FRAUD, WASTE, AND ABUSE
Lessons Learned from Recent Cases, Enforcement Actions, and Settlements

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TOPICS

- Laws Frequently Utilized in Enforcement Actions
- Health Care Fraud and Abuse Control Program
- Recent Cases, Actions, and Settlements
  - Medical Directorships
  - Marketing Practices
  - Relationships with Excluded Individuals
  - Non-compliance with Medicare Coverage Criteria and Standards
FRAUD, WASTE, AND ABUSE LAWS
False Claims Act, Anti-Kickback Statute, and the Stark Law
FALSE CLAIMS ACT, 31 U.S.C. § 3729

“Any person who . . . knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; . . . or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money . . . to the Government, is liable to the United States Government for a civil penalty . . . plus 3 times the amount of damages.”

- Civil Monetary Penalties (CMPs) up to ~$22,000 per claim
- Treble damages
FALSE CLAIMS ACT, 42 U.S.C. § 1320(A)-7B(A)

“Whoever … knowingly and willfully makes or causes to be made any false statement or representation of material fact for use in determining rights to such benefit or payment … shall … be fined … or imprisoned … or both.”

- Fine up to $25,000 per violation
- Imprisonment up to 10 years per violation
ANTI-KICKBACK STATUTE (AKS), 42 U.S.C. § 1320A-7B(B)

“Whoever knowingly and willfully solicits or receives any remuneration . . . in return for referring an individual . . . or in return for . . . ordering . . . or recommending purchasing . . . or ordering any . . . facility, service, or item for which payment may be made . . . under a Federal health care program . . . shall be fined . . . or imprisoned . . . or both.”

“Whoever knowingly and willfully offers or pays any remuneration . . . to induce [a] person to refer an individual . . . or to . . . order . . . or recommend . . . purchasing . . . or ordering any . . . services, or item for which payment may be . . . under a Federal health care program . . . shall be fined . . . or imprisoned . . . or both.”

- Criminal fine of up to $25,000 and imprisonment for up to five years.
- Exclusion
- CMP up to $50,000 per violation
- Liability under FCA
STARK LAW, 42 U.S.C. § 1395

“[I]f a physician (or an immediate family member of such physician) has a financial relationship with an entity ... then the physician may not make a referral to the entity for the furnishing of designated health services ... and the entity may not present or cause to be presented a claim ... to any individual, third party payor, or other entity for designated health services furnished pursuant to a [prohibited] referral.”

- Refund of amounts collected
- CMPs of up to $15,000 for each service
- Exclusion
- CMP of up to $100,000 for each circumvention scheme
- Liability under the FCA
OTHER LAWS USED IN ENFORCEMENT ACTIONS

- Conspiracy to Defraud: 18 U.S.C. § 286
- Submission of Fraudulent claims: 18 U.S.C. § 287
- Theft or Embezzlement: 18 U.S.C. § 669
- Using Mail to Defraud: 18 U.S.C. § 134
- Scheme to Defraud Health Care Benefit Program: 18 U.S.C. § 1347
HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM (HCFAC)
Background, Collections, Enforcement Agencies
HCFAC BACKGROUND

- Established under HIPAA
- Directed by Attorney General and HHS Office of Inspector General
- Coordinates enforcement activities among all levels of government
- Collaborations
  - Health Care Fraud Prevention and Enforcement Action Team (HEAT)
  - Health Care Fraud Prevention Partnership
  - Data Integration and Analytics
HCFAC RESULTS

Billions of Dollars Won, Negotiated, and Collected under HCFAC Program

Source: OIG, Health Care Fraud Abuse Control Program Reports, FY 2016-2019
HCFAC ENFORCEMENT AGENCIES

HCFAC

Department of Health and Human Services
- HHS Office of Inspector General (OIG)
  - Office of Audit Services
  - Office of Evaluation and Inspections
  - Office of Investigations
  - Office of Counsel to the Inspector General
- Centers for Medicare and Medicaid Services (CMS)
  - Unified Program Integrity Contractors
- Administration on Community Living
- Office of the General Counsel
- Food and Drug Administration

Department of Justice
- United States Attorneys
- Civil Division
- Criminal Division
- Civil Rights Division
- DOJ Office of Inspector General
- Federal Bureau of Investigations
CASES INVOLVING MEDICAL DIRECTORSHIPS
Two Recent Settlements and Lessons Learned
HOME HEALTH CARE OF FLORIDA, LLC

- $300,000 Settlement
- Announced September 2, 2020
- Alleged that payments to medical director were designed to induce referrals in violation of Stark Law and Anti-Kickback Statute

FOR IMMEDIATE RELEASE

Home Health Company Agrees To Pay $300,000 To Resolve Allegations Of Illegal Kickback Scheme

Orlando, FL – United States Attorney Maria Chapa Lopez announces today that Home Health Care of Florida, LLC has agreed to pay $300,000 to resolve allegations that it engaged in a kickback scheme related to the referral of Medicare patients for home health services.

