2016 Health Law Year in Review
HCCA Houston Regional Conference

December 9, 2016

Adam Robison

DOJ Continues High Recoveries

• DOJ Recovers More than $3.5 Billion in FY15 from FCA Cases
  – Qui Tam Cases – 737 New FCA Cases (67% healthcare)
  – Whistleblower – $597 (non-intervened)
  – Healthcare -- $1.4 Billion
  – Hospitals – $330 Million
  – Pharma – $$96 Million
  – Stark -- $215 Million
FCA: Fantastic ROI

- HCFAC reported return on investment of $6.10 for every $1.00 invested in FY15
- DOJ reported return of investment of $7.70 for every $1.00 invested for anti-fraud efforts in FY15
- Taxpayers Against Fraud Education Fund reports 20:1 return on investment

FCA and Other Penalties Doubled!

- Bipartisan Budget Act of 2015
  - Sec. 701. Civil monetary penalty inflation adjustments
    - Requires federal agencies to update civil monetary penalties (CMPs) to account for inflation, including penalties under the FCA
  - DOJ interim final rule increased FCA penalties from between $5,500 to $11,000 to between $10,781 to $21,563 per claim.
  - Application: assessments on or after August 1, 2016 for violations occurring on or after November 2, 2015.
New Penalties = Scary Math

• $10,781 to $21,563 / claim filed + 3X amount of damages plus attorney’s fees

Example of Damages
General Defense Contractor vs. Provider ($100k overpayment)

<table>
<thead>
<tr>
<th></th>
<th>Defense Contractor (12 Claims/Yr.)</th>
<th>Provider (2,000 Claims/Yr.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Triple Damages</td>
<td>$300,000</td>
<td>$300,000</td>
</tr>
<tr>
<td>Penalty</td>
<td>$258,756</td>
<td>$22,000,000</td>
</tr>
<tr>
<td>Total Recovery</td>
<td>$558,756</td>
<td>$43,126,000</td>
</tr>
</tbody>
</table>

Statistical Sampling in FCA Cases
Could New Penalties Constitute Excessive Fines

• **U.S. ex rel. Drakeford v. Tuomey**
  - Fourth Circuit affirmed $237 M judgment
  - Punitive = entire civil penalty amount ($119.5 M)
  - Compensatory = actual damages amount ($39.3 M)
  - “Hybrid of punitive and compensatory damages” = trebling of actual damages ($78.6 M)
  - Court determined 3.6 to 1 ratio “falls just under the ratio the Supreme Court deems constitutionally suspect”
  - What about under new penalties which are 2x as high?
  - Tuomey entered into a $72.4 M settlement with the DOJ conditioned on a merger with Palmetto Health

Use Statistical Sampling in FCA cases?

• **Tyson Foods v. Bouaphakeo, et al.**
  - Supreme Court upheld $2.9 M jury verdict against Tyson in a class action involving unpaid overtime that used statistical evidence to infer time spent by employees donning / doffing protective gear
  - In a 6-2 decision, the Court found employees were “forced to rely” on statistical sampling because Tyson did not keep records of the time spent on this activity by employees
  - Court did not forbid or affirm use of statistical evidence:
    - “Whether and when statistical evidence can be used to establish classwide liability will depend on the purpose for which the evidence is being introduced and on the elements of the underlying cause of action ...”
Statistical Sampling / Extrapolation

• U.S. ex rel. Michaels v. Agape Senior Cmty, Inc.
  – Allegations: Agape facilities submitted >50,000 claims for medically unnecessary care
  – Fourth Circuit to interlocutory appeal pending on the following questions:
    1. Whether the government can veto an FCA settlement in a case in which has not intervened
    2. Whether the relator can use statistical sampling to prove liability and damages
  – Oral arguments suggest Fourth Circuit may punt on the statistical sampling issue.
    “It looks to me like it’s an evidentiary ruling that’s committed to the discretion of the district judge. If that’s the case, that issue we ought to perhaps dismiss as improvidently granted.” 4th Circuit Judge Robert B. King.

  Nos. 15-2145 and 15-2147 (4th Cir. Sept. 29, 2015)

TX District Court Rejects Extrapolation

• Allegations: VistaCare hospice knowingly submitted hospice claims for non-terminally ill patients
• Relator’s expert extrapolated the results of a 291 patient review to a universe of 12,000 patients
• Relying in part on Tyson Foods, the court refused to allow a relator to use extrapolation in a hospice FCA case

“The permissibility of statistical sampling turns on ‘the degree to which the evidence is reliable in proving or disproving the elements of the relevant cause of action.” Questions relating to hospice eligibility highly subjective. Each claim implicates “different patients, different medical conditions, different caregivers, different facilities, different time periods, and different physicians.”

