



Accountable Care Organizations, Bundled Payments, Risk Contracting: An Ever Changing Landscape

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ACO Update
&
Impact of ACA Insurance Reforms
on Providers

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ACO Update – Topics Today

- Status of ACOs
- Pioneer Results
- Current ACO Issues

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ACO Background

- Shifting the payment paradigm from FFS/volume to quality/cost
- Triple aim
 - Lower costs
 - Improved quality
 - Better health outcomes

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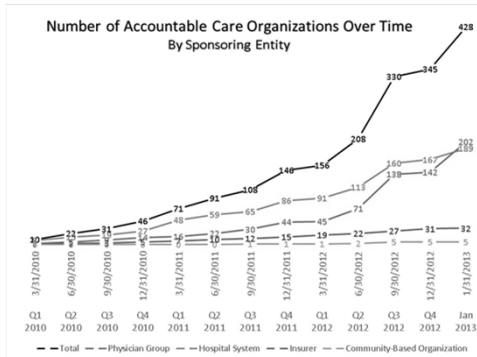
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ACO Models

- Various models
 - CMS – Medicare Shared Savings Program (MSSP) - § 3022
 - Center for Innovation testing different ACO models - § 3021
 - Pioneer ACOs
 - Advance Payment ACOs
 - Commercial ACOs

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Current Status of ACOs



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Current Status of Medicare ACOs

- 23 Pioneer ACOs (down from 32)
- 227 MSSP (220 + 7 converting Pioneer)
- 35 Advance Payment ACOs
- Next round due January 2014

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What Percentage of Medicare Patients are Covered by an ACO?

- 1%
- 3%
- 5%
- 10%
- 25%

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Pioneer ACOs



Source: Centers for Medicare & Medicaid Services

Pioneer ACOs – 1st year results

- Average cost growth of .3% compared to .8% overall
- All participants improved patient care on quality measures and patient satisfaction
- 13 – significant savings, earned reward
- 5 – savings, not enough for reward
- 12 – above budget, but no repayment
- 2 – above budget, repayment due

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Advance Payment ACOs



Advance Payment ACOs

- Designed for small physician groups and rural providers
- Lump sum of \$250k in advance
- \$36 per beneficiary in 1st month
- \$8 per beneficiary every month
- No paybacks

Current Regional ACOs in Medicare

- Notable area participants
 - SERPA-ACO (Advance Payment)
 - Trinity Pioneer ACO (Pioneer)
 - Alegant Health Partners, LLC (MSSP)
 - Mercy ACO (MSSP)
 - Iowa Health Accountable Care, L.C. (MSSP)
 - University of Iowa Affiliated Health Providers, L.C. (MSSP)

ACOs – Current Functional Issues

- Specialist exclusivity/beneficiary attribution
- Lack of beneficiary engagement
- Patient use of non-ACO providers
- Costs to operate
- Quality measurements
- Impact on compensation if only Medicare
- Rebasing

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ACOs – Current Legal Issues

- Extent of waivers
 - Beneficiary inducement
 - Non-ACO activity
- Antitrust
 - Small markets – 30% safe harbor
 - Non-risk contracts
- Effect on tax exemption

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Bundled Payment Program

- On January 31, 2013, CMS announced:
 - Model 1:
 - 32 awardees
 - Models 2-4:
 - Phase 1 – More than 100 participants partnering with over 400 provider organizations to receive more data for Models 2-4
 - Includes 48 different clinical care condition episodes
- Will start 10-1-13 or 1-1-14

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Bundled Payment Program

- For Models 1-3, Providers can share in gain after regular payments are made:
- **Model 1 – Inpatient stay**
 - Can include gain-sharing
- **Model 2 – Inpatient stay and post-acute care (either 30 or 90 days)**
 - Can include gain-sharing. Includes downside risk
- **Model 3 – Post-acute care only (a minimum of 30 days following discharge)**
 - Includes downside risk
- **Model 4 – Inpatient stay**
 - Hospital is paid a bundled amount to encompass all services during the inpatient stay. Hospital responsible to pay all physicians and other practitioners out of the bundled payment

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Impact of ACA Insurance Reforms on Providers – Topics Today

- Essential health benefits
- New insurer competition paradigm
- ED sign-up
- Enrollment/premium assistance
- Impact on 501(r)
- Premium grace periods

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Essential Health Benefits

- | | |
|-----------------------------------|---|
| – ambulatory services | – laboratory services |
| – emergency services | – preventive and wellness services |
| – hospitalization | – chronic disease management |
| – maternity and newborn | – pediatric services, including oral and vision |
| – mental health & substance abuse | |
| – prescription drugs | |
| – rehab services | |

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New Insurer Competition Paradigm

- No longer on coverages
- New payor competition paradigm
 - Narrow network products
 - Premium price points
 - Provider incentives and collaborative delivery systems

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Can a Provider Pay Premiums?

- AHA Legal Advisory – concerns with provider subsidies
 - Anti-kickback statute
 - Tax-exemption
 - Financial assistance?
 - Private benefit to the health plan?

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Can a Provider Pay Premiums?

- Secretary Sebelius - October 30, 2013
 - Marketplace policies are not federal health care programs
 - No anti-kickback concerns
- No current IRS guidance
- CMS Statement, November 4, 2013
 - Skew insurance risk pool

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ED Sign-ups?

- NO
 - Select and pay premium between 1st and 15th of a given month
 - Coverage begins on the 1st day of the following month
 - Select and pay premium between 16th and end of month
 - Coverage begins on the 1st day of the second month

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ED Sign-ups?

- Exchange open enrollment period
 - Open enrollment: 10/1/2013 – 3/31/2014
 - Thereafter 10/15 – 12/7 each year
 - Special enrollment – 60 days
 - Must satisfy certain criteria
 - Birth/adoption
 - Marriage
 - Loss of minimum essential coverage
 - Others

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Impact on 501(r)

- Tax-exempt hospitals must have a written financial assistance policy in place
- Will the exchanges eliminate need for financial assistance?
- Can copays and deductibles be subject to financial assistance?

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Premium Grace Periods

- Consumers will owe monthly premiums once they sign up
- 3-month premium grace period
 - Enrollees who receive advance premium assistance (advance on the tax credit) and pay one month's share of premiums
- Issuers must notify providers "as soon as practical" when in grace period

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Premium Grace Periods

- Health plan is responsible during first 30 days of grace period
- Providers must collect directly from patient for last 60 days
- Issuers may "pend" claims for the second and third months
- Puts providers at risk for patient's failure to pay portion of premium

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Premium Grace Periods

- Current Provider proposals to CMS:
 - Providers requesting that health plans be responsible during entire grace period
 - On-line insurance verification checks, including if in grace period

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“Navigating” the Insurance Exchange Territory – Preparing Your Organization for Consumer Assisters

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“Navigating” the Insurance Exchange Territory –
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Agenda

- Background
- Navigators
- Non-Navigators
- Certified Application Counselors
- Issues facing health care organizations

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Confused by a Sea of Options

55% of Uninsured
Have Never Heard of Exchanges*

*Kaiser Family Foundation, June 2013

36% of Enrollees Need More Information
and Help in Evaluation Process*

*CVS Caremark Survey, July 2013

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Confused by a Sea of Options

- Health insurance marketplaces now open to consumers (Oct. 1)
- Educating and enrolling consumers (new and existing) requires outreach efforts
- “Assister”-like programs are not new and (until recently) have not been controversial (e.g., Medicare enrollment/SCHIP program)

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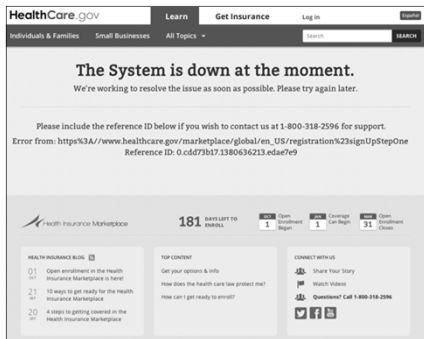
Confused by a Sea of Options

- Marketplaces designed to be “one-stop shop”
- Process of comparing plans, applying for subsidies and enrolling is not always easy
- Many individuals new to insurance process
- Organizations’ missions may include connecting patients with health care

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The Perfect Storm?



