Updating HIPAA+ P&P

HITECH
Red Flags
FERPA
M.U. EHR
Others

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Agenda

- Importance of Policy
- Drivers for Updating P&P
- Writing Effective P&P
- New P&P Needed Today:
 - Privacy and Security
 - Electronic Health Records and "Meaningful Use"
- Implementing P&P

alinurses.com 😞

Jan 12, 2009 10:07 AM



Good Old HIPAA Violation!

by shodobe 💣 🕮

This is for everyon'e info. recently I got into trouble for a HIPAA violation at my hospital. First major infraction in 31 years! Early part of last month I was doing a case in the OR when we heard that a RT employee had come into the ED in full code. I was already in the ER roster looking up a potential patient for the surgeon and saw the name and looked to see if I knewhim. I know alot of the RT but didn't know him by name. I forgot about it until a few days ago when I was called into the "pricipals" office downstairs, not my Directors' office. I was asked if I had indeed loked and I said ves because I wanted to make sure it wasn't a friend of mine. They told me that there had been quite a number of hits, we use computer nursing, and hey were going to talk with everyone. They also told me there would be disciplinary actions taken, but not termination. I thought I would probably get written up and that would be it. Instead I got a 3 day suspension. The HIPAA czar I talked to had said the rules had getten much stricter after the first of the year but I didn't expect this. I went into our HIPAA manual and looked up the policies concerning punishments. It went form verbal consuling to written ,all the way up to suspension and termination. They jumped all the way up to final warning and suspension. I don't mind the suspension as much as they might of chaned the policies concerning punishment and did not inservice or inform the employees of such changes, I only think it would be fair on their part to do formal inservices or at least put out memos to the changes. This post is for info for everyone to watch out, "They are watching"!

Importance of Policy

- Guidance for action consistent with legal, ethical, and organizational requirements
- Policies . . .
 - Establish goals that procedures and technical measures serve
 - Communicate consensus and assign responsibility
 - Define enforcement and consequences for violation
- Policy is a mutual agreement that outlines the expectations your organization has for its workforce

Policies, Procedures, Standards, Technical Controls

- Policies guide action
 - Broad statements
 - Corporate wide
 - Executive approval
- Procedures direct action
 - Specific steps
 - Focus on process
 - Departmental management
- Procedures answer:
 - What to do
 - When to do it
 - Where to do it
 - Who should do it
 - Exactly how to do it

- Standards define minimum expected performance
 - De facto, e.g., "Passwords should be 8 characters"
 - Consensus driven, e.g.,Standards of Practice, HL7
 - Government mandate, e.g., HIPAA Rules
- Technical controls cause operations to meet policy requirements
 - Example: Access controls cause users to gain applicable access to information

Drivers for Updating P&P

- New regulations (e.g., Red Flags, HITECH) on top of old regulations not often complied with
- New threats, e.g.,
 - Identity theft, medical identity theft
 - Economy
 - "Value engineering"
 - HIPAA enforcement
 - "Trusted" third parties
- New vulnerabilities, e.g.,
 - Consumer empowerment
 - Electronic health records
 - Health information exchange
 - Meaningful use requirements

45 CFR §164.308(a)(8) Evaluation:

Perform periodic ...
evaluation...in response
to environmental or
operational changes
affecting security of
ePHI

Writing Effective Policies

- Policy characteristics
 - Enforceable
 - Concise and easy to understand
- Deciding on what the policy should be
 - Understand circumstances pertinent to policy being written (e.g., sending referral information to provider vs. participating in an HIE organization)
 - Determine organization's corporate position (e.g., risk averse, risk tolerant)
- Steps in policy writing
 - Draft
 - Test
 - Introduce, train, reinforce
 - Enforce, reinforce

