

# The HIPAA Years In Review

- What a Short, Strange Trip It's Been
- Marc "Privacy-Dude" Goldstone, Your Conductor and Lead on Air Guitar
- Hal "Band Security" McCard, your Engineer and Chief HIPAA Roadie



# ***D'où venons nous? Que sommes nous? Où allons nous?***

(1897-1898)

Paul Gauguin



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- This is all a figment of our (somewhat twisted) minds.
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# Where Do We Come From ?

- Regulation- HIPAA Privacy, Security, Transactions and Code Sets, EHR
- Litigation- Is That All There Is? (Sorry, Peggy Lee)
- Enforcement- Set Up Like a Bowling Pin
- The Future- The “Ripple” Effect

## HIPAA Administrative Simplification Compliance Deadlines

Date	Deadline
October 15, 2002	Deadline to submit a compliance extension form for Electronic Health Care Transactions and Code Sets.
October 16, 2002	Electronic Health Care Transactions and Code Sets - all covered entities except those who filed for an extension and are not a small health plan.
April 14, 2003	Privacy - all covered entities except small health plans.
April 16, 2003	Electronic Health Care Transactions and Code Sets - all covered entities must have started software and systems testing.
October 16, 2003	Electronic Health Care Transactions and Code Sets - all covered entities who filed for an extension and small health plans.
October 16, 2003	<u>Medicare will only accept paper claims under limited circumstances.</u>
April 14, 2004	Privacy - small health plans.
July 30, 2004	Employer Identifier Standard - all covered entities except small health plans.
April 20, 2005	Security Standards - all covered entities except small health plans.
August 1, 2005	Employer Identifier Standard - small health plans.
April 20, 2006	Security Standards - small health plans.
May 23, 2007	National Provider Identifier - all covered entities except small health plans
May 23, 2008	National Provider Identifier - small health plans

# Where We Come From

## Regulation



# **Medical-privacy law creates wide confusion**

By Laura Parker, USA TODAY(10/17/03)

## **PRIVACY RULES**

- The privacy provisions in the original Health Insurance Portability and Accountability Act began as a 337-word guideline, but the final regulations swelled to 101,000 words.
- The regulations were issued at the end of the Clinton administration but revised by the Bush administration.
- Doctors and other health care providers are required to provide written notice to patients describing the regulations and patients' rights.
- The law prohibits consumers from suing over privacy violations. Consumers must complain to the government instead.
- More than 2,400 complaints have been filed since April. A third have been resolved without penalty. The rest are being reviewed by HHS.

# USA Today (continued)

- In the medical community, there is rising concern about the cost of complying with the privacy rules, too. Many doctors say the government has issued a mandate without providing funds to pay for it.
- Blue Cross estimates the cost of complying with the privacy law at about \$43 billion over five years to cover new staffing, computer software and paperwork.
- A group of 660 physicians in Wisconsin spent \$75,000 on paper, printing, mailing and handling privacy notices for 200,000 patients. A 145-bed hospital in Concord, Mass., calculated that each year it will have to document more than 300,000 disclosures of protected information.



# Where We Come From

## Litigation



# Where We Come From - Litigation

- HIPAA provides a “floor” not a ceiling
- Multiple individual state laws affecting medical privacy
- Some states conflict with other states
- Some diseases and medical conditions receive different privacy treatment
- Majority of issues appear as mundane as determining civil/criminal procedure

# Where We Come From - Litigation

It's Ex Parte and I'll Cry If I Want To



# Where We Come From - Litigation

- **Smith v. American Home Products Corp. Wyeth-Ayerst Pharmaceutical**, 855 A.2d 608 (N.J. Super.L. 2003)
  - (1) No preemption of New Jersey informal discovery process with plaintiff's medical provider;
  - (2) Preemption of content of New Jersey patient disclosure authorizations.
- **Law v. Zuckerman, M.D.**, 307 F.Supp.2d 705 (D.Md. 2004)

HIPAA preempted Maryland state law and governed all ex parte communications between defense counsel and patient's treating physician.

