

New Year New HIPAA Rules!

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Agenda

- Brief 2020-ish Year-In-Review
- Proposed HIPAA regulations
- Impact on Covered Entities and Business Associates
- What else is in store for 2021?


Year(ish)-In-Review
We're Starting to See a Theme



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2020 Enforcement

- Despite COVID-19, OCR enforcement did not slow down
- Enforcement theme: INDIVIDUAL RIGHTS
 - 11 Right of Access Initiative settlements
 - In many cases, OCR provided technical guidance, but the organization did not follow it



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2020 Enforcement

- Other enforcement highlights
 - Second largest settlement (\$6.85M Premera Blue Cross)
 - Continued focus on security incidents
 - Failure to conduct/update security risk analysis
 - Failure to mitigate known risks
 - Lack of policies and procedures

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- 5th Circuit vacates \$4.3M CMP against MD Anderson (3 lost unencrypted laptops)
 - Security Rule requires "a mechanism" and does not require "bulletproof protection of all systems containing ePHI"
 - Did not affirmatively act to disclose PHI and HHS did not prove that someone outside the entity received the information
 - Other covered entities had similar breaches and faced zero financial penalties
 - Penalty amounts contradicted the HIPAA Enforcement Rule

OCR Audit Report – Health Care

- Most met breach notification timelines
- Most posted NPPs on websites
- Most *failed* to include required NPP content
- Most *failed* to include required breach notification content
- Most *failed* to implement individual right of access requirements
- Most *failed* to implement requirements for a security risk analysis and risk management

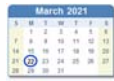
Regulatory Relief in Sight

- An incentive to invest in cybersecurity!
- Amendment to HITECH (Jan. 5, 2021)
 - When assessing penalties, HHS will consider whether the organization had "recognized security practices" in place for the last 12 months
 - Section 2(c)(15) NIST Act
 - Section 405(d) of the Cybersecurity Act of 2015
 - Other programs and processes developed, recognized, or set forth in Federal laws



Speaking of Legislation...

- Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement
- **Comments due March 22, 2021**



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HIPAA: Product of the '90s

- HIPAA signed into law August 21, 1996
- Privacy Rule effective date April 14, 2003



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Fast Forward 2+ Decades

- Evolution of technology
- Widespread adoption of EHRs
- Greater need for communication
 - Patient ↔ Provider
 - Provider ↔ Provider
 - Provider ↔ Payers (i.e. Value Based Care)
 - Provider ↔ Community-Based Organizations

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So Why Now?

- Supports HHS' "Regulatory Sprint to Coordinated Care"
- Regulatory barriers have impeded the transformation of health care
 - From pay for procedure to value-based care/focus on quality

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The Overall Goal

- Reduce burdens that may limit or discourage care coordination and case management
 - Increase data access, sharing, and portability
 - Further emphasize individuals' right of information access

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Proposed HIPAA Rules

Key Provision: "Health Care Operations"

- All case management and care coordination by health care providers and health plans is included in the definition
 - Includes individual-level (not just population-based activities)

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Proposed HIPAA Rules

Key Provision: Individual Care Coordination and Case Management

- Would permit disclosures (treatment activity or HCO) without authorization:
 - Social services agencies
 - Community-based organizations
 - Home and community-based service providers
 - Other similar third parties (who are not health care providers and who may not be covered entities)

Proposed HIPAA Rules

Key Provision: Substance Abuse, Mental Illness, Emergency

- Covered entities historically reluctant to disclose PHI to persons involved in the care of individuals experiencing substance abuse, mental health, or other health emergencies
- Several new modifications to encourage such disclosures

Proposed HIPAA Rules

Key Provision: Replace "Professional Judgement" with "Good Faith Belief"

1. Personal representatives – where a parent/guardian is *not* the personal representative
2. Facility directory information (location and general condition) when the individual is unable to agree

Proposed HIPAA Rules

Key Provision: Replace "Professional Judgement" with "Good Faith Belief"

