COMPLIANCE CONNECTION

MAY 2024

This newsletter is prepared monthly by the Midland Health Compliance Department and is intended to provide relevant compliance issues and hot topics.

IN THIS ISSUE

FRAUD & ABUSE LAWS

The five most important Federal Fraud and Abuse Laws that apply to physicians are:

1. ***False Claims Act (FCA):*** *The civil FCA protects the Government from being overcharged or sold shoddy goods or services. It is illegal to submit claims for payment to Medicare or Medicaid that you know or should know are false or fraudulent.*
2. ***Anti-Kickback Statute (AKS):*** *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 the Federal health care programs (e.g., drugs, supplies, or health care services for Medicare or Medicaid patients).*
3. ***Physician Self-Referral Law (Stark law):*** *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.*
4. ***Exclusion Statute:*** *OIG is legally 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; (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 manufacture, distribution, prescription, or dispensing of controlled substances.*
5. ***Civil Monetary Penalties Law (CMPL):*** *OIG may seek civil monetary penalties and sometimes exclusion for a wide variety of conduct and is authorized to seek different amounts of penalties and assessments based on the type of violation at issue. Penalties range from $10,000 to $50,000 per violation.*

Resource:
https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/

MIDLAND HEALTH

COMPLIANCE TEAM

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False Claims Act Complaint Filed Against Regeneron Pharmaceuticals for Fraudulent Drug Pricing Reporting

The United States filed a complaint under the False Claims Act (FCA) against Regeneron Pharmaceuticals Inc. (Regeneron), a New York-based pharmaceutical company. Regeneron manufactures and sells Eylea, an anti-vascular endothelial growth factor inhibitor approved by the Food and Drug Administration to treat, among other conditions, neovascular Age-Related Macular Degeneration, a prevalent, usually age-related condition that impairs vision.

The complaint alleges that Regeneron fraudulently inflated Medicare reimbursement rates for Eylea by knowingly submitting false average sales price reports to the Centers for Medicare and Medicaid Services that excluded certain price concessions. In particular, the United States alleges that Regeneron knowingly failed to report price concessions in the form of credit card processing fees that Regeneron paid to specialty drug distributors to benefit its customers. According to the complaint, Regeneron paid these credit card fees so that distributors would accept credit cards for Eylea purchases while still charging a lower, cash price for the drug, and so that Regeneron's customers — typically retina and ophthalmic practices — could receive credit card benefits for their purchases, such as "cash back" and other credit card rewards.

"We will not permit pharmaceutical companies to flout price reporting requirements to maintain high drug prices," said Principal Deputy Attorney General Brian M. Boynton, head of the Justice Department's Civil Division. "The department is committed to protecting federal health care programs from improper actions by drug companies or others that drive up the cost of those programs at the taxpayers' expense."

"The government alleges that Regeneron manipulated Medicare's drug pricing process, by knowingly failing to report its payment of credit card processing fees as price concessions to its customers," said Acting U.S. Attorney Joshua S. Levy for the District of Massachusetts. "By doing so, Regeneron greatly inflated the costs of its drug to Medicare over many years and enhanced its revenues. Falsely reported average sales prices cost the Medicare system hundreds of millions of dollars and we will make every effort to prevent such practices."

Read entire article:
https://www.justice.gov/opa/pr/false-claims-act-complaint-filed-against-regeneron-pharmaceuticals-fraudulent-drug-pricing

MIDLAND HEALTH Compliance HOTLINE
855•662•SAFE (7233)
ID#: 6874433130
ID# is required to submit a report.
You can make your report or concern ANONYMOUSLY .

MIDLAND HEALTH

MIDLAND HEALTH POLICYTECH

MIDLAND HEALTH • PT POLICYTECH® Policy & Procedure Management

MIDLAND HEALTH CONFLICT OF INTEREST

Purpose: This policy is designed to implement a procedure requiring disclosure of actual and potential conflicts of interest by members of Midland County Hospital District d/b/a Midland Memorial Hospital's (the "Hospital") medical staff ("Medical Staff") serving in leadership positions, other employees serving in leadership positions, and governing board members (collectively "Hospital Representatives").

As stewards of the Hospital's purposes, Hospital Representatives have an ethical duty to exercise their responsibilities with the utmost good faith, due care and loyalty to the welfare and financial interests of the Hospital. Therefore, in pursuit of the same, the Hospital enacts this Conflict of Interest policy to help ensure Hospital Representatives' continuing commitment to these standards in any and all leadership and/or financial activities and transactions while working or volunteering for the Hospital. This policy is intended to supplement, but not replace, any Hospital policies or state and federal laws governing conflicts of interest applicable to nonprofit and charitable organizations.

This Policy does not supersede or relieve a Hospital Representative from any restrictive covenants contained in their employee agreements.

Policy: Hospital Representatives are required to disclose actual or potential conflicts of interest as set forth herein and shall not in any way use their position, or knowledge gained therefrom, to enhance their personal financial position or interests, or the financial position or interests of any immediate family member, or in any manner which is contrary to the best interests of the Hospital.