But …. in a footnote, the court observed that extrapolation could “be appropriate where the evidence establishes that a defendant’s objective approach was similar in all cases.”
Individual Liability for Corporate Misconduct

Remember the Yates Memo?

• DOJ policy statement

“One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing . . . [accountability] it deters future illegal activity, it incentivizes changes in corporate behavior . . . and it promotes the public’s confidence in our justice system.”

Sally Quilliam Yates
Deputy Attorney General
Sept. 15, 2015
Yates Memo – 6 Key Principals

1. To qualify for cooperation credit – “corporations must provide all relevant facts relating to the individuals responsible for the misconduct”

2. Criminal and civil corporate investigations “should focus on individuals” from inception

3. Criminal and civil attorneys handling corporate investigations “should be in routine communication”

4. Culpable individuals will not be released from civil or criminal liability when resolving a matter with a corporation, absent “extraordinary circumstances”

5. No resolution of the corporate investigation “without a clear plan to resolve related individual cases”

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”

DOJ Makes Good on Promise to Pursue Individuals

![Image]

Former Tuomey CEO to personally pay $1 million to settle False Claims Act case

Legal & Regulatory Issues

Ex-hospital CFO, physicians guilty in $580M kickback scheme

The ex-CFO of the now-defunct Pacific Hospital in Long Beach, Calif., was among those who recently reached a plea agreement with prosecutors for his involvement in a fraud scheme that generated $580 million in false billings, according to the Department of Justice.

Others involved in the scheme, including two orthopedic surgeons, have agreed to plead guilty in coming weeks.

The 15-year-long fraud scheme involved Pacific Hospital’s former CEO and others submitting bills to workers’ compensation insurers and the U.S. Department of Labor for spinal surgeries. The surgeries were performed on patients who had been referred by dozens of physicians.
DOJ Makes Good on Promise to Pursue Individuals
(cont’d)

Law360, New York (August 10, 2016, 1:53 PM ET) -- The former chief financial officer of an Alabama nonprofit health clinic for the poor and homeless will serve 17 years in prison and forfeit nearly $2 million for her role in an $11 million fraud against two clinics and the federal government, the U.S. Department of Justice announced today.

Tori McClure Wallace, 54, has pled guilty to participating in a scheme involving shuffling federal grant money given to Birmingham Health Care and Central Alabama Comprehensive Health St. Teilson Inc. to private entities and then to private individuals, including herself. Chief U.S. District Judge Kermit O. Dawkins sentenced Wallace to 17 years in prison for the scheme in which prosecutors say she personally profited about $1.7 million.

DOJ Also Makes Good on Promise Not to Release Individuals
FCA Settlement Agreement Redline

Subject to the exceptions in Paragraph __ (concerning excluded claims) below, and conditioned upon [defendant]’s full payment of the Settlement Amount, the United States releases [defendant], and its current and former employees, officers, directors, attorneys, agents, subsidiaries, affiliates, and their respective current and former employees, successors, officers, directors, attorneys, and agents, and divisions successors, parent and subsidiary entities from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a; and the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812.
Parallel Investigations

Another DOJ Promise: Pursuit of Parallel Investigations

• DOJ policy statement

“We in the Criminal Division have recently implemented a procedure so that all new qui tam complaints are shared by the Civil Division with the Criminal Division as soon as the cases are filed. Experienced prosecutors in the Fraud Section are immediately reviewing the qui tam cases when we receive them to determine whether to open a parallel criminal investigation.”

Leslie Caldwell
Assistant Attorney General
Sept. 17, 2014
Parallel Investigations

• Warner Chilcott global settlement

Resolved criminal and civil allegations for illegal prescription drug promotion activity

$23 M criminal fine
  • One count healthcare fraud and criminal forfeiture

$102 M civil settlement
  • False claims submitted to federal healthcare programs

Permanent exclusion

Indictment and guilty pleas
  • 3 former executives (including the company’s former president) for criminal conspiracy to violate the AKS


Parallel Investigations

• Tenet and Tenet Subsidiaries enter into global civil and criminal settlement

Resolved criminal and civil allegations of paying kickbacks and bribes to prenatal clinics

$368 Million civil settlement
  • False claims submitted to federal healthcare programs
  • Relator’s share of the combined settlement is $84.43 million

Tenet and subs enter into non-prosecution agreement
  • Subs plead guilty to conspiracy to defraud
  • Will also forfeit $145 million amount paid by Medicare

Who is Bringing Qui Tam Suits?

