ALLIED WORLD

VOL. 1, ISSUE 4 **SEPTEMBER 2016**

SECOND OPINION

SMALL DOSES OF HEALTHCARE INSIGHT

Regulatory Exposures in Healthcare

With 25% of our federal government budget being spent on government health insurance programs, fraud and abuse issues related to them are a major area of concern. Healthcare has traditionally been a highly regulated industry. However, given the current post-Affordable Care Act (ACA) implementation environment, government scrutiny has become even more intense. With millions of Americans receiving health insurance through government-funded programs (including Medicare and Medicaid), the current exposures related to the billing and coding of services within these programs are at an all-time high. In addition to the implementation of new rules and regulations, existing laws continue to evolve and be challenged.

Let's look at some of the commonplace regulations governing Healthcare:

False Claims Act – The government's primary tool for contesting fraud, the False Claims Act (FCA) is a federal law that makes it illegal for a person or organization to fraudulently file a false claim under federal Healthcare programs (Medicare, Medicaid, etc.). Common violations of the FCA include billing a government program for services not provided; unbundling (billing for services separately that are typically billed together such as laboratory tests); and miscoding for procedures that are more expensive than actually performed. Penalties for such violations can result in fines of up to three times the claim, plus up to $11,000 for each claim filed. Many states have also adopted their own versions of the FCA to protect against fraudulent activity at the state level.

Qui Tam – This provision to the FCA provides protection to individuals (known as relators) who first become aware of a situation and file suit on behalf of the United States. This type of reporting is commonly referred to as *"whistleblowing."* Under the FCA, Qui Tam plaintiffs can recover 15-20% of the amount recovered if the government intervenes, or 25-30% if the Qui Tam plaintiff proceeds independently. The relator can proceed independently if the government chooses not to intervene after the government conducts its investigation. Qui Tams have been the most effective source for recoveries related to violations of the FCA.

Stark Law – With the implementation of the ACA, enforcement of the Stark Law has been on the rise. Stark Law governs and sets limitations on physician referrals, specifically referrals for Medicare and Medicaid patients if the physician has a financial relationship with the entity (e.g., ownership, investment, compensation arrangements). These types of referrals are viewed as a conflict of interest, since the physician could financially gain from the referral. Such referrals can drive up healthcare costs as they create an overutilization of services. There are several complex exceptions to the law, but it is enforced widely by the Department of Justice (DOJ), Centers for Medicare & Medicaid Services (CMS), and the Department of Health & Human Services.

Anti-Kickback Statute (AKS) – This statute prohibits the exchange of (or the offer to exchange remuneration in order to induce or reward) a referral for business reimbursed under the Medicare or Medicaid programs. It is a crime to pay for referrals under federal healthcare programs, and violation of the statute can result in fines, exclusion from participation in federal healthcare programs, or even possible imprisonment. Unlike the FCA, the AKS does not afford a private right of action. However, the statute is drafted broadly and parties on both sides of the transaction can face penalties if found to be in violation of the statute.

CONTINUED >

What Are We Seeing?

- During the 2015 fiscal year, the federal government recovered approximately $3.6B through FCA judgments and settlements, marking the fifth year in a row that FCA recoveries exceeded $3B. While this figure is significant, the 2015 recoveries were actually down from 2014, which totaled approximately $5.7B.
- Although the overall recoveries were down slightly in 2015, the recoveries resulting from Qui Tam relators reached a record high of $2.8B, with more than $1B of those recoveries resulting from cases in which the government chose not to intervene, awarding relators $597M – more than a $100M increase from 2014 and higher than any other year prior.
- CMS made several clarifications and revisions to the Stark Law in 2015, which provided exceptions in order to ease compliance among physicians and to align with the delivery and payment system of the ACA. The changes (including loosening the requirements of self-disclosures without compromising the well-being of patients) took effect on January 1, 2016 and were welcomed by providers.

What to watch for?

Based on regulatory activity over the past few years, we see a few trends worth noting. Given the increased awards to relators in 2015, Qui Tam activity may continue to rise. Also, although CMS has provided some flexibility in reporting provisions for the Stark Law, the DOJ noted that many of the FCA settlements involved Stark Law violations in 2015. We believe that this trend is likely to continue.

Impact of Yates Memo. Late in 2015, Deputy Attorney General Sally Quillian Yates issued a memo calling for the DOJ to increase efforts to hold corporate executives individually accountable for corporate wrongdoing. The Yates memo could have significant impact on healthcare entities and their executives as the new directives could alter (1) how investigations under FCA are handled and (2) how healthcare entities will cooperate when under investigation of FCA allegations. Executives may look to their D&O insurance policies for broadened coverage for individuals as a result.

AUTHOR:

Joseph Scarlata
Senior Underwriter
Healthcare Management Liability Division
Allied World Insurance Company

QUESTIONS?

Contact your local Allied World Underwriter.