# Where We Come From - Litigation

- **Keshecki v. St. Vincent's Medical Center**, 785 N.Y.S.2d 300 (N.Y.Sup. 2004)  
Hospital's attorneys violated patient's qualified rights of privacy by unauthorized interview of physicians.
- **Crenshaw v. MONY Life Insurance Co.**, 318 F.Supp.2d 1015 (S.D.Cal. 2004)  
Insurer's attorney's ex parte communications with physician violated HIPAA.

# Where We Come From - Litigation

- **In re Diet Drug Litigation**, 895 A.2d 493 (N.J.Super.L. 2005)

HIPAA did not preempt State case law that allowed ex parte interviews of physicians, and New Jersey law and North Carolina law both allowed for ex parte interviews so long as consumers consented.

# Where We Come From - Litigation

Protective Orders and Other Freaks of Nature



# Where We Come From - Litigation

- **U.S. ex rel. Stewart v. The Louisiana Clinic**, 2002 WL 31819130 (E.D. La.)  
Louisiana law requiring a court order to produce PHI after a hearing was less stringent than the HIPAA privacy regulations and “preempted” by them. Clever (though unsuccessful) “limiting instruction” argument made by defendant’s counsel.
- **Hutton v. Martinez**, 219 F.R.D. 164 (N.D.Cal. 2003)  
HIPAA did not preclude production of defendant's medical records or WC file in response to discovery request, subpoena or court order where there was an adequate protective order in place to safeguard defendant’s privacy.



# Where We Come From - Litigation

- **Westbury Medical Care, P.C. v. Lumbermans Mutual Insurance Co.**, 786 N.Y.S.2d 685 (N.Y. Dist. Ct. 2004)  
No fault insurer was subject to HIPAA, and insurer was entitled to discover documents concerning issue of concurrent care.
- **Bayne v. Provost**, 359 F.Supp.2d 234 (N.D.N.Y. 2004)  
HIPAA controlled ex parte communication with health care provider, and QPO would issue permitting defendants to interview home health care provider outside patient's presence.

# Where We Come From - Litigation

- **Northwestern Memorial Hospital v. Ashcroft**, 362 F.3d 923 (7th Cir. 2004)
  1. supersession clause of HIPAA privacy provisions does not impose state evidentiary privileges on suits to enforce federal law;
  2. HIPAA regulations' procedure for obtaining authority to use medical records in litigation does not create federal physician-patient or hospital-patient privilege;
  3. there is no federal common law privilege for abortion records; but
  4. subpoena imposed undue burden on hospital, when probative value of records in question was weighed against patients' fear of identification and consequent harm to hospital.

# Where We Come From - Litigation

- **Hill v. East Baton Rouge Parish Dept. of Emergency Medical Services**, 925 So.2d 17 (La. App. 1 Cir. 2005)  
911 communications district qualified as a health care provider; information provided during telephone calls to district requesting EMS was prohibited from disclosure by HIPAA.
- **U.S. v. Zamora**, 408 F.Supp.2d 295 (S.D.Tex. 2006)  
Clerk of federal district court was not a “judicial officer” for purpose of HIPAA regulation permitting disclosure of PHI for law enforcement purposes in compliance with a subpoena issued by a judicial officer, but government established probable cause justifying court order for production of medical center's medical records, as permitted under HIPAA.

# Where We Come From - Litigation

- **State ex. rel. Cincinnati Enquirer v. Daniels**, 844 N.E. 2d 1181 (Ohio Mar. 17, 2006)

HIPAA did not protect records required to be disclosed under state PRA. Information was not PHI and did not have identifying information.

# Where We Come From - Litigation

## Challenges to HIPAA Rule Making



# Where We Come From - Litigation

- **Association of American Physicians and Surgeons, Inc. v. US Dep't of Health and Human Services, 224 F.Supp.2d 1115 (S.D. Tx. 2002)**

1. Enactment of HIPAA was within Congress's commerce clause powers;
2. Privacy Rule was within scope of HIPAA;
3. HHS failure to promulgate the Privacy Rule within the time period set forth in HIPAA did not result in the invalidation of HHS's authority to promulgate the Rule.
4. Also held no private right of action under the Paperwork Reduction Act (PRA).
5. This was good enough for the 5<sup>th</sup> Circuit. (aff'd 5<sup>th</sup> Cir. 5/15/03, unpublished)

# Where We Come From - Litigation

- **South Carolina Medical Association v. Thompson**, 327 F.3d 346 (4th Cir. 2003)  
Declaratory judgment action was brought challenging HIPAA and regulations.
  1. HIPAA did not impermissibly delegate the legislative function;
  2. regulations were not beyond scope of congressional grant of authority; and
  3. neither statute nor regulations were impermissibly vague.
  4. This was good enough for the Supremes (U.S.cert.den.11/03/03)

# Where We Come From - Litigation

- **Citizens for Health v. Leavitt**, 428 F.3d 167 (3d Cir. 2005)

Challenge to HIPAA Privacy rule making.