- **CEOs** -- *U.S. ex re Schaengold v. Mem’l Health, Inc. No. 4:11-cv-00058-JRH-BKE (S.D. Ga.)* (CEO to receive $2.3 Million)
- **Compliance Officers** –
- **Physicians** – *United States ex rel. Moore v. Mercy Health Springfield Communities Case No. 12-3019-CV (W.D. Mo.)* (employed physician alleged bonuses to physicians based on referrals)
- **Nurses** – *United States ex rel. Flipp v. Friendship Home Healthcare, Inc., et al., No. 3:14-cv-1262 (M.D. Tenn.)* (alleged billing for services by excluded individual)
- **CFOs** – *United States ex rel. Beaujon v. Hebrew Home Health Network, Inc. et al., Case No. 12-20951 CIV (S.D. Fla.)* (same medical director contracts)
- **Consultants** – *(with cardiac nurse – massive hospital settlements for implanted devices)* *BNA 10/20/15*

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Biggest FCA Case of the Year
Biggest FCA Case of the Year: Escobar

Implied certification can be a basis for FCA liability
- When a defendant submitting a claim (a) makes specific representations about the goods or services provided, and (b) fails to disclose non-compliance with material statutory, regulatory, or contractual requirements that makes those representations misleading half-truths.
- “What matters is not the label the Government attaches to a requirement, but whether the defendant knowingly violated a requirement that the defendant knows is material to the Government’s payment decision.”

Escobar: What is Material?
- Clarifications of Materiality
  1. “A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment.” Slip op. at 15.
  2. “Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant’s noncompliance.” Id.
  3. “Materiality . . . cannot be found where noncompliance is minor or insubstantial.” Id. at 16.
  4. “[I]f the government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence . . . [of lack of materiality].” Id.
  5. The False Claims Act’s materiality and scienter requirements are “rigorous” and “demanding”. Slip op. at 2, 14, 15.
Escobar: Win for Gov’t / Plaintiffs?

A Clear Defeat For FCA Defendants

This is a fantastic decision overall for both taxpayers and whistleblowers.

Tremendous Victory to Whistleblowers

It affirms that government contractors that present half-truths and fail to comply with relevant and important requirements when seeking payment from the government are liable under the False Claims Act.

Or Win for Defendants?

Escobar Is Actually a Win for FCA Defendants

The remainder of the opinion favors potential FCA (and other) defendants by imposing a much more "rigorous" and "demanding" materiality standard in FCA cases and others where materiality must be proved.

Net Win for Federal Government Contractors
Courts Grapple With Answer

• Lower courts generally agree “materiality” is a high standard:
  – *U.S. ex rel. Dresser v. Qualium Corp.*, 2016 WL 3880763 (N.D. Cal. July 18, 2016) (allegation that government would not have paid defendants’ claims had it known of the misconduct was insufficient because the complaint did not explain “why” it would not have paid the claims);
  – *U.S. ex rel. Southeastern Carpenters Regional Council v. Fulton Co.*, 2016 WL 4158392 (N.D. Ga. Aug. 5, 2016) (“Relators have not shown that Defendants misrepresented matters ‘so central’ to the Contract that the government ‘would not have paid [Defendants’] claims had it known of these violations’”);

• Courts disagree on whether there is a two-part test:
  – One court held that “Escobar did not establish a rigid two-part test for falsity that must be met in every single implied certification case.” *Rose v. Stephens Institute* (N.D. Cal. Sept. 20, 2016).
  – But other district courts have found that Escobar does set forth a two-prong test that must be satisfied for the relator’s complaint to survive dismissal. *U.S. v. Crumb* (S.D. Ala. Aug. 24, 2016) (finding that the allegations satisfied both prongs of Escobar).

Significant 2016 FCA Settlements
Hospital Settlements

• **Tenet and subsidiaries** pay $513 million to resolve civil and criminal actions alleging that Tenet paid kickbacks to prenatal clinics to refer patients. The relators received more than $84 million.

