Enforcement Update

HCCA Atlanta Regional Conference
January 25, 2019

Introductions

Speakers

- **Steve Kelly**, Chief Compliance Officer, Northeast Georgia Health System
- **Mina Rhee**, Associate General Counsel, Office of the General Counsel, Emory University
- **Todd Swanson**, Assistant U.S. Attorney, U.S. Attorney's Office for the Middle District of Georgia

Moderator

- **Lynn M. Adam**, Adam Law LLC

Topic Overview

- Recent enforcement trends
- False Claims Act hot topics
- Disconnect between expectations of Government enforcers and reality for compliance personnel
- Pragmatic tips to bridge the disconnect

Recent Enforcement Trends

More assertive Office of Inspector General

- Initiating actions to impose civil monetary penalties (CMPs) more regularly
- Higher settlement amounts for self-disclosures
  - *Example*: St. Francis Health of Georgia agreed to pay over $3.2 million for allegedly violating the Civil Monetary Penalties Law provisions applicable to physician self-referrals and kickbacks.
- Increased use of penalties and exclusions for CIA violations

False Claims Act Enforcement

- 767 actions filed in FY 2018 (trending down in recent years)
- 2/3 of actions allege healthcare fraud

False Claims Act Recoveries in 2018

- **In FY 2018, the U.S. Department of Justice recovered $2.88 billion under the FCA, mainly through healthcare enforcement actions filed by whistleblowers.**
- **Continued emphasis on individual liability for FCA violations**
- **Top enforcement priorities – Opioid Abuse and Elder Care**

Opioid Abuse Toolkit

In June 2018, OIG published a Toolkit on detecting opioid abuse.

- Detailed instructions for using ***claims data*** to analyze patients' opioid levels
- Identify patients at risk of opioid misuse or overdose
- Target Audience: Medicare Part D plan sponsors, private health plans, and State Medicaid Fraud Control Units

False Claims Act Refresher

- Federal False Claims Act
  - DOJ's primary civil fraud enforcement tool
  - Incentives for Whistleblowers
- Most States have adopted versions of the False Claims Act.
  Yes: Georgia, Florida, Tennessee, North Carolina
  No: South Carolina, Alabama
- In summary, the FCA is violated when a person ***knowingly*** obtains or retains Government funds to which the person is not entitled.
- Liability for 3x damages, plus a penalty of up to $22,363 for each false claim

False Claims Act – Litigation Roundup

- Drug & Medical Device Manufacturers
- Post-Acute Care
- Acute Care Hospitals
- Kickbacks
- Medicare Advantage Plans (Part C)

Biggest Recoveries from Drug & Medical Device Manufacturers

Examples:

- AmerisourceBergen paid ***$625 million*** to resolve allegations that it ***repackaged the overfill*** from sterile vials of certain injectable drugs for cancer patients and sold the adulterated drugs to oncologists.
- United Therapeutics Corporation and Pfizer paid large settlements relating to their use of foundations improperly to pay ***co-payments*** on behalf of Medicare beneficiaries.

Post-Acute Care

- ❖HH Patients must be homebound.
- ❖Hospice Patients must be terminally ill.
- ❖SNF Patients must receive only medically necessary level of rehabilitation therapy.
- ❖High risk of kickbacks in vendor relationships.

Fraud in Post-Acute Care

Examples:

May 2018 – ***SNF*** chain Signature Healthcare of KY and TN paid > $30 million to resolve claims it routinely overbilled Medicare Part A using the highest Resource Utilization Group (RUG) for medically unnecessary therapy services.

June 2018 – ***Hospice*** provider Caris Healthcare of SC, TN, and VA paid $8.5 million to settle allegations relating to false claims and retaining overpayments for patients who were not terminally ill. CMO and Nurses reported issues.

July 2018 – ***Home health agency*** HealthQuest of Florida, and 2 ***individual owners***, paid $1.5 million to settle claims they paid kickbacks to marketers to steer patients to HealthQuest.

August 2018 – ***Therapy services*** firm Reliant Rehabilitation Holdings based in Texas agreed to pay $6.1 million to resolve claims it paid kickbacks to SNFs and physicians in exchange for therapy referrals.

OIG Hospice Portfolio Released in July 2018

Inappropriate Billing by Hospices Costs Medicare Hundreds of Millions of Dollars

Hospices frequently bill Medicare for a higher level of care than the beneficiary needs

Reviews of individual hospices have found improper payments ranging from $447,000 to $1.2 million for services not meeting Medicare requirements. In these cases, the hospices billed for inappropriate levels of care, lacked required certifications of terminal illness, or did not have sufficient clinical documentation.[30]

Hospices have also inappropriately billed for expensive levels of care that were not needed. Specifically, in 2012 hospices billed one-third of general inpatient care stays inappropriately, costing Medicare $268 million.[31] General inpatient care is the second most expensive level of hospice care and should only be billed when the beneficiary has uncontrolled pain or symptoms that cannot be managed at home.

