

PHARMACY

Risk Management

A Risk Management
Newsletter provided
as a service by
**Pharmacists
Mutual** Insurance
Company

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The editorial board of *Risk Management in Pharmacy* has elected to experiment with the format of this publication to make it more "reader friendly." Many readers have short intervals of time for reading this kind of material. This new format, with shorter items and more focused lead-ins, should aid those readers. Of course, if any reader wants more in-depth information, it's available by contacting the editor. Comments and suggestions about the new layout are invited. Send them to:

Editor, *Risk Management in Pharmacy*, c/o Pharmacists Mutual, PO Box 370, Algona, IA 50511-0370, call 800-247-5930 ext. 229, or e-mail us at phmic@ncn.net.

Aftermath of North Dakota Flood... many policyholders caught off guard without coverage for building, contents or loss of income. The flood peril is not generally covered under regular business or homeowners policies.

Coverage is available for some damages. A "sewer and water backup" endorsement is available at additional cost to protect property and fixtures below grade. Federally backed flood insurance is available. Limited coverage is expensive, but if a flood is likely... There's a 30 day waiting period between application and effective date, so you have to be somewhat of a forecaster. Loss of income coverage from the flood peril is tough to find.

Recommendations... Watch the long range forecast for your area. If you perceive the need and are eligible, purchase federal flood insurance through your field rep or another insurance agent. At the very least, purchase the "sewer and water backup" endorsement to your existing policy. For the loss of income hazard, use loss prevention. Formulate a plan for evacuation of inventories and/or a business plan to do business temporarily from another "dry" location.

Kudos to ND pharmacists! We congratulate three of our policyholders in Grand Forks, ND. With the flood imminent, together the three set up a temporary pharmacy to serve the needs of their community during the disaster. Dennis Johnson of Wall's Medicine Center, Ron Mattson of The Medicine Shop, and Jeff Theige of Medicap Pharmacy of Grand Forks went above and beyond the call in providing these services to the area. Pharmacists Mutual is proud to be associated with professionals like these.

Take the time to understand your policies. Our claims experience exposes the fact that few policyholders take the time to read or understand their policies. Do yourself a favor - when your policy is delivered, make the time to review it. If you have questions about certain coverage scenarios, ask your field rep or call 800-247-5930. This will help you avoid gaps in coverage.

Wisconsin and Pennsylvania... The Pharmacists Life Insurance Company, a subsidiary of Pharmacists Mutual Insurance Company, was recently authorized to sell life insurance and annuities to Wisconsin and Pennsylvania pharmacists. The Pharmacists Life has been providing term and whole life insurance, as well as retirement annuities, since 1979, and now serves pharmacists in 21 states. For more information, contact your field rep or call 800-247-5930 extension 26.

Pharmacists Mutual hires Group Insurance Specialist. Ms. Nancy Thomas is a seasoned professional in the life insurance, health and dental plans, long term care insurance, and benefits management areas. She has been brought on board to consult with our customers, individual or business, and help them manage these risks. Give her a call at 800-247-5930 extension 240.

Not too early to think about winter driving... have your vehicle tuned up. Keep the gas tank at least half full if possible. If you are stranded, stay with your vehicle. This is an ideal situation for a cellular phone.

Winter driving emergency kit... inside the passenger compartment - a "Call Help" sign, blanket, flashlight, first-aid kit, package of replacement fuses, nonperishable foods, Ziploc bags and toilet paper, and nonalcoholic beverages (don't leave these in your vehicle in freezing conditions). In the trunk - a jack and a piece of plywood for support, spare tire, oil, coolant, windshield washer fluid, small ABC rated fire extinguisher, spare radiator hose or stop leak sealant, extra fan belt, locking pliers (to use as a clamp), wrenches, slotted and phillips screwdrivers, jumper cables, a nonflammable empty container for gas, and a small shovel.

Two hospitals sue their own pharmacist for Rx errors. A large Omaha hospital alleges its employed pharmacist made a mistake. When mixing two IVs, the pharmacist is alleged to have QS'd with 14% saline solution instead of normal saline. Two patients made claims against the hospital. The hospital settled both claims for a total in excess of one million dollars. The hospital has now sued its employed pharmacist to get back its money. In a separate case, a hospital in the Southwest has sued its former employed pharmacist for failing to catch a physician's error. The hospital and physician paid a settlement and now the hospital wants its money back.

