Overview

> Introduction
> Enforcement landscape
> Medical necessity enforcement
> Quality of care issues
> CMS’s perspective on quality of care enforcement
> Questions

U.S. Department of Justice (DOJ)

> Divisions committed to prosecute healthcare fraud
  - Criminal/Civil/Antitrust Divisions
  - Consumer Protection Branch
  - Healthcare fraud coordinators within 94 United States Attorneys’ Offices
  - Federal Bureau of Investigation
  - Drug Enforcement Agency
  - Partnerships with private payors

> Distinct funding sources
Other Enforcement Players

- Local District Attorneys
- Offices of Inspector Generals
  - Federal and State
- Medicaid Fraud Control Units
- Centers for Medicare and Medicaid Services
- Medicaid State agencies
- Tricare Management Authority
- Federal/State contractors
- Commercial payor “special investigative units”
- Licensing boards
- Whistleblowers

Recent DOJ Activity

- DOJ recovered more than $3.5 billion in FY 2015 alone
  - Down from last year’s $5.6 billion recovery
- Continues 4-year record of recoveries over $3 billion
- Of $3.5 billion –
  - $1.9 billion from healthcare industry, including $330 million from hospitals
  - $2.8 billion (more than half) from cases filed by whistleblowers
- Number of Qui tams suits exceeded 600
  - Down from last year’s 700
  - But way up from 1987’s 30
  - Whistleblowers received record $597 million

Enforcement Outlook

- State and federal enforcement actions rising
  - Increased Qui tams in 2016
- Medicare insolvent in 15 years
- State budget shortfalls
- Federal and commercial rules remain complex
- Demonstrating effective compliance is crucial
- Increasing attempts to ensure individuals accountable
- Criminalization of medical decision making
DOJ's Yates Memorandum

> Yates Memo (9/9/2015): "Individual Accountability for Corporate Wrongdoing"
> Emphasizes DOJ's commitment to combat fraud "by individuals"
> Recommends:
  - Not to give cooperation credit unless company provides facts re: individuals
  - To focus investigations on individuals "from the inception"
  - Not to release "culpable individuals" from liability absent "extraordinary circumstances"
  - Not to settle with company without "clear plan to resolve related individual cases"

OIG-HHS Activity

> Creation of Health Care Fraud Prevention and Enforcement Action Team
  - New laws and tools for government to combat fraud, waste, and abuse
> In June 2015 announced formation of new affirmative litigation team to focus exclusively on pursuing civil monetary penalties and exclusions
  - Doubles number of litigators to bring cases
  - Team will review FCA cases as sources of potential enforcement actions

Sources of Cases

> Partnering by enforcement agencies
> Data mining
> Initiatives, working groups, and task forces
> Competitor complaints
> Patient/family complaints
> Self-disclosures
> Whistleblowers
> Social media
> Traditional media
Common Investigation Triggers

- Hotline calls
- Reports to management or compliance
- Vendor communications
- Departing employees
- Industry rumors
- News articles
- Subpoenas or other government requests
- Government interviews of employees or related parties
- Private litigation

USA v. Jacques Roy — North Texas Doctor in Nation’s Largest Criminal Home Healthcare Fraud Scheme

- Roy certified around 11,000 Medicare patients as part of a $375 million Medicare scam
  - USA alleged “swapping” scheme to falsely certify home health patients so he could treat and bill for homebound patients
  - DOJ call Roy its largest medical necessity case
- Roy recruited some patients — including some of Dallas’ homeless
  - to submit fraudulent health care claims
- Roy indicted along with numerous other home health owners and employees

Investigations, continued

- Surveillance
- Consensual monitoring
- Qui tams
- Data analytics
- Interviews
- Search warrants
- CDs
- Subpoenas
  - Grand jury
  - Inspector General
  - AID (HIPAA)
- Requests for information
Investigations, continued

> Obtain information
  - Claims/contracts/payments
  - Interview
> Issue warrant, subpoena, or request
  - Internal/external correspondence/e-mails
  - Policies/practices
  - Specific claims/patient files
> Review information gathered
  - What is knowledge/intent?
> Determine how to proceed
  - Civil/criminal/administrative or parallel

