Texas Public Health Committee

Patient Expectations for Health IT:

Control over Health Records Privacy Solutions for HIE

May 11, 2010 Deborah C. Peel, MD

patientprivacyrights

Patient expectations

Americans expect control over personal health data, but....



Where did this slide come from ? The Medical Information Bureau website. The MBI sells claims/health data to insurers and employers

35% of Fortune 500 companies admit to using medical records for hiring and promotions

What does 'privacy' mean?

The *NCVHS* (June 2006, Report to Sec. Leavitt) defined health information privacy as "an individual's right to control the acquisition, uses, or disclosures of his or her identifiable health data".

(Definition originally from the IOM)

Federal Goal: no health privacy

- 2014: every American will have an electronic health record (EHR)
- All EHRs and PHRs will be data mined for populationbased research, Quality Improvement(QI),
 Comparative Effectiveness Research (CER), P4P, public health, fraud and abuse, personalized medicine, law enforcement, Patriot Act
- violates US and TX Constitutional rights to privacy
- result: black market medical system, only the rich can afford privacy

HIPAA regs eliminate consent and privacy

1996

Congress passed HIPAA, <u>but did not</u> pass a federal medical privacy statute, so the Dept. of Health and Human Services (HHS) was required to develop regulations that specified patients' rights to health privacy.

"... the Secretary of Health and Human Services shall submit to [Congress]...detailed recommendations on standards with respect to the privacy of individually identifiable health information."

2001

President Bush implemented the HIPAA "Privacy Rule" which recognized the "right of consent". HHS wrote these regulations. **65 Fed. Reg. 82,462** "...a covered health care provider must obtain the individual's consent, in accordance with this section, prior to using or disclosing protected health information to carry out treatment, payment, or health care operations."

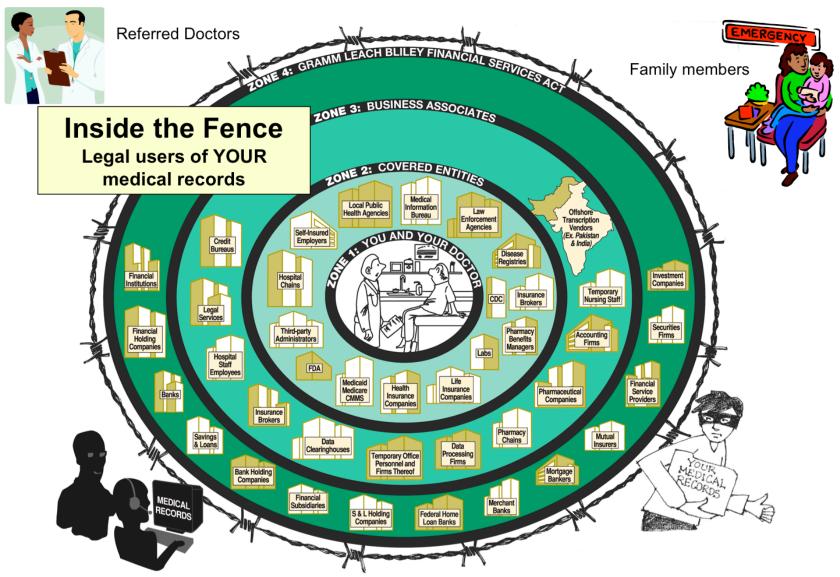
2002

HHS amended the HIPAA "Privacy Rule", eliminating the right of consent.

67 Fed. Reg. 53,183

Public Law 104-191

"The consent provisions...are replaced with a new provision...that provides regulatory permission for covered entities to use and disclose protected health information for treatment, payment, healthcare operations."



www.patientprivacyrights.org

Reality: massive health data mining industry

+

ease of re-identifying health information

2010: Top Fortune 500 Companies health data mining industry

- 4 General Electric (GE Centricity EHR/HIT systems, sells clinical data) revenue 157B
- 14 McKesson (sells Rx data) revenue 107B
- 18 CVS Caremark (sells Rx data) revenue 99B
- 21 <u>UnitedHealth Group</u> (*sells RX data*) thru Ingenix subsidiary) revenue 87B
- 31 WellPoint (sells claims/clinical data via BHI) revenue 65B



Clinical Data Services

About 15,000 MDs (primary care, specialty)

De-identified, standardized data

Warehoused nightly
15 million unique patients, growing at 30% a year

The de-identified data is collected from members using GE Centricity® Electronic Medical Record. The database is used by outcomes researchers, members of the pharmaceutical industry, and academic institutions in the hopes of improving clinical care and outcomes throughout the healthcare industry.

