



HEALTHCARE REGULATORY ROUND-UP - Episode #49

Proposed Amendments to Privacy Rules: Important Aspects and Future Considerations

May 24, 2023

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Speaker Introduction Beyond the Suit...

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Agenda



1. Background – HIPAA Privacy Rule Review
2. Rationale for Updates
3. 2020 Proposed Privacy Rule Updates – General (OCR)
4. 2023 Proposed Updates for Information Blocking (ONC)
5. 2023 Proposed Privacy Rule Updates – Reproductive Health Care (OCR)
6. Future Privacy Considerations

A top-down photograph of a silver stethoscope and a white computer keyboard on a light-colored surface. A dark blue horizontal band is overlaid across the middle of the image, containing the title text.

1. Background – HIPAA Privacy Rule Review

HIPAA Privacy Rule Review



- Establishes national standards to protect individuals' protected health information (PHI) and applies to covered entities (CE) and business associates (BA) that conduct certain health care transactions electronically
- Requires appropriate safeguards to protect PHI and sets limits and conditions on the uses and disclosures
- Gives individuals rights over their PHI, including rights:
 - To examine and obtain a copy of their health records
 - To direct a covered entity to transmit to a third party an electronic copy of their PHI in an electronic health record (EHR)
 - To request corrections



HIPAA Privacy Rule Review (cont.)

- **Key Concepts**



HIPAA Privacy Rule Review (cont.)



- **HIPAA Right to Access Initiative (2019)**

- OCR created this enforcement initiative to support an individual's right to timely access their health records at a reasonable cost.
- HIPAA gives people the right to see and get copies of their PHI from their healthcare providers and health plans.
- After receiving a request, an entity that is regulated by HIPAA has (absent an extension) 30 days to provide an individual or their representative with all requested records in a timely manner.
- The entity is allowed to charge a small, reasonable fee related to the cost of creating the requested records.
- In addition to monetary penalties for non-compliance, settlements include a Corrective Action Plan imposing various obligations, such as policy development, training, and mandatory reporting to OCR.
- **43 settlements as of March 31, 2023**

A top-down photograph of a silver stethoscope and a white computer keyboard on a light-colored surface. A dark blue horizontal band is overlaid across the middle of the image, containing the section header text.

2. Rationale for Updates

Privacy Updates Logic



2020 Proposed Privacy Rule Updates – General (OCR)

- Supports individuals’ engagement in their care
- Removes barriers to coordinated care
- Reduces regulatory burdens on the healthcare industry

2023 Proposed Updates for Information Blocking (ONC)

- Advances interoperability
- Improves transparency
- Supports the access, exchange, and use of electronic health information.

2023 Proposed Privacy Rule Updates – Reproductive Health Care (OCR)

- Protects patient-provider confidentiality
- Prevents private medical records from being used against people for legally seeking, obtaining, providing, or facilitating lawful reproductive health care

A background image showing a stethoscope and a computer keyboard on a light blue surface. A dark blue horizontal band is overlaid across the middle of the image, containing the section header text.