1. Third Circuit upheld HIPAA regulations on a variety of constitutional and administrative grounds.
2. Case presently on petition for cert. to U.S. Supreme Court.
3. Petition to be considered September 25, 2006 per counsel for plaintiffs.
4. Plaintiff's Counsel are a tough bunch!!!



# Where We Come From - Litigation

## The Best of the Rest



# Where We Come From - Litigation

- **Gunn v. Sound Shore Medical Center of Westchester**, 772 N.Y.S.2d 714 (N.Y.A.D. 2 Dept., 2004)

Disclosure of IDs of patients present at time of plaintiff's injury was prohibited by physician-patient privilege, citing HIPAA as a policy reason behind the ruling.

- **Kalinoski v. Evans**, 377 F.Supp.2d 136 (D.D.C. 2005)

Authorization required by HIPAA was adequate to encompass release of plaintiff's ***psychotherapy*** notes.

# Where We Come From - Litigation

- **U.S. ex rel. Camillo v. Ancilla Systems, Inc.**, 233 F.R.D. 520 (S.D. Ill. 2005)  
HIPAA does not create a NEW PRIVILEGE-merely a procedure for obtaining protected medical record. In litigation (and in federal question case), more restrictive IL. law would not be followed.
- **Rogers v. NYU Hospitals Center**, 795 N.Y.S.2d 438 (NY 2005)  
Can Disclose a Hospital Patient's Roommate's Identity. The ID does not violate Roommate's privacy rights. (Gunn distinguished)

# Where We Come From - Litigation

- **In re Christopher M.**, 26 Cal.Rptr.3d 61 (Cal.App. 4 Dist. 2005)

Requiring that all records relating to minor's medical and psychological treatment be made available to court and probation officer was reasonable (citing 164.512(e)(1)(i) (disclosure of PHI in admin./judicial proceedings).

- **Steele v. Clifton Springs Hosp. and Clinic**, 788 N.Y.S.2d 587 (N.Y.Sup. 2005)

HIPAA did not permit plaintiff simply to refuse to provide medical authorizations permitting defense counsel to meet with patient's subsequent treating physicians. (Can you refuse to permit a CE to use your PHI for billing purposes, a la, you know me, but you can't bill me??)

# Where We Come From - Litigation

- **Webdale v. North General Hosp.**, 796 N.Y.S.2d 861 (N.Y.Sup. 2005)  
HIPAA did not bar the release of homicide perpetrator's medical and psychiatric records.
- **State v. Downs**, 923 So.2d 726 (La.App. 1 Cir. 2005)  
HIPAA did not govern defendant's challenge to State's request for disclosure of blood tests taken at hospital where defendant was transported following accident (DA's Office not a CE).

# Where We Come From - Litigation

- **Grove v. Northeast Ohio Nephrology Assoc., Inc.**,  
844 N.E.2d 400 (Ohio App. 9 Dist. 2005)  
State statute on physician-patient privilege was not preempted by HIPAA (state privilege more stringent).
- **Protection & Advocacy System, Inc. v. Freudenthal**,  
412 F.Supp.2d 1211 (D.Wyo. 2006)  
Neither HIPAA nor Medicaid Act barred system from accessing records at hospital and school.

# Where We Come From - Litigation

- **Bugarin v. ChartOne, Inc.**, 38 Cal.Rptr.3d 505 (Cal.App. 2 Dist., 2006)  
Court held that HIPAA did not apply to requests by attorneys for client medical records. (Not a “personal representative” for HIPAA Privacy purposes). Pay to play, Lawyer-Man.
- **Bihm v. Bihm**, 932 So.2d 732 (La.App. 3 Cir. 2006)  
Court held that HIPAA did not preclude the disclosure of records of child's counselor to ex-husband.
- **Giangiulio v. Ingalls Memorial Hosp.**, 850 N.E.2d 249, (Ill.App. 1 Dist. 2006)  
HIPAA did not preempt IL state law on non-party patient medical records which was more restrictive (citing **Nat’l Abortion Fed. v. Ashcroft**).

