Year in Review

Elizabeth B. Carder-Thompson
Reed Smith LLP
Washington, DC
Year in Review

Elizabeth Carder-Thompson
Reed Smith LLP

FRAUD & COMPLIANCE FORUM
September 28, 2015
Baltimore MD

With thanks to many fine contributors of interesting cases and technical assistance:
Nancy Bonifant, Scot Hasselman, Debra McCurdy, Vicki Morris, Mimi Rich, Jack Schroder

Overview

• Fraud and Abuse
• Health Reform
• Public Health
• Medicare and Medicaid
• Pharma and Device
• Research
• Items You May Have Missed
Fraud & Abuse Roadmap

- Numbers + Initiatives
- OIG and CMS Developments
- Criminal False Claims/Individuals
- Civil False Claims/Qui Tam
- Kickbacks
- Stark
- Regulatory Miscellany
- Return of Overpayments
- Exclusions
- Insider Trading
- International Miscellany

Numbers + Initiatives

Hundreds Charged in $712M Medicare Fraud Sweep

- June 17, 2015 takedown
- Largest action to date by Medicare Fraud Strike Force
- 17 federal districts, 7 state AGs
- 900 enforcement personnel
- Targets included 46 physicians, nurses, med professionals
- Particular Part D focus
Numbers + Initiatives

[DOJ & HHS] announce over $27.8 billion in returns from joint efforts to combat health care fraud

Administration recovers $7.70 for every dollar spent to fight health care-related fraud and abuse; third-highest on record.  *Press Release*

3/19/15

*From DOJ Press Release (11/20/14)*
- FCA = $5.6 billion FY 2014 ($22.75 billion since 1/09)
- Health care = $2.3 billion in FY 2014
- Most $$ from pharma
- Hospitals represented $333 million
- Increases in annual qui tam suits:
  - 30 in ‘87,
  - 300-400 in 2000-2009,
  - Over 700 each of last two fiscal years
- Whistleblower awards from 1/09 = $ 2.47 billion

Numbers + Initiatives

New HHS OIG Unit To Specialize In Fines, Exclusions  *Law360 6/15/15*

• Announced at AHLA Annual Meeting
• Dedicated unit to focus on litigation re CMPs, exclusions
• OIG Examples:
  • Sandoz  **$12.6M penalty** 3/15 re faulty drug-price reporting
  •  **$5M settlement** with Medicus Laboratories LLC 2/14 for alleged urine-test fraud
  •  **$1.5M penalty** and 15-year exclusion 3/14: Joseph A. Raia, New York and New Jersey doctor accused of physical therapy fraud.
Fraud Stats
HHS Investigations Lead to $5B Windfall for Taxpayers  OIG Press Release 12/10/14

OIG Touts FY 2014 MFCU Accomplishments  OIG Annual Report 4/21/15
1318 criminal convictions, 874 civil settlements

Advice on Stop Medicare Fraud Website:
“Has anyone approached you in a public area and offered FREE services, groceries, or other items in exchange for your Medicare number? JUST WALK AWAY!”

Fraud and Abuse: Numbers + Initiatives
MedPAC Discusses Draft Recommendations for Reforming RAC Program  AHLA 3/13/15

AHA: Hospitals Appealed 49% of RAC Claims Denials (through June 2015)

64% success rate; 50% spent > $10K on appeals

*No absolute right to appeal by IRF within 90 days*  Cumberland Country Hosp Sys v. Burwell 2015 BL 74013  (EDNC 3/18/15)
Going After Individuals

“Individual Accountability for Corporate Wrongdoing” (DOJ Memo, 9/9/15)

DOJ intends to pursue and prosecute more individuals for corporate malfeasance

- In order to qualify for any cooperation credit, corporations must provide all relevant facts relating to the individuals responsible for the misconduct
- Both criminal and civil corporate investigations should focus on individuals from the inception of the investigation
- DOJ will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation

“If a company wants any consideration for its cooperation, it must give up the individuals, no matter where they sit within the company. And we’re not going to let corporations plead ignorance. If they don’t know who is responsible, they will need to find out.”

Deputy Atty. Gen. Sally Yates

See Memo at: http://www.justice.gov/dag/file/769036/download

The Good The Bad & The Ugly: Individuals

Fake Hospice Nurse Sentenced to 48 Months in Federal Prison

- Jeda Necole Antoine, 34, sentenced
- Stole an RN's driver's license, SSN, and more to obtain employment at 8 different hospices in Dallas area
- She provided services to 243 hospice patients
- Assessed pain, comfort level, digestive function of mentally ill, comatose, and other terminal patients
- Hospice employers submitted $800K in claims for her services 1/09-4/12 – she was paid $107K
The Good The Bad Etc. Individuals

‘Sociopath’ neurosurgeon accused of intentionally botching operations

*Washington Post (Aug. 25, 2015)*

After numerous mishaps, surgeon leaves TX hospital
- Patients died or permanently maimed; alleged cocaine use
- Colleagues called him a sociopath, serial killer & a “clear and present danger”

Obtained “negotiated letter” from hospital implying his record was clean
- Used letter to obtain privileges at 2 other hospitals, where he allegedly hurt other pts.

The fallout so far:
- Texas revoked his medical license
- Charged w/ 5 counts aggravated assault on patients.
- Hospital faces state investigation & at least 3 lawsuits
- Declared bankruptcy; caught shoplifting from Wal-Mart

*Christopher Duntsch*

“*I am ready to leave the love and kindness and goodness and patience that I mix with everything else that I am and become a cold blooded killer.*”

---

The Good The Bad & The Ugly: Individuals

Cases Span the Health Care Delivery System

- Four Convicted in $158M Houston Hospital Medicare Scam  
  *Law360 10/21/14*
- Nonprofit Execs Indicted on Insurance Fraud, Bribery Charges  
  *Law360 10/22/14*
- Ex-Fla Hospital Exec Pleads Guilty in $67M Medicare Fraud  
  *Law360 11/18/14*
- 11th Circuit Affirms Multiple Convictions For Medicare Fraud, Kickback Operation  
  *BNA 2/19/15*
- Nurse Pleads Guilty in Louisiana Medicare Scam  
  *BNA 7/24/15*
- Doctor Gets Two Years in $13M N.Y. Clinic Scam  
  *BNA 8/19/15*
- Michigan Health Agency Operator Gets [6 ½ Year] Prison Term for Fraud  
  *BNA 8/15/15*
**The Good The Bad & The Ugly: Individuals**

