

Examining proposed modifications to HIPAA Privacy Rule

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As many anticipated, the Department of Health and Human Services (HHS) has pushed out a flurry of proposed rules in the months leading up to the Trump administration's departure. Among them is a [Notice of Proposed Rulemaking](#) (NPRM) that would make significant changes to the HIPAA Privacy Rule.

The NPRM, released by the Office for Civil Rights (OCR) on December 10, 2020, includes provisions that build on the themes set forth in the [Interoperability and Patient Access final rule](#), which was published in March. The proposed changes to the HIPAA Privacy Rule are wide-ranging, but the overall intent is clear.

"The main point of this is to eliminate some of the obstacles currently facing us in terms of an individual trying to view their own health record or an individual trying to share that health record, but also for providers to more freely share an individual's health record across other care providers, which is huge," says **Bill Wagner, CHPS, CPCO**, chief operating officer of KIWI-TEK in Indianapolis, Indiana.

Kate Borten, CISSP, CISM, HCISPP, founder of The Marblehead Group in Marblehead, Massachusetts, believes the general direction of the NPRM is toward greater access and fewer barriers for the patient.

She does not expect the new administration to make major changes when finalizing the rule because so much of the rule involves themes the healthcare industry has long been aware of—most notably the push for interoperability and patient access. Healthcare has been moving in this direction for quite some time, and the new administration is likely to emphasize the same initiatives. However, subtle changes could be in store.

Public comments on the proposed rule will be due 60 days after publication in the Federal Register. Comments can be submitted at [regulations.gov](https://www.regulations.gov) by searching for Docket ID number HHS-OCR-0945-AA00.

Below, we'll examine the components of the proposed modifications, highlighting potential concerns that covered entities (CE) could raise during the comment period

Individuals' right of access

Over the past year, OCR has announced 12 settlements with CEs in its HIPAA Right of Access Initiative. These settlements stemmed from situations in which the CE failed to provide an individual with adequate access to their protected health information (PHI), and OCR launched investigations against all types of CEs.

On October 7, St. Joseph's Hospital and Medical Center (SJHMC) in Phoenix, Arizona, agreed to pay \$160,000 to OCR and implement a corrective action plan to settle a potential HIPAA violation. [An OCR investigation](#) found that SJHMC failed to provide a patient with access to health information for more than 22 months.

Smaller practices were targeted as well. Dr. Rajendra Bhayani, a private practitioner specializing in otolaryngology in Regal Park, New York, agreed on November 12 to [enter a corrective action plan](#) and pay \$15,000 to OCR for a potential HIPAA violation. OCR had received complaints that Bhayani failed to provide a patient with medical records in July 2018 and again in July 2019. After the first complaint, OCR intervened and offered technical assistance, but the patient's request for records remained unfulfilled.

Given HHS' recent push for individuals' right of access, it should come as no surprise that the majority of provisions included in the proposed rule were related to furthering this initiative.

Right to inspect PHI

- HHS proposes strengthening individuals' rights to inspect their PHI in person, which includes allowing individuals to take notes or use other personal resources to view and capture images of their PHI

If a patient does not have the money to pay for copies of medical records, the patient is able to view the records at no cost. HHS clearly states this right in the proposed rule, and it provides some examples of how individuals can record their PHI.

"I've always said to family, friends, and clients that you can go into the office and view the record and take notes," says Borten. "You can take a picture. This is your information and it's all free. So, I am very pleased to see that this proposal includes explicitly saying individuals have the right to do things like take photographs."

Rita Bowen, MA, RHIA, CHPS, CHPC, SSGB, vice president of privacy, compliance, and HIM policy at MRO Corp. in Norristown, Pennsylvania, wonders how far a patient will be able to delegate this power.

“Does that mean attorneys can come in and make photocopies of what they want, as well?” Bowen says. “Those are part of my questions back in my comments. It kind of opens the door with a crack, and you know when there’s a crack in that door, somebody is going to push through.”

Jay Hodes, president and founder of Colington Consulting in Burke, Virginia, would like to see HHS provide more concrete guidance.

“What are the logistics of this within an organization?” Hodes says. “Does that mean we have to go to a consultation room? If you have a compliance department that can structure this, that’s great. But the small to mid-sized organizations, they really need the guidance.”

