The Perilous World of Fraud and Abuse: 2015 Year in Review

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Houston, Texas
What We Will Cover:

• Health Care Fraud and Abuse Current State of Affairs
• 2015 Fraud and Abuse Developments
• DOJ Focus on Compliance Programs
• Fraud and Abuse Future Expectations
• Questions
Current Government Enforcement:

State of Affairs
Overview of Healthcare Enforcement Environment

• Healthcare fraud enforcement activity has been increasing, including significant spike in recent years
• Government funding for healthcare fraud enforcement is at an all-time high and continues to increase
• FCA whistleblower lawsuits and ACA enforcement tools are key drivers behind government’s success
• Stark and AKS issues continue to be key components of the government’s enforcement activities
FY 2015 Statistics
DOJ / OIG

• Criminal Actions: 925 New Actions
• Civil Actions: 682 New Actions
• Exclusions: 4,112 I’s and E’s
• Health Care Recoveries: $1.97 Billion
Healthcare Enforcement: 
*The Amazing Investment*

- In 2015, the government reported having a return on investment of $8.10 for every dollar spent on health care-related fraud.
- Taxpayers Against Fraud Education Fund issued a report in 2013 concluding that there was a 20:1 return on investment under the FCA.

The FCA is the Fraud Enforcement Vehicle of Choice for Good Reason

• **FY 2015, more than $3.5 billion in recoveries**
  – More than 700 new whistleblower lawsuits

• **FY 2014, more than $5.6 billion in recoveries**
  – More than 700 new whistleblower lawsuits
  – Recoveries related to health care fraud reached $2.3 billion, $333 million from hospitals

• **FY 2013, more than $3.8 billion in recoveries**
  – Second largest annual recovery in history, whistleblower lawsuits soar to 752
  – Recoveries related to health care fraud reached $2.6 billion

• **Since January 2009**, total recoveries of $14.5 billion in federal health care dollars

Source: Press Release, Dep’t of Justice, Department of Justice Recovers Over $3.5 Billion From False Claims Act Cases in Fiscal Year 2015 (Dec. 3, 2015)
Key Facts Regarding 2015 FCA Recoveries

- Lowest amount from healthcare since 2009.
- No major pharma settlements
- *Largest year for non-intervened FCA recoveries
- Best year ever for relators (nearly $600 million ($335 million + $263 million))
- Significant hospital recoveries from the Stark law.
- Still 737 new FCA cases in the pipeline (632 *qui tam* + 105 non-*qui tam*). 67% relate to healthcare.
## More Money for Fighting Fraud

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>HCFAC Discretionary</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>294</td>
<td>672</td>
<td>706</td>
<td>+34</td>
</tr>
<tr>
<td><strong>HCFAC Mandatory</strong></td>
<td></td>
<td>1,264</td>
<td>1,273</td>
<td>1,342</td>
<td>+69</td>
</tr>
<tr>
<td><strong>Affordable Care Act (non-add)</strong></td>
<td></td>
<td>142</td>
<td>152</td>
<td>169</td>
<td>+17</td>
</tr>
<tr>
<td><strong>Total, Budget Authority</strong></td>
<td></td>
<td>1,558</td>
<td>1,945</td>
<td>2,048</td>
<td>+103</td>
</tr>
</tbody>
</table>

Source: http://www.hhs.gov/about/budget/budget-in-brief/cms/program-integrity/index.html
2015 Fraud and Abuse Developments
Recent Developments Overview

- HIPAA / Privacy Enforcement
- Medicare Fraud Strike Force
- Implementation of New Enforcement Provisions
- New Stark Law Rule: Reducing the Burden
- New Legislation: Shielding Gainsharing from CMPs
- Significant FCA Settlements in 2015
- FCA Highlights
- Continued Enforcement Against Individuals
- Medicare Contractor Dilemmas
- Publication of Physician Payment Data
HIPAA / Privacy Enforcement

Most common types of covered entities required to take corrective action by HHS OCR:

1. Private Practices
2. General Hospitals
3. Outpatient Facilities
4. Pharmacies
5. Health Plans

Due to issues involving: impermissible uses and disclosures of PHI; lack of PHI and ePHI safeguards; lack of patient access to PHI; and use/disclosure of more than minimum necessary.

