7 Trends to Help You Create an Effective Compliance Program in 2022

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It's a lesson that bears repeating – you can't find what you don't look for. To know what to look for and thereby achieve peak performance and tackle key risks, compliance programs must identify and incorporate the trends in government enforcement. To help identify those trends, we recommend reviewing the enforcement priorities announced by the government in 2021, recently announced resolutions, and significant advisory opinions from the Office of the Inspector General.

The change in the presidential administration brought renewed energy to the Department of Justice's ("DOJ") health care fraud enforcement programs and will likely bring additional and more sophisticated resources to the government's enforcement activities. While fraud and abuse cases can be in the investigative pipeline for years before coming into the public eye, certain trends can be detected from public and other pronouncements from the DOJ over the past year. We highlight those notable trends so that they can inform your compliance program.

The Yates Memo is Back. In a policy shift that had significant impact on enforcement in health care, former Deputy Attorney General Sally Yates issued a memo in 2015 that required corporations seeking cooperation credit in fraud investigations to disclose relevant facts about the individuals that were involved in the misconduct. This memo reflected a growing practice of the DOJ, including in the context of False Claims Act investigations, to not be content with solely corporate resolutions of cases but, instead, to investigate the potential liability of individuals. Under the Trump administration, this policy was softened to require prosecutorial focus only on those individuals with "substantial" involvement in corporate fraud. In October, the DOJ restored the 2015 guidance. For those in corporate compliance, this is significant in two ways. First, it will continue to be important to educate personnel at all levels about their compliance obligations because of the significant consequences for the organization and for any individual that fails to take appropriate action when a compliance issue surfaces. Second, internal investigations that may result in a self-disclosure to the government should evaluate the involvement of individuals to best protect the organization's interests.

Medically Unnecessary Services. There was historical resistance on the part of prosecutors to bring enforcement cases based solely on the lack of the medical necessity of the services due in part to perceived difficulties in proving these cases and due in part to hesitancy to impinge on the realm of medical judgment. That historical resistance has evaporated and a significant number of enforcement actions are taking place based either solely on medically unnecessary services or medically unnecessary services spurred by kickback arrangements. Here are three key examples:

1. Three Ascension hospitals in Michigan paid $2.8 million to settle False Claims Act allegations related to gynecologic oncologist services that were not medically necessary, including radical hysterectomies, chemotherapy services, and evaluation and management services.
2. A Florida cardiologist paid $6.75 million to resolve allegations related to medically unnecessary ablations and for stent procedures performed on veins that did not qualify for treatment based on "accepted standards of medical practice." The government further alleged that the physician misrepresented the degree of reflux and diameter of veins and patient symptoms in medical records to cover up the lack of medical necessity.
3. A California hospital paid $11.4 million related to allegations that it billed for in-patient admissions that were not medically reasonable or necessary, including admitting patients for reasons other than their medical status including the lack of available alternative placements.

Anti-Kickback Enforcement Remains Hot. Providing inducements to providers in exchange for referrals remains a steady focus of the DOJ, both as a stand-alone theory of liability and in combination with allegations of services not medically necessary. While many consider kickbacks to be only cash compensation, DOJ enforcement looks at the provision of anything of value that is being potentially violative of the Anti-Kickback Statute. Moreover, as noted in our 2021 article on enforcement trends, the DOJ's sensitivity to these issues is further heightened when an outside private investment in one of the parties is involved. For example, a company that provides EEG testing and the private equity company that invested in the EEG provider paid $15.3 million to resolve allegations that it provided kickbacks to referring physicians. The kickbacks took the form of free EEG test-interpretation results enabling primary care physicians to bill for interpretation services. In another example of violative non-cash compensation, a hospital was alleged to have provided kickbacks when it overpaid to purchase a physician's practice and then entered into an employment contract with the physician that was based on the volume and value of patient referrals to the hospital.

Kickbacks and Copays. Another notable trend is the allegation that routine waiver of patient copays violates the Anti-Kickback Statute. A diabetic testing supplier reached a $160 million settlement to resolve allegations that included routinely waiving and/or failing to make reasonable efforts to collect Medicare co-payments. Specifically, the provider failed to send invoices to beneficiaries for the copayments and failed to take other basic steps – such as sending collection letters or making phones calls – to collect the copayments.

Medical Director Kickbacks. The DOJ continues to scrutinize payments made to medical directors and assess whether those payments were for *bona fide* services or, rather, to simply induce referrals. The government recently intervened in a whistleblower lawsuit against a skilled nursing provider for payments made to its medical directors alleging that the physicians promised in advance to refer a large number of patients, that the provider paid the physicians in proportion to the number of expected referrals, and terminated agreements with physicians when the referrals did not materialize.

Medicare Advantage Plans on the Hot Seat. The DOJ continues to pursue a number of cases against Medicare Advantage ("MA") plans. The capitated payments made to MA plans by CMS are determined in part based on the health status of each plan beneficiary. MA plans are required to submit to CMS diagnoses only for those conditions that required or affected care, treatment or management during an in-person encounter. However, the government has alleged in several cases that MA plans encouraged physicians to add diagnoses after the patient visit that inflated the payments to the plan.

Other Areas and Providers Subject to Scrutiny.

