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The New HIPAA NPRM—The Latest and Greatest in the Evolution of the HIPAA Privacy Rule

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Following a pattern of familiarity for health lawyers, the Department of Health and Human Services (HHS) has released a substantial Notice of Proposed Rulemaking (NPRM) in December at the end of an administration.[1] The NPRM is intended to revise the Privacy Rule under the Health Insurance Portability and Accountability Act (HIPAA). Because comments are not due until after the new Biden administration takes office, the fate of this NPRM is unclear. At the same time, this NPRM reflects two key issues of concern to the Office for Civil Rights (OCR) in its current incarnation: improving patient access to health information (a goal presumably shared by a new administration) and expanding opportunities for increased information sharing in specific contexts (primarily focused on coordinated care and sharing with social service organizations).

The access principles—while detailed and somewhat technical—generally seem consistent with policy goals that have been applied for more than a decade, as government tries to find easier means to allow patients meaningful and useful access to their own information. The more challenging elements of this NPRM stem from the desire to expand information sharing. While pursuing admirable goals (who is against coordinated care?), these elements present much more complicated policy issues and raise a broad variety of concerns in connection with the overall debate about health care privacy.

It is important for health lawyers (and the health care industry in general) to understand these proposed changes in context. While the HIPAA rules have presented a stable privacy baseline for almost 20 years, there is increasing recognition of the critical gaps in HIPAA's structure—both in terms of the vast number of entities collecting and creating health information outside the scope of the HIPAA rules and the enormous expansion in how the health care industry incorporates non-health data into its activities. At the same time, health care entities face ongoing challenges from a variety of other laws (e.g., in California, where health care information can be subject to at least six different regulatory regimes),[2] a global privacy structure that does not isolate health care entities or provide any nuance for health care system activities, and the increasing likelihood of a national privacy law that could fundamentally disrupt the existing HIPAA structure.[3] Accordingly, aside from the immediate political questions surrounding whether this NPRM moves forward, all of these proposed changes should be factored into this broader policy debate.

Proposed Changes to HIPAA Access Provisions

A significant portion of the NPRM is focused on issues related to patient access. The HIPAA access right has been a key part of the Privacy Rule since it was first drafted. At the same time, access challenges have been consistent and ongoing. Incremental changes in the rules have been designed to improve access. Other laws—including the recent interoperability provisions of the 21st Century Cures Act—also are relevant to this fight. In addition, OCR has made enforcement of the access right an important priority with meaningful success through recent enforcement activities.[4] Covered entities are now on notice that gaps in compliance on HIPAA access will not be tolerated.

In its discussion, the HIPAA NPRM notes that “While OCR has issued extensive guidance and performed outreach to the public and regulated entities regarding the individual right of access, OCR continues to hear . . . that individuals frequently face barriers to obtaining timely access to their PHI, in the form and format requested, and at a reasonable, cost-based fee. Associated delays or lack of patient access to their PHI may inhibit care coordination and contribute to worse health outcomes for individuals, and contribute to burden on individuals and systems.”

Accordingly, a key priority of the HIPAA NPRM is to seek means of improving patient access. While commentators should evaluate the particular details (which are very specific and, frankly, technical), the key elements of these proposals focus on:

- Providing faster access to HIPAA PHI
- Providing additional opportunities to inspect records in person
- Reducing the costs associated with access and clarifying applicable costs
- Facilitating disclosures to personal health records and other third parties
- Reducing the identity verification burden on individuals exercising their access rights

Additional Opportunities for Information Sharing

The more complicated part of the HIPAA NPRM (at least from a policy perspective) involves the sections dealing with expanding opportunities for information sharing. These provisions are driven (primarily) by specific policy interests of the current administration—the desire to expand opportunities for “coordinated care” and “value-based” care, and the idea that better information sharing would have led to better results in dealing with the opioid crisis. According to the NPRM, these proposals are being made "[i]n light of ongoing concerns that regulatory barriers across the Department impede effective delivery of coordinated, value-based health care," although it has never really been clear what parts of HIPAA create these "barriers." The HIPAA NPRM recognizes that some of these changes are cosmetic—that covered entities have appropriate means to disclose now, but often do not. OCR's view is that these choices are driven by fear of HIPAA violations (rather than substantive concerns about the sharing in the first place). The goal of the NPRM is to permit more sharing of PHI in specific settings whether through clarification of the existing provisions or creation of new opportunities for this sharing. The goals generally are admirable. The concern, however, in almost all of these situations is that the sharing would be done in expanded situations without specific patient permission—where seeking patient permission would be feasible (at least some of the time) and would be the vehicle for sharing today. This means that these goals are not without privacy costs—the proposals represent reasonable choices to facilitate certain goals of the health care system, despite tensions with patient privacy. These choices are made throughout the HIPAA rules in the core "TPO" approach from the start, in the permitted disclosures for national priority areas, and the like. But these choices should be recognized as choices, and the NPRM reflects stark situations where the interests of the health care system (and the specific policy goals identified in the NPRM) may create meaningful tensions with privacy interests.

