



Compounding or manufacturing: the insurance perspective

The question of whether a practice is either compounding or manufacturing is one that continues to be asked. Most of the time, the answer is less than clear. Imagine that there is a spectrum with compounding on one end and manufacturing on the other. It is easy to determine compounding when an individual patient brings in a single prescription to be compounded. It is also easy to look at the large manufacturing companies and say that they are manufacturing. What about the myriad of practices in between? How does insurance deal with compounding practices?

Compounding is one of the components of Pharmacy Services that is defined in the Pharmacy Professional Liability endorsement and the Individual Pharmacist Professional Liability Policy. For purposes of coverage, the first step is to look to the definitions contained in the policy. The primary definition is the preparation of a product in response to a practitioner's prescription for a particular patient. This is the well-known triad: the patient, physician, and pharmacist relationship.

Compounding also includes preparation of products in anticipation of such prescriptions based on a history of receiving these prescriptions. Assume, for example, that your pharmacy is located near a dermatologist and for the last few months you have received prescriptions for a particular compound twice a day. You could choose to prepare both prescriptions at the same time, even though you

haven't yet received the second prescription.

The definition of compounding also includes other compounding practices approved by the board of pharmacy in your state. This would include practices that do not otherwise fit the definitions above, for example, the compounding of products for use in the physician's office or for sale in your pharmacy as an OTC product. Note that the triad is missing in both of these situations and would therefore not meet the previous definition of compounding. How do you know what is allowed in your state? Refer to the Pharmacy Practice Act and the pharmacy board's regulations for your state. Most states do not allow the compounding of products for OTC sale. Many states allow the compounding of products for use in

the physician's office. However, there may be restrictions on the types of products or the amounts that are allowed. Most states prohibit the compounding of a product that will be distributed to another pharmacy or to a physician and then subsequently re-sold.

Manufacturing is also defined in the Pharmacists Mutual policies and it is excluded from coverage. By definition, manufacturing includes the promotion and marketing of particular drug products (this is not the promotion and marketing of the fact that your pharmacy is a compounding pharmacy). Manufacturing also includes the preparation of commercially available products for re-sale.

The closer a practice moves towards

the manufacturing end of the spectrum, the more likely the practice will garner the attention of the FDA. The FDA is charged with the regulation of the drug supply in this country. This activity has generated some friction with

state boards of pharmacy and compounding pharmacists. This friction results because of the spectrum of activities outlined above. No one knows exactly where the line is crossed between compounding and manufacturing. Using the dermatologist's prescription example above, what would be a reasonable amount to prepare in anticipation of prescriptions? Most pharmacists would agree one day's supply is fine; so would two day's supply or three. What about 6 months? A year? At what point can the compounding pharmacist be assured that the compounded product is still potent, safe, and sterile (if required)?

Many times the pharmacist does not know the line has been crossed until regulators appear on the doorstep. Then it is too late to practice risk management. There are three steps you should take before you cross the line between compounding and manufacturing.

First, you should survey your compounding practices. Make sure you have the proper training and the proper equipment for the types of compounding you are doing. Look closely at any compounding practices that do not involve the triad.

Second, review your state's Pharmacy Practice Act and pharmacy



**Don McGuire,
R.Ph., J.D.,**
General Counsel,
Pharmacists Mutual
Insurance Company

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Report early – Save money



Vic Garman, SCLA,
Director of Claims,
Pharmacists Mutual
Insurance Company

Much has been said about how important it is to “get off on the right foot.” When it comes to handling any insurance claim, what is properly or improperly done at the beginning of the claim can, and often does, have

a lasting implication to how the claim is ultimately resolved.

The importance of the first notice of loss to the insurance carrier cannot be over-emphasized. One of the problems in the claims process is the time delay for us to receive the first notice of loss or first notice of suit. We can readily reference several claim studies that reflect a direct correlation between loss notice delays and the increased cost of

claims.

Most of the obstacles presented by untimely or incomplete notices of a loss seem to consistently point back to one thing – communication. Rarely is there any intention to NOT report the loss. More often than not there are legitimate reasons for the delay, i.e.: correct reporting forms not on hand; absences of supervisors or personnel responsible to report losses; insurance carrier reporting #'s not readily available; other priorities; etc.

Here are examples of the added costs from a one day delay of reporting a claim:

- Automobile loss - \$30 per day car rental for each claimant and/or insured involved
- Homeowners loss - another day of additional living expenses
- Workers Compensation - additional day of workers compensation benefit = \$71.42 (\$500 average weekly wage/ 7 days)

- Liability Medical Pay Coverage or Workers Compensation - additional day of medical benefit = \$75-100 dependant on exam service level
- All Loss Coverages - loss of control of the claim to an attorney – cost = ?

