OCR HIPAA Right to Access Initiative and Information Blocking Rule

January 15, 2021

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1

HIPAA Individual Access Rights

- Patients have the right of access to inspect and obtain a copy of their PHI contained in a Designated Record Set (paper and/or electronic).
- Before providing access, patient identity should be verified.
- Access is to be provided in the form and format requested by the patient if readily producible in such form and format.
- A patient must be provided with access as soon as possible and generally within thirty (30) days after receipt of a request.

45 C.F.R. 164.524

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Exceptions & Unreviewable Denials

- Except that there's NO ACCESS RIGHT for (i) psychotherapy notes; or (ii) information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding
- May DENY (with no review) ACCESS to (i) exceptions listed above; (ii) inmate requests when access would jeopardize health, safety, security, custody, or rehabilitation; (iii) research that includes treatment as per consent and during research; (iv) Privacy Act or 1974 records; (v) PHI obtained from someone other than a provider under promise of confidentiality and access would reveal source

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Reviewable Access Denials
45 C.F.R. 164.524(a)(3)

- Licensed health care provider determines* access is reasonably likely to endanger life or physical safety of individual or another person
- PHI references another person (not a provider) and licensed provider determines* access is reasonably likely to cause substantial harm to other person
- Request is made by personal representative and licensed provider determines* access to rep is reasonably likely to cause substantial harm to individual or another person

*Determinations based on exercise of "professional judgment"

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Form & Manner of Access

- Provide in form and format requested if readily producible, but must produce electronic copy of ePHI, if requested
- If individual directs covered entity to transmit the PHI directly to another person, must do so if request is in writing, signed by individual, and clearly identifies other person and where to send the copy

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Access via Email?

"Yes, as long as the PHI is "readily producible" in the manner requested. … For example, individuals generally have a right to receive copies of their PHI by mail or e-mail, if they request…In such cases, the covered entity must provide a brief warning to the individual that there is some level of risk that the individual's PHI could be read or otherwise accessed by a third party while in transit, and confirm that the individual still wants to receive her PHI by unencrypted e-mail. If the individual says yes, the covered entity must comply with the request."

https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html

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Unreasonable Measures

"While the Privacy Rule allows covered entities to require that individuals request access in writing … a covered entity may not impose unreasonable measures … that serve as barriers to or unreasonably delay the individual from obtaining access. For example, a doctor may not require an individual:

- Who wants a copy of her medical record mailed to her home address to physically come to the doctor's office to request access and provide proof of identity in person.
- To use a web portal for requesting access, as not all individuals will have ready access to the portal.
- To mail an access request, as this would unreasonably delay the covered entity's receipt of the request and thus, the individual's access.

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HIPAA Authorizations

- Obtain valid authorization before disclosing PHI if not otherwise permitted or required under HIPAA (HIPAA requires individual access)
- A valid HIPAA authorization must include specific elements (including, for example, the right to revoke the authorization)
- Do not require a patient to sign an authorization if the patient is making an access request

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8

HIPAA Authorization	Right of Access
Permits, but does not require, a covered entity to disclose PHI	**Requires** a covered entity to disclose PHI, except where an exception applies
Requires a number of elements and statements	Must be in writing, signed by the individual, and clearly identify the designated person and where to the send the PHI
No timeliness requirement for disclosing the PHI Reasonable safeguards apply (e.g., PHI must be sent securely)	Covered entity must act on request no later than 30 days after the request is received
Reasonable safeguards apply (e.g., PHI must be sent securely)	Reasonable safeguards apply, including a requirement to send securely; however, individual can request transmission by unsecure medium
No limitations on fees that may be charged to the person requesting the PHI; however, if the disclosure constitutes a sale of PHI, the authorization must disclose the fact of remuneration	Fees limited as provided in 45 CFR 164.524(c)(4)

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Caveat: Ciox Decision

"This guidance remains in effect only to the extent that it is consistent with the court's order in Ciox Health, LLC v. Azar, No. 18-cv-0040 (D.D.C. January 23, 2020), which may be found at https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv0040-51. More information about the order is available at https://www.hhs.gov/hipaa/court-order-right-of-access/index.html. Any provision within this guidance that has been vacated by the Ciox Health decision is rescinded."

