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Birmingham Medical News: Fraud and Abuse Enforcement Continues Through the Pandemic

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Despite the ongoing COVID-19 pandemic and the resulting challenges facing health care providers, compliance with fraud and abuse laws has not been waived. While some enforcement actions have been "paused" due to difficulties in conducting face-to-face interviews and convening grand juries, and the Government has temporarily "relaxed" certain regulatory restrictions to facilitate pandemic response efforts, there appears to be a recent increase in investigations, settlements and convictions. A few notable items from the past two months:

April 29, 2021 -- Two dozen defendants, including executives, managers, a prescriber, billers, sales representatives and an Alabama pharmacist, were sentenced for conspiracy to commit health care fraud. The sentencings, which in one case involved 170 months in prison, came after an investigation into a prescription drug billing scheme involving a pharmacy in Haleyville, Alabama. According to the OIG press release, from 2013 to 2016 the pharmacy billed insurers for millions of dollars in medically unnecessary prescription drugs. The scheme involved directing employees to obtain medically unnecessary drugs for themselves, family members and friends, changing prescriptions to add non-prescribed drugs, automatically refilling prescriptions regardless of patient need, routinely waiving and discounting co-pays to induce patients to obtain medically unnecessary drugs, and billing for drugs without patients' knowledge. The scheme resulted in insurers paying the pharmacy nearly $50 million in claims in just a two-year period.

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April 30, 2021 -- After self-disclosing conduct to the OIG, several Ascension hospitals in Texas agreed to pay over $20 million for various acts, including: (1) paying physician practices above fair market value for hospital on-call coverage and administrative services, (2) paying a physician practice above fair market value to lease the practice's employed registered nurses and surgical technologists, (3) providing a physician practice the use of a physician assistant without charge, and (4) providing a physician practice free office space and related staff, service and supplies as part of a time-share lease arrangement.

May 10, 2021 -- The University of Miami ("UM") agreed to pay $22 million to resolve a *qui tam* lawsuit alleging that it violated the False Claims Act by: (1) failing to provide Medicare beneficiaries notice of potentially higher charges associated with receiving care in its hospital "provider-based" physician practices, even after being advised by a Medicare Administrative Contractor that its notice practices were deficient, (2) billing Federal health care programs for a pre-set "protocol" of tests (*i.e.,* standing orders) run for patients who received kidney transplants at a UM affiliated facility and which were found to be medically unnecessary, and (3) submitting inflated claims for reimbursement for laboratory testing conducted at a related entity in violation of related party regulations, which limits the reimbursement a provider can obtain for tests performed by a related entity to that entity's actual costs.

May 5, 2021 -- An Alabama doctor and her husband were sentenced to 52 and 30 months in prison, respectively, for prescribing and dispensing controlled substances without a legitimate medical purpose and outside the course of professional practice. According to court documents, the defendants admitted to providing dangerous doses of hydrocodone to patients who were not examined by a medical professional and while the physician was absent from her clinic.

As a reminder, the six most important Federal fraud and abuse laws that apply to health care providers are the False Claims Act, the Anti-Kickback Statute, the Physician Self-Referral Law (*i.e.,* the Stark Law), the Exclusion Statute, the Civil Monetary Penalties Law and new as of 2018, the Eliminating Kickbacks in Recovery Act. Government agencies, including the Department of Justice, the Department of Health & Human Services Office of Inspector General and the Centers for Medicare & Medicaid Services are charged with enforcing these laws.

False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733 -- The FCA makes it a crime for any person or organization to "knowingly" file a false claim with any Federal health care program, including the Medicare or Medicaid programs. For purposes of the FCA, a person acts "knowingly" if that person: (1) has actual knowledge of the falsity of the information, (2) acts in deliberate ignorance of the truth or falsity of the information, or (3) acts in reckless disregard of the truth or falsity of the information. The FCA does not require proof that a defendant specifically intended to commit fraud. In addition to allowing the Government to pursue a FCA case on its own, the FCA allows private citizens to file lawsuits on behalf of the Government (called "*qui tam*" or "whistleblower" lawsuits) against those who have allegedly defrauded the government. Private citizens who successfully bring *qui tam* actions may receive a portion of the Government's recovery. The fact that a claim results from an arrangement in violation of the Anti-Kickback Statute or is made in violation of the Stark Law also may render it false or fraudulent, creating

liability under the FCA.

Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b) -- The AKS is a criminal law that prohibits the knowing and willful payment of "remuneration" to induce or reward patient referrals or the generation of business involving any item or service payable by a Federal health care program, including the Medicare or Medicaid programs. Remuneration includes anything of value and can take many forms besides cash payments, such as free services or pay to a referral source above fair market value. A provider can be guilty of violating the AKS even if the provider actually rendered the service and the service was medically necessary.

Physician Self-Referral Law ("Stark Law"), 42 U.S.C. § 1395nn -- The Physician Self-Referral Law, commonly referred to as the Stark Law, prohibits physicians from referring patients to receive "Designated Health Services" payable by Medicare or Medicaid from entities with which the physician or an immediate family member has a financial relationship, unless an exception applies. Financial relationships include both ownership/investment interests and compensation arrangements. Designated Health Services include clinical laboratory services; physical therapy, occupational therapy, and outpatient speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; DME and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services. The Stark Law is a strict liability statute, which means proof of specific intent to violate the law is not required. A referral arrangement that implicates the Stark Law can only proceed if the arrangement meets all of the requirements of one of the enumerated Stark Law "exceptions".

Exclusion Statute, 42 U.S.C. § 1320a-7 -- The OIG is required to exclude from participation in all Federal health care programs individuals and entities convicted of the following types of criminal offenses: (1) Medicare or Medicaid fraud, as well as any other offenses related to the delivery of items or services under Medicare or Medicaid, (2) patient abuse or neglect, (3) felony convictions for other health care related fraud, theft or other financial misconduct, and (4) felony convictions for unlawful the manufacture, distribution, prescription or dispensing of controlled substances. The OIG also has "discretion" to exclude individuals and entities on several other grounds, including suspension, revocation, or surrender of a license to provide health care for reasons bearing on professional competence, professional performance or financial integrity; provision of unnecessary or substandard services; submission of false or fraudulent claims to a Federal health care program; engaging in unlawful kickback arrangements; and defaulting on health education loan or scholarship obligations. The full effects of an exclusion are outlined in the "*Updated Special Advisory Bulletin on the Effect of Exclusion From Participation in Federal Health Programs*" published May 9, 2013, but the primary effect is that no payment under a Federal health care program may be made for items or services furnished, ordered or prescribed by an excluded individual or entity.

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Civil Monetary Penalties Law ("CMPL"), 42 U.S.C § 1320a–7a – The CMPL authorizes the Government to impose civil money penalties and/or exclude from the Medicare and Medicaid programs individuals and entities who commit various forms of health care fraud and abuse. Further, under the CMPL it is improper to waive coinsurance and deductible amounts (absent a documented financial hardship) or provide free or discounted services to Federal health care program beneficiaries if such activity is "likely to influence such individuals" to seek the services of the provider.

The Eliminating Kickbacks in Recovery Act ("EKRA"), 18 U.S.C. § 220 -- Signed into law in October of 2018 as part of larger legislation to address the opioid abuse crisis, EKRA prohibits a person or entity from knowingly and willfully: (1) soliciting or receiving, "any remuneration (including any kickback, bribe, or rebate)," in exchange for referring a patient to a recovery home, clinical treatment facility or laboratory, (2) paying or offering any remuneration to induce the referral of a patient to a recovery home, clinical treatment facility or laboratory, or (3) paying or offering any remuneration in exchange for a patient using the services of a recovery home, clinical treatment facility or laboratory. EKRA applies to *both* commercial and Federal health care programs and applies to all clinical laboratory services, even those that do not relate to substance abuse treatment. There are, however, several exceptions to the broad EKRA prohibitions.

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