HIPAA Enforcement and the Pandemic

The View from OCR Industry Experts

November 18, 2020
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Introduction to Clearwater

Leading provider of cyber risk management and HIPAA compliance software and solutions for healthcare

100% success rate when deliverables submitted to the Office For Civil Rights (OCR)

Founded in Nashville in 2009, colleagues in 20+ states, growing rapidly

Portfolio company of Altaris Capital Partners, a healthcare PE firm with $4.8B under management

Approximately 400 customers, including 68 IDNs, many with multi-year enterprise programs
Your Presenters:

Jon Moore, MS, JD, HCISPP
Chief Risk Officer & SVP, Consulting Services

- 25+ Years Executive Leadership, Technology Consulting and Law
- 14+ Years Data Privacy & Security
- 10+ Years Healthcare
- Former PwC Federal Healthcare Leadership Team
- Former IT Operational Leader PwC Federal Practice
- BA Economics Haverford College, MS E-Commerce Carnegie Mellon University, JD Dickinson Law Penn State University, HCISPP
- Speaker and Published Author on Security, Privacy, IT Strategy and Impact of Emerging Technologies
Iliana Peters, JD, LLM, CISSP

Shareholder, Polsinelli PC, Former Acting Deputy Director HHS Office for Civil Rights

- Recognized by the healthcare industry as a preeminent thought leader and speaker on data privacy and security, particularly regarding HIPAA, the HITECH Act, the 21st Century Cures Act, the Genetic Information Nondiscrimination Act (GINA), the Privacy Act, and emerging cyber threats to health data
- For over a decade, she both developed health information privacy and security policy, including on emerging technologies and cyber threats, for the Department of Health and Human Services, and enforced HIPAA regulations through spearheading multi-million dollar settlement agreements and civil money penalties pursuant to HIPAA.
- Member: ABA, AHLA, ISC2, Hispanic National Bar Association
Enforcement Actions Hit a New Record Number

At end of July 2020 only three announced settlements for the year. Now we are at 17 a new record.
On November 12th OCR announced settlement of its 11th HIPAA Right of Access Initiative enforcement action. The HIPAA Right of Access Initiative was announced as an enforcement priority in 2019 to support individuals’ right to timely access to their health records at a reasonable cost.

*These cases only involve 1 patient.*
OCR Announcements during COVID Pandemic

- **02/03/20**
  Guidance Bulletin
  HIPAA Still Applies during Pandemic

- **03/13/20**
  Enforcement Discretion
  Community based Testing Sites

- **03/15/20**
  Privacy Rule
  Waiver Hospitals in Disaster Protocol

- **03/17/20**
  Enforcement Discretion on Telehealth

- **04/02/20**
  Enforcement Discretion for BAs to aid Fed, State Health and Oversight Agencies
Risk Analysis an Ongoing Problem

Asked to characterize the state of HIPAA compliance generally, Severino lamented a laundry list of lapses involving some of the law's most elementary privacy provisions. "For enforcement purposes, there's still a lot of low-hanging fruit," the OCR director said. "There are a lot of entities that are not doing the basic steps to make sure they have proper, for example, cybersecurity protections in place. . . – February 2020

88% of ePHI-related cases failed to conduct an OCR-Quality Risk Analysis

Not detailed or comprehensive enough
Not following OCR/NIST guidance
Not enough documentation/evidence

The number of breaches of 500 records or more reported to OCR has now surpassed last year’s total with a month and a half to go in the year.

Year over year we are 13.5% ahead of last year.
A breach under the HIPAA Rules is defined as, “…the acquisition, access, use, or disclosure of PHI in a manner not permitted under the [HIPAA Privacy Rule] which compromises the security or privacy of the PHI.” See 45 C.F.R. 164.402

To demonstrate that there is a low probability that the protected health information (PHI) has been compromised because of a breach, a risk assessment considering at least the following four factors (see 45 C.F.R. 164.402(2)) must be conducted:

1. the nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification;
2. the unauthorized person who used the PHI or to whom the disclosure was made;
3. whether the PHI was actually acquired or viewed; and
4. the extent to which the risk to the PHI has been mitigated.
The Pandemic and resulting shutdown of elective procedures has resulted in many provider organizations experiencing significant financial impact. The AHA estimates a total four-month financial impact of $202.6 billion in losses for America’s hospitals and health systems, or an average of $50.7 billion per month.

https://www.aha.org/guidesreports/2020-05-05-hospitals-and-health-systems-face-unprecedented-financial-pressures-due...
Exploding Investment in Healthcare IT

Despite, or perhaps because of, the Pandemic there has been increasing investment in healthcare IT. This included almost $900M during the week of October 21, 2020.
If OCR continues its practice of sending a letter to inquiry to every organization reporting a breach of 500 records or more, there will be more organizations receiving letters from OCR than ever before.
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