The settlement announced today resolves allegations that between August 1, 2013, and March 31, 2017, Home Health Care of Florida illegally paid its medical director in order to induce him to refer Medicare patients to Home Health Care of Florida for services that were billed to the United States. The medical director entered into a related settlement agreement in December of 2018. The United States alleged that these financial arrangements violated the physician self-referral law, commonly known as the “Stark Law,” and the Anti-Kickback Statute, giving rise to liability under the False Claims Act.
U.S. AND STATE OF GEORGIA EX REL. ESKRIDGE V. STG HEALTHCARE OF ATLANTA, INC., NO. 1:16-CV-0688-LMM (N.D. GA)

- Qui tam suit under FCA
- Allegations included:
  - Hospice submitted claims for patients who were not terminally ill
  - Hospice’s aggressive goals for admitting new patients and the failure to supervise staff and medical directors resulted in ineligible admissions
  - Hospice paid referring medical director who did not serve as a legitimate hospice physician
LESSONS LEARNED

- Structure arrangements under available Stark exceptions and AKS safe harbors
  - 42 C.F.R. § 411.357(d) – Stark exception for Personal Service Arrangements
  - 42 C.F.R. § 1001.952(d) – AKS safe harbor for Personal Services and Management Contracts

- Key Considerations for Compliance
  - Written agreement covering all services
  - Arrangement is reasonable and necessary for legitimate business purposes
  - Compensation is consistent with fair market value and does not take into account referrals or business generated between the parties

- Best Practices
  - Documentation of FMV evaluation and need for services
  - Time sheets
CASES CONCERNING MARKETING PRACTICES
Recent Settlement, Criminal Indictments, and Lessons Learned
**U.S. V PROGENITY, INC., NO. 16-CV-9051-LAP (S.D.N.Y.)**

- **Qui tam** suit brought by former sales representative
- Alleged three kickback schemes, including one involving marketing expenditures benefiting physicians and their staffs:
  - Food, alcohol, and “goodies” such as customized M&Ms, whiskey cakes, and custom food and drink orders
  - Happy hours, birthday parties, and holiday parties

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Department of Justice
U.S. Attorney’s Office
Southern District of New York

FOR IMMEDIATE RELEASE

Thursday, July 23, 2020

Acting Manhattan U.S. Attorney Announces $49 Million Settlement With Biotech Testing Company For Fraudulent Billing And Kickback Practices

Progenity Inc. Admits to Fraudulently Using Wrong Billing Code, Paying “Draw Fees” to Physicians, and Providing Meals and Happy Hours to Physicians and Their Staff

Criminal charges filed against 30 defendants

- Largest home health agency in San Francisco Bay Area, hospice provider, 13 physicians, marketers, case managers, and social workers

Allegations included:

- Marketers were instructed to take case managers, social workers, doctors and their staffs to sporting events and elaborate meals and to provide gifts to incentivize and reward referrals
LESSONS LEARNED

- Marketing expenditures that benefit referral sources can constitute grounds for an enforcement action.

- Utilize Stark exception for nonmonetary compensation, 42 C.F.R. § 411.357(k)
  - Available for compensation in the form of items or services (not including cash or cash equivalents) that does not exceed applicable annual limit ($423 for 2020) if the following conditions are met:
    
    "(i) The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

    (ii) The compensation may not be solicited by the physician or the physician’s practice (including employees and staff members).

    (iii) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission."

- What about the AKS?
LESSONS LEARNED

- Monitor and limit the amount, types, and purposes of marketing expenditures
- Maintain a system to track purchases and amounts spent on items and services that benefit physicians and their family members
- Train staff and evaluate impact of business goals and operations on cultivating a culture of compliance
- Document, document, document
  - Receipts
  - Purpose of purchases
  - Sign-in sheets and other records of parties benefiting from purchases
- Audit documentation
CASES INVOLVING EXCLUDED INDIVIDUALS

Civil Settlements, Criminal Convictions, and Lessons Learned
PROVIDER-SELF DISCLOSURE PROTOCOL

- OIG Provider-Self Disclosure Protocol
- Between January and August 2020
  - 47 total settlements
  - 18 arose from the OIG’s allegations that the provider employed or contracted with an individual the provider knew or should have known was excluded from participation in federal health care programs
  - Approximately $1.87 million will be paid as a result of such settlements
Elder Care formed in 2001
Okwilagwe (owner) and Emordi (employee) excluded in 2012
DON’s certifications on contracts and enrollments with Medicaid and Medicaid MCOs
2015 Medicare survey resulted in referral to FBI
Okwilagwe sentenced to 188 months
Emordi and DON sentenced to 60 months
Restitution payment of $3,559,154
Upheld on appeal on May 14, 2020
LESSONS LEARNED

