





#### FRAUD, WASTE, AND ABUSE

Lessons Learned from Recent Cases, Enforcement Actions, and Settlements



**Todd Moody** 

Brown & Fortunato, P.C.

Allison D. Shelton

Brown & Fortunato, P.C.

## 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





Submission of Fraudulent claims

18 U.S.C. § 287

Theft or Embezzlement

18 U.S.C. § 669

Making False Statements

18 U.S.C. § 1035

Using Mail to Defraud

18 U.S.C. § 134

Scheme to Defraud Health Care Benefit Program

Money Laundering

18 U.S.C. § 1956

Racketeering Activity

18 U.S.C. § 1961



18 U.S.C. § 1347







## HEALTH CARE FRAUD AND ABUSE CONTROL PROGRAM (HCFAC)

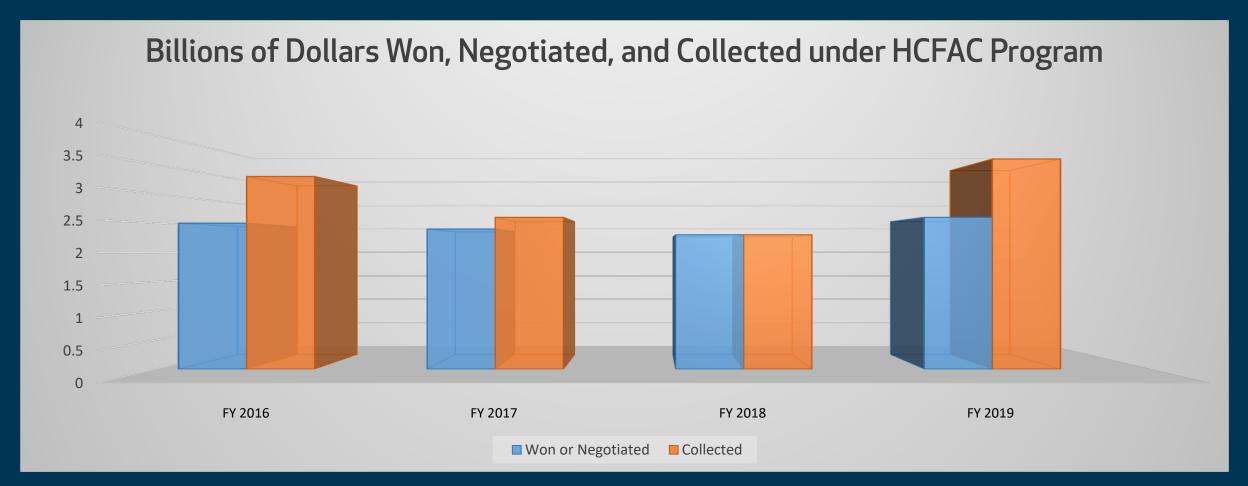
Background, Collections, Enforcement Agencies

### 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**



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



#### HCFAC ENFORCEMENT AGENCIES

HCFAC

Department of Health and Human Services

Department of Justice

- 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

- 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



THE UNITED STATES ATTORNEY'S OFFICE



U.S. Attorneys » Middle District of Florida » News

Department of Justice

U.S. Attorney's Office

Middle District of Florida

FOR IMMEDIATE RELEASE

Wednesday, September 2, 2020

#### 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)



THE UNITED STATES ATTORNEY'S OFFICE

NORTHERN DISTRICT of GEORGIA

U.S. Attorneys » Northern District of Georgia » News

Department of Justice

U.S. Attorney's Office

Northern District of Georgia

FOR IMMEDIATE RELEASE

Wednesday, March 4, 2020

#### Hospice to pay \$1.75 million to resolve false claims act allegations

ATLANTA - STG Healthcare of Atlanta, Inc. ("STG Healthcare") and two of its senior executives, Paschal "Pat" Gilley and Mathew Gilley, have agreed to pay \$1.75 million to resolve allegations that STG Healthcare, operating as Interim Healthcare of Atlanta, submitted or caused the submission of false claims to Medicare and Medicaid for patients who were not eligible for the hospice benefit and that resulted from STG Healthcare's provision of unlawful payments to a referring physician in violation of the Anti-Kickback Statutes.