3. Proposed Privacy Rule Updates – General (OCR)

Proposed Privacy Rule Updates – General: Overhauling Individual Access Rights



Express right to take notes, videos, and photos of PHI



Shorter timeframe for providing PHI access

- Decrease from 30 days to 15 days



Prohibition on creating certain barriers to access and other individual rights

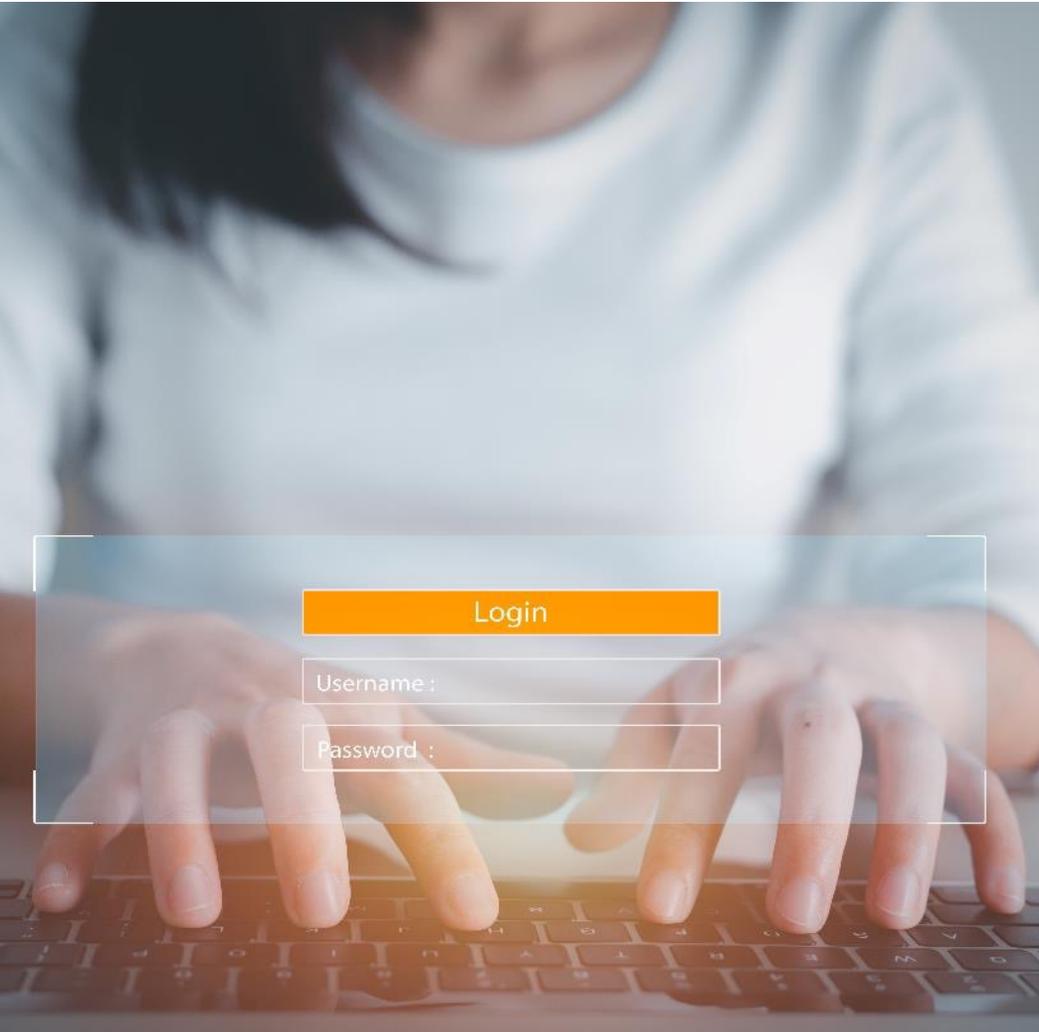
- Restricts CE from imposing “unreasonable measures” on individuals exercising their access rights that create barriers or unreasonably delay access



Changes to the right to direct disclosure of PHI to a third party

- Individual’s right to direct covered health care providers (but not other CE) to transmit an electronic copy of PHI in an EHR directly to a third party within 15 days

Proposed Privacy Rule Updates – General: Overhauling Individual Access Rights (*cont.*)



- **Expanded definition for EHR – aimed to include:**
 - Education records covered by the Family Educational Rights and Privacy Act (FERPA)
 - Adult student medical records
 - Employment records held by a CE in its role as an employer
- **New definition for “Personal Health Application” (PHA)**
 - Will require CE to provide access to PHI through an individual’s PHA, if requested by the individual and “if a copy [of the PHI] is readily producible to or through such application”
 - Could essentially force CE responding to patient access requests to disclose patients’ medical records to third-party application developers providing PHAs, even though such developers would be outside the reach of HIPAA

Proposed Privacy Rule Updates – General: Overhauling Individual Access Rights (*cont.*)

