Celestial Seasonings:

Reading the Tea Leaves of the Trump Administration's Compliance Initiatives

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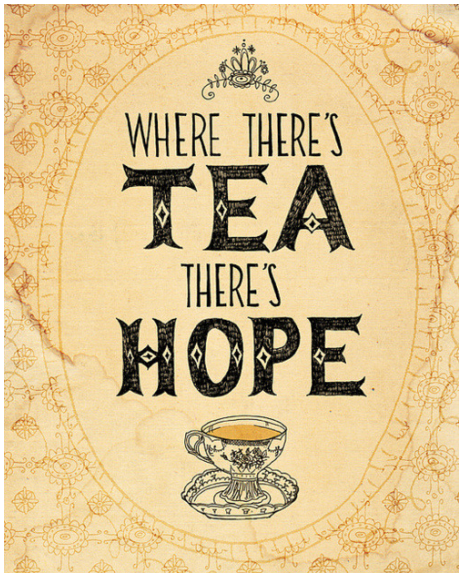
Nebraska Hospital Association Annual Convention

October 26, 2017

Your Speakers



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Who knew?

Reading Tea Leaves -- Tasseography

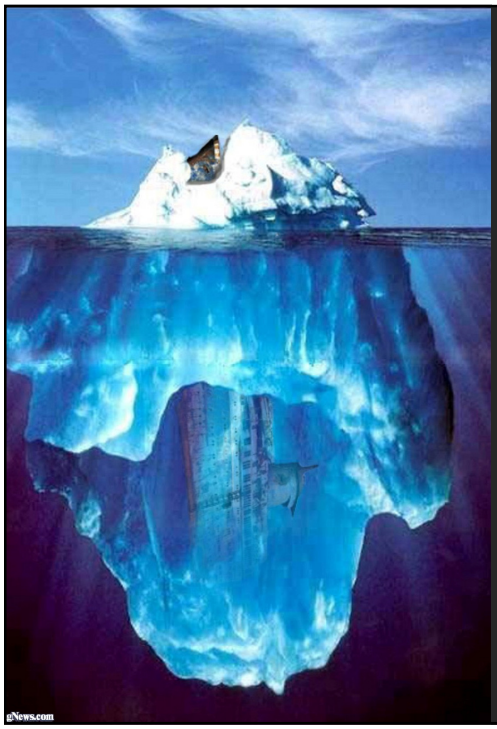
Agenda

- Overview and Key Players
- Initiatives
- Drill Down -- What we are seeing

Do Elections Really Matter?

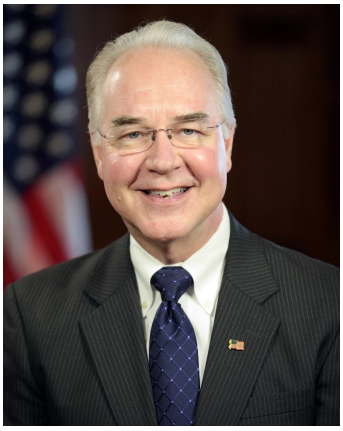
Factors Affecting New Administration Initiatives

- Pre-existing statutes and regulations
- How the statutes were drafted
- Bi-partisan consensus
- Budgetary constraints
- Existing, non-controversial efforts



The "Deep State"

