

(Roughly) Twelve Months in Health Care Law

A Roller Coaster Journey

First Monday in November 2014 (11/3/14)

Elizabeth Carder-Thompson

Washington, D.C. & Princeton

*Portions of this presentation appeared in the Year in Review 2014 Keynote at the American Health
Lawyers Association Annual Meeting (ECarder-Thompson and JSchroder).*

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

Fasten Your Seatbelts

- Fraud and Abuse
- Public Health
- Health Care Reform
- Pharma and Device
- Research
- Medicare and Medicaid
- Health Info and HIPAA
- Items You May Have Missed



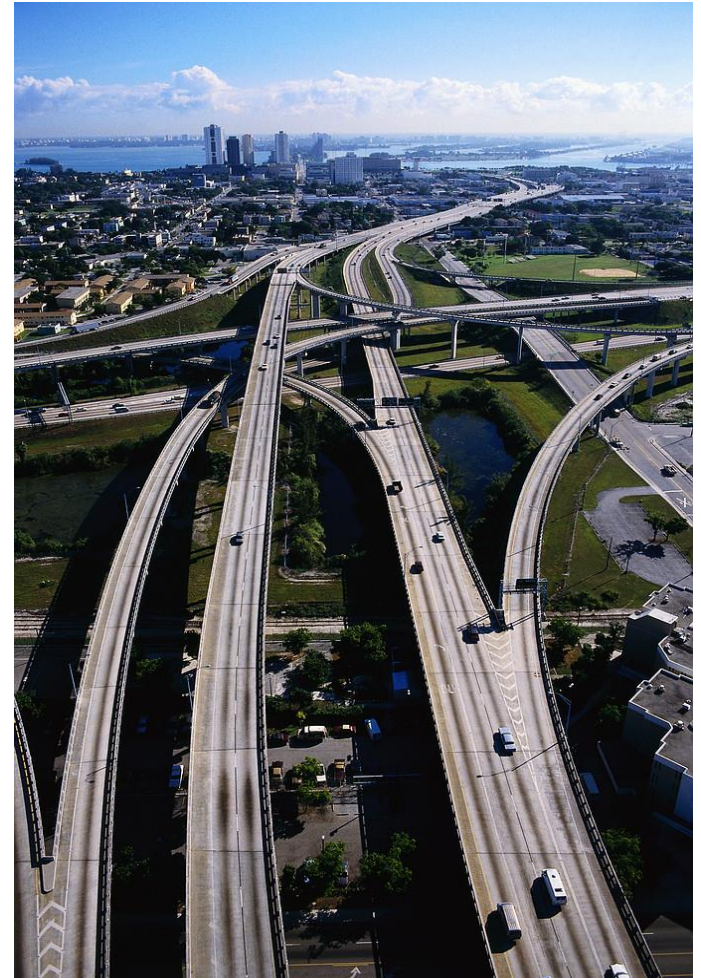


Fraud and Abuse



Fraud & Abuse Roadmap

- Numbers + Initiatives
- OIG and CMS Developments
- Criminal False Claims
- Civil False Claims/Qui Tam
- Kickbacks
- Stark
- Proposed Expansions
- Exclusions
- Insider Trading

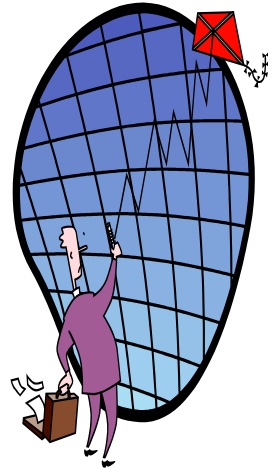


Numbers + Initiatives

DOJ & HHS announce record-breaking recoveries resulting from joint efforts to combat health care fraud

HHS Press Release (2/26/14)

- \$4.3 billion FY 2013, up from \$4.2 billion in FY 2012
- \$19.2 billion over past five years
- 5th consecutive year program has increased recoveries
- For every \$1 spent on health care F&A investigations in the past three years, government recovered \$8.10
- Records in the number of cases filed (137) individuals charged (345), guilty pleas (234) and jury trial convictions (46)
- Average prison sentence: 52 months
- Revoked 14,663 providers from Medicare program



Of the \$3.8 B recovered in FY2013, \$2.9 B related to qui tam FCA suits

“Whistleblower lawsuits were in the range of 300-400 per year from 2000 to 2009, when they began their climb from 433 lawsuits in fiscal year 2009 to 752 lawsuits in fiscal year 2013.”
<http://www.justice.gov/opa/pr/2013/December/13-civ-1352.html>.

Medicare Fraud Strike Force Charges 90 Individuals for Approximately \$260 Million in False Billing

27 Medical Professionals, Including 16 Doctors, Charged with Health Care Fraud
<http://www.justice.gov/opa/pr/2014/May/14-crm-503.html>

Senior Medicare Fraud Patrol Recovers \$5.9M *Health Leaders Media 6/24/14*

**OIG expects to recover over \$3.1 billion in the first
half of fiscal year 2014 as a result of audits and
investigations** *BNA 5/27/14*



GAO: Medicare Contractors Need More Oversight, Guidance to Curb Duplicative Audits *GAO-14-474 (8/13/14)*

GAO: CMS Needs to Improve Oversight of ZPICs
GAO 8/23/13, 12/8/13

CMS 9/14 Report: RACs identified \$3.65B in overpayments in FY 13 (up from \$2.3 B during FY 12)

But See AHA Survey stats: Q4 2013 (3/5/14): Hospitals appealed 49% of denials with 64% success rate; many short-stay medical-necessity denials based on wrong setting



Fraud and Abuse: CMS Initiatives

CMS issues first temporary moratorium on provider, supplier enrollment in three areas *Law360 7/26/13*

Second wave of CMS' moratoria extended for home health and ground ambulance suppliers; four new geographic areas added *CMS Press Release 1/30/14*

CMS Extends by Six Months *CMS Release 7/29/14*



DOJ Urges FCA Attorneys to Aid Criminal Cases

- Remarks by Leslie Caldwell, Assistant AG, Criminal Division 9/17/14
- Remarks by Marshall L. Miller, Principal Deputy Assistant AG, Criminal Division 9/17/14
 - **“Corporations do not act criminally, but for the actions of individuals. The Criminal Division intends to prosecute those individuals, whether they’re sitting on a sales desk or in a corporate suite.”**

Recent Cases

- Co-Owner of Atlanta-Based Medical Clinic Chain and Hospital CEO Pleaded Guilty to Illegal Pay-for-Patient Conspiracy *DOJ Press Release 8/7/14*
- Former Arthrocare Executives Sentenced for Orchestrating \$750 Million Securities Fraud Scheme *DOJ Press Release 8/29/14*
- Former Texas Hospital Chain Owner Found Guilty of Medicare Fraud *dallasnews.com 7/24/14*
- 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-Wellcare CEO Gets 3 Years for Medicaid Fraud *Law360 5/19/14*

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
 - Off-label promotion
 - Reimbursement “swapping”
 - Kickbacks + inducements
 - Stark





Relators Come in Many Forms

Internal health system compliance officers

Jones-McNamara v. Holzer Health Sys., Inc., 2014 WL 1671495 (S.D. Ohio 4/28/14).

Former health system compliance officer turned “Compliance Consultant”

United States ex rel. Bloink v. Carondelet Health Network, D. Ariz., No. CV-11-721-TUC-FRZ, settlement announced 8/18/14 (\$35 M settlement by two nonprofit hospitals in AZ – largest AZ FCA recovery ever)

Former Hospital CEO and Hospital HR Director

US ex rel Bartlett v. Ashcroft, 2014 BL 232444 (W.D. Pa 8/21/14) (mixed Stark, FCA, kickback challenge to physician/hospital arrangement involving radiology business; not final yet)



Some are even general counsel:

US v. Quest Diagnostics 734 F.3d 154 (2d Cir. 2013)

- Mark Bibi was former GC of Unilab, later acquired by Quest
- Joined former CEO + CFO to form “Fair Laboratory Practices Associates” to bring qui tam
- Alleged kickback violation: swapping discounted capitated rates to MCOs/IPAs for commercial patients in return for Medicare/Medicaid
- Second Circuit: violated NY ethics rules – relied on confidential information obtained while working as attorney
- Bibi’s disclosures went beyond what was “necessary” for the exception permitting disclosure to prevent ongoing crime

“Nothing in the False Claims Act evinces a clear legislative intent to preempt state statutes and rules that regulate an attorney’s disclosure of client confidences.”

Worthless Services/Substandard Quality

Extendicare...Agrees to Pay \$38 M to Settle False Claims Act Allegations [re] Substandard Nursing Care and Medically Unnecessary Rehabilitation Therapy *DOJ Press Release 10/10/14*

Eleventh Circuit Affirms Conviction of Nursing Home Owner Based on “Worthless Services”

Allegations against owner (and wife) of three SNFs in GA – failures to provide residents with food, electricity, adult diapers, medication, dialysis – 10 year prison term *US v Houser, 754 F 3d 1335(11th Cir. 6/19/14)*

See also US v. Klein, Dietrich, Menten & Cox, (Indictment W.D. Va. 6/24/14) (Va. federal grand jury indicted owner, managers of SNF: false statements; insufficient nursing staff, supplies; residents in unsanitary conditions; residents with inadequate pressure sore treatment)

But see US ex rel. Absher, et al. v. Momence Meadows Nursing Ctr & Graff, 2014 BL 230754 No. 13-1886 (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)

Regulatory & Other Violations: Device Manufacturers Targeted

- 10/7/14 Presentation at AdvaMed Conference: included Jeffrey Steger, Department of Justice
- Areas of scrutiny cited:
 - Improper coding
 - Marketing of materially inaccurate/unreliable products
 - Submission of false certifications – country of origin
 - <http://www.reedsmith.com/Country-of-Origin-Compliance-The-Top-10-Things-Pharmaceutical-Companies-Need-to-Know-02-06-2014/>
 - Payments of kickbacks to physicians
 - Foreign Corrupt Practices Act

False Claims/Qui Tam:

Regulatory Noncompliance Can't Be Transformed Into FCA Claim

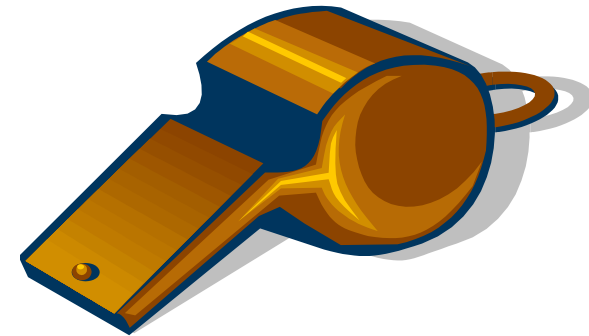


United States ex rel. Rostholder v. Omnicare 2014 WL 661351 (4th Cir. 2/21/14), cert denied 10/6/14

- 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
- Decision follows that court’s adherence to FCA’s statutory elements, & refusal to allow regulatory violations to be transformed into FCA fraud cases

See also ***U.S. ex rel. Simpson v. Bayer Corp.***, 2013 WL 4710587 (D.N.J. 8/30/13) (FCA complaint against Bayer for alleged misbranding, off-label promotion dismissed; FDCA misbranding is not condition of payment)

- Rule 9(b): What does it mean to state fraud “with particularity”?
- What are excessive fines?
- What is the statute of limitations?
- Can overpayments be extrapolated?
- Has the “fraud” been publicly disclosed?
- Was relator the “first to file”?



