Up Next in Digital Health
Digital Health Learning Collaborative
November 18, 2020
• Welcome

• Digital Health Updates & Predictions
  • Jodi Daniel
  • Questions & discussion

• Learning Collaborative Meeting Programming
  • Issues & priorities of Interest
  • Upcoming meetings

• Preview of the Data Justice Principles
  • Authored By: The Gravity Project
  • Discussion
Changing Policy on Health Data in the Digital Age

Jodi G. Daniel, JD, MPH

Consumer Digital Health Learning Collaborative
November 18, 2020
Digital Health Growing Rapidly

- Electronic Health Records
- Mobile Health
- Remote Monitoring
- Telehealth
- Big Data and Data Analytics
- Precision Medicine
- AI, Machine Learning, Blockchain

Interoperability & Data
How Health Technology is Regulated

- **HHS Office of Civil Rights (OCR)**
  - HIPAA Privacy Rule
  - HIPAA Security Rule
- **Office of the National Coordinator for Health IT (ONC)**
  - Health IT Certification Program and Standards
  - Interoperability and information blocking
- **Centers for Medicare and Medicaid Services (CMS)**
  - Interoperability and Patient Access Rules
  - Promoting Interoperability Program
  - Payment and Reimbursement
  - Fraud and Abuse
- **Food and Drug Administration (FDA)**
  - Digital Health Center of Excellence
Source of Concern
With Data Held by Technology Companies

U.S. Data Privacy Protections

No Comprehensive Framework

HIPAA (Health Data)
FERPA (Education Data)
GLBA (Financial Data)
COPPA (Children's online data privacy)
FTC Act (Consumer protection - used to enforce privacy and security policies)
State Laws (e.g., CCPA)
No Protections
The Demand for Data

Health care entities are under increasing pressure to implement technology and allow access to their patient data (and other data)

WHY?

1. **Value Based Care/Population Health**— Focus on data sharing to achieve care coordination and other goals

2. **Patient Engagement**— Increased transparency and accountability for health care decisions

3. **Preventative Care & Wellness**— Keeping health care cost spend down by encouraging healthy behavior

4. **Artificial Intelligence/Machine Learning**— New insights from large amount of data to improve diagnosis and treatment

5. **New Interoperability Regulations**
Health Data Protections?

Not all health data is treated alike

- De-identified Data
- Wellness App
- Self-pay telehealth provider
- Data Analytics Platform
- Most Health Care Providers & Health Plans
- Researcher
- Social Services Org
- Patient PHR
- Remote Monitoring Device
Data Protection vs. Data Access

Laws and Policy are Changing
Health regulations shift the balance from privacy to data access
## Relaxation of Privacy of Health Information

Regulators are promoting greater access to health data

<table>
<thead>
<tr>
<th>Interoperability and Information Blocking (ONC)</th>
<th>Interoperability and Patient Access Rule (CMS)</th>
<th>HIPAA (OCR)</th>
<th>Privacy of Substance Use Disorder Information (Part 2) (SAMHSA)</th>
</tr>
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<tbody>
<tr>
<td>• Penalties for Actors that engage in “information blocking”</td>
<td>• Health plans must disclose claims and encounter data and any clinical data it holds via patient access API, generally within 1 business day</td>
<td>• Possible modifications to support care coordination</td>
<td>• CARES Act modifications will reduce heightened protections and align more closely with HIPAA • Regulations anticipated</td>
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The Balance Shifts to Access Over Protection

Interoperability, Information Blocking, Patient Access

• Concerns
  – Patients have a right to access data under HIPAA but routinely have difficulty in accessing such data
  – Interoperability seemed limited with electronic health information in silos
  – The government invested $34 Billion in adoption of EHRs and have not realized the benefits to health outcomes and efficiencies from easier access to data
  – Data is seen as an asset not to be shared because it is not in data holders’ economic interests

• Goals
  – Improve interoperability so data can follow the patient and for a learning health system
  – Improve easy patient access to electronic health information
Info Blocking & Interoperability

21st Century Cures Act

- **Information Blocking**
  - New legal prohibition against information blocking
  - When an entity *knows or should know* that a particular practice is *unreasonable* and likely to *interfere with, prevent, or materially discourage* access, exchange, or use of electronic health information
  - Applies to health care providers, health IT developers, and health information exchanges and networks (HIE/HIN)
  - Penalties of up to $1 million per violation for developers and HIE/HINs

- **ONC Regulations Implemented the Rules**
  - Shifted the paradigm created by HIPAA
Compliance with Information Blocking & HIPAA