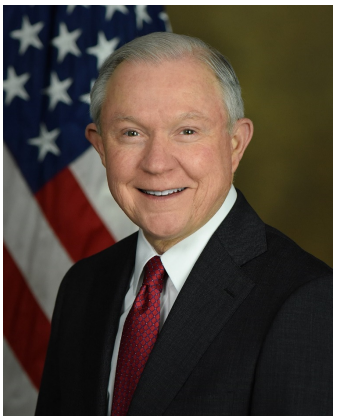
Key Players: Who is out



Key Players: Who is in

CMS Admin.
Seema Verma

Acting HHS Sec.
Eric C. Hargan



AG Jeff Sessions

Who might get in

FierceHealthcare

Healthcare

Former HHS Deputy Secretary Alex Azar among top contenders to replace Tom Price

by *Ilene MacDonald* | Oct 18, 2017 12:39pm

Key Players: Who is still there

Daniel J. Levinson, HHS Inspector General

Career Employees of HHS and DOJ

In principle, most would agree

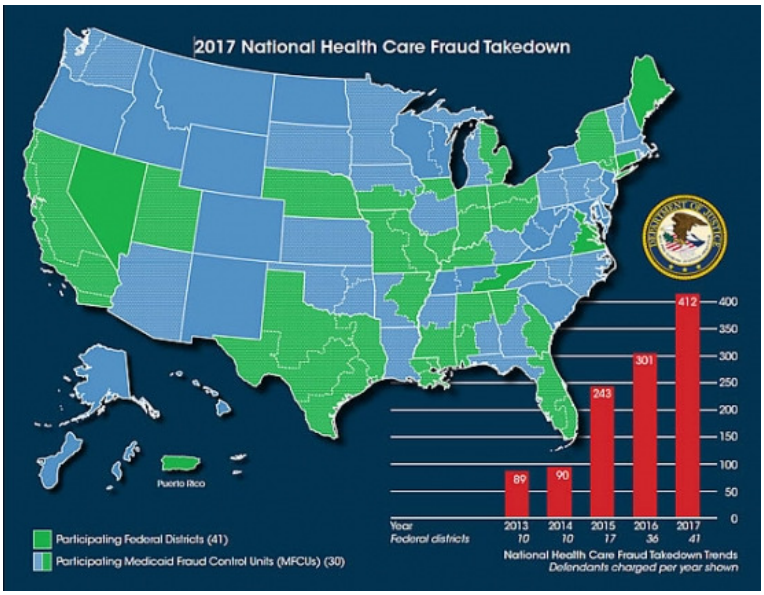
"Thou shalt not steal."

Initiatives

National Health Care Fraud Takedown

July 13, 2017

- 412 charged
- 41 federal districts
- 115 physicians, nurses, Other licensed
- 120 prescribers
- $1.3 Billion in false billings



Recent DOJ Enforcement Actions

Physician Relationships:

- New York Hospital Operator Agrees to Pay $4 Million to Settle Alleged Improper Payments to Physicians (Sept. 13, 2017)
- South Carolina Family Practice Chain, Co-Owner, and Its Lab Director Pay $2 Million to Settle Alleged Illegal Medicare Referrals and Billing for Unnecessary Medical Services (Sept. 11, 2017)
- Los Angeles Hospital Pays $42 Million -- Improper Payments to Physicians (June 28, 2017)

Recent DOJ Enforcement Actions

Medical Necessity

- Three Companies and Executives Pay $19.5 Million to Resolve Allegations about Rehabilitation Therapy and Hospice Services (July 17, 2017).
- Genesis Healthcare Inc. Pays $53.6 Million to Resolve Allegations -- Medically Unnecessary Rehabilitation Therapy and Hospice Services (June 16, 2017).

Recent DOJ Initiatives

Anti-Kickback Statute

- Co-Owners of Home Health Agencies Sentenced to 10+ Years in Prison for $20 Million Home Health Care Fraud Schemes (June 14, 2017).
- Psychiatrist Convicted of Health Care Fraud for Role in $158 Million Medicare Fraud Scheme (May 23, 2017).
- Blood Testing Laboratory to Pay $6 Million to Settle Allegations of Kickbacks and Unnecessary Testing (April, 28, 2017)

Direct from D.C.

- Acting Assistant A.G. Kenneth A. Blanco of the DOJ Criminal Division at the ABA's 27th Annual Institute on Health Care Fraud – (May 18, 2017)

  "… health care fraud is a priority for the Department of Justice. Attorney General Sessions feels very strongly about this. I can tell you that he has expressed this to me personally. The investigation and prosecution of health care fraud will continue; the department will be vigorous in its pursuit of those who violate the law in this area."