When you help us control claims costs, Pharmacists Mutual can pass those savings on to you in the form of lower premiums, dividends, and additional services.

If there is one thing you can do to help us control claims costs, it would be to take any internal measures necessary to ensure all claims are reported to us immediately. Set a goal to see that this is accomplished within 1-2 business days.

I would appreciate hearing any examples of what you have done within your operations to improve this process. You can reach me at 800-247-5930 ext. 7420 or vic.garman@phmic.com.

More on pharmacy thefts!

Another good idea to combat pharmacy theft was brought to our attention recently. It's a very simple solution to law enforcement's effort to track stolen drugs and the people who steal them. The FBI and FDA, along with local law enforcement agencies across the country, are asking all pharmacies to mark the bottoms of their shelf stock bottles with a symbol unique to your phar-

macy. This doesn't have to be fancy or elaborate; marking with a Sharpie® pen would serve the purpose just fine. Then if the bottles are taken and later recovered by law enforcement, those markings will help in tracking the traffic of the stolen drugs.

A new promising theft deterrent product has also come to our attention. The smoke cannon is an adjunct to an existing alarm system. When the alarm

is tripped and signals your alarm station or law enforcement center, it also triggers the smoke cannon to emit a dense but harmless cloud of smoke that completely fills an enclosed space within about 15 seconds. Thieves cannot see to steal and are usually so startled that they leave by the way they came in to escape the smoke. Google™ “smoke cannon” to see the options.

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Compounding -- continued

board regulations. Look for provisions that address the types of activities in which you are engaged. Do not assume that because someone else is also engaged in that practice that it is permissible. Because the language of the insurance policy is tied to the activities that your state board allows, this step is crucial to any future coverage determinations.

Third, look at the motivation behind your compounding practices. Does the patient need a compounded product because of allergy problems,

route of administration, or other such reasons? Greed has been at the heart of some of the most well known compounding tragedies in the last few years. Profit is not a dirty word, but it should not come at the expense of the patient's health and safety. The treatment and care of your patients should be your primary motivation.

Following the three steps outlined above should enable you to distinguish whether your practice is compounding or manufacturing, and determine if you are in compliance with your state's regulations.

Workers Compensation claims handling changes

By Vic Garman, SCLA, Director of Claims, Pharmacists Mutual Insurance Company

Changes are never easy, no matter how large or small they might seem. In the 4th quarter of 2005, we began a process to improve how we manage our workers compensation claims. An important step in that process was hiring a leader who had the experience and capability to make this program a success. We were fortunate in our search process to hire Rich Mahoney as our Workers Compensation Claims Manager. Mahoney comes to Iowa from the great state of Louisiana, having endured firsthand the destruction of Hurricane Katrina.

Mahoney has **30+ years of experience in the workers compensation area** including previous experience managing a third party administrator as well as serving in claims management or supervisory roles with other insurance organizations.

The day-to-day oversight and management of the workers compensation program will be Mahoney's responsibility. He will **also oversee our third party administrator program partner, Crawford and Company**, who we began working with in November 2005.

Mahoney has set up file referral, monitoring and evaluation processes between Pharmacists Mutual and Crawford to ensure our claims are managed properly. Prior to going live with our new program partner, we developed detailed Client Service Instructions to be distributed to each of the Crawford service offices. These instructions detail how Crawford is to handle the claim process and how they are to interface with us and our clients.

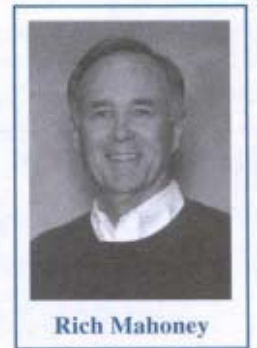
The process works as follows:

- The insured sends all first reports of injury to PhMIC the same day of the incident.
- We set up a new claim in our system within 24 hours of receipt.
- All lost time cases have a 30-day diary set for Mahoney to review.
- We fax/e-mail all claims to Crawford within hours of setting up the claim.
- Crawford sets up the file in their system with a goal to make three point contacts (injured worker, employer, doctor) within 24 hours.
- Acknowledgments containing appropriate contact information go out from Crawford to the employer with a copy to us the same day the file is set up.
- Telephonic Nurse Case Managers at Crawford triage all claims upon receipt.
- Crawford investigates the claim for compensability and provides us with their recommendation to pay or deny.
- Any claim over a prescribed dollar amount is brought to Mahoney for review and approval.
- All related medical bills are put through Crawford's automated bill review software program.
- We process indemnity and medical payments.
- We follow the claims through to conclusion with Crawford.