Source: www.hhs.gov/ocr/privacy/hipaa/enforcement/highlights/index.html
HIPAA / Privacy Enforcement

Increase in Enforcement

Investigated Resolutions
April 14, 2003 through December 31, 2014

Source: www.hhs.gov/ocr/privacy/hipaa/enforcement/highlights/indexnumbers.html
# HIPAA / Privacy Enforcement

<table>
<thead>
<tr>
<th>YEAR</th>
<th>NO VIOLATION</th>
<th>RESOLVED AFTER INTAKE AND REVIEW</th>
<th>CORRECTIVE ACTION OBTAINED</th>
<th>TOTAL RESOLUTIONS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Partial Year 2003</td>
<td>79</td>
<td>5%</td>
<td>1177</td>
<td>260</td>
</tr>
<tr>
<td>2004</td>
<td>360</td>
<td>7%</td>
<td>3406</td>
<td>1033</td>
</tr>
<tr>
<td>2005</td>
<td>642</td>
<td>11%</td>
<td>3888</td>
<td>1162</td>
</tr>
<tr>
<td>2006</td>
<td>897</td>
<td>14%</td>
<td>4128</td>
<td>1574</td>
</tr>
<tr>
<td>2007</td>
<td>727</td>
<td>10%</td>
<td>5017</td>
<td>1494</td>
</tr>
<tr>
<td>2008</td>
<td>1180</td>
<td>13%</td>
<td>5940</td>
<td>2221</td>
</tr>
<tr>
<td>2009</td>
<td>1211</td>
<td>15%</td>
<td>4749</td>
<td>2146</td>
</tr>
<tr>
<td>2010</td>
<td>1529</td>
<td>17%</td>
<td>4951</td>
<td>2709</td>
</tr>
<tr>
<td>2011</td>
<td>1302</td>
<td>16%</td>
<td>4466</td>
<td>2595</td>
</tr>
<tr>
<td>2012</td>
<td>979</td>
<td>10%</td>
<td>5068</td>
<td>3361</td>
</tr>
<tr>
<td>2013</td>
<td>993</td>
<td>7%</td>
<td>9837</td>
<td>3470</td>
</tr>
<tr>
<td>2014</td>
<td>667</td>
<td>4%</td>
<td>10665</td>
<td>1287</td>
</tr>
</tbody>
</table>

### HIPAA / Privacy Enforcement

#### Notable Cases in 2015

<table>
<thead>
<tr>
<th>Date</th>
<th>Institution</th>
<th>Potential HIPAA Violation(s)</th>
<th>Settlement Amount</th>
</tr>
</thead>
</table>
| July 2015    | St. Elizabeth’s Medical Center (Massachusetts) | • Used internet-based document sharing app to store documents containing PHI of 498 individuals.  
• Failed to timely identify and respond to the incident, mitigate the effects, and document. | $218,400          |
| September 2015 | Cancer Care Group, P.C. (Indiana) | • Laptop bag stolen from an employee’s car. Laptop contained info of 55,000 patients.  
• No enterprise-wide risk analysis when breach occurred.  
• No appropriate written policies. | $750,000          |

## HIPAA / Privacy Enforcement

### Notable Cases in 2015

<table>
<thead>
<tr>
<th>Date</th>
<th>Institution</th>
<th>Potential HIPAA Violation(s)</th>
<th>Settlement Amount</th>
</tr>
</thead>
</table>
| November 2015 | Lahey Hospital (Massachusetts)                    | • Laptop stolen overnight from an unlocked treatment room (PHI of 599 patients).  
• Failure to conduct a risk analysis, physically safeguard the workstation, implement policies, implement unique user name for the workstation. | $850,000          |
| November 2015 | Triple-S Management Corporation (Puerto Rico)    | • Multiple breaches  
• Disclosure of PHI to vendor w/o a BAA.  
• No security measures or safeguards to reduce vulnerabilities of ePHI.  
• More than reasonable and necessary use of PHI for mailings.  
• No risk analysis.                                                                 | $3.5 million      |
| December 2015 | Univ. of Washington Medicine (Washington)       | • Employee downloaded email that contained malware, exposing PHI of 90,000 individuals.  
• UWM affiliated entity did not conduct a risk assessment and appropriately respond.                                                                                     | $750,000          |
Medicare Fraud Strike Force
Medicare Fraud Strike Force

- Strike Force in existence since March 2007
- Involves OIG, DOJ, FBI, etc.
- Current Task Force Cities: Brooklyn, Chicago, Dallas, Detroit, South Texas, Los Angeles, Miami, South Louisiana, and Tampa

Source: HHS OIG, “$3.35 Billion Expected to Return to Taxpayers as a Result of OIG Work in FY 2015 Fiscal Year 2015 Report to Congress Outlines Achievements”
Medicare Fraud Strike Force

June 18, 2015: DOJ and HHS announce Strike Force Charges 243 Individuals for approximately $712 Million in False Billing

– Largest criminal fraud health care “takedown” in the history of DOJ
– In Dallas, 7 people were charged in home health fraud schemes (one where $43 million were billed under a single physician)
– In Houston and McAllen, 22 individuals charged for fraud schemes involving more than $38 million in alleged fraudulent billing.
– In Miami, 73 defendants charged for fraud schemes involving $263 million in false billings.
– In Los Angeles, 8 defendants charged involving $66 million.
– In Detroit, 16 defendants charged involving more than $122 million.
– In Tampa, 5 defendants were charged involving millions in physician services and tests.
– In Brooklyn, 9 individuals charged for physical and occupational therapy fraud.
– In New Orleans, 11 individuals charged for home health fraud involving $110 million.

