Responding to Today’s Health Care Regulatory Environment

St. Joseph’s Health

Michael R. Holper
SVP, Compliance and Audit Services
October 26, 2016
We operate in an increasingly transparent health care industry...

_Virtually all our actions and decisions today are subject to public disclosure and scrutiny by patients, our communities, payers, business partners, competitors, and regulators..._

**Examples**

- Prices
- Quality/Safety
- Patient Satisfaction
- Financial Information
- Executive Compensation
- Charity Care and Community Benefits
- Privacy and Security Breaches
- Billing and Claims Data
- Relationships with Industry

**“Are providers prepared to operate in a more transparent health care system?”**

Daniel R. Levinson
Inspector General, Department of Health and Human Services
April 19, 2010
Stories about health care costs, quality, waste and fraud are frequently in the news…
Many eyes are looking at our data...

Industry payments to U.S. physicians, hospitals total $3.5 bln

(Reuters) - U.S. doctors and teaching hospitals received $3.5 billion from pharmaceutical companies and medical device makers in the last five months of 2013, according to the most extensive data trove on such payments ever made public.

THE WALL STREET JOURNAL.

Doctor ‘Self-Referral’ Thrives on Legal Loophole

Part of a series examining how payments are made in the roughly $600 billion Medicare system.

Doctor ‘Self-Referral’ Thrives on Legal Loophole

[Article text]

THE WALL STREET JOURNAL.

MEDICARE UNMASKED

Agents Hunt for Fraud In Trove of Medical Data

[Article text]
What is Fraud?
• Intentional acts of deception or misrepresentation
• Acting with actual knowledge or in “reckless disregard” of the rules

What is Waste/Abuse?
• Improper or excessive use of a program or service resulting in harm

What is a Payment Error?
• Unintentional actions taken or omitted by a provider leading to an incorrect payment
• Often “technical” deficiencies. Example:
  • Lack of physician orders
  • Documentation of clinical services not clear or complete

Regulators often use of “fraud and abuse” interchangeably when describing payment errors, especially in media statements
Medicare payment “error” rates remain highest among all federal programs...

2015 payment error rate of 12.1% = $43.3B in payment errors

Source: http://www.paymentaccuracy.gov/programs/medicare-fee-for-service
… with health care providers increasingly subject to audits and investigations …

<table>
<thead>
<tr>
<th>Type of Audit</th>
<th>Auditor/Contractor</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicare Administrative Contractor (MAC)</td>
<td>National Government Services</td>
<td>Process claims and provider payments</td>
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<tr>
<td></td>
<td></td>
<td>Reduce payment error rates</td>
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<tr>
<td>Zone Program Integrity Contractor (ZPICs)</td>
<td>Contract award currently under protest</td>
<td>Focus on identifying fraud</td>
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<td></td>
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<td>All providers</td>
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<td></td>
<td></td>
<td>Data mining and analysis</td>
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<tr>
<td>Supplemental Medical Review Contractor (SMRC)</td>
<td>Strategic Health Solutions LLC</td>
<td>Nationwide claim review</td>
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<td>All providers</td>
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<tr>
<td></td>
<td></td>
<td>Data mining and analysis</td>
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<tr>
<td>Comprehensive Error Rate Testing Contractors (CERT)</td>
<td>Multiple contractors</td>
<td>Annual audits to determine FFS error rates</td>
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<td></td>
<td></td>
<td>All provider types</td>
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<tr>
<td>Recovery Audit Contractor (RACs)</td>
<td>Performant Recovery (Medicare)</td>
<td>Identify over and under payment errors</td>
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<td>Dept. of Health and Human Services – Office of Inspector General (OIG)</td>
<td>N/A</td>
<td>All federal health programs</td>
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<tr>
<td></td>
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<td>Audits and investigations</td>
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<tr>
<td></td>
<td></td>
<td>Annual Work Plan</td>
</tr>
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<td>Department of Justice (DOJ)</td>
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<td>All federal health programs</td>
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<td>Enforcement actions under the False Claims Act</td>
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<tr>
<td>Medicaid</td>
<td>NY Office of Medicaid Inspector General</td>
<td>Audits, reviews and investigations of Medicaid providers</td>
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<tr>
<td>Pharmacy 340B Program</td>
<td>Health Resources Services Administration/Office of Pharmacy Affairs</td>
<td>Audits of hospitals to assess compliance with federal drug discount program</td>
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</tbody>
</table>
Where are Medicare payment errors occurring?

<table>
<thead>
<tr>
<th>Service Type</th>
<th>Improper Payment Rate</th>
<th>Improper Payment $s</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inpatient Hospitals</td>
<td>6.2%</td>
<td>$7.0B</td>
</tr>
<tr>
<td>Durable Medical Equipment</td>
<td>39.9%</td>
<td>$3.2B</td>
</tr>
<tr>
<td>Physician/Lab/Ambulance</td>
<td>12.7%</td>
<td>$11.5B</td>
</tr>
<tr>
<td>Non-Inpatient Hospital Facilities (A)</td>
<td>14.7%</td>
<td>$21.7B</td>
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<tr>
<td><strong>Overall</strong></td>
<td><strong>12.1%</strong></td>
<td><strong>$43.3B</strong></td>
</tr>
</tbody>
</table>

Source: Centers for Medicare and Medicaid Services 2015 Comprehensive Error Rate Testing (CERT) report

(A) – Hospital outpatient services, home care, hospice, skilled nursing facilities, rehabilitation facilities, and end stage renal disease services
Physician payment errors due to insufficient documentation and incorrect coding...