The Crew

- Navigators
- Non-Navigator Assisters
- Certified Application Counselors (CACs)
- Champions for Coverage
- Everybody else (financial counselors, business office personnel)

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Navigators

- Marketplace must make grants to Navigators
- Available in states with federally-facilitated marketplace and federal-state partnership
- Providers may be Navigators
- HHS standards (30 hours training; conflict of interest rules, etc.)

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Navigators

- **Nebraska**
 - Community Action of Nebraska, Inc.
 - Ponca Tribe of Nebraska
 - Certification/licensure criteria (LB 568, June 2013)
- **Iowa**
 - Genesis Health System (through GVNA)
 - Visiting Nurse Services of Iowa
 - Planned Parenthood of the Heartland
 - Certification/licensure criteria (HF 2645, May 2012)

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Navigators - Duties

- Perform public education and outreach activities
- Distribute fair and impartial enrollment information on health plans and availability of federal subsidies
- Facilitate enrollment
- Provide referrals for grievances/complaints
- Information linguistically and culturally appropriate

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Non-Navigator Assisters

- Provide essentially the same services as Navigators
- Not available for pure Federal exchange states
- HHS standards (30 hours training; conflict of interest rules, etc.)
- Providers may be Non-Navigator Assisters
- HHS requires same education, training, and conflict of interest standards as Navigators

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Certified Application Counselors

- Each exchange/marketplace must offer CAC services
- Community based organizations - existing relationships with potential applicants
 - Modeled after Medicare SHIP program
- Designated entities apply online; written agreements with CMS
- HHS requirements (5 hours training; conflicts of interest standards, etc.)

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Certified Application Counselors

- Fewer “required” duties than Navigators
- Required to provide assistance with enrollment
- No outreach or education requirements
- Not precluded from performing community outreach
- May not charge consumers for assistance

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Champions for Coverage

- Various types (community health centers, hospitals, civic organizations)
- Use publicly available materials from CMS to help individuals understand marketplace options
- Entities complete online application to become Champions for Coverage

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Staying Afloat

- Organizations are motivated to enroll
- Employing assisters/using volunteers
 - Background checks
 - Previous experience?
 - Is your staff already doing similar activities?
- Training front-line staff
- Education throughout the organization

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Staying Afloat

- Targeting and educating consumers (external)
 - Outreach beyond the walls of your organization
 - May or may not be existing patients
 - Creative efforts – traditional advertising; webinars

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Staying Afloat

- Targeting consumers (internal)
 - Accretive Health – managed billing and debt collection for MN hospitals
 - Efforts to maximize revenue (ED patients upfront; bedside demands)
 - AG alleged Accretive accessed too much information about patients
 - \$2.5M settlement with MN Attorney General
 - Stemmed from privacy violation; expanded to debt collection practice

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Staying Afloat

- Targeting consumers (internal)
 - Process should be similar to assistance already provided for Medicare/Medicaid enrollment
 - HIPAA concerns
 - Disclosures to outside/community-based CACs
 - Timing – disclosures/referrals before a visit?

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Staying Afloat

- EMTALA
- Time-intensive efforts
 - HHS estimates 1 hour for typical client
- Physical space
- Separate set of privacy and security standards
- Follow-up questions and assistance

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Full Speed Ahead

- Navigators
 - <http://www.cms.gov/CCIIO/Programs-and-Initiatives/Health-Insurance-Marketplaces/Downloads/navigator-list-10-18-2013.pdf>
- CACs
 - <http://localhelp.healthcare.gov>
- Champions for Coverage
 - <http://marketplace.cms.gov/help-us/champions-for-coverage-list.pdf>

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Physician Compensation: Fair Market Value Compliance in a Changing World

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Physician Compensation – Fair Market
Compliance in a Changing World

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Physician Compensation – Who’s
Watching?

- IRS
- OIG
- CMS
- State Attorney Generals
- Property Tax Assessors
- Congress
- Unions
- The Press
- The Public
- Qui tam plaintiffs and law firms

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Goals of Physician Compensation System

- Fair both internally and externally
- Motivate/induce
- Retain good physicians
- Consistent with culture
- Compliance with law

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Qui Tam

- Most new Stark/anti-kickback cases are *qui tam*
- Whistleblower files suit, can earn 15-25% if U.S. intervenes, 25-30% if not, plus attorney fees and costs
- Employees are protected
- Several law firms advertising for such cases on internet
- Sanctions for frivolous, vexatious suits

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Safe Harbors?

- No safe harbor for physician compensation
- CMS: Reference to multiple, objective, independently published surveys remains a prudent practice for evaluating fair market value

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Commercial Reasonableness

- It's not just FMV
- Stark definition of "commercially reasonable"
 - Makes commercial sense in absence of referrals
 - If by a reasonable entity, similar type and size
 - And a reasonable physician of similar scope and specialty

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Reliance on Survey Data - ABA Health
Law Journal article, November 2013

- Is it FMV when losing money?
- Is it commercially reasonable when losing money?
- Issues with reliance on survey data
 - Effect of local market reimbursement
 - Not statistically valid
 - Does not consider cost and income

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Scenario 1

- Hospital acquires medical practice of FP Clinic, physicians don't want to be employed
- Hospital contracts with the PC to staff the clinic
- Hospital clinic offers lab, x-ray, and PT services
- Hospital pays the PC 51% of collections (all services at the clinic)
- PC divides the amount into 2 pots
 - Non-Stark services – paid based on percentage of such services ordered
 - Stark services – paid based on Stark services ordered in *prior* year

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Comments on Scenario 1

- *Heeseh v Diagnostic Physicians Group*
 - Qui tam action filed in Alabama federal court
 - Filed by physician formerly with PC
 - US intervened in July 2013
 - Alleged to violate Stark
 - Now pending

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Scenario 2

- Hospital contracts directly with individual ENT for:
 - Medical directorship
 - Emergency on-call coverage 5 days per month
- ENT is shareholder of private practice PC
- ENT retains billings for emergency services provided while on call
- Flat compensation for both duties at \$20,000/year
- ENT is not asked to document her time dedicated to medical directorship

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Comments on Scenario 2

- IRS takes aggressive position on mischaracterized employment:
 - Medical directorship at risk based on recent IRS comments
 - On-call service more likely independent contractor
 - Retained reimbursement for services
- Risk of recharacterization reduced if contracted directly through PC
- IRS audits focus on employment/independent contractor
 - Payroll tax withholding

