

# Proposed Rule Aims to Modify Constraints under HIPAA and the HITECH Act

The Office of Civil Rights (OCR) has proposed sweeping changes in an attempt to modify the current privacy standards which can present barriers to covered entities and patient care. The modifications aim to remove administrative burdens relating to PHI. The objectives of the proposed rule is to allow for optimal flow of information to better serve patients and covered entities providing care. The proposed rule was released on December 10, 2020 and posted in the Federal Register on January 21, 2021. The comment period ends March 22, 2021.

## What you should know:

### ***Shortening the required response to for record request to 15 days down from the current 30 days.***

The proposed rule is aiming to shorten the amount of time a covered entity has to respond to requests of access to protected health information down to 15 calendar days.

Currently, covered entities have 30 days to respond to requests, unless stricter requirements exist under state law. The covered entity must provide, within 30 days, what was requested or issue a written statement as to the delay or only issuing part of the request and reason for denial for the remainder of the request. The OCR believes entities can provide individuals access to their records in half the time. As a result, the OCR is proposing to reduce the current time period to 15 calendar-days to provide access and only allowing a 15 calendar-day extension. States who currently have shorter requirements would preempt the final rule.

The proposed rule is also mandating under 164.524(b)(2)(ii)(G) that covered entities must have written policies for prioritizing urgent or other high priority access requests.

The OCR has an enforcement focus beginning this past year on patient's Right to Access. Currently, they have imposed penalties on 16 covered entities for failing to provide records within the required timeframe and have issued over \$1 million in penalties.

## What practices should do now:

Absent a final rule and in light of continued enforcement action on the Right to Access PHI by the OCR providers should look at their current release or access processes to ensure compliance under existing law. Covered entities should be asking questions within their operations:

- Does the entity hire out this function to a third-party vendor?
- Is there a dashboard on various metrics to ensure the services they are providing on your behalf are in compliance?

- Have staff been trained on current federal and state law requirements?
- If a vendor function, does the entity receive monthly status dashboard reports?
- Have privacy and security policies been updated?
- Does the onboarding hiring process of employees or vendors provide updated training on Privacy and Security including training policies and procedures?
- If the final rule or state law were to require a shorter timeline responding to PHI requests, what risks if any, would that create?

Practice operations could potentially pose a risk in responding timely to PHI requests. Some practices operate with few staff over holidays. For example, dental offices may be closed for a set two weeks in the summer. How are requests going to be handled with those operational variances?

### ***Adjusting the access and fees associated with the right to inspect PHI and obtain copies.***

The proposed rule sets out major changes to the right to direct PHI to a third-party and clarifying fees for access. First, the OCR is proposing access to records in certain categories cannot be charged a fee. Second, in certain circumstances the rule sets a framework for allowable fees.

## No Fees when:

An individual inspects PHI of their own record in person, which may include recording or copying PHI in a designated record set with the individual's own device or resource.

An individual using an internet-based method to view or obtain a copy of electronic PHI maintained by or on behalf of the covered entity cannot be assessed a fee. This would include, for example, access obtained by an individual through the covered entity's certified health IT (e.g., view, download, or transmit), or by a personal health application connecting securely to the entity.

## Reasonable Cost-Based Fees Can Be Assessed when:

- There is labor for copying the PHI requested by the individual in electronic or non-electronic form;
- supplies are utilized making non-electronic copies;
- for actual postage and shipping for mailing of non-electronic copies; and
- preparing an explanation or summary of electronic and non-electronic PHI, if agreed by the individual submitting the request by means other than an internet-based method.

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### Requesting a Copy of PHI in an EHR to a Third-Party Can Incur a Fee when:

When the request is for an electronic copy of PHI in an EHR to a third-party through a method other than an internet-based method. The fee can only include the cost of:

- Labor for copying the PHI by the individual in an electronic form; and
- Preparing and explaining or providing a summary of the electronic PHI, if agreed by the requesting individual.

The third-party fees would only apply for a copy of PHI that cannot be fulfilled through an automated process. For example, requests to copy PHI in an EHR onto electronic media and mailed to a physical address would fall into this category or the requestor asking for the copy to be placed on a secure thumb-drive or CD.

