A Look at Compounding and Regulations

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On June 2, 1963 I graduated from pharmacy school with a Bachelor of Science degree. After 50 years of active practice in retail pharmacy, compounding pharmacy, infusion pharmacy, clinical respiratory, HME-DME and home health, I decided to retire. Much changed in the practice of pharmacy over those 50 years. One area that I saw great change in was compounding.

As we know, all prescription drugs are required to be pre-approved by the Food and Drug Administration (FDA) to demonstrate safety and efficacy. They also must be properly labeled and manufactured according to FDA Current Good Manufacturing Practice (cGMP) requirements. cGMP requirements are stringent as they address identity, strength, quality, and purity in the compounding or manufacturing process. A full description of cGMP requirements can be found listed under FDA regulations. The requirements are many and some are costly to meet.

In 1997, Congress added a codified section 503A to the Food, Drug and Cosmetic Act. The FDA has now identified two classes of compounding pharmacies. One of the two classes of compounding pharmacies is 503A. Pharmacies under 503A are exempt from three FDA requirements: premarket approval, cGMP requirements, and certain labeling requirements. 503A pharmacies are to compound drugs only on prescriptions from authorized providers. The compounded drug should be patient specific, and should not be compounded in bulk. There are some very limited exceptions to the patient specific rule and state boards of pharmacy should be contacted for these exceptions.

In November 2013, a year after the huge fungal meningitis outbreak experienced in around 20 states, Congress enacted the Drug Quality & Security Act (DQSA), which added the second class of pharmacies known as 503B. This class of pharmacies must be licensed by the FDA and meet many additional requirements. They must be inspected by the FDA and operate strictly under cGMP. 503B pharmacies can compound in bulk and are not required to operate patient specific. Since these pharmacies compound in bulk, many patients can be treated from the bulk compound. This can be a significant risk if the bulk compound is possibly contaminated. Therefore every compound should be sent to an external lab for testing to verify reliability. As an example of the high risk liability that 503B pharmacies can exhibit, one only needs to look at the bulk compounding performed by the pharmacy involved with the 2012 fungal meningitis outbreak. The FDA estimated that as many as 14,000 people received contaminated drugs from that pharmacy and over 600 people suffered injuries with many suffering death. This case recently went to trial and the trial result can be viewed on the internet. This episode was a tragedy for all pharmacies.

All pharmacies doing sterile compounding should be following USP 797 regulations in their operation. There are two categories of Compounded Sterile Products (CSPs). Category designation is determined by the conditions under which they are made and the time within which they will be used. Category 1 CSPs...
have a maximum BUD (beyond use date) of 12 hours or less at room temperature, or 24 hours if refrigerated. Category 2 CSPs may have a BUD of greater than 12 hours at room temperature, or greater than 24 hours if refrigerated. The BUD calculations are explained in the USP 797 guidelines. All CSPs should be compounded in a sterile environment that includes a clean room, aseptic technique, full body garbing, cleaning and disinfection, methods of sterilization/depyrogenation, use of hoods or aseptic isolator, and sterilizing equipment. Training is essential for all employees in any aspect of sterile compounding. Schedules should be established for observation of compliance and retraining of employees. Policies and procedures should be in place and kept up to date. These policies and procedures should be effective in covering all compounding activity. Logs should be kept and signed by appropriate personnel. These logs should be applicable to all aspects of compounding, environmental conditions, shipping and receiving. Certificates of analysis for all chemicals should be obtained from suppliers and retained on file. All equipment such as balances, thermometers, sterilization equipment, and refrigerators/freezers should be checked and certified for accuracy according to an established schedule. All compounds that have sample product sent to an outside lab for verification of sterility, strength, etc., should be held until the lab sends verification of product safety analysis. From a liability risk position, most pharmacies will not register as 503B. There are approximately sixty 503B pharmacies in the U.S.

The FDA has issued a list of chemicals that have been banned for human use. Several of these chemicals have been used in the compounding of topical creams and ointments for many years. I personally have compounded products in years past that called for some of these chemicals in the formula. These banned chemicals should no longer be used and need to be properly disposed of. Use of any of these drugs would create a liability risk if used.

Another issue that compounding pharmacies face today is that a negative pressure clean room is required to be used when compounding certain products. A list of the drugs that require the use of a negative pressure room is available from the FDA. I advise that pharmacists consult their state’s Board of Pharmacy about the use of the negative pressure room.

The FDA is inspecting all 503B pharmacies as required by the DQSA. Most of the inspections have resulted in 483 observations being issued. Pharmacies are required to respond to the 483s in a timely manner. If the pharmacy response to the 483s is not accepted, a warning letter may be issued. It is important that all 503B pharmacies comply with the FDA and cMPG requirements, as liability risk for these pharmacies can be great. Many people can be adversely affected if a compounded bulk drug is bad.