Each hospital contends it has the right as an employer to recoup any loss it actually pays from any employee who makes a mistake and causes the hospital to pay. One of the hospitals says it would not have sued its pharmacist had the pharmacist not purchased an individual professional liability policy, but it contends it would have the right to do so regardless of whether such a policy exists.

The important question is the right of the hospital to subrogate back against its employee when the hospital alleges the employee was negligent. If the hospital can sue their employees, can they "pick and choose" which to sue — only those with insurance — only those they don't like — only those close to retirement? When an employee purchases an individual policy, who is the employee trying to protect — himself/herself or the hospital? Who will pay the additional premiums if individual pharmacist professional liability starts protecting the hospitals? Can professional employees trust the hospital to not sue them if the employee does not purchase an individual professional liability policy? Would a hospital sue if the pharmacist has a savings account? What if the employed pharmacist has a retirement account or owns a house?

These are interesting times.

Medicare Supplier Bond... With the recent passage of the 1997 Balanced Budget Bill (HR2015), Medical Equipment Suppliers will be required to maintain a minimum of \$50,000 Surety Bond if they bill directly to Medicare. This bond **appears** to be required by 1/1/98.

Pro Advantage Services, Inc. can handle this bonding need. If you have questions, contact 800-247-5930 extension 256 or 352.

Contract Sale risk management... Many pharmacies change ownership through a contract sale these days. Of course, both parties need an attorney for the transaction. Good risk management might also involve your field rep and a financial planner. What if... the buyer passed away before paying off the contract? ... the seller passed away before the term had run? ...the estate needed a balloon payment to settle affairs? A life insurance policy on each party, with the other being owner and beneficiary, will ensure available funds to complete the contract upon the death of either party. A disability policy could provide continuity of payments should the buyer become unable to work for a lengthy period. The basic principle of risk management is to invest in any economically feasible tool available to control or prevent whatever risks are deemed to be the most probable to occur. These relatively inexpensive policies fit the bill.

Dryer vent fires... Our claims files from last winter are full of claims on fires which started in dryer vents. Animal and insect nests and/or lint buildup can cause vent blockage, which can cause overheating, which can cause short circuits, which can cause fires.

Loss prevention- Check, or have checked, your dryer vent pipe to assure that the exhaust from the dryer can escape without obstructions.

Crooks are getting smarter. The best way to fight back - make your store(s) a less attractive target to thieves. The pros will go look for an easier mark. Keep minimal cash overnight. Keep minimum amounts of street drugs on hand. Erect all feasible barriers and equipment to delay entrance to the premises and accessibility to valuables. Call 800-247-5930 extension 229 for a consultation, or contact your security company for a review of your equipment and procedures.

Cell phones and driving - a deadly combination... Insurance Institute for Highway Safety test results show a definite correlation between cell phone use and increased risk of serious accidents. And, the same test shows that using a "hands free" model does not better your chances. The simple fact is that when you are talking on a cell phone, you are not concentrating on the task at hand - driving.

Best advice... Pull over to a rest area or the side of the street when you must make a call or when you receive a call.

Do you have "traps" in your lease? If you have ever read your lease, it was probably when you originally signed it or during a dispute with your landlord. Recent claims for uninsured damages to air conditioners, doors, and interior walls, point out a serious problem. If you don't have time to read the entire lease, at least read the section on lessee's (tenant's) responsibilities. If you have questions about language or intent, contact your attorney. If you think you may have coverage gaps for your responsibilities, contact your local PhMIC field rep.

Are you prepared for the Year 2000 Millennium Bug? Will your computer system recognize '00' in a YY information field as the year 2000 or the year 1900? Time for risk assessment and correction, if necessary, is now - not the autumn of 1999. This is not just a mainframe or mid-range problem. Some of the most "at-risk" systems are PCs and LANs. Ask your software and/or hardware vendor provider(s) for written certification that your system is Y2K "compliant." Not "ready," not "enabled," COMPLIANT! If the system isn't compliant, find a vendor(s) that can provide you with the service, hardware, and certification you need to hurdle January 1, 2000 in full stride.

Compounding Pharmacy — Where is the line?

