

## Compliance! Compliance! Compliance!

Kelly S. Selby, R.Ph.

Are you tired of the never-ending list of compliance requirements? Struggling to comply with all the expanding regulations? Do you worry that a compliance issue will arise if you take the day off or that third party audits will claw back your hard earned money? You are not alone! Running a pharmacy today has become very complex. State and Federal laws, USP, OSHA, DEA, FDA, DMEPOS, Specialty Pharmacy contracts, and accreditations all have compliance requirements. Finding simple and effective ways to track compliance will reduce stress associated with the endless list of requirements. These steps will make your pharmacy more efficient at the same time. The last thing we need is more stress in the work environment.

Here are some steps that you can take to improve your pharmacy operations and safety. These steps will also create efficiency:

- 1. Create a compliance officer position.** Pick someone who is detail orientated and is good at completing tasks in a timely manner. This could easily be one of your well-trained technicians. Creating this position will have a big impact on your overall compliance.
- 2. Use an electronic calendar to record due dates of compliance tasks and training.** Assign someone in your organization to be responsible for each designated task and training item and report back to the compliance officer when completed. Collecting compliance items is an ongoing process.
- 3. Purchase software that tracks employee training.** Several options are available on the web that are easy to implement. Software is available to track training for blood borne pathogens, CPR, FWA, and HIPAA compliance.
- 4. Consider accreditation as a great pathway to improve your business practices and compliance.** As you complete the requirements, you will find that efficiency and work flow improves through the implementation of written policies and procedures.
- 5. Create simple internal audits that require less than one hour to complete.** This is an easy way to see if you are compliant and you can track improvements by repeating on a set schedule. These audits can be compiled from state board checklists and PBM common audit checks.

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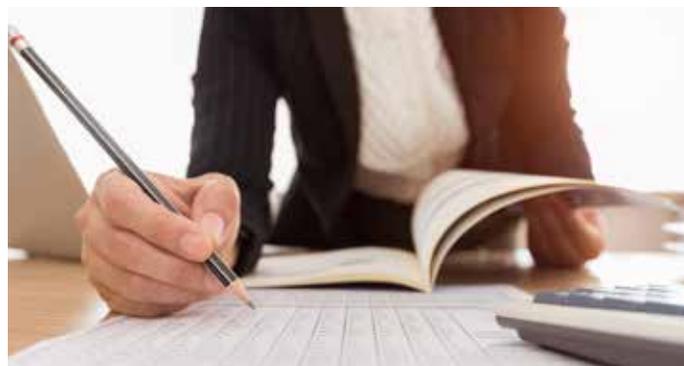
**Please share this newsletter when you are finished.**

- 6. Hold frequent staff meetings.** Use these opportunities to provide training, reinforce knowledge of requirements, and encourage overall quality of pharmacy services.

These steps can dramatically improve your pharmacy's ability to comply with the rigorous requirements, and can reduce your exposure for expensive losses. Taking just one or two of these steps and documenting them will get your pharmacy's training and performance improvement plan moving in the right direction.

**Examples of items to track for improved compliance:**

- Employee license renewals
- FWA/HIPAA requirements
- Pharmacy license and DEA renewals
- Employee competency training
- OSHA yearly requirements for small business
- DEA Self Certification for Methamphetamine training
- USP 797 and 795 compliance for compounding
- Accreditation renewals: PCAB (ACHC), URAC, DMEPOS, Retail Pharmacy, and Specialty Pharmacy
- Onboarding new employees, I-9, W-2, job descriptions, background checks, drug testing
- Annual disaster, evacuation, fire drill, robbery, and security safety training
- PPE (personal protective equipment) training for immunizations



*Kelly Selby is President and owner of Community Pharmacy in Denton, Texas and has been a member of the Pharmacists Mutual Board of Directors since 2009. Kelly is a member of the National Community Pharmacy Association, the American Pharmacists Association, the International Academy of Compounding Pharmacists, and the Texas Pharmacy Association. Kelly is a graduate of Southwestern Oklahoma State University.*

## Like a Card Up Your Sleeve

*Jen Aultman, CPhT, Risk Management Consultant, Pharmacists Mutual*

In a world that seems more complicated than ever, managing your pharmacy business is no less difficult. Increased demand, lower reimbursements, working with employees, maintaining autos or property, and many other things you juggle can cause consternation; what gives you peace of mind?



