

*From the 30<sup>th</sup> Annual ACCC Meeting*

## Attorney urges healthcare providers to stay informed about anti-kickback laws

**T**he notion that it is better to give than to receive does not apply to anti-kickback statutes, says Susan W. Berson, JD, a lawyer who advises proprietary healthcare providers and not-for-profit companies.

Ms. Berson discussed federal and state anti-kickback laws at the 30<sup>th</sup> Annual National Meeting of the Association of Community Cancer Centers. She confirmed that giving and receiving are just two of the many ways to violate the statutes, and she urged providers to stay informed about anti-kickback laws.

According to the US Department of Health and Human Services (HHS), the main purpose of the federal anti-kickback law is to protect patients and federal healthcare programs from fraud and exploitation by curbing the corrupting influence of money on healthcare decisions. The law states that anyone who knowingly

and willfully receives or pays anything of value to influence the referral of federal healthcare program business can be held accountable on both a civil and criminal basis. Recommending and arranging for items and services can also be a violation, noted Ms. Berson. “You don’t necessarily have to be the direct provider or the direct recipient to need to consider whether or not you are involved in conduct that could violate the anti-kickback statute.”

Generally, the statute requires intent to consider an act a violation, but there is little agreement among the various circuit courts around the country about the definition of intent. Ms. Berson said that some define it by the “one purpose rule,” which means that intent is demonstrated if *any* purpose of the arrangement is to induce an unlawful act or referral. Other courts require that the inducement be the *primary* purpose.

HHS has designated 21 “safe harbors” for various business practices that would not be prosecuted, even though they are potentially prohibited by the statute. These safe harbors are areas of conduct where the federal government believes the anti-kickback statute would not apply—if all the requirements are met, “and that’s a big ‘if,’” Ms. Berson said.

## **Become acquainted with ‘safe harbors’**

She urged people to become acquainted with the safe harbors and outlined some of the areas they cover. They include investments in recipients by referrers, space rental arrangements between referrers and recipients, equipment rentals between referrers and recipients, personal services supplied by referrers to recipients, and management services provided pursuant to a contract between a recipient and a referrer.

Safe harbors may also cover the sale of physician or practitioner practices, payment between individuals or entities and a referral service, manufacturer or supplier warranties provided to a provider or beneficiary, some discounts, employment-related compensation, and fees that group purchasing organizations charge to providers who buy through them or from them.

Other safe harbors include waiving healthcare beneficiary co-payments, offering some benefits to health plan enrollees, healthcare providers offer-

ing price reductions to health plans, and making recruitment payments to practitioners for relocating to a Health Professional Shortage Area (HPSA) and for malpractice insurance subsidies in an HPSA.

Ms. Berson noted that the Office of Inspector General (OIG) of HHS provides guidance to providers about what it considers acceptable or unacceptable behavior under the anti-kickback statutes. The OIG issues special advisory bulletins and publishes opinions on its Web site, [www.hhs.gov](http://www.hhs.gov). Ms. Berson urged providers to acquaint themselves with safe harbors and the guidance on the OIG Web site and advised them to look at those opinions that cover areas of conduct that are of concern to the provider or practice.

## **Interactions between drug manufacturers and managers drawing attention**

One of the most significant ongoing areas of government attention is the interaction between drug manufacturers and managers. Actionable conduct includes involvement in formulary placement, kickbacks for drug choices, and off-label use. The OIG advisories and guidance in this area are helpful to anyone interacting with pharmaceutical manufacturers, said Ms. Berson, including purchasers, pharmacy benefit managers, formulary committee members, or “anyone in a position to generate government

healthcare business.”

According to OIG guidelines, interactions between drug companies and professionals should focus on scientific and educational information and supporting scientific or medical research, and not include entertainment. Drug companies may provide support to those who sponsor conferences but may not pay individuals. Companies may provide legitimate consultants, but not simply justify payments to referral sources that are otherwise unsupported. No personal items should be offered or distributed to professionals, except for those that provide educational or practice benefits that ultimately aid patients.

Most states also have anti-kickback statutes and other laws that may impact relationships with referral sources, Ms. Berson said. For example, Vermont requires pharmaceutical companies to disclose gifts or cash payment to physicians, hospitals, and other providers. Minnesota prohibits companies from giving gifts to physicians or other healthcare providers in excess of \$50. Hawaii requires drug companies to report how much they spend on marketing, including the cost of television advertisements broadcast in the state.

Referring to the state laws, Ms. Berson advised providers to take them into account when considering activities in certain jurisdictions. “State claims can be as onerous as federal claims,” she added.