COMPLIANCE CONNECTION

OCTOBER 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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Organ Federal Court Permanently Prohibits Ohio Physician from Prescribing Opioids and Imposes $4.7M Judgment for Alleged Unlawful Opioid Distribution

A federal court prohibited a Sandusky, Ohio-area physician from prescribing opioids and other controlled substances and ordered him to pay $4.7 million in a case alleging violations of the Controlled Substances Act (CSA) and the False Claims Act (FCA).

In a civil complaint filed in August 2018, the United States alleged that Dr. Gregory Gerber, MD, who operated an office in Sandusky, unlawfully issued prescriptions without a legitimate medical basis for opioids and other controlled substances in violation of the CSA and the FCA. The complaint alleged that one patient died from an overdose of fentanyl patches prescribed by Gerber. The complaint further alleged that Gerber received kickback payments from a drug manufacturer as part of a scheme to unlawfully prescribe Subsys, a powerful opioid drug containing fentanyl, in violation of the FCA.

"Medical professionals who knowingly facilitate the abuse of opioids violate their legal obligations," said Principal Deputy Assistant Attorney General Brian Boynton, head of the Justice Department's Civil Division. "The department will pursue justice against anyone who seeks to profit from unlawfully prescribing opioids."

"All doctors must follow the law when prescribing opioids — their patients, and the public more generally, rely on such compliance," said U.S. Attorney Rebecca C. Lutzko for the Northern District of Ohio. "Gerber's patients trusted him. But instead of safeguarding that trust, Gerber accepted payments from a drug company in exchange for prescribing dangerous, addictive drugs and wrote thousands of prescriptions that were not for a legitimate medical purpose. Our office will use all available tools — civil and criminal — to fight the opioid epidemic and protect patients and their families so that doctors like Gerber do not profit from abusing our healthcare system."

"Dr. Gerber betrayed the trust placed in him and willfully violated his oath to protect the public and the provisions of the Controlled Substance Act," said Special Agent in Charge Orville O. Greene of the Drug Enforcement Administration (DEA)'s Detroit Field Division. "His reckless behavior contributed to the opioid crisis gripping the nation and brought suffering to many communities in northern Ohio. This ruling will hopefully deter other medical practitioners who are inclined to put profit over patient health and safety."

Read entire article:
https://www.justice.gov/opa/pr/federal-court-permanently-prohibits-ohio-physician-prescribing-opioids-and-imposes-47m

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

Compliance Program Progressive Discipline Policy

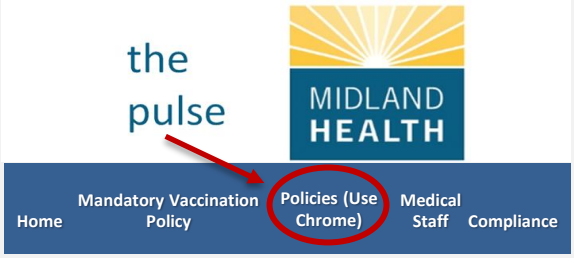
POLICY: Corrective action shall be imposed as a means of facilitating Midland Memorial Hospital's Compliance Program Plan and overall compliance program goal of hospital-wide compliance. Corrective action plans shall assist Midland Memorial Hospital employees, agency staff, medical staff, allied health professionals, vendors, volunteers and students ("Workforce Members") to understand specific issues and reduce the likelihood of future non-compliance. Corrective action, however, shall be sufficient to effectively address the particular instance of non-compliance and should reflect the severity of non-compliance and the Workforce Member's past record of adherence to compliance standards.

1. Basis for Corrective Action: Internal investigation reports, audit reports, consultant reports, reports of questionable practices and/or a person having knowledge of a violation and failing to report such violation may form the basis for imposing corrective action.
2. Elements of a Corrective Action Plan:
   - **a.** As appropriate given the nature of the non-compliance, a corrective action plan shall include, but will not necessarily be limited to, the following:
     - **i.** A resolution of specific problems identified;
     - **ii.** A recommendation to repay or not bill inappropriate claims;
     - **iii.** As directed by hospital counsel, a report to appropriate government authorities about the non-compliance;
     - **iv.** A recommended policy and/or procedure to modify any improper billing practices to reduce the likelihood of recurrence and to monitor any necessary adoption of and compliance with the recommendations;
     - **v.** Additional mandatory education and training for Workforce Members who are the subject of the corrective action;
     - **vi.** Other corrective action measures as required by hospital administration;
     - **vii.** Focused reviews of relevant documentation for a defined period of time;
     - **viii.** Other reasonable corrective measures calculated to ensure adherence to the compliance program.
   - **b.** The Compliance Officer shall follow up and audit corrective action plans to determine whether the corrective action plan is being followed and is effective. The failure of an individual subject to a corrective action plan to adhere to the plan shall be grounds for further corrective action.