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Comments on Scenario 2

- Fair Market Value of medical services
 - Medical directorship
 - Typically at hourly rate specific to specialty
 - Market research needed
 - On-call coverage – market driven
 - Varies geographically
 - May need valuation expert

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Comments on Scenario 2

- Documentation of ENT hours
 - Medical directorship
 - Required by CMS: cost report practices
 - Call coverage
 - Not so important in acute hospital
 - CAHs need to back out direct patient care services so as not to pass through on-call comp on cost report if Part B reimbursement is already paid

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Scenario 3

- Governmental hospital employs general surgeon
- Pays flat salary at median MGMA
- Pays hourly rate for medical director services at median MGMA, anticipates 20 hours/month
- Pays for call coverage at median MGMA on-call rate
- Pays a quality incentive of up to 10% of base
- Pays him \$10k/year for services on quality committee
- General surgeon is married to hospital CFO

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Comments on Scenario 3

- Stacking – Each component appears to be FMV, but problem when aggregated
- *US v Campbell* – Part-time employment of cardiologists to teach, lecture, research, \$50k to \$180k – Excess payment for referrals
- *US v Borrasi* – Nursing home comp of medical directors, no services despite contract

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Comments on Scenario 3

- Section 501(c)(3) entities
 - Intermediate sanctions
 - Presumption based on expert opinion on FMV/reasonable comp, reviewed and approved by governing board
- Governmental entities without 501(c)(3) exemption
 - Still benefit from expert valuation advice with regard to AKS and Stark compliance and public body expenditures issue

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Scenario 4

- CAH employs FP, who supervises 2 PAs
- Paid at 65% of his own gross billings plus \$10k for supervision
- Annual comp is at 90th percentile (MGMA)
- He is third FP, community need is 2.5, production at 40th percentile (MGMA)
- PCP is scheduled only 4 weekdays in the office; rotates for Saturday clinic
- PCP is on-call one weekend in four

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Comments on Scenario 4

- MGMA analyzes productivity only on RVU basis
 - CAH may need to engage valuation expert to convert gross billings to RVU to determine productivity
- Need for staff despite low demand for services may justify higher %tile comp than productivity would support
 - Must document unique market influences

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Comments on Scenario 4

- Valuation of call
 - Changed within past 10 years when local rural physicians demanded call rate equal to that paid locum tenens or other contracted physicians
 - Substantial call can support substantial comp
- FTE valued by WPS at \$248k, based on Department of Labor data, including call, administrative duties and PA supervision

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Comments on Scenario 4

- Tuomey Healthcare System facts:
 - Base Salary based on professional collections
 - Productivity bonus: up to 80% of net collections
 - Incentive bonus of up to 7% of productivity bonus
 - Full-time benefits to part-time employed physicians
 - Government alleged that total comp package exceeded 130% of net professional collections
 - Relied on hospital reimbursement for funding

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Scenario 5

- Hospital employs ortho at fixed salary
- Hospital concern over long LOS for knee replacements
- Hospital will pay \$x for each day that LOS is reduced, but only down to regional avg.
- Hospital pays quality bonus of 10% of base, divided as follows:
 - 25% – patient satisfaction score
 - 25% – good documentation
 - 25% – meeting objective quality measures
 - 25% – subjective evaluation of quality by CMO

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Comments on Scenario 5

- Performance bonus issues
- Issues with subjective bonus
- CMP for payments to reduce services

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Scenario 6

- Hospital employs FP physician
- Pays based on wRVUs at median MGMA rate
- Includes wRVUs of PA since billed under physician number
- Passes through PMPM (per member per month) payment received from insurer for patient management

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Comments on Scenario 6

- Physician productivity compensation should be based only on services personally performed by physician
- PA supervision comp based on volume of PA services or time spent in supervision
- PMPM fees include costs in addition to physician management: social services, clerical personnel calling with patient reminders, etc.

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The Most Bizarre (and Most Scary) Qui Tam Case of the Year

- *Baklid-Kunz v Halifax Hospital*
 - Daytona Beach Halifax Hospital – 678 bed public hospital
 - Qui tam suit, US intervened
 - Many claims involve Stark, others involve medical necessity
 - Alleged 74,000 false claims, seeking damages and penalties between \$725 million and \$1.14 billion
 - If successful, Baklid-Kunz would be eligible for 15 percent to 25 percent

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Allegations

- Psychiatrists – paid bonus of 100% of collections above base comp, free rent, free billing employee
- Neurosurgeons – paid bonus of 100% of collections after covering base comp and cost of medical secretary, includes PA services, exceeds FMV (all 3 over \$1 million, one at \$1.9 million)
- Oncologists – offered six employed oncologists' bonuses based on 15% of the hospital oncology department's operating margin
- Directorships – paid at hourly rate to non-employees well above 90th percentile, no real services performed

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Important Legal Issues So Far

- Scope of attorney-client privilege with in-house counsel
- Stark applies to Medicaid claims
- Government hospitals not immune
- Defendant must prove Stark exceptions
- New: Destruction of records problem

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Baklid-Kunz – Who is She?

- Native of Norway, came to the United States to learn English in 1986 after graduating high school
- MBA, CPC, CCS
- Halifax compliance officer until '08, suit filed in '09
- Said she tried to resolve questions she had about Halifax physician contracts and other issues internally
- Now the Halifax Director of Physician Services

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Baklid-Kunz – Who is She?

- Hospital's in-house counsel says arrangement violates Stark
- Hospital gets second opinion from a law firm- "reasonable argument" that Stark compliant
- Hospital alleges she sought advice from hospital lawyers and then filed suit in an "intentional and clandestine act"
- Says she's being shunned by employees and stress has taken a toll on home life
- Status: Scheduled for Trial in March 2014

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Glossary of Abbreviations

CAH-	Critical Access Hospital
CMO-	Chief Medical Officer
CMS-	Centers for Medicare/Medicaid Services
ENT-	Ear, Nose, Throat (Doctor)
FMV-	Fair Market Value
FP-	Family Practice/Practitioner
FTE-	Full-Time Equivalent
IRS-	Internal Revenue Service
LOS-	Length of Stay
MGMA-	Medical Group Management Association
OIG-	Office of Inspector General (U.S. Dept. of Health & Human Services)
PA-	Physician Assistant
PC-	Professional Corporation
PCP-	Primary Care Physician
PMPM-	Per Member/Per Month
RVU-	Relative Value Unit
WPS-	Wisconsin Physician Service



You Can't "Afford" to Ignore Compliance! Understanding Implications of Health Care Reform and Increased Enforcement

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Understanding Implications of Health Care Reform
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Your Compliance Program is Out of
Date

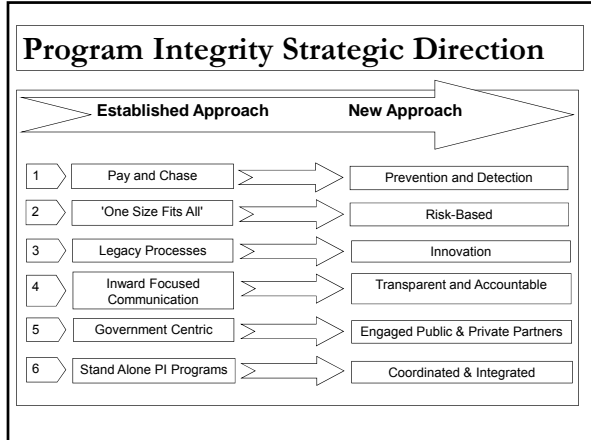
- Not the language, but the implementation
- There have been major shifts in approach, investigative techniques and enforcement
- Compliance programs need to become more sophisticated to respond effectively