Source: DOJ, “National Medicare Fraud Takedown Results in Charges Against 243 Individuals for Approximately $712 Million in False Billing”
Implementation of New Enforcement Provisions
<table>
<thead>
<tr>
<th>ACA Provision</th>
<th>Status of Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stark Law Disclosure Protocol for Stark Law</td>
<td>Implemented by CMS</td>
</tr>
<tr>
<td>Disclosure Requirements for In-Office Ancillary Services Exception</td>
<td>Implemented by CMS</td>
</tr>
<tr>
<td>Limitations on Physician-Owned Hospitals</td>
<td>Implemented CMS</td>
</tr>
<tr>
<td>Lowered Criminal Intent Standard for AKS</td>
<td>Self-Implementing</td>
</tr>
<tr>
<td>Violation of AKS Triggers FCA liability</td>
<td>Self-Implementing</td>
</tr>
<tr>
<td>Violation of AKS is a “federal health care offense”</td>
<td>Self-Implementing</td>
</tr>
</tbody>
</table>
## ACA Fraud and Abuse Provisions

### False Claims Act

<table>
<thead>
<tr>
<th>ACA Changes</th>
<th>Status of Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lessened public disclosure bar</td>
<td>Self-Implementing (significant case law)</td>
</tr>
<tr>
<td>Makes Health Insurance Exchange payments subject to FCA if Fed Funds</td>
<td>Self-Implementing</td>
</tr>
<tr>
<td>60 Day Overpayment Rule</td>
<td>Self-Implementing</td>
</tr>
</tbody>
</table>
# ACA Fraud and Abuse Provisions

## Civil Monetary Penalty Provisions

<table>
<thead>
<tr>
<th>ACA Changes</th>
<th>Status of Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ordering or prescribing item or service while excluded.</td>
<td>Proposed Rule 2014 (79 FR 27079)</td>
</tr>
<tr>
<td></td>
<td>(Final Rule currently scheduled for 5/2016)</td>
</tr>
<tr>
<td>Knowingly making or causing to be made false statement, omission, or</td>
<td>Proposed Rule 2014 (79 FR 27079)</td>
</tr>
<tr>
<td>misrepresentation on application, bid, or contract.</td>
<td>(Final Rule currently scheduled for 5/2016)</td>
</tr>
<tr>
<td>Failing to grant timely access to HHS OIG for audits, investigations, etc.</td>
<td>Proposed Rule 2014 (79 FR 27079)</td>
</tr>
<tr>
<td></td>
<td>(Final Rule currently scheduled for 5/2016)</td>
</tr>
<tr>
<td>Knowingly making, using, or causing to be made or used, false record or</td>
<td>Proposed Rule 2014 (79 FR 27079)</td>
</tr>
<tr>
<td>statement material to a false claim.</td>
<td>(Final Rule currently scheduled for 5/2016)</td>
</tr>
<tr>
<td>Failing to report and return overpayments within 60 days of identification</td>
<td>CMS Proposed Rule 2012 (Extended) and</td>
</tr>
<tr>
<td></td>
<td>OIG Proposed Rule 2014 (Final Rule currently scheduled for 5/2016)</td>
</tr>
<tr>
<td>ACA Provision</td>
<td>Status of Implementation</td>
</tr>
<tr>
<td>------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------</td>
</tr>
<tr>
<td>Permissive exclusion for convictions in connection with obstruction or</td>
<td>Proposed Rule 2014 (79 FR 26810)</td>
</tr>
<tr>
<td>interference with an audit</td>
<td>(Final Rule currently scheduled for 5/2016)</td>
</tr>
<tr>
<td>Permissive exclusion for false statements, omissions or misrepresentations of</td>
<td>Proposed Rule 2014 (79 FR 26810)</td>
</tr>
<tr>
<td>material facts in provider or supplier applications</td>
<td>(Final Rule currently scheduled for 5/2016)</td>
</tr>
<tr>
<td>Permissive exclusion for failing to supply payment information for items or</td>
<td>Proposed Rule 2014 (79 FR 26810)</td>
</tr>
<tr>
<td>services for which payment may be made under Medicare or Medicaid</td>
<td>(Final Rule currently scheduled for 5/2016)</td>
</tr>
</tbody>
</table>
### ACA Fraud and Abuse Provisions