Type of Access	Recipient of PHI	Allowable Fee
<b>In-person inspection:</b> including viewing and self-recording or copying.	Individual (or personal representative).	Free
<b>Internet-based method of requesting and obtaining copies of PHI</b> (e.g., using View-Download-Transmit functionality (VDT), or a personal health application connection via a certified-API technology).	Individual	Free
<b>Receiving a non-electronic copy</b> of PHI in response to an access request.	Individual	<b>Reasonable cost-based fee,</b> limited to: <ul style="list-style-type: none"> <li>• labor for making copies;</li> <li>• supplies for copying;</li> <li>• actual postage &amp; shipping; and</li> <li>• costs of preparing a summary or explanation as agreed to by the individual.</li> </ul>
<b>Receiving an electronic copy of PHI through a non-internet-based method</b> in response to an access request (e.g., by sending PHI copied onto electronic media through the U.S. Mail or via certified export functionality)	Individual	<b>Reasonable cost-based fee</b> limited to: <ul style="list-style-type: none"> <li>• labor for making copies and costs of preparing a summary; or</li> <li>• explanation as agreed to by the individual.</li> </ul>
<b>Electronic copies</b> of PHI in an EHR received in response to an access request to direct such copies to a third party.	Third party as directed by the individual through the right of access.	Reasonable cost-based fee limited to: <ul style="list-style-type: none"> <li>• labor for making copies and for preparing a summary or explanation agreed to by the individual.</li> </ul>

### What appears to be removed in the proposed rule are per page fees.

The per-page, or initial cost for a set number of pages and a fee schedule for additional pages appear not to apply.

### Third-party vendor heyday could be over

Third-party record release companies often have arrangements with covered entities to handle PHI requests at “no-charge” to the organization. The record release vendor directly charges the requesting party often based on a per-page fee schedule. This could impact their operations.

### Health Plan Record Requests

If the rule is finalized, this could curb the record request costs for health plans as well. Often, health plan contracts would have an agreed upon fee that could be charged to the health plan for requesting records of a covered entity. Depending on the chart size, the record request fee could be hundreds of dollars. Should the rule become final, it may curtail the cost of record production altogether.

### Eliminating Notice of Privacy Practice Requirement Related to Obtaining Signature.

In an effort to reduce the burden of paperwork the OCR is proposing to eliminate the requirement for covered entities to obtain a written acknowledgment of receipt of the Notice of Privacy Practice (NPP). The proposed rule is looking to modify the requirements of the NPP in an effort to help patients understand the content of the NPP. The OCR is suggesting to modify the headings of the notice to provide information about: *(1) how to access health information, (2) how to file a HIPAA complaint; and (3) individuals’ right to receive a copy of the notice and discuss the contents with a designated person.*

Additionally, there would be a required header to specify whether the designated contact person is available onsite and must include the phone number an email address of the individual.

The NPP would also be revised to describe how an individual can exercise the right of access to obtain a copy of their records at limited cost or, in some cases, free of charge. The NPP would also require information on methods of transmitting information of PHI in an EHR to a third-party. The NPP would also explain the right of sending PHI to a third-party and also when their PHI is not an EHR or not in an electronic format and how they can be sent to a third-party.

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### Who does this apply to?

The proposal of the NPP changes applies to all covered entities, and not just covered health care providers with direct treatment relationships with individuals. The intent is to ensure consistency in how the NPP content is represented to individuals.

#### ***Allowing Permitted Disclosure of PHI to Telecommunications Relay Services (TRS) for those who have hearing, visual, or speech impairment.***

The OCR is proposing to add a new paragraph (m) to 45 CFR 164.512 to expressly allow disclosures to TRS communications assistance relating to any covered function performed by, for, or on behalf of covered entities and clarify for covered entities that a business associate agreement is not needed with a TRS communication assistant.

#### ***The terms of Electronic Health Record or EHR and Personal Health Record to be defined.***

Currently, the Privacy Rule does not define the term “electronic health record” but the HITECH Act has a codified definition of EHR which applies to the Act’s privacy and security provisions. Under the proposed rule, the definition of EHR is to be added in 45 CFR 164.501.

#### ***Technical Changes to the General Rule for Required Business Associate Disclosure of PHI.***

The proposed rule, if finalized, would insert clarifying language requiring business associates to provide copies of PHI to covered entities, individuals, or designee to satisfy the covered entities obligation under the right of access. The language would clarify when the business associate would be required to disclose PHI and to whom.

#### ***Reducing the Burden of Identity Verification for Individuals Right of Access.***

Currently, the Privacy Rule does not mandate how verification of an individual is to be done or by which pieces of documentation. The type and manner of verification is left to a covered entity along with discretion of personal judgement.