- **Recommended changes related to access fees**
 - Prohibits CE from charging a fee for certain categories of access:
 - In-person inspection
 - Use of a PHA to request and obtain PHI
 - For other categories of access, CEs would be permitted to charge a reasonable cost-based fee to cover expenses for:
 - Labor to prepare the record
 - Supplies, such as paper, toner, electronic media
 - Labor to provide a summary of the PHI
 - Postage
 - CE must provide advance notice of fees for copies of PHI:
 - Fee schedules must be posted online and made available at the point of service upon request.
 - Provide an individualized estimate of the approximate fee for requested copies of PHI and an itemized list of specific charges for labor as well as supplies and postage.

Proposed Privacy Rule Updates – General: Notice of Privacy Practice (NPP)

Could eliminate the requirement for individuals to provide written acknowledgement of receipt of NPP

- Replaces acknowledgement with an individual right to discuss the NPP with a person designated by the CE.

Update content requirements

- Amends the prescribed header language, in part to reflect the new right to discuss the NPP with a designated person.
- Brings the required statements on individual rights into alignment with the related substantive proposals, such as Part 2.

Proposed Privacy Rule Updates – General: Care Coordination and Case Management

- Adds an exception to the minimum necessary standard for disclosures to, or requests by, a health plan or covered health care provider for individual-level care coordination and case management.
- Permits CE to disclose PHI to social services agencies, community-based organizations, home and community-based services (HCBS) providers, and other similar third parties that provide health or human services to specific individuals for individual-level care coordination and case management.
- Allows such disclosures to be made without authorization as a treatment or health care operations activity, regardless of whether the third-party is a health care provider.
- Changes the punctuation from commas to semi-colons in the definition of “health care operations” to clarify that the term encompasses all care coordination and case management activities, whether population-based or focused on particular individuals.

Proposed Privacy Rule Updates – General: Use of “Professional Judgment” to “Good Faith”