Procedures

Scenario

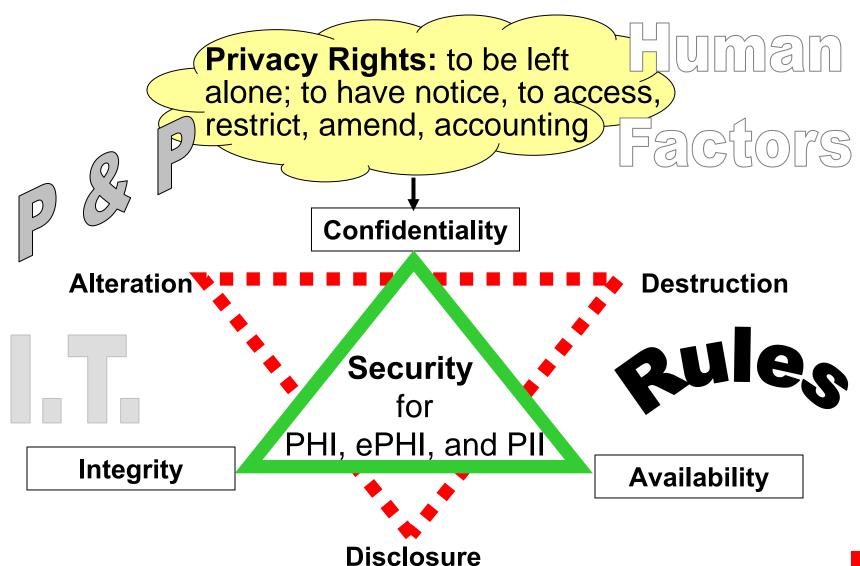
- "I want to review my patient's record before I enter the exam room"
- "I don't want to be logging on and off constantly"
- "Every time I log on, I have to click through screens I've already looked at"
- Workflow and process changes with HIT must be studied in light of patient care, hassle factors, privacy & security
- A process map or even a use case can be an effective tool to design and document procedures

David Blumenthal, MD, ONC – on meaningful use, Dec. 7, 2009: "It's not the technology that's important, but its effect. Meaningful use is not a technology project, but a change management project. Components of meaningful use include sociology, psychology, behavior change, and the mobilization of levers to change complex systems and improve their performance.

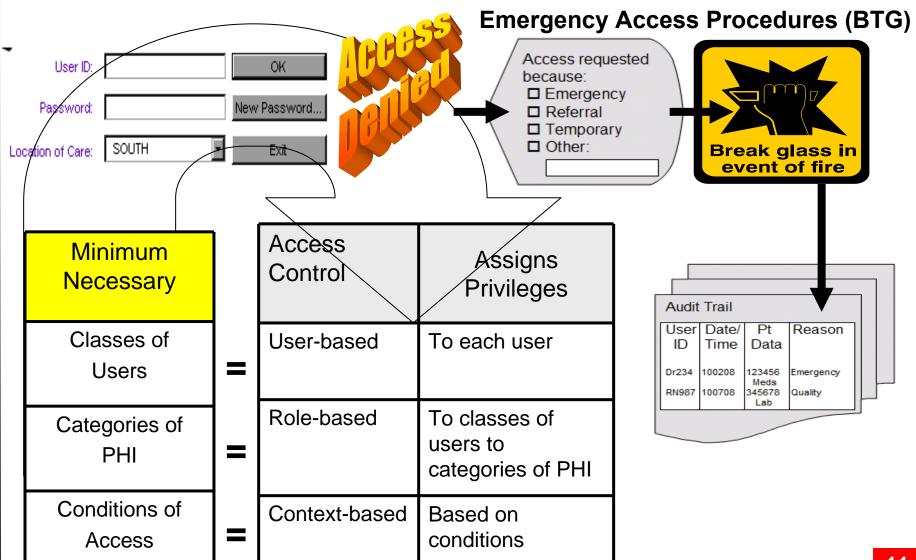
Writing Effective Procedures

- Many organizations adopt the HIPAA implementation specifications as their procedures
- ■These often are not enough:
 - Accounting for Disclosures
 - Telling a clerk what disclosures NOT to account for is not telling the clerk what disclosures TO account for
 - Incorporating accounting for disclosures requirement in health information management department procedures does not explain to all other departments their obligation to report disclosures that must be tracked
 - Minimum Necessary
 - Requiring the minimum necessary information to be disclosed without explaining precisely what that means is not an effective procedure