The CDS Advantage Patient encounters since 1996; average 3 years data

Expanded demographic information (+ 3 digit zip code), insurance

Pharmaceutical therapeutic class, and brand name

Clinical Data Services

GE Healthcare's Clinical Data Services Business provides access to de-identified ambulatory electronic medical record data. It is one of the largest anonymized clinical databases in the United States providing access to real-world longitudinal patient information.



Clinical Data Services

The CDS Advantage

Disease Counts in Database

Hypertension 2,284,249

Hyperlipidemia 2,212,629

Depression 1,185,828

Cardiovascular Disease 1,004,214

GERD 984,864

Diabetes 922,169

Asthma 750,963

Osteoarthritis 602,043

COPD 319,310

ADD/ADHD/HKD 188,424

Rheumatoid Arthritis 85,757

Alzheimer's 35,790

Parkinson's 22,017

Note: Data reported as of

February 28th, 2010

Codified Medical Problems

Prescriptions/Historical Meds

Patient Allergies, Medical Orders

and Events

Vital Signs and Physical Findings

Lab Values

https://www2.gehealthcare.com/portal/site/usen/ menuitem.b399d8492e44a6765c09cbd58c829330/?

<u>vgnextoid=ae0f4fb9efff5210VgnVCM100000382b3903RCRD&fromChannel=7e0f4fb9efff5210Vgn</u>VCM100000382b3903



Prime*Research part of an* EHR/ Practice Management Suite

"Key Benefits for Physicians"

"Make clinical research
participation a revenue source"ie, doctors sell access to their
patients and patients' records
for:

clinical trials
Phase II - IV trials
Post marketing surveillance
Patient registries
Peri- and post-approval research
Safety and surveillance monitoring
evidence-based medicine
pharmaceutical research
clinical and financial benchmarking services.

<u>The result – increased practice revenues</u> and access to patient care improvements."

GREENWAY HELPS PHYSICIANS SELL:

- "de-identified" clinical data
- "de-identified" financial data
- population data
- information on 19 million active patients
- data on 18 million encounters/yr
- data on 8 million prescriptions/yr
- data on 8,000 active providers
- data on 30 specialties and subspecialties in 48 states

http://www.greenwaymedical.com/solutionprime-research/





By combining award-winning software, services, and a proprietary rules database, we've created a network that is used by **19,500 physicians** and medical providers nationwide.

http://www.athenahealth.com/strategic-alliances/index.phphttp://www.athenahealth.com/strategic-alliances/index.php





Athenahealth Paying Dearly to Take on Larger Rivals by Ryan McBride 5/6/10

"Athena might be able to halve the amount that physicians pay to use its EHR if they participate in "AthenaCommunity."

Athena's EHR customers who opt to share their patients' data with other providers would pay a discounted rate to use Athena's health record software.

Athena would be able to make money with the patient data by charging, say, a hospital a small fee to access a patient's insurance and medical information from Athena's network.

http://www.xconomy.com/boston/2010/05/06/ athenahealth-paying-dearly to-take-on-largerrivals/3/

Healthcare IT News

Practice Fusion expands, shows signs of rapid growth By Diana Manos, Senior Editor 12/31/07

Practice Fusion subsidizes its free EMRs by selling de-identified data to insurance groups, clinical researchers and pharmaceutical companies.

Howard said he does not expect data-sharing will be a concern to physicians who use Practice Fusion's EMRs. "Every healthcare vendor is selling data."

DARTNet

Distributed Ambulatory Research in Therapeutics Network

- extracts "de-identified" Critical Care Record (CCR) from EHRs of 400K patients treated by 500 primary care docs
- patient consent not obtained -research uses physician consent instead
- physicians prompted to obtain specific information <u>during</u> patient visits
- 2nd study on Depression needs 2.4 M patients, will add a RHIO

8 DARTNet orgs/EHR vendor

Medical Clinic of North Texas NextGen®
WellMed Medical Group (TX) SmartClinic®

Tiena Health (TX) Allscripts Professional®

Wilmington Health Asso. Allscripts Professional®

University of Colorado Allscripts Enterprise®

University of Minnesota Allscripts Enterprise®

Cranford Family Medicine (AK) e-MDs[®] Family Health Center of Joplin e-MDs[®]

http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-andreports/?pageaction= Displayproduct&productID=151

Patient info available via DARTNet but not through claims data

Medication allergies

Reason for appointment

Family history

Findings (BP, weight, height, etc.)