When details about running your business and potential risk are on your mind, let us help you. The Pharmacists Mutual mission is "To help our customers attain peace of mind through specialized insurance products, risk management solutions, and superior personal service." Our consultants can help you identify exposures and give recommendations to mitigate risks you may not have detected.

If your pharmacy is in Minnesota, you automatically watch walkways outside your pharmacy when snow or other precipitation falls. Why? You already know the risk and hazard. When less obvious needs become apparent where will you go for information or suggestions? Let us help you identify risks and the hazards associated with the less common aspects of business.

You likely started your business because you wanted to help people. Many business owners find it taxing to handle the more mundane aspects of managing a business. By mitigating risk, you avoid confronting a huge problem and have a plan when a hiccup comes along. Pharmacists Mutual's Risk Management Team can help you avoid risks you may not have considered. Here is a sample of the things we can help with – but this is only the tip of the iceberg.

- Policies regarding medical marijuana and your employees/drivers
- Return to work plans
- OSHA recordkeeping
- Protecting your employees against customer threats
- Reducing workers compensation injuries
- Disaster plans
- Alarms and other crime avoidance techniques
- Dispensing and other pharmacy procedures
- Preventing filling errors
- Safety policies/procedures

Our goal is to help you avoid risk. Take time to consider your business and areas that need improvement. Do you have areas of your property or business which concern you? Have you always wanted to implement or improve employment policies? Which concerns have kept you awake at night?

With a staff that includes expertise in pharmacy, law and risk management, we are confident we can assist you. Consider us a card up your sleeve; a resource to help you manage your business in an easier and more effective way.

# Are aggressive efforts to control opioid addiction fueling an increase in pharmacy crime?

Michael Warren, Risk Manager, ARM, OHST

The rate of opioid addiction in the United States that was flagged by the CDC in 2010 continues at an alarming rate, despite aggressive measures to control the problem.

- An estimated 15 million Americans abuse prescription drugs each year (National Institute on Drug Addiction, NIDA 2015)
- Opioid deaths have quadrupled since 1999 (CDC)
- Medical emergencies from prescription opioid abuse increased by 183% over the past 7 years (Center for Lawful Access and Abuse Deterrence)
- Heroin deaths reached 12,900 in 2015, but prescription narcotic overdose deaths reached 20,101



Since 2010 we have seen new prescribing guidelines, significantly greater use of prescription drug monitoring programs, more physician education, drug take back initiatives, tighter controls on emergency room prescriptions for narcotics, and a multitude of other initiatives. In 2017 the DEA is restricting the amount of almost every Schedule II opiate and opioid medication that may be manufactured by an average of 25%. Hydrocodone will be limited to 66% of 2016 levels.

At the same time, while we justifiably fight addiction, we face emerging problems in efforts to keep drug dependence in check, and challenges in treating addiction itself. While recidivism rates for drug treatment programs are high, treatment can be effective with close monitoring and the ability to influence psychological and psychosocial triggers. Unfortunately, treatment is expensive.

While the country faces an uphill battle to manage an existing problem, the criminal element does whatever it can to keep demand high. An illustration is the length taken to introduce powerful narcotics to the country. In August 2016, the CDC announced that hundreds of thousands of Fentanyl-laced counterfeit pills labeled as Oxycodone, Xanax, and Norcol entered the U.S. last year. High addiction rates keep criminals employed and guarantee high margins.

## What does this mean for pharmacy crime?

Pharmacists Mutual saw an increase of 62% in burglary and robbery frequency and the costs of these crimes have more than doubled since 2012. High numbers of addicts continue to seek drugs as does organized crime. A recent trend involves professional thieves targeting pharmacies in remote areas then sending the drugs to areas where the demand is high.