Hospices often billed for general inpatient care when the beneficiary needed only routine home care. As a result, these hospices were paid $672 per day instead of $151 per day.[32] At other times, the hospice

Acute Care Hospitals

- August 2018 – Beaumont Hospital in Detroit paid $84.5 million to settle FCA claims that it paid ***excessive compensation*** to 8 referring physicians and gave them free office space, in violation of the Stark Law and Anti-Kickback Statute.
- December 2018 – Pennsylvania Health System, Coordinated Health, and its ***CEO*** settled billing allegations for $12.5 million. They were alleged to have routinely ***misused Modifier 59*** to unbundle payments for orthopedic surgeries to generate greater reimbursement.
- December 2018 – DOJ joined a whistleblower lawsuit brought by the former Executive Vice President of Wheeling Hospital in West Virginia, alleging the ***hospital, its CEO, and a consulting firm,*** R&V Associates, caused violations of the Stark Law leading to false claims.

Acute Care Hospitals
Unnecessary Inpatient Admissions

- April 2018 – Banner Health paid $18 million to resolve allegations that 12 of its hospitals in Arizona and Colorado improperly admitted ***short-stay patients*** as inpatients instead of outpatients, and inflated observation hours.
- August 2018 – Prime Healthcare and its ***Chief Executive Officer*** agreed to pay $65 million following allegations of a corporate-driven scheme at 14 of its California hospitals to increase medically ***unnecessary inpatient admissions*** through the ED and to inflate coding of patients' diagnoses including complications and comorbidities.
- September 2018 – Hospital chain Health Management Associates (HMA), now owned by Community Health Systems (CHS), paid over $260 million to settle civil and criminal allegations relating to ***unnecessary inpatient admissions, kickbacks paid to referring physicians,*** and other issues.

Inpatient Admissions

--Consultants in the Hot Seat

- In ongoing litigation, consulting firm, Accretive Health, now known as R1 RCM Inc., is alleged to have provided "concurrent reviews" of patient status for dozens of hospitals that often (allegedly) resulted in the ***improper reversal of the on-site physician's decision*** to admit a patient as an outpatient for observation.

  --*U.S. ex rel. Grazios v. Accretive Health, Inc.*, Case No: 1:13-cv-01194 (N.D. Ill)

- In separate litigation, consulting firm, Executive Health Resources, Inc. (EHR), now part of Optum, likewise is accused of providing its hospital customers with ***false certifications of inpatient status*** for Medicare patients who did not meet the criteria for inpatient admission.

  --*U.S. ex rel. Polansky v. Executive Health Resources*, Civil Action No. 12-4239 (E.D. Pa.)

- The allegations against EHR and Accretive Health have not been adjudicated on the merits, and the companies deny liability.

Inpatient Hospital Billing

OIG Report To Be Released in 2020

Assessing Inpatient Hospital Billing for Medicare Beneficiaries

In 2016, hospitals billed Medicare $114 billion for inpatient hospital stays, accounting for 17 percent of all Medicare payments. The Centers for Medicare & Medicaid Services and the Office of Inspector General have identified problems with upcoding in hospital billing: the practice of mis- or over-coding to increase payment. OIG will conduct a two-part study to assess inpatient hospital billing. The first part will analyze Medicare claims data to provide landscape information about hospital billing. OIG will determine how inpatient hospital billing has changed over time and describe how inpatient billing varied among hospitals. We will then use the results of this analysis to target certain hospitals or codes for a medical review to determine the extent to which the hospitals billed incorrect codes.

Announced or Revised	Agency	Title	Component	Report Number(s)	Expected Issue Date (FY)
December 2018	Centers for Medicare & Medicaid Services	Assessing Inpatient Hospital Billing for Medicare Beneficiaries	Office of Evaluation and Inspections	OEI-02-18-00380	2020

Kickbacks for Lab Tests

Example: U.S. v. BlueWave Healthcare Consultants

- January 2018 – Jury in Charleston S.C. found 3 individuals and 2 laboratory companies liable under the FCA for paying kickbacks to induce physicians to order medically unnecessary lab tests.
- They paid "process and handling fees" to physicians for each referral.
- Cases were filed by 3 whistleblowers.
- In May 2018, the District Court entered judgment of ***> $111 million*** against the ***individual defendants***.
- Other Defendants settled before trial.