#### Fraud and Abuse Prevention Provisions

<table>
<thead>
<tr>
<th>ACA Provision</th>
<th>Status of Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td>New Medicare provider and supplier screening procedures in which provider and supplier types are categorized as either “limited,” “moderate” or “high” risk.</td>
<td>Final Rule 2011</td>
</tr>
<tr>
<td>Permissive exclusion for failing to supply payment information for items or services for which payment may be made under Medicare or any State health care program</td>
<td>Final Rule 2011</td>
</tr>
<tr>
<td>More flexibility to suspend Medicare payments to providers.</td>
<td>Final Rule 2011</td>
</tr>
</tbody>
</table>
| Permits temporary moratoria on the enrollment of new providers and suppliers if the Secretary determines such moratorium is necessary to prevent or combat fraud, waste, or abuse. | Final Rule 2011
|                                                                                                         | CMS is currently using frequently |
New Stark Law Rule:
Reducing the Burden
New Stark Law Rule: Reducing the Burden

• In November 2015, CMS finalized a rulemaking that relaxed and clarified several Stark Law requirements. (80 FR 70885)

• In part, the rule was in response to disclosures made under the new self-disclosure protocol.
New Stark Law Rule: Reducing the Burden

• Under the new rule:
  – Certain hospitals may provide remuneration to a physician to assist with the recruitment of nonphysician practitioners.
  – The writing requirement for Stark exceptions may be satisfied by a collection of contemporaneous documents in lieu of a formal contract.
  – The “term” requirement for Stark exceptions may be satisfied if the arrangement lasts for a year or longer.
  – CMS clarified the applicability and fleshed out the details of the obligation to disclose physician ownership of a hospital.
New Stark Law Rule: Reducing the Burden

• Under the new rule:
  – For the purposes of the space and equipment rental and personal services exceptions, holdovers of unlimited duration are permitted if the arrangement remains compliant with an exception.
  – For the purposes of the FMV compensation exception, renewals of arrangements of any length of time are permitted, if FMV comp.
  – CMS reaffirmed its position that a “split bill” arrangement does not involve remuneration, because the physician and the hospital do not provide benefits/compensation to one another.
    • CMS’s view is contrary to that of the Third Circuit in U.S. ex rel. Kosenske v. Carlisle HMA, 554 F.3d 88 (3d Cir. 2009)
New Stark Law Rule: Reducing the Burden

• Under the new rule:
  – For the purposes of the definition of a group practice, referrals of all physicians (including non-owners) is considered in determining whether compensation takes into account the volume or value of referrals.
  – CMS created a new exception for timeshare arrangements that include the use of office space but do not convey a possessory leasehold interest.
  – Parties have 90 days to obtain required signatures for agreements, regardless of whether the failure to obtain a signature was inadvertent.
New Legislation: Shielding Gainsharing from CMPs

Public Law 114–10
114th Congress

An Act

To amend title XVIII of the Social Security Act to repeal the Medicare sustainable growth rate and strengthen Medicare access by improving physician payments and making other improvements, to reauthorize the Children’s Health Insurance Program, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE—This Act may be cited as the “Medicare Access and CHIP Reauthorization Act of 2015”.

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—SGR REPEAL AND MEDICARE PROVIDER PAYMENT MODERNIZATION

Sec. 101. Repealing the sustainable growth rate (SGR) and improving Medicare payment for physicians’ services.
Sec. 102. Priorities and funding for measure development.
Sec. 103. Encouraging care management for individuals with chronic care needs.
Sec. 104. Empowering beneficiary choices through continued access to information.
Sec. 105. Expanding availability of Medicare data.
Sec. 106. Reducing administrative burden and other provisions.

TITLE II—MEDICARE AND OTHER HEALTH EXTENDERS

Subtitle A—Medicare Extenders

Sec. 201. Extension of work GPCI floor.
Sec. 202. Extension of therapy cap exceptions process.
Sec. 203. Extension of ambulance add-ons.
Sec. 204. Extension of increased inpatient hospital payment adjustment for certain low-volume hospitals.
Sec. 205. Extension of the Medicare-dependent hospital (MDH) program.
Sec. 206. Extension for specialized Medicare Advantage plans for special needs individuals.
Sec. 207. Extension of funding for quality measure endorsement, input, and selection.
Sec. 208. Extension of funding outreach and assistance for low-income programs.
Sec. 209. Extension and transition of reasonable cost reimbursement contracts.
New Legislation: Shielding Gainsharing from CMPs

• In April, Congress passed the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), containing significant changes related to gainsharing arrangements.