False Claims – Rule 9(b)

United States ex rel. Nathan v. Takeda 707 F.3d 451 (4th Cir. 2013), petition for cert. denied (U.S. 3/31/14) (2013 WL 136030)

- How much “particularity” is required?
- Circuits split (those generally requiring claims’ samples = 4th, 6th, 8th, 11th; those generally favorable to relators = 1st, 3rd, 5th, 7th, 9th)
- In 2013, 4th Circuit affirmed dismissal of the relator’s complaint on Rule 9(b) grounds – decision was appealed, but.....
- U.S. Solicitor General asked Supreme Court not to hear case, raising concerns the Court would enforce stricter FCA pleading standards

More Recent Cases:

Foglia v. Renal Ventures Mgmt,

2014 BL 158467 (3d Cir., 6/6/14)

Thayer v. Planned Parenthood

2014 BL 239809 (8th Cir., 8/29/14) (*representative examples not required if indicia of reliability*)

US ex rel. D’Agostino No. CIV.A. 10-11822-

RSC (D. Mass 9/30/14) (*FCA not vehicle for second-guessing FDA device approval*)



Sixth Circuit Must Weigh Extrapolation, Life Care Says *Law360 10/14/14*

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 ex rel Martin v. Life Care Centers of America, case no. 1:08-cv-251 (E.D. Tenn. 2/18/14), consolidated with US ex rel. Taylor v. Life Care Centers of America, case no. 1:12-cv-00064*

Notable Non-Health Care Cases

What's an Excessive FCA Fine?

- 4th Circuit refused to eliminate \$24 million statutory penalty in FCA case with no established damages
- District court had said the judgment would contravene the Eighth Amendment's ban on excessive fines – 4th Circuit left up in the air, *US ex rel. Bunk v. Gosselin World Wide Moving*, 741 F.3d 390 (4th Cir. 2013), cert. denied 10/6/14

Does the Wartime Suspension of Limitations Act (WSLA) Toll the FCA's Six-Year Statute of Limitations?

- 4th Circuit held WSLA – triggered by Iraq and Afghanistan conflicts – tolled SOL indefinitely for ALL civil and criminal cases
 - Also held “first-to-file bar” inapplicable because prior actions had been dismissed
 - AHA, AMA, PhRMA urge US Supreme Court to reverse – WSLA should apply only to criminal cases, not civil fraud claims by private relators, and first-to-file ruling bad precedent
- Kellogg, Brown & Root Serv. v. US ex rel. Carter*, No. 12-1497 (US cert granted 7/1/14)

Are Internal Compliance Investigations Privileged?

- Preliminary decision by US District Court for DC: Not necessarily....
- Documents related to internal investigations of possible violations of corporate code of conduct were not protected from disclosure under attorney-client or work product privilege
- Investigations “were undertaken pursuant to regulatory law and corporate policy rather than for the purpose of obtaining legal advice.”
 - *US ex rel Barko v Haliburton Co.*, 2014 WL 1016784 (D.D.C. 3/6/14)
- But DC Circuit issued writ of mandamus to vacate ruling.
 - *In re Kellogg Brown & Root, Inc., et al.*, 756 F 3d 754 (D.C. Cir. 6/27/14)

And While We're On That Subject...

US Court in Georgia Says FCA Defendant Waived Attorney-Client Privilege By Arguing It Did Not Knowingly Violate Law (BNA 9/5/14)

Columbus Regional Health System denied it bought cancer center for more than FMV – US district court then compelled disclosure of communications with attorneys re anti-kickback and Stark issues (*Barker ex rel. US v. Columbus Reg'l Healthcare*, 2014 WL 4287744, (M.D. Ga., 8/29/14))

Community Health Systems Inc. to Pay \$98.15 Million to Resolve False Claims Act Allegations

- Largest acute-care hospital system in the U.S. settlement with DOJ, plus 5-year CIA, to resolve seven False Claims Act actions <http://op.bna.com/hl.nsf/r?Open=etor-9mpkzh>.
- Allegations by multiple relators: unnecessary patient admissions allegedly occurred between 2005 and 2010 in 119 hospitals in 20 states
- \$9M of settlement resolves one Stark law allegation

CareMed Forks Over \$10M to Settle Phone Fraud Suit

Law360 10/10/14 US ex rel. Sorkin's LTD d/b/a CareMed Pharmaceutical Services, case no. 1:12-cv-04366 (S.D.N.Y.)

Attorney Deserves Sanctions for Baseless FCA Claims, Judge Says Law360 10/16/14

- Personal injury lawyer/relator claimed personal knowledge of conspiracy to defraud Medicare by Allstate Insurance and FedEx
- Per judge, he did not know exactly who was involved – planned to use discovery to determine the actual players.
- *“Litigation is not a game played by the rules of one of the parties.”* US Magistrate Judge Jeremiah McCarthy

US ex rel. Hayes v. Allstate Ins Co, et al., case no. 1:12-cv-01015, W.D.N.Y.



Fraud and Abuse: Moving on to Kickbacks

Many cases are settlements involving drug + device entities' alleged remuneration to physicians, or include FCA

Government, Teva Pharmaceuticals Settle Over Alleged Kickbacks Paid to Psychiatrist *BNA 3/11/14*

Abbott Paying U.S. \$5.5 Million to Settle Kickback Claims *Devices and Diagnostics Letter 1/4/14*

Omnicare Settles With DOJ for \$4.19M Over Amgen Kickback, FCA Allegations *(BNA 2/28/14)* [Unrelated] **Omnicare Finalizes Settlement with DOJ over Nursing Home Kickback Arrangements** *(AHLA 7/10/14)*

Device Maker CareFusion Settles Kickback, Other DOJ Charges for \$40 Million *BNA 1/9/14*

DaVita To Pay \$389M, Unwind Deals To End Kickback Probes *Law360 2/14*

Medtronic Settles Suit Over Heart-Device Kickback Claims *(Bloomberg 5/28/14)* [Corollary:] **States Settle With Medtronic on Alleged Medicaid Violations** *(BNA 9/18/14)*

Kickbacks (cont.)

But cases/settlements also implicate physicians, labs, hospitals, PTs

Hospital Inks \$4M FCA Deal Over Possible Doctor Kickbacks

St. James Healthcare/Sisters of Charity of Leavenworth – MT Law360 1/6/14

Former Imaging Center Owner Sentenced To Prison Term, Ordered to Forfeit \$2 Million

Multiple cites – see BNA 4/29/14

Physical Therapy Cos. Pay \$30M to Settle FCA Kickback Suit

US ex re Health Dimensions v. RehabGroup case no 4:12-cv-00848 (ED MO 3/14)

Oncologist Hit with \$90M Judgment in Whistleblower Case

Law 360 5/19/14

And some were more creative:

Home Care Co. Can't Escape Whistleblower's \$9M FCA Case

Law 360 11/8/13 (HHA hired at least 7 physicians' spouses and one physicians' boyfriend to perform sham marketing duties)

Fall-Out: Physician-Owned Distributors OIG Special Fraud Alert *March 26, 2013*



PODs are “inherently suspect” under anti-kickback statute;
Warning both to physicians and hospitals/ASCs using PODs

See Reliance Med. Sys., LLC v. HHS, (device company mounted unsuccessful challenge to OIG Fraud Alert – court said no “chilling effect” on First Amendment right of free speech) C.D. Cal., No. 13-cv-7451, 2/5/14

Most recently: **“DOJ Complaints Allege Improper Payments Involving Physician-Owned Distributors”** *US v. Reliance Medical Sys., C.D. Cal. No. 14-6979, complaint filed 9/8/14*

- 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



Special Fraud Alert: Laboratory Payments to Referring Physicians (6/25/14)

Suspect Specimen Processing Arrangements

- List of characteristics, including payment per specimen for > one specimen during single patient encounter
- OIG's concerns not abated by "carve outs" of federal health care program beneficiaries

Suspect Registry Payments

- A/K/A "observational outcomes databases"
- Extensive list of suspect characteristics

Moving on to Stark (and more): Settlements

Florida Hospital Settles FCA Action On Alleged Doctor Pay Scheme for \$7 Million <http://op.bna.com/hl.nsf/r?Open=etor-9jgqar>

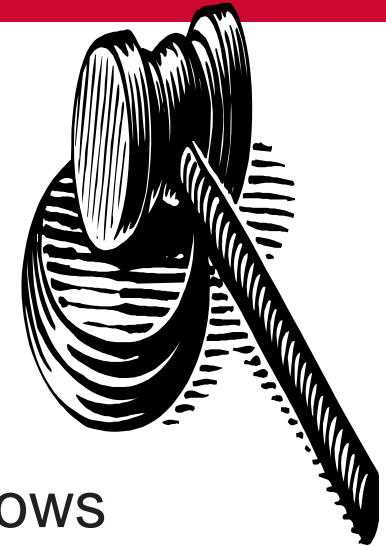
Kentucky Physicians Settle FCA Allegations, Agree to Repay \$15.75 M <http://op.bna.com/hl.nsf/r?Open=jcon-9g8ske>.

