“Sharing of Medical Records Pursuant to an Authorization”

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Overview

- My background
- The history of HIPAA
- Non-coercion rule for providers & other covered entities
- No similar rule for other entities, such as employers or insurers
- FACT Act has new non-coercion provisions for financial institutions

Today's Themes

- A great deal of sharing with an authorization is to third parties who are not covered entities
- For non-c.e., the HIPAA process did not address what public policy is appropriate where an authorization exists
- This Committee has an important role to play in addressing those public policy issues

I. My Background

- From 1999 to early 2001, Chief Counselor for Privacy in OMB
- White House Coordinator for 1999 proposed HIPAA privacy rule and 2000 final rule
  - Gary Claxton the lead at HHS

My Background

- Currently Professor at Moritz College of Law of the Ohio State University
  - Director of its D.C. Program
- Since 2001, consultant to Morrison & Foerster, LLP – practical experience
- Markle Foundation, Connecting for Health
  - Electronic medical records that go beyond electronic payment records

II. History of HIPAA

- Kennedy –Kassebaum bill in 1996 to address pre-existing medical conditions
- Unfunded mandate on industry
  - They asked for transactions rule
  - From thousands of formats to fewer than 10
- If all medical transaction become electronic, then should have privacy and security as well

HIPAA Privacy

- Congress tried to write medical privacy statute in 1996 but failed
- Deadline of statute by Aug. 1999 or else HHS would issue rule
- Contentious in Congress – no bill even emerged from subcommittee

HIPAA History

- Proposed privacy rule in Oct. 1999
- 52,000 public comments by Feb. 2000
  - 14% of GDP
  - *Many* stakeholders and our desire to have a workable regime
- 70-person team from 15 agencies
- Final rule in Dec. 2000

HIPAA History

- Calls to cancel rule in winter, 2001
- 24,000 additional comments
- Decision by Pres. Bush to keep the rule
- Aug. 2002 Revised Final Rule
  - No important changes on authorizations
  - Did have changes on marketing and some other issues
  - Retained much of the 2000 final rule
- In effect, April 2003

III. The Non-Coercion Rule

- Today, not discussing Sec. 512 disclosures, such as research & law enforcement, where no authorization is required
- General rule is that valid HIPAA authorizations permit disclosure to third parties
- Sec. 508(a)(4) has “non-coercion rule” for covered entities and authorizations

Non-Coercion Rule, 508(a)(4)

- "A covered entity may not condition the provision to an individual of treatment, payment, enrollment in the health plan, or eligibility for benefits on the provision of an authorization"
- The logic: patient entering ER on gurney, "sign here" or we won't treat you
- This provision was widely accepted & created almost no controversy

Exceptions to Non-Coercion

- To participate in a clinical research trial
- For eligibility for a health plan
- Protected health information created specifically for a third party can be given to that third party (e.g., fitness exam)
- These illustrate the need for practical exceptions, where should permit the authorization to be required

Scope of Non-Coercion Rule

- Applies to “covered entities” only
- Reason: under the HIPAA statute, that was the group that could be governed by the privacy rule
- Implication: HIPAA did not consider whether authorizations should suffice for employers, insurers, etc.
  - No policy process to date about what is good policy for these situations

Non-Coercion and Employers

- HIPAA allows an employer to condition employment on giving authorization
- No statutory authority to go further
- In California, I am told, stricter state law
- In E.U., is not considered “voluntary”
- Many would think it is not “voluntary” when the employer tells employees they must turn over medical records

Non-Coercion and Employers

- Employers have legitimate interest in testing for “fitness for duty” – can this worker lift this weight?
- Possible distinction, though, could lead to limits on authorizations that go beyond the scope of what the employer needs for fitness or other workplace purposes

IV. The FACT Act

- Fair Credit Reporting Act update in 2003
  - The FACT Act
- Sec. 411 prohibits obtaining or using medical information in connection with granting of credit
- Even an authorization by the individual borrower is not sufficient
- This is a version of the non-coercion rule

Purpose of Sec. 411

- Based on my participation with Hill and agency staff:
  - "Medical redlining" is bad – don't turn down the mortgage based on high cholesterol
  - Repeated assurances from financial firms that they don't want to use medical information
  - Political consensus that medical data shouldn't be used for financial underwriting

Need for Exceptions

- In practice, a flat prohibition raises important problems
- E.g., lenders who finance elective surgery: to prevent fraud, isn't it a good idea to learn whether the surgery was performed?
- Sec. 411 allows exceptions by regulation
- April 28, 2004 proposed rule for details

Concluding Thoughts

- Do not assume that the HIPAA policy process worked out the issues of when authorizations are sufficient
- The HIPAA non-coercion provision only applies to HIPAA covered entities
- There has been no systematic process to consider other situations where authorizations should not be considered enough

Concluding Thoughts

- There likely are additional situations where the authorization should not be considered truly "voluntary"
- It is important to look for those situations
- It is also important to recognize the need for practical exceptions
- Thus, the importance of today's hearing and your continuing work

Thank you.

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