

COMPLIANCE CONNECTION

DECEMBER 2024

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

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Feature Article:

Drug Maker Teva Pharmaceuticals Agrees to Pay \$450M in False Claims Act Settlement to Resolve Kickback Allegations Relating to Copayments and Price Fixing

Midland Health PolicyTech: Policy #3755
Code of Conduct (See Page 2)

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/>



Drug Maker Teva Pharmaceuticals Agrees to Pay \$450M in False Claims Act Settlement to Resolve Kickback Allegations Relating to Copayments and Price Fixing

Teva Pharmaceuticals USA Inc. (Teva USA) and Teva Neuroscience Inc. (collectively, Teva) have agreed to pay \$450 million to resolve two matters that allege Teva violated the Anti-Kickback Statute (AKS) and the False Claims Act (FCA). Teva, headquartered in Parsippany, New Jersey, is the largest generic drug manufacturer in the United States. The settlement amount was based on Teva's ability to pay.

"Kickbacks designed to induce referrals or purchases of healthcare goods or services distort physician and patient decision-making, thwart competition and bypass controls put in place to protect federal health care programs," said Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Justice Department's Civil Division. "The Justice Department is committed to pursuing those who engage in kickback violations, including drug manufacturers, to ensure that federal health care programs continue to serve the interests of taxpayers and program beneficiaries."

The settlement encompasses two alleged kickback schemes. First, Teva has agreed to resolve allegations in a complaint the United States filed in the District of Massachusetts in August 2020 that Teva violated and conspired to violate the AKS and FCA by paying Medicare patients' cost sharing obligations (copays) for the multiple sclerosis drug Copaxone from 2006 through 2017, while steadily raising Copaxone's price.

Read entire article:

<https://www.justice.gov/opa/pr/drug-maker-teva-pharmaceuticals-agrees-pay-450m-false-claims-act-settlement-resolve-kickback>



HIPAA Compliance Tips During the Holiday Season



The holiday season is a time for celebration, joy, and spreading goodwill. However, for those working in healthcare, it's also necessary to remain cautious about protecting sensitive patient information. As festivities begin and work environments shift, here are some key tips to uphold HIPAA compliance during this joyous time.

Safeguard Patient Data

It's important to safeguard patient data especially during office parties or gatherings where discussions might inadvertently touch upon patient information.

Secure Physical Documents

With increased holiday traffic in workplaces, it's important to secure physical documents containing patient information. Implement measures such as locking file cabinets and guaranteeing documents are not left unattended in public spaces.

Read entire article:

<https://totalmedicalcompliance.com/hipaa-compliance-tips-during-the-holiday-season/#:~:text=The%20holiday%20season%20is%20a%20time%20for,tips%20to%20uphold%20HIPAA%20compliance%20during%20this>



MIDLAND HEALTH

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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 CODE OF CONDUCT

Purpose: Midland Memorial Hospital (“MMH”) is committed to conducting business in an ethical and honest manner and within the bounds of the law. This Code of Conduct provides governing board members, medical and allied health staff, employees, agency staff, independent contractors, vendors, volunteers and students of Midland Memorial Hospital (“MMH Representatives”) with guidelines for conducting business and operations in a manner which fulfills this commitment. This Code of Conduct further provides the foundation principals for implementing the MMH Compliance Program, which serves to prevent the occurrence of illegal or unethical behavior, and is supplementary to the mission, vision, and values of MMH, its policies and procedures, as well as pertinent state and federal law.

This Code of Conduct has been distributed to all MMH Representatives and sets forth general standards applicable to all MMH business and operations. In addition to this Code of Conduct, there are a number of more detailed and specific MMH policies and procedures covering the particular issues described herein.

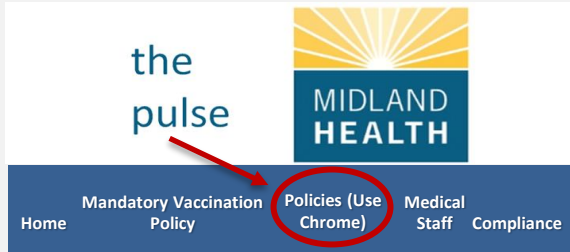
Policy

- MMH’s Commitment to Legal and Ethical Behavior
- Complying with the Law
- Providing for Excellent Patient Care
- Protecting Confidential Information
- Adhering to Anti Kickback and Healthcare Fraud and Abuse Legislation
- Declining Inappropriate Gifts or Gratuities
- Policy Pertaining to Business Courtesies Received from Vendors
- Not Providing Inappropriate Gifts to Patients and Visitors
- Avoiding Conflicts of Interest