- 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



U.S. Attorneys » Southern District of New York » News » Press Releases

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

Audrey Strauss, the Acting United States Attorney for the Southern District of New York, Scott J. Lampert, Special Agent in Charge of the New York Regional Office of the U.S. Department of Health, Office of Inspector General ("HHS OIG"), Leigh-Alistair Barzey, Special Agent in Charge of the Northeast Field Office of the U.S. Department of Defense - Office of Inspector General's Defense Criminal Investigative Service ("DCIS"), and Christopher Algieri, Special Agent in Charge of the Department of Veterans Affairs ("VA"), Office of Inspector General, Northeast Field Office ("VA OIG"), announced today a \$49 million settlement with PROGENITY, INC. ("PROGENITY"), a San Diego-based biotechnology company that provides molecular and



#### U.S. V. ADVENT CARE, INC., NO. 31971459 (N.D. CAL.) U.S. V. RIDHIMA SINGH, NO. 31971430 (N.D. CAL)

United States Department of Justice

THE UNITED STATES ATTORNEY'S OFFICE

NORTHERN DISTRICT of CALIFORNIA

U.S. Attorneys » Northern District of California » News

Department of Justice

U.S. Attorney's Office

Northern District of California

FOR IMMEDIATE RELEASE

Thursday, September 5, 2019

Bay Area's Largest Home Health Care Agency And 28 Health Care Industry Workers Charged In Patients-For-Cash Kickback Scheme

Amity Home Health and CEO, Ridhima "Amanda" Singh, And 13 Doctors Are Among Dozens Charged In Alleged Multi-Million Dollar Scheme to Receive Referrals for Medicare Patients

SAN FRANCISCO – Federal complaints have been filed against 30 defendants charged in a patients-for-cash kickback scheme, announced United States Attorney David L. Anderson, Federal Bureau of Investigation Special Agent in Charge John F. Bennett, and Special Agent in Charge for the Office of Inspector General of the U.S. Department of Health and Human Services (HHS-OIG), Steven J. Ryan.

The complaints, unsealed this morning, describe a wide-ranging patients-for-kickback scheme. At the center of the scheme are Amity Home Health Care, the largest home health care provider in the San Francisco Bay Area, and Advent Care, Inc., a provider of hospice care. According to the complaints, all the defendants participated in the scheme whereby Amity, under the leadership of Chief Executive Officer Ridhima "Amanda" Singh, paid kickbacks to marketers, doctors, and other medical

- 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?



20

#### 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





# U.S. V. PAUL EMORDI; LOVETH ISIDAEHOMEN; CELESTINE OKWILAGWE AKA ADETUTU ETTI, NO. 19-10400 (N.D. TEX.)



- Elder Care formed in 2001
- Okwilagwe (owner) and Emordi (employee) excluded in 2012
- DON's certifications on contracts and enrollments withMedicaid and Medicaid MCOs
- 2015 Medicare survey resultedin 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







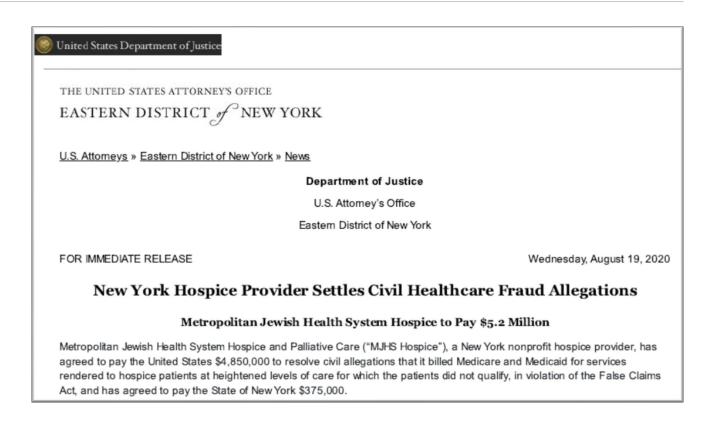


## CASES INVOLVING COVERAGE CRITERIA AND MEDICARE STANDARDS

Three Recent Settlements and Lessons Learned

# U.S AND STATE OF NEW YORK, EX RE. ELLYN WARD V. MJHS HOSPICE AND PALLIATIVE CARE, INC. AND METROPOLITAN JEWISH HEALTH SYSTEM FOUNDATION (E.D.N.Y)

