

De-Identifying Protected Health Information

Using Expert Determination and Safe Harbor Methods to De-Identify PHI

TUESDAY, FEBRUARY 26, 2013

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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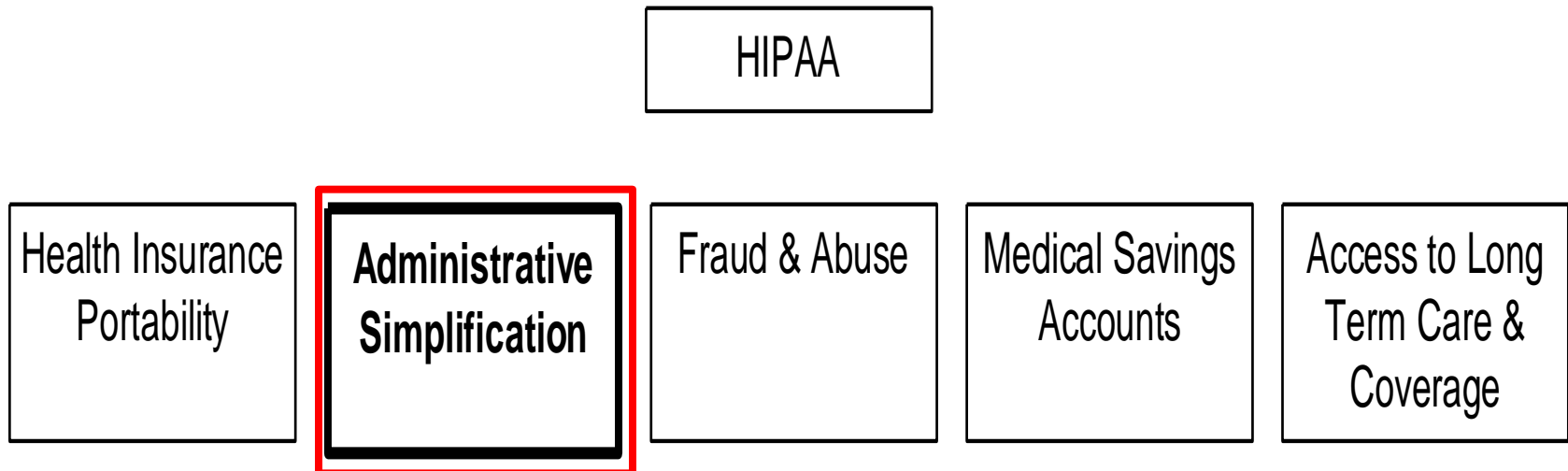
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***DE-IDENTIFYING
PROTECTED HEALTH INFORMATION***

**FEBRUARY 26, 2013
DIANNE J. BOURQUE,
ESQ.**

STRAFFORD WEBINARS AND TELECONFERENCES

“HIPAA” is: the Health Insurance Portability and Accountability Act of 1996 (a very big law)



Administrative Simplification HIPAA provisions impacting health care providers

Administrative
Simplification

Standardized
Transactions
and
Code Sets

National
Standard
Provider
Identifier

National
Standard
Employer
Identifier

Security
Standards

Electronic
Signature
Standards

Privacy
Standards

Administrative Simplification

- HIPAA was amended in February, 2009 by the Health Information Technology for Economic and Clinical Health Act (“HITECH”)
- Final regulations (the HIPAA Omnibus Rule) were published on January 17, 2013
- Much of HITECH will be implemented via guidance

Administrative Simplification

- The [HITECH Act](#) focuses on:
 - the establishment of a national health infrastructure and on providing incentives for the adoption of electronic health records (EHRs) and setting goals for Meaningful Use
 - It also provides for "enhanced" privacy and security protections and closes perceived gaps in the original HIPAA legislation