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Changing Paradigms

- "Pay and Chase" to "Prevent and Detect"
- "Case Investigation" to Network/System Analytics
- Quantity of Services performed to Quality of Services performed
- White Collar Investigation to Blue Collar

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Reasons for the Shift

- Medicare Challenge (2012)
 - Claims paid each day 5.4 million
 - Value of claims paid each day \$1.1 billion
 - Providers paid each day 1.5 million
 - Maximum time to claims payment 30 days
 - Enrollment applications received per month 19,000
 - Total beneficiaries covered 47 million
 - Total outlays per year \$497 billion
 - Claims currently reviewed pre-payment 3%
 - Pages of regulation -300,000

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Reasons for the Shift

- Medicaid Challenge (2012)
 - State and territory programs 56
 - Claims paid each year 4.4 million
 - Total beneficiaries covered > 54 million
 - Dual eligibles 8.8 million (18%)
 - Cost of dual eligibles 39% of Medicaid spending
27% of Medicaid spending

By 2014, Americans who earn less than 133% of the poverty level (approximately \$29,000 for a family of four) will be eligible to enroll in Medicaid

CMS is 5 times larger in spending than the largest private payer

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Other Reasons

- Nationalization of program integrity for Medicare and Medicaid
- Increased involvement of organized crime in health care fraud
- ACA mandates for collaboration/correlation
 - Among government agencies – state/federal/local
 - Public/private collaborations

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Other Reasons

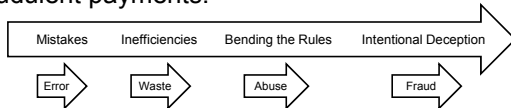
- Rapidly developing technology resources for sophisticated analysis plus electronic billing, plus increasing prevalence of EHR
- Financial resources through ACA and predecessor programs to pay for these activities

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Range of CMS Program Integrity Activities

Program Integrity encompasses a range of activities to target the causes of improper and fraudulent payments:



Examples: Incorrect billing Medically unnecessary service Improper billing practice (e.g., up-coding) Billing for services or supplies that were not provided

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Four Key Approaches to PI Activities

- Prevention: CPI is moving beyond the “pay and chase” model to prevent fraud by screening providers and suppliers effectively and spotting fraudulent practices early before claims are paid
- Detection: CPI is adopting the best strategic use of tools and techniques to detect fraud, waste and abuse and is sharing these best practices with our partners
- Transparency and Accountability: CPI has developed a comprehensive PI strategy to share key information with internal and external stakeholders
- Recovery: CPI has key activities with strong emphasis on the identification and recovery of overpayments

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Organized Crime in Health Care

- Attraction of Organized Crime to Healthcare
 - Big money
 - Florida, Texas, California, New York and Michigan are hot spots
 - Not violent, safer
 - Lower penalties relative to other felonies
 - Relatively easy to hide

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Organized Crime in Health Care

- Social network analytics (“SNA”)
- Identifies relationship clusters using “big data” and advanced linking
- Reveals hidden relationships in organized crime networks
 - “The Rise of Organized Crime in Health Care, White Paper,” Lexis Nexis (December 2011)

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Organized Crime in Health Care

- Twitter®, Facebook®, LinkedIn®, and other social network platforms
 - Graph analysis to determine who’s connected to whom in the cyber sphere

Lexis Nexis is now marketing social network analytics

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Organized Crime

- *Modus Operandi*
 - Usually starts with purchase or theft of provider and patient numbers
 - May be run through “legitimate” providers or fly by night storefronts
 - Service fraud may involve “ping-ponging” (intra-office referrals, gang visits, and steering patients to particular providers)
 - Some schemes are elaborate; e.g., staged car accidents followed by fraudulent medical and rehab care billing

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Organized Crime

- Risks
 - Organized crime is a major contributor to the \$60 billion annual estimate of inappropriate billing to Federal Health Care programs
- May involve real risk to patients/others
 - Physical threats and attacks
 - Provides unnecessary care that may carry risks and adverse outcomes

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Organized Crime

New Techniques Being Applied to All

Goal is shifting from a case approach to a network approach for attacking fraud. The HEAT Task Force is an example. Rather than starting with informants, HEAT uses sophisticated technology and collaboration among agencies to spot inexplicable billing practices, possible fraud and abuse.

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Blue Collar Investigation Techniques

- Unannounced “visits”
- Interviews with staff
- Interviews with former staff
- Search warrants v. subpoenas

➤ Every employee needs to know how to respond in interview with a regulator

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New Techniques – Typical Questions

- What is fraud and abuse?
- Do you have a compliance program?
- Who is the compliance officer?
- How do you report a compliance problem?

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New Techniques –
Onsite Investigation More Likely

- Brief compliance education is inadequate
- Compliance policies need to include a detailed procedure for responding to onsite investigations
- Key employees need to be trained in the procedure

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New Enforcement Techniques

- Increases in the offense level for arraigning defendant convicted of a Federal health care offense
 - 2 level increase \$1-7 million loss
 - 3 level increase \$7-20 million
 - 4 level increase ↑ \$20 million

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Techniques under ACA

- Automated Provider Screening System that identifies ineligible and potentially fraudulent providers and suppliers prior to enrollment or validation
- 150,000 ineligible providers have been removed from the System since 2012
- More stringent provider screening standards in high risk areas

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New Techniques Under ACA

MACs now review all provider applications. The application may be denied for non-compliance with Medicare requirements, misconduct, conviction of a felony with 1-10 years, owning a non-operational facility, falsifying the application, having a payment suspension or retaining an overpayment.

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ACA Changes to the False Claims Act

- 60-day overpayment rule – now failure to report and refund is a violation of the FCA (Final regulations not yet issued)
- CMPs for each FCA offense up from \$5,500-11,000 per claim to \$50,000 per claim
- Violators are subject to treble damages – 3 x \$50K

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New Techniques - Corporate Officers

- Statement of Daniel Levinson, OIG testimony to the Senate Committee of Finance, March 2, 2011
 - “Alter the cost-benefit calculus” for corporate executives. Corporate executives who either directly or indirectly engaged in fraud in their position of authority were convicted and excluded 3 executives (2008) for misbranding OxyContin
- The OIG has discretionary authority to exclude corporate officers without a conviction

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Chase-finding Through Technology –
The Pareto Principle/Outliers

- Follow the money
- You don't want to stand out in the crowd
 - Outliers draw investigation
 - Also aberration/unusual variances
- Focus on what the government will focus on
 - High dollar claims
 - High volume claims
 - Issues identified in OIG work plan

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The Pareto Principle

- Conduct pre-submission review – get it right before it is submitted
- Know where you are an outlier
 - PEPPER report
 - www.pepperresources.org

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Integration of Quality and Compliance

- The ACA and other statutes incorporated a number of quality initiatives:
 - Reducing readmissions
 - No reimbursements for HACs
 - “Quality of Care” false claims
 - Quality reporting
 - Pay for performance

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Integration of Quality and Compliance

- Many compliance programs do not adequately include quality, especially in internal investigations
- Always consider/address quality concerns when investigating compliance concerns
- Address any quality concerns in corrective actions/including training

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Medicaid Program Integrity

- National Correct Coding Initiative adopted for Medicare claims processing systems
- Medicaid RACs
- HH – Medicaid – also has F2F requirement
- Payment suspensions during pending investigation of credible allegations of fraud, 42 CFR Part 1007

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CMS – Nationalization of Program Integrity

- Submitted a RFI “Req for Information” for FY 2014
 - Justification of Estimates for Appropriateness Committees
- The Center for Program Integrity (CPI), part of CMS is developing a “unified program strategy to identify fraudulent or wasteful billing behavior that goes undetected when programs are reviewed in isolation.”

