

HITeCH Privacy, Security, Enforcement, Breach, and GINA – The Final Rule

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Faculty

Adam Greene, JD, MPH is a partner in the Washington, DC office of Davis Wright Tremaine and co-chair of its Health Information Group. Mr. Greene primarily counsels healthcare providers, technology companies, and financial institutions on compliance with the HIPAA privacy, security, and breach notification rules. Previously, Adam was a regulator at the US Department of Health and Human Services (DHHS), where he played a fundamental role in administering and enforcing the HIPAA rules. At DHHS, Mr. Greene was responsible for determining how HIPAA rules apply to new and emerging health information technologies and was instrumental in the development of the current HIPAA enforcement process.

Mr. Greene is the chair of the HIMSS Cloud Security Workgroup and is a frequent speaker and author on health information privacy and security issues



Table of Contents

AHIMA Audio Seminar/Webinar Terms of Use Agreement	i
Disclaimer	ii
Document Usage Rights	iii
Sponsors	iii
Faculty	iv
Agenda	1
The Wait is Over	1
The “Omnibus Rule”	2
What’s Still Missing?.....	2
Breach Notification Rule	3
New “Compromise Standard”	3
Risk Assessment Factors	4
Risk Assessment	4
New Limits on Uses and Disclosures of PHI	5
The Good News: Fundraising	5-6
The Good News: Research	6-7
The Good News: Student Immunization Records.....	8
The Good News: Decedent Information.....	8
The Bad News: Marketing	9-10
The Bad News: Sale of PHI.....	10-11
The Bad News: Genetic Information.....	11
Business Associates and Subcontractors.....	12
Who Is A Business Associate?.....	12
Subcontractors, Welcome to the HIPAA Party	13
Liability of Business Associates	13
Business Associate Contracts.....	14
Increased Patient Rights	14
Electronic Copy of PHI	15-16
Restriction for Out-of-Pocket Payments	17
Notice of Privacy Practices.....	17
Changes to Notice of Privacy Practices	18
Increased Enforcement	18
Focus on Willful Neglect	19
Other Enforcement Changes.....	19
Action Items.....	20
HIM Impact	21
Questions.....	22

Agenda

- Breach Notification Rule
- New Limits on Uses and Disclosures of PHI
- Business Associates and Subcontractors
- Increased Patient Rights
- Notice of Privacy Practices
- Increased Enforcement
- Action Items

1

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The Wait is Over



2

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The “Omnibus Rule”

- Most of HITECH Act privacy and security provisions
- Breach Notification Rule
- Genetic Information Nondiscrimination Act (limit on underwriting)
- Enforcement Rule
- Several workability amendments
- General Compliance Date:
September 23, 2013

3



What's Still Missing?

- Accounting of disclosures/access reports
- Minimum necessary guidance
- Distribution of penalties/settlements to harmed individuals



4



BREACH NOTIFICATION RULE

5



New “Compromise Standard”

- ~~“Significant risk of financial, reputational, or other harm”~~
- ~~Exception for limited data set without ZIP codes or dates of birth~~
- Presumption of reportable breach, unless **low probability** the PHI has been **compromised** after risk assessment

6



Risk Assessment Factors

- Nature and extent of PHI involved
- The unauthorized person who used the PHI or to whom the disclosure was made
- Whether the PHI actually was acquired or viewed
- The extent to which the risk to the PHI has been mitigated

7



Risk Assessment

- Comment to interim final Breach Notification Rule suggesting compromise standard:

“inappropriately viewed, re-identified, re-disclosed, or otherwise misused”

8



NEW LIMITS ON USES AND DISCLOSURES OF PHI

9



The Good News: Fundraising

- Adds categories of PHI that may be used or disclosed for fundraising:
 - Department of service
 - Treating physician
 - Outcome information
 - Health insurance status



10



The Good News: Fundraising

- Strengthens opt-out for fundraising:
 - Clear and conspicuous
 - Must not require undue burden
 - May not condition treatment or payment
 - Covered entity may not make fundraising communications after opt-out (previous standard was “reasonable effort”)
- Covered entity may provide method of opting back in

11

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The Good News: Research

- Covered entities may combine “conditioned” and “unconditioned” authorizations
 - For example, conditioned authorization for clinical trial may be combined with unconditioned authorization for tissue specimen repository



12

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The Good News: Research

- Authorization must differentiate between conditioned and unconditioned portions
- Unconditioned authorization must be opt in, e.g.,
 - Check box
 - Second signature line



13

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The Good News: Research

- HHS changed interpretation on authorization for future research:
 - Prior interpretation – Authorization for research must be study specific
 - New interpretation – Authorization may govern future research
 - Authorization must reasonably put individual on notice of potential future research

14

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The Good News: Student Immunization Records

- Covered entity may release student immunization records to school without authorization
 - If state law requires school to have immunization record
 - Written or oral agreement (must be documented)



15

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The Good News: Decedent Information

- No longer PHI 50 years after death
- Covered entity may disclose PHI to persons involved in decedent's care or payment if not contrary to prior expressed preference



16

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The Bad News: Marketing

- General Rule:
Communication about a product or service that encourages purchase or use is marketing and requires an authorization



17

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The Bad News: Marketing

- Old Exception to Definition of Marketing:
 - Treatment (e.g., providing alternative treatment options)
 - Health care operations (e.g., describing health-related product or service offered by covered entity)

