

HIPAA

HIPAA Notice of Proposed Rulemaking

Be prepared for these new upcoming rules.

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The Office for Civil Rights (OCR) proposed many changes in 2020. Early in the year, we saw two proposed rules: ONC’s 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program¹; and CMS’ Interoperability and Patient Access rule.² These two directives empower patients and caregivers by giving them better access to and control of their health information. On December 10, 2020, the Department of Health and Human Services (HHS) published the proposed modifications to the HIPAA Privacy Rule designed to empower patients, improve care coordination, and reduce regulatory burdens.³ On January 21, 2021, the proposed rule was published in the Federal Register.

What Do Healthcare Providers Need to Know?

The HIPAA Privacy Rule’s proposed changes will impact healthcare operations, patient access rights, and disclosures to third parties. Below is

tain or direct protected health information (PHI) copies to a third party and strengthens individuals’ rights to inspect;

- Reduces the identification burden and creates a pathway for indi-

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a summary of the significant changes included in the proposal:

- Adds definitions for electronic health records and personal health applications, and amends the definition for healthcare operations;
- Reduces time to respond to a patient request for access from 30 days to 15 days;
- Requires covered entities to inform individuals of their right to ob-

viduals to direct the sharing of PHI but limits the individual right of access to direct the transmission of PHI to a third party;

- Requires covered healthcare providers and health plans to respond to certain records requests according to the right of access;
- Specifies when electronic PHI (ePHI) must be provided to the indi-

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vidual at no charge and clarifies form and format;

- Amends the permissible fee structure to direct records to a third party and requires covered entities to post estimated fee schedules;
- Creates an exception to the minimum necessary standard;
- Clarifies the scope of covered entities' abilities to disclose PHI;
- Replaces the phrase "professional judgment" with "good faith belief";
- Expands the ability of covered entities to disclose PHI when a harm is "serious and reasonably foreseeable" instead of "serious and imminent";
- Removes the requirement to acquire written acknowledgment of the Notice of Privacy Practice (NPP) and establishes a patient's right to discuss the NPP with a designated person; and
- Eases information sharing during care coordination and case management and improves disclosure to family members and caregivers.

What Do Healthcare Providers Need to Do?

Start now! Review the proposed rule and compare it to your current policies, procedures, and standard practices to identify necessary changes. In addition to your policies and procedures, you also need to review your Notice of Privacy Practices and add the additional required content.

We recommend that you wait until the final rule is published to effect changes to your policies. After OCR reviews the comments submitted, it could make changes to the rule. It may also answer common questions that help you with interpreting the intent of these changes.

Potential Process Changes

One specific change that you need to make is removing the requirement to record an acknowledgment for your NPP receipt. For some providers, this is a paper process that would be simple to modify. However, for some providers, their EMR manages this process and may be a required field or process that they must complete to move forward in the registration process.

The rule also lays out specific content for the header of your NPP:

- How patients can access their information;
- How patients can file a HIPAA complaint;
- Their right to receive a copy of the NPP and discuss the NPP's content with a designated person; and
- Contact information for the des-

ignated person, including a telephone number and email address, and if they are on-site.

While you are finding processes that may need to change, it is crucial to identify system limitations in your applications that store ePHI. Start working with your EMR vendor early.

Patient Access Changes

Your release of information processes could be significantly affected. If you already struggle to meet the requirement to respond to requests for access within 30 days, cutting the requirement in half could put a significant strain on staff. Adding staff or outsourcing this process should be evaluated, which may be increasingly difficult as you may be required to reduce your fees for copies. The proposed rule also requires you to post your fee schedule on your website.

You may also need to adjust your patient identification process for the release of information. The proposed rule(3) states, "... the Department's view is that the Privacy Rule does not mandate any particular form of verification (such as viewing an individual's driver's license at the point of service), but instead generally leaves the type and manner of the verification to the discretion and professional judgment of the covered entity, provided the verification processes and measures do not create barriers to, or unreasonably delay, the individual from obtaining access to their PHI."

Most providers have a flexible identification process, but there should be an internal review to ensure your process is compliant with these changes.

Comment Period

The comment period began January 21, 2021, and ended March 22, 2021. The final rule will include

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questions and comments received and HHS' response(s). The effective date will be 60 days after publication of the final rule, and the compliance date will be 180 days from the effective date (or 240 days from publication). **PM**

References

¹ Department of Health and Human Services. 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program. Available at <https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification>. Accessed January 28, 2021.

² CMS.gov. Reducing Provider and Patient Burden by Improving Prior Authorization Processes, and Promoting Patients' Electronic Access to Health Information. Available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index>. Accessed January 28, 2021.

³ Department of Health and Human Services. Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to Coordinated Care and Individual Engagement. Available at <https://www.hhs.gov/sites/default/files/hhs-ocr-hipaa-nprm.pdf>. Accessed January 28, 2021.



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