Repayment and Disclosure

> FIRST fix any problems
> Federal law requires repayment of known overpayments within 60 days
  - CMS issued final rule at 71 fed. reg. 6/1/2006
> Disclosure to DOJ
  - Possible non-prosecution of business entity
    • See USAM § 9–28.000, et seq.
    • Limited civil FCA multiplier
      • See False Claims Act § 3720
> HHS-OIG Self-Disclosure Protocol
  - Lower damages/no integrity obligations
> CMS Voluntary Self-Referral Disclosure Protocol
  • Do not disclose both to CMS and OIG
  • Use OIG protocol if implicates other laws

Outcome - U.S. v. Jacques Roy

> Awaiting Sentencing
  - Roy surrendered medical license and faces more than 40 years in prison
  - Each conspiracy and fraud count has statutory penalty of 10 years in federal prison and $250,000 fine
  - Obstruction of justice and each false statement have a maximum penalty of five years in federal prison and $250,000 fine
  - Co-conspirators already sentenced from 10 to 3 years
> Raising suspicion
  - CMS said Roy came to the agency’s attention following a data analysis targeting suspicious billing.
  - More physicians refer fewer than 100 patients for home health services but Roy had “by far” submitted the most Medicare claims in the nation for home health services
  - This type of data analysis is routinely used to find outliers
  - Large majority of “suspicious” home health agencies were suspended by Medicare due to “association” with Roy
    • Virtually all are out of business
Resources for Enforcement Information

> Advisory opinions
> Published cases
> OIG Compliance program guidance publications
> State and federal work plans/audits/evaluations
> Settlement/integrity agreements
> Press releases
> GAO reports
> Comments/preambles to safe harbors/exceptions

Common Quality/Medical Risk Areas

> False/fraudulent claims
- Worthless services (failure of care) shown by insufficient documentation of care furnished
- Billing for items or services not rendered
  - Upcoding and product substitution
  - Potential for patient harm
- Misrepresenting nature of items or services
  - Overutilization of surgical, diagnostic, and ancillary procedures
  - Furnishing medical procedures or pharmaceuticals to maximize reimbursement

> Improper financial relationships/referrals
- Sham compliance with safe harbor or exception for medical directorships
- Excessive payments to falsely certify patients for home health, DME, hospice, pharmacy, lab or other services

> Retention of known overpayments arising from foregoing

Key Takeaways

> Use of data analytics and focus on outliers are now common bases for identifying/investigating subjects
> Enforcement increasing against clinicians’ medical decision-making
> Individual clinicians can no longer hide beyond healthcare corporations

> Compliance Matters
- Have a demonstrably effective compliance program
  - An organization’s formal policy on a violation of state or federal laws, the government
  - A written plan that includes a description of the procedures

> Self-Disclosure = effectiveness
- A company discloses conduct that might give rise to FCA liability, it should consider self-disclosure
  - Might lead to an immunity agreement
  - Reduce damages, and integrity obligations
The Medical in Medical Necessity

CJ Wolf, MD, CHC, CCEP, CIA, COC, CPC
Healthicity | Senior Compliance Executive
cj.wolf@healthicity.com
DOJ sues cardiologist for ‘unnecessary procedures’

-CNBC
January 5, 2015
Cardiology allegations

- Asad Qamar—Florida cardiologist
- *Qui tam* suit filed by physician and biller in US District Court (Middle District of Florida; Case 5:15-cv-00179-WTH-TBS)
- Second highest recipient of Medicare dollars in 2012 ($18.2 Million)
- Settlement $2 million plus $5.3 million
- 3 year exclusion followed by 3 year integrity agreement
- Unnecessary procedures
- Kickbacks to patients (waiving co-payments)

Cardiology allegations

- “Drive-by” renal aortography
- E/M at same time of Protine/Coumadin checks
- Unnecessary nuclear stress test
- Unnecessary erectile dysfunction ultrasounds
- Cardiac caths performed without examining first
  - Unnecessary peripheral interventions
  - Unnecessary groin artery checks

Cardiology allegations

- Overestimated the extent of arterial blockage (leading to unnecessary angioplasty, atherectomy and stents)
- Unnecessary carotid ultrasounds
- Unnecessary Holter monitors
- Unnecessary extremity ultrasounds leading to procedures
- Unnecessary transcranial Doppler
- Routine waiver of patient co-pays and deductibles
Society for Vascular Surgery

• Don’t use interventions (including surgical bypass, angiogram, angioplasty or stent) as a first line of treatment for most patients with intermittent claudication.
• Trial of smoking cessation, risk factor modification, diet and exercise as well as pharmacologic treatment should be attempted before most procedures.

• Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II).

Clinical background with coding

• CPT 75724 (~$293.50) vs. G0725 (~$14.50)

• CPT 75724--Angiography, renal, bilateral, **selective** (including flush aortogram), radiological supervision and interpretation

Clinical background with coding

• G0275--Renal angiography, **nonselective**, one or both kidneys, performed at the same time as cardiac catheterization and/or coronary angiography, includes positioning or placement of any catheter in the abdominal aorta at or near the origins (ostia) of the renal arteries, injection of dye, flush aortogram, production of permanent images, and radiologic supervision and interpretation (List separately in addition to primary procedure)
“While withdrawing the catheter during a cardiac catheterization procedure, physicians often inject a small amount of dye to examine the renal arteries and/or iliac arteries. These services when medically reasonable and necessary may be reported with HCPCS codes G0275 or G0278. A physician should not report CPT codes 75722 or 75724 (renal angiography) unless the renal artery(s) is (are) catheterized and a complete renal angiogram including the venous phase is performed and interpreted.”
"Renal artery angiography at the time of cardiac catheterization should be reported as HCPCS code G0275 if selective catheterization of the renal artery is not performed. HCPCS code G0275 should not be reported with CPT code 36245 for selective renal artery catheterization or CPT codes 75722 or 75724 for renal angiography. If it is medically necessary to perform selective renal artery catheterization and renal angiography, HCPCS code G0275 should not be additionally reported."

Cardiology allegations

- Elie Korban--Tennessee cardiologist
- Whistleblower suit from another physician (Chief of Cardiology) filed in US District Court (Western District of Tennessee, case 07-cv-01116-SHL-egb)
- $1.15 million settlement
- Corporate Integrity Agreement
- Unnecessary cardiovascular stent procedures
- Improper Locum Tenens billing
Cardiology allegations

Unnecessary:
- transthoracic echocardiography
- scintigraphic stress imaging
- transesophageal echocardiography
- heart catheterization
- diagnostic coronary angiography
- various coronary peripheral intervention procedures, including stent placements

American Society of Echocardiography

- Avoid using stress echocardiograms on asymptomatic patients who meet “low risk” scoring criteria for coronary disease.
- Stress echocardiography is mostly used in symptomatic patients to assist in the diagnosis of obstructive coronary artery disease. There is very little information on using stress echocardiography in asymptomatic individuals for the purposes of cardiovascular risk assessment, as a stand-alone test or in addition to conventional risk factors.

American Society of Echocardiography, released Feb. 21, 2013

Cardiology allegations

Falsification of medical records:
- Blockage more severe than demonstrated by films
- Documented patients had continual chest pain, symptoms and positive stress tests when this was not the case

Estimated that approximately 40% of Medicare claims for stent placement and approximately 25% of his TennCare claims for stent placement falsely certified that those procedures were medically indicated and necessary
JAMA Study-2011

- Large U.S. study of over 500,000 interventions performed at over 1000 hospitals
- For nonacute indications, 72,911 PCIs (50.4%) were classified as appropriate, 54,988 (38.0%) as uncertain, and 16,838 (11.6%) as inappropriate.

JAMA Study-2015

- CathPCI Registry—U.S. study of over 2.7 million interventions performed at over 766 hospitals
- Significant decline in non-acute PCI (89,704 in 2010 and 59,375 in 2014)
- ‘Inappropriate’ non-acute PCIs decreased from 26.2% to 13.3% (absolute numbers were 21,781 to 7,921).

JAMA Study-2015

- Graphs showing trends in appropriateness of PCI interventions from 2008 to 2014.
Vein Procedures

Vein Ablation Allegations

- Donald Woo Lee—Physician in Temecula, CA
- Indicted in US District Court (Central District of California; Case 2:16-cr-00415-GW)
- Over 3 years $14.7 Million of Medicare billings of which $12.4 Million was for vein ablation
- MAC required non-invasive, conservative treatments first
- No need for vein ablations
- Performing vein ablations on different days instead of same session
A 3-month trial of conservative therapy such as exercise, periodic leg elevation, weight loss, compressive therapy, and avoidance of prolonged immobility where appropriate, has failed, AND