18

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The Bad News: Marketing

- **New Exception to the Old Exception**
 - Marketing if covered entity receives financial remuneration from the third party whose product or service is described
- **New Exception to Definition of Marketing**
 - Marketing does not include subsidized refill reminders about drug that is currently prescribed – remuneration must be reasonably related to cost of communication

19



The Bad News: Sale of PHI

- Covered entity may not receive remuneration in exchange for PHI
- Exceptions (no limit):
 - Treatment
 - Payment
 - Sale of covered entity and related due diligence
 - Required by law

20



The Bad News: Sale of PHI

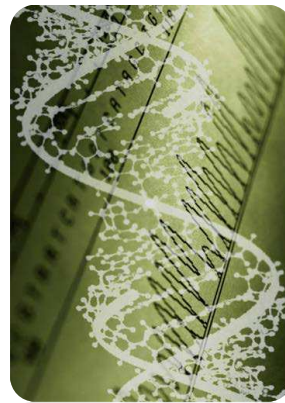
- Exceptions (no limit)
 - Business associate activities
- Exceptions (limits)
 - Research
 - To an individual for access and accounting
 - Any other permissible purpose if remuneration limited to reasonable, cost-based fee for preparation and transmittal

21

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The Bad News: Genetic Information

- Clarification that genetic information is health information
- Health plan (other than long-term care plan) may not use or disclose genetic information for underwriting purposes



22

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BUSINESS ASSOCIATES AND SUBCONTRACTORS

23



Who Is a Business Associate?

- New definition of business associate
 - ~~Uses or discloses individually identifiable health information~~
 - Creates, receives, maintains, or transmits protected health information

24



Subcontractors, welcome to the HIPAA Party!

- Subcontractor + PHI = Business Associate
- Subcontractor = Person to whom a business associate delegates a function, activity, or service
- Subcontractor ≠ workforce member
- All the way down the chain (contractual relationships should remain the same)



25

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Liability of Business Associates

- Impermissible uses and disclosures
- Breach notification to covered entity
- Failure to provide e-copy of ePHI as specified in the business associate contract
- Failure to disclose PHI to HHS for HIPAA investigation
- Failure to provide an accounting of disclosures
- Failure to comply with the applicable requirements of the Security Rule

26

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Business Associate Contracts

- Must specify compliance with Breach Notification Rule
- Should specify to whom BA provides electronic access
- If CE delegates HIPAA responsibility, must specify that BA will comply with HIPAA
- Grandfathering may be available



27

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INCREASED PATIENT RIGHTS

28

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Electronic Copy of PHI

- Old Rule:
 - Form or format requested, if readily producible
 - If not readily producible, then readable hard copy



29

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Electronic Copy of PHI

- New Rule:
 - Form or format requested, if readily producible
 - If not readily producible and maintained in paper, then readable hard copy



30

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Electronic Copy of PHI

- New Rule:
 - If not readily producible and maintained electronically, then electronic copy
 - May charge for only labor and electronic media



31

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Electronic Copy of PHI

- Individual may designate third party to receive copy
 - Must be in writing
 - Clearly identify the designated person
 - Clearly identify where to send the copy
- Access vs. Authorization further confused

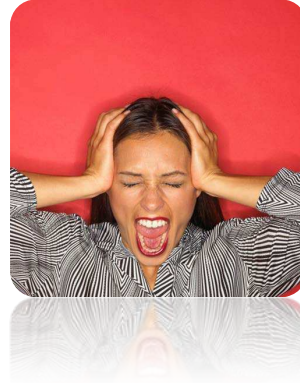


32

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Restriction for Out-of-Pocket Payments

- Covered entity must agree to individual's request to restrict disclosure to health plan
 - For payment or health care operations
 - Unless required by law
 - Individual or person on individual's behalf pays for item or service out of pocket in full



33

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NOTICE OF PRIVACY PRACTICES

34

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Changes to Notice of Privacy Practices

- Prohibition on sale of PHI
- Duty to notify affected individuals of a breach of unsecured PHI
- Right to opt out of fundraising (if applicable)
- Right to restrict disclosure of PHI when paid out of pocket
- Limit on use of genetic information (certain health plans only)

35



INCREASED ENFORCEMENT

36



Focus on Willful Neglect

- Willful neglect: Conscious, intentional failure or reckless indifference
- OCR will investigate all cases of possible willful neglect
- OCR will impose penalty on all violations due to willful neglect

37



Other Enforcement Changes

- Revised definition of reasonable cause (fills gap between “did not know ...” and willful neglect)
- Greater OCR discretion to proceed directly to penalty without seeking informal resolution
- Vicarious liability for business associate agents (discussed in next webinar)
- Factors impacting CMP calculation

38



ACTION ITEMS

39



Action Items

- Review and revise policies, procedures, and training
 - Opportunity to consider what has not been working
 - Consider addressing issues such as social media, use of personal mobile devices, etc.
- Create/revise breach response plan
- Begin process of updating BA agreements
 - Consider whether BA is agent
 - What are BA's safeguards?
- Amend notice of privacy practices

40



HIM Impact

- Address operation for:
 - Fundraising
 - Restrictions
 - Decedents
 - Access
 - Form and format
 - Fees

41


HIM Impact

- Authorization
 - Marketing
 - Sale of PHI
 - Research





42

Questions



43



**HITECH Privacy, Security,
Enforcement, Breach, and
GINA – The Final Rule**

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