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HIPAA Preemption and Access

- HIPAA generally preempts State law that is "contrary to" HIPAA, unless any of the following apply:
  - The Secretary of HHS makes an exception determination pursuant to 45 C.F.R. 160.204
  - The State law relates to privacy of individually identifiable health information and is "more stringent" than HIPAA
  - The State law provides for the reporting of disease, injury, birth, death, public health surveillance, investigation, or intervention
  - The State law requires a health plan to report or provide access to certain information related to audits, program monitoring, or licensure/certification of individuals or facilities

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HIPAA Preemption and Access

- "More stringent" means that the State law
  - Prohibits or restricts a use or disclosure otherwise permitted under HIPAA, except when the disclosure is to Secretary for determining compliance with HIPAA or to the individual
  - Provides the individual greater rights to access or amend the information
  - Provides the individual access to a greater amount of information
  - If related to legal permission from the individual, provides requirements that narrow scope or duration, increase privacy protections, or reduce coercive effect
  - If related to recordkeeping or accounting of disclosures, provides longer period
  - For any other matter, provides greater privacy protection to the individual

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OCR Enforcement Actions

OCR Settles Thirteenth Investigation in HIPAA Right of Access Initiative

The Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services (HHS) announces its thirteenth settlement of an enforcement action in its HIPAA Right of Access Initiative. OCR announced this initiative as an enforcement priority in 2019 to support Individuals' right to timely access their health records at a reasonable cost under the HIPAA Privacy Rule.

December 22, 2020

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HIPAA Preemption and Access

"At least eight states have statutory requirements to provide patients with copies of their health records in less time than the Privacy Rule's current 30-day limits, and at least five states require the opportunity to view or inspect the record in fewer than 30 days."

-- December 10, 2020 NPRM
https://www.hhs.gov/sites/default/files/hhs-ocr-hipaa-nprm.pdf

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OCR Enforcement Actions: Examples

- The University of Cincinnati Medical Center, LLC (UCMC) agreed to take corrective actions and pay $65,000
  - In May 2019, OCR received a complaint alleging that UCMC failed to respond to a patient's February 22, 2019, records access request directing UCMC to send an electronic copy of her medical records maintained in UCMC's electronic health record (EHR) to her lawyers.

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OCR Enforcement Actions: Examples

- Beth Israel Lahey Health Behavioral Services (BILHBS) has agreed to pay $70,000 to OCR and to adopt a corrective action plan to settle potential violation.
  - In April 2019, OCR received a complaint alleging that BILHBS failed to respond to a February 2019 request from a personal representative seeking access to her father's medical records. OCR initiated an investigation and determined that BILHBS' failure to provide the requested medical records was a potential violation of the HIPAA right of access standard.

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OCR Enforcement Actions: Examples

- Dignity Health, doing business as St. Joseph's Hospital and Medical Center ("SJHMC"), agreed to take corrective actions and pay $160,000 to settle a potential violation of the HIPAA Privacy Rule's right of access provision.
  - On April 25, 2018, OCR received a complaint from a mother alleging that beginning in January 2018, she made multiple requests to SJHMC for a copy of her son's medical records, as his personal representative. SJHMC provided some of the requested records, but despite the mother's follow up requests in March, April, and May 2018, SJHMC did not provide all of the requested records

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New ONC "Information Blocking" Rules

- 21st Century Cures Act provisions to promote interoperability and prevent information blocking (including to individuals requesting access)
- Applies to "actors" – "Actor means a health care provider, health IT developer of certified health IT, health information network or health information exchange." 45 C.F.R. 171.102.
- Applies to ePHI
- Takes effect beginning April 5, 2021

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Information blocking means a practice that —

- (1) Except as required by law or covered by an exception … is likely to interfere with access, exchange, or use of electronic health information; and
- (2) If conducted by a health information technology developer, health information network or health information exchange, such developer, network or exchange knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; or
- (3) If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

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Information Blocking Exceptions

- Preventing Harm Exception
  - Type of harm consistent with HIPAA reviewable access denial standard at 45 C.F.R. 164.524(a)(3)
  - Must have organizational policy or determination based on facts/circumstances
- Privacy Exception
  - State or federal law requires precondition(s) for providing access that hasn't been satisfied (need non-discriminatory written policy, training, documentation
  - Health IT developer not covered by HIPAA (disclosed privacy policies)
  - Denial consistent with HIPAA access rights exceptions

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Information Blocking Exceptions, cont.

- Security Exception
- Infeasibility Exception
  - NOTE: must respond to requestor within 10 business days of receipt of request (shorter than 30 day timeframe for access requests under HIPAA)
- Health IT Performance Exception
- Content and Manner Exception
- Fees Exception

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Compliance Implementation

- This is a systemwide effort and your electronic health record vendor cannot prepare you for every possible violation of information blocking.
- Gather teams and evaluate current state and do a gap analysis.
- Decide who will be responsible for managing the project.

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Compliance Implementation/ what type of actor are you?