The tension is quite explicit in the NPRM. For example, "Nearly all commenters who identified as family members of patients agreed that in many cases more information related to an individual's SMI [serious mental illness] or SUD [substance use disorder] should be disclosed to family caregivers, and shared personal stories about the devastating consequences—such as suicide, missed appointments, homelessness, and lack of continuity in treatment and medication—that occurred because of a lack of information disclosure." At the same time, OCR is clear that "Commenters who identified as patients or privacy advocacy groups almost universally opposed modifying the Privacy Rule to expand permitted disclosures of information related to SMI and opioid use disorder or other SUDs. Many commenters expressed fear of family members and employers having access to this information, citing potentially adverse consequences, including fear of discrimination, abuse, and retaliation." In addition, HHS notes that "Many health care providers expressed concern about the chilling effect that increased disclosures would have on individuals seeking treatment for opioid use disorders and stated that the Privacy Rule is already flexible enough to permit the amount of disclosure needed to address the opioid epidemic."

This is the core tension with this component of the NPRM. The health care system—and some individuals who have specific roles such as family members—would like to see more information sharing. At the same time, this enhanced information sharing, while typically with admirable goals in mind, usually will be conducted without individual permission, and the entire point of these proposed changes is to encourage these additional disclosures without obtaining patient authorization.

HHS also notes that "Despite issuing extensive guidance, OCR continues to hear that some covered entities are reluctant to disclose information to persons involved in the care of individuals experiencing these health issues, even when the Privacy Rule permits such disclosures." It is critical to note that, assuming this is accurate, this is not necessarily a bad thing. Today the key question is whether providers are choosing not to make these disclosures (1) because they don't think that such disclosures should be made; OR (2) because they do not believe they are allowed or otherwise are worried about the legal implications of making these disclosures.

Social Service Organizations

The idea of "social determinants of health" is becoming increasingly important in the health care system. We now recognize that not having access to good food or good housing can impact health, particularly for minorities and other disadvantaged individuals. The issue addressed by this NPRM is what to do about the HIPAA provisions that could restrict disclosures to social service organizations that can provide assistance in these areas—recognizing that disclosures probably can be made under the rules today, at least by health care providers, with patient authorization and that these organizations typically are outside the entire scope of the HIPAA rules (as they are not covered entities or business associates), meaning that any disclosures of PHI to these organizations will result in that information no longer being protected by the HIPAA rules.

Specifically, HHS is proposing to add a new subsection 164.506(c)(6), which would "expressly permit covered entities to disclose PHI to social services agencies, community based organizations, HCBS [home and community based service] providers, and other similar third parties that provide health-related services to specific individuals for individual-level care coordination and case management, either as a treatment activity of a covered health care provider or as a health care operations activity of a covered health care provider or health plan." According to the discussion, this disclosure could only occur "without authorization to a third party that provides health-related services to individuals," but this could include "non-health care providers" who "may be providing health-related social services or other supportive services—e.g., food or sheltered housing needed to address health risks." Under this provision, "a covered entity could disclose the PHI of a senior individual experiencing chronic illness to a senior center attended by the individual to check on his or her health periodically, and to ask the senior center to give reminders about effective disease self-management." HHS "believes that such disclosures generally are permitted under the existing Privacy Rule for treatment or certain health care operations," but is suggesting this "additional, express regulatory language" would provide greater regulatory clarity, and help ensure that covered entities are able to disclose PHI to coordinate care for individuals with social services agencies or other similar third parties that are providing health-related services to those individuals. The goal is to "facilitate and encourage greater wraparound support and more targeted care for individuals, particularly where it would be difficult to obtain an individual’s authorization or consent in advance, because the individual cannot easily be contacted (e.g., when an individual is homeless). Note, however, that there is no requirement in this proposal that a health care provider evaluate whether it is difficult to contact a patient before proceeding down this path.

Covered Entity Standards for Decision-Making

HHS also is proposing to address what it views as insufficient information sharing by adjusting the standard for evaluating a covered entity’s behavior in this area. While the standard today involves a covered entity’s activities in “the exercise of professional judgment,” HHS is suggesting a different standard permitting certain disclosures based on a “good faith belief” about an individual’s best interests. Moreover, HHS is proposing “a presumption that a covered entity has complied with the good faith requirement, absent evidence that the covered entity acted in bad faith.” It views these changes as “improv[ing] the ability and willingness of covered entities to make certain uses and disclosures of PHI.”

