

HIPAA & HEALTH INFORMATION EXCHANGE

(Perspective from the Private Sector)

Helen Oscislawski, Esq.

March 26, 2012

20th National HIPAA Summit

Washington D.C.



Attorneys at
Oscislawski LLC

© 2012 Oscislawski LLC

Where Should We Start?

Privacy &
Security with
Health
Information
Exchange



© 2012 Oscislawski LLC

HIPAA & HITECH

* State Law considerations too

- Notice of Privacy Practices (*Privacy Rule*)
- Permitted Uses & Disclosures (*Privacy Rule*)*
- Authorization & Consent (*Privacy Rule*)*
- Patient Access Rights (*Privacy Rule/HITECH*)*
- Accounting of Disclosures (*Privacy Rule/HITECH*)
- Preemption (*HIPAA/Privacy Rule*)
- Role-Based Access (*Security Rule*)
- Authentication (*Security Rule*)
- Auditing (*Security Rule*)
- Breach Notification (*HITECH*)*
- Security Gap Assessment (*Security Rule*)
- Complaints & Sanctions (*Privacy/Security Rules*)
- HIPAA BA Agreements (*Privacy/Security/HITECH*)



© 2012 Oscislowski LLC

ONC Guiding Principles for HIE

http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_privacy_security_framework/1173

- Openness & Transparency
- Individual Choice
- Collection, Use & Disclosure Limitation
- Safeguards
- Data Quality & Integrity
- Correction
- Accountability
- Individual Access



© 2012 Oscislowski LLC

CROSSWALKING HIE GUIDING PRINCIPLES *with* HIPAA

1. OPENNESS & TRANSPARENCY

There should be openness and transparency about policies, procedures, and technologies that directly affect individuals and/or their IHI.	Policy 11 – Notice of Privacy Practices with HIE Educational Brochures Policy 19 – Complaints
Individuals should be able to understand what IHI exists about them.	Policy 5 – Patient Participation & Choice Policy 11 – Notice of Privacy Practices HIE and PHR Educational Brochures
Individuals should be able to understand how their IHI is collected, used, and disclosed.	Policy 5 – Patient Participation & Choice Policy 11 – 2-layer Notice of Privacy Practices with HIE Educational Brochures
Individuals should be able to understand whether and how they can exercise choice over such collections, uses, and disclosures.	Policy 5 – Patient Participation & Choice Form G – Opt-Out Form Form H – Revocation of Prior Opt-Out Form J – PHR Authorization Form Form K – Revocation of PHR Authorization Policy 11 – Notice of Privacy Practices
Persons and entities that participate in a network for the purpose of electronic exchange of IHI should provide reasonable opportunities for individuals to review who has accessed their IHI or to whom it has been disclosed , in a readable form and format.	Policy 4 – Patient Rights (Access, <u>AOD</u> , Amendment) Policy 16 – Security Incidents & Breaches Policy 17 – Auditing
Notice of policies, procedures, and technology—including what information will be provided under what circumstances—should be timely, and, wherever possible, made in advance of the collection, use, and/or disclosure of IHI.	Policy 4 – Patient Rights (Access, <u>AOD</u> , Amendment) Policy 5 – Patient Participation & Choice Policy 11 – 2-layer Notice of Privacy Practices with HIE Educational Brochures



© 2012 Oscislowski LLC

HIE Policies (1-20)

1. Compliance with National Privacy and Security Framework
2. Table of Contents and Definitions
3. Governance
4. Patient Rights
5. Patient Participation and Choice
6. Participants and Authorized Users
7. Security Risk Assessment
8. Authorization and Access
9. Authentication
10. Compliance with Laws & Policies
11. Notice of Privacy Practices
12. Permitted and Prohibited Uses and Disclosures
13. Information Subject to Special Protection
14. Minimum Necessary
15. Business Associates
16. Security Incidents & Breaches
17. Auditing
18. Data Integrity and Correction
19. Complaints
20. Enforcements and Sanctions



© 2012 Oscislowski LLC

New Jersey Sequestration Pilot

- **Exchange Type:** *Hospital-based*
- **Governance:**
 - *HIE "Council"*
 - *Physician Usage Committee*
 - *Privacy & Security Committee*
- **Technology:**
 - Centralized HIE (Wellogic)
 - Plug-in for "tagging" sensitive data – the "sequestration" safeguard (EnableCare)
- **Consent Model:**
 - Opt-Out as baseline for hospital and basic providers
 - Opt-In for "sensitive" provider-*types*
 - Episodic consent for tagged/sequestered data



© 2012 Oscislowski LLC

Consent Models for HIE*

- No Consent
- **Opt-Out**
- Opt-Out, with Granularity of Choice
- Opt-In
- Opt-In, with Granularity of Choice

* *Consumer Consent Options for Electronic Health Information Exchange: Policy Considerations and Analysis*, Department of Health Policy, School of Public Health and Health Services, George Washington University medical Center (March 23, 2010).