• **Vibra Healthcare LLC** pays $32.7 million to resolve allegations it violated the FCA by billing for medically unnecessary LTCH and Inpatient rehab services.

• **Tuomey former CEO** pays $1 million to settle FCA allegations for billing Medicare in violation of Stark. This was in follow-up to a $237.4 million judgment against Tuomey that was settled for $72.4 million.

Hospital Settlements (cont’d)

• **Mount Sinai Beth Israel et al** paid $2.95 million to settle allegations that it violated the FCA by failing to return Medicaid overpayments in accordance with the 60 day rule.

• **Lexington Medical Center** paid $17 million to resolve allegations that it violated the FCA by billing Medicare for services in violation of the Stark Law, due to improper financial relationships with 28 physicians. The relator received $4.5 million.

• **51 hospitals** pay $23 million to settle allegations of violating the FCA by billing for medically unnecessary implantable cardiac devices. This was the culmination of nationwide investigation that has yielded more than $280 million.
Nursing Home Settlements

- **LifeCare (and its owner)** pays $145 million to resolve allegations that it falsely billed for “ultra high” therapy services to maximize financial profits. Relators received $29 million.
- **Kindred** pays $125 million to resolve similar allegations. The relator received $24 million.
- **Omnicare** pays $28 million to resolve allegations that it solicited kickbacks from Abbott Laboratories for promoting Depakote to nursing home patients.

Hospice Settlements

- **Evercare Hospice** pays $18 million to resolve allegations that it violated the FCA by billing for patients who were not terminally ill.
Overpayments and Self-Disclosures

The Affordable Care Act Law

- **March 23, 2010**: Enactment of the Affordable Care Act (ACA)
- **Section 6402(a) of the ACA** (now codified at 42 U.S.C. § 1320a-7k(d)):
  - A person who has received an overpayment must report and return the overpayment within either 60 days after the date on which the overpayment was identified or on the date any corresponding cost report is due, whichever is later.
  - The term “overpayment” means any Medicare or Medicaid funds that a person receives or retains to which the person, after applicable reconciliation, is not entitled.
Timeline of Significant Overpayment Developments

1. **March 2010**: Medicare Parts C/D Proposed Rule
2. **February 2012**: Medicare Parts C/D Final Rule
3. **January 2014**: Four Years
4. **February 2016**: No Medicaid Proposed Rule to date
5. **December 2016**: Medicare Parts A/B Final Rule

"Identification" Defined: A/B Final Rule

- **Medicare Parts A/B Final Rule**: New regulatory definition in 42 C.F.R. § 401.305(a)(2)
  - An overpayment is identified "when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment."

- This definition includes two key concepts:
  1. Concept of reasonable diligence
  2. Quantification
Concept of Reasonable Diligence

• The finalized definition of “identification” incorporates concept of “reasonable diligence.”

• In the Final Rule, CMS stated that reasonable diligence includes both proactive compliance activities and reactive investigative activities.
  • Size and scope of compliance programs will vary, but having no compliance activities may expose the provider to liability.

• When does the 60-day clock begin to tick?
  1. When the exercise of reasonable diligence is completed, or
  2. If there is a failure to exercise reasonable diligence, on the day when the person received credible information of a potential overpayment.

Credible Information of “Potential” Overpayments

• Keyword—Potential Overpayments.

• Receipt of “credible information” triggers a duty to investigate.
  • “Credible information” is not specifically defined, but includes information that “supports a reasonable belief that an overpayment may have been received.”
  • CMS specifically rejected an evidentiary standard—instead adopted credible “information” standard.
Potential Sources of “Credible” Information (Not Exhaustive)

- Certain hotline reports
- Subpoenas
- QIO audits
- MACs
- RACs
- CMS contractor audits
- Internal compliance reviews/audits
- Qui Ttems
- Revenue spikes
- Ineligible persons

Potential Sources of “Credible” Information of Potential Overpayments

Medicare Parts A/B Overpayment Final Rule: Timeline

Final Rule’s General Timeframes for Reporting and Returning Medicare A and B Overpayments

- Receipt of “Credible Information” of a Potential Overpayment
  - No More than 6 Months to Investigate and Quantify Potential Overpayments (absent “extraordinary circumstances”)
  - 60 days to report and return the Overpayments

Triggers Duty to Investigate

Unless “Extraordinary Circumstances,” No More Than 8 Months to Investigate and Report and Refund Medicare Parts A and B Overpayments
Lookback Period

• Pursuant to the Medicare Parts A/B Final Rule, Medicare Parts A/B overpayments must be reported and returned “only if a person identifies the overpayment within six years of the date the overpayment was received.”

