2020 Fraud and Abuse Year in Review

Jan 27 2021

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Practice Area: Health Law & Regulatory Compliance and Fraud and Abuse

One of the hallmarks of an effective compliance program is the incorporation of current trends in fraud and abuse into the risk assessment process that drives a provider's compliance activities. This review of notable trends in fraud and abuse from 2020 is intended to inform that risk assessment process for health care providers.

While 2020 was not a typical year in many, many ways, the pursuit of fraud and abuse in the health care industry by the United States Department of Justice ("DOJ") did not veer off course. Because fraud and abuse cases can be in the investigative pipeline for years before they are resolved and become public, the effects of the pandemic on fraud and abuse enforcement may not be known for several years. While there are many unknowns about how the pandemic will affect the fraud and abuse landscape, increased utilization of services such as telemedicine will certainly garner the attention of the enforcers. Beyond the impact of the pandemic, this *Legal Update* highlights other notable trends that have surfaced as a result of cases that were resolved or became public in 2020 so that they can inform your compliance program.

Telemedicine is the New Black. While telemedicine was a lifeline for many health care providers during the early stages of the pandemic and its use has surged during the past year, the DOJ has already investigated a number of criminal cases focused on telemedicine fraud. For example, in September, the DOJ announced its annual health care fraud "take down" which involved indictments of 86 individuals involved in telemedicine schemes. Specifically, the indicted individuals included telemedicine executives who were alleged to have paid doctors and nurse practitioners to order unnecessary durable medical equipment, genetic and other diagnostic testing, and pain medications, either without any patient interaction or with only a brief telephonic conversation with patients they had never met or seen. Those durable medical equipment companies, genetic testing laboratories, and pharmacies which received the kickback-tainted orders then submitted false and fraudulent claims to Medicare and other government insurers. In light of the anticipated scrutiny of these services, strong documentation supporting telemedicine services will be critical.

Private-Equity Investment in Heath Care Providers Garners Investigation. The perceived emphasis on profits by private equity investors in the health care industry is clearly attracting the DOJ's attention. In one case, a *qui tam* was filed against a North Carolina laboratory, its private equity investor, and several principals of the private equity firm alleging that the laboratory submitted medically unnecessary claims for certain panels of testing for "function medicine." The relator alleged, among other things, that the laboratory improperly used requisition forms that forced physicians to order medically unnecessary tests. While the *qui tam* complaint alleged that the private equity investor had knowledge of the improper billings, the $43 million settlement that was announced was only with the laboratory entity (although it's hard to imagine that an independent laboratory would be able to pay a $43 million settlement without the participation of its investors).

Similarly, a holding company and its wholly-owned subsidiaries that owned and operated pain management ambulatory surgery centers in the Midwest was investigated pursuant to the False Claims Act related to financial incentives provided to physicians in order to boost profits. It was alleged that the holding company improperly gifted shares of incentive stock to non-employee physicians who performed pain management procedures at the ambulatory surgical centers. The incentive stock was to be redeemed upon a sale of the holding company and was dependent on the profitability of the holding company, which was determined largely by referrals from the non-employee physicians. The incentive stock was allegedly given as a reward for past and anticipated referrals to the ambulatory service centers. The matter settled for approximately $900,000.

Kickbacks Driving Medically Unnecessary Services. The DOJ continues to focus much of its enforcement muscle on violations of the Anti-Kickback Statute ("AKS") that purportedly cause claims for medically unnecessary services. For example, the government alleged that a Florida home health company made sham medical director payments to two physicians in order to induce referrals from those physicians. Further, the government alleged that the home health agency provided medically unnecessary services to avoid the "low utilization payment adjustment" for home health reimbursement. The matter settled for $5.15 million.

Physician Compensation Continues to Attract Attention. Continuing the trend that began with the *Tuomey* case, an Oklahoma orthopedic hospital, an affiliate physician practice, and two individual physicians entered into a $72.3 million settlement to resolve allegations under the AKS and Stark law. Specifically, it was alleged that the hospital provided improper remuneration to the physician practice and some of its physicians in exchange for patient referrals in the form of (i) free or below-fair market value office space, employees, and supplies, (ii) compensation in excess of fair market value for the services provided by the physicians, (iii) equity buyback provisions and payments for certain physicians that exceeded fair market value, and (iv) preferential investment opportunities in connection with the provision of anesthesia services at the orthopedic hospital.

Electronic Health Records and Kickbacks. While the DOJ's 2020 mega settlement with Purdue Pharma is notable on many fronts, health care providers should pay attention to a lesser-noted component of that resolution related to electronic health records (EHR). Among other things, the Purdue settlement resolved allegations that Purdue paid kickbacks to an EHR vendor. The EHR—marketed by Practice Fusion—included the capability to prompt prescribers during a patient visit to take certain clinical actions based on health information and circumstances entered into the EHR. These prompts were known as clinical decision support ("CDS") alerts and were originally intended to aid physicians in making treatment decisions by providing unbiased information consistent with medical practice guidelines. However, the government alleged that Purdue paid Practice Fusion to create a CDS alert that prompted providers to take clinical actions that Purdue improperly influenced so as to increase prescriptions for Purdue products. The global settlement of criminal and civil allegations against Purdue included a release for this conduct. Practice Fusion earlier entered into a deferred prosecution agreement related to its role in the scheme.