Privacy and Security Integration



Access and Audit Controls



New P&P: Breach Notification*

- 1.Incident occurs. Determine if breach:
 - a. Acquisition, access, use, or disclosure of PHI which compromises the security or privacy of PHI
 - Poses a significant risk of financial, reputational, or other harm to the individual
 - ii. De-identified data is excluded
 - Breach discovery starts 60-day clock for notification
- 2. Determine if PHI:
 - a. Secured (e.g., via encryption), breach notification may not be required
 - b. Unsecured PHI,
- 3.If unsecured, determine if exception applies that eliminates notification:
 - a. Unintentional access by member of CE or BA workforce
 - b. Inadvertent disclosure to person at same CE or BA and no further use or disclosure in violation of Privacy Rule
 - c. Disclosure where CE or BA believes unauthorized recipient would be unable to retain PHI
- 4.Delay notification if law enforcement agencies have requested delay where notification may hinder investigation

- 5. Determine if breach may result in imminent misuse of unsecured PHI, in which case CE should notify individuals by telephone or other means in addition to written notice
- 6. Send notification letters via first-class mail within 60 days of breach discovery.
 - 5. Record breach in a log. If fewer than 500 individuals affected, report breach annually
 - 6. If 500 or more individuals affected, notify HHS: http://transparency.cit.nih.gov/breach/index.cfm
 - 7. If 500 or more live within one state, send a press release to major media outlets
 - 8. If 10 or more letters returned due to out-of-date or insufficient contact information, provide substitute notice (e.g., email, website notice, major print or broadcast media)
- 7. Notice must be in plain language and include:
 - 5. Description of breach, date of breach, and date of discovery
 - 6. Description of types of information breached
 - 7. Steps individuals should take to protect themselves
 - 8. Description of what CE is doing to mitigate harm and protect against further breaches
 - 9. Contact procedures for individuals to ask questions, including toll-free number, email address, web site, or postal address

12

New P&P: HITECH Privacy

- Proposed Rule published July 14, 2010
- Several very controversial requirements have generated considerable comment
- ■For your P&P:
 - Decide if and when to adopt proposed regulations
 - Some may be helpful and unlikely to change, such as for business associates
 - Others may have long term impact and could cause future confusion, such as restricting disclosure to payer for cash payment

Some Tips: Business Associates

- Business associate contract (BAC):
 - Incorporate direct accountability to certain provisions of HIPAA Privacy and Security Rules into BAC; but do not abdicate your responsibility to safeguard PHI
 - Do BACs continue to be needed?
- Incorporate breach notification requirements into BAC some considerations:
 - Within what timeframe does CE want to receive notification of a breach? Who sets the timeframe? Should there be a uniform timeframe?
 - Do you want to receive notice of all incidents or will you permit BA to determine whether incident is a breach?
 - How do both parties define "incident?"
 - Is BA an agent or a subcontractor? (How are these terms defined by OCR?) If agent, will you request the BA to conduct the notification?
- Consider addressing other concerns more proactively, such as:
 - Prohibit exchanging PHI for remuneration without individual authorization
 - Address requirements for de-identification; or prohibit de-identification
 - Address requirements for BA's agents and subcontractors
 - Require BA to conduct P&S assessments; require audits of such

Some Tips: Other Potential Changes

- Authorization for future research use and disclosure
- Period of protection for decedent information
- Disclosures about a decedent to family or others involved in care
- FERPA vs. HIPAA
- Minimum necessary as limited data set and applicability to healthcare operations and business associates
- Permission (opt-in) for fundraising; use of service and outcomes data in fundraising
- Timing of NPP revision relative to breach and other proposed changes; need for acknowledgment
- Request for restriction to disclose information to payer when full cash payment many downstream issues
- Access to copy of health information in electronic format (of patient choosing) and secure transmission vs. access to content maintained in electronic EHR
- Request for provision of electronic copy of PHI to designee vs. authorization
- Authorization for use and disclosure of psychotherapy notes and marketing and subsidized treatment communications
- Hybrid entity definition
- Assessment of remuneration requirements for disclosures, such as to public health
- Disclosures required by law in relationship to patient requested restrictions