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CMS

It is designed to:

1. Break down boundaries between Medicare and Medicaid
2. Unified, coordinated Medicare and Medicaid strategy; national goals and priorities
3. Enable coordination/cooperation among Regional program integrity contractors

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CMS

It is designed to:

4. Strength CMS's national level direction of contractor's work
5. Ensure that new centralization fraud detection systems, e.g., Fraud Prevention System predictive analytics tool (FPS) and the Health Care Fraud Prevention Partnership (HFPP) are fully leveraged on a national basis

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CMS

- New unified contractor to be called a Unified Program Integrity Contractor (UPIC)
- The CPI plans to establish several reg UPICs (between 5 and 15)
- UPICs will encompass ZPICs including Medicare/Medicaid data match (medi-medi) plus PSCs and MICs

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CMS

- Limited to Medicare Parts A & B for now plus Medicaid
- In the future:
 - Medicare Drug Integrity Contractor
 - Medicare Part C Drug Integrity tasks may also be rolled in

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CMS

- Move from “pay and chase” to “prevention and detection”
- UPICs will interact with a CMS-developed toolset – Integrated Data Repository (IDR)

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CMS

- Plans to have providers submit medical records electronically in response to record request
- RACs will not be affected

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Too Much to Keep Track Of

- Multiple audit contractors
- Multiple integrity contractors
- State and federal regulators
- Seemingly innocuous inquiries – e.g., self-audits
- All have different rules

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Too Much to Keep Track Of

- Few compliance policies effectively identify the majority of regulatory contacts between the organization and audit contractors or regulators
- The risk is these contacts will be viewed later as putting the organization on notice of a compliance issue; evidence of intent if the problem is repeated

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Too Much to Keep Track Of

- Should be recognized/handled as a compliance “event,” triggering investigation, analysis, corrective action
- Develop a process, set the expectation that these inquiries will all be reported to the compliance officer
 - A corollary to the reporting line

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Latest Word

OFCCP/Affirmative Action

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NLRB Update

Mark McQueen

Immigration Update

Amy Erlbacher-Anderson

OCR Compliance

Laura A. Feldman

BOME Discipline

Barbara E. Person

Meaningful Use Audits

Vickie B. Ahlers

Direct Bank Placement: A Trend in Tax-Exempt Financing

T. Parker Schenken

Mandatory Flu Shots

Alex M. (Kelly) Clarke

501(r) Remedial Provisions

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Latest Word

OFCCP/Affirmative Action
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Hospitals and AA Obligations

- TRICARE = AA obligations
- National Defense Authorization Act signed by Obama = no AA obligations
- Stubborn OFCCP = AA obligations (most likely)

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Final Rules on Vets/Disabled

- Section 503
 - Utilization goals (7%) for each job group (or establishment if less than 100 employees)
 - Applicant/hire data collection
 - Invitation to Self-Identify (x 3)
 - Incorporation of EO Clause
 - Records Access
 - ADA

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Final Rules on Vets/Disabled (cont.)

- VEVRAA
 - Hiring Benchmarks (8% or contractor established)
 - Data collection
 - Invitation to self-identify (x 2)
 - Incorporation of EO Clause
 - Job listings
 - Records access

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Latest Word

NLRB Update
Mark McQueen

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NLRB UPDATE

- Partisan fight over Board members resolved, and quorum now established
- “Quickie Election” rules remain on hold, for now
- New standards governing “confidentiality” of employer investigations
- New standards governing employment at will
- Renewed emphasis on “no access” rules

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Latest Word

Immigration
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Conrad 30 Program

- Each state has 30 waivers to grant to foreign physicians
- Physician must work in healthcare shortage area for a minimum of 3 years

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Comprehensive Immigration Reform

- Add waivers for academic medical centers
- Increase available waivers if 90% are used nationwide
- Extension for physicians denied waivers due to state reaching quota
- Permanent

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Status of CIR

- Senate bill passed (S.744)
- House bill introduced (H.R.2131) with similar provisions
- Year-end vs. post-short-term spending in mid-January

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Latest Word

OCR Compliance
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OCR Compliance Review:
CAH Language Access Programs

- Focus on compliance with Title VI of the Civil Rights Act of 1964
- Expansion of ten-state pilot review
- Ensure meaningful access for limited English proficiency individuals
 - Duty to provide language assistance based on four-factor analysis
 - Flexibility in developing plan

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Latest Word

BOME Discipline
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BOME Discipline: Disruptive Physician

- Disruptive Behavior:
 - Use of profanity toward hospital staff, within hearing of patient/family
 - Inappropriate documentation in NF residents' medical records regarding their condition
 - Entry of wrong date and time in NF records; and on orders and prescriptions
- BOME Discipline:
 - Attendance at physician's expense of training for disruptive physicians
 - Physical and mental health assessment

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BOME Discipline: Disruptive Physician

- Disruptive Behavior:
 - Suspension of privileges by hospital for noncollegiality with hospital employees and another member of the medical staff
 - Referred by hospital to a program for disruptive physicians, under which he was monitored for four quarters
 - Privileges were reinstated upon request following completion of program for disruptive physicians
- BOME Discipline:
 - \$2,000 in civil money penalties

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Latest Word

Meaningful Use Audits

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Meaningful Use Audits

- September 2012: Sebelius/Holder letter warning of abuse of EHR technology
- 2012: CMS began audits
- 2013: CMS states "small" percentage of providers will be randomly selected for pre-payment and post-payment audits
 - Figliozi and Company (CPAs) selected as auditor
- Auditing Eligible Hospitals, CAHs, and Eligible Professionals

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Meaningful Use Audit - Process

- Letter from Figliozi/CMS (e-mail)
- Document request
 - Approximately 1 month to respond
 - Documentation to support attestation to selected core/menu measures
 - Evidence of security risk analysis
- Instructions for submission
 - Electronic submission vs. paper
- Hurry up and wait! (For a follow-up request)

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Latest Word

**Direct Bank Placement
A Trend in Tax-Exempt Financing**

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Direct Placement Trend

- Brief Review of Principles of Tax-Exempt Financing:
 - Principal Areas of Concern:
 - Federal Tax Laws (IRC Sections 103, 141-148, 150, 265, etc.).
 - Arbitrage Rebate – Addresses Earnings on Bond Proceeds in Excess of Bond Yield
 - Private Use – Addresses Use of Bond-Financed Properties for Non-Governmental (or Non-501(c)(3)) Purposes
 - Compliance with State Laws governing Municipal Obligations
 - Compliance with State and Federal Securities Laws