“The OIG may impose a penalty; an exclusion; and, where authorized, an assessment against any person who it determines... [a]rranges or contracts (by employment or otherwise) with an individual or entity that the person knows, or should know, is excluded from participation in Federal health care programs for the provision of items or services for which payment may be made under such a program.” 42 C.F.R. 1003.200

- Provider liability arises when “an excluded person participates in any way in the furnishing of items or services that are payable by a Federal health care program.”
  - OIG, “Special Advisory Bulletin on the Effect of Exclusion from Participation in Federal Health Care Programs” (May 2013)
LESSONS LEARNED

- Regularly conduct background screenings and document searches
  - All new employees and independent contractors
  - Periodic screening of current employees and contractors
  - Databases
    - OIG’s List of Excluded Individuals and Entities (LEIE)
    - GSA’s System for Award Management (SAM)

- Include representations and warranties regarding exclusions in contracts

- Ensure submission of accurate and complete information on CMS 855 forms / PECOS and all other enrollments and applications to federal and state health care programs
CASES INVOLVING COVERAGE CRITERIA AND MEDICARE STANDARDS

Three Recent Settlements and Lessons Learned
Qui tam suit by former nurse

Federal and state governments intervened

Alleged that hospice knowingly submitted claims for Continuous Home Care (CHC) and General Inpatient care (GIP) when higher level of care was not medically necessary
U.S. AND STATE OF FLORIDA EX REL. MARGARET PETERS V. HOPE HOSPICE AND COMMUNITY SERVICES, NO. 2:16-CV-6FTM-99MRM

• *Qui tam* suit by former Director of Hospice Care
• Government intervened
• Allegations included that hospice knowingly submitted claims for GIP when the higher level of care was not medically necessary
U.S. AND STATE OF NEW YORK, EX. RE. EDWARD LACEY V. VISITING NURSE SERVICE OF NEW YORK, 1:14-CV-057 (S.D.N.Y.)

- *Qui tam* suit brought by former VP of Operations
- Government did not intervene
- Allegations included
  - Agency accepted referrals without regard to capacity
  - Agency did not comply with plans of care and only provided a portion of prescribed services
  - Executives ignored relator’s requests for correction
- June 2020 Settlement
  - $57 million
  - No admission of liability
LESSONS LEARNED

- Conduct internal and external audits
  - Implement ongoing, routine process for regular audits and appropriate corrective actions
  - Identify and audit areas of potential non-compliance within organization
    - Issues identified in payor audits
    - Available data comparing organization’s performance to peers
  - Review areas deemed high risk by governmental agencies
**LESSONS LEARNED: AUDIT**

### Frequent Issues that Result in Overpayment Liability

**Home Health**
- Issues relating to face-to-face requirements
  - No signature
  - Encounter notes do not address all elements of eligibility
- Issues with recertification
  - No estimate of continued need
  - Missing initial certification

**Hospice**
- Billing for incorrect level of care
- No or deficient certification of terminal illness
- Clinical documentation does not support certification
Figure 3: Percentage Breakdown of CERT Error Subcategory for Improper Claims Caused by Insufficient Documentation From FYs 2014 Through 2017

### LESSONS LEARNED: AUDIT

**Characteristics of Providers that could have a High Risk of Improper Billing Practices**

<table>
<thead>
<tr>
<th>Home Health</th>
<th>Hospice</th>
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<tbody>
<tr>
<td>High average outlier payment per beneficiary</td>
<td>High number of patients residing in ALFs and NFs</td>
</tr>
<tr>
<td>High percentage of beneficiaries for whom other HHAs have billed Medicare</td>
<td>High rates of discharging patients alive</td>
</tr>
<tr>
<td>High average number of late episodes per beneficiary</td>
<td>High number of patients with long hospice stays</td>
</tr>
<tr>
<td>High average number of therapy visits per beneficiary</td>
<td>High percent of beneficiaries with diagnoses that require less complicated care</td>
</tr>
<tr>
<td>High average number of denials for issues relating to homebound status, certifications, and face-to-face requirements</td>
<td>Beneficiaries with high numbers of Part D drugs</td>
</tr>
</tbody>
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See OIG, “Vulnerabilities in the Medicare Hospice Program Affect Quality Care and Program Integrity: An OIG Portfolio” OEI-02-16-00570 (July 2018); OIG, “Inappropriate and Questionable Billings by Medicare Home Health Agencies,” OEI-04-11-00240 (Aug. 2012)
LESSONS LEARNED

- Implement effective compliance program
  - Identify potential compliance issues
    - Hotline
    - Exit interviews
  - Log compliance concerns, investigate, and track responsive actions
QUESTIONS?
THANK YOU!

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