Some Tips: Accounting for Disclosures

- Address policy and technical controls to account for disclosures from EHR for TPO within past 3 years
 - Disclosure
 - Same meaning as in 45 CFR §160.103: the release, transfer, provision of, access to, or divulging in any other manner of information outside the entity holding the information
 - Does not mean to turn over you audit logs to the patient
- Disclosures through an EHR are most likely to occur in an HIE environment, such as when electronically sending CCD or CCR to a physician to who patient is being referred, sending a prescription to the retail pharmacy, sending immunization data to a statewide registry
- Are your information systems able to capture a transmission from your EHR?

Enforcement Considerations for P&P

- Technical guidance on safeguards (Feb. 18, 2010; annual updates)
- Unsecured PHI (Guidance Apr. 27, 2009)
 - Encrypt
 - Destroy
 - (De-identify ≠ HIPAA)
- Enforcement by State Attorneys General (applies after Feb. 17, 2009)
- Enforcement amendments (October 30, 2009)
- Willful neglect provisions in HIPAA Enforcement Rule (Aug. 18, 2010)
- Sharing civil money penalties or settlements with harmed individuals (Feb. 18, 2012)
 - Impact on organizational policies? Training? Awareness

Consumer Empowerment

- FERPA (Joint Guidance Aug. 2008)
 - Applicable to your organization?
- FTC Health Breach Notification Rule
 - Published Aug. 25, 2009, effective Sept. 24, 2009, full compliance required by Feb. 22, 2010
 - Impacts Personally Identifiable Information (PII) in personal health records (PHRs) provided by vendors or other entities, such as schools, charities, and non-profits
 - Applicable to your organization?
 - Buried disclosures in privacy policy?
- Red Flags Rules (Dec. 31, 2010-?)
 - Applicable to your organization?
 - If not, should you not watch for warning signs?

Electronic Health Records

- Mission critical system requiring . . .
 - Contingency planning and disaster recovery
 - Technical redundancy: servers, network, telecom
- Use as intended (not just "meaningful use")
 - At point of care by clinician
 - To capture and receive structured data
 - And integrate with information from all sources
 - Ensuring data quality, including with ICD-10-CM codes (October 1, 2013) embedded in many HIT applications
 - In support of clinical decision making,
 - Using evidence-based standards of practice to ensure health care quality
 - With appropriate sensitivity levels established
 - And rationale for overriding alerts
 - While enabling and assuring application of professional judgment

Policy Implications for Meaningful Use Requirements

- Adoption of HIT standards
 - Including X12 5010 version by January 1, 2012
 - Including Operating Rules forthcoming from the Affordable Care Act
- What measures; "through EHR"
- Exclusions
- Donations of EHR
- Hospital-based physicians
- "Meaningful use" attestation
- Reassignment of incentives
- Audits of attestation

CORE Set of Criteria Stage 1			
Objectives (Standards)	EP/H	Measures	Application
1. Use CPOE for medication orders directly entered by any licensed health care professional	Both	> 30% of pts w/one medication on EHR med list have ≥ 1 order entered via CPOE	□CPOE
2. Implement drug-drug and drug-allergy interaction checks	Both	Enabled (Y/N)	□CPOE/eRx □CDS
3. Generate and transmit permissible prescription electronically (eRx) (NCPDP)	EP	>40% transmitted via EHR Exclusion if <100 prescriptions written in reporting period	□ eRx
4. Record demographics (or "decline"): Preferred language Gender Race Ethnicity Date of birth Date/preliminary cause of death	Both Both Both Both Both	> 50% recorded as structured data for all pts	□ PMS □ R-ADT □ EHR Connection
5. Maintain up-to-date problem list of current and active diagnoses (ICD-9-CM or SNOMED)	Both	> 80% all pts have one entry or indication of no problems recorded as structured data	□Problem List □ Mapping tools
6. Maintain active medication list (RxNorm)	Both	> 80% all pts have at least one entry recorded as structured data	☐ Med List ☐CPOE/eRx Connection