Home-Health Provider Amedisys Settles FCA Action for \$150 Million Multiple cites – see BNA 4/23/14

Pittsburgh Health System to Pay \$1.5 Million To Resolve Kickback, Stark Law Allegations BNA 3/20/14

Memorial Hospital Settles Self-Disclosed False Claims Allegations for \$8.5 Million BNA 3/14/14

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 53 reported self-disclosure settlements on CMS site (as of 10/29/14); many more expected
- Primarily hospitals
 - <http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements.html>

Stark = Big Recoveries

The Saga of *US ex rel Drakeford v. Tuomey*

Jury assessed damages at \$39 M – in 5/22/13 hearing, govt said minimum was \$277 M (\$5,500/claim) but could accept less since pockets may not be that deep; judge ordered \$237 M (2013 WL 5503695 D. S.C. 10/2/13) – appeal to 4th Circuit filed 10/3/13

Tuomey reportedly preparing for bankruptcy 5/1/14

This Year's Winner: Halifax Hospital Medical Center

\$85M settlement of Stark, false claims allegations

Relator – former compliance officer – to receive \$20.8 M

Hospital also hit w/sanctions for evidence destruction (5/25/14);

\$1M settlement of remaining claims (7/15/14)



- 2005: community hospital entered employment agreements with six medical oncologists + bonus
- Bonus pool = 15% of the “operating margin” (revenue minus expenses) of oncology program (including revenue from DHS not personally performed by the oncologists)
- Each physician rec’d share of pool based on personally performed services
- Halifax argued that the arrangement satisfied the Stark employment exception, or alternatively, the indirect compensation exception
- Court disagreed:

The Incentive Bonus was not a “bonus based on services personally performed” by the Medical Oncologists, as the exception requires.... Rather, as described by the Defendants themselves, this was a bonus that was divided up based on services personally performed by the Medical Oncologists. The bonus itself was based on factors in addition to personally performed services -- including revenue from referrals made by the Medical Oncologists for DHS. The fact that each oncologist could increase his or her share of the bonus pool by personally performing more services cannot alter the fact that the size of the pool (and thus the size of each oncologist’s bonus) could be increased by making more referrals.

Relator – Director of Physician Services at Halifax

Promise of more enforcement activities to come

- **May 9, 2014: OIG proposed rule to significantly expand exclusion authorities**
 - Including limitless look back authority
- **May 12, 2014: OIG proposed rule to expand CMP authorities**
 - Including penalties for: failure to grant OIG timely access to records; ordering/ prescribing while excluded; making false statements, omissions, misrepresentations in enrollment application; failure to report & return an overpayment; making/using false record or statement that is material to a false or fraudulent claim.
- **Oct. 3, 2014: OIG proposed rule re new safe harbors, CMP beneficiary inducements and gainsharing**

<http://www.reedsmith.com/Analysis-of-HHS-OIG-Proposed-Rule-to-Amend-the-Anti-Kickback-Safe-Harbors-CMP-Rules-on-Beneficiary-Inducements--Gainsharing-Regulations/>

Excluded Employee's Application for Reinstatement Leads to CMS Settlement [with current nursing home employer] *Report on Medicare Compliance* 9/8/14

- Brookdale Senior Living screened for excluded individuals, but used names only and not SSNs
- Occupational therapist who at one time had been excluded following conviction of program-related crime was missed in screening
- OT applied for reinstatement – OIG denied, and imposed \$353,248 civil monetary penalty on Brookdale – her current employer – for hiring an excluded individual



Fraud and Abuse: Update on Insider Trading

Matthew Martoma Convicted; sentenced to 9 years imprisonment (*Forbes* 9/8/14)

More or Less Asked Every Doctor that Crossed His Path for Material Non-Public Information

- SAC hedge fund manager Matthew Martoma traded on clinical trial information from neurologist/med school professor Sidney Gilman [*since retired*]... and 20 other physicians
dealbreaker.com 8/23/13
- Martoma trades netted \$276 M for fund – charged with conspiracy and securities fraud *New York Times* 12/15/12
- Hedge fund SAC agreed to plead guilty and pay \$1.8 B; six SAC employees have pleaded guilty; Martoma was convicted by jury in March.
- Stanford B-School strips [Martoma] diploma *WSJ* 3/5/14



Tipsy Lawyer Disclosed Secret \$3.6B Pfizer Deal, SEC Says Law360

9/23/13 (case characterized by abovethelaw.com as "TMII")

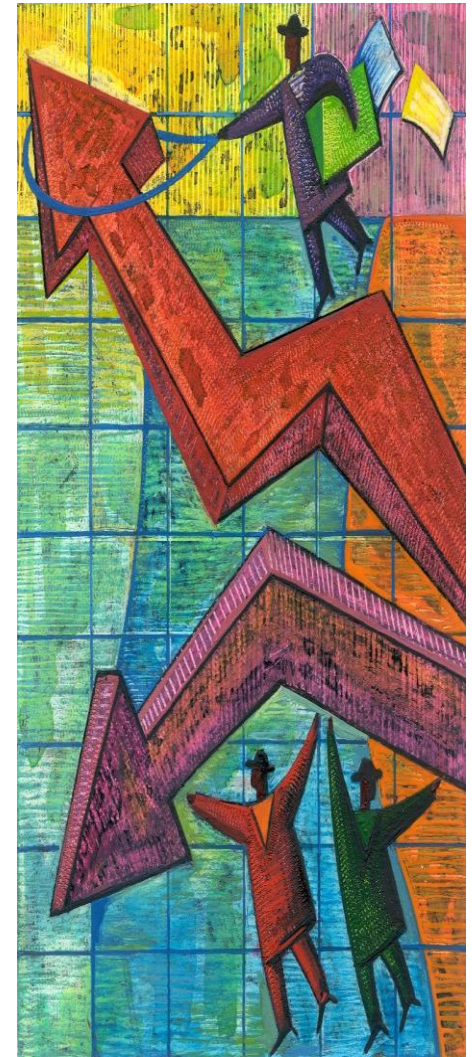
SEC Claims Drunk Lawyer Had Inside Tittle
Financial Times 2/20/14

House [Ways and Means] Panel is Subpoenaed as Trading Probe Heats Up

*Prosecutors Gathering Evidence for Grand Jury in [CMS]
Leak Case Online/wsj.com*

SEC is seeking documents and testimony, and DOJ is seeking testimony, on information provided to Height Securities on a pending favorable decision on Medicare Advantage rates, spiking a surge in trading in Aetna, Humana, etc.

*SEC Says House Insider Probe Involves 44 Funds,
Entities (Bloomberg 7/18/14)*



Public Health



Ebola

- Global public health community has been addressing in Africa
- Now a top health issue in the US
- CDC Guidance <http://www.cdc.gov/vhf/ebola/index.html>
- Joint Commission: Ebola Preparedness Resources [webpage](#)
- Besides patient treatment considerations for providers, the crisis raises issues for all health care entities in employment, discrimination/HIPAA, insurance, and more.





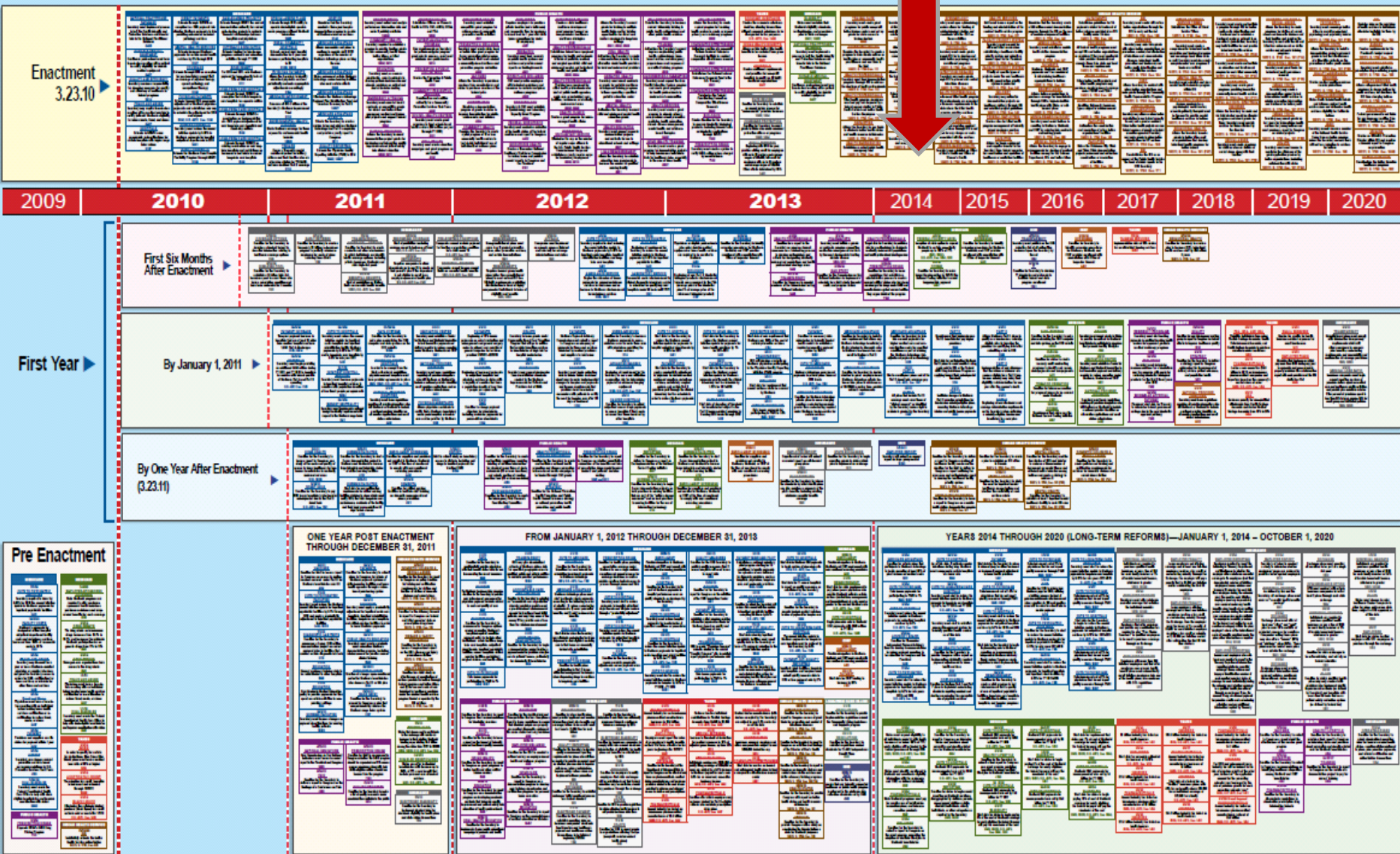
Even in gridlocked Congress, public health bills are signed into law