The OCR is proposing to expressly prohibit an entity from imposing unreasonable identity verification measures. The OCR is proposing to clarify what is unreasonable, such that, expending unnecessary effort or expense when a less burdensome verification would be practicable. Unreasonable measures would include, notarization of a request, submitting an access in writing, and applying infeasible registration requirements that would impose a barrier or impede access.

#### ***Allowing an Exception to the Minimum Necessary Standard for Individual-Level Care Coordination and Case Management.***

The minimum necessary standard requires covered entities to employ safeguards as necessary to limit unnecessary or inappropriate use and disclosure of protected health information.

The OCR is proposing permissible disclosure of PHI for care coordination and case management allowing an exception to the minimum necessary standard. The exception would apply to request by health plans or covered health care providers for care coordination and case management. The exception would apply to those activities related to care coordination and case management which are at an individual-level.

The proposal would relieve the covered entity from the requirement to make a determination about the minimum necessary information when the request is from, or disclosure is made to, a covered health care provider or health plan to support the individual-level care coordination and case management activities.

The intent of this exception is to remove the responsibility of the covered entity providing information to make an assessment whether the requested information is for purposes that are reasonable under the circumstances. The purpose is to allow health plans (such as wellness programs) and covered entities (e.g., treating mental health) to more easily and efficiently provide care coordination and case management to individuals. The burden on the covered entity releasing the requested PHI would be removed.

#### ***Encouraging Disclosures of PHI when Needed to Help Individuals Experiencing Substance Abuse Disorder, Including Opioid Use Disorder, and Serious Mental Illness, and in Emergency Circumstances.***

The OCR recognizes that family, friends, and caregivers, play an important role in the health and wellbeing of those with substance abuse and mental health disorders. As a result, the OCR is proposing to amend five provisions of the Privacy Rule to replace “the exercise of personal judgement” standard and allowing disclosures based on a “good faith belief” about the individual’s best interest. The OCR is proposing to replace the Privacy Rule provision that currently allows a covered entity to use or disclose an individual’s PHI based on a “serious mental and imminent threat” with a “serious and reasonably foreseeable threat” standard.

The five provisions proposed to amend the Privacy Rule based on good faith belief:

- 1) Replace “exercise of professional judgement” with “good faith belief” as the standard to which a covered entity would be allowed to make certain uses and disclosures in the best interest of the individual. Covered entities would still be required to take into account the facts and circumstances surrounding the disclosures, such as an individual’s prior expressed privacy preference and knowledge of any abusive relationship between the person to whom the covered entity would disclose PHI.
- 2) Allow covered entities to disclose PHI of an unemancipated minor to a parent or guardian who is not the personal representative of the individual under HIPAA if consistent with

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state or other applicable law and a licensed health care professional which has a good faith belief that disclosing PHI is in the best interest of the individual.

- 3) Permitting a covered entity to include an individual's name in a facility directory and to disclose, for directory purposes, the individual's location and general condition, when the individual is unable to agree or object and the covered entity has a good faith belief that the disclosure is in the best interest of the individual.
- 4) Allowing covered entities to disclose relevant information to a person involved in the individual's care or payment for care when the covered entity reasonably infers, based on good faith belief, that the individual does not object. This provision addresses specifically emergency contacts in which a facility may lack a written designation of an emergency contact. Based on a good faith belief under the circumstance the propose rule would allow disclosure or relevant information.
- 5) Permitting covered entities to disclose relevant information about the individual to family or other caregivers who are involved in the individual's care or payment of care, when the individual cannot agree to the disclosure because of absence, incapacity, or emergency circumstances when the covered entity has a good faith belief it is in the best interest of the individual.

### Conclusion

The Proposed Rule aims to decrease the administrative burden and clarify certain aspects of the HIPAA Privacy Rule. These proposed rule and modifications to existing rules are historic in nature. Nearly every care provider would be impacted by these rules.

There remain many unanswered questions and ambiguity remains in some areas based on how the proposed rule is written.

Healthcare providers should watch the proposed rule carefully. While it is likely not all parts of the proposed rule will become final, more likely than not, most sections will be finalized. As a result, the healthcare industry will need to train staff on the rule once finalized to ensure compliance.

### About

Rivet Health Law, PLC specializes in legal and compliance issues associated with medical Coding, Billing, Reimbursement, Third-Party Payor Audits, and provides custom education and training.

### Reference

U.S. Dep't of Health and Hum. Serv. (HHS) Office for Civil Rights (OCR), Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinate Care and Individual Engagement (Jan. 21, 2021), <https://www.govinfo.gov/content/pkg/FR-2021-01-21/pdf/2020-27157.pdf> [hereinafter "Proposed Rule"].