Social history (alcohol and tobacco use, etc.)

Laboratory orders and results

Prescribed medications

Past medical history

Date of onset of disease

Referrals

Provider-level data

Practice-level data

Data collected/<u>prompted for collection</u> at point of care

2010: Top Fortune 500 <u>Health Care: Pharmacy and Other</u> <u>Services</u> (health data mining industry)

Rank Company 500 rank Revenues(\$ billions)

1 Medco Health Solutions #35 59.8 (sells Rx data)

2 HCA (largest US hospital chain) #77 30 (?? sells hospital and Rx data)

3 Express Scripts #96 25 (sells Rx data)

4 Quest Diagnostics #303 7 (sells data/sends data to HIEs)

"transforms millions of test results into valuable information products" http://www.questdiagnostics.com/brand/careers/index.html#services

5 Omnicare #347

6.3 (???)

(leading Rx provider for seniors) "we capture a tremendous amount of data" ...combines data with outcomes algorithm technology

6 Lab Corp. of America #442

4.7 (sells data??/sends data to HIEs)



What is BHI® (Blue Health Intelligence)?

share critical health information with employers premier health intelligence resource in the nation unmatched detail about healthcare trends and best practices while protecting individual privacy

BHI sets the new standard for healthcare data aggregation, reporting and analysis

Size and Value

- 1) longitudinal data on 54 million BCBS members [used for this purpose without consent]
- 2) 36 months of historical information
- 3) reporting not only by MSA, industry and product type, *Diagnosis Related Groups (DRGs)* code, *age group* and *gender* [allows re-identification]

How does BHI ensure the privacy and security of members' healthcare information?

- 1) adheres to HIPAA regs [no consent for use and sale of data] throughout the collection and processing of company data [your health information is BCBS' corporate asset]
- 2) Use a <u>system-generated identifier</u>, allowing <u>longitudinal analysis</u> [allows re-identification]
- 3) **fully de-identified in accordance with HIPAA** [17 identifiers removed, still allows re-identification of .04%]

http://www.bcbs.com/innovations/bhi/bhi-faqs-1-12-09.pdf

Health Research Data for the Real World: the MarketScan Data Bases

David M. Adamson, PhD Stella Chang, MPH Leigh G. Hanson, MS, MBA

Research and Pharmaceutical Division Thomson Medstat January 2006

Medicare and Medicaid data is for sale

Uninsured Medicaid 15% 12% Individual 5% Medicare w/o ES Medicare & Employer Supplemental (ES) Employer Source: State Health Facts Online, The Henry J. Kaiser Family Foundation, www.statehealthfacts.kff.org; U.S. residents - 285,007,110. Note: Percentages do not add to 100% because of rounding.

Figure 1: Population Distribution by Insurance Status — 2002

To address the need for better data on privately insured Americans, Thomson Medstat created the MarketScan® data collection. Since its creation, MarketScan has been expanded to include data on Medicare and Medicaid populations as well, making it one of the largest collections of claims-based patient data in the nation. MarketScan data reflect the real world of treatment patterns and costs by tracking millions of patients as they travel through the healthcare system, offering detailed information about all aspects of care. Data from individual patients are integrated from all providers of care, maintaining all healthcare utilization and cost record connections at the patient level.

Personal health information is for sale

Table 1: Sample Data Elements for Commercial and Medicare Databases

Demographic	Medical Information (Inpatient and Outpatient)	Health Plan Features	Financial Information	Drug Information	Enrollment Information
Patient ID	Admission date and type	Coordination of benefits amount	Total payments	Generic product ID	Date of enrollment
Age	Principal diagnosis code	Deductible amount	Net payments	Average wholesale price	Member days
Gender	Discharge status	Copayment amount	Payments to physician	Prescription drug payment	Date of disenrollment
Employment status and dassification (hourly, etc.)	Major diagnostic category	Plan type	Payment to hospital	Therapeutic class	
Relationship of patient to beneficiary	Principal procedure code		Payments—total admission	Days supplied	
Geographic location (state, ZIP Code)	Secondary diagnosis codes (up to 14)			National drug code	
Industry	Secondary procedure codes (up to 14)			Refill number	
	DRG			Therapeutic group	
	Length of stay				
	Place of service				
	Provider ID				
	Quantity of services				