© 2012 Oscislowski LLC

Approaches Considered by NJ Pilot

- **No restrictions on sharing, including sensitive information.** Concern is patient trust and comfort with a system that treats all information the same; *it's not*.
- **"One for All".** Concerns that if the consent covers *everything*, still does not offer true confidentiality for patient, especially for sensitive data. Also prone to "sign here" blanket approach, which is not *meaningful*.
- **Item-by-item restriction (granularity).** Although this increases patient control, very, very difficult to administer. Also, too much choice is not always a good thing – patients may forget previous preferences, may be too cumbersome for even the patient. Also not in line with current workflows where information *is* already being exchanged.

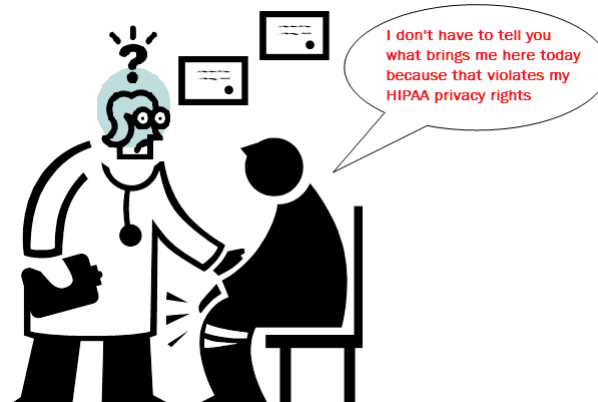
* *Data Segmentation in Electronic Health Information Exchange: Policy Considerations and Analysis*, Department of Health Policy, School of Public Health and Health Services, George Washington University medical Center (September 29, 2010).



© 2012 Oscislowski LLC

Why Sequestration?

Balances Medical Need & Privacy Interests



© 2012 Oscislowski LLC

What on Earth is "Sequestration"?

- February 20, 2008 Letter - the **National Committee on Vital and Health Statistics** (NCVHS) first used the term in its letter to then-Secretary of the U.S. Department of Health, Michael O. Leavitt.
- The Letter says on page 3:

*"NCVHS recommends permitting an individual to **sequester sensitive information** based on **predefined categories** of information as defined below. Every individual would have the option of designating one or more categories for sequestering. If a category is selected, all of the information in that category, as the category is defined, would be sequestered. The individual would **not** have the option of selecting only specific items within that category to sequester (an approach discussed below that we rejected)." (emphasis added).*



© 2012 Oscislowski LLC

NCVHS 2008 Recommendations

- 1.a. Patients should be permitted to **sequester specific sections** of their health record in one or more **pre-defined categories**.
- 1.b. HHS should initiate an open, transparent, and public process to **identify the possible categories of sensitive information** for sequestration, and to defined with specificity the criteria for inclusion and exclusion within each category.
- 1.c. **Categories of information that are sequestered should be notated** that certain information is sequestered patient's request
- 1.d. Design should permit individuals ability to **authorize selected** health care providers to access sequestered information.
- 1.e. **Emergency** access should be permitted,
- 1.f. **Audit** trails must capture all break glass episodes.
- 1.g. Patient must be **notified** of break glass situations
- 1.h. Provider who accesses the information is responsible for ensuring that information is **either re-sequestered** or otherwise further disclosed only as permitted by applicable law.



© 2012 Oscislowski LLC

HITECH “Segmentation”

February 2009, HITECH Act (H.R. 1) includes §3002(b)(2)(B) which specifically directs the HIT Policy Committee (at ONC) to make recommendations for:

*“technologies that protect the privacy of health information and promote security in a qualified electronic health record, including for the **segmentation** and **protection from disclosure of specific and sensitive individually identifiable health information** with the goal of minimizing the reluctance of patients to seek care (or disclose information about a condition) because of privacy concerns, in accordance with applicable law...”*
(emphasis added).