Tools Used

- **DOJ's Health Care Fraud Unit**
  - Within the Fraud Section of the Criminal Division of the DOJ.
  - 56 prosecutors focused solely on prosecuting complex health care fraud cases throughout U.S.
  - Identify and respond to emerging fraud trends across the country
- **Medicare Fraud Strike Forces located in 9 "hot spot" cities (and growing)**
  - Prosecutors
  - Investigators
  - Analytical resources with Criminal Division
  - U.S. Attorney's offices, FBI, HHS-OIG, CMS, state and local law enforcement

Medicare Fraud Strike Forces

- Use a wide array of investigative and prosecutorial tools.
- Traditional methods for developing information and evidence.
- Highly advanced data analysis to identify aberrant billing levels to target suspicious billing patterns and emerging schemes.
- Obtaining billing data from CMS in close to real time.

Medicare Fraud Strike Forces: Data Analysis

- Key part of investigations
- Permits focus on the most aggravated cases
- Helps quickly identify emerging schemes and new types of Medicare fraud
- Close to real time access to CMS billing data

"permits us to remain a step ahead. We have the opportunity to halt schemes as they develop. This cutting-edge method has truly revolutionized how we investigate and prosecute health care fraud."

Ass't AG Kenneth Blanco, speech before ABA's 27th Annual Institute on Health Care Fraud (May 18, 2017)

What Happens to the Information

". . . .we are pushing out the data we develop to U.S. Attorney's Offices and investigative agencies across the country, not just our Strike Force cities. Doing so empowers other prosecutors whether or not they are in a city with a Strike Force **by providing key data to fuel their investigations and prosecutions**.

This approach is proving to be very successful. Not only are violators being punished, often with steep fines and long prison sentences, but we are deterring further conduct. Specifically, our prosecutions have significantly reduced Medicare fraud and lowered payments for certain Medicare-reimbursed goods and services."

Ass't AG Kenneth Blanco, speech before ABA's 27th Annual Institute on Health Care Fraud (May 18, 2017) (emphasis added).

HHS Data Mining Efforts

- HHS-OIG Consolidated Data Analysis Center Program Manager, Steve Shandy
- "We fight fraud, waste, and abuse in Medicare, Medicaid, and more than 100 other HHS programs."
- HHS-OIG Consolidated Data Analysis Center
  - Mission: Provide data analytics, modeling, and tools to assist OIG oversight activities to detect and prevent fraud and protect HHS programs and beneficiaries.

Consolidated Data Analysis Center Program

- Analytic support for OIG components
- Analytic support for Interagency projects and initiatives – e.g., Medicare Fraud Strike Forces
- Develop new analytic systems and tools

  (e.g., apps for investigators)
- Develop fraud detection methods and predictive models -- 5 models
- Data acquisition & warehousing
- Staff: 10 analysts in Regional Offices and in DC.

OIG Analysis Approaches

- ✓Total Payments and Trends
- ✓Per Capita Payments
  - ✓Total eligible
  - ✓Beneficiary utilization (avg. payment/bene)
- ✓Disproportionate Payments
- ✓Questionable Billings (See published OEI reports for Part D pharmacies, HHAs, etc.)
- ✓High-Risk Providers (Not published)
  - ✓Several provider types for Medicare parts A, B & D

Payments by Geographic Area (PAYGAR)

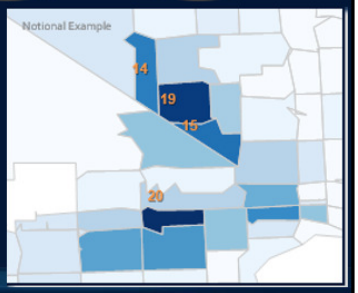
- Analytic methodology OIG developed for Medicare Fraud Strike Force expansion
- Current Metrics
  - Total Payments
  - Per Capita Payments ($ / Enrolled Benes)
  - Disproportionate Payments Exceeding 2X US Avg.
  - Disproportionate Payments Exceeding 3X US Avg.
- Future possibilities
  - Per Patient Payments ($/patient who rec'd service)
  - Medicaid (T-MSIS) and HHS grants