Businessweek July 23, 2008: "They Know What's in Your Medicine Cabinet,

How insurance companies dig up applicants' prescriptions—and use them to deny

coverage" http://www.businessweek.com/magazine/content/08_31/b4094000643943.htm?chan=magazine+channel_in+depth

DATA ON DEMAND

Two companies dominate the field of selling prescription information to insurance companies:

	MEDPOINT	INTELLISCRIPT		
Parent	UnitedHealth Group's Ingenix	Milliman		
Location	Eden Prairie, Minn.	Brookfield, Wis.		
History	UnitedHealth acquired MedPoint in 2002 from a small, Utah- based health-technology company, Nex2	Milliman, a Seattle consulting firm, acquired IntelRx and its IntelliScript product in 2005		
Fine print	Delivers five-year history of drug purchases, dosages, refills, and possible medical conditions	Similarly provides five-year purchase history, which includes information on pharmacies and treating physicians		
Pitch to insurers	"Identify high-risk individuals, reduce costs, lower loss ratios, and increase revenue"	"Clients report financial returns of 5:1, 10:1, even 20:1"		
Data: MedPoint and IntelliScript				

Anonymous data isn't

"... a common practice is for organizations to release and receive person specific data with all explicit identifiers, such as name, address and telephone number, removedbecause the resulting data look anonymous.

However,... the remaining data can be used to re-identify individuals by linking or matching the data to other data .."*

Latanya Sweeney, PhD, Director, Laboratory for International Data Privacy, School of Computer Science, Carnegie Mellon University

^{*}k-anonymity: a model for protecting privacy. *International Journal on Uncertainty, Fuzziness and Knowledge-based Systems,* 10 (5), 2002; 557-570.

Anonymous data isn't

"We must respond to the surprising failure of anonymization"

Anonymization, [is] the name for techniques for protecting the privacy of individuals in large databases by deleting information like names and social security numbers

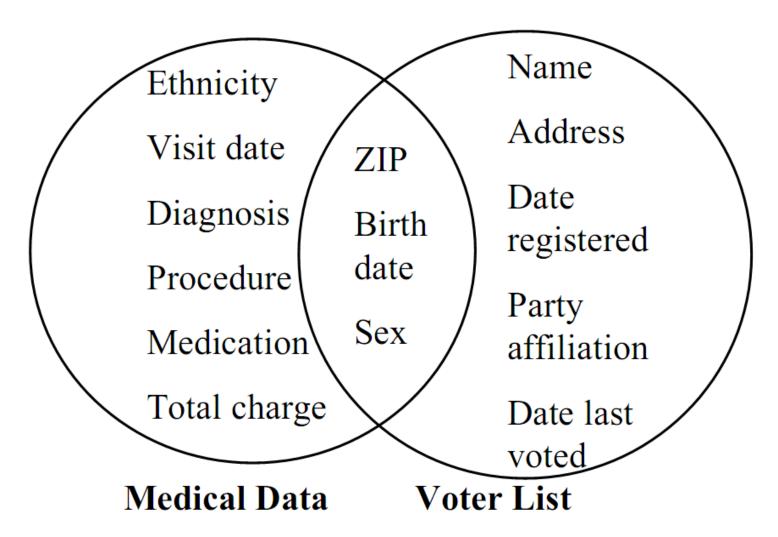
"[S]cientists have demonstrated they can often "reidentify" or "deanonymize" individuals hidden in anonymized data with astonishing ease"*

Paul Ohm, Associate Professor, University of Colorado Law School

* Broken promises of Privacy: Responding to the Surprising Failure of Anonymization, VER. 0.99 SSRN: 8/14/2009:

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1450006&rec=1&srcabs=1446862

Linking to re-identify data



L. Sweeney. Weaving technology and policy together to maintain confidentiality. *Journal of Law, Medicine and Ethics*. 1997, 25:98-110.