The patient is symptomatic and has one, or more, of the following:
- Pain or burning in the extremity severe enough to impair mobility
- Recurrent episodes of superficial phlebitis
- Non-healing skin ulceration
- Bleeding from a varicosity
- Stasis dermatitis
- Refractory dependent

Endovenous Ablation

- Multi-society consensus quality improvement guidelines for the treatment of lower-extremity superficial venous insufficiency with endovenous thermal ablation
- Recommended Reporting Standards for Endovenous Ablation for the Treatment of Venous Insufficiency
  [http://www.sirweb.org/clinical/cpg/Endovenous_Ablation_for_the_Treatment_of_Venous_Insufficiency.pdf](http://www.sirweb.org/clinical/cpg/Endovenous_Ablation_for_the_Treatment_of_Venous_Insufficiency.pdf)
- The care of patients with varicose veins and associated chronic venous diseases: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum

Appropriate Use Criteria (Peripheral)
Duplex for Venous Insufficiency

Ultrasound Guided Sclerotherapy (UGS) Allegations

- Ravi Sharma—Physician in Tampa, FL
- Qui tam suit filed by office manager in US District Court (Middle District of Florida; Case 8:12-cv-00133-JSM-EAJ)
- $400,000 settlement
- 3 year integrity agreement
- Vein injections and physician office visits performed by unqualified personnel
- Dr. Sharma instructed non-qualified personnel to perform services while he was not present

Local Coverage Determination

*All non-invasive vascular diagnostic studies must be:
(1) performed by a qualified physician, or
(2) performed under the general supervision of a qualified
physician or technologist who has demonstrated minimum entry level competency by being credentialed in
vascular technology, and/or
(3) performed in a laboratory accredited in vascular technology.*
Text messages from physician

BCBS Massachusetts

Endovascular ablation accreditation required for claims to pay

Date Issued: Aug 16, 2013
Effective Date: Jan 1, 2014

To: The physicians and facilities that offer endovascular ablation to our members

From: Sue Flemming, M.D., Vice President, Medical Management and Policy

In January, we notified you that we would require all providers who currently perform endovascular ablation, or who wish to perform it, to obtain Joint Commission on Accreditation of Healthcare Organizations (JCAHO) varicose vein center accreditation by September 1, 2013. For currently participating providers who want additional time to complete the accreditation process, we have extended the deadline to January 1, 2014.

Pain Management
Pain clinic allegations

- Pain center in Missouri
- $860,000 settlement
- Upcoding of evaluation & management services and nerve conduction studies
- Corporate Integrity Agreement
Pain clinic allegations

• Clinic in Long Island, NY

• $1.1 million settlement

• Whistleblower was receptionist (US District Court, Eastern District of New York, Case 2:10-cv-03851-LDW-WDW)

• Medically unnecessary nerve conduction studies

Pain clinic allegations

• Altered documents so it would appear studies were done on different days even though tests done on same day
  • (Tests done on the same day would be denied per payor policy)

• Tests were not medically necessary

• Staff compensated for administering multiple tests to multiple patients

What do You Do?

Some auditing and monitoring should be done by those with a clinical background

“The individuals from the physician practice involved in these self-audits would ideally include the person in charge of billing (if the practice has such a person) and a medically trained person (e.g., registered nurse or preferably a physician).”

OIG Compliance Program Guidance
Federal Register, Volume 65, No. 194, page 59437
The thoughts and opinions expressed in this presentation are my own and do not necessarily represent those of the Centers for Medicare & Medicaid Services or the United States Department of Health and Human Services.
The CMS Vision

Better Smarter Healthier.
Working across all boundaries to ensure the shared goal of: better care, smarter spending and healthier people.

Current Pathway: Employ Multiple Levers to Transform System

Pre-ACA System:
- Producer-Centered
- Volume Driven
- Fragmented Care
- Unsustainable

Post-ACA System:
- Patient-Centered
- Outcomes Driven
- Coordinated Care
- Sustainable

Current Payment Taxonomy Framework:

