Compliance Issues Facing Practices

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Government scrutiny of healthcare organizations has increased exponentially over the past decade; and since the initiation of healthcare reform, we have seen some of the largest recoveries to date. In fact, since 2009, the Justice Department has recovered $17 billion under the False Claims Act. Practice groups have been largely untouched by many of these False Claims Act issues because the focus has historically been on hospitals; however, enforcement actions have been taken against practice groups during the past couple of years, highlighting a changing tide.

The daily pressures faced by practice groups should not deter organizations from ensuring they have an effective compliance program. The following sections highlight some of the top compliance issues facing practice groups.

FALSE CLAIMS ACT

The False Claims Act was enacted during the Civil War to deter government contractors from taking advantage of the United States’ need for supplies and commodities during war time. A century and a half later, the False Claims Act continues to be used to deter healthcare fraud. In fact, during 2014, the Justice Department recovered nearly $6 billion under the False Claims Act.1 For practice groups, False Claims Act risk can arise if the practice group:

- Knew, should have known, or disregarded information that a claim was false;
- Submitted a claim for services that were not medically necessary;
- Submitted a claim for services that were not provided; or
- Failed to submit documentation supporting the claim billed even if the service was provided and was medically necessary.

The False Claims Act allows “whistleblowers” to bring actions on behalf of the government. If the government intervenes, the whistleblower can share the recovery if the lawsuit is successful. The Affordable Care Act’s changes to the False Claims Act have made whistleblower actions easier. Furthermore, such changes have offered more protections for whistleblowers who bring lawsuits on behalf of the government.

Practice groups should take a proactive approach to limiting False Claims Act risks. First, ensure internal reporting is occurring routinely within your organization. Employees often become whistleblowers due to fear of retaliation by the employer for reporting compliance issues. Second, make sure that data to support the claim billed are submitted accurately and on time. By highlighting potentially problematic areas, your organization can investigate and fix any issues moving forward. Finally, ensure members of your organization are being educated regarding the False Claims Act. This means all members of your organization, including providers.

ANTI-KICKBACK STATUTE

The Anti-Kickback Statute prohibits both individuals and organizations from knowingly or willfully offering or paying, directly or indirectly, remuneration for or to induce referrals of patients covered under Federal or state healthcare programs to a specific practice. The term

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remuneration is expansive, in that it includes any type of benefit, not just monetary gifts. The Anti-Kickback Statute presents a considerable pitfall for all practice groups because violations can result in criminal penalties. For example, if one purpose of a transaction, such as renting office space to a referral source, is to induce referrals, and remuneration is provided, such as a discount on rent, then the Anti-Kickback Statute may have been violated.

In 2014, a cardiology group in Kentucky settled Anti-Kickback Statute allegations for $380,000. The Department of Justice alleged that the physician group was paid for management services that allegedly did not occur. The government alleged that in exchange for these payments, the group entered into an exclusive agreement to refer patients to that hospital. This is just one example of the many ways in which the Anti-Kickback Statute can be implicated.

To limit the risks of the Anti-Kickback Statute, ensure that employees and members of your practice group are fully aware of the statute’s contents. Include routine education sessions for providers and management regarding these risks. Further, review all internal procedures to ensure no payments are being made to referral sources outside of signed agreements and transactions. This includes a close review of outside activities with pharmaceutical or medical device companies. There are safe harbors that can eliminate many risks of the Anti-Kickback Statute; however, meeting the safe harbors can be a considerable hurdle for many organizations.

**THE SUNSHINE ACT**

The Sunshine Act represents a move toward transparency in healthcare. In particular, the Act requires certain manufacturers of pharmaceutical drugs, biologics, medical supplies, and devices to report payments or other transfers of value made by those manufacturers to physicians or teaching hospitals. At a minimum, consulting, research, and lunches are disclosed under the Sunshine Act and are included in the Centers for Medicare & Medicaid Services reports for physicians. This means that pharmaceutical and medical device companies will be required to disclose any payments to physicians within practice groups.