We have established weekly meetings with all PhMIC claims examiners and supervisors to discuss any issues that might arise. On a monthly basis,

the PhMIC examiners and Mahoney have teleconference calls with our Client Service Manager at Crawford to find collaborative ways to improve our claims handling.

Medical case management referral guidelines have also been created to ensure Dr. Stephen Richards', PhMIC Medical Director, ongoing involvement in medical case management. Richards and Mahoney recently traveled to Chicago to meet with Crawford's Medical Director to further discuss medical and disability management strategies.



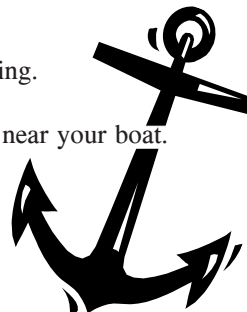
Rich Mahoney

Mahoney will also be performing field audits of select Crawford service offices to review files and have face-to-face discussions with the examiners handling our files. The goal of these reviews will be to provide technical and administrative oversight, maintain control, improve consistency and drive improved claim results.

We believe that this program and this partnership will provide us with better technical oversight to our workers compensation claims. If you have any questions or concerns regarding this, feel free to contact me at 800-247-5930, extension 7420, or Rich Mahoney at extension 7447. 📧

DOs AND DON'Ts OF BOATING SAFETY

- **Do** wear life jackets. They float. You don't.
- **Do** know the water and environment where you're boating.
- **Do** keep a good watch while moving.
- **Do** shut down engines when swimmers are in the water near your boat.
- **Do** observe the nautical rules of the road.
- **Do** keep a balanced load and a trim boat.
- **Do** check the weather before going out.
- **Do** have your boat properly registered!
- **Do** have your boat properly insured!
- **Don't** overload your boat.
- **Don't** sit on the gunwale, bow or any place not designed for seating.
- **Don't** stand in a small boat.
- **Don't** drink and boat.
- **Don't** lose your temper. You're bound to see some stupid things from others. 📧



Pharmacists Mutual Companies:

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Editor: Jack Williams
Assistant Editor: Shelly Brown

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Open letter to compounding pharmacists

To All Compounding Pharmacists:

Pharmacists Mutual Insurance Company (PhMIC) encourages practices that enhance the quality of patient care. We initiated the marketing of a total quality management program that can help pharmacies ensure quality delivery of pharmacy services. We offer risk management ideas through this newsletter and on our website. PhMIC supports pharmacy education and professional services through state and national associations.

In recent years, we have become aware of the special risks (as well as the patient benefits) associated with the practice of compounding. While many insurance companies have withdrawn from this market, PhMIC is dedicated to continuing our practice of insuring compounding pharmacies. We understand that quality compounding practice procedures are being developed and implemented to ensure safe patient care. These steps will go a long way to ensure insurance affordability in this specialized practice setting. As another means of encouraging quality compounding procedures and standards, we have been working closely with the recently established Pharmacy

Compounding Accreditation Board (PCAB™) – an independent, voluntary standards organization created for and by the profession of pharmacy.

Pharmacists Mutual Insurance Company urges each of our insured compounding pharmacies to evaluate the value of accreditation to your practice. You can learn more about this on the PCAB website at www.pcab.info or you may click on the PCAB link on the Pharmacists Mutual website at www.phmic.com. Application for accreditation can also be made directly on the PCAB website.

We think you will agree that PCAB accreditation is an investment in the future of compounding pharmacy. You will have the pride of knowing your pharmacy is an “Accredited Compounding Pharmacy™,” and your patients will know that their pharmacy has established quality control procedures for their safety. In addition, accredited pharmacies will receive special consideration from us on their future insurance rates. Pharmacists Mutual will continue working with the pharmacy community to provide the best insurance and risk management services in all areas of pharmacy practice.

Questions or requests concerning

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

call **800-247-5930 ext. 7229**
or e-mail jack.williams@phmic.com

Sincerely,



Edward T. Berg, MBA, CPA, CPCU
President & CEO

Pharmacists Mutual Insurance Company

Pharmacists
Mutual Companies

P.O. Box 370
Algona, IA 50511-0370

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