Know the Laws Covering Pharmacy-Physician Business Relationships

by Jeffrey S. Baird, Esq.

A physician is a referral source to the pharmacy. If a pharmacy pays money to a physician for services, or provides meals, gifts, and entertainment to a physician, or subsidizes a trip that the physician will take, then both the pharmacy and the physician need to comply with the federal and state laws that govern these arrangements.

The Medicare anti-kickback statute states that a health care provider cannot provide anything of value to a person or entity in exchange for referring, or arranging for the referral of, patients covered by a government health care program. The payer and the payee are equally liable under the statute. Courts have enumerated the "one purpose" test, which states that if one purpose behind a payment to a referral source is intended to induce referrals, then the anti-kickback statute is violated notwithstanding that the primary purpose of the payment is to pay for legitimate services. Because the anti-kickback statute is so broad, the Office of Inspector General has published a number of "safe harbors." A safe harbor is a hypothetical fact situation. If the arrangement falls within the fact situation, then the compensation paid does not violate the anti-kickback statute. A relevant safe harbor is the Personal Services and Management Contracts (PSMC) safe harbor. This safe harbor contains a number of requirements, including the following:

- The pharmacy and physician will enter into a written agreement with a term of at least one year.
- The pharmacy will pay the physician for legitimate services.
- The compensation will be set one year in advance (such as $6,000 over the next 12 months).
- The compensation will be the fair market value equivalent of the physician's services.

STARK SELF-REFERRAL STATUTE

The Stark physician self-referral statute states that if a physician has an ownership/compensation arrangement with a provider that furnishes "designated health services," then the physician cannot refer patients, covered by Medicare or Medicaid, to the provider. A pharmacy falls within the definition of a provider that furnishes DHS. There are a number of exceptions to Stark. Two of the exceptions are the non-cash/non-cash equivalent expenditure exception, and the personal services exception. The non-cash/non-cash equivalent expenditure exception states that a provider can expend up to $380 per year on non-cash/non-cash equivalent items for a referring physician. Non-cash/non-cash equivalent items include meals, trips, conference fees, and concert tickets, to name several. Cash, gift cards, gift certificates, and similar "cash equivalent" items do not fall within this exception. The personal services exception is similar to the PSMC safe harbor.

Most states have their own versions of the Medicare anti-kickback statute. Some state anti-kickback statutes apply only if the payer is the state's Medicaid program. Other state anti-kickback statutes apply regardless of the payer. Some states have physician self-referral statutes that are similar to Stark. Each state has a version of a medical practices act (MPA), which is a set of statutes that are specific to physicians. Many of the MPAs have physician-specific statutes that address "fee splitting," "kickbacks," "referral fees," and "patient brokering."

The pharmacy can provide gifts, entertainment, trips, meals, and similar items to a physician so long as the combined value of all of these items do not exceed $380 in a 12-month period. For example, if a pharmacy wants a physician to accompany the pharmacist on a trip to a continuing education conference, then the pharmacy can safely subsidize up to $380 of the physician's trip expenses. The amount of the trip subsidy will be

▶ ***Continued on page 55***

▶ *Continued from page 18*

affected by other expenditures the pharmacy has made on behalf of the physician within the preceding 12 months.

PAYMENT FOR LEGITIMATE SERVICES

Additionally, the pharmacy can pay the physician for legitimate services. For example, if the pharmacy has a legitimate need for a medical director, then the pharmacy and physician can enter into a medical director agreement that complies with both the PSMC safe harbor to the Medicare anti-kickback statute and the personal services exception to Stark.

Another legitimate way for money to exchange hands between a pharmacy and a physician is for the physician to rent space to the pharmacy or vice versa. The rental agreement needs to comply with the space rental safe harbor to the Medicare anti-kickback statute and the space rental exception to Stark. Among other requirements, the parties must execute a written lease agreement that has a term of at least one year; the rent paid must be fixed one year in advance (such as $48,000 over the next 12 months); and the rent must be fair market value. ■

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.