# Where We Come From

Enforcement





# Where We Come From- Enforcement

- DOJ- June 1, 2005 Memorandum
  - Only Covered Entities and “those persons rendered accountable by general principles of corporate criminal liability” may be directly liable under the criminal enforcement provisions of HIPAA

# Where We Come From- Enforcement

- HHS Final Rule
  - (Effective March 16, 2006)
  - Amended interim rule on CMP, modifies elements of investigations, addresses potential defensive pleading, describes hearing and appeal process for CMP imposition
  - Mandates CMP if violations occur, in accordance with factors outlined in the Rule

# Where We Come From- Enforcement

- 2 reported Criminal cases (and one of those was probably a mistake, if you read the DOJ memo)
- No CMP assessments, so far

# Where Do We Come From ? Enforcement

## **Medical Privacy Law Nets No Fines Lax Enforcement Puts Patients' Files At Risk, Critics Say**

By Rob Stein, Washington Post Staff Writer  
Monday, June 5, 2006

# Where Do We Come From ? Enforcement

- In the three years since Americans gained federal protection for their private medical information, the Bush administration has received thousands of complaints alleging violations but has not imposed a single civil fine and has prosecuted just two criminal cases.

# Where Do We Come From ? Enforcement

- 19,420 grievances
- The government has "closed" more than 73 percent of the cases -- more than 14,000 -- either ruling that there was no violation, or allowing health plans, hospitals, doctors' offices or other entities simply to promise to fix whatever they had done wrong, escaping any penalty.

# Where Do We Come From ? Enforcement

- "Our first approach to dealing with any complaint is to work for voluntary compliance. So far it's worked out pretty well," said Winston Wilkinson, who heads the Department of Health and Human Services' Office of Civil Rights, which is in charge of enforcing the law.

# Where Do We Come From ?

## Enforcement

- Wilkinson would not discuss any specific complaints but said his office has "been able to work out the problems . . . by going in and doing technical assistance and education to resolve the situation. We try to exhaust that before making a finding of a technical violation and moving to the enforcement stage. We've been able to do that."
- A "kinder and gentler" OCR?



# Where Do We Come From ?

## Enforcement

- About 5,000 cases remain open, and some could result in fines, Wilkinson said.
- His office has referred at least 309 possible criminal violations to the Justice Department. Officials there would not comment on the status of those cases other than to say they would have been sent to offices of U.S. attorneys or the FBI for investigation. Two cases have resulted in criminal charges: A Seattle man was sentenced to 16 months in prison in 2004 for stealing credit card information from a cancer patient, and a Texas woman was convicted in March of selling an FBI agent's medical records.

# Where Do We Come From ?

## Enforcement

- Top OCR complaints:
  - Private healthcare practices;
  - General hospitals;
  - Outpatient facilities;
  - Group health plans and
  - Health insurance insurers; and
  - Pharmacies

# Where Do We Come From ?

## Enforcement

- Top complaints received by OCR :
  - The impermissible use or disclosure of an individual's identifiable health information;
  - The lack of adequate safeguards to protect identifiable health information;
  - Refusal or failure to provide the individual with access to or a copy of his or her records;
  - Disclosure of more data than is minimally necessary to satisfy a request for information; and
  - Failure to have the individual's valid authorization for a disclosure that requires one.

# What Are We?

## Stuff Happens



# Stuff Happens

- **The Art of Checking Your Laptop as Luggage** By Wayne Rash  
August 17, 2006

Opinion: New air travel safety concerns have made it more likely that you'll have to send your laptop as checked luggage.

The threat was terrorism, so it's understandable why passengers on some trans-Atlantic flights suddenly found themselves trying to find a way to stash their electronics, including their laptop computers and BlackBerry devices, into their checked luggage.

Some of those items, such as cell phones, will travel fine there, but others, notably your laptop computer, aren't designed to handle the stress of luggage handlers and baggage sorting machines.