CDAC Predictive Modeling

- Developing statistical models to calculate "risk scores" for providers who may be defrauding Medicare

Assemble training data → Develop predictors → Train model → Apply model to new data

- Developing statistical models to calculate "risk scores" for providers who may be defrauding Medicare
- Mapping of high-risk provider locations
- Leverage access to new data sources to add richness to the models



9/26/2017 32

Source:
OIG Analytics and Medicare Trends, Steve Shandy, Supervisory Program Manager HHS-OIG Consolidated Data Analysis Center, AHLA Fraud and Compliance Conference, October 6, 2017

Questionable Billing: Home Health Fraud Hot Spots

High percentage of …
1. Episodes for which the beneficiary had no recent visits with the supervising physician
2. Episodes that were not preceded by a hospital or NH stay
3. Episodes with a primary diagnosis of diabetes or hypertension
4. Beneficiaries with claims from multiple HHAs
5. Beneficiaries with multiple home health readmissions in a short period of time

9/26/2017 31

Source:
OIG Analytics and Medicare Trends, Steve Shandy, Supervisory Program Manager HHS-OIG Consolidated Data Analysis Center, AHLA Fraud and Compliance Conference, October 6, 2017

The Yates Memo

-- September 9, 2015

- ❑Cooperation credit requires providing the Department all relevant facts about individuals involved in corporate misconduct
- ❑Criminal/Civil corporate investigations focus on individuals from beginning of investigation
- ❑Unless extraordinary circumstances, no provide protection from criminal or civil liability for any individuals

The Yates Memo

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

Sally, you're Fired!
Jan. 30, 2017

Is "Yates" still operative even though Sally is gone?

"We must now follow the Yates memo. "It's still in place, and it's still in effect." AUSA Margaret Hutchinson (E.D. Pa.) (*Bloomberg BNA*, June 8, 2017)

Individual Accountability

Former Executive of Tenet Healthcare Corporation Charged in $400 Million Scheme to Defraud (Feb. 1, 2017)

But, Wait. . . There's More!

Deputy AG Rod Rosenstein
(Sept. 14, 2017)

"I don't have any announcement about that today, but I do anticipate that we may in the near future make an announcement about what changes we're going to make to corporate fraud principles."

"Corporations, of course, don't go to prison. They do pay a fine, ...The issue is can you effectively deter corporate crime by prosecuting corporations or do you in some circumstances need to prosecute individuals. I think you do."

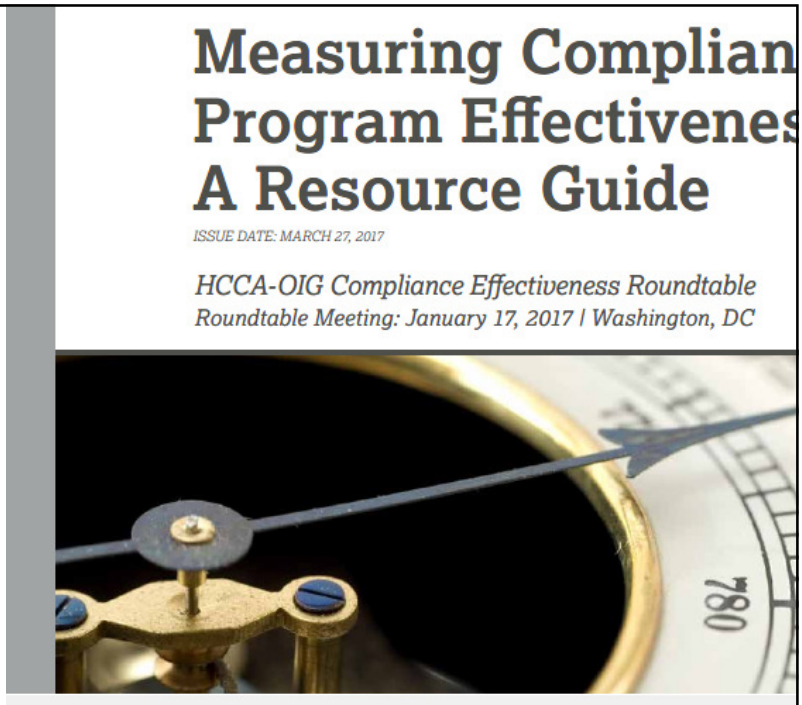
http://www.politico.com/blogs/under-the-radar/2017/09/14/corporate-crimes-prosecutions-rod-rosenstein-242721