The Act represents significant risks to practice groups, for a number of reasons. First, the data available have been disputed and are claimed, at times, to be inaccurate. This creates risks because potentially inaccurate data can create a misrepresentation of a practice group’s involvement with pharmaceutical and medical device companies. Second, individuals and attorneys around the country are analyzing these data for the purpose of seeking any possible inappropriate relationships. These individuals may utilize the information to support bringing a *qui tam* lawsuit against the practice group. These are just a few of the concerns, and practice groups need to ensure they are protected.

Practice groups need to ensure they are being proactive with respect to relationships with pharmaceutical and medical device companies related to such reporting. For example, practice groups should ensure there is a mechanism in place to review the data submitted by these manufacturers to ensure accurate reporting. Although practice groups and physicians are not directly liable for these reports, it is possible that disclosed payments and arrangements could increase liability under the Anti-Kickback Statute. Above all, practice groups should ensure arrangements that must be disclosed under the Act are structured to protect the interests of both the group and the physicians.

**STARK LAW**

The Stark Law is one of the primary enforcement mechanisms used by the federal government against healthcare fraud. The Stark Law is different from the Anti-Kickback Statute primarily because it is a strict liability law. This means there need be no element of intent; rather, an individual can violate the law simply by inadvertently not adhering to complex requirements. Generally, the Stark Law prohibits a physician from making a referral to an entity for the furnishing of designated healthcare services payable by Medicare if the physician or a member of the physician’s immediate family has a financial relationship with the entity, unless an exception applies. In short, the law was developed to prevent physicians from being incentivized to order ancillary services.

Various exceptions must be met if the Stark Law applies; otherwise, a practice group violating the law may face denials for payments, required refunds of amounts collected under the arrangement, and possible exclusion from Medicare or Medicaid. The biggest concern is that any arrangement in violation of the Stark Law subjects all funds related to that arrangement to be refunded to the federal government. This number can be very high, because the government often includes False Claims Act damages with Stark Law violations. For example, Tuomey Healthcare System in South Carolina was ordered to pay approximately $237 million in fines after a jury found the system violated the False Claims Act and the Stark Law.³

One of the most important exceptions, as applied to practice groups, is the in-office ancillary services exception, which allows physicians within a group practice to make referrals within the practice for certain services. If the exception is not met, these referrals for in-office services such as imaging or laboratory tests may violate the Stark Law. In a recent case, highlighting enforcement in this area, New York Heart Center of Syracuse, New York, settled alleged Stark Law violations for over $1.3 million.⁴

This is significant because the Stark Law prohibits physician practices from furnishing certain imaging, physical therapy, and other services that are ancillary to the physician’s
core practice unless an exception is met. The New York Heart Center of Syracuse offered imaging services in its office locations; and, allegedly, the group’s physicians were being remunerated based on the volume of referrals they made for those imaging services. Such practice is prohibited under the Stark Law because practice groups must meet specific requirements from a compensation perspective to fit within an exception under the Stark Law. The primary issue often is meeting the compensation requirements rather than the general in-office ancillary service requirements.

Lately, some of the biggest issues concerning hospital–physician relationships and the Stark Law relate to fair market value compensation. All Children’s Hospital in Florida recently agreed to settle a lawsuit based on Stark Law violations for $7 million. The suit alleged the hospital paid more than fair market value for physician services and physicians it employed. The reason fair market value is important in the Stark Law context is that it is a requirement of numerous exceptions.

Practice groups can be at risk too. The Infirmary Health System affiliated physician group allegedly had issues meeting the requirements of the in-office ancillary services exception of the Stark Law. Although historically the focus of Stark Law enforcement has been on hospitals, there appears to have been a recent increase in cases implicating the physician groups involved.

CONCLUSION

Practice groups should be aware of the various compliance concerns discussed in this article. Although practice groups have fewer resources than large health systems, the risk related to these compliance issues is still high. One thing that is clear is that enforcement by the government is on the rise as the government receives a considerable return on investment when investigating healthcare fraud. In addition, practice groups have been the focus of many investigations during the past few years, highlighting the increased focus on groups. Therefore, it is necessary to ensure your organization is limiting its risks of being forced to refund reimbursement or even being excluded from Medicare and Medicaid by starting to build and maintain an effective compliance program in your organization.

REFERENCES