Of course, things in checked luggage have a way of not being there when you reach your "final destination".

# Questions Over Veterans' Data Loss-Officials' Response To News Of Information Theft Scrutinized

**CBS News May 22, 2006**

A day after the government announced the loss of sensitive personal information on more than 26 million U.S. veterans, questions remain about how truly deep the problem is.

That's because officials admit that data from some veterans' family members was lost, too. Veterans are asked to provide the Social Security numbers of their spouses and children.

## Veterans' Data Loss, continued

- VA Secretary James Nicholson is announcing a new data security program that will begin immediately:

"I have promised America's veterans that I intend to make VA information security a model of data security, and this expedited encryption program is a major step in that direction," Nicholson said in a statement. "A system-wide encryption program will be a tremendous step forward in improving the safety and security of sensitive veteran information." (8/18/06)

# Where Are We Going?

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# Where Are We Going?

- The Value of Personal Health Records-A Joint Position Statement for Consumers of Health Care by American Health Information Management Association (AHIMA) and American Medical Informatics Association (AMIA), July 2006

AHIMA and AMIA advocate empowering individuals to manage their healthcare through the use of a personal health record (PHR). The PHR is a tool for collecting, tracking and sharing important, up-to-date information about an individual's health or the health of someone in their care. Using a PHR will help people make better health decisions and improves quality of care by allowing them to access and use information needed to communicate effectively with others about their healthcare.

Or, will a comprehensive PHR just make it easier for criminals to get hold of your personal and confidential information in less time and with less effort than stealing your laptop? There are economies of scale to consider, even for evil-doers ...

# Where Are We Going?

- HIT for Small Business Health Care Providers Act of 2006 (Introduced in House) HR 5971 IH (Reps. Kelly and Johnson)
- To establish the Health Information Technology Loan Program within the Small Business Administration.

# Where Are We Going?

- the purpose of the guarantee is to help a small business acquire capital for the purchase of materials relating to health information technology;
- the amount of the guarantee, in the case of a guarantee under the 504 loan program, may not exceed \$75,000.

# Where Are We Going?

- 8/22/06 Executive Order (Pres. Bush):
- HIT for federal agencies: “...[agencies] as they... upgrade...shall utilize [HIT] systems and products that meet recognized interoperability standards...” (by Jan. 1, 2007)
- For contractors:”... agencies shall require in contracts with providers/health plans/health ins... recognized interoperability standards...” (by Jan. 10,2007)

# Anonymous Opinions From People We Like

- Changes in Administration/Congress may change enforcement philosophies- More emphasis on fines and punishment, more coercive
- Growth of nat'l health information superstructure including RHIOs will result in more breaches and negative publicity and may slow growth of eHealth expansion

# Anonymous Opinions From People We Like

- US privacy issues might not be resolved without comprehensive privacy laws, similar to EU approach.
- Promise lies in anonymous data mining efforts, with “de-anonymization” occurring only under approved circumstances
- Continued tension between privacy advocates and the tech. side-Trend toward interoperability, but privacy and security concerns hold back some tech. advances due to fear of mis-use

# Anonymous Opinions From People We Like

- Development of biometrics in HIT, permitting secure access to PHI wherever patient is located
- Issues subject to political process, messy compromises and “band-aid” fixes- More conservative administration favor free market approach, more liberal administrations favor individual privacy/security approach.

# Anonymous Opinions From People We Like

- HIPAA Privacy regs. on research will change due to conflicts with Common Rule and others.
- Security will become more important than privacy for media highlighted breaches
- Attempted expansion of HIPAA to entities other than current list of CEs
- Various initiatives to identify “best practices”, with potential return to federal regulation to implement (“HIPAA revisited”)



# Anonymous Opinions From People We Like

- Too many current separate initiatives in Privacy, Security and Interoperability that right now are not communicating with each other and talking to each other- Too many “silos”.
- Ever hear of Pay for Performance? You can't do that without an EMR system. Docs' won't buy it. You have to give it to them. Will they use it for EMR purposes only, or will they use the Internet connection for what EVERYONE else uses it for ... Fantasy Football drafts, of course. The liability possibilities are limitless.

# Questions?

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