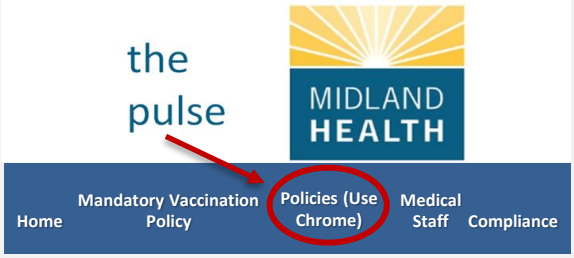
PRINCIPLES AND DEFINITIONS:

1. Conflicts of interest are interests, relationships or situations that a reasonable person would believe may have the potential to improperly influence, affect or conflict with the interests of the Hospital. Conflicts of interest include outside interests or relationships that could:
   - Affect or conflict with the interest of the Hospital;
   - Impair one's ability to remain objective in his/her relationship with the Hospital;

Read entire Policy:
Midland Health PolicyTech #79 – "Conflict of Interest"

Midland Health PolicyTech Instructions

Click this link located on the Midland Health intranet "Policies"
https://midland.policytech.com/dotNet/noAuth/login.aspx?ReturnUrl=%2f



IN OTHER COMPLIANCE NEWS

LINK 1

New Jersey Nursing Facility to Pay $100,000 CMP to Resolve HIPAA Right of Access Violation

https://www.hipaajournal.com/new-jersey-nursing-facility-100000-cmp-hipaa-right-access/

LINK 2

HHS Issues Guidance to Teaching Hospitals and Medical Schools on Informed Consent Requirements

https://www.hipaajournal.com/hhs-guidance-teaching-hospitals-medical-schools-informed-consent/

LINK 3

OCR Opens HIPAA Compliance Investigation of Change Healthcare

https://www.hipaajournal.com/ocr-opens-hipaa-compliance-investigation-of-change-healthcare/

LINK 4

Indiana Attorney General Files Lawsuit Against Apria Healthcare Alleging HIPAA Violations

https://www.hipaajournal.com/indiana-attorney-general-lawsuit-apria-healthcare/

MISAPPROPRIATION OF COVID-19 FUNDS

Woman Pleads Guilty to Theft and Misappropriation of COVID-19 Funds

A Louisiana woman pleaded guilty today to theft of public money in connection with a scheme to misappropriate over $780,000 from the Provider Relief Fund (PRF), a COVID-19 pandemic relief program administered by the Health Resources and Services Administration.

According to court documents, Melissa J. Watson, of Slidell, operated a primary care clinic. Following the onset of the COVID-19 pandemic, Watson submitted false and fraudulent attestations on behalf of her clinic to obtain PRF funds to which she was not entitled. Watson's attestations included falsely affirming that such funds would only be used by the clinic to prevent, prepare for, and respond to coronavirus, and to reimburse health care related expenses or lost revenues attributable to coronavirus. Despite the attestations, Watson used the PRF funds for personal purposes, including making numerous cash withdrawals and purchasing, among other items, hundreds of thousands of dollars in real estate, a luxury vehicle, a boat and trailer, and a time share condominium.

The government seized over $500,000 in bank accounts held by Watson, along with several assets, including a boat and trailer, and a Range Rover Sport vehicle.

Watson is scheduled to be sentenced on July 16 and faces a maximum penalty of 10 years in prison. A federal district court judge will determine any sentence after considering the U.S. Sentencing Guidelines and other statutory factors.

Read entire article:
https://www.justice.gov/opa/pr/woman-pleads-guilty-theft-and-misappropriation-covid-19-funds

MEDICAL EQUPMENT FRAUD SCHEME

Telemedicine Nurse Practitioner Sentenced for $7.8 Million Durable Medical Equipment Fraud Scheme

Defendant signed over 2,000 orders for durable medical equipment without performing an assessment

A Virginia-based nurse practitioner was sentenced in federal court in Boston in connection with a $7.8 million telemedicine fraud scheme involving medically unnecessary durable medical equipment (DME), including orthotics such as back and knee braces.

Daphne Jenkins, 64, was sentenced by U.S. District Court Judge Nathaniel M. Gorton to 18 months in prison followed by two years of supervised release, with the first year to be served in home confinement. Jenkins was also ordered to pay $3,952,761 in restitution. In November 2023, Jenkins pleaded guilty to one count of conspiracy to commit health care fraud.

Between December 2018 and April 2020, Jenkins worked with a purported telemedicine company to sign orders for medically unnecessary durable medical equipment (DME). These DME orders were pre-populated by telemarketing companies that called Medicare beneficiaries to solicit their information. Through DocuSign, Jenkins signed these DME orders even though she did not have any contact with the beneficiaries and did not have a provider-patient relationship with them.

Read entire article:
https://www.justice.gov/usao-ma/pr/telemedicine-nurse-practitioner-sentenced-78-million-durable-medical-equipment-fraud

Do you have a hot topic or interesting Compliance News to report?

If so, please email an article or news link to:

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