Genetic Testing Under Scrutiny. Settlements with genetic testing laboratories demonstrate the DOJ's continued focus on this evolving technology. For example, AutoGenomics, a California laboratory, settled allegations that it paid kickbacks to a marketing company to induce the referral of patients for its genetic testing services. Specifically, the government contended that AutoGenomics violated the AKS when it entered into agreements with a California-based health care marketing company and, pursuant to these agreements, AutoGenomics paid the health care marketing company a fee that was based on the amount of Medicare's reimbursement for each test that was referred. The laboratory paid $2.5 million to resolve the allegations. Separately, a nursing home operator who allowed its residents to be tested earlier settled with the government for nearly $1 million for its role in the scheme.

Medically Unnecessary Behavioral Health Services. Universal Health Services ("UHS") —a nationwide provider of behavioral health services—entered into a blockbuster settlement of $117 million to resolve allegations related to inpatient mental health services. The government alleged that UHS admitted patients who were not eligible for inpatient or residential care because their conditions did not require those levels of care and that UHS failed to appropriately discharge patients when they no longer needed the level of care they were receiving. Additionally, the government alleged that UHS facilities failed to develop and/or update individual assessments and treatment plans for patients, failed to provide adequate discharge planning, and failed to provide required individual and group therapy services in accordance with federal and state regulations.

Opioids. The government's war against the opioid epidemic continued on many fronts. Of course, the DOJ resolved allegations against Purdue Pharma related to the marketing of OxyContin and Indivior pled guilty to criminal charges and paid a $600 million fine for providing false and misleading information in the context of marketing and promotional efforts for Suboxone. Additionally, the DOJ continues to pursue individual practitioners both criminally and civilly related to issuing prescriptions outside the usual course of professional practice and other providers involved in the distribution of opioids for violations of the Controlled Substances Act. For example, a North Carolina pharmacy paid a $1 million civil penalty and entered into a consent decree because the pharmacy issued prescriptions for opioids while allegedly ignoring so-called "red flags of diversion" and drug-seeking behavior of customers who filled prescriptions at its pharmacy.

Fraud Impacting Value-Based Payments. As the health care environment continues to move towards value-based reimbursement, it is increasingly important for providers to focus on the integrity of the data submitted supporting those quality-based payments as a potential basis for liability. As an example of the types of theories that could be pursued by the government in this realm, Kaiser Health Foundation of Washington, a Medicare Advantage Organization, recently paid $6.3 million to resolve allegations that it submitted invalid diagnosis information and, therefore, received inflated payments, for Medicare Advantage beneficiaries.

OIG Advisory Opinions. Finally, the Office of the Inspector General ("OIG") for the Department of Health and Human Services issued nine advisory opinions this year. The following are brief summaries of three of the more broadly applicable opinions that provide insight into the OIG's current thinking on potential AKS violations that present low risk of abuse and for which it would not exercise enforcement authority.

Advisory Opinion 20-07 involved a free web-based platform where patients could find and compare health care providers based on various metrics. The platform also allowed the providers to remit to patients and the patients' payor a portion of the claims for certain services for which payment may be made by the Medicare program as a secondary payor (and the platform kept a portion of the remittance as payment for the service). The OIG found that the proposed arrangement resulted in several remuneration streams that could implicate the federal anti-kickback statute, and some of which could implicate the beneficiary inducements CMP. In spite of this, the OIG found the arrangement presented a minimal risk of fraud and abuse and therefore would not impose sanctions in connection with the arrangement.

Advisory Opinion 20-06 involved a management company's provision of below fair market value Medicaid enrollment application assistance services to certain individuals and affiliated skilled nursing facilities' payments for those services. In some cases, the individual would pay the company for these services and, in other cases, the affiliated facility would pay for the services on behalf of the individual. Although the OIG found the arrangement would implicate the beneficiary inducement CMP, the arrangement fell within the Promotes Access to Care Exception[1] because (1) the remuneration would promote access to care by facilitating the application process for individuals who otherwise would struggle to navigate the process and might not be able to afford assistance and (2) the remuneration would pose a low risk of harm because it is unlikely to interfere with clinical decision making or increase costs to federal health care programs. The opinion also found the payment at below fair market value for the services could induce referrals and therefore would implicate the AKS, but the arrangement's safeguards would sufficiently mitigate the associated risk of fraud.

Advisory Opinion 20-01 involved a hospital's provision of discounted training to a fire department's personnel at the hospital's facility. The nonprofit hospital operated the only training facility in the metropolitan area capable of providing certain types of complex training. The hospital allowed the fire department's EMS to train at a discounted rate at the facility. Although the OIG stated the arrangement implicated the AKS due to the hospital providing below market services to a referral source, the opinion found the arrangement presented a low risk of fraud and abuse because (1) the arrangement posed little risk of increased federal health care program utilization or costs, (2) the arrangement was unlikely to cause the fire department to steer patients to the hospital, (3) the arrangement benefited the community, and (4) the remuneration inured to the public, and not private, benefit.

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[1] A safe harbor to the beneficiary inducements CMP that shields remuneration that "promotes access to care and poses a low risk of harm to patients and Federal health care programs." See 42 USC 1320a-7a(i)(6)(F); 42 CFR 1003.110.