• MACRA:
  – Amends the statute to specify that CMPs may be imposed for gainsharing arrangements only if they “reduce or limit medically necessary services” to Medicare beneficiaries.
  – Directs HHS to submit a report to Congress within a year, listing options for statutory and regulatory changes to permit certain gainsharing arrangements.
Significant Provider Settlements of 2015
<table>
<thead>
<tr>
<th>Date</th>
<th>Amount</th>
<th>Company</th>
<th>Allegations</th>
</tr>
</thead>
<tbody>
<tr>
<td>February</td>
<td>$75 million</td>
<td>Community Health Systems Professional Services Corporation</td>
<td>Provider related donations made to counties in support of Medicaid IGTs.</td>
</tr>
<tr>
<td>March</td>
<td>$10 million</td>
<td>Robinson Health System, Inc.</td>
<td>Compensating physicians who failed to provide bona fide management services in violation of Stark and AKS.</td>
</tr>
<tr>
<td>April</td>
<td>$20 million</td>
<td>Medical Center of Central Georgia</td>
<td>Providing services in the inpatient setting instead of outpatient.</td>
</tr>
<tr>
<td>April</td>
<td>$21.75 million</td>
<td>Citizens Medical Center</td>
<td>Paying cardiologists above FMV and ER physicians bonus that varied with the volume or value of referrals in violation of Stark and AKS.</td>
</tr>
<tr>
<td>May</td>
<td>$15.69 million</td>
<td>16 hospitals</td>
<td>Providing medically unnecessary psychotherapy services.</td>
</tr>
<tr>
<td>June</td>
<td>$450 million</td>
<td>DaVita Healthcare Partners, Inc.</td>
<td>Billing government for unnecessary administration of drugs to dialysis patients and waste.</td>
</tr>
<tr>
<td>Date</td>
<td>Amount</td>
<td>Company</td>
<td>Allegations</td>
</tr>
<tr>
<td>----------</td>
<td>-----------------</td>
<td>----------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>June</td>
<td>$12.9 million</td>
<td>Children’s Hospital, Children’s National</td>
<td>Misstating bed count and overhead costs.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medical Center, Inc.</td>
<td></td>
</tr>
<tr>
<td>September</td>
<td>$25-$35 million</td>
<td>Columbus Regional Healthcare System</td>
<td>Above FMV comp paid to medical director in violation of Stark and level of</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>service allegations.</td>
</tr>
<tr>
<td>September</td>
<td>$69.5 million</td>
<td>North Broward Hospital District</td>
<td>Compensating 9 employed physicians in excess of FMV in violation of Stark.</td>
</tr>
<tr>
<td>October</td>
<td>$256 million</td>
<td>Millennium Health</td>
<td>Paying employed physicians bonuses based on the volume of referrals and</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>miscoding claims.</td>
</tr>
<tr>
<td>October</td>
<td>$250 million</td>
<td>500 hospitals</td>
<td>Provision of unnecessary testing and providing free testing for physicians in</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>violation of AKS.</td>
</tr>
<tr>
<td>December</td>
<td>$28 million</td>
<td>32 hospitals</td>
<td>Billing for kyphoplasty on an inpatient rather than outpatient basis.</td>
</tr>
</tbody>
</table>
Key FCA Developments
FCA Key Development No. 1: Increased Use of FCA to Enforce Stark Law

- Arguably requires only: “knowingly” having (i) financial relationship between physician and entity, (ii) referrals by physician to entity for DHS; and (iii) submission of DHS claims by the entity.

- If established, burden shifts to defendant to prove an exception applies (e.g., FMV, commercially reasonable, vary with the volume or value of referrals).

- Extremely complex law that is ultimately being interpreted in numerous ways by courts through FCA cases.
# FCA-Stark Cases and Settlements in 2015

<table>
<thead>
<tr>
<th>Defendant</th>
<th>Stark Law Allegations</th>
<th>Status of Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tuomey Healthcare System</td>
<td>Paying part-time employed physicians above fair market value</td>
<td>Judgment rendered in the amount of $237.5 million. Affirmed July 2015. Settled $72.4 million</td>
</tr>
<tr>
<td>Columbus Regional Healthcare System</td>
<td>Excessive salary and directorship payments to a physician.</td>
<td>Settled $25 million plus additional contingent payment of up to $10 million.</td>
</tr>
<tr>
<td>Robinson Health System, Inc.</td>
<td>Compensating physicians who failed to provide bona fide management services.</td>
<td>Settled $10 million.</td>
</tr>
<tr>
<td>Memorial Health, Inc.</td>
<td>Payment of employment compensation above FMV and failure to return overpayments to the government after learning of same.</td>
<td>Settled $9.9 million.</td>
</tr>
<tr>
<td>North Broward Hospital District</td>
<td>Compensating 9 physicians in excess of FMV and tracking referrals.</td>
<td>Settled $69.5 million.</td>
</tr>
<tr>
<td>Citizens Medical Center</td>
<td>Paying cardiologists above FMV and ER physicians bonus that varied with the volume or value of referrals.</td>
<td>Settled $21.75 million.</td>
</tr>
<tr>
<td>Adventist</td>
<td>Paying employed physicians bonuses based on the volume of referrals and miscoding claims.</td>
<td>Settled $115 million.</td>
</tr>
</tbody>
</table>
A concurring judge "emphasize[d] the troubling picture this case paints: an impenetrably complex set of laws and regulations that will result in a likely death sentence for a community hospital in an already medically underserved area."