In summary, pharmacy compounding has become more common each year. It is a practice that can be done safely if done correctly. Sterile compounding should be practiced only by pharmacies that are properly equipped and whose employees possess the proper training and skill. Be sure to communicate with your field representative or the home office if you make any changes in your pharmacy practice. You want to be sure to have proper coverage.

The Importance of Pharmacy Professional Liability Coverage

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

Most people realize the importance of insuring the things that they value in their life: their home, their cars, even the lives of loved ones. But sometimes there is a reluctance to insure their pharmacy practice. This is difficult to understand given the importance of their practice, to both the pharmacy owner and to their patients.

Insurance policies provide two types of coverage. The Indemnity coverage is what most people are familiar with. This is the coverage that pays the damages sustained by another person due to the insured’s negligence. This is important coverage, but there is a second type of coverage provided, Defense coverage. This coverage pays for the expenses of defending the insured against allegations of negligence. One of the most expensive components here is the cost of an attorney to defend the case. The importance of this coverage is that this will benefit the insured in those cases where the allegations are baseless. Even if nothing is paid under the Indemnity coverage, the Defense coverage can provide benefit to the insured. This is especially important when it comes to the cost of defending lawsuits. Winning a lawsuit can be expensive. With the increasing ease and willingness of people to file lawsuits, this relatively unknown coverage becomes extremely important.

You need to make sure that the policy you purchase covers the professional acts that your perform in your pharmacy. Activities to be mindful of include providing immunizations, sterile compounding, and Medication Therapy Management. Purchasing a policy that does not include the activities that you perform is not a wise purchase. What are the dangers of not having any pharmacy professional liability coverage, or having inadequate limits, or having a professional activity excluded from your policy?

The cost to defend a claim is expensive and sometimes exceeds the cost of the negligence claim itself. Without the proper coverage, all of these costs will fall on the pharmacy owner. At least, this can be very disruptive to the pharmacy’s cash flow. At worst, a significant judgment could leave the owner with a lien against their pharmacy.
or even force the pharmacy to close. Another factor to consider is the possibility of negative publicity brought on by these developments.

Without the proper coverage, the pharmacy owner is left to handle the claim themselves. The proper insurance coverage brings with it the assistance of the insurance company’s claims department, along with the help of attorneys and experts that the insurance company retains. These are people who deal with claims every day and are professionals in this area. For the pharmacy owner who is forced to handle it themselves, they can encounter procedures and rules that they are unfamiliar with. And this must be done in addition to all of their normal responsibilities as an owner and a pharmacist. Having someone to lean on during this process can be extremely valuable.

Some pharmacists are willing to rely on the goodwill of the patient to not sue them. While this might work in some cases, it is not a stable risk management plan. The outcome of a prescription mis-fill is tremendously unpredictable. What causes minimal harm to one patient could result in serious harm to another. Regardless of the good intentions, a patient who is faced with significant medical costs and no way to pay them will have to make a practical decision to protect themselves. Faced with even only one claim in a year, the expense of handling the claim and the lack of professional assistance will reinforce the importance of carrying appropriate professional liability coverage.

There is an additional concern that the existence of a pharmacy professional liability policy makes the pharmacy a target for lawsuits. Our experience has shown this not to be true. A good plaintiff’s attorney brings all potentially liable persons into a suit. Most often, this happens even before the existence of insurance policies is known. While I believe this target idea is a myth, even if it is true, it is outweighed by other considerations above.

Most of us don’t take chances with the people and things that are important to us. It seems short-sighted to gamble with your pharmacy practice that has taken you years to build. Every pharmacist and pharmacy owner should take steps to protect their career and reputation.

Are We Driving Better?

Jen Aultman, Risk Management Consultant, CPhT

In December, the Bureau of Labor Statistics released the 2015 census of occupational injuries. For many years, the number one workplace fatality has been transportation related. 2015 was no different; in fact, transportation deaths rose from 1,984 in 2014 to 2,054 in 2015. Keep in mind this number includes all forms of transportation, including aircraft, water vehicles, and automobile incidents. The vast majority (61.5%) of these incidents were roadway incidents involving a land vehicle. In 2015, more than five workers were killed EACH day (365 days a year) in motor vehicle crashes.