Direct Placement Trend

- Recent Trend – Direct Placement of Bonds with Banks
 - Recent Growth in Practice sparked due to 2009-2010 ARRA Modification to Limitations on Bank Qualified (aka BQ) Bonds (now expired) – But Trend Continues
 - Factors to Consider When Considering Options
 - Interest Rate Options
 - Term/Amortization and Refinance Risk
 - Prepayment Limitations/Charges
 - Flexibility for Construction Disbursement Draws
 - (cont'd)

Direct Placement Trend

Factors to Consider (cont'd):

- Bank Covenants vs. Bond Covenants
- Credit Enhancement
- Reserve Fund Requirements
- Benefit of BQ Status
- Disclosure Obligations
- Banking Relationships and Flexibility for Modification/Waiver
- Other Bank Products
- Others

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Mandatory Flu Shots

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Mandatory Flu Shots

- Background: trend toward mandatory flu shots for clinical staff with religious and medical exceptions
- LB 458 (effective September 6, 2013) – each acute general hospital shall:
 - Annually offer flu shots to all hospital employees

Mandatory Flu Shots

- Offer single dose tetanus – diphtheria – pertussis vaccine to those employees who have not received it
- Require all hospital employees to get flu shots “*except that an employee may elect not to be vaccinated*”
- Keep records

Mandatory Flu Shots

- LB 459 (effective September 6, 2013) – each general hospital, ICF, NF and SNF shall offer on-site vaccination for diphtheria, tetanus and pertussis to all inpatients prior to discharge
- LB 1077 (effective 2012) – each general hospital, ICF, NF and SNF shall annually beginning no later than October 1 and ending April 1 offer on-site vaccination for influenza and pneumonia to all residents and inpatients prior to discharge
- Facility not required to pay

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501(r) Remedial Provisions

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501(r) - Remedial Provisions

- 501(r) Refresher
 - CHNA at least once every three tax years
 - FAP
 - Limitations on charges
 - Emergency care
 - No extraordinary collections actions

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501(r) - Remedial Provisions

- Excise tax is specific to CHNAs
- What if non-compliant in other 501(r) requirements?
- CHNA proposed regulations issued April 5, 2013

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501(r) - Remedial Provisions

- Three tiers
 - Minor & inadvertent omissions and errors
 - Neither willful nor egregious & self-disclose
 - Willful or egregious or fail to self-disclose
- Minor & inadvertent omissions and errors
 - Reasonable cause
 - Corrects the omission or error promptly after discovery

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501(r) - Remedial Provisions

- Neither willful nor egregious
 - Correct & disclose
 - Self-disclosure process
 - IRS sees OIG process as potential guide
 - May still be subject to an excise tax
- If willful or egregious or fail to disclose:
 - IRS will determine whether the hospital continues to qualify for exemption based on the facts and circumstances

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340Bargains: Defending Drug Discounts in 2014 and Beyond

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340Bargains: Defending Drug Discounts
in 2014 and Beyond

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340Basics

- Incentives . . .
 - Manufacturers must offer 340B discounts in order for their drugs to qualify for Medicaid coverage
 - 340B participants (“covered entities”) entitled to substantial discounts on these drugs
- . . . and controversy
 - How covered entities use 340B savings/profits

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340Basics

- Congressional intent of the Program is to permit CEs “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services”
- OPA has stated that Program benefits are “intended to accrue to the CEs”

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340Background

- **Registration:** Enroll and complete annual recertification with OPA to participate
 - Contract pharmacies
 - Offsite outpatient facilities
- **GPO:** Hospitals (but not CAHs) are subject to group purchasing exclusion
- **Orphan drugs:** Hospitals (*including* CAHs) cannot buy orphan drugs at 340B prices used to treat a rare/orphan condition

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340Background

- **Covered drugs:** 340B covers “covered outpatient drugs” used for eligible patients, including—
 - FDA-approved outpatient prescription drugs & insulin
 - Prescribed OTC drugs
 - Prescription biological products

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340Background

- **Drug diversion:** Obtaining the 340B price on a drug not used for an eligible patient.
- An “eligible patient”—
 1. Has a relationship with the CE such that the CE is both *responsible for* and *maintains records of* the patient’s care; and
 2. Receives services from a provider *employed by* or under *contractual/other arrangements with* the CE

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340Background

- Duplicate discount: Obtaining the 340B price *and* a Medicaid rebate on the same drug
 - Indicate “carve in” or “carve out” status to OPA for the Medicaid Exclusion File
- Compliance:
 - Audits by HRSA and manufacturers
 - Penalties may include corrective action; repayment; and removal from the Program

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340Benefits

- Expansion of CE categories, along with ability to contract with multiple retail pharmacies to dispense 340B drugs have led to exponential Program growth
- Participants commonly report using Program savings to—
 - Offset pharmacy losses or losses in other hospital departments
 - Increase/improve services offered by the CE
 - Reduce medication costs for patients
 - Increase quantity/variety of available drugs

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340Benefits

- Increased scrutiny of Program benefits post-PPACA through audits
 - HRSA reviews compliance with eligibility, recordkeeping, & registration requirements in addition to looking for diversion/duplicate discounts
 - Manufacturers are more limited in audit scope, but have strong motivation to examine suspicious CE practices

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340Benefits

- Continuing calls for increased oversight of 340B benefits from Congress and Program stakeholders
 - Sen. Grassley leading congressional efforts
 - February report issued by a number of drug industry trade groups
 - SNHPA responded with its own July report

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340Best Practices

1. Implement written 340B compliance policies
2. Create a definitive list of “eligible prescribers”
3. Evaluate systems for maintaining “auditable record trail” for all 340B purchases
4. Monitor third-party vendors
5. Monitor contract pharmacies

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340Best Practices

6. Maintain relationships with 340B drug manufacturers and wholesalers
7. Implement tracking system for orphan drugs
8. Schedule periodic audits and regularly conduct more abbreviated internal checks
9. Train pharmacy staff
- 10. Articulate a clear plan to govern use of Program savings**

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The Real World Challenges of HIPAA: Can We Keep Up?

Vickie B. Ahlers

Alex M. (Kelly) Clarke

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The Real World Challenges of HIPAA:
Can We Keep Up?

Vickie Ahlers
Kelly Clarke

#1222461

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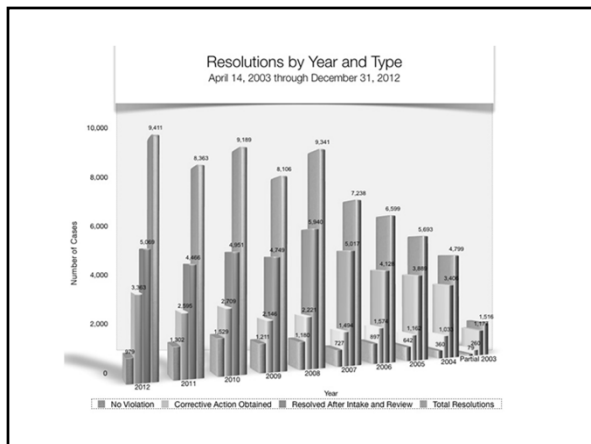
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Quiz:

In the first 10 years of enforcing
HIPAA, how many complaints did
OCR receive?

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Enforcement Pays!