- H.R. 594, Paul D. Wellstone Muscular Dystrophy Community Assistance, Research and Education Amendments
- S. 2154, Emergency Medical Services for Children Reauthorization Act
- H.R. 4631, Autism Collaboration, Accountability, Research, Education, and Support (CARES) Act
- H.R. 3548, Improving Trauma Care Act
- S. 330, HIV Organ Policy Equity Act
- S. 252, Prematurity Research Expansion and Education for Mothers who deliver Infants Early Reauthorization Act
- H.R. 2094, School Access to Emergency Epinephrine Act

Health Care Reform



ACA Implementation... You



House Republicans Take 47th Vote to Repeal Obamacare Daily Kos 11/15/13

- New York Times calculated that, as of May, these efforts had accounted for 15% of time on House floor *NY Times 5/14/13*
- *Quiz question: Which politician's strenuous effort was marked by these words? "I'll talk until I can't stand anymore. Don't worry, I have government-run health insurance. I'll be fine."* <http://swampland.time.com/2013/09/25>

As Government Shuts Down, Obamacare Moves Forward

Washington Post 9/30/13

Throughout, agencies have continued to implement health reform regulations under the ACA

Avalanche of Rules Continues:

- Final ACA Exchange/Qualified Health Plan (QHP) financial integrity and oversight standards (*Oct. 30, 2013*)
- CMS interim final rule with comment period on 2014 ACA enrollment deadlines -- a bit of a moving target in the closing months of 2013 (*Dec. 17, 2013*)
- HHS final rule on payment and policy provisions for health insurers participating in Exchanges in 2015 (*March 11, 2014*)
- HHS final rule establishing the Basic Health Program, and a separate final rule establishing the specific methods for calculating and providing payment to states (*March 12, 2014*)
- CMS interim final rule with comment period that requires QHP issuers to accept premium and cost-sharing payments made on behalf of enrollees by the Ryan White HIV/AIDS Program, Indian tribes, and other government programs that provide premium/cost-sharing support (*March 19, 2014*).
- CMS final rule on Exchange and insurance market standards for 2015 and beyond (*May 27, 2014*)
- HHS/IRS/EBSA final rule on treatment of employment orientation periods for purposes of ACA health insurance coverage waiting period limitation (*June 25, 2014*)
- CMS final rule to specify additional options for annual eligibility redeterminations, renewals, and re-enrollment notices for Exchange QHPs (*Sept. 5, 2014*)
- HHS/IRS/EBSA interim final rule with additional path for eligible nonprofits to provide notice of religious objection to covering contraceptive services (*Aug. 27, 2014*)

And those were just the final HHS/CMS regs; more in the avalanche:

- IRS final rule on employer insurance reporting requirements (*March 10, 2014*)
- IRS/EBSA/CMS request for information on nondiscrimination rules for group health plans (*March 12, 2014*)
- IRS final rule on requirements for Affordable Insurance Exchanges to report information on ACA health insurance premium tax credits (*May 7, 2014*)
- EBSA proposed rule to align COBRA notice requirements to align with ACA provisions (*May 7, 2014*)
- CMS notice seeking comments on Quality Rating System framework for rating QHPs offered through an ACA Exchange (*Nov. 19, 2013*)
- HHS proposed rule to update ACA Exchange and insurance market standards beginning in 2015 (*March 21, 2014*)
- HHS, Labor, Treasury final rule generally prohibiting health plans from imposing more than a 90 day waiting period for insurance coverage (*Feb. 24, 2014*)
- HHS/IRS/EBSA proposed rule to accommodate certain “closely-held” for-profit entities (eg Hobby Lobby) with religious objections to covering contraceptive services (*Aug. 27, 2014*)
- IRS final rule on annual ACA fee on entities that manufacture or import branded prescription drugs (*July 28, 2014*)

THE YOUTOONS GET READY FOR OBAMACARE

HEALTH INSURANCE CHANGES COMING YOUR WAY UNDER
THE AFFORDABLE CARE ACT





LOS YOUTOONS SE PREPARAN PARA OBAMACARE

CAMBIOS EN LOS SEGUROS MÉDICOS QUE LLEGARÁN CON LA
LEY DEL CUIDADO DE LA SALUD A BAJO PRECIO



0:10 / 6:48

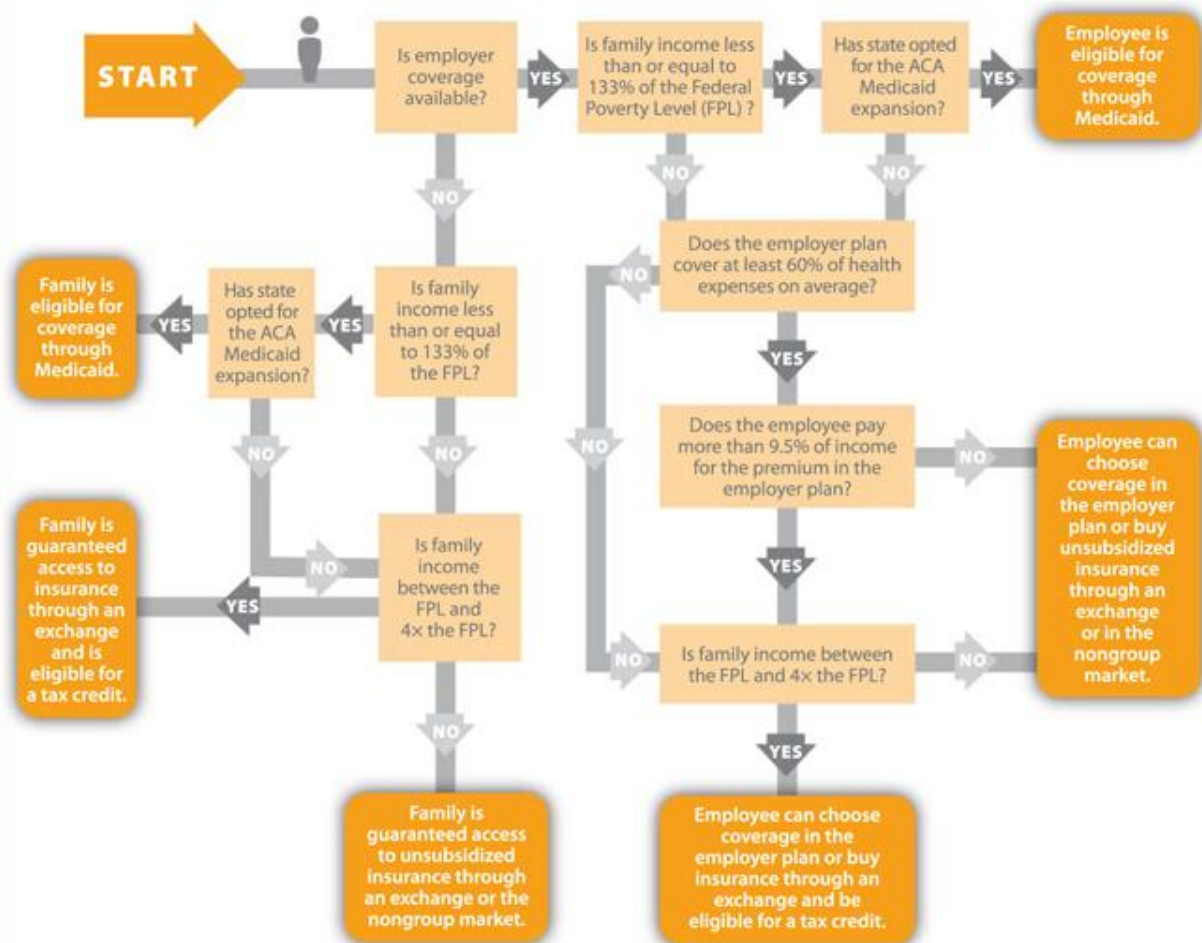


YouTube



HEALTH COVERAGE UNDER THE AFFORDABLE CARE ACT (ACA)

How to Get Coverage Beginning in 2014



KEY FACTS

- The FPL in 2012 is \$11 170 for a single individual and \$23 050 for a family of 4.
- In 2012 employees paid \$951 on average towards the cost of single coverage in an employer plan and \$4316 for a family of 4.

<http://kff.org/aca-consumer-resources/>

When the ACA enrollment period began...

A Smattering of Washington Post Headlines:

- HealthCare.Gov was originally built in a garage 10/9
- ‘HealthCare.gov is in de facto shutdown’ 10/23
- Medicare chief Marilyn Tavenner apologizes for botched rollout of HealthCare.gov 10/29
- ‘Hold me responsible’ Sebelius testifies.... 10/30
- Health-care enrollment on Web plagued by bugs 12/2
- Thousands of Healthcare.gov sign-ups didn’t make it to insurers 12/14

Whom to Call When the Going Gets Tough?

- Sebelius asks OIG to review development of Healthcare.gov website.
BNA 12/11/13

Later Obama administration to dump IT firm behind HealthCare.gov (1/9/14)

GAO finds HealthCare.gov still not fully secure (9/18/14)

Put It On My Tab

THE FUTURE OF HEALTH CARE

Now on your restaurant bill: Obamacare fee

CNNMoney

By Tami Luhby @Luhby February 27, 2014: 7:09 AM ET

Recommend 42k



Restaurants in Florida have added an Obamacare surcharge to pay for employees' health insurance.