  • Maximum Threshold - providers should not be foreclosed from using a more limited lookback period if justified by the relevant circumstances (coverage change or EHR system conversion).

• Practical challenges of lookback period:
  • Recordkeeping difficulties
  • Evolving regulatory standards
  • Audit resources
  • Potential need for statistical sampling resources

FCA Enforcement of 60-Day Rule

  – Healthcare provider erroneously submitted claims to Medicaid for payment due to a software error. The provider failed to fully investigate and identify all overpayments until two years later.
  – The court interpreted “identification” to include situations where “*a person is put on notice that a certain claim may have been overpaid*.”

• Parties settled for $2.95 million on August 23, 2016
Retained Overpayments

• *U.S. ex rel. Odumosu v. Pediatric Servs. of Am. Healthcare (PSA); U.S. ex rel. McCray v. PSA*
  
  – Home healthcare provider to pay $6.88 M to settle allegations that it failed to refund overpayments from TRICARE and 20 state Medicaid programs between 2007 and 2013

  “First of its kind” settlement stemming from a provider’s failure to “actively investigate whether they have received overpayments and, if so, promptly return the overpayments”

  John Horn, U.S. Attorney
  Northern District of Georgia
  (Aug. 4, 2015)


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Stark and Anti-Kickback Statute
Recent Stark Settlements

• North Broward Hospital District Pays $69.5 Million to Resolve Stark Allegations (9/15/15)
  – Allegations: 9 employed physicians compensated above FMV, not commercially reasonable, and varied with the volume or value of referrals
  – Compensation in excess of 90th percentile

• Adventist Health Pays $119 Million to Resolve FCA Action Based on Stark (9/21/15)
  – Allegations: Payment of physicians based on the number of tests and procedures ordered and use of improper modifiers for higher reimbursement

Recent Stark Settlements (cont’d)

• Columbus Regional Healthcare System pays $25 million plus up to $10 million in contingency payments
  – Allegations: Medical oncologists were paid in excess of FMV and compensation system incentivized upcoding of E/M billings
Tuomey: Final Results

- **Original Suit**: Filed 2005
- **Jury Trial**: Jury assessed $39 Million in singles and court issued judgment of $237 Million.
  - **Concurrence**: “impenetrably complex set of laws and regulations that ill result in a likely death sentence for a community hospital in already medically underserved area.”
  - **Dissent**: “a booby trap rigged with strict liability and potentially ruinous exposure – especially when coupled with the FCA.”
  - Tuomey settled for $72.4 Million but also required that hospital settle.
- **CEO pays $1 million**

Stark SDP Disclosure Settlements

<table>
<thead>
<tr>
<th>Calendar Year</th>
<th>Number of Disclosures Settled</th>
<th>Range of Amounts of Settlements</th>
<th>Aggregate Amount of Settlements</th>
</tr>
</thead>
<tbody>
<tr>
<td>2011</td>
<td>3</td>
<td>$50 - $579,000</td>
<td>$709,060</td>
</tr>
<tr>
<td>2012</td>
<td>14</td>
<td>$1,600 - $564,700</td>
<td>$1,236,200</td>
</tr>
<tr>
<td>2013</td>
<td>24</td>
<td>$760 - $317,620</td>
<td>$2,468,348</td>
</tr>
<tr>
<td>2014</td>
<td>41</td>
<td>$3,322 - $463,473</td>
<td>$5,175,168</td>
</tr>
<tr>
<td>2015</td>
<td>49</td>
<td>$5,081 - $815,405</td>
<td>$6,706,450</td>
</tr>
<tr>
<td><strong>Totals</strong></td>
<td>131</td>
<td>$69 - $815,405</td>
<td>$16,295,234</td>
</tr>
</tbody>
</table>

Avg settlement = $124,391
New(ish) Stark Rules

• Exceptions
  – Recruitment / Retention payments for non-physician practitioners
  – Time-Share arrangements

• Technical Requirements
  – Writing requirement
  – One year term
  – Holdovers
  – Signatures

• Clarifications regarding:
  – Locum tenens
  – Takes into account volume or value of referrals
  – Retention payments in underserved areas
  – “Remuneration” definition
  – Stand in shoes
  – Locums
  – Doc owned hospitals

OIG Activity
OIG CMP / Exclusion Taskforce

- **Announcement:** OIG announced in July 2015 the institutions of a new litigation team dedicated to pursuing CMP and exclusion cases.
- **Purpose:** 1) holding individuals accountable, 2) enforcing the OIG’s industry guidance, 3) filling enforcement gaps (e.g. pursuing cases that DOJ does not), and 4) amplifying other OIG component work.