Significant Paradigm Shift

• HIPAA covered entities that are subject to interoperability rules must walk a fine line between old and new requirements
  – Information blocking rules apply to much of the same health information as HIPAA (although covered actor differ)
  – HIPAA provides for *permissible* disclosures. Information blocking rules *require* disclosure of EHI by Actors where permitted by HIPAA. (E.g., health care operations, research)

• Patient right of access
  – Information blocking builds on HIPAA Individual Right of Access
  – Supports patient access via 3rd party app of their choice
  – Actors cannot prohibit access based on privacy policy of app
  – Actors are encouraged to educate patients about privacy and security risks of third party applications.
Information Blocking Will Increase Data Sharing

Examples

• Hospital requests medical record from competing hospital for treatment of a patient
• A health care provider requests that electronic health information be transferred to a new EHR system
• A health care provider asks their EHR vendor to provide an interface to a lab
• An app developer requests access to health data through an EHR to provide a clinical decision support product to the health system
• Health plan requests access to bulk data from an HIE for population health management
• Pharmaceutical company requests access to thousands of records for research pursuant to an IRB waiver of authorization
• Mobile app pings a provider’s patient portal for daily access to health data for the patient who has signed up for the app (App may provide the data to researcher or marketers)
Health Data in Patient Facing Apps

Not all health data is covered by HIPAA

• HIPAA/FTCA Patchwork
  – HIPAA privacy and security protections pertain to HIPAA covered entities (and business associates) only
  – Most non-HIPAA covered entities only subject to own privacy policies, usually not focused on protections
    • FTC Act prohibits companies from engaging in deceptive or unfair acts or practices in or affecting commerce
    • Entities must not mislead consumers about what is happening with their health information.
    • FTC also regulates breach notification for a limited number of non-HIPAA covered entities that maintain health information

• The fact that a health care provider shares data with a 3rd party app does not determine whether the app is covered by HIPAA as a business associate
HIPAA Regulatory Updates

HIPAA Reform on the Horizon: December 2018 RFI

- Individual Access
- Sharing Information with Caregivers and other Non-Covered Entities
- Minimum Necessary Rule
- Role and Responsibility of Clearinghouses
- Required Disclosures
- Notice of Privacy Practices

Proposed rules expected CY 2020
HIPAA Regulatory Updates

Proposed rule at end of Trump Administration?

• Focus on care coordination and facilitating greater access to data

• Possible topics if proposed rule is released:
  – Modifications to enhance a patient right of access
  – Discussion of intersection with Interoperability and Information Blocking Rules
  – Focus on data sharing with social care providers and treatment of social determinants of health
  – Considerations on requirements regarding disclosures for treatment
  – Changes to enable greater sharing with family members (may reduce privacy protections for minors)

• Path for proposed rule??
Biden Administration – Changes?

Reading the Crystal Ball

- Not clear if HIPAA proposed rule will proceed
- Changes to Part 2 will go forward under CARES Act
- Focus on health data portability and patient-centric data models
  - Rigorous data blocking/interoperability enforcement
  - Provider requirements to guarantee expedient patient data access
  - Continued push for access to CMS data by patients and others
- Will likely be continued efforts to support data privacy legislation
Contact

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Education
Georgetown University Law Center, J.D.
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- Leads the firm's Digital Health Practice and provides strategic, legal, and policy advice to all types of health care and technology clients navigating the dynamic regulatory environment related to technology in the health care sector to help them achieve their business goals.

- Led health IT policy and regulations for HHS as founding director of the Office of Policy in the Office of the National Coordinator for Health Information Technology (ONC) at HHS.

- One of the key drafters of the original Health Insurance Portability and Accountability Act (HIPAA) Privacy Rules and Enforcement Rules

- Collaborated with the Food and Drug Administration (FDA), to develop a risk based approach to oversight of health IT, and provided health IT expertise on FDA mobile medical app and clinical decision support guidance
Questions?
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COLLABORATIVE PROGRAMMING

• Issues of interest
  • Health information exchange
  • Social determinants of health data
  • Big data/ non-HIPAA covered data
  • Virtual visits
  • Digital divide

• Priorities of interest
  • Health equity
  • Access
SAVE THE DATE!

Wednesday, December 9, 2020
@ 2:00 PM ET

• **Topic: SDOH Data & The Gravity Project**
  • A National Collaborative to Advance Interoperable Social Determinants of Health Data

• **Speaker: Mark Savage**
  Director of Health Policy at the Center for Digital Health Innovation at the University of California, San Francisco
COMING SOON!

Winter 2021 (Jan. or Feb.)
@ 2:00 pm ET

• **Topic:** Non-HIPAA Health Data & the [Draft Consumer Health Data Privacy Framework](#)

• **Speakers:** eHealth Initiative (eHI) and Center for Democracy & Technology (CDT) – invited
CLOSING THOUGHTS

• Questions, comments, reactions? Contact us:
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