Clearly we are not driving better. Do you think it is safe to say a large number of these deaths could have been prevented? If you do, it is time for action. Begin by looking at your losses, even if you had no fatalities. Look at the details regarding each incident. If those workers are still your employees, sit down and ask them what might have or could have changed the outcome (a crash) in their opinion. So you may be thinking to yourself “Why would I do this when I had no fatalities?” My challenge to you is to avoid ever having one. Getting your drivers to think about their actions when they are in the vehicle is critical to reducing crashes and in turn fatalities. You want your employees to go home to their families each night and I know they would agree.

Please do not ask your drivers to work faster or drive faster than they are able. Speeding, driving more aggressively, and trying to find client homes on a strict timeline are all ingredients that do not properly mix. Realizing you are in business to make a profit, ask yourself how much profit will mean when you have to look a family in the eye after a fatal crash involving one of your employees while on the clock.

OSHA and NETS (Network of Employers for Traffic Safety) partnered to produce a step-by-step program any employers with a fleet can implement and maintain: https://www.osha.gov/Publications/motor_vehicle_guide.pdf. This program provides sample policies within a larger fleet policy. They have also included a worksheet to calculate the cost of a crash to your business. Use this to calculate a crash one of your drivers has had in the past.

Consider some telematics applications. Telematics are devices that track vehicle speed, braking, cornering and other information. You may be surprised by the results. You can motivate your employees with a little challenge to see who has the best/safest driving for the week/month. Some of these apps even disable phone use while a vehicle is moving. Many products are on the market. We suggest you research to find a product compatible with your business. You can do better for your business and your employees by putting your expectations in writing, discussing distractions, and providing training. Do this with every new driver, and annually with everyone. Ask Risk Management how we can help you send your employees home safely each night.
The EEOC and the Future of EPLI

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General Reinsurance provides reinsurance protection for Pharmacists Mutual. As leaders in the insurance industry, they follow important and emerging trends affecting companies across the United States. Pharmacists Mutual wanted to share a recent article they provided about Equal Employment Opportunity Commission and Employment Practices Liability Insurance. For additional information or questions about preventing losses, contact Pharmacists Mutual Risk Management. - Mike Warren, Risk Manager

The U.S. Equal Employment Opportunity Commission (EEOC) has recently released its statistical details for the 91,000 charges of workplace discrimination the agency received in the 2016 fiscal year. Since 2014, the number of charges filed with the EEOC has been steadily increasing. Once again, retaliation leads the frequency of charges.¹

One of the key items to come out of the EEOC’s 2016 statistics is that detailed information concerning LGBT charges are included for the first time. Over the past few years, charges filed by LGBT individuals alleging sex discrimination have steadily increased. In fiscal year 2016, 1,768 LGBT charges were filed as compared to 808 charges in 2013. In 2013 the monetary benefits paid totaled $0.9 million while in 2016 the monetary benefits paid quadrupled to $4.4 million. The EEOC has spent considerable effort advocating for the protection of LGBT rights under the existing anti-discrimination laws.

In 2012 the EEOC concluded that transgender discrimination is a form of sex discrimination on the basis of a perceived failure to adhere to gender stereotypes. In 2015 the agency held that Title VII extends to claims of sexual orientation discrimination.

Recently, the EEOC has increased its focus on areas it considers to be developing and emerging in the workplace. These areas include issues related to complex employment relationships and structures in the 21st century, including “backlash discrimination,” equal pay for all workers and additional protections against immigrant and migrant workers. However, it’s possible this focus on LGBT rights along with other EEOC key areas of enforcement may change, given the priorities of the new Executive Branch administration.

Various new outlets have recently reported that the EEOC will focus on “job growth” moving forward and speculation suggests the agency may be withdrawing from some LGBT discrimination cases due to “administration-related changes.”

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Endnote
¹ A single individual’s charge can allege multiple employment law violations (e.g., disability discrimination and retaliation), hence the type of charge numbers will add up to more than 100% of the total of individuals filing charges.
Marijuana is the most widely used drug in the United States. While it may be hard to define the actual costs to employers, marijuana is linked to decreased motivation and productivity. Currently the ability to quantify the level of THC in the body and correlate it with impairment does not exist. This, along with conflicting laws from state to state, is why it is so important for employers to address marijuana use prior to an issue arising.

Depending on where you are located around the country, marijuana use may be common place. This Schedule I drug has all but escaped the tether of the Federal Government in many regards. By 2018, over 25 states will have legalized medical marijuana and 7 states plus the District of Columbia will have legalized recreational marijuana. Social acceptance of marijuana is on the rise. In 2002, almost 40% of the country saw using the drug once a month as very risky, whereas now just over 26% see this as risky behavior. Not only is the social acceptance increasing, so is the drug content! The amount of active ingredient in the pot grown in 1970 was about 1% compared to today’s content of 13%, with some strains claiming 25% potency.