- 3 & 4. Disclosures to family/friends
 - Individual is present and does not object
 - Individual is incapacitated/emergency
- 5. Verifying identity of a requestor of PHI

Proposed HIPAA Rules

Key Provision: Emergencies/Threats to Health or Safety

- Existing rule requires "serious and imminent threat to health or safety"
- Proposed Rule expands the ability to disclose PHI to avert a threat to health or safety when harm is "serious and reasonably foreseeable"

Proposed HIPAA Rules

Key Provision: "Reasonably Foreseeable"

- Would a similarly situated covered entity believe that a serious harm is reasonably likely to occur?
 - Does not mean a *majority* of covered entities would have such a belief.
 - Does not permit application of assumptions regarding diagnosis/circumstances (i.e., depression)

Proposed HIPAA Rules

Key Provision: Telecommunication Relay Services

- New provision to expressly permit disclosure of PHI to TRS communication assistants to conduct covered functions
- Business Associate Agreement is not necessary

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Proposed HIPAA Rules

Key Provision: Minimum Necessary Standard

- Exception to Minimum Necessary for certain care coordination and case management uses and disclosures
 - Must be at the individual level
 - Regardless of whether such activities constitute treatment activities or health care operations

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Proposed HIPAA Rules

Key Provision: Notice of Privacy Practices

- Current: provide NPP and make good faith efforts to obtain written acknowledgement
 - This has become an administrative burden
- Proposed: individual right to discuss NPP with a designated representative
 - Revised content requirements to make it easier for patients to understand their rights

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Proposed HIPAA Rules

Key Provision: Notice of Privacy Practices

- Revised Header
 - How to access health information
 - How to file a HIPAA complaint
 - Right to receive a copy of the NPP and discuss it with a designated person
 - Designated contact phone and e-mail

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Proposed HIPAA Rules

Key Provision: Notice of Privacy Practices

- Revised content requirements
 - (Required) access right – how to obtain a copy at a limited cost (of free), and the right to direct CE to transmit an electronic copy of PHI in an EHR to a third party
 - (Optional) directing PHI to a third party when the PHI is not in the EHR or not in an electronic format

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Proposed HIPAA Rules

Key Provision: Identity Verification

- Reasonable steps to verify the identity of a person before disclosing the PHI
- Prohibited from imposing unreasonable identity verification measures (including notarization or in-person proof of identity)

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Proposed HIPAA Rules

Key Provision: Individual Right of Access

- Current 30-day response time reduced to 15 calendar days
- Permit in-person inspection, including taking notes or using personal devices to take pictures of their records
- When ePHI must be provided at no charge

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Proposed HIPAA Rules

Key Provision: Individual Right of Access

- Allow individuals to direct covered entities to share EHR with a third party
- Individual access may be satisfied through a personal health application
- Requirement to post estimated fee schedules on website

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Next Steps

- Remember, these are only proposed (for now – Biden administration hold on proposed rules)
- Submit your comments by March 22
- New/final rules will require updates to policies, procedures, processes, NPPs, and other documents
- Proposed compliance date: 240 days after Final Rule



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So ... for all the
Privacy Officers, Security
Officers, Compliance Officers,
HIM Directors



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Resources

- Right of Access Guidance
– <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html>
- OCR Settlement Agreements
– <https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/index.html>

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Resources

- Information Blocking Final Rules
 - <https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification>
- OCR HIPAA/COVID-19
 - <https://www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-covid19/index.html>

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Resources

- New HIPAA Rules (Proposed)
 - <https://www.govinfo.gov/content/pkg/FR-2021-01-21/pdf/2020-27157.pdf>
- Cybersecurity relief bill
 - <https://www.congress.gov/bill/116th-congress/house-bill/7898/text?r=2&s=1>

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Resources

- OCR Audit Report – Health Care
 - <https://www.hhs.gov/about/news/2020/12/17/ocr-issues-audit-report-health-care-industry-compliance-hipaa-rules.html>

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