**Civil Liability of Officers and Directors**


Upheld $2.25M verdict against directors & officers of bankrupt nonprofit nursing home

- Included punitive damages against administrator & CFO for “outrageous” conduct
- Reversed previous award of punitives against 5 individual Board members

Defendants failed to ensure home was properly managed, despite warnings of auditors & 2 patient deaths from neglect

- Sufficient evidence to find defendants liable for deepening the home's insolvency
- Violations of duty of care and duty of loyalty to the insolvent home
- No treasurer, financial records or finance comm.; incomplete minutes kept

“This evidence supported the jury’s finding that the Director Defendants… stuck their heads in the sand in the face of repeated signs that residents were receiving care that was severely deficient.”

---

**The Reality of the Civil False Claims Act Today**

1) **There are many many relators (whistleblowers) out there watching health care**

2) **They are alleging many many theories of FCA liability**

- Worthless services
- Regulatory violations of every shape + form
- Retaining overpayments
- Off-label promotion
- Reimbursement “swapping”
- Kickbacks + inducements
- Stark
False Claims/Qui Tam

Today’s Relators

Compliance Officer
- Compliance officer awarded $1.5 M under SEC whistleblower program  FCPA Blog 4/22/15 (SEC Release No. 74781)


Physician  United States ex rel. Moore v. Mercy Health Springfield Communities f/k/a St. John’s Health System, Inc., et al., Case No. 13-3019-CV (W.D. Mo.) (physician employed by home health agency alleged bonuses to physicians based on referrals)

Nurse  United States ex rel. Flippo v. Friendship Home Healthcare, Inc., et al., No. 3:14-cv-1262 (M.D. Tenn.) (alleged billing for services by excluded individual, and more)

CFO  United States ex rel. Beaujon v. Hebrew Homes Health Network, Inc., et al., Case No. 12-20951 CIV (S.D. Fla.) (alleged sham medical director contracts)

Overview: Procedural and Other Issues in Civil False Claims Act Cases Today

- What is “worthless care” under FCA?
- Rule 9(b): What does it mean to state fraud “with particularity”?
- Can overpayments be extrapolated?
- Has the “fraud” been publicly disclosed, and was the relator an original source?
- Was relator the “first to file”?
Worthless Services/Substandard Quality

Extendicare…Agrees to Pay $38M to Settle False Claims Act Allegations [re] Substandard Nursing Care and Medically Unnecessary Rehabilitation Therapy  

DOJ Press Release 10/10/14

Contra: 7th Cir. Tosses $9M Verdict, Finds No Proof Home Falsely Billed Medicare

US ex rel. Absher et al. v. Momence Meadows Nursing Ctr & Graff, 764 F.3d 699 (7th Cir. 8/20/14) (relators – former clinical staff – alleged facility provided worthless services; 7th Circuit said fact that facility was allowed to continue operations meant services had “some value” - diminished value not same as worthless)

False Claims/Qui Tam

Use of Extrapolation/Statistical Sampling

Judge Balks at 6th Circuit Review of FCA Extrapolation  

Law 360 11/24/14

Issues in nursing home overpayment case:
1. Can extrapolation satisfy government’s burden of proof?
2. Is due process violated if defendant can’t mount claim-by-claim defense?

• DOJ started with claims involving 10 patients – now seeks to review 400 specific admissions out of 1,700 claims, and apply findings to 55K admissions involving 155K claims
• US District Court Judge in TN, rejecting request for interlocutory appeal, stated that text and history of FCA support sampling and extrapolation – too early for appeal

US ex rel Martin v. Life Care Centers of America, case no. 1:08-cv-251 (E.D. TN 2/18/14), consolidated with US ex rel. Taylor v. Life Care Centers of America, case no. 1:12-cv-00064
False Claims/Qui Tam
Public Disclosure Bar/Original Source

Does a relator need both direct and independent knowledge to qualify as an original source?


Must the relator “have a hand in the underlying public disclosure”?

- 9th Circuit: No. Court invalidated its prior precedent, finding US Supreme Court’s decision in *Rockwell Int’l Corp v. US* dictated different result – remanded case
- New two-part test:
  1. Before filing action, whistleblower must voluntarily inform government of facts underlying complaint’s allegations; and
  2. Whistleblower must have direct and independent knowledge of allegations underlying complaint


False Claims/Qui Tam
Public Disclosure Bar/Original Source

Does a RAC audit mean there’s been public disclosure?

No. NV district court denied hospital’s motion to dismiss; RAC audit report rejecting a high percentage of hospital’s inpatient Medicare claims that was later shared with hundreds of hospital physicians didn’t constitute public disclosure because the physicians weren’t “outsiders.” *US ex rel. Guardiola v. Renown Health*, 2014 BL 313122, D. Nev., No. 3:12-cv-00295-LRH-VPC, 11/4/14
False Claims/Qui Tam
Public Disclosure Bar/Original Source

Does a government investigation trigger the public disclosure bar?

- No. Anonymous tip re alleged false claims re short term inpatient stay, then AdvanceMed audit, then OIG audit, then Deloitte internal investigation (disclosed to govt).
- AdvanceMed instructed by OIG to resolve – matter administratively closed prior to whistleblower’s FCA action
- Court: No “public disclosure”: allegations contained in a government investigation or audit aren't within the public domain if they are never disclosed to the “wider public.”

*United States ex rel. Whipple v. Chattanooga-Hamilton County Hospital Auth., 782 F.3d 280, 6th Cir., No. 13-6645, 2/25/15; No. 13-6645, en banc petition denial 4/20/15*

False Claims/Qui Tam
Public Disclosure Bar/Original Source

Do news reports, ads, websites trigger the public disclosure bar?

- Yes. Relator filed action against Medicare Advantage insurer Humana and several Miami clinics, alleging free transportation, meals, perks provided to Medicare beneficiaries
- Perks had been disclosed in prior litigation, news articles, ads, websites
- FCA’s public disclosure bar is triggered by prior allegations “substantially similar” to those in later lawsuit, and don't have to allege specific wrongdoing.

