

RECENT FRAUD SETTLEMENTS

ILLUSTRATE CURRENT COMPLIANCE RISK AREAS



Everyone knows that compliance and health care go hand in hand. But identifying which areas the government prioritizes and will target for compliance enforcement is challenging. Fortunately, recent cases the government has pursued and settled illustrate the compliance risk areas the government is prioritizing. The compliance areas highlighted in the recent settlements announced by the Department of Justice (DOJ) summarized below are issues health care entities should consider when structuring transactions and business arrangements and when providing, and billing for, health care services.

Overprescribing Opioids without Demonstrated Medical Justification

The DOJ recently announced a settlement representative of the government's use of fraud enforcement to combat the opioid epidemic. The government alleged that a chiropractor billed Medicare and a state Medicaid program improperly for painkillers, including opioids. The government alleged that the defendants prescribed painkillers and caused pharmacy claims to be submitted where there was no legitimate medical purpose for the prescriptions. Additionally, the government alleged that the clinics up-coded and billed Medicare for office visits that were not reimbursable at the levels sought. The clinics were also accused of billing for nurse practitioner services that were provided without the required collaboration arrangement in place. The case involved four managed pain clinics, all of which were closed through the course of the case. The settlement also required a nurse practitioner to pay \$32,000 and surrender her Drug Enforcement Agency registration to settle allegations that she violated the Controlled Substances Act.

The DOJ's press release announcing the settlement directly comments on the opioid issues involved in the case and leaves no ambiguity regarding the government's focus.

"More Americans are dying because

of drugs today than ever before—a trend that is being driven by opioids," said Attorney General Jeff Sessions. "If we're going to end this unprecedented drug crisis, which is claiming the lives of 64,000 Americans each year, doctors must stop overprescribing opioids and law enforcement must aggressively pursue those medical professionals who act in their own financial interests, at the expense of their patients' best interests." This recent enforcement action demonstrates the government's commitment to compliance in this area.

Lease Agreements that are Disguised Referral Payments

Two northern California urologists have agreed to pay \$1.085 million to resolve a False Claims Act charge relating to image guided radiation therapy, commonly used to treat patients with prostate cancer. The government alleged that the doctors submitted claims for services that were referred and billed in violation of the Stark Law and the Anti-Kickback Statute.

The government claimed that the doctors improperly billed for services they referred to their separately owned radiation oncology center. The doctors were also accused of soliciting urologists to enter into lease agreements with the oncology center that enabled the urologists to profit from their referrals of image guided radiation therapy. The government continues to

target and closely analyze health care arrangements.

Unnecessary Breast Cancer Testing

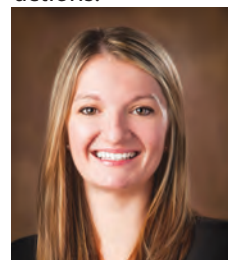
A company will pay around \$2 million to settle allegations of making false claims to Medicare for Breast Cancer Index (BCI) tests that were alleged to be not reasonable and necessary for the diagnosis and treatment of breast cancer. The government accused the company of knowingly promoting and performing BCI testing for breast cancer patients who had not been in remission for five years and who had not been taking tamoxifen. The government alleged that performing BCI testing under these circumstances was not reasonable and necessary based on published clinical trial data and clinical practice guidelines. This case highlights the need to ensure there is clinical support for providing and billing for services. In this case, the government took the position that patients who did not meet certain criteria would not benefit from the BCI testing.

The cases and fraud settlements above illustrate three areas where the government is focusing compliance enforcement and where, therefore, health care entities should focus compliance efforts—controlled substance, health care arrangements, and billing. We expect these compliance

trends to continue in government enforcement actions.



Attorneys John Fisher
and Emilu Starck,
Ruder Ware



178724_06-11-18_854448