The judge also stated that "[i]t seems as if, even for well-intentioned health care providers, the Stark Law has become a booby trap rigged with strict liability and potentially ruinous exposure-especially when coupled with the False Claims Act."
FCA Key Development No. 2: Enforcement of 60 Day Overpayment Rule


• **Facts:** Hospital systems in NY learned of double payments (Medicaid and Medicaid MCO) caused by Medicaid MCO’s software glitch. Hospital system refunded the money, but not timely enough according to the government.

• **Holding:** The 60-day rule clock begins “*when a provider is put on notice of a potential overpayment rather than the moment when an overpayment is conclusively ascertained.*”
FCA Key Development No. 2: Enforcement of 60 Day Overpayment Rule

- In February, CMS extended by 1 year the timeline for publication of a final rule concerning policies and procedures for reporting and returning overpayments to the Medicare program. (80 FR 8247)
- Proposed rule was published in 2012. (77 FR 9179)
- The final rule deadline is now 2/16/2016.
FCA Key Development No. 3: SCOTUS to Weigh In on Implied Certification

• In December, SCOTUS granted certiorari to resolve the federal circuit split on the theory of “implied certification.”
  – *U.S. ex rel. Escobar v. Universal Health Services, Inc.*

• The opinion, expected in June 2016, will decide:
  – 1) Whether the theory of implied certification is viable, and, if it is,
  – 2) Whether the law or contractual provision allegedly violated by defendant must state that it is a condition of payment for the claim to be legally false.
FCA Key Development No. 3: SCOTUS to Weigh In on Implied Certification

• Courts recognize two types of false claims:
  – 1) Factually false claims: false factual information.
  – 2) Legally false claims: false representation of compliance with the law or a contractual requirement.

• An **express** legally false claim represents compliance with a specific law or requirement (“express certification”).

• Most courts have also recognized the existence of **implied** legally false claims, where a request for payment implies compliance with governing federal rules that are a precondition to payment (“implied certification theory”).
## FCA Key Development No. 3: SCOTUS to Weigh In on Implied Certification

<table>
<thead>
<tr>
<th>Law/contractual provision need not state it is a requirement for payment</th>
<th>Law/contractual provision must state it is a requirement for payment</th>
<th>Rejection of implied certification theory</th>
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<td>• First, Fourth, and DC Circuits</td>
<td>• Second and Sixth Circuits</td>
<td>• Seventh Circuit</td>
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- SCOTUS was asked to determine which among these three views is the correct interpretation of the FCA.
FCA Key Development No. 4: Use of Statistical Sampling in FCA Cases


- Fourth Circuit agrees to hear interlocutory appeal on the use of statistical sampling to prove FCA liability. First appeals court to consider issue.
- The question presented is whether the relator can use statistical sampling to prove liability and damages.
- Decision expected in 2016.
FCA Key Development No. 5: SCOTUS Decision on First to File

*Kellogg Brown & Root Services, Inc. v. US ex rel. Carter*

- SCOTUS held that (i) Wartime Suspension of Limitation Act does not toll the FCA statute of limitations and (ii) first-to-file bar only applies to pending actions and not dismissed or settled actions.

- Shortly after the KBR decision, the DC Circuit reconsidered a case that had been previously dismissed based on the first-to-file bar.
Continued Enforcement Against Individuals
Healthcare Fraud Enforcement: Recent Focus on the Individual

- The Government has begun to focus on holding individuals accountable in healthcare fraud investigations with emphasis on executives of healthcare companies.

- OIG reported 925 criminal actions against individuals or entities that engaged in crimes against some of the 100 HHS programs overseen by OIG for FY 2015.

- In June 2015, OIG issued a new Fraud Alert for physician compensation, instituted new litigation and exclusion team, and hired additional attorneys to focus on pursuing individuals and physicians.
Testimony of Former OIG Chief Counsel Lewis Morris Before Congress (March 2, 2011)

• Some hospital systems, pharmaceutical manufacturers, and other providers play such a critical role in the care delivery system that they may believe that they are ‘too big to fire’ and thus OIG would never exclude them and thereby risk compromising the welfare of our beneficiaries. We are concerned that the providers that engage in health care fraud may consider civil penalties and criminal fines a cost of doing business. As long as the profit from fraud outweighs those costs, abusive corporate behavior is likely to continue.