*US ex rel. Osheroff v. Humana, 776 F.3d 805 (11th Cir., 1/16/15)*
Regulatory Noncompliance Can’t Be Transformed Into FCA Claim

United States ex rel. Rostholder v. Omnicare 2014 WL 661351 (4th Cir. 2/21/14), cert denied 10/6/14
Relator argued Omnicare violated FCA when it sought reimbursement for drugs allegedly packaged in violation of FDA Current Good Manufacturing Practices regulations (“cGMP”) 4th Circuit: REJECTED - government reimbursement for drugs is not tied to compliance with cGMP regulations

United States ex rel. Ortolano v. Amin Radiology, 2015 BL 20940, M.D. Fla., No. 5:10-cv-00583-WTH-TBS, 1/28/15
Compliance with Florida law mandating certification for nonphysicians performing PET/CT scans is NOT a Medicare condition of payment for physician practice groups
But see U.S. v. Universal Hlth. Svs., 780 F.3d 504 (1st Cir. 3/17/15)
Relator claimed clinic violated state regs re supervision of counselors;
Ct. ruled appropriate supervision was a condition of payment & allowed claim

See US ex rel. Donegal v. Anesthesia Assoc. WD MO No 4:12-cv 876 (6/9/15) (provider relying on “reasonable interpretation” of Medicare regulation can’t “knowingly” submit a false claim)

Many FCA Cases Eventually Settle – Big Dollars

CHS to Pay $75M in FCA Settlement (BNA 2/2/15) (alleged illegal donations to New Mexico county officials to fund state share of Medicaid payments)

Dignity Health to Pay $37M to End Medicare Payments Row Law360 10/30/14 US ex rel. Hawkins v. Catholic Healthcare West case no. 09-cv-5604 (ND CA) (alleged admissions of patients for elective cardiovascular procedures who could have been treated as outpatients)

Two Cardiovascular Disease Testing Laboratories to Pay $48.5M to Settle Claims of Paying Kickbacks and Conducting Unnecessary Testing (Health Diagnostics Lab, Singulex) DOJ Press Release 4/9/15

More FCA Settlements – Lower Dollars….

Georgia Hospital to Pay $20 Million (BNA 4/27/15)

Texas Hospital to Pay $22 Million (BNA 4/22/15)

FL Health Care Providers Settle FCA Claims for $7.5 Million (Law360 5/8/15)

Sixteen Hospitals End Bogus-Psychotherapy FCA Suit for $16 Million (Law360 5/8/15)

Children’s Hospital Settles FCA Case ($12.9 M - BNA 6/15/15)

False Claims/Qui Tam: Anatomy of a Case

Relator Dispute re Share

Former Endo pharma rep Peggy Ryan brought qui tam suit alleging off-label use of Lidoderm, wore wire for 3 years, first of 3 relators

Sought 24% share of $140 M settlement

Government said case settled – didn’t go to trial, and very large recovery – should be only 19% share

Court: Ryan provided not only the spark for the investigation, but … she nurtured the flame at the darkest times when the possibility of a favorable outcome seemed most remote. Throughout the nine year period from her first qui tam Complaint… Ryan continually provided access behind the corporate walls of Endo. Ryan's insider status, conferred by her employment with Endo, enabled the Government investigatory team to recover evidence which would have otherwise been unobtainable.

United States ex rel. Ryan v. Endo Pharm., Inc., 2015 BL 226337, E.D. Pa., No. 2:05-cv-3450, 7/15/15
False Claims/Qui Tam: Anatomy of a Settlement

Columbus Regional to Pay $35M to End Whistleblower Suit

- Former cancer center administrator filed qui tam alleging facility overbilling (lack of documentation)
- Amended suit alleged overpayments to medical director
  - $425K -- medical director repayment
  - $10M -- Columbus Regional initial payment
  - $3M / year -- Columbus payments for next 5 years
  - $1M -- related to commercial property purchase
  - $9M -- will be contingent on facility’s bottom line over 5 years


Fraud and Abuse: Moving on to Kickbacks

Proposed OIG Rule to Modify Safe Harbors


- Local Transportation Services
- Remuneration Between Medicare Advantage Organizations and Federally Qualified Health Centers
- Manufacturer Discounts Under Part D Coverage Gap Discount Program
- Technical Correction to Referral Services Safe Harbor
- Cost-Sharing Waivers

Also, sought comments on CMP for gainsharing – payments to physicians to reduce or limit services
Fraud and Abuse – New CMP Legislation

Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) 4/16/15

-- SGR and other reforms discussed later

Important clarification to civil money penalty (CMP) law on gainsharing:

• **Previously**: Law prohibited payments to a physician as an inducement to reduce or limit services.
• **Now**: Applies only to inducements to reduce or limit “**medically necessary**” services
• **Requires report to Congress in next year**

Criminal Kickbacks - Update

**Jury Finds Chicago Hospital Execs Guilty in Kickbacks Case**

• Sacred Heart Hospital: now-defunct for profit entity
• Former owner/CEO and two administrators guilty after 7-week trial – sentenced to 4 ½ year prison term
• Kickbacks to physicians for patient referrals, conspiracy
• Two other physicians have plead guilty, four await trial

Criminal Kickbacks - Update

Hospital Exec Gets 40-Year Prison Sentence in Fraud Case

- Mohammad Khan, 65, assistant hospital administrator, plead guilty in 2012 to conspiracy to commit health-care fraud and kickback charges
- Scheme ’08-’12 to submit medically unnecessary or unprovided Medicare claims for partial hospitalization programs (PHPs) - Riverside General Hospital in Houston
- $116 Million in Medicare claims
- 10 individuals have pleaded guilty

US v. Khan, S.D. Tex., No. 12-cv-64, sentencing 5/21/15

Fraud and Abuse – What is a Kickback?