Additionally, Wagner wonders about patient visits being lengthened due to the time spent inspecting PHI, possibly due to different applications within the electronic health record (EHR) for physician’s notes, lab results, radiology, etc. Sorting through all these applications can be time-consuming, and Wagner asks whether clinicians will be compensated for the extra time spent with the patient.

Shortened response time

- HHS proposes shortening CEs’ required response time to no later than 15 calendar days (from the current 30 days) with the opportunity for an extension of no more than 15 calendar days (from the current 30-day extension)

Experts agree that the concept here makes perfect sense. Borten says it is common for organizations to wait until day 29 to reach out to a patient, ask for clarification, and then start the 30-day clock at that point. As HHS continues to emphasize patient access, clearly this is not an acceptable practice.

However, from a practical standpoint, implementing the 15-day deadline may be problematic for a lot of organizations, says Hodes.

“I think you have to take into consideration legacy systems, if organizations use document storage with off-site locations, and their ability to retrieve them,” Hodes says. “If I were a larger CE, I would be proposing to keep it to 30 days. I think it’s going to be an administrative burden to try to comply with the 15 days. I don’t have an issue shortening the extension period to 15 days.”

It should be noted that some states are already requiring a 15-day response time and CEs are complying.

Identity verification

- HHS proposes reducing the identity verification burden on individuals exercising their access rights

Currently, the Privacy Rule requires CEs to take reasonable steps to verify the identity of a person requesting PHI before disclosing the PHI to help ensure that unauthorized people do not obtain an individual’s information. The manner of verification is generally left to the CE’s discretion.

The proposed rule would prohibit CEs from taking unreasonable identity verification measures, such as requiring individuals to obtain notarization of requests to exercise their Privacy Rule rights and requiring individuals to provide proof of identity in person when a more convenient method for remote verification is practical for the CE.

While the proposed rule details what will be eliminated, HHS should provide examples of what the new verification process should look like, Wagner says.

Right now, many organizations are identifying patients with name, date of birth, and the last four digits of Social Security numbers, or other similar measures. Hodes does not view this as particularly burdensome on either the CE or the patient.

“I think now when there are so many bad actors trying to compromise health information, I think I would push back on that one,” Hodes says.

Concerns about verifying electronic signatures—which could be a common practice as remote communication between CEs and patients continues to increase—should facilitate discussions about potential solutions. Providing patients with an electronic method of requesting records through a portal would be advantageous for organizations, says Bowen.

Sharing of PHI

- HHS proposes creating a pathway for individuals to direct the sharing of PHI in an EHR among covered healthcare providers and health plans by requiring covered healthcare providers and health plans to submit an individual’s access request to another healthcare provider and to receive back the requested electronic copies of the individual’s PHI in an EHR
- HHS proposes requiring covered healthcare providers and health plans to respond to certain records requests received from other covered healthcare providers and health plans when directed by individuals pursuant to the right of access

As interoperability continues to be emphasized across the healthcare continuum, most organizations should be prepared for these modifications.

“Some of this, especially when it’s between CEs, both of whom are clearly caring for this one individual, there shouldn’t be any sort of barrier,” says Borten. “This should be routine processing today, and I think for many organizations it is.”

With larger organizations, compliance should not be an issue. But smaller organizations, such as those in rural areas, may experience greater privacy and security concerns associated with the transmission and storage of records, says Wagner. Additionally, issues may arise when organizations using Epic, for example, are sending information to organizations using Cerner, says Bowen. She urges organizations to submit comments on this modification.

Finally, Hodes views the lack of a timeline as problematic. If a patient asks his or her primary care physician to send medical records to a specialist, there is currently no specified timeline for the transmission to occur, whereas the provider would have 30 days to produce the records if the individual was requesting them for personal use. Hodes would like HHS to clarify if a provider-to-provider transaction follows the same timeline as provider-to-individual.

Form and format

- HHS proposes clarifying the form and format required for responding to individuals’ requests for their PHI

HHS proposes that a readily producible form and format includes access through an application programming interface (API) using a personal health application. This requirement falls in line with the [Interoperability and Patient Access final rule](#), which will require healthcare organizations to adapt standards-based APIs set forth by CMS-regulated payers. Enforcement on this requirement will begin on July 1, 2021.

Still, some privacy and security concerns remain.

“If I’m the privacy and security officer at a CE and we create an API, how do I know the device the individual is using to access the API is secure?” says Wagner. “The last thing you want to do is have a patient access their record through an API with a device that is not secure. If I were the health system or covered entity, I think I’d want that all clarified.”