The cultural changes with the use of marijuana and different aspects of each state’s laws can make navigating employment issues difficult. Issues arise at work with safety, motivation and productivity.

Safety should be the number one concern in the work environment. Federal law requires employers to address impaired workers who contribute to unsafe work environments. Not only are workplace injuries a concern but other side effects of the drug include impaired body movement, difficulty with thinking and problem solving, memory problems and an altered sense of time. Think about how these side effects could affect patient care and prescription filling. A study was conducted by Stanford researchers with nine active pilots, each given a marijuana cigarette (20 mg of THC). They were put in a flight simulator just before smoking it and then again after 15 minutes, 4 hours, 8 hours, 24 hours and 48 hours of smoking the cigarette. Seven of the nine pilots still showed impaired performance after 24 hours. Only one of the pilots actually felt aware of the high.

Employers have options for navigating state laws and maintaining a drug free workplace to ensure safety of workers, patients and customers. Legalization of marijuana does not remove the ability to terminate employees for drug use, especially with the proper policies and training in place. For example, employers can have policies to prohibit employees from showing up drunk or drinking on the job.

- Work with an attorney to develop a drug free workplace with robust policies. These policies should address drug testing, use of drugs (legal or illicit) at work, being under the influence of drugs (legal or illicit) while at work and reporting of suspected use. Drug testing policies should address pre-employment, for-cause and random screening.
- Educate staff about policies. Communicate changes and updates regularly.
- Educate supervisors to recognize impairment and steps to be taken if they suspect an employee is impaired.
- Embrace an overall culture of safety.

Establishing policies is only the beginning. It is important to stay abreast of changes in laws governing marijuana use. While federal laws still maintain marijuana as a Schedule I drug, many groups are pushing Congress to change its status. In addition, as more states legalize its use, laws concerning testing, driving, and employment will likely change as well.
Managing Threats to Data Security

Mike Warren, Risk Manager

Phrases like “data breach” and “cyber threat” are unfortunately used too often to describe new and growing challenges facing pharmacy business. The ransomware attack in May, 2017 that struck 74 countries and hit the healthcare system hard was a wake-up call.

For pharmacies specifically, as they function more and more like medical clinics they are increasingly exposed to similar risks that have plagued hospitals and physician practices. We also see an increased risk as pharmacies handle more and more prescriptions electronically.

What do you need to do to protect your practice?

Cyber threats can be complex and strike from unexpected sources. Recovering from a cyber-attack can be difficult. The good news is that a clear understanding of risk, systematic application of controls, and having a plan of action can significantly reduce the likelihood of an attack, or that the attack will be serious.

Identify Information that is sensitive – For pharmacy, the first thing that comes to mind is Personal Health Information (PHI), but any Personally Identifiable Information (PII) can be a larger risk. PII becomes a risk when a person’s first name or initial and last name are combined with social security, financial account information, credit or debit cards, or other information that links an individual to a financial account.

Review current cyber security procedures – What is protected and what is the level of protection? Consider the following:
- Policies and procedures
- Network and asset protection
- Data protection and recovery
- Anti-malware measures


Mitigate or minimize the exposure – Through administrative, technology, or physical security safeguards.

Prepare for a breach – Have contingency plans in place range for vendors, forensic consultants, attorneys, communications experts and other resources you will need if a breach occurs.

Comply with laws – Make sure you know and comply with state, local, and federal laws with regard to data protection and response to a data loss.

Policies and procedures – Have things in place to permit consistent and ongoing monitoring and to ensure that staff understands what needs to happen in the event of a disaster.

Phish test – Test for both intentional and inadvertent breaches.

Vendor management – Inquire about and require cyber security protections and insurance coverage from vendors.

For additional information about planning and protecting against cyber threats, contact Risk Management at rskmgmt@phmic.com.

Avoid a Bite

Jen Aultman, Risk Management Consultant, CPhT

If you go to customer or client homes on a regular basis, you undoubtedly encounter dogs. Whether the dog belongs to your client or to the neighbors, there might be situations where you are face-to-face with a dog who may not be sure he or she wants you near. There are a few things you can do to potentially deescalate the situation and hopefully avoid being bitten.

You should never approach a dog you are not familiar with. You also should NEVER touch any dog (even your own) without letting it know you are there. Being startled can result in a response the dog would never intend. Remember the dog perceives wherever he or she is as its “space”. You should understand any dog who does not know you may see you as a threat or unwelcome intruder. The goal is to get the dog to agree (mentally, of course) to share space with you. If the dog can accept you each having your own space you will avoid being bitten. The vast majority of dogs are not aggressive by nature, but can become aggressive based on the situation.