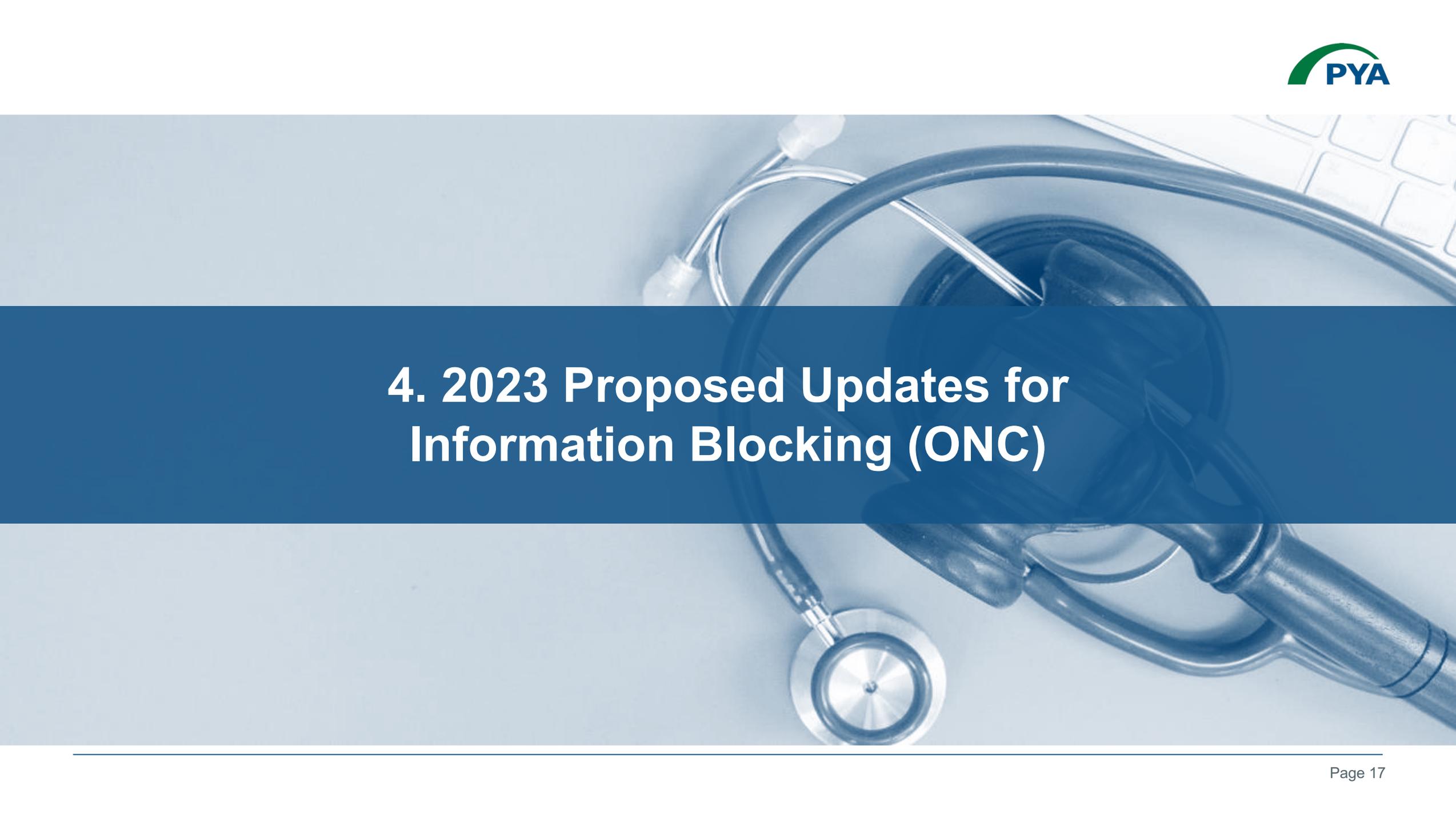
- **Would change the standard for disclosure of PHI in emergencies and other circumstances**
 - Encourages CE to share PHI with family members and caregivers of individuals—especially those experiencing substance use disorder (SUD), serious mental illness, or an emergency situation.
 - Replaces the “professional judgment” standard with a “good faith” standard for certain determinations that disclosure is in the individual’s best interest or otherwise appropriate.
 - Adds a presumption of compliance with the “good faith” standard when CE makes a disclosure based on the belief that it is in the best interest of the individual.



Proposed Privacy Rule Updates – General: Exclusion for Telecommunications Relay Service (TRS) Providers



- **Will help clarify the scope of the exception under which CE and their BA may disclose PHI to TRS providers to conduct covered functions without a business associate agreement (BAA)**
 - Adds a new public policy exception and updates the definition of a BA to expressly exclude TRS service providers from the definition of BA.
 - TRS is a public service that is available for free without the need to establish a business relationship.
 - Ensures that workforce members and individuals who are deaf, hard of hearing, or deaf-blind, or who have a speech disability, would be able to communicate easily using TRS for care coordination and other purposes.
 - CE will be permitted to disclose PHI to a TRS provider without patient authorization, even when there is no opportunity to agree or object.