Health IT and HIE: 2 separate worlds

Corporations, Govt, & some Doctors

- Industry-centered system
- LOTS of Data = commodity = \$\$\$\$
- massive data flows and 2^{ndary} use of sensitive personal data
- Data theft, no consent
- Robust HIT systems
 - One hospital = 200+ HIT systems
- Robust HIE
- Vendors and users sell data
- Data flows outside US
- Massive security flaws
- "Wild West"-- data mining for profit and discrimination
- Unfair and deceptive trade practices

Patients, Family, & some Doctors:

- Not "patient-centered"
- Hardly any data
- Limited control over PHI
- Limited access to PHI
- Limited benefits from HIT
- Limited HIE
- Massive harms/risks from HIT/HIE
- Limited recourse from harms
- Can't restore data privacy = no way to "make whole" or repair exposure
- Generations of discrimination
- Secret health data bases
- No transparency/accountability
- No privacy and weak security
- Patient Safety—EHRs can harm, be source of errors, can't delete/amend

ARRA—new privacy rights and MU

Old rights under HIPAA:

- Providers may offer consent (Original HIPAA Privacy Rule), so patients can restrict disclosures---not addressed in MU
- Psychotherapy Notes require consent to disclose---not addressed in MU

New rights under ARRA:

- Ban on sales of PHI (Protected Health Information)---2010 (waiting for NPR)
- Segmentation---delayed
- Audit trails x 3 years---2011 or later
- Breach notice---2010
- Encryption---2010 industry is not doing this
- Patient can prevent disclosures of PHI for 'payment and healthcare operations' if pays out-of-pocket---not addressed
- Consent Technologies---2014 or later

Latanya Sweeney on defects of Meaningful Use (MU) EHRs and NHIN/HIEs

Secondary use of PHI by Business Associates is "unbounded, widespread, hidden, and difficult to trace."

Implementing MU EHRs will "increase data sharing, but adding the NHIN will massively increase data sharing."

The two models HHS proposed for the National Health Information Network to link all Americans' health information online do not offer "utility or privacy".

Consequences

No right to privacy & no federal definition of 'privacy' =

- > 4 million Covered Entities (CEs) access PHI for TPO
- Millions of employees of CEs and Business Associates (BAs) access PHI
- Consumers do not control access to PHI

Weak security

- Easy to hack (security far weaker than financial industry standards)
- Clouds unsafe, P2P software leaks data, web apps (SaaS/SSL) leak data*
- Hospital/enterprise 'role-based' rather than person-by-person access to millions of records allows massive 'insider' snooping and theft
- Strong 2nd factor authentication for access not required
- Encryption at rest, in use, in transit not implemented
- Ease of copying, stealing, losing mobile devices

Secondary use of data

The business model for many HIT systems is selling data

No trusted seals-of-approval for privacy (yet) or security (yet) Industry seal-of-approval for security (HITRUST)

^{*} http://www.informatics.indiana.edu/xw7/WebAppSideChannel-final.pdf

EHRs without consent
PHRs without consent
HIEs without consent
NHIN without consent
Research without consent

Key References:

EHRs "Your Medical Records Aren't Secure" by Deborah C. Peel in the WSJ, March 23, 2010 http://online.wsj.com/article/SB10001424052748703580904575132111888664060.html

PHRs "Who can snoop in your PHR? A Personal Health Record Report Card http://patientprivacyrights.org/personal-health-records/

HIEs and NHIN "Designing a Trustworthy Nationwide Health Information Network (NHIN) Promises Americans Privacy and Utility, Rather than Falsely Choosing Between Privacy or Utility" by Latanya Sweeney, PhD, April 22, 2010, Congressional Briefing on the "Implementation of Health Information Technologies in a Healthcare Environment"

http://patientprivacyrights.org/wpcontent/uploads/2101/04/SweeneyCongressTestimony-4-22-10.pdf

Research "Improve Privacy in Research by Eliminating Informed Consent?" IOM Report Misses the Mark. In The Journal of Law, Medicine & Ethics, Volume 37, Issue 3 (p 507-512) by *Mark A. Rothstein*.

NHIN/ HIEs/HIOs models

- some HIEs/HIOs hold data and exchange data
- some HIEs/HIOs only exchange data

NHIN/ HIEs/HIOs flaws

- ALL allow broad "stakeholder" (insurers, employers) access to data
- patients don't want "stakeholder" access
- impossible to share data selectively (segment sensitive records)
- Illegal, blanket consents = impossible to share data 1-to-1
- Labs and Rx data industry will dump 1,000s of "batched" test reports and prescriptions into HIOs—patients' privacy will be violated even if they opt-out
- without segmentation, HIE/NHIN can't exchange data across state lines with states that DO comply with state laws for segmentation
- without segmentation can't put teens data, genetic data, STDs, mental health, addiction data into HIT systems