Do on-call payments to ER physicians = kickback?
No – FCA action dismissed US ex rel. Cooper v. Pottstown Hospital 2015 BL 68515 (E.D. PA 3/13/15)

Does free housing offered by a drug clinic to Medicaid patients = kickback?
Yes – NY judge issues preliminary injunction USA v. Narco Freedom 2015 BL 95258 (SDNY 4/2/15)

Do payments by a home health agency to a physician for HHA certifications = kickback?
Yes – certifications are “referrals” US v. Patel 778 F.3d 607 (7th Cir. 2015)
Fraud and Abuse – Kickback Settlements

Many cases are settlements involving drug + device entities’ alleged remuneration, and include FCA claims

Express Scripts/Accredo Settle Kickback Referral Allegations
BNA 5/7/15

Daiichi Sankyo Reaches $39 Million Settlement of FCA Action Alleging Kickback Scheme AHLA Weekly 1/16/15

AstraZeneca Agrees to $7.9 Million Settlement of FCA Action Alleging Kickback Scheme with PBM AHLA Weekly 2/13/15

Kickback Settlements – Also Providers

DaVita Agrees To Pay $400 Million to Settle Civil Charges Related to Provider Kickbacks Probes BNA 10/23/14

2nd Circuit Upholds Hospital Workers’ Kickback Convictions Law360 12/10/14

Ex-MultiPlan Exec Gets 1 Year for $2.3M Kickback Scheme Law 360 12/5/14

US to Settle with Home Health Provider Over False Claims [to pay kickbacks to patients’ families] Law 360 4/29/15

Co-Owner of Atlanta-Based Medical Clinic Chain and Hospital CEO Plead Guilty to Illegal Pay-for-Patient Conspiracy DOJ Press Release 8/7/14

Meridian Surgical Partners Reaches Settlement Over Kickback Allegations BNA 9/10/14

Florida Nursing Home Group to Pay $17 Million BNA 6/18/15
Fraud and Abuse: Kickbacks

Fall-Out from OIG Fraud Alert
On Physician-Owned Distributors (3/26/13)


Alleges Michigan neurosurgeon and spinal implant company in which he had interest accepted improper payments from two distributors as quid pro quo for using their products

- Separate complaint against company owners
- Relators = two physicians; allegations of unnecessary/excessive surgeries
- Defendants filed motion to dismiss, arguing the hospitals (not them) filed the false claims -- denied 11/5/14

Fraud and Abuse

CMS Open Payments Data Released – Payments by Industry to Physicians/AMCs

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>$972 million</td>
<td>$2.56 billion</td>
</tr>
<tr>
<td>Research</td>
<td>$1.55 billion</td>
<td>$3.23 billion</td>
</tr>
<tr>
<td>Ownership</td>
<td>$908 million</td>
<td>$703 million</td>
</tr>
<tr>
<td>Total</td>
<td>$3.43 billion</td>
<td>$6.49 billion</td>
</tr>
</tbody>
</table>

http://www.policymed.com/2015/06; note changes to Open Payments regulations adopted 11/13/14
**Fraud and Abuse: Kickbacks**

**OIG 6/9/15 Fraud Alert: Physician Compensation Arrangements May Result in Significant Liability**

Focus on **medical directorships** in wake of 12 individual physician settlements:

- Improper remuneration under anti-kickback statute:
- Payments took into account volume/value of referrals
- Payments did not reflect FMV
- Non-performance by physicians of agreement
- For some, affiliated entity paid physicians’ front office staff

Result = CMP liability by physicians

---

**Moving on to Stark: (Mixed) Stark Settlements**

**Westchester Medical Center Agrees To Pay $18.8 Million in Kickback [and Stark] Case** BNA 5/15/15

**Ohio-Based Health System Pays United States $10 Million to Settle False Claims Act [and Stark, and Kickback] Allegations** DOJ Release 3/31/15

**But Watch This Space:** Council for Urological Interests v. Burwell, 790 F.3d 212 (D.C. Cir. 2015) (Remand: HHS charged with explaining rationale for banning “per-click” equipment leases between physicians and hospitals); United States ex rel. Schaengold v. Mem’l Health, 2014 BL 343436, S.D. Ga., No. 4:11-cv-00058-BAE-GRS, 12/8/14) (pending reverse false claims challenge on retention of improper Stark payments).
Recent Stark Settlements

Florida Hospital District Settles Action Alleging FCA, Stark Violations for $69.5M  

- Suit alleged that nine employed physicians were compensated at levels that were above fair market value, not commercially reasonable, and based in part on volume, value of referrals
- Comp in excess of 90th percentile

Adventist Health to Pay $119M To End FCA [and Stark] Claims


- Allegedly paid physicians based on number of tests, procedures ordered
- Also allegations of improper coding modifiers for higher reimbursement

Fraud and Abuse: Stark

Saga of US ex rel Drakeford v. Tuomey

Qui tam filed 2005. Jury assessed damages at $39M; in 2013 hearing, govt said minimum was $277M ($5,500/claim) but could accept less since pockets may not be that deep; judge ordered $237M; appeal to 4th Circuit

Judgment affirmed

- Concurring opinion: “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.”
- Dissenting opinion: “a booby trap rigged with strict liability and potentially ruinous exposure—especially when coupled with the FCA.”
- Majority opinion: “It is for Congress to consider whether changes to the Stark Law’s reach are in order.”

792 F.3d 364 (4th Cir. 2015)
Fraud and Abuse: Stark

Stark Self-Disclosures On CMS Website

ACA established a self-disclosure protocol that allows providers to disclose voluntarily actual or potential Stark violations with a potential for reduced penalties

- Now 69 reported self-disclosure settlements on CMS site (as of 9/8/15); primarily hospitals.

Technical Changes to Stark Whole Hospital Exception (11/10/14)
Process for facility expansion; use of external data sources

Regulatory & Other Miscellany

Oct. 3, 2014: OIG proposed rule on S/H also included CMP for beneficiary inducements; would amend “remuneration” for:
  - Copay reductions for certain hospital outpatient department services;
  - Certain remuneration posing low risk of harm, promoting access;
  - Coupons, rebates, some retailer reward programs;
  - Certain remuneration to financially needy individuals; and
  - Copay waivers for first fill of generic drugs.