Maturing Compliance Programs

- DOJ Publication – Criminal Division Fraud Section February 2017 -- Evaluation of Corporate Compliance Programs -- https://www.justice.gov/criminal-fraud/page/file/937501/download
- Questions that the Fraud Section has "frequently found relevant in evaluating a corporate compliance program"
- Not a checklist or formula

Other Initiatives

- **HCCA-OIG Publication –**
- ***Measuring Compliance Program Effectiveness: A Resource Guide*, March 2017**



Program Effectiveness

- Collects as many ideas as possible
- Broad enough to help any type of organization
- Allows the organization to choose which ones best suit needs

Element 4: Communication, Education, and Training on Compliance Issues		
	What to Measure	**How to Measure**
	Training:	
4.1	The organization provides risk area specific training to employees designated to be in high risk positions.	• Audit to ensure the organization has designated the positions deemed to be high risk (coding, billing, physicians, etc.) and established training requirements for these high risk positions. • Compare risks posed by these positions against training materials to ensure specific risks are addressed. • Audit high risk training completion rates.
4.2	The organization has established a compliance training plan. The organization assures that training is completed according to the established plan. The training plan is periodically updated or refreshed.	• Conduct document review to ensure the training plan exists and includes required training, expected audience, topics covered, and method for deployment. • Audit sign-in sheets or other tracking tools to ensure individuals are attending required training. • Review to ensure training plan is periodically updated.
4.3	The organization defines the appropriate audience for each type of compliance training (general, issue specific, high risk, etc.).	• Audit job codes to ensure the correct training has been assigned. • Review job codes to ensure training, including job specific job training is being conducted according to the established training plan.
4.4	The organization offers CEU's, when appropriate, for its compliance education and training.	• Perform a documentation review to determine the extent to which the organization offers CEUs for compliance training. • Evaluate the effect of offering CEUs on training completion rates.
4.5	The organization has established a process, policy	Conduct a document review to ensure a process for communicating and training employees on

Measuring Compliance Program Effectiveness

- Not a "checklist"
- May choose to use only a small number of these in any given year.
- Using all or even a large number is "impractical and not recommended. "
- The utility of any suggested measure depends on organization's needs

OIG Work Plan

- Previously, updated once or twice each year
- Effective June 15, 2017, OIG will update its Work Plan website monthly
- The monthly update includes newly initiated Work Plan items
  - Found on the Recently Added Items page
  - This web-based Work Plan will evolve

OIG Work Plan: https://oig.hhs.gov/reports-and-publications/workplan/index.asp

- **Active Projects: https://oig.hhs.gov/reports-and-publications/workplan/active-item-table.asp**
- **New Items: https://oig.hhs.gov/reports-and-publications/workplan/updates.asp**

OIG Advisory Opinions

- Relatively few so far
- Adv. Opin. 17-03 (Aug. 18, 2017) -- Pharmaceutical manufacturer's proposal to replace products that require specialized handling at no additional charge to the purchaser – OIG would not impose administrative sanctions
- Adv. Opin. 17-04 (Aug. 24, 2017) -- preferred hospital" network as part of Medicare Supplemental Health Insurance ("Medigap") policies, provide a premium credit of $100 to policyholders who use a network hospital for an inpatient stay -- OIG would not impose administrative sanctions

OIG Advisory Opinions

- Adv. Opin. 17-05 (Aug. 30, 2017) -- Retail pharmacy chain proposal to allow Federal health care program beneficiaries to participate in a paid membership program providing discounts on certain prescriptions and clinic services – No sanctions

Drill Down – Other Current Trends

UCR – Usual and Customary

- Non-participating Providers are taking a hit as insurance companies ratchet non-par UCR rates down.
- Payers are reimbursing non-par providers at a much lower rate :
  - reduce their liability for payment;
  - save money; and
  - disincentivize their members to use out of network providers.
- The result is lower payments for non-par providers and risk in having to collect the balance from patients.