"Patient-centered" solutions: consent tools health banks trustworthy HIEs/HIOs/NHIN

Health Record Banks

- Cradle-to-grave PHI is stored in a Health Record Bank account
- Patient (or designee) controls all access to account information [copies of original records held elsewhere]
- When care received, new records sent to bank for deposit in patient's account
- All data sources must contribute PHI at patient request (per HIPAA and ARRA)

Privacy-enabled Research

- The public does not agree with broad research access to PHI
- Consent technology enables cheap and easy contact and recruitment of millions of patients instantly
- Health record banks can enable Americans to participate in research without risk, because data does not have to be disclosed
- Independent consent management tools and health record banks facilitate <u>research</u>

Secondary use w/consent & health banks

- Independent consent management tools ensure privacy
- Health record banks facilitate <u>desired</u> secondary uses
 - Searches over large populations is easy
 - Not necessary to release PHI
 - Counts of matches with demographics normally sufficient
 - Eliminates issues of "de-identification" and reuse
 - Can combine searches over multiple banks
 - Bank notifies consumers according to consumer preferences (clinical trial recruitment, drug withdrawal from market, etc)

Patient-centered HIT system

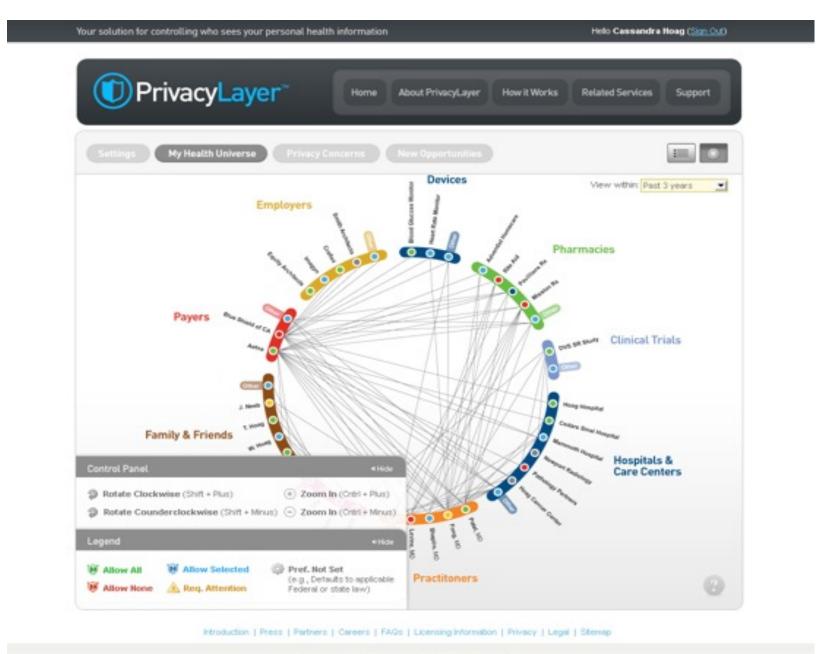
- 1. independent online consent tools--benefits
 - dynamic, not static
 - works like online banking "Bill Pay"
 automatic rules (like monthly payments), or case-by-case
 - ability to share selectively (in accord with laws, rights, expectations)
 - no need to update consents in many locations
 - no need for MPI or single patient ID
 - independent audit trails of all uses and disclosures
 via use of authentication systems (employees have unique access codes)