…

• One way to address this problem is to attempt to alter the cost-benefit calculus of the corporate executives who run these companies. By excluding the individuals who are responsible for the fraud, either directly or because of their positions of responsibility in the company that engaged in fraud, we can influence corporate behavior without putting patient access to care at risk.”
Yates Memo: Individual Accountability for Corporate Wrongdoing

• In September, Deputy Attorney General Sally Yates issued a memo to all US Attorneys, titled “Individual Accountability for Corporate Wrongdoing.”

• “One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing. Such accountability is important for several reasons: it deters future illegal activity, it incentivizes changes in corporate behavior, it ensures that the proper parties are held responsible for their actions, and it promotes the public's confidence in our justice system.”
Yates Memo: Individual Accountability for Corporate Wrongdoing

• The memo emphasizes the effectiveness of individual accountability and outlines 6 “key steps to strengthen [DOJ’s] pursuit of individual corporate wrongdoing.”
Yates Memo: Individual Accountability for Corporate Wrongdoing

1. In order to qualify for any cooperation credit, corporations must provide to the Department all relevant facts relating to the individuals responsible for the misconduct;

2. Criminal and civil corporate investigations should focus on individuals from the inception of the investigation;

3. Criminal and civil attorneys handling corporate investigations should be in routine communication with one another;
Yates Memo: Individual Accountability for Corporate Wrongdoing

4. Absent extraordinary circumstances or approved departmental policy, the Department will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation;

5. Department attorneys should not resolve matters with a corporation without a clear plan to resolve related individual cases, and should memorialize any declinations as to individuals in such cases; and

6. Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual's ability to pay.
“Although in the short term certain cases against individuals may not provide as robust a monetary return on the Department's investment, pursuing individual actions in civil corporate matters will result in significant long-term deterrence. Only by seeking to hold individuals accountable in view of all of the factors above can the Department ensure that it is doing everything in its power to minimize corporate fraud, and, over the course of time, minimize losses to the public fisc through fraud.”
Medicare Contractor Dilemmas

Quick Review of Contractors

• Medicare
  – Medicare Administrative Contractors (MACs)
  – Zone Program Integrity Contractors (ZPICs)
    – Program Safeguard Contractors (PSCs)
  – Recovery Audit Contractors (RACs)
  – National Supplier Clearinghouse (NSC) *not a claims auditor*

• Medicaid
  – Medicaid Integrity Contractors (MICs)
  – Medicaid RACs
  – Medicaid OIG
  – Medicaid Fraud Control Units (MFCU)
Medicare Contractor Dilemmas

Challenges with RACs

- CMS lacks means to prevent inappropriate duplication among contractors
- RAC denials lack quality and are often inaccurate
- QICs often lack thorough review of decisions
- Appeal challenges tie up significant $$ in provider reimbursement and patient care
- Misaligned financial incentives associated with RAC audits
- Technical issues with audits not resolved until appeal process
- **Significant appeals backlog at OMHA**
- Significant costs associated with appeals (HHS’s cost per appeal is $1,388 ($100mm OMHA budget for FY 2015/72,000 cases)
- Hospital appeal success rate typically between 60 to 80%, well above the 3 to 7% identified by CMS
- Overwhelming majority of audits focus on inpatient claims

*See GAO report to Congressional Requesters, “Medicare Program Integrity - Increased Oversight and Guidance Could Improve Effectiveness and Efficiency of Postpayment Claims Reviews” (July 2014)*
Medicare Contractor Dilemmas

CMS Announces RAC Program Improvements for New Contracts

On Dec. 30, 2014, CMS published an updated list of RAC program improvements. Key changes include:

– New contracts will require RACs to expand review topics to include all claim and provider types and require RACs to review certain topics based on referrals, such as an OIG report, as opposed to focusing solely on inpatient hospital claims

– Limit the RAC look-back period to 6 months from the date of service for patient status reviews if the hospital submits the claim within 3 months of the date of service

– Provide RACs with 30 days to complete complex reviews and notify providers of their findings

– Establish that RACs will only receive a contingency fee after the second level of appeal is exhausted

Medicare Contractor Dilemmas

MedPAC Recommendations

Recommendations:

- The Secretary should:
  - direct recovery audit contractors (RACs) to focus reviews of short inpatient stays on hospitals with the highest rates of this type of stay,
  - modify each RAC’s contingency fees to be based, in part, on its claim denial overturn rate,
  - ensure that the RAC look-back period is shorter than the Medicare rebilling period for short inpatient stays, and
  - withdraw the “two-midnight” rule.

- The Secretary should evaluate establishing a penalty for hospitals with excess rates of short inpatient stays to substitute, in whole or in part, for RAC review of short inpatient stays.
Medicare Contractor Dilemmas

Status of OMHA Backlog

• ALJ appeal backlog involves more than 500,000 cases.