<table>
<thead>
<tr>
<th>Year</th>
<th>Exclusions</th>
<th>Civil Monetary Penalties</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>3,131</td>
<td>$15.1M</td>
</tr>
<tr>
<td>2013</td>
<td>3,214</td>
<td>$23.1M</td>
</tr>
<tr>
<td>2014</td>
<td>4,017</td>
<td>$47.5M</td>
</tr>
<tr>
<td>2015</td>
<td>4,112</td>
<td>$66.9M</td>
</tr>
</tbody>
</table>
Noteworthy OIG Settlements

• OIG Levies Largest Penalty Under a Corporate Integrity Agreement Against Nation's Biggest Provider of Post-Acute Care
  – Kindred pays a penalty of more than $3 million for failing to comply with its CIA by failing to correct improper billing for hospice services
  – "This penalty should send a signal to providers that failure to implement these requirements will have serious consequences[.]"

Noteworthy OIG Settlements

• NJ OB/GYN Pays $5.25 Million and Agrees to 20-Year Exclusion
  – Allegations: Dr. Riachi submitted 1000s of claims for Pelvic Floor Therapy (PFT) for services that were either never provided or were otherwise false or fraudulent.
  – Gregory E. Demske: "Twenty years is a substantial period of exclusion and is a clear signal to physicians that they face significant consequences, beyond monetary penalties, for taking advantage of Federal health care programs and their beneficiaries ... In cases such as this, collecting money from a wrongdoer is not sufficient and OIG will pursue exclusion to protect our patients and programs."
OIG Fraud Alert to Docs

OIG alerted physicians that compensation arrangements may violate the Anti-Kickback Statute if even one purpose of the arrangement is to compensate a physician for his or her past or future referrals of Federal health care program business.

2017 OIG Work Plan

<table>
<thead>
<tr>
<th>Issue</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hyperbaric Oxygen Therapy</td>
<td>Determine whether services are provided for covered conditions, documentation supports, and treatments were provided in excess of what was medically necessary.</td>
</tr>
<tr>
<td>Incorrect Claimed Medical Assistance Days</td>
<td>Review whether MACs properly settled cost reporting for Medicare DSH payments.</td>
</tr>
<tr>
<td>Inpatient Psychiatric Facility Outlier Payments</td>
<td>Review if facilities complied with documentation, coverage, and coding requirements for stays resulting in outlier $7.</td>
</tr>
<tr>
<td>Drug Waste of Single-Use Vials</td>
<td>Review waste from single-use vial drugs with the highest payment for waste as identified by the JW modifier to identify opportunities to significantly reduce waste.</td>
</tr>
<tr>
<td>Intensity-Modulated Radiation Therapy</td>
<td>Review to determine whether services were correctly billed (planning versus delivery) and reimbursed.</td>
</tr>
<tr>
<td>Outpatient Outlier Payments For Short-Stay Claims</td>
<td>Study to determine the potential Medicare program savings if hospital outpatient stays ineligible for an outlier payment.</td>
</tr>
<tr>
<td>Comparison of Provider-Based and Freestanding Clinics</td>
<td>Evaluate potential impact on the Medicare program and beneficiaries of hospitals claiming provider-based status for such facilities.</td>
</tr>
<tr>
<td>Hospital Use of Outpatient and Inpatient Stays Under Medicare's Two-Midnight Rule</td>
<td>Study to determine how hospitals' use of outpatient and inpatient stays changed under Medicare's two-midnight rule by comparing claims for hospital stays in the year prior to and the year following the effective date of the rule.</td>
</tr>
</tbody>
</table>
## 2017 Work Plan (cont’d)

