



COMPLIANCE CONNECTION

Newsletter

JULY 2026

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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Takeda Agrees to Pay \$13.6M to Resolve False Claims Allegations Relating to Improper Payments to Physicians

Midland Health PolicyTech: Policy #15217 Acceptable Use of Artificial Intelligence (AI)
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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

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Takeda Agrees to Pay \$13.6M to Resolve False Claims Allegations Relating to Improper Payments to Physicians



Takeda Pharmaceuticals, U.S.A. Inc. has agreed to pay \$13,670,921 to resolve allegations that it knowingly caused the submission of false claims to Medicare and other federal health care programs by paying kickbacks to healthcare providers to induce prescriptions of Trintellix, an antidepressant medication that Takeda marketed and sold to treat major depressive disorder.

"The Department of Justice is committed to vigorously pursuing violations of the False Claims Act arising from illegal kickbacks," said Assistant Attorney General Brett A. Shumate of the Justice Department's Civil Division. "Such conduct can erode the trust that patients place in their healthcare providers and lead to higher drug costs for American taxpayers."

"This settlement demonstrates the continued commitment of my office to ensure that patients' best interests remain paramount," said U.S. Attorney Eric Grant for the Eastern District of California. "Prescribing decisions should not be influenced by drug companies' payments or side perks made available to physicians."

"Alleged kickback schemes such as those described in this matter undermine the trust that patients place in their providers and federal health care programs," said Acting Deputy Inspector General for Investigations Scott J. Lampert of the U.S. Department of Health and Human Services, Office of Inspector General (HHS OIG). "This settlement underscores that HHS-OIG, together with our law enforcement partners, will investigate and hold accountable entities that attempt to disguise purported honoraria or other improper payments as legitimate compensation. Decisions regarding patient care should never be influenced by extravagant meals or other inducements."

"As the investigative arm of the Department of Defense Office of Inspector General, the Defense Criminal Investigative Service is committed to protecting the integrity of programs that directly affect our service members and their families," said Special Agent in Charge John E. Helsing for the Department of Defense Office of Inspector General, Defense Criminal Investigative Service (DCIS), Western Field Office. "When companies use kickbacks to influence prescribing, they erode trust in healthcare providers, misuse federal healthcare funds, and put the health and readiness of our warfighters at risk. DCIS will continue working with our law enforcement partners and the Department of Justice to stop schemes that threaten those who faithfully serve our country."

Read entire article:

<https://www.justice.gov/opa/pr/takeda-agrees-pay-136m-resolve-false-claims-allegations-relating-improper-payments>

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



Acceptable Use of Artificial Intelligence (AI)

Purpose: This policy establishes guidelines for the appropriate and secure use of artificial intelligence (AI) tools and services within Midland Health. As AI technologies continue to evolve and offer benefits in healthcare and operational workflows, it is critical to ensure their use aligns with patient safety, regulatory requirements, and our organization's values.

General Guidelines for AI Use:

- Approval Required:** Use of AI tools for any Midland Health operations, clinical workflows, patient interactions, or internal decision-making must be approved in advance by the AI Governance Committee and any additional stakeholders required, depending on the area of use. Unauthorized use is prohibited.
- AI Tool Inventory:** All AI tools or systems in use or under evaluation must be documented in an internal AI inventory managed by IT Security and Compliance. Staff are responsible for submitting requests and ensuring tools are properly recorded.
- All AI usage must adhere to HIPAA, state and legal privacy laws, and other applicable legal and ethical standards.
- Where required, informed consent must be obtained before AI is used in clinical decision-making or patient-facing functions.
- Prohibited Use Cases:**
 - No sharing of PHI (Protected Health Information), PII (Personally Identifiable Information), or PCI (Payment Card Information) with any AI platform under any circumstances.
 - AI tools that are not publicly accessible or vetted by IT (e.g., private, beta, or unreleased models) may not be used for any Midland Health purpose.
 - AI may not be used to make autonomous clinical decisions without oversight from licensed professionals.
 - Midland Health data cannot be used to train AI models without written approval from Legal, Compliance and IT Security.
 - AI cannot be used in ways that could exacerbate inequity, cause harm, or produce discriminatory outcomes.
- Transparency and Oversight:** Any output generated by AI must be reviewed by qualified staff before use in clinical or operational decisions. AI-generated content must not be treated as final or authoritative without human validation.