<table>
<thead>
<tr>
<th>Category 1: Fee for Service—Link to Quality</th>
<th>Category 2: Pay for Service—Link to Quality</th>
<th>Category 3: Alternative Payment Models—Link to Fee for Service philosophy</th>
<th>Category 4: Population-Based Payment</th>
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<td>Payments are based on volume of services and not linked to quality or efficiency.</td>
<td>At least a portion of payment is based on the quality or efficiency of health care delivery.</td>
<td>Some payment is linked to the effective management of populations or an episode of care. Payment can be triggered by delivery of services, the achievement of shared savings or 2nd gap.</td>
<td>Payment is not directly triggered by service delivery or volume is not linked to payment. Clinicians and organizations are rewarded for the care of a beneficiary for a long period (e.g. 2 years).</td>
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Examples:
- Medicare fee-for-service
- Medicare advantage plans
- Hospital value-based purchasing
- Physician Value-Based Incentive Program
- Accountable care organizations
- Shared savings
- Shared savings
- Duals initiatives
- Medicaid initiatives
- Innovation Center

Eligible Persons:
- Person with a health care resource utilization in years 1-3.
Moving toward...

- Active vs Passive Monitoring and Oversight
- Quality Incentives
- Transparency

Active Monitoring

- Onsite Surveys
- Expansion of Enforcement Remedies
- Systems Improvement Agreements
Linking Quality to Payment (Hospitals)

- Readmissions Reduction
- Hospital Value-based Purchasing Program
- Hospital Acquired Conditions

Hospital Readmissions Reduction Program

The Affordable Care Act authorizes Medicare to reduce payments to acute care hospitals with excess readmissions that are paid under CMS’s inpatient prospective payment system, beginning October 1, 2012. The program initially focuses on patients who were readmitted for selected high-cost or high-volume conditions, namely, heart attack, heart failure, and pneumonia.

High rates of readmission within 30 days of discharge from the hospital may result from such factors as:
- Complications from treatments received during a hospital stay
- Inadequate treatment
- Inadequate care coordination and follow-up care in the community
- Unexpected worsening of disease after discharge from the hospital

Hospital readmissions may cause undue suffering to patients and their families and may lead to significant increases in health care spending.

Hospital Value-Based Purchasing (VBP) Program

Medicare now has information about how the quality of a hospital’s care affects the payments it gets from Medicare. The Hospital VBP Program, established by the Affordable Care Act, implements a pay-for-performance approach to the payment system that accounts for the largest share of Medicare spending. The Hospital VBP Program, established by the Affordable Care Act, implements a pay-for-performance approach to the payment system that accounts for the largest share of Medicare spending. The Hospital VBP Program, established by the Affordable Care Act, implements a pay-for-performance approach to the payment system that accounts for the largest share of Medicare spending. The Hospital VBP Program, established by the Affordable Care Act, implements a pay-for-performance approach to the payment system that accounts for the largest share of Medicare spending.

Under Hospital VBP, Medicare is adjusting a portion of payments to hospitals beginning in Fiscal Year (FY) 2013 based on either:

- How well they perform on each measure compared to all hospitals,
- How much they improve their own performance on each measure compared to their performance during a prior baseline period.

The Hospital VBP Program is designed to promote better clinical outcomes for hospitalized patients and improve their experience of care during hospital stays.
Hospital-Acquired Condition (HAC) Reduction Program

The Affordable Care Act authorized Medicare to reduce payments to subsection (d) hospitals that rank in the worst performing quartile of subsection (d) hospitals with respect to hospital-acquired conditions (HACs). The worst performing quartile is identified by calculating a Total HAC score, which is based on the hospital’s performance on risk adjusted quality measures. Hospitals with a Total HAC score above the 75th percentile of the Total HAC Score distribution may be subject to payment reduction beginning October 1, 2014.

The HAC Reduction Program is designed to encourage hospitals to reduce the incidence of HACs.

2015 HACs

AHRQ PSI 90 composite measure includes the following eight PSIs:

- PSI 03 - Pressure Ulcer
- PSI 06 - Iatrogenic Pneumothorax
- PSI 07 - Central Venous Catheter-Related Bloodstream Infections
- PSI 08 - Postoperative Hip Fracture
- PSI 12 - Perioperative Pulmonary Embolism or Deep Vein Thrombosis
- PSI 13 - Postoperative Sepsis
- PSI 14 - Postoperative Wound Dehiscence
- PSI 15 - Accidental Puncture or Laceration

Data Transparency

(Medicare.gov)
- Hospital Compare
- Physician Compare
- Dialysis Compare
- Nursing Home Compare
- Home Health Compare

- Open Payments (cms.gov/openpayments)
- Charge Master (cms.gov)