Compounding not only contains an element of “art” that many pharmacists find enjoyable and professionally satisfying, but it can also be profitable. Compounding pharmacy allows a physician the flexibility of treating a patient with a combination of drugs not sufficiently popular to warrant the costs and time required to manufacture the compound for general distribution. Recognizing this, federal law exempts extemporaneous compounding from FDA registration.¹ A pharmacist who manufactures a compound, however, must meet the same federal requirements as a commercial manufacturer.

The problem with compounding is there are few set rules and it is often difficult for the pharmacist to determine where the line exists between compounding and manufacturing. The difference is important because compounding is legal for a licensed pharmacist while manufacturing places the pharmacist under the federal jurisdiction of the FDA and requires more paperwork and additional licenses. Compounding is a part of the practice of pharmacy. Manufacturing is not.

The National Association of Boards of Pharmacy define compounding and manufacturing in its Model Practice Act. Basically, the Model Practice Act defines compounding as the preparation of a drug as the result of a prescription or initiative based on the physician, patient, pharmacist triangular relationship. Compounding is for sale at retail, not wholesale. A compounded prescription is prepared for a particular patient, but the pharmacist may prepare larger quantities in anticipation of routine prescribing patterns. Not all states have enacted the Model Practice Act.

The FDA does not have a good, usable definition of compounding. Instead, the FDA

takes the position that all compounding is manufacturing and thus is subject to FDA control, if the FDA wanted to involve itself. According to the FDA, federal law exempts the compounding pharmacist from registration, but not from the other requirements of the law. In effect, the FDA chooses not to involve itself in compounding.

Compounding pharmacists should understand what factors the FDA considers in determining whether a mixture is an exempt compounded prescription or a manufactured drug requiring a new drug application. These factors are listed in a 1992 FDA compliance policy guideline.² In no particular order, the factors indicating manufacturing to the FDA are: [1] soliciting compounding business for a particular drug; [2] the compounding of commercially available products (i.e. generics); [3] compounding inordinate amounts of a drug; [4] using commercial scale equipment; [5] offering compounded drugs at wholesale; [6] distributing inordinate amounts of compounded drugs out of state; [7] failing to operate in compliance with applicable state pharmacy laws.

Pharmacists should avoid crossing the line from compounding to manufacturing. FDA enforcement may be pervasive and expensive. FDA actions may include seizure, injunction and prosecution. In addition, most boards of pharmacy will use guidelines similar to those of the FDA, and board action may be equally painful. Fines, penalties and associated defense costs, whether from the state board or the federal government, are usually not covered by insurance.

Compounding pharmacists should recognize the fine line between manufacturing and compounding. Sell compounded drugs only on a physician’s prescription for a particular patient, and sell only at retail.



Ken Baker, R.Ph., J.D. Vice President, General Counsel, Pharmacists Mutual Insurance Company

¹ 21 U.S.C. 360(g) in connection with 21 CFR 207.10(a).

² FDA Compliance Policy Guides 7132.16, March 16, 1992.

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Risk Management challenge

The winners of the two \$50 prizes for their solutions to last issues' challenge are Bradley Mowry of Missouri and Patrick Mascaro of Ohio. They submitted the most comprehensive plans to prevent a reoccurrence of the disappearing bank deposits. The basis for the solution(s) to the problem is a system of checks and balances on **all** the people who handle the receipts. Each cashier should be responsible for balancing his/her individual cash drawer. When they balance, they should verify with a manager, and both of them should sign off on a duplicate master deposit slip and place the deposit in the vault. When the armored car pickup occurs, the manager and driver should verify and sign off on the master deposit, attesting to the number of deposits transferred to the bank bag. (The master deposit slip must be dated and easily identifiable as the pharmacy's.) Then, when the bank bag arrives at the bank, there is a

paper trail with two people verifying the contents all along the line. Job rotation was mentioned by many submitters. That is an effective way to prevent over-dependence, without checks and balances, on any one person.

Not mentioned by any of the submitters but certainly worth bringing up is checking out the bank's and the armored car services's policies and procedures. If they are not up to standards, consider moving your accounts to another bank and/or changing pickup service vendors. Another unmentioned loss prevention tool is enforcing mandatory vacations for money handlers of at least one week duration. This is usually enough time to expose any irregularities in cash handling.

Most of these problems happen because victims assume everyone else is honest and competent. Unfortunately, we all know that is not the case these days.

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P.O. Box 370
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