- 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



THE UNITED STATES ATTORNEY'S OFFICE

MIDDLE DISTRICT of FLORIDA

U.S. Attorneys » Middle District of Florida » News

#### Department of Justice

U.S. Attorney's Office

Middle District of Florida

FOR IMMEDIATE RELEASE

Wednesday, July 8, 2020

#### Hope Hospice Agrees To Pay \$3.2 Million To Settle False Claims Act Liability

Fort Myers, FL – United States Attorney Maria Chapa Lopez announces today that Hope Hospice has agreed to pay the United States \$3.2 million to resolve allegations that it knowingly submitted false claims to Medicare, Medicaid, and TRICARE for hospice care provided to beneficiaries who did not qualify for the service. Founded in 1979, Hope Hospice is a subsidiary of Hope Healthcare. Hope Healthcare is a not-for-profit organization that provides a variety of programs for the elderly in Lee, Hendry, and Glades Counties, including hospice and palliative care services.

- 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



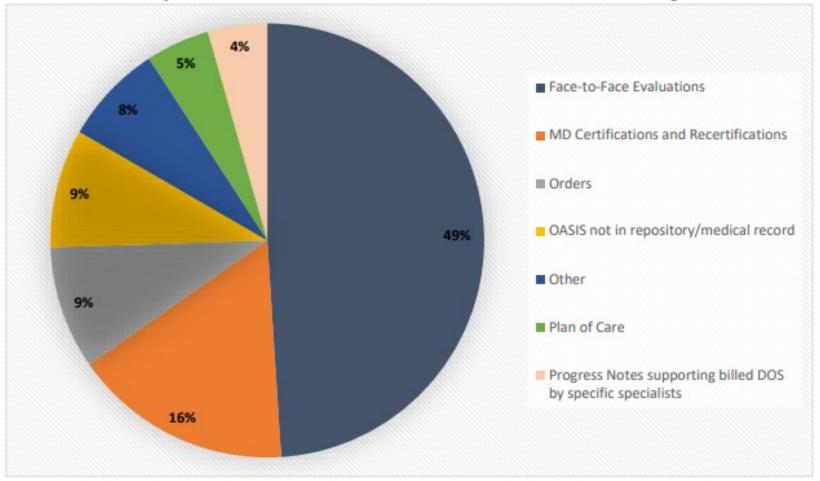


#### LESSONS LEARNED: AUDIT

#### Frequent Issues that Result in Overpayment Liability

Home Health	Hospice
<ul> <li>Issues relating to face-to-face requirements</li> <li>✓ No signature</li> <li>✓ Encounter notes do not address all elements of eligibility</li> <li>Issues with recertification</li> <li>✓ No estimate of continued need</li> <li>✓ Missing initial certification</li> </ul>	<ul> <li>Billing for incorrect level of care</li> <li>No or deficient certification of terminal illness</li> <li>Clinical documentation does not support certification</li> </ul>

Figure 3: Percentage Breakdown of CERT Error Subcategory for Improper Claims
Caused by Insufficient Documentation From FYs 2014 Through 2017



Source: HHS OIG, Data Brief: The Centers for Medicare and Medicaid Services Could Use Comprehensive Error Rate Testing Data to Identify High-Risk Home Health Agencies, A-05-17-00035, Aug. 2019



#### LESSONS LEARNED: AUDIT

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

Home Health	Hospice
<ul> <li>High average outlier payment per beneficiary</li> <li>High percentage of beneficiaries for whom other HHAs have billed Medicare</li> <li>High average number of late episodes per beneficiary</li> <li>High average number of therapy visits per beneficiary</li> <li>High average number of denials for issues relating to homebound status, certifications, and face-to-face requirements</li> </ul>	High number of patients residing in ALFs and NFs High rates of discharging patients alive High number of patients with long hospice stays High percent of beneficiaries with diagnoses that require less complicated care Beneficiaries with high numbers of Part D drugs

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











#### THANK YOU!

Beth Anne Jackson, J.D. Brown & Fortunato, P.C. 905 S. Fillmore, Ste. 400 Amarillo, TX 79101 bjackson@bf-law.com | 806-345-6346 Allison D. Shelton, J.D. Brown & Fortunato, P.C. 905 S. Fillmore, Ste. 400 Amarillo, TX 79101 ashelton@bf-law.com | 806-345-6338