Because of the extent of the problem, issues with funding and the complexity of effective treatment programs, curbing dependency and addiction will require a long-term effort. Measures that have been taken to limit abuse, such as Prescription Drug Monitoring, revised treatment guidelines and physician education may have created an unintended consequence. Where drug seekers cannot acquire narcotics by fraud or deceit, indications are that they are committing more pharmacy burglaries and robberies.

Chain stores are studying the problem and implementing new security measures, including time delay safes, tracking devices, and advanced technologies for visual surveillance and facial recognition. As chain stores add protective measures criminals may be turning increasingly to independent pharmacies as an easier target.

## What can you do?

1. Focus on the basics. Add strong doors and locks, protect front windows from smash and grabs, and use reliable alarms and safes. Make sure your staff knows how to react if confronted by an armed robber.
2. Educate yourself and your staff. Learn how criminals act and train your staff how to react in a robbery. Review the Pharmacists Mutual Crime Report at [www.phmic.com](http://www.phmic.com).
3. Take advantage of discounts available to Pharmacists Mutual members for tracking devices, safes, time delay devices, and verified video monitoring. (see page 7)

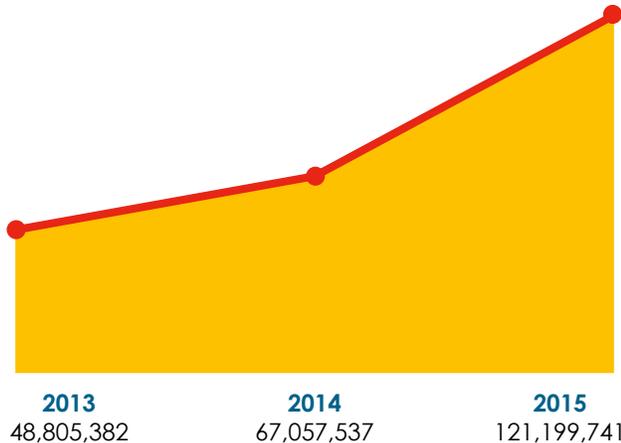
Pharmacists Mutual will continue to monitor developments and control measures to help stem the tide. If you have questions about pharmacy security, please contact us at [rskmgmt@phmic.com](mailto:rskmgmt@phmic.com).

# Cyber Attacks

Joyce Dornbier, Pharmacists Mutual Member Services Representative

Cyber attacks are escalating at a rapid pace, and criminals continue to introduce new ways to gain access to records. It's time to educate ourselves on the targeted areas that interest cyber criminals, and how to protect ourselves from being attacked.

## Increase in the number of records compromised by data breach

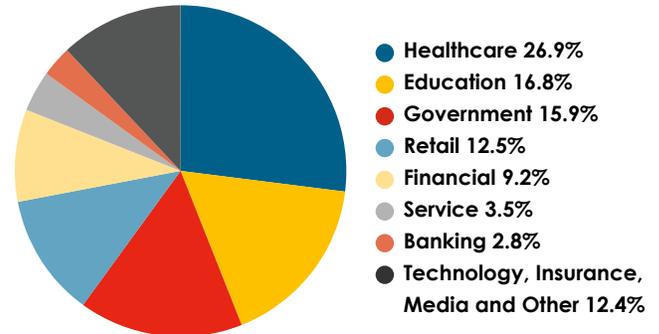


Source – Privacy Rights Clearing House

Cyber attacks are occurring at a more frequent rate due to the increased use of e-commerce, web-based file storage, and the proliferation of smart phones, laptops, and tablets in businesses of all sizes. The risks associated with data security are growing quickly.

- In 2015, over 169 million confidential records were exposed through more than 780 reported security breaches according to the national nonprofit Identity Theft Resource Center (ITRC).
- The #1 risk to data in 2015 was hacking or phishing incidents (up 8.4% from 2014). The #2 risk was employee error/negligence (more than doubled since 2013).
- Lost customer business, legal services (defense), investigations and forensics have the highest level of spending when a breach occurs (Ponemon).
- Regulatory fines and penalties have been on the rise as the government is enforcing the FTC Safeguards Rule, HIPAA, the Red Flags Rule, and the Hi-Tech Act.