Dec. 3, 2014: CMS final rule on provider enrollment; revocations for patterns/practices of improper claims; deferral of expanded awards for Medicare fraud tipsters

Feb. 20, 2015: CMS announces delay of final rule on returning overpayments within 60 days

July 24, 2015: Proposed Stark Law changes included in proposed update to physician fee schedule
**First Decision: ACA 60-Day Overpayment Rule**

**US ex rel Kane v. Continuum Health Partners/HealthFirst**


- Continuum employee Robert Kane reviewed hospital Medicaid claims that could have been subject to a computer glitch by managed care entity HealthFirst.
- In 2010, provided data w/ 900 potentially erroneous claims.
- Asserts he was fired shortly thereafter.
- Continuum repayments stretched 2011-2013.
- When did the 60-day clock start to run?
  - *Began with awareness of likelihood of overpayment*.
  - *BUT violation of FCA “only when an obligation is knowingly concealed or knowingly and improperly avoided.”*

**First Settlement: ACA 60-Day Overpayment Rule**

**US ex rel McCray v. Pediatric Services of America**

SD GA No. 4:13-cv-127 settlement announced 8/3/15

- Two suits by former employees alleged (1) failure to disclose and return overpayments, (2) home nursing claims w/no RN supervisory visit, (3) claims overstating staff time.
  - issues with credit balances on books, write offs w/o investigations.
- $6.88 M settlement and CIA.
Fraud and Abuse: Insider Trading
Broker Pleads Guilty After SEC BigLaw Tipster Case Law360 11/5/14
Tip on Medicare Spurs Insider Trading Investigation New York Times 11/14/14
SEC Hits Intermune Exec with Insider Trading Law360 10/30/14
House Panel Says DC Circ. Is On Its Side In SEC Fight Law360 5/18/15
Ex-Simpson Clerk Indicted For Trades As Broker Takes Plea Law360 1/15/15
Ex-JPMorgan Banker, Father Charged With Insider Trading Law360 5/14/15
SEC Settles Insider-Trading Charges Over GE Deal Law 360 9/9/15

Fraud and Abuse: International Miscellany
SEC Charges California-Based Bio-Rad Laboratories With FCPA Violations SEC Release 11/3/14
Improper payments to foreign officials in Russia, Vietnam, and Thailand in order to win business; self-disclosed; will pay $55M
DOJ Monitors Biomet For Another Year For FCPA Violations Law360 3/18/15
Suspected bribery, Foreign Corrupt Practices Act violations in Mexico and Brazil
11 Charged in Alleged Scheme Linking Florida, Nicaragua, Dominican Republic
Scheme involved signing up Nicaraguan and DR residents for Medicare/Medicaid plans US v Hernandez SD FL indictment unsealed 11/19/14
Health Care Reform

What’s happened since the Supreme Court upheld the Affordable Care Act?

OIG, GAO slam CMS for healthcare.gov rollout (1/15)
-- OIG has published many reports on ACA reforms and effectiveness – listed here: http://oig.hhs.gov/reports-and-publications/aca/

House Passes 56th Anti-Obamacare Measure Huffington Post 2/4/15

House Republicans’ ACA Suit Moves Forward (9/9/15)
- NYT Editorial 9/11/15: House Stretches Legal Logic on Health Reform
Obamacare Headlines

• Insurance exchange enrollment spikes as 2015 nears  
  Modern Healthcare 12/10/14

• CMS announces 147K sign ups during special enrollment period  
  AHLA 5/22/15

• CMS, OIG extend fraud and abuse waivers for [ACO] shared savings program into 2015  
  BNA 10/16/14

• HHS says hospital uncompensated care costs down 21% under ACA  
  AHLA 3/27/15

• Physicians aren’t facing swell of new sicker patients since ACA, study says  
  AHLA 4/3/15

• Health care reform is good for the economy, Chairman of White House Advisors says  
  AHLA 4/3/14

• Health Insurers Seek Hefty Rate Boosts  
  WSJ 5/21/15

• Top LA Eateries Plotted Price Hike for ACA Costs, Suit Says  
  Law 360 9/2/15

December -- President Obama stands in for Stephen Colbert:

“They could pass a bill repealing Obamacare. But the President still has the veto and if I know that guy, he is willing to use it. And let's face it, even if Republicans somehow did repeal it, they would have to replace it with their own health care plan. Once they touch it, they own it, and then if anything goes wrong, suddenly everybody will be complaining about Mitch McConnell-care.”
Contraceptive Mandate
ACA requires health plans to cover women’s “preventive care” services, including all contraceptive methods; exception for religious employers.
Recall Supreme Court: Contraception Coverage Mandate Impermissibly Burdens Closely-Held Corporations’ Religious Exercise

Secular Nonprofit Pro-Life Group Wins Challenge to ACA Mandate

Eighth Circuit Enjoins Contraception Coverage Requirement Against Religions Groups
• Reached different result than in seven other federal courts of appeal (5th, 3rd, 6th, DC, 7th, 10th, 2nd)
High Court Won’t Hear Attack on ACA Cost Control Panel  
**Law360 3/30/15; U.S., 135 S. Ct. 1699 3/30/15**

- *Coons v. Lew:* Challenge to constitutionality of ACA’s 15-member Independent Payment Advisory Board
- District court had upheld, but Ninth Circuit found no jurisdiction
- IPAB cannot convene or issue recommendations until 2019, so allegations “highly speculative” and “certainly not impending”

Fifth Circuit Rejects Origination Clause Challenge to ACA  
**Hotze v. Burwell, 784 F.3d 984 (5th Cir. 4/24/15)**

Physician plaintiff and employer lacked standing

Affordable Care Act Survives Supreme Court Challenge

- Issue: If a state chooses not to run a health insurance exchange, can its citizens still be provided with tax subsidies?
- *Dispute over four words in ACA….
- Justices agree 6-3 with Obama administration; subsidies should be available to all

**King v. Burwell, 135 S. Ct. 2480 (June 25, 2015)**

Appeal from 759 F.3d 358 (4th Cir 2014) – affirmed – “Congress passed the [ACA] to improve health insurance markets, not to destroy them. If at all possible, we must interpret the Act in a way that is consistent with the former, and avoids the latter.”