Read entire Policy:
[Midland Health PolicyTech #3755 – “Code of Conduct”](#)

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
Change Healthcare Cyberattack Affected 100 Million Individuals
<https://www.hipaajournal.com/change-healthcare-responding-to-cyberattack/>

LINK 2
Email Incidents Reported by Survival Flight and Jacksonville Children’s Multispecialty Clinics
<https://www.hipaajournal.com/email-incidents-reported-by-survival-flight-and-jacksonville-childrens-multispecialty-clinics/>

LINK 3
Patient Data Compromised in Email Breaches in Indiana, New York & Wisconsin
<https://www.hipaajournal.com/patient-data-compromised-email-breaches-indiana-new-york-wisconsin/>

LINK 4
More Than 909,000 Individuals Affected by Cyberattack on New York IT Services Provider
<https://www.hipaajournal.com/atsg-data-breach-909000-individuals/>

HIPAA VIOLATION FINES

Jail Terms for HIPAA Violations by Employees: FAQs

What HIPAA violation fines apply to employees? HIPAA violation fines do not usually apply to employees because employees (as members of the workforce) are considered “under the control” of a Covered Entity or Business Associate. Consequently, a Covered Entity or Business Associate is liable for civil violations of HIPAA by one of their employees. However, criminal HIPAA violation fines apply to employees if they are found guilty of the knowing and wrongful disclosure of PHI contrary to 42 USC § 1320d-6 of the Social Security Act. In such cases, there are three tiers of HIPAA violation fines for employees:

- *Tier 1* – If an individual obtains PHI, discloses PHI, or enables a third party to obtain/disclose PHI, the maximum fine is \$50,000 plus up to one year in prison.
- *Tier 2* – If an individual commits a Tier 1 crime under false pretenses, the HIPAA violation fines for employees increase up to \$100,000 and up to five years in prison.
- *Tier 3* – If an individual commits a Tier 1 or Tier 2 crime with the intent to sell, transfer, or use the PHI for commercial advantage, personal gain, or malicious harm, the maximum fine increases to \$250,000, and the maximum jail time for violating HIPAA to ten years.

Are criminal HIPAA fines and jail time only for employees? Criminal HIPAA fines and jail time are not only for employees. Any member of the workforce that violates 42 USC § 1320d-6 of the Social Security Act can be fined and sent to jail for a criminal violation of HIPAA – as can employers if, through their negligence, they enable a third party to obtain, use, or disclose PHI without authorization.

Read entire article:
<https://www.hipaajournal.com/jail-terms-for-hipaa-violations-by-employees/>

FALSE CLAIMS ACT

California Mobile Phlebotomy Lab and Its Owners to Pay \$135,000 to Resolve Allegedly False Claims for Blood Testing Services and Travel Mileage

Veni-Express Inc. (Veni-Express), headquartered in California, and its owners Myrna and Sonny Steinbaum have agreed to pay at least \$135,000 to resolve False Claims Act allegations that they submitted false claims for mobile phlebotomy services and associated travel mileage and paid kickbacks to a third-party marketer of these services, in violation of the Anti-Kickback Statute (AKS). Veni-Express has agreed to pay \$100,000, plus additional amounts based on the sale of company property. Myrna Steinbaum has agreed to pay \$25,000, and Sonny Steinbaum has agreed to pay \$10,000. These settlements are based on their ability to pay.

The United States alleged that from 2015 to 2019, Veni-Express and the Steinbaums knowingly caused false or fraudulent claims to federal health care programs for mobile phlebotomy services and associated travel mileage. Specifically, with the Steinbaum’s oversight and approval, Veni-Express submitted false claims for venipuncture (blood draw) procedures that the company did not actually perform during homebound patient visits, and for travel mileage associated with these visits that was not reimbursable by Medicare. The United States further alleged that, from July 2014 to June 2015, Veni-Express paid unlawful kickbacks (in the form of a percentage of company revenue) to a third-party, Altera Laboratories also known as Med2U Healthcare LLC, for the marketing of Veni-Express’ services, in violation of the AKS.

“Health care providers that bill for services they did not provide or offer illegal incentives to increase profits will be held accountable,” said Principal Deputy Assistant Attorney General Brian M. Boynton, head of the Justice Department’s Civil Division. “We will continue to safeguard federal health care programs against those who seek to abuse them.”

Read entire article:
<https://www.justice.gov/opa/pr/california-mobile-phlebotomy-lab-and-its-owners-pay-135000-resolve-allegedly-false-claims>



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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