- This can be difficult to decide and you need to evaluate your organization to determine what type or types of actor or actors you are.
- There are different penalties for the different actors.
- After careful consideration, it was decided that our organization was a Provider actor. This includes individual providers and the health system.

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Compliance Implementation: Who might be included in this work?

- Executive Leadership Sponsors
- Compliance and Privacy Officer
- Health Information Management (HIM)
- IT specialists
- Legal

We developed a steering committee, an interoperability working group (IWG), and smaller work groups, to guide and drive this work.

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Compliance Implementation: Executive Leadership

- Your executive leadership should be included in your steering committee. This committee will make decisions to take to your workgroups.
- You need leadership sponsors to support the necessary work that needs to be done.
- Leadership needs to be kept informed regularly to assist with decisions and to communicate progress throughout the organization.

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Compliance Implementation: Workgroups

- HIM
- Legal – review of policies, business agreements and contracts
- Communication/Education for staff and patients
- IT/Interoperability with subgroups
  1. MyChart – Holding results/progress notes/risk of physical harm
  2. Care Everywhere
  3. FHIR API's for USCDI V1 required data classes
- Compliance

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Compliance Implementation: Interoperability Work Group

- The Interoperability work group comprised all workgroup leaders and any additional staff that were essential to project updates.
- This group can grow as you learn who needs to be involved.
- We use this team to update all stakeholders on progress and discuss gaps.

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Compliance Implementation: Compliance and Privacy

- Identify how Information Blocking rule applies to organization.
- Assist with policies and procedures that need to be reviewed and amended to comply with the rule.
- Provide leadership guidance and support

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Compliance Implementation: Information Technology/Systems

- Include your IT specialists to implement the requirements within your EMR for information sharing and assuring you are compliant and not information blocking.
- Epic's patient portal is MyChart and this is a very beneficial tool to share patient information as soon as it is available. All USCDI V1 data should be available by April 5th.
- Care Everywhere is used within Epic to share patient information with outside organizations.
- Your IT architecture team will need to implement FHIR APIs for USCDI V1 required data classes.

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Compliance Implementation: Health Information Management

- HIM is a key stakeholder and will be a part of much of this work.
- Many of your policies related to information sharing likely were developed by your HIM and therefore you will want to work with HIM to review and revise all impacted policies. There may be additional policies that other departments developed that need review.
- Provide leadership support and decision making.

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30

Compliance Implementation: Legal

- Your legal department will be very vital in all aspects of this implementation.
- Many of our workgroups included the legal team at some point and we are still working through many issues that are not yet resolved.
- The policy review has been a big piece of this work and we have found that we have had to rereview these policies as we learned new information.

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31

Compliance Implementation: Lessons Learned

- Include all possible stakeholders when you start your work. It is better to have too many than too few. You can always narrow down the team as needed.
- Consider interplay between regarding state law, HIPAA and Information Blocking rule. Work very closely with your legal department to assure you are compliant. Adolescent and behavioral health populations are more complicated to work through.
- Include patient research groups if you participate in research. They may have special concerns that you will need to work through or help them work through.

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32

Compliance Implementation: Lessons Learned, cont.

- Meet weekly or biweekly with workgroups and steering committee. It is easy to get pushed back in priority. Set timed expectations so you keep the work flowing.
- Reach out to other organizations in your state to see what they are doing. Each state may have laws that will impact how you comply.
- Start as soon as possible and include marketing and education as soon as you you know how changes will impact staff, providers and patients.
- The sooner you can go live, the more time you can measure compliance and troubleshoot prior to deadline.

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33

HHS Proposed HIPAA Amendments

NPRM announced December 10, 2020:

> "The proposed changes to the HIPAA Privacy Rule include strengthening individuals' rights to access their own health information, including electronic information; improving information sharing for care coordination and case management for individuals; facilitating greater family and caregiver involvement in the care of individuals experiencing emergencies or health crises; enhancing flexibilities for disclosures in emergency or threatening circumstances, such as the Opioid and COVID-19 public health emergencies; and reducing administrative burdens on HIPAA covered health care providers and health plans, while continuing to protect individuals' health information privacy interests."

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34

Key Proposed Changes

- Provide examples of "unreasonable measures" (such as only allowing requests through online portal, or only in paper form)
- Clarify "readily producible" include copies of ePHI requested through secure, standards-based APIs using apps chosen by individuals
- Shorten access response from 30 to 15 days
- Narrow scope of access right when individual directs PHI to third party – right will only apply to ePHI in an EHR
- Apply new fee limitations for access

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35

Thank You

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36