CORE Set of Criteria Stage 1, Continued			
Objectives (Standards)	EP/H	Measures	Application
7. Maintain active medication allergy list	Both	> 80% all pts have at least one entry recorded as structured data	☐ Med List ☐CPOE/eRx Connection
8. Record/chart changes in V/S: Height, weight, blood pressure Calculate and display BMI Plot and display growth charts (for 2-20 y/o, including BMI)	Both	>50% pts age ≥ 2 y/o have height, weight, BP recorded as structured data in EHR Exclusion if pts ht, wt, & BP have no relevance to scope of practice	□Vital signs □Trend data
9. Record smoking status ≥ 13 y/o	Both	>50% unique pts age ≥ 13 y/o recorded as structured data in EHR Exclusion if no pts ≥ 13 y/o	□Social hx
10. Implement one CDS rule relevant to specialty or high clinical priority, w/ability to track compliance w/rule	Both	Implement (Y/N) one CDS rule	□CDS
11. Provide pts on request electronic copy (CCD or CCR) of: Diagnostic test results Problem list Medication list Medication allergy list Discharge summary Procedures	Both Both Both Both H	>50% of pts who request, within 3 business days from EHR Exclusion if no pts request electronic copy during reporting period	□ CD, PHR, pt portal, with encryption

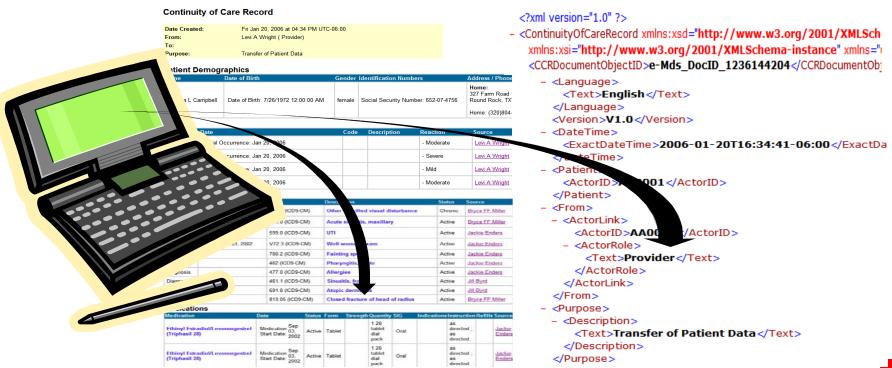
CORE Set of Criteria Stage 1, Continued			
Objectives (Standards)	EP/H	Measures	Application
12. Provide pts electronic copy of discharge instructions	Н	>50% of pts w/EHR who request Exclusion if no pts request electronic copy during reporting period	□ CD, PHR, pt portal ,with encryption
13. Provide pts clinical summaries (CCD or CCR) for each office visit	EP	>50% of all visits w/EHR w/in 3 business days Exclusion if EP has no office visits	□ CD, PHR, pt portal, with encryption
14. Ability to exchange key clinical information w/providers & pt authorized entities (CCD or CCR), e.g., Problem list Medication list Medication allergies Diagnostic test results	Both	At least one test of capacity (Y/N)	□ CD, PHR, provider portal, with encryption □HIE
15. Protect electronic health information created or maintained by EHR through implementation of appropriate technical capabilities	Both	Conduct or review a security risk analysis per HIPAA and implement security updates as necessary and correct identified security deficiencies (Y/N)	
16. Report clinical quality measures (CQM) to CMS or State	Both	2011: Attest to aggregate numerator, denominator, exclusions	□Report writer □Select from all measures