14K
TOTAL SHARES

11K	2K		621

But in more recent Washington Post headlines

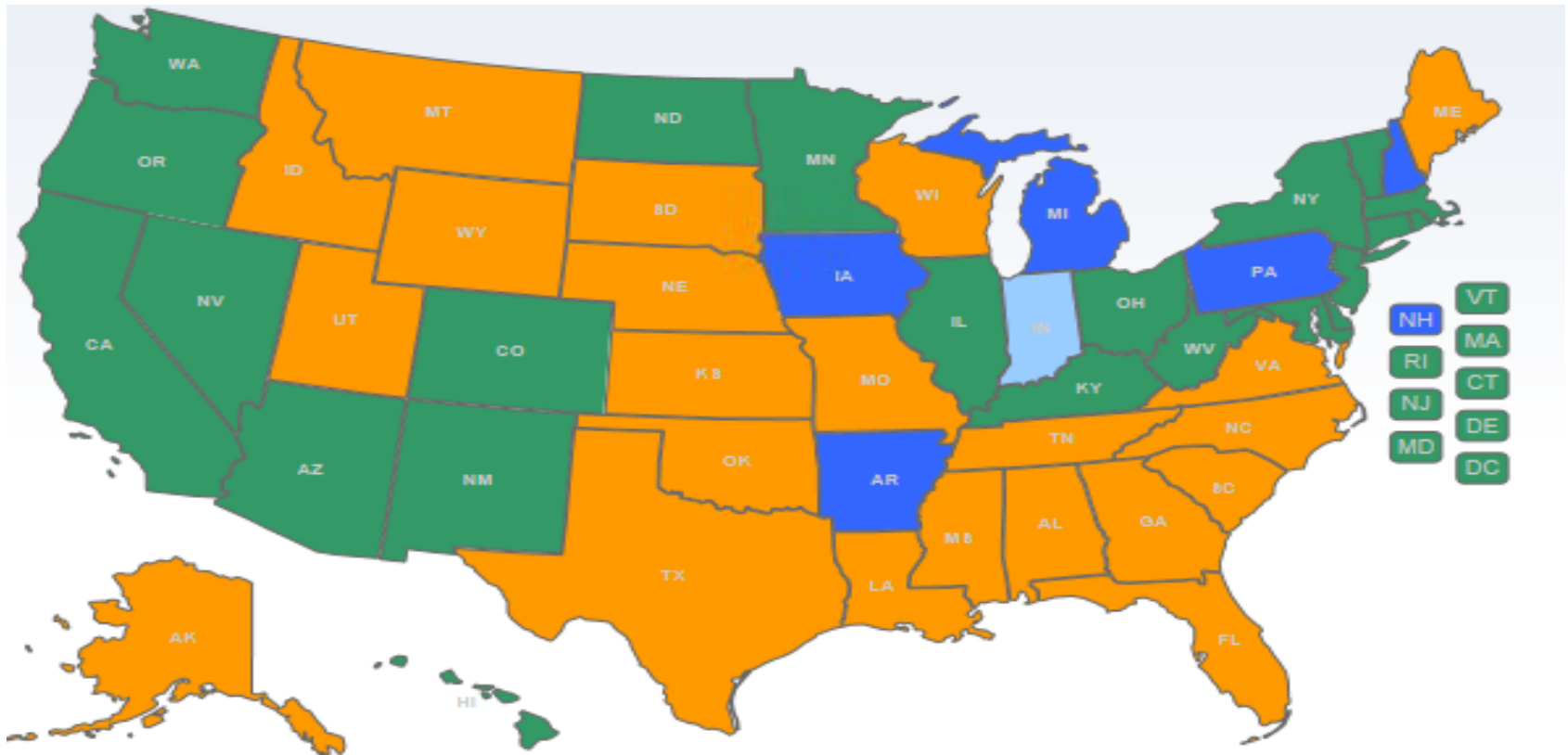
- ‘Between Two Ferns’ [YouTube] video leads to 40% more visits to healthcare.gov 3/12/14
- Obama administration will allow more time to enroll 3/25/14
- Healthcare.gov finishes strong, despite rocky start... Eight Million Americans enrolled through online marketplaces 5/1/14
- CMS Reports 7.2 Million Increase in Medicaid Enrollment Since ACA 8/15/14

Leading to the inevitable question:

- What's the GOP Strategy to Deal With Obamacare's Success? *Huffington Post* 12/31

As for Presidential Reflections (WHCD 5/3/14):

- *“In 2008, my slogan was ‘Yes, we can.’ In 2013, my slogan was ‘control alt delete.’”*



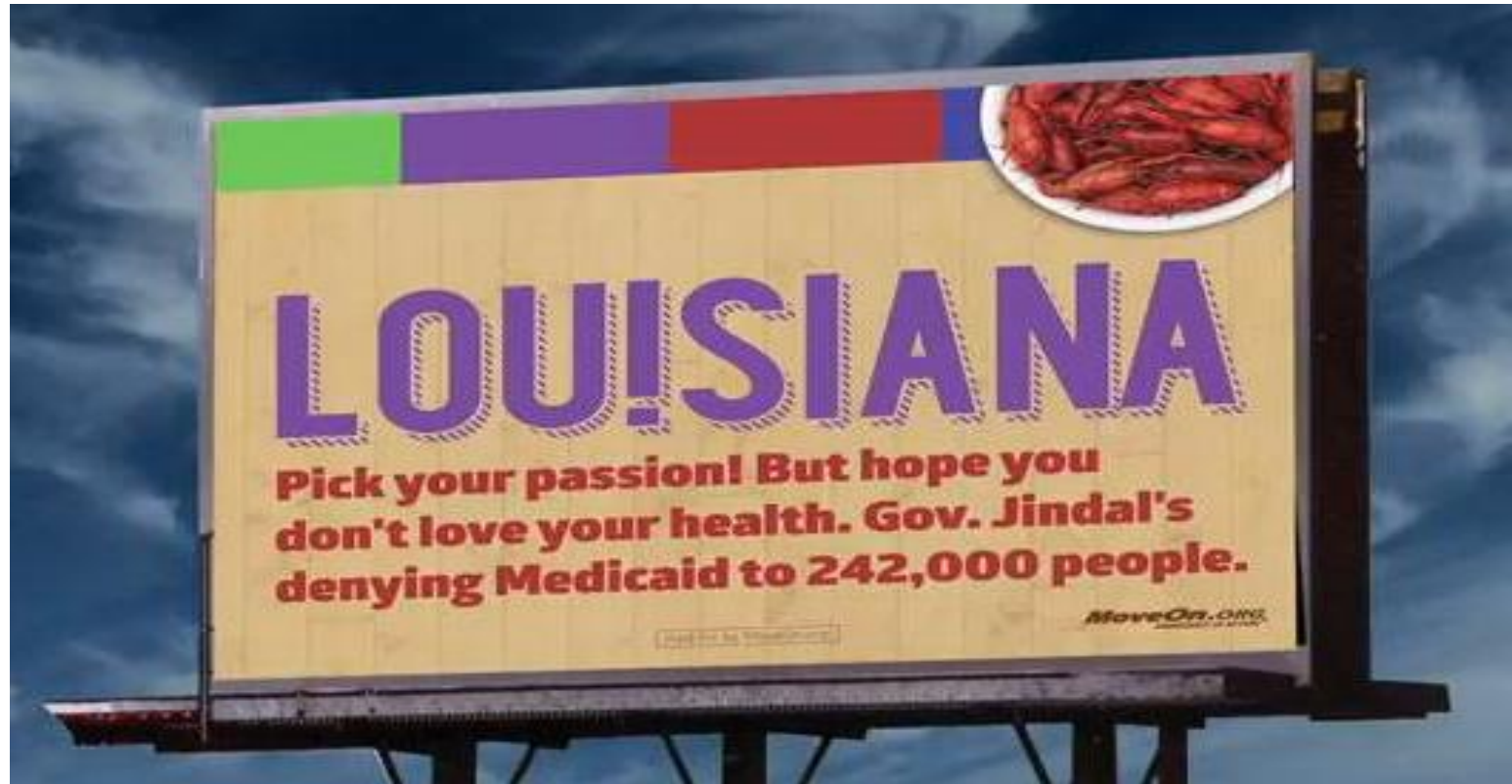
Produced by:
staterforum

Key:

- 22 states are not expanding Medicaid in 2014
- 23 states (count includes the District of Columbia) are expanding Medicaid in 2014
- 5 states are expanding Medicaid in 2014, but using an alternative to traditional expansion
- 1 state with a Medicaid expansion waiver pending approval from CMS

As of 10/24/14

Not all state residents agree on the right course of action

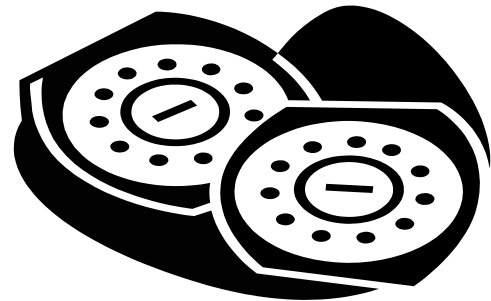


In KY, Health Law Helps Voters but Saps Votes *NYT 9/16/14*

Contraceptive Mandate Challenge

- ACA requires health plans to cover women’s “preventive care” services, including all contraceptive methods; exception for religious employers
- Justice Sotomayor delayed implementation hours before effective date and her inaugural New Year’s Ball Drop
- Multiple pending suits led to Supreme Court argument in March, when “Justices Divide By Gender In Hobby Lobby Contraception Case” *NPR 5/25/15*
- Supreme Court in June: Contraception Coverage Mandate Impermissibly Burdens Closely-Held Corporations' Religious Exercise

Burwell v. Hobby Lobby Stores, Inc., 723 F. 3d 1114 (U.S. 6/30/14).



Scams Sprout with Rollout of ObamaCare *USA Today*

11/11/13

Does Signing Up for ObamaCare Make You a Cybercrime Target? *CNN*

Money 4/11/14

Fraudster Activities: blast emails, calls, faxes, home visits, invoking the ACA as a pretext for seeking Medicare numbers, bank identifiers from consumers.

New OIG Alert: <https://oig.hhs.gov/fraud/consumer-alerts/alerts/marketplace.asp>; new HHS/FTC interagency initiative announced 9/18/13 re consumer fraud, privacy violations

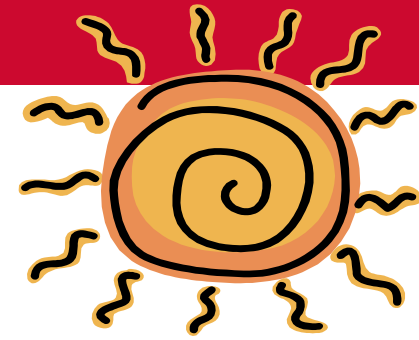
Concerns:

- Fraudulent exchange navigators
- Bogus exchange websites
- Selling exchanges to Medicare beneficiaries
- Consumer income eligibility fraud
- Cybercrime
- Agent/broker fraud



Pharma & Device





CMS “Sunshine Act” Follies

Act requires drug + device manufacturers to report payments and transfers of value to “covered recipients” – physicians and teaching hospitals – for CMS publication *78 Fed Reg. 9458 (2/8/13)*

- Including distributors taking title
- Including physician ownership by manufacturers and GPOs (e.g., most PODs)

Since then, ongoing uncertainty:

- Confusing postings
- CMS “rejected” over one-third of submitted data – returned 10/30/14
- CMS has already proposed *and finalized (as of 10/31/14)* revised regulations – changing CME reporting, requiring marketed names of products, and more
- More user-friendly version of Open Payment website posted 10/27/14
- Bottom Line: \$3.5 B in payments from industry in five months

GlaxoSmithKline says it will stop paying docs for promotional engagements; others likely to follow. *Modern Healthcare 12/17/13*

Facebook page lands drugmaker in hot water with FDA *Law 360*
3/13/14

FDA warns 3 drug compounders over sloppy practices *Law 360*
3/4/14

FDA shuts down over 1,600 online pharmacies *CBS News* 1/9/14

GAO Report: FDA spied on staff without considering legal risks *Law360* 2/27/14; *OIG-12-14-01*

It's Not Just You: FDA Regulatory Requirements Really Are Increasing – 15% increase from 2000 – 2012 <http://www.raps.org/Regulatory-Focus/News/2014/10/30/20656/Its-Not-Just-You-FDA-Regulatory-Requirements-Really-Are-Increasing/#sthash.WF3wgcNM.dpuf>



With FatFoe™ Eggplant Extract you can  your dieting days goodbye!