## Data Breaches by Industry Group



## What a business can do to protect against cyber attack

- Use the spam center for your work email to limit traffic that is not legitimate.
- Own your online presence. Consider hiding your email address and other personal information from online profiles and social networking sites.
- Allow only certain people to view your personal information.
- Use trusted sites before entering any information.
- When in doubt, throw it out: links in email, tweets, posts, and online advertising are often the way cybercriminals compromise your computer. If it looks suspicious, it's best to delete or, if appropriate, mark it as junk email.
- Think before you act: be wary of communications that implore you to act immediately. If something sounds too good to be true, it probably is.
- Make passwords long and strong. Combine capital and lowercase letters with numbers and symbols to create a more secure password.
- Never provide personal information when you are uncertain of the requester.
- When registering for online accounts, use different user names and passwords site to site. It may be more difficult to remember, but this is a best and safest practice.

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### Transferring the risk

Risk transfer is a risk management technique where a portion of the financial risk is transferred to a third party. The most common form of risk transfer is insurance. Pharmacists Mutual provides cyber insurance through NAS Insurance Services as part of the pharmacy business owner's policy. This insurance provides coverage with the following benefits:

- Full limits can be applied to privacy breach response, voluntary notification, and network asset protection as needed to respond to the loss. Coverage for privacy breach response costs outside the limit is also available.
- Broad cyber crime coverage that provides protection against financial fraud, telecommunications fraud, phishing attacks and fraudulent wire transfer requests.
- Brand guard coverage for reputational harm due to attacks from a cyber breach.
- Business Interruption coverage to protect you in the event that the cloud provider goes down. This also provides coverage as a result of outages caused by an insured's cloud provider or web host.

- Allows you to choose breach response vendors and attorneys.
- An available option for a per-identity breach response limit.
- PCI DSS fines/penalties and related PCI assessment expenses are now covered up to the data breach policy limit.
- Unknown prior acts coverage is available for covered cyber incidents occurring any time prior to the inception date of policy.

*For additional information on how to protect your company against cyber attacks, contact our risk management department at [rskmgmt@phmic.com](mailto:rskmgmt@phmic.com). To inquire about cyber coverage or to learn about increased limits, contact your Field Representative or you can email us at [info@phmic.com](mailto:info@phmic.com).*

## Changes Associated with Office Use Compounding

*Kristen Jones, PharmD, Pharmacy Risk Management Consultant*

Drugs compounded for "office use" are compounded in bulk without a prescription for future administration or dispensing to unidentified patients on an as-needed basis, often in a physician's office. This gives physicians quick access to commonly used compounded drugs instead of waiting for a prescription to be filled. This practice has historically been allowed in several states across the nation. However, the end of 2016 brought final guidance documents from the FDA with regard to office use compounding. There is a clear statement from the FDA prohibiting compounding of office-use products or non-patient specific prescriptions provided to physician's offices or clinics by 503A pharmacies. Continuing to compound these non-patient specific prescriptions is in violation of the DQSA and removes the exemptions provided by it for new drug applications, CGMP requirements, and additional labeling requirements.

This rule will no doubt have an effect on many providers and patients. The effects of these changes will be felt in the dermatology office, dental office, obstetrics clinics, among many other specialties. Often times, office use products are utilized in provider's offices to initiate therapy immediately, improve compliance, and protect patients from harmful chemicals.

Office use compounding can be risky for many reasons. First, products may be produced in large batches. These batches can then sit on shelves in provider's offices for long periods of time. Storage conditions vary as well as handling practices. All of these coupled together can result in bacterial growth, product degradation, labeling mix-ups, and potentially patient harm.

Providers who need compounded products in their practices will have to obtain these medications from registered outsourcing facilities or provide patients with prescriptions prior to office visits. While this may not be the most convenient option for your providers or patients, the ramifications for the pharmacy not following this new guidance can be abundant.