• Hospital appeals settlements with CMS have done little to address the backlog.

• FFY 2015 Average Processing Time: 547.1 Days

• 1\textsuperscript{st} and 2\textsuperscript{nd} level appeals are arguably “rubber stamp” events and the ALJ affords the only meaningful appeal.
Medicare Contractor Dilemmas

Status of OMHA Backlog

• In June and again in December 2015, Senate Finance Committee approved the AFIRM Act to address the Medicare appeals backlog.

• The AFIRM Act would (among other provisions):
  – Provide for the transfer of $125 million to OMHA and $2 million to the Departmental Appeals Board for FY16 and each FY thereafter for the purposes of conducting claims reviews, hearings, and appeals;
  – Increase the minimum amount in controversy to qualify for judicial review from $1,000 to $1,500; and
  – Create Medicare Reviews and Appeals Ombudsmen who duties would include assisting in the resolution of complaints related to the Medicare audit and appeal process,
Publication of Physician Payment Data
Publication of Physician Payment Data

- In April 2014, CMS made first publication of Medicare Part B payments to individual physicians and physician practices after federal judge ruled against a 1979 prohibition in May 2013 on disclosing data.

- Database includes 9.2 million lines describing transactions worth $77 billion by 880,000 physicians and physician practices certified to collect from Medicare.

- Data includes physicians’ names and office locations, services billed to Medicare, average payments for services and number of patients who received each service.

Publication of Physician Payment Data

Case Study – Dr. Asad Qamar, Florida Cardiologist

- Data made available last year reveals that Dr. Qamar is highest paid cardiologist in 2012 making $18 million.
- 6 medical facilities, 10 doctors, and approx. 60 staff billed through Dr. Qamar’s Medicare number.
- Government alleges unnecessary invasive heart testing and kickbacks by waiving patient copays and deductibles.
Sunshine Act

Open Payments
Sunshine Act

- CMS publicly posted data in searchable format and 2013 data initially published Sept. 30, 2014
- CMS updated 2013 data on Dec. 19, 2014
- 2014 payments posted June 30, 2015

www.cms.gov/openpayments/

- 2014 totals include $6.49 billion made by 1,444 companies to 607,000 physicians and 1,121 teaching hospitals
- $6.49 billion includes: (i) $2.56 billion in general payments, (ii) $3.23 billion in research payments, and (iii) $703 million in ownership / investment interest payments
- Over $5 billion of the $6.49 billion were made to physicians.
Who Will Be Reviewing Physician Payment and Sunshine Act Reports?

Industry/Physician Relationships

- U.S. Congress
- Regulatory and Enforcement Agencies
- Physician Groups
- Industry Groups
- Medical Institutions
- State Legislatures
- Press

The Wall Street Journal
The New York Times
The Washington Post

Executive Board of IOM

American Dental Association
American Medical Association
Focus on Compliance Programs
DOJ Focus on Compliance Programs

• Assistant AG for Criminal Division Leslie Caldwell emphasized in November 2, 2015 speech importance of functioning compliance programs.

• DOJ Criminal Division hired compliance counsel to assist DOJ in assessing compliance programs.

• Caldwell also outlined the “Hallmarks” of an effective compliance program that will be assessed by compliance counsel.
DOJ Focus on Compliance Programs

• Does the institution ensure that its directors and senior managers provide strong, explicit and visible support for its corporate compliance policies?
• Do the people who are responsible for compliance have stature within the company?
• Are the institution’s compliance policies clear and in writing?
• Does the institution ensure that its compliance policies are effectively communicated to all employees?
• Does the institution review its policies and practices to keep them up to date with evolving risks and circumstances?
• Are there mechanisms to enforce compliance policies?
• Does the institution sensitize third parties like vendors, agents or consultants to the company’s expectation that its partners are also serious about compliance?
Fraud and Abuse
Future Expectations
Fraud and Abuse
Future Expectations

1. Continued use of FCA to enforce Stark Law, 60 day rule, and quality of care.
2. More hospital executives subject to civil and criminal enforcement actions.
3. Increased dual civil and criminal investigations by DOJ.
4. Increased self-disclosure for Stark and AKS violations.
5. Significant CMS program integrity contractor reform.
6. Expanded use of physician payment database and other publicly available data for qui tam lawsuits.
7. More court decisions addressing ability of defendants to win MTD for meeting Stark / AKS exceptions.
8. Attempts to enact legislation to improve the Stark Law.
9. Increased use of statistical sampling in FCA cases.
10. Increased use of temporary enrollment moratoria, payment suspensions, and other fraud prevention tools.
11. Increased non-intervened FCA recoveries by whistleblowers.
Questions
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