Feast on Your Favorite Foods...

and Lose up to 2 Pounds a Day!

Click Here to
**ORDER
NOW!**

FatFoe™ FAQs
Success Stories
Contact Us
En Español
En Français

Wouldn't it be nice to enjoy your favorite foods – pizza, pasta, fried chicken, gooey chocolate deserts – and watch the pounds melt away? Best of all, wouldn't it be nice to have the trim, shaply figure you've always wanted without having to diet or exercise? **NOW – FINALLY – YOU CAN!**

How it works: Just take two FatFoe™ capsules before each meal. The safe, all-natural active ingredient in FatFoe™, auberginium, binds with food to block the absorption of fat, carbs, AND calories. Lose up to 10 pounds per week – with no sweat, no starvation!

Every Dieters Dream!

FatFoe™ is **GUARANTEED** to work for everyone – regardless of how much you eat, regardless of how much you'd like to loose. With FatFoe™, kiss calorie counting and sweaty exercising good-bye as you lose those unsightly pounds permanently!

Order Today!

You've read about products like this in the news. You've seen them on TV. To facilitate distribution FatFoe™ is available **ONLY** on the Internet. You can't buy it in stores. **ORDER** today while supplies last.



"FatFoe has been clinically proven to help my patients lose weight... and keep it off."
Dr. L.P. Sunset Beach, CA

Bonus Offer!!

Order now and
get a free 60-day trial of FatFoe™
UltraThin Gel. Target the stubborn fat on your
hips & thighs with this proven flab fighter.
Click here for your free trial!

Take this quiz to find out if
FatFoe™ is right for your
unique metabolism.

- Yes No I tend to gain weight around the hips and thighs.
- Yes No I find it hardest to control my appetite late at night.
- Yes No I've tried other diets before, but have never been able to keep the weight off.
- Yes No I have a family history of weight gain.
- Yes No I sometimes step on the scale and find that I've gained 3-4 pounds for no reason.
- Yes No I often crave sweets and salty snacks.
- Yes No I find myself snacking in front of the TV even when I'm not hungry.

Submit Answers

FTC also takes action, but of a different kind....

<http://www.wemarket4u.net/fatfoe/index.html>

Scrutiny continues of compounding pharmacies

Owners drew \$16M from [New England Compounding Center] pharmacy tied to deaths *Boston Globe* 1/22/13

Judge freezes assets of NECC execs *Law360* 1/28/13

FDA investigators find safety concerns at 30 drug compounding pharmacies *CBS News* 4/12/13

Pharmacy owners agree to \$100 million settlement after meningitis outbreak *CNN* 12/24/13



**FDA Warns of Fraudulent
Ebola Drug Claims** *Reuters* 8/14/14

Recent Pharma/Device Off-Label Settlements

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

Recent Pharma/Device Off-Label Settlements (cont.)

Company	Settlement Amount	Anticipated Settlement Break Down	Issue(s)
<p>Pfizer Inc./Wyeth Pharmaceuticals, Inc.</p> <p>August 2014</p>	<p>\$35 million</p>	<p><u>Civil Settlement:</u> 41 States and DC</p>	<p>Wyeth's promotion of Rapamune</p>

Recent Pharma/Device Off-Label Settlements (cont.)

Company	Settlement Amount	Anticipated Settlement Break Down	Issue(s)
<p>GlaxoSmithKline PLC</p> <p>June 2014</p>	<p>\$105 million</p>	<p><u>Civil Settlement:</u> 44 States and DC</p>	<p>Marketing and promotion of Advair, Paxil and Wellbutrin</p> <p>Concealed risks associated with Paxil</p>

Recent Pharma/Device Off-Label Settlements (cont.)

Company	Settlement Amount	Anticipated Settlement Break Down	Issue(s)
Pfizer Inc. and Warner-Lambert Co. LLC May 2014	\$325 million	<u>Civil Settlement:</u> Class of third-party payors	Deceptive marketing of Neurontin First Circuit determined that off-label prescriptions harmed patients

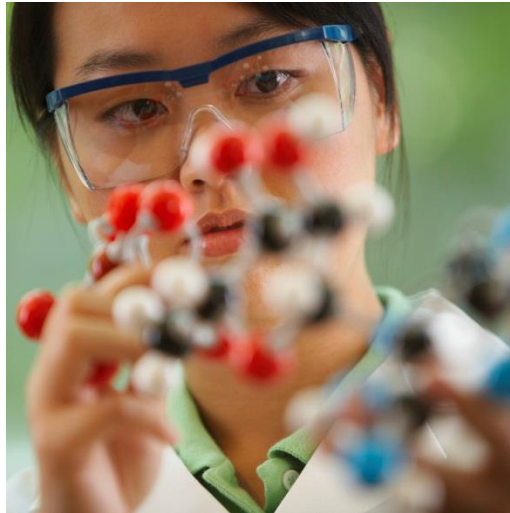
Recent Pharma/Device Off-Label Settlements (cont.)

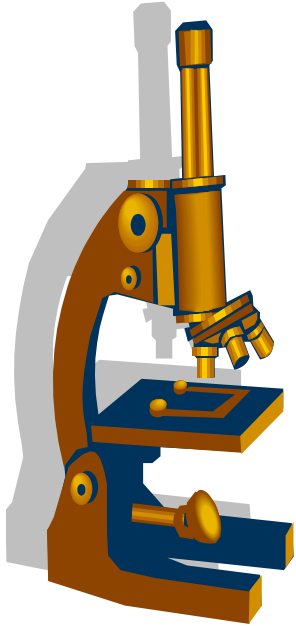
Company	Settlement Amount	Anticipated Settlement Break Down	Issue(s)
<p>Endo Pharmaceuticals, Inc.</p> <p>February 2014</p>	<p>\$193 million</p>	<p><u>Forfeiture of Assets:</u> \$20.8 million</p> <p><u>Civil Settlement:</u> Federal and State Governments : \$171.9 million</p>	<p>Marketing of Lidoderm</p>

Recent Pharma/Device Off-Label Settlements (cont.)

Company	Settlement Amount	Anticipated Settlement Break Down	Issue(s)
Astellas Pharma US Inc. April 2014	\$7.3 million	<u>Civil Settlement:</u> Federal and State Governments	Marketing and promotion of Mycamine

Research





Generally hard times for research:

NIH trials turn away new patients as shutdown obstructs work of scientists, researchers *Washington Post* 10/4/13

Up to 1000 NIH Investigators Dropped Out Last Year
Science/AAAS 3/7/14

Except this kind:

PCORI Approves More Than \$1 Billion In Funding for Effectiveness Research
BNA 11/25/13

PCORI Announces \$102 Million in Funding for Comparative Effectiveness Research Projects *AHLA HLW* 10/3/14

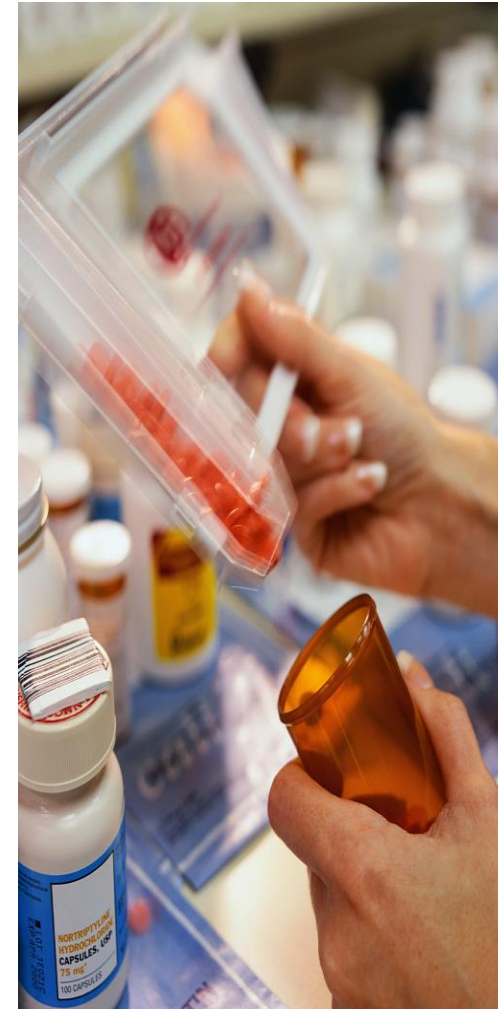
23andMe Hit with False Ad Suit Over DNA Tests *Law360 12/2/13*

US Court in Alabama Dismisses Negligence, Lack of Consent in SUPPORT [Clinical] Trial Class Action

Looney v. Moore, 2014 WL 234676
(N.D. Ala. 1/22/14)

Northwestern University to Pay \$2.9 Million To Settle Research FCA Fraud Complaint *US ex rel Theis v. Northwestern University,* (N.D. Ill., 09-cv-1943, settlement 7/30/13).