- Per OCR - ROI on enforcement (per \$1 spent)
 - Historical: \$5.00
 - Past 3 years: \$7.20
- Enhanced penalties strengthen OCR's hand in settlement/penalty negotiations
- OCR is mining required self-reported breaches for claims to pursue
- The education phase is over
- State attorneys general separately enforcing

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Enforcement Pays!

- Providence Health & Services (Jul 2008 – backup tapes and laptops stolen - \$100K)
- CVS Pharmacy (Jan 2009 – improper disposal - \$2.25M)
- Rite-Aid (Jul 2010 – improper disposal - \$1M)
- Management Services Organization of Washington (Dec 2010 – improper disclosure - \$35K)
- Cignet (Feb 2011 – denying patient access; failure to cooperate - \$4.3M)
- Massachusetts General Hospital (Feb 2011 – records left on train - \$1M)
- UCLA Health Services (Jul 2011 – snooping - \$865K)

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Enforcement Pays!

- Blue Cross Blue Shield of Tennessee (Mar 2012 - 57 unencrypted computer hard drives stolen – \$1.5M)
- Phoenix Cardiac Surgery, P.C. (Apr 2012 – posting appointments to internet - \$100K)
- Alaska Medicaid (Jun 2012 – unencrypted USB stolen - \$1.7M)
- Massachusetts Eye and Ear Infirmary (Sep 2012 – unencrypted laptop stolen – \$100K)
- Hospice of Northern Idaho (Dec 2012 – unencrypted laptop stolen – \$50K)
- Idaho State University (June 2013 – unsecured servers - \$400K)
- Shasta Regional Medical Center (June 2013 – improper disclosure - \$275K)

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And just when you thought you had HIPAA all figured out.....

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Omnibus Final Rule – January 2013

- Changes to:
 - Privacy Rule
 - Security Rule (minor)
 - Breach Notification Rule
 - Enforcement Rule

Still Pending:
Final Rule on Accounting for Disclosures
Minimum Necessary Guidance

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What Does OCR Think of the Omnibus Rule?

"This final omnibus rule marks the most sweeping changes to the HIPAA Privacy and Security Rules since they were first implemented. These changes not only greatly enhance a patient's privacy rights and protections **but also strengthen the ability of my office to vigorously enforce the HIPAA privacy and security protections**, regardless of whether the information is being held by a health plan, a health care provider, or one of their business associates."

Leon Rodriguez, OCR Director

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Omnibus Rule Key Changes

- **Business Associates**
- **Increased penalties**
- New rules for fundraising
- Stricter marketing standards
- Sale of PHI prohibited
- Enhanced individual rights
- Notice of Privacy Practices changes
- **Breach Notification changes**

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Changes Affecting Business Associates

- Expanded definition of BA to include:
 - Subcontractors *and Subs of Subs*
 - An entity that provides data transmission services of PHI to a CE and requires access on a routine basis
 - An entity that maintains PHI on behalf of a CE, even if the entity does not access the PHI
 - Patient safety organizations

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Business Associates as Agents

- Final Rule removed affirmative defense of covered entity that if a BAA was in place with the BA, covered entity not liable for acts of BA
- Now, Hospital is liable for the acts of its BAs if those BAs are found to be agents of the Hospital
- Agency can be defined by agreement, practice, and BAA

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Business Associates as Agents

- When is a business associate your *agent*?
 - Standard: Federal common law of agency
 - Why is this so important?
 - Reports indicate over 50% of breaches are caused by business associates

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Business Associates - Disposal

- Goldwaith Associates (01/07/2013)
 - BA – billing agent for 4 pathology groups
 - Disposed of 67,000 records in the trash
 - Local investigative reporter at the landfill!
 - State attorney general enforcement including state law causes of action
 - \$140,000 settlement with Goldwaith and the 4 pathology groups

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Business Associates - Disposal

- South Shore Hospital (Mass.)
 - Shipped 3 boxes with 473 unencrypted backup computer tapes to Texas to be erased and resold by Archive Data Solutions.
 - Did not inform of content or pre-determine Archive's capabilities
 - Two boxes lost in transit
 - No BAA with archive and inadequate policies and training
- \$750,000 settlement
- Exposure remains to individual state law claims

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Enforcement Rule Changes

- Inadvertent:
 - \$100/violation to \$25,000/year
- Reasonable cause and not willful neglect:
 - \$1,000/violation to \$100,000/year
- Willful neglect - Corrected:
 - \$10,000/violation to \$250,000/year
- Willful neglect – Not Corrected:
 - \$50,000/violation to \$1,500,000/year

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Enforcement Rule

- Don't forget important affirmative defense
 - Violation of HIPAA that was not due to willful neglect and covered entity corrects the violation within 30 days of discovery, OCR cannot impose penalty.

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Criminal Penalties “Clarified”

- Fines up to \$50,000, imprisonment up to 1 year, or both
- If committed under false pretenses, fines up to \$100,000, imprisonment up to 5 years, or both
- If committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, fines up to \$250,000, imprisonment up to 10 years, or both

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Breach Notification Rule Changes

*Give a man a fish
and you feed him
for a day.*

*Teach a man to
fish and he'll use
your credit card to
buy dinner.*

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Reported Breaches

613,506,431 records
from **3,950** data breaches
made public since 2005

Source: Privacy Rights Clearinghouse (www.privacyrights.org)

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Data Breaches: Who are the Victims?

37% of breaches affected financial organizations (+)

24% of breaches occurred in retail environments and restaurants (-)

20% of network intrusions involved manufacturing, transportation, and utilities (-)

20% of network intrusions hit information and professional services firms (+)

38% of breaches impacted larger organizations (+)

27 different countries are represented

Legend
(+) indicates a 10% or greater increase from the previous year's report
(-) indicates a 10% or greater decrease from the previous year's report

Source: Verizon 2013 Data Breach Investigations Report (<http://www.verizonenterprise.com/DBIR/2013/>)

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Data Breaches: How do they Occur?

- 52%** used some form of hacking (-)
- 76%** of network intrusions exploited weak or stolen credentials (-)
- 40%** incorporated malware (-)
- 35%** involved physical attacks (+)
- 29%** leveraged social tactics (+)
- 13%** resulted from privilege misuse and abuse

Legend
(+) indicates a 10% or greater increase from the previous year's report
(-) indicates a 10% or greater decrease from the previous year's report

Source: Verizon 2013 Data Breach Investigations Report (<http://www.verizonenterprise.com/DBIR/2013/>)

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Breach Notification

- Notification required if "breach" of "unsecured PHI"
- "Unsecured PHI" means:
 - PHI not rendered unusable, unreadable or indecipherable to unauthorized individuals through use of technology or methodology specified by the Secretary
 - *Encryption or destruction*
- Notification to individual
- Notification to HHS/OCR
- OCR will investigate all breaches >500

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Breach Notification

- "Breach" means:
 - Access, acquisition, use or disclosure of PHI not permitted under the Privacy Rule that **compromises** the security or privacy of the PHI
- Could include many scenarios (lost laptop; snooping; sending letter to wrong recipient; misdirected fax or e-mail; leaving record in plain view; failure to shred)

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Breach Notification Changes

- Old standard – compromises PHI if significant risk of financial, reputational or other harm to individual
- NOW – *presumed* to be a breach unless low probability that PHI has been compromised based on 4-part risk assessment
- Train to new standard; revise policies

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Breach Notification Changes

- Risk Assessment Factors
 1. Nature and extent of PHI, including types of identifiers and likelihood of re-identification.
 2. Who is the unauthorized recipient?
 3. Was the PHI actually acquired or viewed?
 4. Extent to which the potential risk to the PHI has been mitigated.