<table>
<thead>
<tr>
<th>Part B Service</th>
<th>Error Rate</th>
<th>No Doc</th>
<th>Insufficient Doc</th>
<th>Medical Necessity</th>
<th>Incorrect Coding</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Office visits – Established</td>
<td>7.7%</td>
<td>4.8%</td>
<td>35.5%</td>
<td>0.0%</td>
<td>59.7%</td>
<td>0.0%</td>
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<tr>
<td>Hospital visit – Subsequent</td>
<td>19.1%</td>
<td>4.3%</td>
<td>55.9%</td>
<td>0.4%</td>
<td>38.3%</td>
<td>1.0%</td>
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<tr>
<td>Hospital visit – Initial</td>
<td>30.2%</td>
<td>3.7%</td>
<td>29.1%</td>
<td>0.0%</td>
<td>66.2%</td>
<td>0.9%</td>
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<tr>
<td>Office visit - New</td>
<td>17.8%</td>
<td>0.7%</td>
<td>18.2%</td>
<td>0.9%</td>
<td>77.1%</td>
<td>3.1%</td>
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<td>Nursing home visit</td>
<td>19.8%</td>
<td>9.9%</td>
<td>40.8%</td>
<td>0.0%</td>
<td>49.3%</td>
<td>0.8%</td>
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<td>Hospital visit – critical care</td>
<td>27.8%</td>
<td>1.4%</td>
<td>41.7%</td>
<td>0.2%</td>
<td>56.2%</td>
<td>0.5%</td>
</tr>
</tbody>
</table>

Source: Centers for Medicare and Medicaid Services 2015 Comprehensive Error Rate Testing (CERT) report
Common Compliance Risks in Physician Practices

• Documentation and Coding
  - E&M services
  - E&M services during global surgery
• Use of Non-Physician Practitioners
  - Incident to billing
  - Shared split billing
• Highly-Productive Providers
  - Coverage requirements
  - Medical necessity and appropriateness
• Use of Billing Modifiers – 25, 59
• Provider Relationships with Industry
  - CMS Open Payments/Sunshine Act Data
• Use of Electronic Health Records
  - Copy, paste, pull-forward notes
• Provider Enrollment Information
Beware use of extrapolation…

- Regulators increasingly using extrapolation to determine repayment liabilities in audits and investigations
  - DHHS Office of Inspector General
  - CMS Audit Contractors
  - State Medicaid Auditors
- Error rates determine through audit of small sample of claims (e.g. 100) are extrapolated to population of all claims over 3-4 year period
- Small repayment amounts become significant repayment liabilities
Tips to Ensure Compliance

• Appoint designated compliance leader for your practice
  • Go-to person for questions and issues
• Stay current
  • Review and distribute regulatory bulletins and transmittals (CMS, Medicaid, NCDs and LCDs)
  • Current CPT and ICD manuals in offices and billing locations
  • Qualified coding resources
  • Compliance training for key leaders and staff
• Auditing and monitoring
  • Annual medical records documentation, coding and billing review
  • Periodic benchmarking of practice data to peers
  • If you find payment errors, don’t ignore!
False Claims Act (FCA)

- Federal law that makes it a crime to **knowingly** make a false record or file a false claim involving federal health care programs like Medicare and Medicaid

- “Knowingly” includes having **actual knowledge** a claim is false or acting in “reckless disregard”

- Most states have similar laws

- Penalties for violating the FCA include:
  - Fines up to $21,600 per claim
  - Penalties equal to 3 times the amount of the claim
  - Criminal penalties for willful violations
  - Exclusion from participation in federal health care programs

- Threat of FCA penalties and exclusion frequently used by regulators to reach settlements

- Very few FCA cases ever reach a court
“Qui Tam”/Whistleblower Laws

• The False Claims Act (and similar state laws) allows individuals with information concerning fraud to file lawsuits on behalf of the government.

• If successful, individuals (called “relators”) can receive up to 30% of any recoveries.

• False Claims laws provide individuals who file “whistleblower” lawsuits protection from firing, demotion, or harassment.

• Who can be a whistleblower?
  • Employees
  • Vendors
  • Physicians
  • Competitors

• Whistleblower lawsuits are a leading source of regulatory investigations in health care today.
Regulators are performing sophisticated data mining to identify high-risk physicians

Payments Attributable to High-Risk Physicians by Judicial District
November 2013 – October 2015

Data used to target High-Risk Physicians

Under the Patient Protection and Affordable Care Act (ACA), “high-risk” providers are identified and subjected to enhanced scrutiny.