Emory to Pay HHS \$1.5 Million to Settle Double Billing Claims for Cancer Studies *Settlement <http://1.usa.gov/15cFhcj> BNA 9/18/13*



Final rule issued as part of physician fee schedule revises criteria, process for obtaining Medicare coverage of investigational device (IDE) clinical trials

78 Fed. Reg. 74230 (12/10/13)

Fifth Circuit finds public university could not be sued under FCA

- Terminated professor alleged TX Health Sciences Center falsified research data; further alleged retaliation and wrongful termination
- Fifth Circuit affirmed district court: Center was arm of state + not “person” under FCA, and retaliation claim barred under sovereign immunity
- *US ex rel King v. University of TX Health Sci. Ctr.*, 2013 WL 5881083 (5th Cir. 11/4/13)

Health Researchers Using EHRs to Identify Patients With Possible Undiagnosed Diseases *BNA 4/24/14*

Medicare and Medicaid



In October – Government Shutdown

See <http://www.thewire.com/politics/2013/10/ranking-best-newspaper-front-pages-government-shutdown/70049/>



Surprise ending to tumultuous year: Bipartisan Budget Act (H.J. Res. 59) signed on Dec. 26, 2013:

- Sets federal budget targets for FYs 2014 and 2015
- Provides sequestration relief for some federal programs, but not for Medicare providers – in fact, extends those cuts for two years, through 2023
- Includes three-month reprieve from 20.1% SGR cut (Jan 1-March 31, 2014) to provide time for broader reform
- Temporary extension of other Medicare provisions (therapy cap exceptions, geographic adjustments to physician payments, low-volume hospital payments, etc.)
- Various other Medicare policies impacting LTCHs, plus increased cuts in Medicaid DSH spending

And in April ... the “Protecting Access to Medicare Act of 2014”

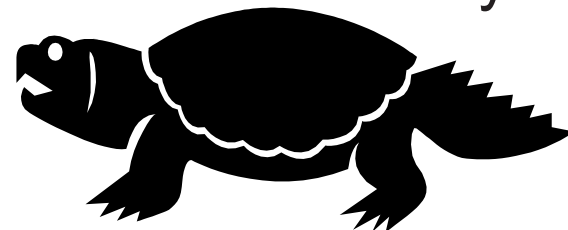
- Eliminates pending 24% physician SGR cut for a year
- Reforms physician fee schedule relative valuation process
- Extends two-midnights moratorium (more shortly)
- Reforms Clinical Lab Fee Schedule
- Adds imaging quality provisions
- Mandates SNF value-based purchasing
- Extends exception process for outpatient therapy cap
- Extends Medicare Advantage SNPs
- Delays until 10/1/15 transition to
- ICD-10



Sen. Ron Wyden “Approving another [SGR] patch simply defies common sense. It seems bizarre even by Beltway standards.”

10th Revision to Codes supposed to provide heightened coding precision in critical areas:

- W22.02XA: Walked into lamppost, initial encounter
- W22-02XD: Walked into lamppost, subsequent encounter
- Y93.J4: Injuries received while playing brass instruments
- Nine codes for macaw mishaps
- Separate codes distinguish “bitten by turtle” and “struck by turtle”
- R46.1: Bizarre personal appearance
- R46.0: Very low level of personal hygiene
- V91.07XA: Burn due to water skis on fire



CMS Final Rule: Two-Midnights Policy 8/2/13

- Hospital inpatient admissions presumed appropriate for beneficiaries requiring >1 Medicare utilization day (“crossing two midnights”)
- FAQs initially instructed MACs + RACs not to audit against rule through year end – unless hospitals gamed the system.
- Now “enforcement delayed” until March 2015 – but only by RACs – “Probe and Educate Audits” continue!
- Two federal court challenges filed by AHA + providers
- Final IPPS rule (8/4/14) included no changes to rule



More Payment Miscellany for Hospitals

Hospital Payments Under 8/1/14 Rule, Effective 10/1/14

- 3400 acute-care hospitals (IPPS hospitals): operating payment decline of approx 0.6%
- 435 long-term care hospitals (LTCHs) (primarily PPS hospitals): payment increase of 1.1%
- Percentage changes for hospital acquired condition

CMS Offers Partial Payment to Hospitals to Lessen Medicare Appeal Backlog *9/14*

AMA Sounds Alarm As Medicare Penalties Mount *Law360* *10/22/14 (citing a “tsunami of rules and policies” in recent years)*



Second round of CMS red tape reductions published 5/12/14 (first was 5/2012); among others:

- No need for medical staff member on governing board
- Critical access hospitals need not have physician present every two weeks
- ASCs need not have supervising radiologist
- Nursing homes will have three years to meet fire safety reqts
- Eliminates requirement for critical access hospitals to develop policies with outside CAH staff

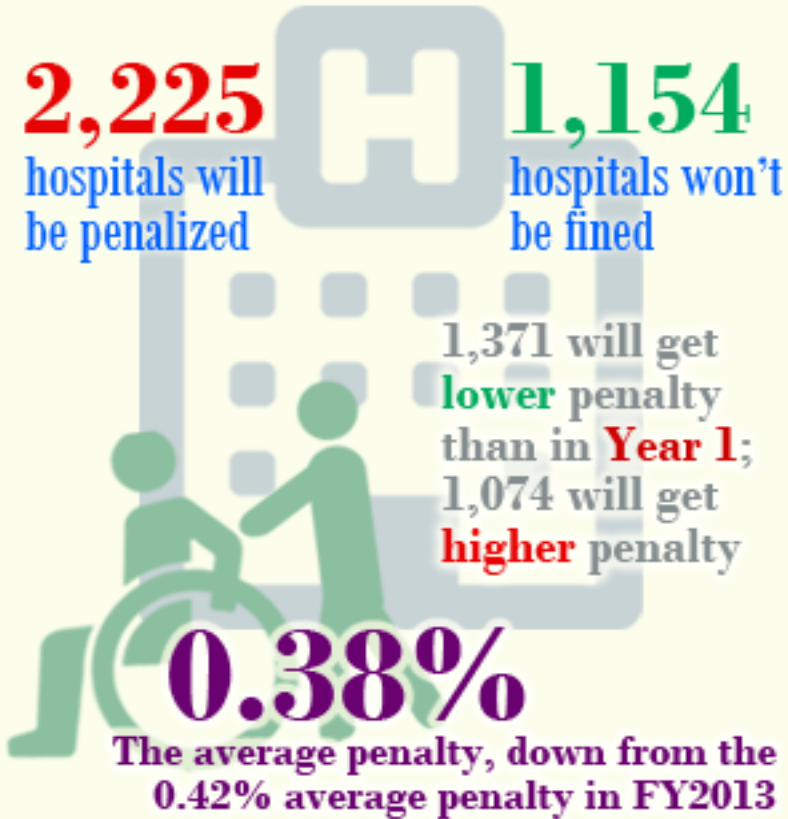
And in Other Medicare News:

Medicare To Cover Sex-Change Surgery *NY Times 5/30/14*

Hospital Charges Soar for Common Ailments, Data Shows *NY Times 6/2/14*

Hospital Readmission Reduction Program

Hospital Penalties Year 2 Medicare Readmissions Reduction Program



Source: KHN analysis of data from the Centers for Medicare & Medicaid Services

Medicare Fines 2,610 Hospitals in Third Round of Readmission Penalties Kaiser Health News 10/2/14

Hospitals serving large number of low-income patients were twice as likely to receive penalties (77%) as hospitals with the fewest poor patients (36%).

http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=102

Maximum reduction scheduled to increase from 2% to 3% in FY2015
(BNA 8/8/14)

Preventable Hospital Returns Cost Medicare Billions Law360 3/3/14

Graphic: Kaiser Health News 8/2/13

Medicare payments cut for more than 1,400 hospitals under value-based purchasing program *Modern Healthcare 11/15/13*

Program established by ACA; CMS “takes back” 1.25% of reimbursement, and then disperses based on quality measures plus patient satisfaction (approx \$1.1 B)

[April Fix] establishes VBP program for SNFs based on performance on hospital readmission



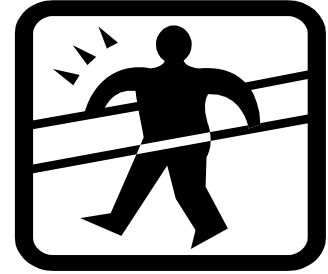
NOTE RE SUBMISSION OF QUALITY DATA: PAY ATTENTION TO DUE DATES

- *PAMC Ltd v. Sebelius*, 2014 WL 1363953 (9th Cir. 4/8/14) (*upholding 2% rate cut when quality data was submitted by hospital’s vendor 12 hours late*)

Long-Term Care Miscellany

Medicare Payments to SNFs To Increase \$750M

for FY 2015 *Final Rule 8/5/14*



SNF adverse events cost Medicare \$2.8 Billion...OIG finds

- 22% of Medicare beneficiaries with post-acute SNF stays had adverse events (including death)
- 59% were preventable:
- Issues were substandard care, inadequate resident monitoring, failure or delay of care *OEI-06-11-00370*

State Law Headlines of Interest

Oklahoma Law Allows Nursing Home Residents to Install Surveillance Cameras in Rooms *AHLA 11/24/13*

Long Island Nursing Home Workers Hired [Male] Stripper To Put On Show For Residents *CBS New York 4/8/14*

New “face-to-face encounter” regulations delayed ⁷⁷

Fed Reg 68891 (11/16/12) - but implementation delayed to TBD date in 2014 (9/13/13)

Medicare Competitive Bidding

Challenge to DME Bidding Rules Fails on Appeal in 8th Circuit

Key Med. Supply v. Burwell, 764 F3d 955 (8/25/14)

New DMEPOS regulations published 10/31/14

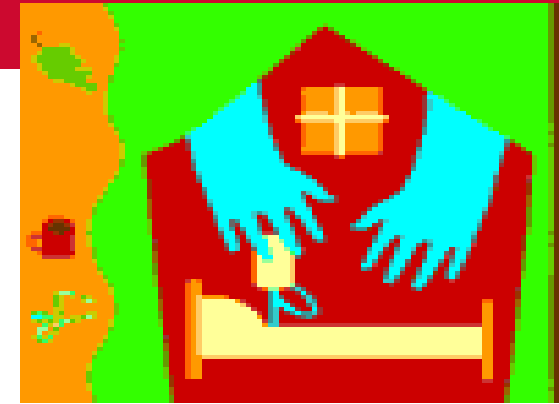
Define methodology for using competitive bidding prices to make national price adjustments

Decline to make changes to definition of “minimal self-adjustment,” for purposes of what individuals have “specialized training” for custom fitting

DME-MAC Medical Directors joint letter warns physicians about DME supplier marketing schemes See ngsmedicare.com

3/5/14





Hospice Patient Eligibility

The problem of patients living too long....

US ex rel. Smallwood v. Thi of Mich., N.D. Ala., No. 2:14-cv-00227, settlement announced 3/13/14.