Read entire Policy: Midland Health PolicyTech #3887
"HIPAA Section 14:1 Compliance Program Progressive Discipline Policy"

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

OCR: Don't Neglect Physical Security Controls for ePHI

https://www.hipaajournal.com/ocr-physical-security-facility-access-controls-hipaa/

LINK 2

Enzo Biochem Settles HIPAA Violations with State Attorneys General for $4.5 Million

https://www.hipaajournal.com/enzo-biochem-hipaa-settlement-ny-nj-cty/

LINK 3

Organ Transplant Coordinator Convicted of Illegally Accessing Health Records of Supreme Court Judge

https://www.hipaajournal.com/organ-transplant-coordinator-guilty-medical-record-access-ginsburg/

LINK 4

Indiana Attorney General Drops Privacy Lawsuit Against IU Health

https://www.hipaajournal.com/indiana-attorney-general-drops-privacy-lawsuit-against-iu-health/

FALSE CLAIMS ACT

Medical Device Company to Pay $700,000 to Resolve False Claims Act Allegations Concerning Inflated Reimbursements from Medicare and Medicaid

Medical device manufacturer THD America Inc., located in Natick, Massachusetts, and its corporate parent, THD SpA of Italy (collectively, THD), have agreed to pay $700,000 to resolve allegations that THD violated the False Claims Act by knowingly causing physicians to use incorrect codes to obtain inflated reimbursement from Medicare and State Medicaid programs for the use of THD's hemorrhoid removal system called the Slide One Kit (the Kit).

The Kit was sold to physicians for use in transanal hemorrhoidal dearterialization, a surgical procedure that involves cauterizing certain blood vessels. The United States alleged that, between 2014 and 2017, physicians performing procedures using the Kit were required to bill for the procedure using a temporary code, also known as a "T-Code," assigned for new and emerging services. Because a procedure that is assigned such a code is considered experimental, reimbursement for the use of the Kit was often denied. To avoid such denials and increase potential reimbursement, THD allegedly encouraged colorectal and general surgeons improperly to bill Medicare and Medicaid programs using the T-Code plus an additional Current Procedural Terminology (CPT) code or to bill for CPT codes other than the T-code.

The federal share of the civil settlement is $598,121.23, and the state Medicaid share of the civil settlement is $101,877.77. State Medicaid programs are jointly funded by the federal and state governments. "The integrity of federal healthcare programs depends upon compliance with coding and billing rules that are used to make coverage and reimbursement decisions," said Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Justice Department's Civil Division.

Read entire article:
https://www.justice.gov/opa/pr/medical-device-company-pay-700000-resolve-false-claims-act-allegations-concerning-inflated

FALSE CLAIMS ACT

Pharmaceutical Company Pays $25M to Resolve Alleged False Claims Act Liability for Price-Fixing of Generic Drug

A generic pharmaceutical manufacturer, Glenmark Pharmaceuticals Inc. USA (Glenmark), located in Mahwah, New Jersey, has agreed to pay $25 million, based on its ability to pay, to resolve its alleged liability under the False Claims Act for conspiring to fix the price of a generic drug. The government alleged that, between 2013 and 2015, Glenmark paid and received compensation prohibited by the Anti-Kickback Statute through arrangements on price, supply and allocation of customers with other pharmaceutical manufacturers for a generic drug manufactured by Glenmark, pravastatin, which is widely used to treat high cholesterol and triglyceride levels.

"Illegal collaboration on the price or supply of drugs increases costs both to federal health care programs and beneficiaries," said Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Justice Department's Civil Division. "The department will use every tool at its disposal to prevent such conduct and to protect these taxpayer-funded programs from abuse."

"At a time when excessive drug costs are already imposing unprecedented burdens on our country's vulnerable citizens, an illegal conspiracy to fix the prices of generic drugs is alarming," said U.S. Attorney Jacqueline C. Romero for the Eastern District of Pennsylvania. "My office is proud to work with the rest of the department and our investigative partners to hold companies accountable when they illegally inflate prices on drugs used for the health and well-being of our citizens." "Conspiring to raise prices on generic medications is illegal and could prevent patients from being able to afford their needed prescription drugs. Americans have the right to purchase generic drugs set by fair and open competition, not collusion," said Special Agent in Charge Maureen R. Dixon of the Department of Health and Human Services Office of the Inspector General (HHS-OIG), Philadelphia Regional Office. "HHS-OIG will continue to work with our law enforcement partners to investigate allegations of health care fraud that put the public and the Medicare program at risk."

Read entire article:
https://www.justice.gov/opa/pr/pharmaceutical-company-pays-25m-resolve-alleged-false-claims-act-liability-price-fixing

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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