Nationally, 4 of the top 10 high-risk physicians are in SDTX.*

Data mining of both real-time and recent physician records is conducted.

Source: Department of Justice, Health Care Compliance and Enforcement Institute, Oct. 2016

*For the period Nov. 2013 – Oct. 2015
60-Day requirement to repay Medicare overpayments…

• Final Rule established by 2010 Affordable Care Act issued in February

• The Basics
  • Providers have 60 days to report and return Medicare overpayments
  • 6 year look-back period
  • Overpayments retained beyond deadline may be subject to False Claims Act penalties (“Reverse False Claims”)
  • Clock starts when a provider has both determined and quantified an overpayment
  • No longer than 6 months to investigate and quantify unless “extraordinary circumstances”
Quality, Medical Necessity and Appropriateness of Care

- Historical view: “No or Worthless Care” = potential False Claims liability
- Today: Regulators focusing on medical necessity, appropriateness of care and coverage issues
- Examples: National and local Medicare coverage requirements
  - Cardiology - ICDs, pacemakers
  - Orthopedics - joint replacement
  - Neurosurgery - spinal surgery
- Reimbursement Tied to Quality Outcomes
  - Accuracy and completeness of quality and other performance data
Enforcement activity continues at a high pace...

- **2015**
  - $2.0B in healthcare fraud recoveries by Department of Justice
  - Over 600 new whistleblower lawsuits filed
  - Over 4,000 individuals and entities excluded from participation in federal health programs

Source: Bass Berry & Sims, *Healthcare Fraud and Abuse in Review 2015*
Financial Relationships with physicians and other referral sources present significant risks…

- Federal laws apply to all types of financial relationships with physicians and other referral sources including:
  - Employment
  - Professional or administrative services
  - Office or equipment leases
  - Joint ventures
  - Gifts and entertainment
- Certain business practices common in other industries are illegal in health care
- Failure to comply can result in significant penalties
  - Inability to bill and receive payment from Medicare and Medicaid related to “tainted” relationships
  - False Claims penalties
  - Civil monetary penalties
  - Potential exclusion from federal health care programs
Recent cases in the headlines

Tuomey will pay U.S. $72.4 million to duck $237 million False Claims verdict

By Lisa Schenck | October 16, 2015

Tuomey Healthcare System has agreed to settle with the government for $72.4 million—less than a third of the $237 million that a federal appeals court said it would have to pay for illegal compensation arrangements with doctors. The sum required by the verdict would otherwise have been the largest levied against a community hospital and would have exceeded the Sumter, S.C., system’s annual revenue. As part of the settlement, Tuomey will also be sold to Palmetto Health, a system based in Columbia, S.C. Tuomey previously signaled it planned to partner with Palmetto. Tuomey said in a statement Friday that the settlement will bring its decade-long struggle with Palmetto to an end.

Two former Tenet hospitals plead guilty to Medicaid kickbacks; $514M settlement finalized

By Erica Teichert | October 3, 2016

Two of Tenet Healthcare Corp.’s former subsidiaries admitted to conspiring to defraud Medicaid by using referral contracts for translation services to funnel pregnant patients through their doors. Atlanta Medical Center and North Fulton Hospital in Georgia each pled guilty to one count of conspiracy to violate federal anti-kickback laws and defraud the United States. Tenet said on Monday, as it finalized a $514 million settlement over its involvement in the scheme. In 2014, the U.S. Justice Department joined a whistleblower lawsuit accusing Tenet and four of its hospitals of allegedly making illegal payments to clinics operated by Clinica de la Mama and Hispanic Medical Management in exchange for Medicaid patient referrals, a violation of the federal anti-kickback statute and Stark law.

Adventist Health System to pay $118.7 million settlement over Stark, False Claims allegations

By Lisa Schenck | September 21, 2015

Adventist Health System will pay the government $118.7 million to settle allegations it offered doctors excessive compensation for referrals—a settlement amount that nearly doubles a record set last week. In 2012, three whistleblowers brought the case against the Florida-based system, which includes 44 hospital campuses in 10 states. They alleged that Adventist paid doctors for referrals in Florida, North Carolina, Tennessee and Texas in violation of the Stark law, which in turn, led to tainted claims to the government in violation of the False Claims Act. The whistleblowers said the system also paid for the leases of a BMW and Mustang for a surgeon and paid $710,000 in bonuses and salaries to a dermatologist who worked three days a week. Adventist noted in a statement Monday.
Trinity Health Policies

Trinity Health has established system-wide policies for all financial relationships with physicians and other referral sources.

**Trinity Health Policy Framework**

- Financial Arrangements in Writing
- Fair Market Value
- Legal Review
- Health Care Objectives and Commercial Reasonableness
- Board Approval
DOJ intent to hold individuals to greater accountability for compliance failures…

“And it is our obligation at the Justice Department to ensure that we are holding lawbreakers accountable regardless of whether they commit their crimes on the street corner or in the boardroom. In the white-collar context, that means pursuing not just corporate entities, but also the individuals through which these corporations act.”

Sally Q. Yates
Deputy Attorney General, DOJ
September 2015
Closing

Thank You!