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Breach Notification Changes

“[a]nd we expect these risk assessments to be thorough”

Preamble to Final Rule at 78 Fed. Reg. 5566, 5643

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Costs of Data Breaches on the Rise*

- 2011 - \$130 per compromised record
- 2012 - \$136 per compromised record
 - Third party error (+\$19)
 - Lost or stolen device (+\$8)
 - Rapid notification (+\$7)
 - Strong security posture (-\$15)
 - Incident response plan (-\$13)
 - Appointment of CISO (-\$8)
 - Engagement of data breach remediation consultants (-\$5)

*2013 Ponemon Institute

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Where Do We Focus Our Efforts?

1. Security Risk Assessments (and mitigation plans)
2. Mobile Devices
3. Understanding Where PHI is Stored
4. Employee and Medical Staff Education
5. Comprehensive policy structure (and effective enforcement)
6. Cyber Risk Insurance

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1. Security Risk Assessments

- Final guidance on conducting security risk assessment released 7/14/10
- All settlements since that date with the exception of two have included finding that no or inadequate risk assessment was performed
- Periodically updated based on change in environment, risks or regulations

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2. Mobile Devices

- PDAs, laptops, USB drives, other portable media
- Continues as single biggest risk area
- Low hanging fruit for OCR
- Mobile device strategy
- ENCRYPTION!

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Encryption, encryption, encryption!

Advocate Health slapped with lawsuit after massive data breach



Advocate Lutheran General Hospital in Park Ridge, Ill. (Wikimedia Commons, Zol87)

Advocate "flagrantly disregarded" privacy of 4 million patients, lawsuit says

DOWNERS GROVE, IL | September 6, 2013

Tweet 29 | +1 4 | Recommend 24 | Share 32

Advocate Health Care – who in August reported the second largest HIPAA data breach to date after four unencrypted laptops were stolen from its facility, compromising the protected health information and Social Security numbers of more than 4 million people – has now been slapped with a class action lawsuit filed by affected patients.

Two plaintiffs, representing patients affected by the breach, assert that Advocate Health Care failed to take the necessary precautions required to safeguard patients' protected health information. The unencrypted laptops were stolen from an "unmonitored" room, one with "little or no security to prevent unauthorized access," the lawsuit read.

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Advocate Breach - Timeline

- Theft – July 15th
- Notice to affected patients – **Aug. 23rd**
- Class action lawsuit filed – **Sept. 5th**

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Mobile Device Strategy

- BYOD or company-owned?
- Same rules generally apply
 - Register / track
 - Rules on use
 - Photos? Texting?
 - Rules on downloads (and backing up)
 - Rules on loaning
 - Security/Encryption

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Mobile Device Strategy

- Rules on facility's right to TAKE POSSESSION OF THE DEVICE
- Rules on lost devices – immediate reporting, but who do you call FIRST?
- Wiping capabilities – what gets wiped?
- Cannot disable security settings
- Strong passwords

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Portable Devices - Enforcement

- Deficiencies noted:
 - Failure to encrypt stored PHI
 - Insufficient security/risk management measures
 - Lack of device inventory controls
 - Failure to analyze risks of ePHI on portable devices
- Penalty range for > 500 = \$1M - \$1.5M
- A big challenge/barrier as physicians seek greater use of cutting edge technology
 - Encrypted in motion?
 - Encrypted at rest?

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3. Understand Where PHI is Stored

- Hard drives
- External hard drives
- Mobile devices
- The Cloud
- Equipment (fixed, movable, owned, leased)

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CBS Exposé leads to Settlement

HHS Settles with Health Plan in Photocopier Breach Case

Under a settlement with the U.S. Department of Health and Human Services (HHS), Affinity Health Plan, Inc. will settle potential violations of the HIPAA Privacy and Security Rules for \$1,215,780. OCR's investigation indicated that Affinity impermissibly disclosed the protected health information of up to 344,579 individuals when it returned multiple photocopiers to a leasing agent without erasing the data contained on the copier hard drives. In addition, the investigation revealed that Affinity failed to incorporate the electronic protected health information stored in copier's hard drives in its analysis of risks and vulnerabilities as required by the Security Rule, and failed to implement policies and procedures when returning the hard drives to its leasing agents.

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4. Employee and Medical Staff Education

- "Eight years of research on data breach costs has shown employee behavior to be one of the most pressing issues facing organizations today" 2013 *Ponemon Institute Report*
- Security training as important as privacy training
- Training must combat both intentional and innocent risky conduct

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Execs Improper Disclosure to News Media

- Shasta Regional Medical Center
 - Shasta accused in media of fraud on a patient's bill
 - Execs defended Shasta through the media by providing patient details to set the record straight
 - Execs broadly distributed e-mail to its workforce to set the record straight
 - No authorization from the patient
- \$275,000 settlement (6/6/2013)
- California Dept. of Public Health added fine of \$95,000 and corrective action plan (and tacked on \$25K for a case of snooping)

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Medical Staff Education Needed

- The mustache that went viral
 - Torrence Memorial Medical Center – in 2011 female patient sedated for surgery
 - Anesthesiologist drew mustache and put stickers on her face – ha ha
 - Nurses aide with cell phone took picture
 - Naturally, the picture made it to Facebook
 - State investigation and civil lawsuit – certain penalties
 - (latimes.com 9/4/13)

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5. Comprehensive Policy Structure

- Policies must be thorough enough to guide employees when situations arise
- Management must understand policies
- Enforce consistently from top down
- Champion someone in the organization to know the rules and ask them first!
- Sanction for every violation; prevent future actions
- "Rogue employee" defense – preserve through action!

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“Walgreens must pay woman \$1.44 million over HIPAA violation”

- Walgreens pharmacist in Indiana accessed her husband’s ex-girlfriend’s prescription data and disclosed it to her husband
- Husband sent text to ex-girlfriend (of course he did!)
- Customer called to complain and alert them of the breach; Walgreens didn’t prevent pharmacist from accessing record a second time, which she did (of course she did!)

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“Walgreens must pay woman \$1.44 million over HIPAA violation”

- Legal theory of suit: *negligent supervision*
- Walgreens argued at trial that the pharmacist admitted she was aware of its privacy policies and she had violated them
- Plaintiff argued Walgreens did nothing to stop second violation.
- July 2013 jury verdict: *Walgreens 80% at fault*

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“Walgreens must pay woman \$1.44 million over HIPAA violation”

“Because of the relentless industry rallying cry that ‘HIPAA does not allow a private cause of action,’ most attorneys are cowed out of trying to do anything about HIPAA violations”....“10 years into the HIPAA privacy rule, I should not be the only attorney in the country doing this type of work. My hope is that this opens eyes — both by lawyers like me and by the health care providers.”

-Neal F. Eggeson, counsel for plaintiff

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6. Cyber Risk Insurance

- Traditional medical malpractice policies adding on cyber risk as part of coverage.
- Very low limits; consider more (and evaluate other sources)
- Review carefully (definitions and exclusions are key)
- Negotiate approved breach counsel prior to purchase

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