If you are currently engaged in an office use compounding relationship with providers, work with these providers to establish a process that allows access to these medications through patient prescriptions. Failure to follow the FDA's rules can open your business up to an FDA visit, 483 form, FDA warning letter, or even a product recall.

## When a workers' compensation claim turns bad

Michael Warren, Risk Manager, ARM, OHST

On a busy Monday morning, a pharmacy technician tells you he injured his hand carrying a tote. You think to yourself, the last thing you need is another workers' compensation claim and maybe it would be best to handle it out of pocket. You tell the employee to go to the doctor and figure if the injury is worse than expected, you can let Pharmacists Mutual know later.

The employee does not come back to work the next day, but leaves a voice mail message that the doctor sent him to an orthopedic surgeon for an evaluation. The employee also said he had to provide his health insurance information, even though you had said you would take care of it. You try to reach the employee with no success. Next thing you know, he is upset because bills are coming to his home. His health insurer is denying payments, and he needs more treatment. He threatens to report the injury to OSHA and then you receive a letter that he is now represented by an attorney. Time to contact Pharmacists Mutual.



Most employees injured on the job have never reported a work related injury. They do not understand that the rules are different. Faced with uncertainty, things can spiral out of control quickly.

- Even an apparent minor injury can turn into discovery of an underlying physical problem associated with comorbidities and complicated treatment. Obesity, diabetes, and previous injuries can represent significant challenges for recovery. Without the correct treatment plan and proper monitoring, costs escalate.
- Doctors want to be paid. If necessary, they will bill the employee.
- The employer can easily lose track of treatment progress.
- The employee may reach out to friends and family when bills come to the home, when they don't understand the treatment, or when they feel they are not getting better and when they fear for their job.
- Uncertainty leads to getting attorneys involved, which can mean significant increases in costs without necessarily translating to a better outcome for the employee.
- Once an attorney is involved, both the employer and Pharmacists Mutual are limited in what they can do to control the situation.

The best way to control workers' compensation costs is to prevent the injuries from happening in the first place. If an injury does occur, use these tips to keep them in check:

- Let Pharmacists Mutual know right away when an employee is injured on the job, particularly when a doctor's visit is required.
- Accompany the injured employee to the doctor or emergency room.
- Tell the medical provider this is a workers' compensation claim, and you will provide a claim number when received from your insurer, Pharmacists Mutual.
- Cooperate with the adjuster when they reach out to you.
- Stay in contact with the injured worker. If they have concerns, let the adjuster know.
- Keep the focus on getting the employee back to work. Remember: there is a reason workers' compensation attorneys advertise during the day – to target injured employees who are sitting at home.

When an employee is injured on the job, their experience with the workers' compensation system can be confusing and frustrating. Fear and advice from friends and family can lead them to hiring an attorney when one is not needed. When an attorney is hired, costs increase significantly. When treatment is delayed or the employee is not focused on returning to work, both the employee and employer may lose.

## Follow-up to T3 Article (December 2016 newsletter)

*Don R. McGuire Jr. R.Ph., J.D., General Counsel, Sr. Vice President Risk Management and Compliance*

Edition IV of our Risk Management newsletter in 2016 contained an article entitled "T3 for Hypothyroidism – Understanding and Managing the Risks." We received feedback on that article and would like to address that feedback in this follow-up article.

Staying current on practice standards is important for pharmacists. The need is driven by their expanding role in health care. It is also imperative for patient safety. Pharmacists can provide valuable advice and expertise and should never be merely order-takers for prescribers for any patient or condition. That being said, treatment of hypothyroidism is not settled at this time, and our article might have implied otherwise. There is disagreement between physicians and physicians' groups about the proper place of monotherapy with T3.

