HIPAA Rules: Changes On The Horizon

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Today's Program

Today's program covers

- Overview of pandemic-related HIPAA rule changes
- Discussion of the intersection between Information Blocking Rule (IBR) and HIPAA
- Review of proposed HIPAA rule changes

COVID-19 and HIPAA

HHS temporarily modified a handful of HIPAA rules to accommodate providers' response to the pandemic

HIPAA and COVID-19 Issues

Per notice, the federal government made a few HIPAA modifications, effective during the public health emergency, and opined on several related privacy and security issues:

- OCR will use enforcement discretion flexibility during the public health emergency on various issues, including relaxing some HIPAA Security requirements for telehealth and online scheduling systems, and relaxing HIPAA requirements related to community based testing sites
- Public Health Activities promoted and made (slightly) more flexible
- How to contact patients about therapies clarified
- Rules for first responder/workforce exposure (and disclosure of patient status) clarified
- Aggressive reminder about NOT allowing film crews and media onsite
- If you are relying on regulatory flexibility be sure to document, particularly if it is
 misaligned with your policies and procedures (follow the notices carefully, these are not
 broad or global changes)

Information Blocking and HIPAA are Interconnected

Information Blocking only applies to instances when you do not fulfill a request from a requester who **would be allowed access [including under HIPAA]**

5

Information Blocking Theme

An Actor is "Information Blocking" if it has practices that are: "likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information"

By anyone legally allowed to access the data – not just patients

HIPAA Still Plays Key Role in Release Decisions

Every time a provider/Actor creates a barrier -- does <u>something</u> -that makes it harder for a valid requester to access, exchange or use EHI, or discourages the requester from seeking or obtaining access, the Actor is suspect as potentially Information Blocking

Valid requester includes a requester that has a HIPAA-compliant pathway to access the record

Interference

The "<u>something</u>" that creates the interference could be, for example:

- Technical barriers (hardware, software, technical specs and information)
- Administrative barriers (fees, forms, consents, policies)
- Failure to allow access when HIPAA would allow access

"Actors" are Subject to Information Blocking

"Actor" means any of the following:

- Health Care Provider: entities that provide treatment services (without regard to HIPAA status)
 - -Note: Health Insurers and coverage programs are HIPAA Covered Entities, but are not IBR "Actors"
- Health Information Network/Health Information Exchange
- Certified Health IT

Examples of *Possible* Information Blocking

- A provider requires patients **to sign a written consent** before sharing routine treatment information with another treater, but the same provider shares with treaters in the provider's own health system without requiring patient consent.
- A health system requires that community providers use the health system's EHR platform as the **only** easy method to access patient records.
- A provider's EHR platform can be set to provide real-time exchange with health apps or other platforms that meet the same or similar technological standards, but the provider picks and chooses which apps to allow based on the provider's preference and familiarity with the app.

Examples of *Possible* Information Blocking

- Provider (*incorrectly*) asserts that "HIPAA doesn't allow me to share" with the requesting entity. For example, refusing a request from an ambulance company for patient outcome data about a common patient.
- Provider has strict security measures in place, with multiple standards that exceed what would be required for HIPAA Security compliance. The provider cites to those enhanced security measures as a blanket reason to deny other providers' electronic access to patient information.
- BA with **significant market power** makes it difficult for its covered entity customers to exchange EHI, maintained by the BA, with health care providers that use an EHR system of one of the **BA's competitors**.

Information Blocking -- Eight Exceptions

Five exceptions that might excuse failure to allow access, exchange or use:

- Preventing Harm Exception
- Privacy Exception
- Security Exception
- Infeasibility Exception
- Health IT Performance Exception

Three exceptions that allow modification or additional features (i.e., some interference) when providing access, exchange or use:

- Content and Manner Exception
- Fees Exception
- Licensing Exception

Detailed commentary and explanations in May 1, 2020 Federal Register on pages 25820-25900:

https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf

Information Blocking Concepts

Goals of the Information Blocking Rule include:

- To change thinking to favor flow of data, and to promote routine sharing of data, when it's not prohibited by law
- To stop the (incorrect) perception that providers own the data
- To de-emphasize the idea that you should aggressively protect data instead of seek legitimate pathways to exchange
 - To increase the types of exchange consistent with current technologies and make them routine
 - Very different from HIPAA; HIPAA Privacy Rule includes a focus on stopping unauthorized access, which favors limiting flow of data

\$64,000 Question

Why aren't Information Blocking Rules and HIPAA better aligned?

December 10, 2020 proposed rule release tried to bridge the gap.

Major HIPAA Rules That Might Be Changing

These are *proposed only* (so far)

- 30 days to 15 days for maximum time to fulfill request (paper and electronic)
- Free copies for direct patient requests
- Posting of copy fees schedule in advance
- Estimate of actual fees on demand
- Patients must be allowed to take notes or photographs of their records
- Patients must be allowed in-person records inspection
- Clarifies patient rights to direct release to HIPAA entities and other third parties
- New NOPP rights must be listed, including rights to copies and to direct disclosures

- Clarifies health insurer obligations to allow record access and process disclosure requests
- Eliminates NOPP acknowledgement requirement
- Clarifies use of existing rule on disclosures made to avert a serious health threat
- Expands some "good faith" data uses by covered entities
- Revises the minimum necessary standard and definition of healthcare operations to allow for expanded uses of care coordination and case management
- Clarifies and expands existing military services uses

Key Takeaways, While We Await Final Rule Changes

- OCR, CMS, ONC are moving toward free (or mostly free) records, and will make it harder to charge fees
- Perception is that 30 days is too long to wait
- Burdensome "acknowledgement" process may be dropped
- Emphasis on "minimum necessary" scrutiny for data uses may complicate other release decisions
 - In trying to expand allowed uses for care and case management, the rules may have unintended consequences

More Questions Than Answers

- No clear timeline for when "final rules" will be available, and no clear indication of timeline for adjusting compliance practices
- Even if every one of the proposed HIPAA rules changes are adopted, there will still be an unworkable tension between information blocking and HIPAA
- Technology can solve for many things in healthcare, but it cannot automate privacy effectively
- We are still waiting for previously announced Cares Act alignment between HIPAA and 42 CFR part 2



Tools & Resources

Guidance Materials | HHS.gov

COVID-19 and OCR:

<u>https://www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-covid19/index.html</u>

ONC Information Blocking Final Rule:

- <u>https://www.healthit.gov/curesrule/</u>
- <u>https://www.healthit.gov/sites/default/files/cures/2020-03/InformationBlockingExceptions.pdf</u>