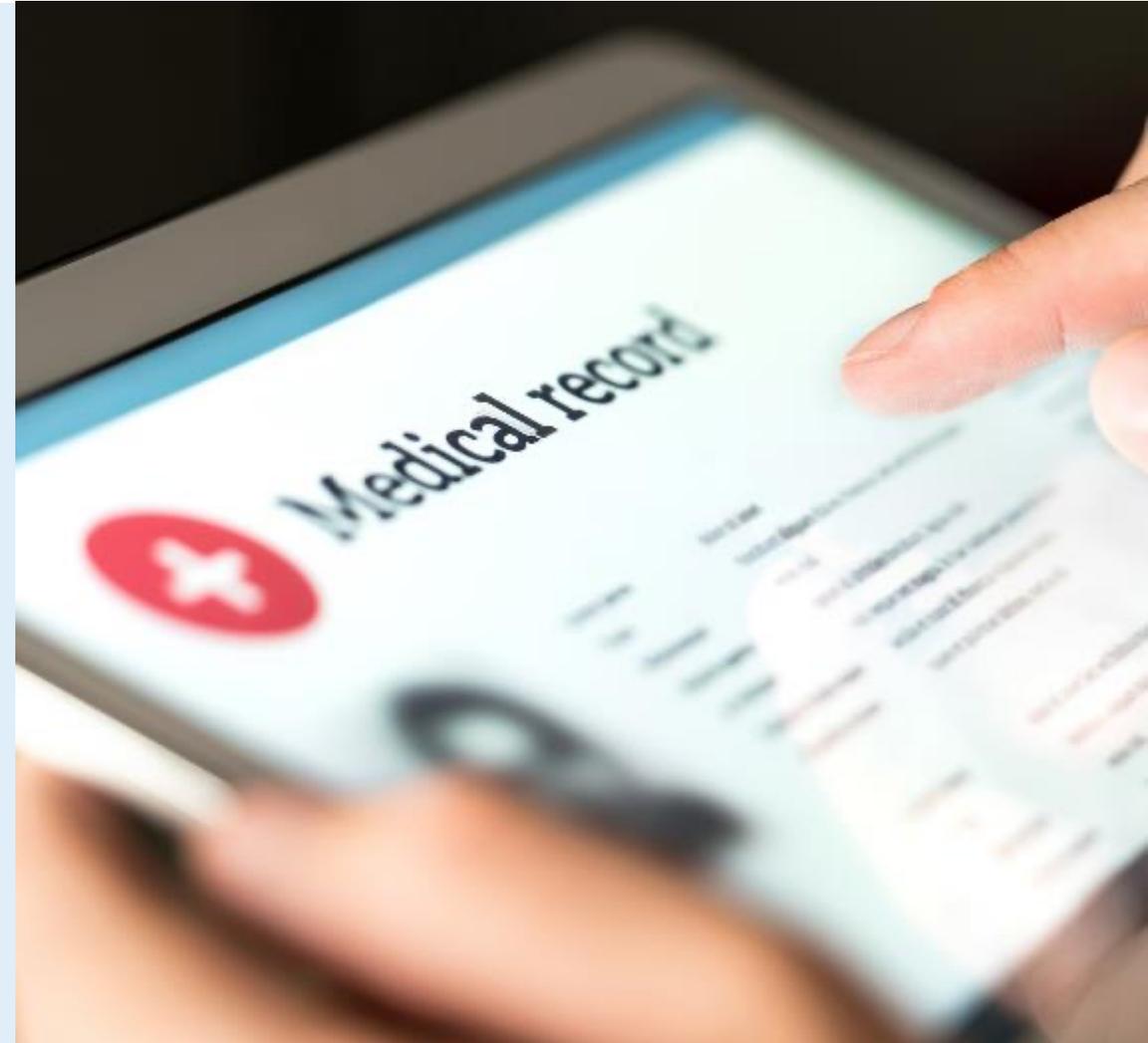
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4. 2023 Proposed Updates for Information Blocking (ONC)

Proposed Changes to the Information Blocking Rule



- **Technical changes to remove references to limited Electronic Health Information (EHI) definition**
 - Originally, EHI subject to information blocking was temporarily limited to data elements represented in the USCDI v.1 standard.
 - **On October 6, 2022, ONC adopted a limited definition of EHI.**
 - Proposed rule:
 - Removes references to the narrower EHI definition given that the USCDI limitation is no longer in effect
 - Re-names the “Content and Manner Exception” the “Manner Exception” because there is no longer a need to specify a different rule for the content of responses to EHI requests



Proposed Changes to the Information Blocking Rule (*cont.*)

- **Updated definition of “developer” to clarify what constitutes “offering” Certified Health IT**
 - Holding out for sale, selling, reselling, licensing, or relicensing Certified Health IT
 - **Will exclude:**
 - Donation and subsidized arrangements to partially or fully cover the costs of a health care provider’s health IT
 - Issuing user accounts and/or login credentials to employees, public health authority employees, and other health care providers
 - Making available production APIs or online portals to query or transmit EHI from or across Health Information Exchanges/Health Information Networks
 - Certain consulting, legal, administrative, and management services arrangements.
 - Health care provider that that self-develops health IT “not offered to others”

