Physicians and Compounding Pharmacies: Liability Issues Related to the Prescribing and Investing in Such Ventures

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The health care industry has seen a recent, dramatic increase in the number of compounding pharmacies entering the marketplace due to a number of reasons. Compounding pharmacies and the use of their products are more accepted by physicians. It is more recognized that compounded drugs may provide relief to those patients who, for some particular reason, cannot use a non-compounded drug or do not experience relief from that drug. Federal and state initiatives providing regulation and oversight in the production and use of such drugs have addressed some of the safety concerns that hamper the industry's acceptance. Financial considerations play into this as well. Compounding pharmacies are very lucrative. Revenue derived from a compounded drug may be many times higher than that of single-ingredient drugs. These factors have resulted in more-prevalent investment opportunities for physicians if properly structured. With these positives come negatives as highlighted by recent events where patients died because of the sterility of the compounding drugs and the conditions in which those drugs were produced. Also, there are conflict-of-interest and fraud-and-abuse concerns. In turn, these negatives may result in liability to physicians if they do not properly review and monitor the compounded pharmacies and their operations if they intend to refer or invest in that pharmacy.

What Is a Compounding Pharmacy?

A compounding pharmacy is a licensed pharmacy that provides an avenue for physicians to prescribe certain pharmaceuticals that individually are approved by the U.S. Food and Drug Administration (FDA) but not approved in their compounded state. FDA defines pharmacy compounding as the "practice in which a licensed pharmacist combines, mixes, or alters ingredients in response to a prescription to create a medication tailored to the medical needs of an individual patient."[1] FDA recognizes that a compounded drug may serve an important public need if the patient's condition may not be treated properly by a single FDA-approved drug.[2] FDA is the primary regulator of commercial pharmaceutical manufacturing, while pharmacies such as large chain and "mom and pop" drug stores and in-store pharmacy counters are regulated by the states. This regulatory scheme results in inconsistent regulation of compounding pharmacies because each state may address such pharmacies differently.

What Are the Instances Where a Compounded Drug May Be Used over an Individually Approved FDA Drug?

A compounded drug may be used when a patient does not respond optimally to the use of, or there may be a shortage of, a particular drug that would normally be prescribed.[3] In other instances, the patient may not tolerate a particular drug due to her medical condition or allergies.[4] Generally speaking, the physician may prescribe the compounded pharmaceutical to the patient as long as the physician has a sufficient level of knowledge of the patient's condition and the drugs being compounded and has obtained the informed consent of the patient. All of these conditions are subject to the regulatory and licensure rules of the state where the physician practices medicine.

Physician Liability for Prescribing Compounded Pharmaceuticals

Since the 2012 outbreak of fungal meningitis cases resulting from the use of compounded drugs, federal and state authorities have issued significant safety measures related to compounding pharmacies.[5] The Centers for Disease Control and Prevention has maintained a current multistate case count of meningitis cases involving infections and deaths.[6] In reality, there were other cases that preceded the well-publicized fungal meningitis outbreak that indicated possible safety concerns with compounding pharmacies.[7]

Physician liability for prescribing compounded drugs revolves around the choice of the compounding pharmacy used and the need of the patient to utilize the compounded drug over a single FDA-approved drug.[8] As to the choice of compounded drug used, the major issues pertain to the environment and conditions of the facility used and whether there have been instances where compounds have been exposed to contamination. To reduce the liability exposure, a physician should conduct due diligence on the pharmacy and its licenses and certifications, its safety record, and its notification and recall procedures in the event it determines a contamination issue has occurred. While Congress recently passed legislation to improve drug safety in the compounding area,[9] it is acknowledged that it is a first step to addressing these concerns.[10] Therefore, it is incumbent upon the physician to be aware of the conditions of how the prescription is being compounded because he generally directs the prescription to the compounded pharmacy.

As for liability related to patient care, the physician should take the necessary steps to ensure the compounded drug should be prescribed over an FDA-regulated drug.[11] If the physician prescribes an FDA-regulated drug, he may rely on the fact that it has been determined to be of sufficient quality, safety, and efficacy because it passed through the New Drug Application process.[12] If a physician determines that the compounded drug is required, the due diligence regarding the regulatory requirements it satisfied is not sufficient to reduce liability. The physician also should become knowledgeable as to the source and grade of the pharmaceuticals used in compounding, the sterility of the environment where the

drug is compounded, what equipment is used, and other factors related to the safety of the compound pharmaceutical itself.

The regulatory climate has certainly changed in regard to governmental oversight to ensure safety in this area. As mentioned, the recent bill passed by the U.S. House of Representatives establishes a platform by which additional regulations may be developed in this area. Because the states are the primary enforcement vehicle, most of the legislative initiatives have been at that level. As of September 2013, state initiatives resulted in a total of 27 bills or resolutions filed in 16 states, with action taken on 25 of them. This resulted in nine being adopted or enacted in law.[13] It is expected there will continue to be increased regulations and enforcement in the future.

Physician Liability for Investing in Compounding Pharmacies

Physician investment opportunities in compounding pharmacies have seen a dramatic increase in light of the expansion of the industry. While referring to the compounding pharmacy may not be a requirement to qualify for ownership, the vast majority of those investing will do so. The referral itself creates conflicts of interest and fraud and abuse issues that must be addressed especially because the liability is not just for a compounded drug. Rather, the referral is directed to the compounding pharmacy in which the physician maintains an ownership interest.