© 2012 Oscislowski LLC

HITECH on NCVHS' Recommendations

Section 3002(b)(8) of the HITECH Act then goes on to require that:

*“The National Coordinator **shall ensure that the relevant and available recommendations and comments from the National Committee on Vital and Health Statistics are considered in the development of policies.**”*



© 2012 Oscislowski LLC

NCVHS November 2010 Recommendations

- **November 10, 2010 Letter** - NCVHS issues second letter to DHHS Secretary with Recommendations Regarding Sensitive Health Information. Provides suggested categories of sensitive information:

- Federal law
 - HIPAA Psychotherapy Notes
 - HITECH "Out of pocket" services
 - 42 CFR Part 2
 - GINA
- State law: HIV/AIDS; STDs; Genetic; Mental Health; Emancipated Minors
- "Other":
 - Mental Health
 - Sexuality and Reproductive Health
 - Domestic Violence



© 2012 Oscislowski LLC

NJ Pilot – Defining What is "Sensitive"

- **FEDERAL:**
 - 42 CFR Part 2 Records;
 - GINA (Genetic Information and Nondisclosure Act)
 - Services paid for "out of pocket" (HITECH)
 - Psychotherapy Notes – as defined under HIPAA, disclosure requires prior written authorization of the individual
- **STATE:**
 - HIV/AIDS Information ([N.J.S.A. 26:5C-8](#))
 - Venereal Diseases ([N.J.S.A. 26:4-41](#))
 - Drug & Alcohol Rehabilitation Information ([N.J.S.A. 26:2B-8](#))
 - Mental Health Rehabilitation ([N.J.A.C 10:37-6.79](#))
 - Genetic Privacy Act of New Jersey ([N.J.S.A. 10:5-43](#))
 - Minor's Emancipated Treatment ([N.J.S.A. 9:17B-1](#))
 - Social Security Numbers.
- **NCVHS Recommendations**
 - Reproductive Rights
 - Domestic Violence



© 2012 Oscislowski LLC

Initial Numbers*

Total reports analyzed: **1,663,730** (all hospital and ED)

Reports by Type:

▪ Anatomic Pathology:	50,011
▪ Radiology:	636,012
▪ ED visits	463,701
▪ History and Physical	77,078
▪ Discharge Summary	88,598
▪ Consults	97,121
▪ Operative Report	57,701
▪ Other	193,508 (cardiology, surgery, L&D)

* Based on preliminary testing and analysis. Numbers do not necessarily reflect final results.



© 2012 Oscislowski LLC

Initial Numbers*

- Total with multiple sensitive flags: **1.2%**
- Total with one sensitive category: **3.4%**
- **Total Sensitive: 4.6%**
- Total with negated vocabulary: **3.5%**
(sensitive terms with negation language – e.g. *not*, *no evidence of*, ...)
(not included in the sensitive % above)

* Based on preliminary testing and analysis. Numbers do not necessarily reflect final results.



© 2012 Oscislowski LLC

Initial Numbers*

Sensitive Data Tagged by Category (per rules):

▪Abortion	3.8%
▪Genetic testing/diseases	11.4%
▪HIV	6.1% of sensitive
▪Mental health treatment	6.9%
▪Sexual abuse (<i>minors</i>)	0.2%
▪Sexual activity (<i>minors</i>)	8.2%
▪Sexually Transmitted Diseases	18.4%
▪Substance abuse (<i>minors</i>)	0.7%
▪Suicidal ideation	44.3%

* Based on preliminary testing and analysis. Numbers do not necessarily reflect final results.



© 2012 Oscislowski LLC

Why Sequestration?

Balancing Competing Interests

Benefits of EHR

Longitudinal, comprehensive, and interoperable EHR presents opportunities for enhancing coordination of care, avoiding duplication of services, and improving the effectiveness and efficiency of health care. Also makes it possible for all health care providers who may be consulted to have access to an individual's EHR from all current and past providers.

vs. Electronic health information exchange (HIE) is a major shift from decentralized, disconnected, largely paper-based health record system currently in use. There are significant implications for individual privacy and confidentiality. If HIE networks do not afford some level of protection, privacy could be compromised and patients may resist participating.



© 2012 Oscislowski LLC

Questions?

Helen Oscislawski, Esq.

Principal, Attorneys at Oscislawski LLC

helen@oscislaw.com

609-835-0833

HIE Blog: www.legalhie.com

HIE, HIPAA & HITECH Legal Forms: www.ohcsolutions.com



Attorneys at
Oscislawski LLC

www.oscislaw.com