<table>
<thead>
<tr>
<th>Issue</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Payment Credits for Replaced Medical Devices That Were Implanted</td>
<td>Review accuracy of Medicare payments for replaced medical devices because of defects, recalls, mechanical complications, etc.</td>
</tr>
<tr>
<td>Medicare Payments for Overlapping Part A Inpatient Claims and Part B Outpatient Claims</td>
<td>Review certain types of inpatient hospitals to determine whether outpatient claims billed to Medicare Part B for services provided during inpatient stays were made in accordance with Federal requirements.</td>
</tr>
<tr>
<td>Selected Inpatient and Outpatient Billing Requirements</td>
<td>Review Medicare payments to acute care hospitals to determine compliance with selected billing requirements that may be at risk for overpayments.</td>
</tr>
<tr>
<td>Medicare Education Payments</td>
<td>Identify duplicate Graduate Medical Education payments and improperly calculated Indirect Medical Education payments.</td>
</tr>
<tr>
<td>Cardiac Catheterization and Endomyocardial Biopsies</td>
<td>Identify improper payments to hospitals for outpatient right heart catheterizations and endomyocardial biopsies performed during the same encounter.</td>
</tr>
<tr>
<td>Inpatient Rehabilitation Facility Payment Requirements</td>
<td>Review whether claims were billed in compliance with Medicare documentation and coverage requirements.</td>
</tr>
<tr>
<td>Payments for Kwashiorkor</td>
<td>Review payments for claims that include a diagnosis of Kwashiorkor to determine whether the diagnosis is adequately supported by the medical record documentation.</td>
</tr>
</tbody>
</table>

## Medical Record Privacy
Privacy and Data Security

Hacks Update

1. Cyber attacks cost healthcare providers $6 billion per year. Bloomberg (5/7/15)
2. Almost 90% of healthcare providers hit with breaches in the last 2 years. (Id.)
3. 100 Million medical records hacked in 2015 (FoxNews.com (12/23/15))
4. Hacking of Healthcare records increased 11,000% last year

Privacy and Data Security

Hacks Update (cont’d)

• “Four out of five victims [of a breach] don’t realize they’ve been attacked for a week or longer.” 2016 Data Breach Investigations Report (Verizon)
• “80% of analyzed breaches had a financial motive.” (Id.)
• Cyberattacks will cost hospitals more than $305 billion over the next 5 years and 1 in 13 patients will have their data compromised by a hack. (Accenture)
• “99% of computer users are vulnerable to exploit kits (software vulnerabilities).” (Heimdal Security)
Top Hacks of 2016

• **February 2015:** Anthem reported that a 78.8 million patient records were breached
• **March 2016:** 21st Century Oncology reports 2.2 million patient records hacked
• **August 2016:** Banner Health announces that 3.7 million patients had their records breached through a cyber attack
• **August 2016:** Newkirk Products reported that it had experienced a data breach compromising 3.4 million plan members
• **August 2016:** Valley Anesthesiology and Pain Consultants announced 882,590 patient records affected by cyber attack

2016 Ransomware Attacks

• **Hollywood Presbyterian MC:**Hackers took the hospital’s computers hostage for more than a week using ransomware until the hospital ultimately agreed to pay $17,000 in Bitcoin.
• **Henderson Methodist Hospital:** Attackers prevented hospital from accessing patient files resulting in the facility declaring a “state of emergency.” However, Methodist was able to restore the systems using backups and did not pay a ransom.
• **MedStar Health:** Ransomware attack prevented hospital from accessing lost access to more than 370 computer programs for days. The system was eventually able to restore access to its programs without paying a ransom.
2016 Top Breaches
Not Involving Hacks

- **2016**: OCR reports over 200 data breaches affecting nearly 11 million patients. [https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf](https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf)
- **Centene** (Jan. 2016) – Reported loss of 6 hard drives with PHI for 950,000 individuals
- **Radiology Regional Center** (Dec. 2015) – Paper records were found on a street on December 19, 2015 containing PHI for over 480,000 individuals.
- **CA Correctional Health Care Services** (May 2016) – 400,000 health records potentially exposed when an unencrypted laptop computer was stolen.
- **Premier Healthcare, LLC.** (April 2016) – The device theft resulted in the exposure of 205,748 patient records.