Justice Scalia dissent, citing “interpretive jiggery-pokery,” says “We should start calling this law SCOTUScare.”
**Public Health**

**Ebola**
- Global public health community has been addressing Ebola in West Africa; now a top health issue in the US
- FDA Warns of Fraudulent Ebola Drug Claims *Reuters 8/14/14*
- Joint Commission: Ebola Preparedness Resources [webpage](http://www.jointcommission.org)
- Some US Hospitals Weigh Withholding Care *Reuters 12/9/14*
- Besides patient treatment considerations for providers, the crisis raises issues for all health care entities in employment, discrimination/HIPAA, insurance, and more.
Medicare and Medicaid

Medicare/Medicaid Legislation

**IMPACT Act**: 10/6/2014 - H.R. 4994, the Improving Medicare Post-Acute Care Transformation Act of 2014 (the "IMPACT Act").
Requires development of standardized assessment data for quality improvement, payment, and discharge planning purposes for post-acute care providers: HHAs, SNFs, IRFs, LTCHs.

Allows individuals with disabilities to establish tax free savings accounts for medical and other qualified expenses. Includes three Medicare offsets related to:
- MPFS misvalued service payment adjustments
- ED systems/ED drug payment
- Oral-only ESRD drugs
4/16/15: Bipartisan Bill Scrapping Sustainable Growth Rate Formula Enacted

- Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) reforms Medicare physician payment policies
- Overrides 21.2% SGR cut
- Applies 0.5% bump in payment, beginning July 2015 through 2019
- Eventually: will link physician payment updates to quality, value measurements, participation in alternative payment models
- Note that CMS Office of the Actuary warns of future payment/incentive cliff in 2025, so Congress may be fated to wrestle with MPFS methodology in years to come…..

- Delays enforcement of two midnights rule
  - See infra

More re SGR/MACRA Reform

- Extends CHIP funding for 2 years
- Complex financing: reduces market basket updates for post-acute providers, revises inpatient rate updates, restructures DSH reductions, imposes income-related adjustments in Parts B and D premiums, and more
- PIMA (Protecting the Integrity of the Medicare Act of 2015) Provisions: extends PAMA re Two Midnights, eliminates SSNs on Medicare cards, requires outreach and education by MACs, modifies DME face-to-face provisions, makes gainsharing CMP changes referenced earlier
Watch This Space!

May 21, 2015: House Energy and Commerce Committee unanimously approved H.R. 6, the 21st Century Cures Act -- passed by House 7/17/15

High-profile, bipartisan bill seeking to accelerate pace of medical cures through reforms addressing drug and device development and approval, clinical trial design, research funding, interoperability of health technology, and other issues. Senate working on companion bill.

Thorny Issues for Hospitals

Two Midnights Challenges Continue (final rule 8/2/13)

Hospital inpatient admission presumed appropriate for beneficiaries requiring >1 Medicare utilization day (“crossing two midnights”) Audit enforcement delays extended (8/11/15) – unless hospitals game the system.

• “Probe and Educate Audits” continue
• Two federal court challenges filed by AHA unsuccessful, but note recent (9/21/15) decision in US district court for D.C: HHS failed to allow adequate comment under APA – must restart rulemaking – but judge stopped short of vacating rule. See Law360 9/21/15 citing Shands Jacksonville Medical Center et al. v. Sylvia Mathews Burwell et al., case number 1:14-cv-00263, in the U.S. District Court for the District of Columbia.
Hospital Readmission Reduction Program

Most hospitals face 30-day readmissions penalty in fiscal 2016
- 2601 of 3400 hospitals will be penalized
- Now 3% penalty – COPD and total hip and total knee included

Modern Healthcare 8/3/15

Interventions Aimed at Reducing Readmissions Don’t Work, Study Finds  BNA 10/21/14

Quality Initiatives


One-Third of US Hospitals Ranked as ‘Top Performers,’ Joint Commission Says  BNA 11/14/14

HHS: Hospital Quality Improvements Saved $12 Billion, Thousands of Lives  (HHS Quality Patient Safety Report 12/1/14)

Nearly 40% of Physicians, Other Providers, Will Have Payments Docked 1.5% This Year After Failing to Submit Data on Patients’ Health  CMS Report April 2015
MedPAC on CMS

MedPAC comments on 329-page list of quality measures being considered by CMS: agency is “relying on too many clinical process measures that are, at best, weakly correlated with health outcomes.”

MedPAC Comment Letter 1/5/15

---

CMS Quality/Payment Reform Goals

Goals Announced 1/26/15

By 2016:
30% of Medicare provider payments under alternative payment models (ACOs, bundling, medical homes, etc.) (50% by 2018)

85% of Medicare fee-for-service payments tied to quality and value (90% by 2018)


Note that CMS proposes “Comprehensive Care for Joint Replacement” model to mandate bundled acute/post-acute Medicare payment in 75 MSAs, 25% of U.S. hip/knee replacement surgeries (July 14, 2015)

Goals Announced 9/8/15

CMS Equity Plan for Improving Quality in Medicare: will reduce health disparities over four years cms.gov/newsroom
**Hospital/Physician Miscellany**

**Final FY 2016 Medicare IPPS/LTCH Rule**

**Half of Doctors Listed as Serving Medicaid Patients are Unavailable, Study Finds**  
*NY Times* 12/8/14

**Some Doctors Reap Outsize Share of Medicare Payments**  
*WSJ* 6/2/15

**Medicare Overbilling Probes Run Into Political Pressure**  
*WSJ* 12/11/14

**CMS Adds Star Ratings to Hospital Compare**  
*AHLA* 4/17/15

**CMS Proposes New Medicare Payment Model for Hip and Knee Replacement**  
(7/14/15 *Fed. Reg.*)

---

**Long Term Care Miscellany**

**SNF PPS Rate, Policy Updates 8/4/15**
*80 Fed Reg 46390*

**Court: Nursing Facility Can't Skip Appeals To Address Medicare Payment Suspension**  
*Optade Springhill SNF, LLC v. Burwell*, 2015 BL 115145, W.D. La., No. 5:14-cv-03139-SMH-MLH, 4/21/15

**Skilled Nursing Facility Denied Temporary Restraining Order Against Law Firm's Ads**  

*iowa v. Rahons* case received national attention -- focused on the need for nursing homes to develop policies regarding their residents' sexual activity.