EKRA

New *Private Pay* Anti-Kickback Statute

- Eliminating Kickbacks in Recovery Act (EKRA) became law in October 2018 (in your materials)
- Last minute addition to the SUPPORT Act relating to opioid measures.
- ***Makes kickbacks a federal crime when paid for referral of a private-pay patient to a recovery home, clinical treatment facility, or laboratory.***
- Not limited to patients in substance abuse treatment
- Clinical Labs take note.

Medicare Advantage Plans

Inflated risk adjustment scores for claims submitted to Medicare Advantage Plans (Medicare Part C).

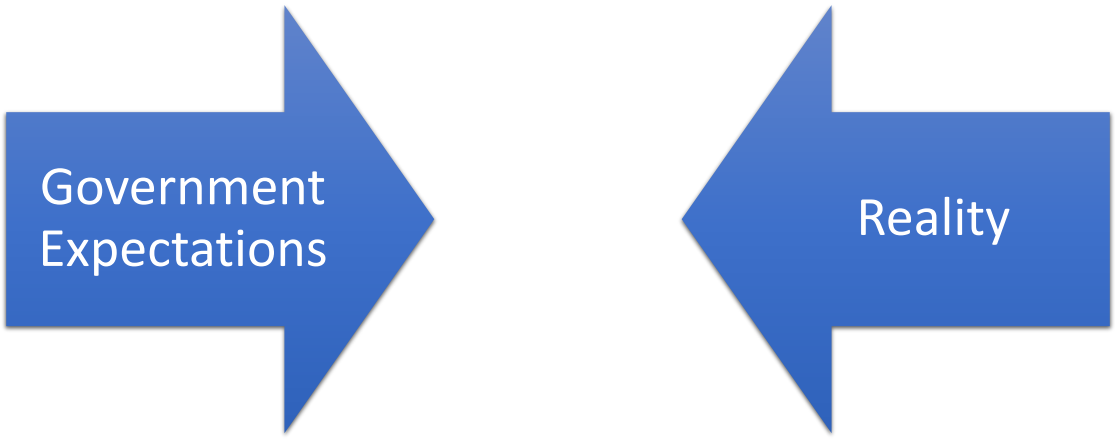
- October 2018 -- HealthCare Partners Holdings LLC, doing business as DaVita Medical Holdings LLC, agreed to pay ***$270 million*** to resolve issues related to inflated diagnosis coding by physician practices on claims submitted to MA Plans.
- December 2018 -- DOJ joined a whistleblower case against Sutter Health and an affiliate alleging over $100 million in losses due to improper risk adjustment scores submitted to MA Plans.
- Ongoing – DOJ is also litigating allegations of inflated risk adjustment payments against UnitedHealth Group, the largest MA organization, in a case it filed in 2017.

Again with the ACA Litigation…

Mid-December 2018 – A federal District Court in Fort Worth, Texas, invalidated the 2010 Patient Protection and Affordable Care Act (ACA) based on a constitutional challenge lead by the State of Texas.

- Ruling is suspended pending appeal
- If upheld, significant disruption in the market would occur, and several ***enforcement provisions would be cast aside***:
  - Overpayment Rule
  - Changes to FCA public disclosure bar
  - Authorization for CMS Stark Law self-disclosure protocol
  - Amendments to Anti-Kickback Statute

Case to Watch: *Texas v. United States*

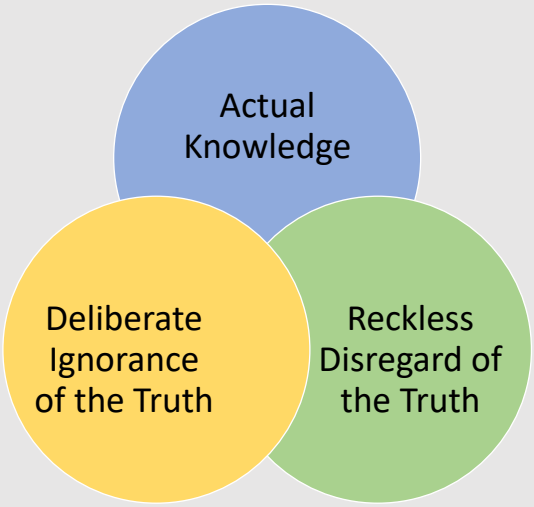


Compliance IRL

Key Point for Compliance Team

No FCA Liability Unless The Organization Acted "***Knowingly***"

- ✓ Good faith is a good defense.
- ✓ Importance of reasonable compliance policies and procedures.



OIG's New Compliance Resource Portal

In your materials:

OIG's 2-page checklist

"Operating an Effective Compliance Program"

Compliance Resources

- HCCA-OIG Resource Guide: *Measuring Compliance Program Effectiveness (March 2017)*
- Corporate Integrity Agreements

OIG Videos & Podcasts

Liven Up Your Daily Commute?

Compliance Mastermind Podcast

Thank You!

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