Frequently Asked Questions Regarding Compounding Pharmacies

by Jeffrey S. Baird, Esq.

Editor's Note: *part one of a two-part article.*

Over the past several years, there has been a steady growth of compounding pharmacies. This is due to a number of factors, including the recognition by physicians of the clinical benefits of medications compounded specifically for patients. As compounding proliferates, a number of legal issues arise. Part one of this article discusses a number of important "frequently asked questions" pertaining to compounding operations. Part two of this article in the November issue will discuss additional FAQs.

Q: Please give a general overview of state/federal regulations regarding sampling. Is there a legal way to do it, such as obtaining a patient specific pre-prescription?

A: While sampling and starter packs are common with commercially-available drugs, providing compounded drugs in these formats present significant challenges. The majority of states prohibit compounding in advance of receiving a patient-specific prescription. While many states allow compounding in advance based on a history of prescriptions, this would not cover the compounding of samples. Absent state law allowing compounding in advance of a prescription on some basis other than a history of prescriptions that would support the compounding of samples, the compounding of samples would not fit within state compounding guidelines, and would be considered by the Food and Drug Administration to be manufacturing. Although in-office use of compounded medications by a physician may be permissible, many states also restrict the ability of a physician to dispense compounded medications to the end-user, which would prohibit the physician from dispensing samples to the patient. Whether or not there is a way to provide samples of compounded drugs to physicians to provide to patients depends on state law.

Q: Most states allow the pharmacy name and information to be included on a pre-printed prescription fax form. I believe that most states require the prescription form to have a blank "other Medication" slot below other printed formula options. Is my understanding correct?

A: Every state has specific requirements for prescription blanks. Along with state law, there are FDA issues that should also be addressed. For example, the prescription blank form should not represent that a compounded medication is safe or effective for treating a certain condition, because compounded medications have not been approved by the FDA.

Q: If a physician charges an initial consultation fee that covers all necessary medications, and the physician nevertheless transmits a patient-specific prescription to the pharmacy, and the pharmacy mails the drug directly to the patient, then can the pharmacy technically bill the physician for those orders?

A: We believe that this situation would be a problem because the drugs would not be considered "in office" use, if they are being mailed directly to the patient. In this situation, the pharmacy would be acting as a wholesaler to the physician, allowing the physician to "resell" the drugs to the patient. If a pharmacy acts as a wholesaler and allows the resale of drugs, then in the eyes of the

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FDA, the pharmacy would likely be acting outside the scope of a traditional pharmacy.

Q: If government insurance plans disallow commissions to 1099 independent contractor marketing reps, then why does the OIG website talk about Medicare Part D and Medicaid but not TRICARE and such?

A: The federal anti-kickback law clearly states that it applies to the generation of business which is paid for, in whole or in part, by any federal health care program. While these are known to include Medicare and Medicaid, it also includes TRICARE, and other lesser-known federal health care programs.

Q: With copays, we do not waive but we do not attempt to collect the entire copay. We collect a flat rate. Is this legal? Is it necessary to obtain financial hardship papers?

A: By discounting the copayment owed by the patient, you are essentially waiving the remainder of the copayment. A waiver of copayment (whole or partial) should only be made when financial hardship is documented. Furthermore, up-front discounting of the copayment could be viewed as a reduction of the pharmacy's actual charge for the medication and will likely affect the pharmacy's usual and customary charge for the medication.

Q: Can you leave out an ingredient when billing but still include it in the compound that is sent to the patient?

A: It depends on the rationale for doing so. If the pharmacy wants to leave out the ingredient because it is a bulk ingredient and the payer refuses to pay for compounds with bulk ingredients, then that is likely problematic as it could be viewed as fraud. If there is a legitimate reason for doing so, it would depend on the language of your provider agreement and provider manual. ■

Jeffrey S. Baird, Esq. is chairman of the Health Care Group at Brown & Fortunato, P.C., a law firm based in Amarillo, Texas. He represents pharmacies, infusion companies, home medical equipment companies and other health care providers throughout the United States. Baird is board certified in health law by the Texas Board of Legal Specialization. He can be reached at (806) 345-6320 or jbaird@bf-law.com.