---

**DMEPOS/Home Health Miscellany**

**Challenge to DME Bidding Rules Fails on Appeal in 8th Circuit**  
*Key Med. Supply v. Burwell*, 764 F3d 955 (8/25/14)

**CMS Further Extends Moratoria On Ambulance Suppliers, Home Health Agencies in Certain Cities**  
7/29/15
Hospice Miscellany

CMS Plans To Add Sequestration Dollars To Hospice Cap (11/14)

CMS Finalizes Medicare Hospice Wage Index Rule / Rates for FY 2016 (8/6/15)

CMS Issues Memo to State Survey Agencies: “Extraordinary Circumstances Due to Nursing Shortage” 10/13/14


Government Wins

• U.S. Supreme Court says providers may not challenge Medicaid reimbursement rates Armstrong v. Exceptional Child Ctr, 135 S. Ct. 1378 (U.S. Mar 31, 2015)

• Agency interpretive changes don’t require rulemaking, unanimous Supreme Court says. Perez v. Mortgage Bankers, 135 S. Ct. 1199 (3/9/15)

• D.C. Circuit upholds Secretary’s reimbursement adjustment for rural, sole community hospitals Adirondack Med. Ctr. V. Burwell, 782 F.3d 707 (D.C. Cir. Apr. 10, 2015)


• Judge kills suit over fickle Medicare pay policies CA Clinical Laboratory Assn v. HHS 2015 BL 158553 (DDC 5/20/15)

Provider Wins…

- Second Circuit Revives Medicare Beneficiaries’ Due Process Challenge to ‘Observation Status’ Barrows v. Burwell 777 F.3d 106 (2d Cir. 1/22/15)
- 9th Cir. Hands Nursing Home Partial Win In Appeal on Care Deficiencies, Reviews Plott Nursing Home v. Burwell, 779 F.3d 975 (9th Cir., 3/3/15)

New Appointments

Andy Slavitt, CMS Administrator
Surgeon General Vivek Murthy (PHS)
At Last, ICD-10 Codes Are Pending

_Long-delayed codes will fill gaping holes in system, enabling professional coders to define with more precision:_

- **W56.22xAX:** Struck by orca, initial encounter
- **W55.29XA:** Other contact with cow, subsequent encounter
- **Y92149:** Hurt at swimming pool of prison as place of occurrence
- **Y92.253:** Hurt at opera house as place of occurrence
- **Z89.419:** Acquired absence of unspecified great toe
- **S10.87XA:** Other superficial bite of other specified part of neck
- **V97.33XD:** Sucked into jet engine, subsequent encounter
- **R46.1:** Bizarre personal appearance
- **Z73.4:** Inadequate social skills, not elsewhere classified

_Pharma & Device_
FDA Recalls Kim Kardashian’s Instagram Post

“OMG. Have you heard about this? As you guys know my #morningsickness has been pretty bad…”
Compounding Pharmacy Developments

Two Face Murder Charges in Meningitis Outbreak Case

Tennessean 12/17/14
14 individuals including owners arrested – 131 racketeering counts
751 people were sickened – 64 died

[Pharmacist] tied to tainted medicine arrested at Logan - was on way to Hong Kong; charged with count of federal mail fraud  Boston Globe 9/4/14


Judge Approves $200M Settlement in 2012 Meningitis Outbreak  NYT 5/19/15

Drug and Device Miscellany

Obama Proposes that Medicare Be Given the Right to Negotiate the Cost of Drugs  NYT 4/27/15 (Noting paradox: at same time, proposes expensive precision medicine initiative)

340B 'Mega-Guidance' May Narrow Drug Discounts  Modern Healthcare 8/28/15

Ebola Vaccine Makers Get Liability Immunity from HHS  Law360 12/9/14

OtisMed, Ex-CEO Cop to Distributing Device After FDA Denial  Law360 12/8/15  CEO Gets Two Years  Law360 6/26/15

Obama Taps FDA Deputy Commissioner [Robert Califf] to Lead Agency  Law360 9/15/15
Drug Abuse Epidemic

HHS Takes Strong Steps to Address Opioid Drug Related Overdose, Death + Dependence  CMS Release 3/36/15

Three priority areas to address crisis:

- Training and education resources, including prescriber guidelines
- Increasing use of naloxone
- Expanded use of medication-assisted treatment (MAT)

Also CDC prevention program

Separately:  W. Va Court Says 'Wrongful Conduct' Rule No Bar to Claims Brought by Rx Drug Addicts  Tug Valley Pharmacy, LLC v. All Plaintiffs Below in Mingo Cnty., 2015 BL 148172, W. Va., No. 14-0144, 5/13/15

Different Approaches to Vaccine Issues

Commentary in The Onion (satire site):
www.theonion.com/blogpost/i-dont-vaccinate-my-child-because-its-my-right-to--37839

Facebook Post:  "Hey, remember that time you got polio?
No, you don't, because your parents got you #@!% vaccinated."

Maine S. Ct:  state can vaccinate child over mother’s wishes 8/14/15
FDA restrictions on off-label marketing

Amarin wins early victory against FDA in "free speech" case over drug promotion

USNews 8/7/15 (now stayed pending settlement talks 9/4/15)

- Amarin Pharma v. FDA – maker of fish oil challenged FDA’s off-label restrictions as violation of free speech
- FDA position during 6/22 preliminary injunction hearing: constitutional challenge to restrictions on off-label marketing represented a “frontal assault” on the nation’s drug approval process and is highly unlikely to succeed

Law360 6/23/15

- Court: Amarin has the First Amendment right to give physicians truthful information about non-approved indications of its drug Vascepa, used to lower a certain kind of fat.