If you are suddenly put in a situation where you are meeting a dog in his or her own yard alone for the first time. Start by respecting the space and try to slowly and calmly put
space between you and the dog. You may turn slightly to the side to look like a smaller target but avoid the urge to turn around and run and/or yell. Avoid eye contact with the dog. Dogs see eye contact with a stranger as a challenge/threat. Try to remain as still as possible, and if you move, do it slowly and deliberately. Once the dog loses interest in you, you may back away. Never turn your back on the dog.

Try to get anything you are able to between you and the dog, a purse, a bicycle, the delivery you are planning to make, or perhaps your jacket. Being bitten on the lower arm or calf is better than being bitten on your upper arm or thigh which can cause extreme bleeding. Your fingers, neck or face are places you want to protect as much as possible, so keep fingers curled in. If you fall down and the dog comes toward you or does bite, curl into a ball covering your ears and neck. Try not to scream or roll around. If you are bitten and you have an open wound, immediately wash it with warm soap and water.

Contact your employer immediately and seek medical help if needed. Report the bite to the local animal control authorities or the police. Ask clients to have dogs contained when you plan to visit their residence. If your deliveries or visits are usually unplanned perhaps you should try to schedule a time so the client can have their dog inside or contained. This protects you from injury and the dog from being labeled vicious or your client from having to potentially make a very difficult decision regarding their pet.

### Keys to Successful Workers’ Compensation Claims Outcomes

**Mike Warren, Risk Manager**

When an employee is injured on the job it can have a significant effect on the employee and their family, and on the organization they work for. In situations where the claim is not effectively managed the situation can be far worse.

Here are some tips for achieving the best possible outcomes should an employee be injured.

1. **Report claims as soon as possible**

   Early reporting allows management of the claim and oversight of the medical treatment to begin. When reporting is delayed, one of the biggest dangers is that the injured employee gets lost in the system. Fear, frustration, and uncertainty can drive the employee to less than optimal medical care and into the hands of attorneys.

   When claims are promptly reported, adjusters and medical case managers, if assigned, can guide the employee through the process.

2. **Focus on Return to Work**

   The medical community has long recognized the physical and psychological benefits of mobility and activity following an injury. Procedures that used to require a hospital stay are now conducted on an outpatient basis. The same holds true for injuries to employees. In general, the goal is to get the employee back to productive work as soon as it is medically safe to do so. Why?

   Consider the costs. According to the Integrated Benefits Institute, the direct costs of an employee injury, including lost time payments, medical, legal, and benefit costs, make up only 28% of the total costs of a disability. 72% of the costs are not covered by insurance. These include lost productivity, the cost of hiring and training replacement workers, extra management or supervisor time, and administrative costs associated with reporting and monitoring the claim.

   Costs that are more difficult to measure but are just as real are the psychological costs to the injured worker. Studies have shown that the longer a worker is away from work, the less likely they will ever return to work. Depression, feelings of not being able to contribute, being disconnected from friends and co-workers are all factors that are associated with prolonged absence from the workplace.

3. **Stay in communication**

   One of the biggest mistakes an employer can make is to lose contact with the injured worker. Overwhelmingly, when an employee is injured on the job, it is their first experience. Unlike health insurance claims, they are not sure how or if their injuries will be treated. They may be confused and frightened. They can also be influenced by friends and family, or sales pitches by local attorneys.

   Unless you are prohibited due to a pending lawsuit, stay in touch with the injured worker to check on their well-being, find out if they have any questions, and to keep them connected with the workplace.

4. **If you have questions, ask**

   Employers can get just as frustrated as the injured worker and feel that things are out of control. The system can be complicated and it operates by different rules than general health insurance.

   If you have questions about the status of a claim, contact your adjuster. If they can’t help, ask for a supervisor or call Pharmacists Mutual.
Coming Soon!
An Efficient, Cost-Effective and Time-Saving Resource

Incorporated into a suite of tools and resources to help members manage risk and insurance, Pharmacists Mutual will be providing a Risk Management Center. Anticipated for release later this year, the Center and additional resources will be easily accessible through a portal on our website at no cost to our members.

Of particular interest to pharmacists and pharmacy practices will be a Learning Management System that will allow you to assign, monitor and track training for your pharmacists, technicians and other employees.

The resource also contains additional tools that include best practices for preventing and managing loss, tools for investigating and reporting, auditing program development, and human resources management forms, sample programs and guidance.

We are looking forward to providing our members with this cutting-edge resource. As always, if you have any questions about managing risk in your practice, you can contact us at rskmgmt@phmic.com.

More information to follow!