Patient-centered HIT system

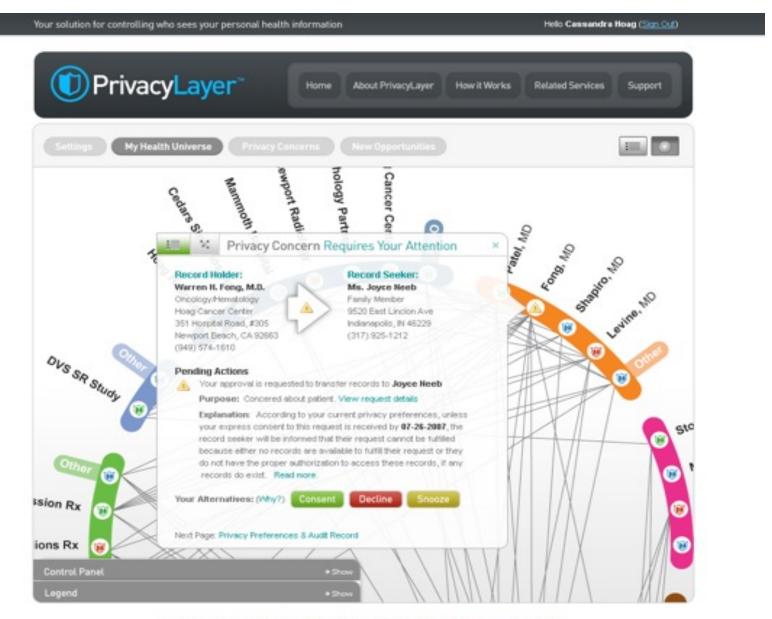
2. health banks

- ironclad security and architecture
- today there is no place w/ a complete and accurate copy of our health records
- patients control access and use of PHI
- only patients can collect complete and <u>accurate</u> PHI
- 'safe' research without risk of exposing data
 - like census bureau: run research queries on individual data
 - unlike census bureau, no research without consent
 - sensitive data is NOT released
- no need for MPI or UPIN (single ID)---patients have separate ID at each location = better privacy protections (stolen data has less value)

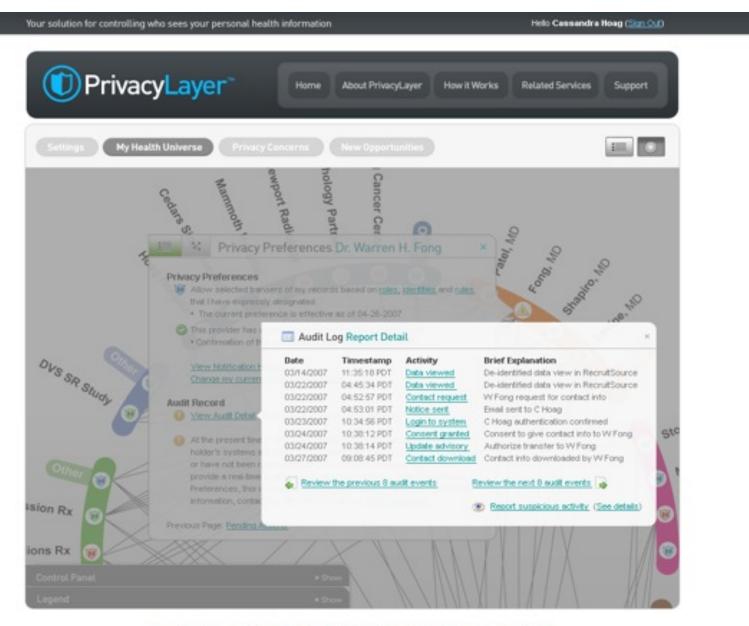
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Open Source Consent Solutions

- 1. Make the National Data Infrastructure Improvement Consortium (NDIIC) open source electronic consent module the minimum standard for consent tools in all HIT systems
- 2. Extend 42 CFR Part 2 to cover all PHI wherever it is held.

Audit trails based on authentication

Mar 01, 2010

Imprivata's PrivacyAlertTM Detects Snooping and Identity Theft:

- detects snooping, identity theft and inappropriate access
- automated and scalable privacy monitoring
- investigate and report data breaches
- investigate employees, patients or both
- Out-of-the-box supports all leading healthcare applications--Eclipsys,
- GE Centricity Enterprise, MEDITECH Magic, Siemens Invision, etc.

http://www.marketwire.com/press-release/Imprivatas-New-Product-Helps-Hospitals-Proactively-Investigate-Audit-Access-Patient-1123908.htm

Industry Challenges

- cost to add ARRA/HITECH privacy and security protections
- cost to comply with <u>existing</u> privacy rights
- time to upgrade technologies
- conflicts of interest
- don't view patients as their customers
- fear innovation will be stifled
- **liability**: state defendants AZ/Havasupai, TX Newborn Bloodspots, will industry be next for defective products, noncompliance with laws?

Industry Solutions

- partner with consumers/privacy advocates
- commit to progress over time
- test/research/fund consent tools and privacy-enhancing HIEs/HIOs
- seek state/federal funding for "patientcentered" HIT systems and HIEs/HIOs
- risk analyses of all NHINs/HIEs/HIOs

Goals for Texas

- #1 in the nation for trusted HIT
- #1 in biomedical research w/consent
 - -build on Texas' leadership & investments in healthcare,technology, innovation

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