or faxes, often over their TDD line, to send fairly large orders for various items, many times vitamins, out of the country. A credit card number is offered as means of payment.

Often the shipments are bound for Africa (Nigeria seems the most prevalent destination). In a couple of instances from our files, the payment has even “authorized” the first time, but the bad news is, the second and subsequent times the same card is presented in rapid fire sequence, the system has caught up, the card has been reported stolen, and the charge rejected.

**Generally, these kinds of losses are not covered by your Business Owners Policy (BOP).** In the most used Pharmacists Mutual BOP form, the situation is excluded under the Voluntary Parting Exclusion.

### What to do to protect yourself–

1. Be extremely **wary of international orders** coming in on the TDD relay or via fax.
2. Be wary of larger than normal orders, especially those with several of the same item.
3. Ask the customer to **fax you a copy of the front AND back of the credit card**. You might even ask for a copy of the front and back of the signator’s driver’s license or other picture ID.
4. Always **ask for the expiration date and the 3 digit security code** on the signature box.
5. If they can’t or won’t fax the copies, ask for the name of the issuing bank and its phone number.
6. Then call that number to ask for a **code 10 “address verification” authorization**.

If you **suspect fraud, back away** from the transaction and report the chain of events to local law enforcement and/or to your state’s Attorney General Fraud Department. 

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## Reporting -- continued

time of the accident can change, especially in construction zones. All potential responsible parties (construction company or sign maintenance company) may never be identified. Drivers' and witness' memories of exactly what happened fade and change over time. Vehicles are moved and repairs could begin before our adjuster has a chance to inspect the damages. The involved parties, who previously reported they were not injured, now are claiming injuries.

**Potential control factors** - With immediate notice of this loss, it may have been possible to protect the accident scene and vehicles, as they existed at the time of the loss. Statements of all involved parties may have documented their version of the accident and any claimed injuries. These early versions are usually the most credible, allowing the insurance company to make proper decisions on liability, damages, and injuries. Carrying a disposable camera in your vehicle would allow you to take pictures of the accident scene and damaged vehicles immediately after the incident.

**Scenario 3: Professional Liability loss** – a patient returns a misfilled prescription to the pharmacy where it was purchased. The prescription was filled the previous day. The patient indicates that 2 of the 3 doses scheduled were taken with only “minor” side effects before noticing the information on the bottle was incorrect. The pharmacist dealt with the situation internally. The first notice to the insurance carrier was 6 months later from the customer’s attorney, filing suit.

**Potential control factors** - With immediate notice of this loss, it would have been possible to immediately and completely investigate this incident to determine potential liability exposure. Early contact with the claimant/customer by a claims representative may have led to a prompt resolution of the matter and prevented attorney involvement.

**Scenario 4: Workers Compensation loss** – an employee sustains a low back injury on 11/01/04 with no apparent lost time and tells his employer that, “I think it will be fine and don’t want to turn it in.” Approximately 2 weeks later, the employee continues to experience low back pain and begins to miss time from work. The injured worker is subsequently diagnosed with a low back sprain/strain, is to stay off work for 3 weeks and to return for

regular chiropractic or physical therapy treatment. The insurance company receives the First Report of Injury from the employer on 11/22/04 with the employee already losing time from work.

**Potential control factors** - If this loss were reported when the employer was first notified: the insurance company would have contacted the injured worker, explained the workers compensation system, referred the employee to an appropriate care provider (where allowed) to get cost effective medical care, and worked with the employer to supply modified duty work. These steps may have avoided this becoming a lost time claim.

In workers compensation law, when determining First Report of Injury reporting compliance to the State Insurance Departments, the day the employer is aware of an injury is equal to the day the insurer is aware. In the above example, the employer’s and the insurance company’s notice was 11/01/04. While reporting requirements vary from state to state, the State Insurance Departments require the form to be filed within certain time-frames and failing to file within those time-frames, can lead to fines or penalties.

Some other “food for thought” on early reporting: a recent workers compensation case study reveals the following:

- The average total loss costs increase 2-3% for every day the first report is delayed.
- The average loss costs increase 20% when the first report of injury is reported after 7 days and 41% after 15 days.

Each one of the scenarios presented are representations from claims handled at Pharmacists Mutual. All of these examples demonstrate missed opportunities to potentially control the exposure these claims presented.

We believe there are many mutual benefits when combining forces to improve this aspect of the claim process. We are willing to work with you to improve your process for claims reporting.

Here is a short list of things you can do to improve loss reporting:

- Have the Pharmacists Mutual reporting number readily available in ALL locations in event of a loss. (automobile(s), home(s), business location(s), etc...)
- Educate employees about the importance of immediate loss reporting.

- If possible, designate one person to coordinate your insurance loss reporting process.
- For workers compensation, have the state First Report of Injury form readily available to be completed at the time an employee first notifies you of any injury.
- Maintain good records that document the exact circumstances of a reported loss. Preserve any evidence provided to you, where appropriate.

If you have any further questions or would like to learn more, feel free to contact your claims representative at Pharmacists Mutual. ☎

## RxPATROL® update

RxPATROL® is an information clearinghouse that collects, analyzes and shares information concerning pharmacy thefts with police agencies across the country. **Six months ago we started a pilot project in one region of the country. That has gone so well, that Pharmacists Mutual has decided to go nationwide with this alliance.**

Currently a pharmacy calling to open a claim for a theft of controlled substances is asked to send in a copy of the police report, the DEA 106, and a completed loss notice. Additionally, we will now be asking you to complete the online RxPATROL® theft report form. Instructions will be included in the claim filing information packets sent to those that have been victims of crimes against pharmacies. ☎

### Pharmacists Mutual Companies:

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# Dummy camera recommendation rescinded

Dear Editor,

In your Fall 2004 newsletter you made reference to the use of "Dummy Cameras" as a tool in combating burglaries and robberies. Based on my 20 years in the security profession, I would like to respectfully disagree with your promotion of these false security devices.

Surveillance cameras are typically installed as an investigative tool and not as a deterrent. According to a 1999 article from Sandia National Laboratories, "There is no empirical research that could be identified to date that has examined the effectiveness of security cameras in relation to decreased violence and crime..." and since 1999 our society has increased the use of surveillance cameras over 40% with no appreciable

reduction in the crime rate. It is my professional opinion that in today's culture, with the population becoming more and more accustomed to seeing cameras and being recorded in most public places, that the deterrent factor of cameras is decreasing not increasing. Also, probably the most significant reason not to use "Dummy Cameras" is the increase in liability. There have been many cases over the years of organizations being sued for lack of security or a false sense of security due to dummy cameras. When customers or visitors see cameras they expect, at a minimum, there will be an availability of evidence of any crime (video tape or digital recording) if one would occur while they are in your facilities. If "Dummy Cameras" are used there

is no such evidence available. To conclude I believe that these false security devices are appropriately named, only dummies would use "Dummy Cameras" in today's society.

Respectfully,  
Jerry D. Loghry, MS, CSP, CPP

*Editor's note: Mr. Loghry was Chairperson for ASIS (American Society of Industrial Security) International, Iowa Chapter, has served on the ASIS International Business Practices Council and currently serves on the Banking and Financial Institution Council. He holds the prestigious CPP (Certified Protection Professional) designation. Given his well recognized expertise in the security field, I am going to defer to Mr. Loghry's judgment and withdraw my recommendation of using "dummy cameras" for security purposes. All references to such devices will be expunged from the pertinent templates on the phmic.com website. 📧*

## Do you have any questions or requests concerning

- ✓ The contents of this newsletter?
- ✓ Safety Consultation Services?  
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