Privacy and Security Rules

- Inextricably linked - no privacy without security
- Rules apply to “covered entities” or health care providers, payers and health care clearing houses
- Security Rule and some Privacy Rule provisions apply directly to “business associates” of HIPAA covered entities
 - Business associates may be audited by the federal government and are subject to enforcement

De-Identification

- Removes PHI from the restrictions of HIPAA
- ...*"the requirements of this subpart do not apply to information that has been de-identified in accordance with the applicable requirements of § 164.514..."*
- Useful for clinical research, policy assessment, QA/QI initiatives, market research and litigation
- Business Associates may de-identify PHI for their own use

The Identifiers that Make Health Information PHI

- 1) Name
- 2) Address
- 3) Birth date
- 4) Fax number
- 5) Medical records number
- 6) Health plan beneficiary number
- 7) Finger or voice prints
- 8) Account number
- 9) Photographic images
- 10) Certificate/license number
- 11) Vehicle or device serial number
- 12) Names of relatives
- 13) Names of employers
- 14) Telephone numbers
- 15) Social Security number
- 16) Electronic mail addresses
- 17) Internet protocol address number
- 18) Web universal resource locator
- 19) Any other unique identifying number, characteristic or code

De-Identification

- **Safe Harbor Method**

- 45 CFR § 164.514(b)(2)
- Removal of all 18 types of identifiers (plus the catch all)
- No actual knowledge that remaining information could identify the individual

- **Statistical Method**

- 45 CFR § 164.514(b)(1)
- Some identifiers may be used
- Applies scientific principles to confirm that the risk of identifying individuals with remaining information is "very small"

De-Identification - Safe Harbor Method

- The cleanest way to de-identify if you can do it.
- Removal of all 18 identifiers required
- Includes identifiers of the individual or the individual's relatives, employers, or household members
- The covered entity also must have no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual who is the subject of the information

De-Identification - Safe Harbor Method

- Covered entities may de-identify PHI without authorization as a permissible "health care operation"
- Business Associates must have permission from their covered entity collaborators to de-identify PHI

Statistical De-identification

- The covered entity may obtain certification by "a person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable" that there is a "very small" risk that the information could be used by the recipient to identify the individual who is the subject of the information, alone or in combination with other reasonably available information.
- The person certifying statistical de-identification must document the methods used as well as the result of the analysis that justifies the determination.
- A covered entity is required to keep such certification, in written or electronic format, for at least 6 years from the date of its creation or the date when it was last in effect, whichever is later.

Statistical De-identification

- Who is an "expert?"
 - The rule is flexible on requisite fields of expertise (statistics, math, or other scientific domain)
 - OCR will review the de-identifying expert's professional training as well as de-identification experience
- How does the expert assess the risk of identification?
 - The rule is flexible on technical approaches
 - However, the analysis justifying the conclusion must be available to OCR upon request

Principles for Determining the Identifiability of Health Information

- **Replicability**
 - What are the chances that the information will consistently occur in relation to an individual (blood glucose level vs. birth date)
- **Data Source Availability**
 - Are there external sources of patient identifiers? (lab test results vs. birth date, marriage records)

Principles for Determining the identifiability of health information

- Distinguishability
 - To what extent can the subject's data be distinguished (3 digit zip code, year of birth and gender vs. 5 digit zip code, date of birth and gender)
- The greater the replicability, availability and distinguishability of the information, the greater the risk of identification

What if the risk of re-identification is larger than "very small?"

- Risk may be mitigated (or reduced to "very small") by modification of the data set
- Key consideration: balancing reduction of risk against data utility
- If reducing the risk to "very small" destroys the value of the data set, other approaches should be explored (suppression, generalization, perturbation)

Coding De-identified Information

- A de-identified data set may be coded (assigned a code, algorithm or pseudonym to individual records permitting re-identification)
- The code should not be derived from the data set
- The code must not be provided to anyone without authority to view the identified data

Helpful Links

- OCR Website <http://www.hhs.gov/ocr/privacy>
- OCR's De-identification guidance
<http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html>

THANK YOU!

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