Fee structure

- HHS proposes specifying when electronic PHI (ePHI) must be provided to the individual at no charge

- HHS proposes amending the permissible fee structure for responding to requests to direct records to a third party
- HHS proposes requiring CEs to post estimated fee schedules on their websites for access and for disclosures with an individual’s valid authorization and, upon request, provide individualized estimates of fees for an individual’s request for copies of PHI, and itemized bills for completed requests

The labor costs for record retrieval in the past were understandable and legitimate, says Borten. But when all records can be accessed with the simple click of a button, it makes sense to eliminate fees for ePHI.

The proposal also sorts out some of the issues related to charges for third-party access. The ambiguity that allowed organizations to charge state rates for third parties has been eliminated which will result in a shift in cost back to the facilities, says Bowen. In a time when CEs have been hit financially due to the pandemic, it is not wise to be shifting cost from third parties (attorneys, record retrieval companies, etc.) back to the CE.

“In the proposed rulemaking, it basically says if the information is in electronic format, then the fee structure must be based off the cost-based formula,” Bowen says. “That’s going to have some impact and cost shift to the CE.”

Significant changes

While much of the proposed rule focuses on enhancing patient access, there are other impactful modifications discussed. They include the following:

Adding definitions for an electronic health record and a personal health application

Currently, the Privacy Rule does not define the term “electronic health record.” The proposal seeks to implement the following definition:

- Electronic health record means an electronic record of health-related information on an individual that is created, gathered, managed, and consulted by authorized healthcare clinicians and staff. Such clinicians shall include, but are not limited to, health care providers that have a direct treatment relationship with individuals, such as physicians, nurses, pharmacists, and other allied health professionals. For purposes of this paragraph, “health-related information on an individual” covers the same scope of information as the term “individually identifiable health information (IIHI).”

Case management and care coordination

- HHS proposes amending the definition of healthcare operations to clarify the scope of permitted uses and disclosures for individual-level care coordination and case management that constitute healthcare operations.
- HHS proposes creating an exception to the “minimum necessary” standard for individual-level care coordination and case management uses and disclosures. The minimum necessary standard generally requires CEs to limit uses and disclosures of PHI to the minimum necessary needed to accomplish the purpose of each use or disclosure. This proposal would relieve CEs of the minimum necessary requirement for uses by, disclosures to, or requests by a health plan or covered healthcare provider for care coordination and case management activities with respect to an individual, regardless of whether such activities constitute treatment or healthcare operations.
- HHS proposes clarifying the scope of CEs’ abilities to disclose PHI to social services agencies, community-based organizations, home and community-based service providers, and other similar third parties that provide health-related services, to facilitate coordination of care and case management for individuals.

In the past, a CE may have been extra cautious about sharing all the details of a patient record with social services or case management because the provider may have been unsure about the case manager’s qualifications to view the entire record. This has been revised to facilitate greater coordination of care.

“My question would be—both in the change of minimum necessary and in the increased and expanded version of disclosure—do those social services and community-based organizations have a safe and secure portal for receiving and storing that information? When you go down to lower levels of sophistication in healthcare providers, that would be a concern of mine,” says Wagner.

HHS is requesting comments on the benefits and costs of the amended definition of healthcare operations. Additionally, HHS is seeking commentary on how the clarified definition—which would include individual-level care coordination and case management—would affect a CE’s decision-making regarding uses and disclosures of PHI for these purposes.

Notice of Privacy Practices

- HHS proposes eliminating the requirement to obtain an individual’s written acknowledgment of receipt of a direct treatment provider’s Notice of Privacy Practices (NPP)

Experts agree that many patients do not read the NPP, but there are mixed opinions on the need to eliminate the requirement altogether. Hodes views the NPP as an administrative burden, “an exercise in additional use of trees to generate the three pages of the NPP.”

Meanwhile, Borten acknowledges that most patients do not take the time to time to read the NPP, but she does not believe this is reason to make such a significant change.

“At this stage, I question the level of burden that’s out there because it’s already built into the processes,” she says. “If it were proposed as a new requirement, I think it would be fair to assess the administrative burden, but it should be totally routine now. I don’t see it as hugely burdensome.”

Eliminating the NPP acknowledgement should come with enhanced patient rights awareness through other means.