Geographic Reimbursements

- Obviously, geography plays a large part in reimbursement throughout the country.
- Medicare has rates tied to the location of the facility.
- California is higher, Mississippi is lower.
- The number of insurance companies in the area also has a factor because there is less incentive to negotiate (on either side).

- Nebraska has one of the highest reimbursement rates in the US because;
  1. It has a very spread-out population
  2. The population is relatively financially sound
  3. There is one major insurance company that holds the majority of the market (BC/BS of Nebraska

- The proposed fees for the PAMA (Protecting Access to Medicare Act) have been proposed, the ACLA is protesting due to:
  - The new proposed rates are so low that smaller and clinical labs with less volume will not be able to financially survive these Medicare cuts.
  - This could mean significantly reduced fees for all Medicare providers should these fees be implemented.

- Physicians who were previously employed with large hospital groups are beginning to return to private practice:
  - Initial physician salaries and benefits are being reduced because of lack of volume, admissions or other evaluating factors
  - Non-competes are being rescinded for physicians with large patient panels, and those who provided high numbers of referrals to the hospital.
  - In Louisville, 25 physicians were laid off when Jewish Hospital and St. Mary's Hospital announced they were for sale.
  - Physicians with non-competes are, in some cases, taking a sabbatical, attending a fellowship, and returning in one year to resume practice, outside of the hospital.

- The inability to pass a new healthcare bill and the reluctance to pass funding for individual subsidies leaves the individual mandate for healthcare in turmoil.
- Open enrollment for the exchanges and many other insurance plans begins October 1, 2017 for coverage beginning 1/1/2018.
  - Beef up your front line of defense.
  - Get downpayments, co-pays and co-insurance for all procedures.
  - Verify and validate coverage prior to any procedure.
  - Many who had coverage will no longer be covered
  - Protect yourself financially, at least cover cost of procedure

- As of 10/13/17, Trump has determined that insurance subsidies will no longer be paid to insurance companies for Exchange policies to lower coinsurance and copays. These subsidies were due October 20, 2017.

- Investigations and litigation have been ramped up in the healthcare world
  - On September 22, 2017, the OIG published a report that alleges that acute care hospitals owe CMS more than 51.6 million.
  - These fees are related to outpatient services that were provided to patients when they were inpatients at other facilities, such as:
    - Lab
    - Radiology
    - Medical testing (EKG, EMG, etc.)
    - Physical therapy, occupational therapy, speech therapy
  - The encounter dates are as between Jan1, 2013 and 8/31/2016.

- Fair Market Value
  - As hospitals begin the difficult task of renewing physician employment agreements, the subject of fair market value rears it's ugly head. Agreements must:
    - Be assessed for providers (or any entity) being reimbursed at fair market value for service rendered.
    - Have a list of what services would be provided in exchange for this reimbursement.
  - Documentation must be kept as to services actually being provided for that reimbursement
    - Appointment schedules
    - Medical director schedules, records reviewed, and meetings attended
    - Etc. – you get the picture

- HEAT – Healthcare Fraud Prevention and Enforcement Action Team
  - Comprised of both DOJ and HHS members
  - Usually crosses state lines
  - Usually involves more than one provider
  - Can be targeted a one multi-state provider
  - Usually has the potential of a very large recovery

  - CAN BE WRONG

- Most targeted areas in 2017 by HHS, OIG and CMS
  - Pill Mills, Pain Management and Drug Testing
  - Genetic testing labs – lack of medical necessity
  - Lack of oversight – billing companies, internal billing staff and "adjusting medical records"
  - Home health agencies – false reporting, providing worthless services
  - Hospice – lack of certification by physician in terms of prognosis
  - Kickbacks by prescription drug and DME salesmen
  - Behavioral health – billing inconsistencies