OCR Settlements

- **UMass** (11/16) -- Paid **$650,000** to resolve potential HIPAA violations. Payment “is reflective of the fact that Umass operated at a financial loss in 2015.
- **Advocate Health** (8/16) – Paid $5.55 Million to resolve breaches affecting more than 4 million patients’ records. Breaches stemmed from failure to conduct accurate and thorough assessment, implement policies and access controls, enter into BAAs, and safeguard an unencrypted laptop. Largest ever settlement by a single entity due to duration of breach, number of patients affected, and involvement of the State AG.
- **Feinstein Inst. for Med. Res.** (March 17, 2016) – Improper disclosure of research participants’ PHI. Computer contained ePHI of names of research participants, DOB, addresses, SSN, diagnosis, lab results, medications, and medical info for participation in study. Agreed to pay $3.9 million to settle and will undertake a substantial corrective action plan.
2016 Privacy Litigation

- **OCR v. Lincare** (1/16) – ALJ upheld $239k fine against Lincare based on an employee leaving patient records at home.
- **St. Joseph Health Sys.** (3/16) – Hospital settled class action suit for $28 million based on leaving 32,000 patient’s records online for one year.

OCR Audits

- OCR Starts Phase 2 of HIPAA Auditing Program (3/21/16 OCR Press Release)
- OCR’s goals:
  - Understand compliance efforts by entities
  - Guide development of OCR technical assistance
  - Develop tools to assist in compliance
- Audit will include both covered entities and BAs, selected based on size, affiliations, location, public/private.
- Audit will comprise over 200 desk audits and a “smaller number” of onsite audits.
- On July 11, 2016, OCR notified 167 covered entities of selection for desk audits.
- Check HIPAA policies and procedures
Case Examples

- **Delibertis v. Pottstown Hosp.** (1/16) – Hospital must rely on its own screening protocols and cannot rely on physician’s
- **Fewins v. CHS** (1/16) – The patient received an appropriate medical screening; comparison patient cases involved patients that were more elderly and in poorer health
- **Sonoma Valley Hospital** (10/16) – OIG sanctions Sonoma for allegedly failing to provide needed stabilization and an appropriate transfer for a 59 year old woman. Although Sonoma had the capabilities to perform surgery related to sepsis, patient was transferred to another hospital 7.5 hours after the patient arrived to Somoma’s ED. Patient underwent surgery but died shortly thereafter.
Case Examples (cont’d)

- **T.J. Samson Community Hospital** (9/16) – TJ Sampson agreed to pay $35,000 to resolve allegations that it failed to accept an appropriate transfer of a 29-year old woman in need of specialized capabilities available at T.J. Sampson. According to the OIG, the patient presented to the hospital’s ED with complaints of abdominal pain and right side back pain. When the on-call surgeon was told that the patient did not have insurance, he refused to accept the transfer.

- **Jackson Health System** (9/16) – Virgin Island hospital asked Jackson to transfer a patient who required immediate cardiothoracic surgical intervention. Jackson declined to accept the transfer of the patient unless it received a guarantee of payment. Guarantee of payment obtained, but Jackson still declined to accept the transfer because the request needed to be approved by a supervisor who would not be in until the following business day. The patient died at the requesting hospital.

Sunshine Act / Open Payments

**The Facts About Open Payments Data**

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<th>2013 Totals</th>
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**Total Companies Making Payments**: 1,456
**Total Physicians with Payment Records**: 618,000
**Total Teaching Hospitals with Payment Records**: 1,110

Use the Search Tool to conduct your own specific search
Who Is Reviewing Physician Payment and Sunshine Act Reports?

Industry Groups

Press

Industry/Physician Relationships

Medical Institutions

State Legislatures

U.S. Congress

Physician Groups

Regulatory and Enforcement Agencies

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Hospital Governance

- Governing board compliance guidance issued by OIG, AHIA, AHLA, and HCCA.
  - “Board must ... exercise of its oversight responsibility ... , including making inquiries to ensure: (1) a corporate information and reporting system exists and (2) the reporting system is adequate to assure the Board that appropriate information relating to compliance with applicable laws will come to its attention timely and as a matter of course.”
  - “Compliance is an enterprise-wide responsibility.”
  - “Although compliance program design is not a ‘one size fits all’ issue, Boards are expected to put forth a meaningful effort to review the adequacy of existing compliance systems and functions.”
Bold Predictions Under Trump

• Spending for fraud and abuse will remain high although there may be a focus on different areas
• The Stark Law will be curtailed
• Primary fraud and abuse ACA provisions will remain
• More requirements to require price transparency from providers
• States will continue to enhance Medicaid fraud and abuse efforts
• Increased efforts to ensure tax payer dollars are not used to pay for healthcare provided to illegal immigrants

Questions?