Additional Points to Make—Important Miscellany

The Accounting Rule

For those HIPAA history buffs, the NPRM does not address the Health Information Technology for Economic and Clinical Health Act (HITECH) changes to the HIPAA accounting rule in any way. The accounting rule provisions—a longstanding holdover from the 2009 HITECH law—have been controversial from the start, and it seems clear that HHS has no realistic idea of how to implement them.[5] While HHS sought input on potential accounting rule changes, “[b]ased on the comments received in response to the 2018 RFI, and the history of previous rulemaking on this topic, the Department intends to address this requirement in future rulemaking.”

Notice of Privacy Practice Changes

HHS is also proposing to modify certain obligations related to the HIPAA Notice of Privacy Practices (NPP). Specifically, HHS is proposing to eliminate the “written acknowledgement” of receipt of a privacy notice from a direct treatment health care provider. In its place, the rule would provide “an individual right to discuss the NPP with a person designated by the covered entity.” There also are certain proposed content changes to the NPP (mainly in the headings), but no wholesale modification of the voluminous requirements for what needs to be in the HIPAA Privacy Notice.

Minimum Necessary Discussion

There is a meaningful discussion of the role of the “minimum necessary” rule in connection with expanded information disclosures. This provision, while important as a concept, does not tend to create meaningful restrictions on information sharing activity where there is a reasonable basis for information sharing. Nonetheless, OCR is proposing to be more explicit on how the minimum necessary rule can be applied (or not applied) in these areas. For example, the NPRM "would relieve covered entities of the minimum necessary requirement for uses by, disclosures to, or requests by, a health plan or covered health care provider for care coordination and case management activities with respect to an individual, regardless of whether such activities constitute treatment or health care operations."

Health Plans

As a related issue, there is an important recognition of some of the needs of health plans because of the historic conclusion in the HIPAA rules that health plans do not engage in "treatment" activities. From the beginning of the HIPAA Privacy Rule, this distinction has created tensions, as health plans have engaged in more efforts to manage care. The issues have reached critical points in certain government health programs, particularly Medicaid managed care programs where the (not unreasonable) demands of state Medicaid agencies have run directly into some of the limits of the HIPAA Rules. According to OCR, "the current rule imposes greater restrictions on disclosures to and requests by health plans than on disclosures to and requests by covered health care providers when conducting care coordination or case management activities related to an individual." One goal of the NPRM is to put health plans on roughly equivalent footing with health care providers in connection with uses and disclosures of PHI for coordinated care related to specific individuals.

Conclusion

Politics and timing aside, this NPRM represents an important and useful step forward in the evolution of the HIPAA Privacy Rule. The proposed access changes seem consistent with a broad range of efforts that have been underway for several years, with full support from the patient community and only limited opposition or objections from the covered entity side. The interest in expanding information sharing is much more complicated as a policy matter. Commenters should carefully consider these policy questions, and the new administration will need to decide how much to push forward with these efforts, where information sharing goals are introduced as benefits for the health care system even while perhaps resulting in sharing without permission from the affected patients.

About the Author

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Endnotes

[1] Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement (HIPAA NPRM) (Dec. 10, 2020), https://www.hhs.gov/about/news/2020/12/10/hhs-proposes-modifications-hipaa-privacy-rule-empower-patients-improve-coordinated-care-reduce-regulatory-burdens.html#:~:text=The%20proposed%20changes%20to%20the,involvement%20in%20the%20care%20of.

[2] *See* Kirk Nahra, *Top Five Health-Care Privacy, Security Developments to Watch in 2021*, Bloomberg Law (Dec. 9, 2020), https://www.wilmerhale.com/en/insights/publications/20201209-top-five-health-care-privacy-security-developments-to-watch-in-2021.

[3] Kirk Nahra, *Healthcare in the National Privacy Law Debate*, ABA Health eSource, vol. 16, no.4, (Dec. 2019), https://www.wilmerhale.com/en/insights/publications/20200114-healthcare-in-the-national-privacy-law-debate.

[4] *See, e.g., OCR Settles Five More Investigations in HIPAA Right of Access Initiative* (Sept. 15, 2020), https://www.hhs.gov/about/news/2020/09/15/ocr-settles-five-more-investigations-in-hipaa-right-of-access-initiative.html#:~:text=OCR%20announced%20this%20initiative%20as,the%20Right%20of%20Access%20Initiative.

[5] This is not at all a bad thing. *See* Kirk Nahra, *The HIPAA Accounting NPRM and the Future of Health Care Privacy*, Bloomberg Law (July 1, 2011), https://news.bloomberglaw.com/health-law-and-business/the-hipaa-accounting-nprm-and-the-future-of-health-care-privacy.