The American Medical Association (AMA) has raised the ethical issue of physicians referring to an entity outside the medical practice in which the physician has an ownership interest. In Opinion 8.0321, AMA has issued the ethical standards that should be followed when there is a referral to an entity in which the physician maintains any type of financial interest.[14] These standards include:

- Ensuring referrals are based on criteria that are objective and medically relevant;
- The arrangement is appropriate to deliver high-quality services and products that fall within the limitations imposed by law;
- Steps have been taken to address conflicts of interest; and
- The patient is informed of the financial interest.[15]

While these standards address the ethical issues related to the physician referral to a pharmacy where he has a financial interest, they only indirectly address the fraud and abuse issues that must be examined.

From a federal perspective, there are legal implications related to the Anti-Kickback Statute[16] (AKS) and the Stark Law[17] (Stark) when there are referrals to an entity where the physician has a financial relationship. Many times, the compounding pharmacies will not accept reimbursement from governmental payers in its attempt to bypass those concerns. In reality, this is only one half of the battle. States commonly incorporate federal law into state law so the same issues must be addressed even when removing governmental payers from the equation. In addition, many states have separate statutes and regulations that expand into tangential

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areas related to kickback, self-referral, and conflicts of interest that must be addressed as well. From a physician standpoint, this may raise not just fraud and abuse concerns but licensure concerns as well.

To ensure the conflict-of-interest and fraud-and-abuse issues are properly considered, a physician must conduct a legal review delving into contemplated referral patterns, internal processes dealing with patient involvement and disclosure of the referral, and the impact of the federal and state fraud-and-abuse and licensure concerns. It is highly likely that deviation from legal compliance in one area will have a domino effect and implicate some or all of these other issues. A review of one pharmacy deal will not address these legal concerns related to investment in other pharmacy investment opportunities because each compounding pharmacy is a separate and distinct operation. Due to the sensitive nature of the authority in this area, particular attention must be paid not only to the conflicts-of-interest and fraud-and-abuse rules but also the aforementioned issues regarding physician utilization of the compounding pharmacy.

Do the Negatives Outweigh the Positives of Physician Involvement in Compounding Pharmacies?

When dealing with any type of patient care that implicates regulatory concerns, liabilities generally will be present. Physician involvement with compounding pharmacies is no different. The key to reducing liability and ensuring compliance is engaging in a thorough due diligence of the opportunity and review of the underlying operations of both the pharmacy and the physician's practice. A thorough review allows the physician and his advisors to determine whether liabilities may be addressed. This due diligence must not just be from the pharmacy standpoint. The physician is the person making the referral and upon whose judgment the patient will rely. Since this may implicate more than just financial loss but also licensure concerns, this should be factored into the analysis. There are opportunities where physician involvement with compounding pharmacies is acceptable. The key to a successful relationship with a compounding pharmacy is to determine the right pharmacy and incorporate the proper patient care.

1 U.S. Department of Health & Human Services, Food and Drug Administration (FDA) (2013). The Special Risks of Compounding Pharmacies, *available at* www.fda.gov/ForConsumers/ConsumerUpdates/ucm107836.htm.

2 *Id.*

3 Wynkoop, K. (2012). Compounded Products: Use, Regulation, and Risk. OMIC Digest (Fall 2012. Vol. 22, No. 4), *available at* www.omic.com/wp-content/uploads/2012/12/Fall-Digest-11-30-12.pdf.

4 Sellers, S. and Utian, W (2012, Dec. 19), Pharmacy Compounding Primer for Physicians: Prescriber Beware, *available at* www.medscape.com/view-article/776329.

5 FDA (2013). The Special Risks of Compounding Pharmacies. FDA identified that the Fall 2012 fungal meningitis outbreak was the result of contamination of injectible steroid medications.

6 Centers for Disease Control and Prevention. Multi-State Meningitis Outbreak—Current Case Count, *available at* www.cdc.gov/hai/outbreaks/meningitis-map-large.html.

7 FDA (2013). The Special Risks of Compounding Pharmacies. In August 2011, FDA issued an alert regarding serious eye infections from a repackaged product. From November 2011 through April 2012, patients using a compounded pharmaceutical suffered fungal eye infections. In both instances, the infections resulted in various levels of vision impairment.

8 Sellers, S. and Utian, W (2012, Dec. 19), Pharmacy Compounding Primer for Physicians: Prescriber Beware.

9 HB 3204, the Drug Quality and Security Act, *available at* beta.congress.gov/bill/113th/house-bill/3204/text. The U.S. House of Representatives passed HB 3204 on September 28, 2013 that was subsequently passed by the U.S. Senate on November 18, 2013. At the time of press, President Barack Obama had not signed the legislation into law.

10 Reuters. (2013. Feb. 25). U.S. Congressional Panels Agree on Bill to Regulate Drug Compounding, *available at* www.reuters.com/article/2013/09/26/us-compounding-pharmacies-legislation-idUSBRE98P00B20130926.

11 Sellers, S. and Utian, W (2012, Dec. 19), Pharmacy Compounding Primer for Physicians: Prescriber Beware.

12 *Id.*

13 National Conference of State Regulators. (2013) State Regulation of Compounding Pharmacies. *Available at* www.ncsl.org/research/health/regulating-compounding-pharmacies.aspx.

14 American Medical Association (AMA). AMA Opinion 8.0321, *available at* www.ama-assn.org//ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion80321.page.

15 *Id.*

16 42 U.S.C. § 1320a-7b.

17 42 U.S.C § 1395nn.