One of the goals of Risk Management is to learn something from every claim and continue to improve the quality and safety of pharmacy services. Missing from the prior article were these lessons learned. The most important factor in these claims was the use of aliquots. The inaccuracy of aliquots is a recurring issue in compounding claims. There are a number of things to watch for. The first problem in these cases was that the concentration of the T3 and T4 powder used was different than the last time it had been compounded. This change caused the end calculations to be incorrect.

Educating your compounding staff is essential to reducing compounding errors from APIs that require aliquots. Teaching

staff to recognize that T3 and T4 may be available in two strengths is a foundational principle. Knowing the difference between a diluted aliquot and the pure concentrated form is critical to preparing these compounds. The concentrated API should be diluted to a proper aliquot and tested, when appropriate, before use to ensure safety of the patient.

Another option to minimize errors is to agree on a standard aliquot for particular drugs. This will reduce guesswork and produce more uniform calculations. This will increase the likelihood that the compounder will be able to estimate that their answer is within the expected range. With ever-changing aliquot concentrations, there is no normal to compare today's output against.

Other factors to consider with the use of aliquots is the need to adjust for the salt form of the raw material and to account for any loss on drying that might occur. When looking at our data for all compounding claims since 2001, we see that 22.5% of those claims result from a calculation error. Another 21% resulted from measurement errors. These two categories comprise just under half of the compounding claims, and both functions are essential components in an aliquot. Calculating, measuring, and outside testing are tremendously important parts of compounding and necessitate the need for an efficient and effective procedure for the use of aliquots.

Thank you to those members who took time to provide us valuable feedback on this topic. Our risk management efforts are definitely improved with the participation of our members.

## Crime Prevention Discount Programs Available from Pharmacists Mutual

### Pharmacy Bottle Tracking Device

Stand-alone tracking device disguised as a pill bottle with monitoring service.

#### 15% discount

Pharmacists Mutual will also waive the deductible up to \$1,000 if the pharmacy has a monitored device on premises and the pharmacy is burglarized or robbed.

For additional information, visit [www.3sisecurity.com/products/pharmatracker](http://www.3sisecurity.com/products/pharmatracker).

### Pharmacy, Narcotics, Cash and Office Safes

#### 25% discount

Scripps Safes offers a variety of pharmacy safes and time-delay locking devices. For additional information visit [www.4saferx.com](http://www.4saferx.com) or call 1-844-4Safe-Rx.

### Alarm System with Video Verification

When a motion detector with camera activates, it records video that can be transmitted from the alarm company to the police department. The technology reduces false alarms and unnecessary police response. It also provides the police department with verification of a crime in progress.

Entire system (control panel, keypad, badge reader, power adaptor, three motion viewers with camera, and five Videofied Prox tags) available for under \$1,000 with a monthly monitoring rate of \$25.

For additional information visit Videofied at [www.ppvar.org](http://www.ppvar.org).



*For electronic or hardcopy brochures on these programs, or to obtain discount codes and information on how to order, please contact Pharmacists Mutual Risk Management at [rskmgmt@phmic.com](mailto:rskmgmt@phmic.com).*

**Your Risk Management Newsletter – In this Issue – More on T3 for Hypothyroidism**

## Common Sense When Delivering Prescriptions

*Michael Warren, Risk Manager, ARM, OHST*

While the situation where a delivery driver is robbed occurs only rarely, drivers are at risk. There are some common sense measures to take to avoid becoming a victim.

- Know the route. Plan the route ahead of time or use GPS.
- Don't make any unscheduled stops.
- Carry a cell phone. Make sure to have key contact numbers loaded and that customer phone numbers are on your delivery order sheets.
- If you cannot confirm the address, call the customer to verify.
- Park as close to the door at the destination as possible.
- If you feel uncomfortable about the surroundings or suspicious persons, don't make the delivery.
- Be alert to vehicles that may be following you. If the vehicle follows you to the delivery destination, do not exit the car. Keep the doors locked and call the police.



If you are approached by someone who is armed or threatening and demanding drugs, stay calm. Follow directions and do not resist. Try to remember details and call 911 as soon as possible.

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For information on reprints, please contact [mike.warren@phmic.com](mailto:mike.warren@phmic.com).

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