CMS Announces Pilot Program to Give Hospice Patients Options for Palliative, Curative Care <http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-03-18.html>

New Restrictions: diagnoses of debility, adult failure to thrive, prohibited after 10/1/14

CMS final hospice payment rule for FY 2015 estimated to increase payments by 1.4% (\$230 million) in FY 2015; make various policy changes. 8/22/14

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

Home Health Agency Note: PPS Rule Finalized 10/30/14

New HHS Secretary Confirmed By the Senate 6/4/14: Sylvia Mathews Burwell



Health Info and



Baby Pictures at the Doctor's?

Cute, Sure, but Illegal **New York Times (8/10/14)**

Time-honored tradition of posting photos 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

Hackers Hit Health Care

April 2014: FBI warned H/C industry its protections were lax, making it vulnerable to hackers

April 2014: DeKalb Health (Ind.) website hacked

- Overseas hacking attack potentially impacted three different groups of patients

April 2014: Centura Health announces hackers breached pts' PHI through sophisticated "phishing" email attack targeting employees

June 2014: Hackers hit Montana Dept. of Public Health

- Stole data affecting 1 million persons

Aug. 2014: Community Health Systems announces it was victim of Chinese hackers

- Resulted in theft of SSNs and other personal data of 4.5 million patients

Aug. 2014: "Virulent Chinese Hacking Group Mows Through Medtech, Pharmaceutical Industries" (BNA Health Law Reporter 8/21/14)

- Health care now most targeted industry for hackers, surpassing retail



Did You Know...?

According to the Ponemon Institute:

- Breaches of medical info cost the industry **\$5.6B** each year
- The number of reported data breaches declined slightly last year, but criminal attacks on provider data increased **100%**



Fourth Annual Benchmark Study on Patient Privacy and Data Security (3/12/14)

<http://www.ponemon.org>

“The people in the healthcare industry are good people who sometimes do stupid things, and that is the source of a lot of the problems.”

“...[I]n the world of black market information, a medical record is considered more valuable than everything else.” Larry Ponemon, Ponemon Institute

“[Payment card] data expires rather quickly because financial institutions replace the cards. Your Social Security number and personal health record don't change. They have a long shelf life.” Rick Kam, President, ID Experts

Notable Breaches

Univ. of Washington Med. Ctr., Seattle (Dec. 2013)

- Hosp. employee opened email attachment w/ virus, which took control of computer w/ patient data; 90,000 patients notified

North Carolina Medicaid Agency, Raleigh (Jan. 2014)

- Medicaid cards for 49,000 children mailed to the wrong people

Detroit Medical Center, Detroit (March 2014)

- Employee found w/ PHI on 1000+ patients

Boston Medical Center (April 2014)

- Transcription co. posted MD notes of 15,000 pts. on website

Cedars-Sinai Medical Center, LA (Aug. 2014)

- 33,000 unencrypted pt. records on stolen laptop



“Medical information is among the most sensitive there is. There is simply no excuse to allow the data to be stored unencrypted on an employee’s laptop.”

Marc Rotenberg, Electronic Privacy Info. Ctr.

Federal Enforcement

Skagit County, WA (March 2014)

- First settlement w/ county govt; \$215K for posting ePHI on public server

Concentra Hlth. Svcs. (April 2014)

- Unencrypted laptop stolen; risk of theft recognized in prior analyses, but efforts to avoid risk were incomplete & inconsistent
- \$1.75M settlement with HHS

QCA Health Plan (April 2014)

- Unencrypted laptop stolen; \$250K settlement with HHS

NY-Presby. Hosp. & Columbia Univ. Med. Ctr. (May 2014)

- \$4.8M settlement; ePHI of 6800 pts. leaked when server errantly reconfigured

Parkview Health System (June 2014)

- Hosp. employees dumped boxes of pt. records on MD's driveway; \$800K settlement



Notable Settlements

Resnick v. AvMed, 2011 WL 1303217 (S.D. Fla., settlement approved 2/28/14)

Class action over theft of laptops w/ PHI of 1.2M customers

- 11th Cir. had allowed claims when plaintiffs showed actual identity theft and damages (693 F.3d 1317 (11th Cir. 9/5/12))

AvMed will pay \$3M into settlement fund for class members

- Those who suffered identify theft can file claims to recover their losses
- Those w/o proof of identity theft still can recover up to \$30 each (portion of ins. premiums that were supposed to be used to improve security)

First data breach settlement that also pays class members who didn't suffer identity theft



“[T]he lack of security we've seen with respect to the security standards at hospitals and other corporations is astonishing.” Plaintiffs' Atty

Also State Enforcement

Cal. v. Kaiser Found. Health Plan, 2014 WL 323740 (Cal. Super. Ct., Alameda Cnty., 2/14/14) \$150K settlement re three-month delay notifying 20,000 employees

- External hard drive w/ PHI donated, later purchased at public thrift shop

Triple-S Management Corp. (Puerto Rico, Feb. 2014)

- **\$6.8M** fine for including patient claim #s on mailing labels

Springer v. Stanford Hosps. and Clinics, #BC470522 (Cal. Super. Ct. LA, settlement filed 3/13/14)

- \$4M settlement for hospital vendor's posting PHI of 20,000 pts on student homework help website for one year

Women & Infants Hospital of Rhode Island (July 2014)

- Mass. AG collects \$150K for hospital's loss of 19 unencrypted backup tapes containing PHI of over 12,000 Mass. residents

No Harm, No Foul

No cause of action for PHI breach if no evidence of actual injury

- ***Polanco v. Omnicell, Inc.***, 2013 WL 6823265 (D.N.J. 12/26/13)
- ***Vides v. Advocate Health & Hosps. Corp.***, #13-ch-2701 (Ill. Cir. Ct., 5/27/14); ***Maglio***, 2013L-000538 (Ill. Cir. Ct. Kane Co 7/10/14); ***Tierney***, 2014 BL 252063 (N.D. Ill. 9/4/14) ***Sutter Hlth. v. Super. Ct. Sacramento Cnty.***, 174 Cal. Rptr. 3d 653 (Cal. Ct. App. 7/21/14)

But see:

- ***Tabata v. Charleston Area Med. Ctr.***, 2014 WL 2439961 (W. Va. 5/28/14)
 - Class status granted even though no evidence plaintiffs were victims of identity theft

Finally, some items you may have missed



How Being a Doctor Became the Most Miserable Profession



The Daily Beast (4/14/14)

- 9 of 10 doctors discourage others from joining the profession
- 300 physicians commit suicide every year
- Just processing ins. forms costs \$58 every patient encounter
- Average face-to-face clinic visit lasts about 12 minutes

*“Simply put, being a doctor has become a miserable and humiliating undertaking...
Not surprisingly, many doctors want out.”*

The stock market worries us sick

- A one-day **drop** in stocks of only 1.5% is followed by a 0.26% **increase** in hospital admissions over the next two days
 - Anxiety or panic attacks jump twice that much in just one day
 - Even people who don't own any stocks show same trend
 - Results based on three decades of admission data for CA hospitals
- This extrapolates to \$650M/yr in additional health costs
- Another study showed a “significant increase” in heart attacks during 2008-09 stock market crash

See report at:

<http://rady.ucsd.edu/faculty/directory/engelberg/pub/portfolios/HEALTH.pdf> 93

Startling Statistic of the Year – Part II

According to the Competitive Enterprise Institute:

The cost of federal regulations is now bigger than the entire economies of all but nine countries in the world

- On a per-household basis, federal regulatory costs average \$14,974, which is more than the typical household spends on just about anything else
- Last year, regulators issued 3,659 rules, equal to one new rule every 2½ hours of every day, or nearly two federal rules issued every business hour



“If U.S. regulatory costs of \$1.863 trillion were a country, it would be the world’s 10th largest economy.”

<http://cei.org/sites/default/files/Wayne%20Crews%20-%20Ten%20Thousand%20Commandments%202014.pdf>

Facebook, Apple Pay for Egg Freezing, Sperm Donors

Up to \$20,000 in benefits to help employees pay for infertility treatments, sperm donors, freezing eggs.

“The move comes amid stiff competition for skilled engineers, and as many of the biggest firms try to diversify their male-dominated ranks to include and appeal to more women.” abcnews.go.com 10/14/14

News prompts satire website “The Onion” to post story on: “Facebook Offers to Freeze Employees’ Newborn Children” theonion.com 10/17/14



Surgery photo leads to privacy lawsuit



LA Times (9/4/13)

- Anesthesiologist decorated pt's face with stickers while pt was unconscious; nurse took photo with cellphone
- Prompted a state investigation and privacy lawsuit
- Anesthesiologist disciplined but kept hosp. privileges

"I thought she would think this is funny and she would appreciate it."

-Anesthesiologist's deposition testimony

Issue with Hospital-Employed Physician

Johns Hopkins Hospital (Md.)

Hospital-employed physician wore hidden camera during GYN exams of over 3800 women over 25-year span

Physician committed suicide as police prepared to search his home

Victimized patients filed class action against hospital for common law invasion of privacy, battery & negligent hiring claims

Hospital settled class action for \$190 Million



“Nice Try” Award

Dietl v. Oz, 2013 WL 5511365 (N.Y.Sup.Ct. 10/10/13)

Dr. Oz recommended a “heated rice footsie” for sleeplessness

- Neuropathy prevented plaintiff from noticing overheated rice
- Feet seared; he claimed TV physician had duty to warn

Court found no physician-patient relationship

“Dietl has pointed to no authority that would lead this court to find a duty of care between a television talk-show host and his vast home-viewing audience, and Dietl fails to convince this court that creating such a duty would be sound public policy.”



Penn. Hospital to Open Country's First Inpatient Treatment Program for Internet Addiction

FoxNews.com (9/1/13)

Bradford Regional Med. Ctr. offering 10-day inpatient program following “digital detox” (no computer for 72 hrs.)

- During detox, many pts. exhibit depression, irritability & violence
- One patient resorted to chewing styrofoam cups & punching wall



“[Internet addiction] is a problem in this country that can be more pervasive than alcoholism. The Internet is free, legal and fat free.” Dr. Kimberly Young, program founder

Contact our presenter:



[Elizabeth Carder-Thompson](#)

Partner

Princeton/Washington, D.C.

ecarder@reedsmith.com

202.414.9213

Visit our webpage and blogs:

- [Life Sciences and Health Industry Group](#) webpage
- [Health Industry Washington Watch](#)
- [Life Sciences Legal Update](#)

Global Service Platform

USA
1,278
lawyers



Asia
130
lawyers



Europe/
Middle East
473
lawyers



History

- Founded in 1877
- More than 1,800 lawyers worldwide
- 25 offices throughout the United States, Europe, the Middle East and Asia

Thank You