



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.

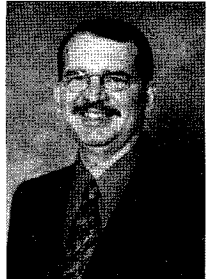
The closer a practice moves towards

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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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. ■