Proposed Changes to the Information Blocking Rule (*cont.*)

- **Updates to the “infeasibility” exception**

- **Definition:** Inability to **fulfill** a request to access, exchange, or use of EHI due to complex or problematic circumstances
- **Key Conditions:**
 - **Uncontrollable events:** The actor cannot fulfill the request for access, exchange, or use of electronic health information due to a natural or human-made disaster, public health emergency, public safety incident, war, terrorist attack, civil insurrection, strike or other labor unrest, telecommunication or internet service interruption, or act of military, civil or regulatory authority.
 - **Segmentation:** The actor cannot fulfill the request for access, exchange, or use of EHI because the actor cannot unambiguously segment the requested EHI.
 - **Infeasibility under the circumstances:** The actor demonstrates through a contemporaneous written record or other documentation its consistent and nondiscriminatory consideration of certain factors that led to its determination that complying with the request would be infeasible under the circumstances.
 - The actor must provide a written response to the requestor within 10 business days of receipt of the request with the reason(s) why the request is infeasible.

Proposed Changes to the Information Blocking Rule (*cont.*)

- **Addition of the new “TEFCA manner” condition for fulfilling requests for EHI**
 - Trusted Exchange Framework and Common Agreement (TEFCA)
 - The overall goal of TEFCA is to establish a universal floor for interoperability across the country.
 - Establish the infrastructure model and governing approach for users in different networks to securely share basic clinical information with each other—all under commonly agreed-to expectations and rules, and regardless of which network they happen to be in.
 - The TEFCA Manner condition helps to mitigate the burden of satisfying requests for healthcare data by allowing providers to fulfill information sharing obligations through participation in TEFCA.
 - Under TEFCA, providers who connect to a Qualified Health Information Network (QHIN) may rely on that connection as a substitute for fulfillment of tailored requests for electronic health information.

Proposed Changes to the Certification Program



- Replaces year-specific “Editions” of health IT certification criteria with a single set of “ONC Certification Criteria for Health IT”.
- Updates several Certification Program certification criteria and standards.
- Revises the requirements to obtain and maintain health IT certification under the Certification Program (“Conditions and Maintenance of Certification Requirements”).
- Establishes an EHR Reporting Program as a new condition of certification for health IT.
 - Data will address information gaps and provide insights on the use of certified health IT.
 - Program will provide clarity and transparency around four key areas:
 - Individuals’ access to EHI
 - Public health information exchange
 - Clinical care information exchange
 - Standards adoption and conformance

A top-down view of a stethoscope and a portion of a white keyboard on a light blue surface. A dark blue horizontal band is overlaid across the middle of the image, containing the title text.

5. 2023 Proposed Privacy Rule Updates – Reproductive Health Care (OCR)

2023 Proposed Privacy Rule Updates: The Definition of “Reproductive Health Care” (RHC)

- The proposed rule broadly defines RHC to mean “care, services, or supplies related to the reproductive health of the individual”.
- Regardless of the individual’s age or whether the care is pregnancy-related, the definition includes:
 - Contraception
 - Pregnancy-related health care, including:
 - Miscarriage management
 - Molar or ectopic pregnancy treatment
 - Pregnancy termination
 - Pregnancy screening
 - Products related to pregnancy, and prenatal care
 - Fertility or infertility-related health care (including assisted reproductive technology)
- Potential impact of this proposed defined term is that most CEs, rather than only providers of gynecological or fertility-related care, would be required to implement changes.