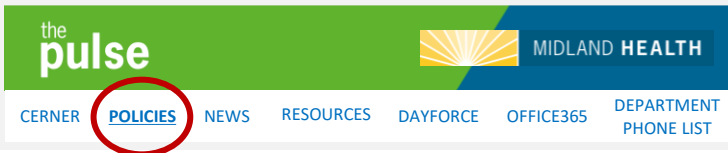
Read entire Policy:

Midland Health PolicyTech #15217 – "Acceptable Use of Artificial Intelligence (AI)"

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 Fines Four Regulated Entities for HIPAA Violations That Led to Ransomware Attacks

<https://www.hipaajournal.com/ocr-fines-four-regulated-entities-hipaa-violations-ansomware-attacks/>

LINK 3

What is the Relationship Between HITECH, HIPAA, and Electronic Health and Medical Records?

<https://www.hipaajournal.com/relationship-between-hitech-hipaa-electronic-health-medical-records/>

LINK 2

OCR Releases Video on HIPAA Security Rule Risk Management Requirements

<https://www.hipaajournal.com/ocr-risk-management-guidance-video/>

LINK 4

What are the Penalties for HIPAA Violations?

<https://www.hipaajournal.com/what-are-the-penalties-for-hipaa-violations-7096/>

The United States Files False Claims Act Complaint Against Three National Health Insurance Companies and Three Brokers Alleging Unlawful Kickbacks and Discrimination Against Disabled Americans

The United States filed a complaint under the False Claims Act (FCA) against three of the nation's largest health insurance companies — Aetna Inc. and affiliates, Elevance Health Inc. (formerly known as Anthem), and Humana Inc. — and three large insurance broker organizations — eHealth, Inc. and an affiliate, GoHealth, Inc., and SelectQuote Inc. The United States alleges that from 2016 through at least 2021, the defendant insurers paid hundreds of millions of dollars in illegal kickbacks to the defendant brokers in exchange for enrollments into the insurers' Medicare Advantage plans.

Under the Medicare Advantage (MA) Program, also known as Medicare Part C, Medicare beneficiaries may choose to enroll in health care plans (MA plans) offered by private insurance companies, such as defendants Aetna, Anthem, and Humana. Many Medicare beneficiaries rely on insurance brokers to help them choose an MA plan that best meets their individual needs. Rather than acting as unbiased stewards, the defendant brokers allegedly directed Medicare beneficiaries to the plans offered by insurers that paid brokers the most in kickbacks, regardless of the suitability of the MA plans for the beneficiaries.

Read entire article:

<https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-three-national-health-insurance>

Oglethorpe Inc. and Top Executives Agree to Pay \$32M to Resolve False Claims Act Allegations

Oglethorpe Inc. (Oglethorpe), an operator of psychiatric hospitals headquartered in Tampa, Florida, along with its founder and principal owner, Robert Cohen, CEO John Picciano, and Chief Operating Office James O'Shea, have agreed to pay \$32 million to resolve allegations that they violated the False Claims Act by knowingly failing to return overpayments received from the Medicare program for the admission of beneficiaries to three of Oglethorpe's Ohio facilities.

The settlement resolves allegations that, from 2021 through the present, Oglethorpe and its executives knowingly failed to return to Medicare overpayments that Oglethorpe's own consultants had identified. The overpayments related to beneficiaries who had been admitted to two hospitals (Ridgeview Behavioral Hospital and Georgetown Behavioral Hospital) and a substance abuse clinic (The Woods at Parkside), even though they did not qualify for inpatient psychiatric care.

Read entire article:

<https://www.justice.gov/opa/pr/oglethorpe-inc-and-top-executives-agree-pay-32m-resolve-false-claims-act-allegations>

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Health Observances Calendar

Days to Note

July 10 Chronic Disease Awareness Day

July 28 World Hepatitis Day

<https://b2b.healthgrades.com/insights/blog/2026-health-observances-calendar/>



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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