Potential beginnings of a major trend? See Pacira Pharmaceuticals, Inc. v. FDA. S.D.N.Y.. No. 1:15-cv-07055

Recent Pharma/Device Off-Label Settlements

<table>
<thead>
<tr>
<th>Company</th>
<th>Settlement Amount</th>
<th>Issue(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amgen Inc.</td>
<td>$71 million</td>
<td>Amgen’s off-label marketing and promotion of Aranesp (anemia drug) and Enbrel (plaque psoriasis drug)</td>
</tr>
<tr>
<td>August 2015</td>
<td>Civil Settlement: 48 states and DC</td>
<td></td>
</tr>
</tbody>
</table>
### Recent Pharma/Device Off-Label Settlements

<table>
<thead>
<tr>
<th>Company</th>
<th>Settlement Amount</th>
<th>Anticipated Settlement Break Down</th>
<th>Issue(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspire Pharmaceuticals Inc.</td>
<td>$6 million</td>
<td>Civil Settlement Federal Government *$1,200,000 to Relator</td>
<td>Inspire’s off-label promotion of AzaSite</td>
</tr>
<tr>
<td>Medronic Inc.</td>
<td>$2.8 million</td>
<td>Civil Settlement Federal Government and 20 states *$602,000 to Relator</td>
<td>Medronic’s promotion of SubQ stimulation</td>
</tr>
</tbody>
</table>
## Recent Pharma/Device Off-Label Settlements

<table>
<thead>
<tr>
<th>Company</th>
<th>Settlement Amount</th>
<th>Anticipated Settlement Break Down</th>
<th>Issue(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shire Pharmaceuticals LLC</td>
<td>$56.5 million</td>
<td>Civil Settlement: Federal Government and State Medicaid Programs</td>
<td>Shire's marketing and promotion of Adderall XR, Vyvanse, Daytrana, Pentasa and Lialda</td>
</tr>
<tr>
<td>September 2014</td>
<td></td>
<td>*$5.9 million to Relator</td>
<td></td>
</tr>
</tbody>
</table>
Clinical Trials

Proposed new NIH rules on clinical trial transparency 11/19/14
--including data on unapproved products
"There is a disappointing record on disseminating clinical trial results. It's simply not acceptable...." Francis Collins, NIH Director

IBM's Watson to Guide Cancer Therapies at 14 Centers NYT 5/5/15

HHS and 17 agencies that oversee research/clinical trials issue proposed changes to Common Rule protecting human research subjects 80 Fed. Reg. 53,931 (Sept. 8, 2015)

Research Miscellany

Jury Finds Two Florida Scientists Guilty Of $10.5 Million Research Grant Fraud BNA 3/27/15

Court Dismisses FCA Allegations of Research Fraud Against University BNA 11/14/14

Columbia University to Pay $9 M to Resolve False Claims Case on AIDS Research Grants BNA 10/29/14

Unsealed Whistle-Blower Case Targets Cancer Center, Nursing Homes BNA 10/27/14

PCORI's Board Backs Efforts To Fund Hepatitis C Treatment Research BNA 12/11/14
Finally, some items you may have missed
With thanks to Annual Meeting Year in Review
Co-Presenter Jack Schroder

Did You Know…..?

According to JAMA Internal Medicine:
- Patients with heart failure & cardiac arrest had lower mortality when admitted during dates cardiologists were out of town
- Compared over 20,000 cardiac pts admitted during two biggest national cardiology meetings v. those treated during weeks before and after the meeting
- 30-day death rates for cardio meeting-day v. non-meeting day pts:
  - 60% v. 70% for cardiac arrests
  - 18% v. 25% for sickest heart failure pts
- Might indicate MDs who don’t attend meetings are less inclined to try most invasive treatments, and a less intensive approach is better for sickest patients

Source: JAMA Internal Medicine (Jan. 5, 2015)
Telemedicine on Steroids

The doctor can see you now ...on your iPhone

CNBC (July 30, 2014)

New app, HealthTap, allows people to see a doctor virtually via video conference on a smartphone

- Costs $99/mo for one family member & $10/mo per additional family member for unlimited virtual doctor visits
- Will even send reminders to pts. to take their medicine & personalized tips to improve their care

*There’s no co-pay, you can come to us anytime.*
- Ron Gutman, HealthTap CEO

Technology Marches On

The cute robot that may eventually take your job

Bloomberg (5/24/15)

- 25 mobile robots at UCSF Medical Center now perform duties once handled by nurses, orderlies, cafeteria staff and maintenance crews
- Studies predict that 47% of all U.S. jobs are at risk over the next two decades of being given over to computers

*And watch out lawyers:*

- Software now capable of scanning documents and emails to figure out what’s admissible in trials

*“What used to take a hundred attorneys can now be done with one.”*
- Andy Wilson, CEO of Logikcull
The “Brain Dead” Conundrum

Brain dead girl Jahi McMath released to coroner, mother  

NBCNews.com (1/6/14)

- 13 year old declared brain dead after tonsillectomy
- Family demanded continued care, even after coroner pronounced death
- After Ct-ordered settlement conference, child transferred to NJ facility, which performed surgery

Family seeks to have brain-death ruling overturned, girl declared alive  
San Jose Mercury News (10/1/14)

- Attorney says new MRI shows brain activity & reduced swelling
- Video shows her responding to oral commands, and she has started menstruation
- Case could reignite discussion of statutes defining brain death

“This is a dangerous and scary development for all of society. Number one, we can't afford it. And number two, it's never going to help this girl.”

Dr. Larami MacKenzie

Hackers Hit Healthcare

Medical identity theft jumped  

22% in 2014  
Bloomberg (2/24/15)

- Resolving incidents cost victims average $13K in expenses

Experts warn 2015 could be ‘Year of the Healthcare Hack’  
Reuters (2/11/15)

- Identities can sell for $20 apiece or more and used later to obtain medical services, commit ID theft & file tax returns

Rising Cyber Attacks Costing Health System  

$6 Billion Annually  
Bloomberg (5/7/15)

- Nearly 90% of H/C providers were hit by breaches in the past two years, half of them criminal in nature

“The health-care industry is being hunted and hacked by the elite financial criminal syndicates that had been targeting large financial institutions until they realized health-care databases are more valuable.”
HIPAA Gone Haywire

*Baby Pictures at the Doctor’s?*  
*Cute, Sure, but Illegal*  
New York Times (8/10/14)

Time-honored tradition of posting pix of delivered babies on office bulletin board now a thing of the past

- HIPAA enforcers say practice violates law
- Even if a parent sends in photo, it is considered private unless parent also sends written authorization for its posting

> “A patient’s photograph that identifies him/her cannot be posted in public areas unless there is specific authorization from the patient or personal representative.”
> Rachel Seeger, OCR

> “I think we have to have some common sense with this HIPAA business.”
> Dr. J. Moritz, Manhattan OB/GYN

Thank You!