2023 Proposed Privacy Rule Updates: Strengthen Privacy Protections for PHI Related to RHC

- **Dobbs v. Jackson Women's Health Organization**
 - Landmark decision of the U.S. Supreme Court in which the court held that the Constitution of the United States does not confer a right to abortion.
- **Executive Order 14076 (Protecting Access to Reproductive Healthcare Services)**
 - Response to the subsequent threats and potential impact of state-level prosecution and law enforcement actions related to the provision of RHC
 - Prohibits the use and disclosure of such PHI in certain criminal, civil or administrative proceedings
 - Imposes new attestation requirements for certain uses and disclosures of PHI
 - Requires NPP changes
 - Revises the law enforcement exception



2023 Proposed Privacy Rule Updates: Use and Restricted Disclosure of RHC-Related PHI



- Prohibits CEs and BAs from identifying any person or using or disclosing RHC-related PHI for investigations and prosecutions of CEs and other persons related to seeking, obtaining, providing, or facilitating RHC that is either of the following:
 - Provided lawfully according to the law of the state where it was provided
 - Federally protected, required, or authorized
- These uses and disclosures would be prohibited even with an individual's authorization.
- No restrictions for CEs from making other currently permitted uses and disclosures, such as those for treatment, payment and health care operations.
- Will not affect disclosures otherwise required for criminal or civil proceedings when they are unrelated to the prohibited purposes.
- CEs will be required to carefully review requests that could be viewed as investigative or related to law enforcement actions to confirm the medical records requested do not relate to a Restricted Disclosure.

2023 Proposed Privacy Rule Updates: New Attestation Requirement

Would prohibit a CE from using or disclosing RHC-related PHI under the following Privacy exceptions:

- The health oversight exception
- The judicial/administrative proceedings exception
- The law enforcement exception
- The exception for disclosure of PHI regarding deceased individuals to coroners or medical examiners unless the CE first obtains from the requestor an attestation that the purpose of the request is not a Restricted Disclosure.

Example: Request for five years of a patient's medical records

- Patient requested and received birth control at one point within that timeframe.
- An attestation from the requestor must be obtained by the CE before releasing that portion of the records.
- CE will need controls in place to examine all PHI requests to determine whether there is potential disclosure of PHI related to RHC.

2023 Proposed Privacy Rule Updates: Notice of Privacy Practices – Expanded Content

- All CEs would be required to update their NPP.
- NPP will have to separately describe:
 - The Restricted Disclosures
 - The attestation requirement



2023 Proposed Privacy Rule Updates: Modifying Standards for Personal Representatives



- Prohibits a CE from denying personal representative status to a person when the primary basis for denying that authority was the fact that the person has facilitated or provided, or is facilitating or providing, RHC for the patient

2023 Proposed Privacy Rule Updates: Information Blocking and Interoperability Considerations



- Would pose practical challenges for CEs in distinguishing between RHC records and other PHI
 - Health Information Exchanges typically promote automated exchanges of PHI without the opportunity to review requested information line-by-line for potential RHC information.
 - Certified EHR systems often do not allow for data segmentation.

2023 Proposed Privacy Rule Updates: Updates to the Law Enforcement Exception

- The administrative request portion of the law enforcement exception would only apply to requests for which a CE is required by law to respond.
- This would potentially complicate the ability of CEs to comply with the Privacy Rule when a law enforcement agency is authorized to request records, but a response by the CE is not clearly required by law.



A top-down photograph of a stethoscope and a computer keyboard on a light-colored surface. The stethoscope is the central focus, with its chest piece and earpieces visible. The keyboard is partially visible in the upper right corner. A dark blue horizontal band is overlaid across the middle of the image, containing the section header text.

6. Future Privacy Considerations

Looking to the Future



- Continued increase in demand for virtual visits:
 - Patients will want to know who is recording and monitoring their PHI, who can access it, how it is used, and how it is protected.
- Patients have an increased awareness that sharing PHI can lead to better personal health outcomes.
- Confirming privacy might become a brand-enhancing competitive advantage that could position some organizations ahead of others in the marketplace.
- New interoperability requirements may necessitate the collection and integration of more data across different platforms.
- The patchwork of privacy standards needs to be harmonized to strengthen PHI protection and strengthen patient confidence.



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