MENU Set of Criteria Stage 1			
Objectives (Standards)	EP/H	Measures	Application
17. Implement drug-formulary checks	Both	Enabled (Y/N) with access to at least one internal or external formulary for reporting period	□ eRx □ PBM data feed (e.g., SureScripts)
18. Incorporate clinical lab test results (in +/- or numerical format) into EHR as structured data	Both	>40% of lab test results ordered w/EHR in reporting period Exclusion if no lab tests in +/- or numerical format	□ LIS □ Trend data
19. Generate lists of pts by specific conditions for QI, reduction of disparities, research, or outreach	Both	Generate at least one report (Y/N) listing pts with a specific condition	☐ Report writing
20. Use EHR to identify pt-specific education resources and provide if appropriate	Both	> 10% of all pts provided pt- specific education resources	☐ Pt portal☐ Education resource integrated w/EHR
21. EP or H who receives a patient from another setting of care or provider of care or believes an encounter is relevant should perform medication reconciliation	Both	>50% of transitions of care w/EHR Exclusion if EP or H not recipient of transitions	☐ CPOE☐ Pharmacy IS☐ E-MAR☐ Medication reconciliation utility
22. Capability to submit electronic syndromic surveillance data to public health & actual submission	Both	One test (Y/N) of capacity and follow up submission (unless no capacity) Exclusion if does not collect reportable data on pts	☐ Report writing☐ Transmission routine☐ HIE☐

MENU Set of Criteria Stage 1, Continued			
Objectives (Standards)	EP/H	Measures	Application
23. EP or H who transitions pt to another care setting or refers pt to another provider provide summary of care record for each transition or referral	Both	>50% of transitions of care and referrals w/EHR Exclusion if no transfer of care	□ Report writing □ CCD/CCR □ Encryption
24. Capability to submit electronic data to immunization registries or Immunization Information Systems and actual submission in accordance with applicable law and practice	Both	One test (Y/N) of capacity & follow up submission (unless no capacity) Exclusion if immunizations not administered	☐ Report writing☐ Transmission routine☐ HIE
25. Capability to submit electronic data on reportable lab results to public health and actual submission	Н	One test (Y/N) of capacity and follow up submission Exclusion if public health has no capacity to receive	☐ Report writing☐ Transaction☐
26. Record advance directives for pts ≥ 65 y/o	Н	>50% of pts status recorded in EHR Exclusion if no pts ≥ 65 y/o	□ R-ADT
27. Send reminders to pts per pt preference for preventive/follow up care	EP	>20% of pts ≥ 65 y/o, or ≤ 5 y/o sent via EHR reminder for reporting period Exclusion if no pts in ages	☐ Report writing☐ PHR, pt portal, with encryption
28. Provide pts timely electronic access to lab results, problem list, med list, allergies within 4 business days of information being available	EP	>10% of all pts provided timely electronic access subject to discretion to withhold information	□ CD, PHR, pt portal, with encryption

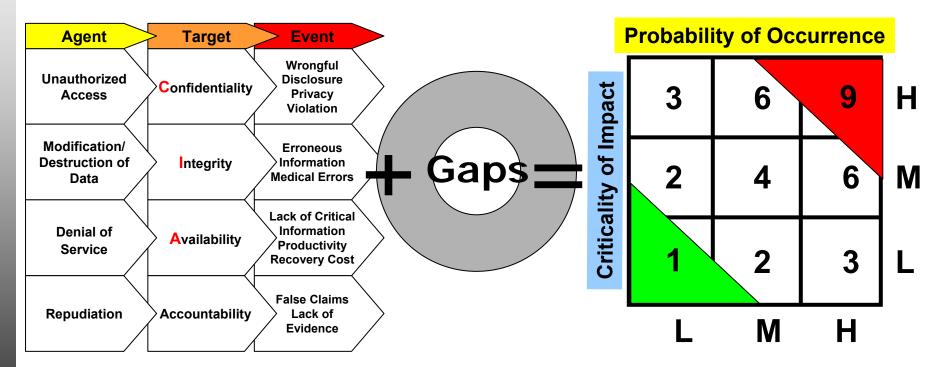
Patient Summary Record Standards

- ASTM CCR is a core data set that supports referrals, transfers, and other uses by different providers
- HL7 CDA is a document markup specification providing a multi-level architecture accommodating varying degrees of markup granularity
- CCR + CDA = CCD may be incorporated into a data exchange by reference to a PDF (in HL7 V2.x) or embedded as an XML format (in HL7 V3)