- Opioids: In light of the ongoing opioid epidemic, the DOJ continues to aggressively pursue providers that distribute or prescribe opioids, including clinics, physicians and pharmacies – with pharmacies being the new target of choice. The allegations against physicians and clinics are typically brought under the Controlled Substances Act requiring that prescriptions be issued for a legitimate medical purpose and within the usual scope of medical practice. Pharmacies are being targeted for ignoring indications of drug diversion and/or drug-seeking behavior of its customers.
- Urine Drug Screens. Both those providers treating patients for chronic pain with opioids and those treating addiction rely heavily on urine drug testing to monitor patients for compliance. In recent years, the Drug Enforcement Agency has scrutinized providers who do not employ adequate monitoring of patients receiving controlled substances prescriptions and this scrutiny has helped to drive utilization of urine drug screens. At the same time, the DOJ continues to investigate alleged excessive utilization of urine drug screens with a heavy focus on the failure of providers to sufficiently document the need for that screening.
- Addiction Treatment Providers. Despite the high need for addiction treatment, the DOJ has aggressively pursued addiction treatment providers for a number of violations, including providing inducements to patients and medically unnecessary services.
- Telemedicine. There was a massive increase in the use of telemedicine services at the beginning of the pandemic. Several recently announced cases have involved telemarketers recruiting patients for services such as genetic testing and durable medical equipment. In order to cover up the potential lack of medical necessity of services, the telemarketing company and/or the provider of those services have allegedly paid physicians to review patient information and then order or prescribe the product, often without face-to-face contact with the patient.

Bonus Round: OIG Advisory Opinions. Finally, the Office of the Inspector General ("OIG") for the Department of Health and Human Services issued 20 advisory opinions in 2021. Brief summaries of three of the more broadly applicable opinions that provide insight into the OIG's current thinking on potential Anti-Kickback Statute ("AKS") violations follows.

Joint Venture – Advisory Opinion 21-18 involved a proposed joint venture between a therapy services company that provides rehabilitation services in long-term care facilities and the owner of several long-term care facilities. The therapy company would establish a joint venture entity and the facility owner would purchase a 40% stake in the joint venture. The therapy company would contract with the joint venture to provide back-office employees, space and equipment and the joint venture would contract with the therapy services company to provide therapy services in the long-term care facilities.

The OIG found that the proposed arrangement failed to qualify for protection under the "Small Entity Investment Safe Harbor" because it did not meet either the "revenue test" or the "investment offer" test. Moreover, the OIG determined the proposed arrangement would implicate the AKS and presented *more than a minimal risk of fraud and abuse*. The joint venture effectively would permit the therapy company to do indirectly what it cannot do directly: pay the facility owner a share of the profits from the referrals from the facility. The OIG cited several additional considerations in its determination: (1) the therapy company would be expanding into a related line of business that would be dependent on business generated by the joint venture partner; (2) the facility owner would have little financial and business risk in the joint venture; and (3) the therapy company is an established provider of the same services that the joint venture would provide.

Provider Advertising on a Per-Click Basis – Advisory Opinion 21-18 involved an online platform which the general public could use at no charge to search for home-based health care service providers. The platform would generate a list of enrolled providers based on user input and the user would choose how to sort the results. The enrolled providers pay the platform a fixed monthly participation fee and variable per-contact fee. Conspicuous notices on the platform inform users that results include only those providers that have paid the platform fees and not all potential providers.

The OIG found the proposed arrangement implicated the AKS. Despite the implication of the AKS, the OIG found that the "totality" of the proposed arrangement presented *only a minimal risk of fraud and abuse* for a combination of reasons: (1) the platform is not a provider or supplier and is not affiliated with any enrolled providers; (2) the use of the platform is initiated by the user and is available to everyone; (3) the platform includes several safeguards that mitigate the risk of fraud and abuse, including: (a) the listing of providers would not promote any specific items or services; (b) the platform would notify users that listings include only providers who have paid to be included; (c) if the user's search identified no enrolled providers, the platform would list non-enrolled providers; and (d) the platform requires that enrolled providers agree that the links to them (and their websites) will not prohibit users from directly returning to the platform.

With respect to the Beneficiary Inducements CMP, the platform was free for federal health care program beneficiaries, which could influence beneficiaries to select an enrolled provider, but for the reasons stated in relation to the AKS discussion, the OIG would use its discretion and not impose sanctions.

Joint Replacement Complications Warranty – Advisory Opinion 21-12 involved a critical access hospital providing something like a warranty to patients for specific joint replacement procedures. Under the so-called warranty, patients that met certain qualifications would not be charged for treatment of complications that occurred within 90 days of the surgery. The hospital developed the patient qualification criteria in collaboration with the surgeons and would defer to the surgeons for all clinical decisions. All qualifying patients would be eligible for the warranty and would be asked to sign a detailed disclosure prior to undergoing a covered procedure.

The proposed arrangement would not be protected by the "warranties safe harbor" under the AKS because the safe harbor only protects remuneration offered by a "manufacturer or supplier" and the hospital is a provider.

In the absence of an applicable safe harbor, the OIG considered "the totality of the facts and circumstances" and determined that the proposed arrangement would present a *minimal risk of fraud and abuse* for the following reasons: (1) the proposed arrangement seems designed to promote quality of care and better outcomes by providing an incentive to prevent covered complications, which could also reduce costs to Federal health care programs; (2) the safeguards in the proposed arrangement reduce the risk that it would interfere with clinical decision making or cause the provider to choose only the healthiest patients or refer more complicated patients to other providers; (3) the proposed arrangement is unlikely to lead to overutilization because eligibility for surgery would be based on the surgeons' independent medical judgment; and (4) although the proposed arrangement could result in steering of patients to the hospital, the potential for inappropriate steering was reduced because the hospital is a critical access hospital and the nearest hospital is more than 40 miles away.

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