Security Risk Analysis

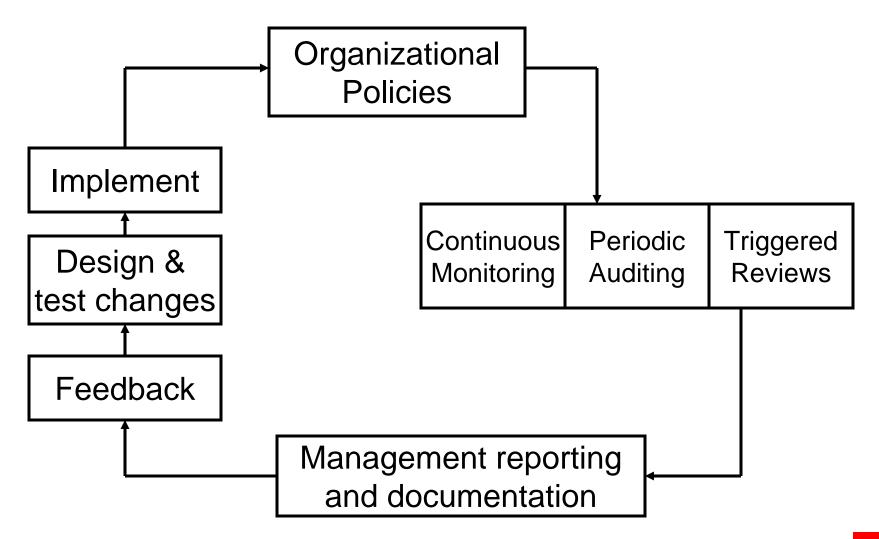
Threats Vulnerabilities Risk



Computer Security Division Computer Security Resource Center

- SP800-122, Jan. 13, 2009 Draft Guide to Protecting Confidentiality of Personally Identifiable Information (PII)
- SP800-115, Sept. 2008 Technical Guide to Information Security Testing and Assessment
- SP800-114, Nov. 2007, User's Guide to Securing External Devices for Remote Access
- SP800-111, Nov. 2007, Guide to Storage Encryption Technologies for End User Devices
- SP800-88, Sept. 2006, Guidelines for Media Sanitization
- SP800-66 Oct. 2008 Introductory Resource Guide for Implementing HIPAA Security Rule
- SP800-53, Aug. 2009, Recommended Security Controls for Federal Information Systems and Organizations
- SP800-53A, Jul. 2008, Guide for Assessing Security Controls in Federal Information Systems
- SP800-52, Jun. 2005, Guidelines for Selection and Use of Transport Later Security (TLS) Implementations
- SP800-39, Apr. 3, 2008, Draft Managing Risk from Information Systems: An Organizational Perspective

Implementing Policies



Chicago Tribune Opinion

Blundering past HIPAA

Privacy laws running amok

SUNDAY, January 24, 2010

Recently, at my local Starbucks I asked the barista behind the counter about a medical problem she had that will require surgery. Her answer left me astonished, "Management said I can't talk about my health — it's a HIPAA violation."

This shows what a farce things have become with HIPAA, the 1996 Health Insurance Portability and Accountability Act. Forget for a moment about the kind of management that mandates such nonsense. From the outset, this law has been poorly understood and badly implemented.



's har information for personal gain faces a maximum of 10 years imprisonment, a \$250,000 fine or both.

Andrea Smith, LPN, 25, of Trumann, Arkansas, and her husband, Justin Smith, were indicted on federal charges of conspiracy to violate and substantive violations of the Health Insurance Portability and Accountability Act (HIPAA) in December. At the time, Smith worked as a nurse at Northeast Arkansas Clinic, a multispecialty clinic in Jonesboro, Arkansas.

Smith accessed a patient's private medical information on November 28, 2006, according to the indictment. She then shared that information with her husband, who on that same day, called the

patient. Justin Smith reportedly told the patient he intended to use the information against the patient in an upcoming legal proceeding.

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