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Health Law Daily Wrap Up, STRATEGIC PERSPECTIVES: Will data privacy shift under Secretary Becerra?, (Apr. 27, 2021)

Health Law Daily Wrap Up

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By Bryant Storm, J.D.

Will the new administration pick up where the Trump Administration left off, or will the Biden Administration go a step further and redefine data privacy enforcement?

Health care data privacy and the enforcement of data privacy rules under the Health Insurance Portability and Accountability Act (HIPAA) have, over the last several years, become priorities for HHS and the Office for Civil Rights (OCR). However, with a new administration, an outstanding Trump Administration-era proposed rule, and changes in HHS leadership, there is some question about how HHS will approach data privacy going forward. This Strategic Perspective considers HHS' current approach to health care data privacy enforcement and evaluates likely policy positions for HHS' new Secretary, Xavier Becerra.

Areas of Focus

Secretary Becerra has been transparent about his policies throughout his confirmation process, shining some light on where the agency may be headed. Breanne M. Rubin, an attorney and Member with the Business Law and Health Care practice groups at Eastman & Smith LTD, expects that Secretary Becerra "will focus on patient privacy initiatives such as improving patients' rights to access and control the disclosure of their health data."

Colleen Brown, a partner in the Privacy and Security group at Sidley Austin LLP, also expects "continuity in the access rights initiative." Brown noted that "patients' access to their identifiable health information is not just a privacy issue, but impacts quality of care, as well as mobility and market choices. It truly enables patients to more fully participate in their health care." Brown also thinks COVID-19 will have an impact on the priorities of HHS. She explained that she expects "there will be sensitivity over the privacy considerations in relation management and recovery from the pandemic."

Rubin also noted that Secretary Becerra is expected to "continue to advance the use of digital health technologies while also focusing on the security and secure transmission of patient data." Brown added that that she expects "security of PHI, and cyber resiliency of the U.S. health care system generally, to be a key issue."

Secretary Becerra as Attorney General

Before his appointment as HHS Secretary, Becerra served as California's Attorney General. His priorities in that role may offer some insight into his likely agenda at HHS. Brown observed that "Secretary Becerra's experiences in California will be critical to tackling some of the most difficult issues." For example, as Attorney General, Becerra played a significant role in the <u>publicity</u> and enforcement of the California Consumer Privacy Act (CCPA)—a piece of <u>legislation</u> designed to grant new data privacy rights to California businesses and consumers. Some of the privileges granted by the legislation include the right to know the kind of personal information being collected, the right to delete information held by businesses, the right to opt-out of the sale of personal information, and the right to non-discrimination in terms of price or service when a consumer exercises a right under the (CCPA). Becerra's support for the legislation went beyond influence in California, including a <u>letter</u> to Congress, asking federal lawmakers to draft federal legislation based upon the California law. Brown believes because of his experience in California, "Secretary Becerra understands the complexities of privacy and technology innovation and will carry that over to work related to the explosion in MedTech and digital health."

Rubin also thinks Secretary Becerra's record in California will have an impact. She noted that "Secretary Becerra's focus on data privacy in California is an indicator of the types of policies he will seek to implement at the federal level. At its core, the California Consumer Protection Act (CCPA) provides consumers the right to



access, correct, and delete personal data that has been collected; minimize data collection, processing, and retention; and know what data is being collected and the reason for collection." Rubin cautioned, however, that although she "think these key concepts will carry over to Secretary Becerra's agenda with respect to health data privacy," there are limits to the degree the CCPA will influence Becerra's position as HHS Secretary. For example, Rubin noted, "as the name implies, the California Consumer Protection Act applies to privacy rights of consumers." Thus, Rubin does "not expect Secretary Becerra to focus on consumer privacy protection at the federal level which is generally handled by the Federal Trade Commission (FTC)." However, she does "expect that Secretary Becerra will make efforts to apply the same types of protections afforded to consumers under the CCPA to patients under HIPAA."

Federal Legislation

When asked whether we can expect federal privacy legislation modeled on the CCPA, Brown told Wolters Kluwer, "while there is great need for, momentum for, and bipartisan interest in federal privacy legislation, there are still persistent sticking points, including preemption and the scope of remedies." She acknowledged that "the Biden Administration is clearly putting further emphasis on privacy and cybersecurity issues" and "expects privacy issues to receive heightened focus from several agencies and commissions." However, she cautioned that privacy legislation may not be a priority. She explained that "federal legislation related to the pandemic, as well as infrastructure legislation, are likely to receive greater political capital at least in the short term." Thus, Brown does not expect big legislative changes for privacy law under the new administration. She expects "any federal data privacy law to leave the HIPAA regime generally intact in recognition of the unique data ecosystem in the U.S. healthcare sector and public health policy needs."

Right of Access

Over the past year, a clear trend has developed in the priorities of the HHS OCR—the Right of Access initiative. Through the <u>initiative</u>, designed to support individuals' right to timely access of their health records at a reasonable cost under the HIPAA Privacy Rule, the agency has already settled its <u>eighteenth investigation</u>. Rubin expects "patients' right of access will remain a top enforcement priority under the Biden Administration." She explained, "patients must have timely access to their health records so they can make informed decisions about their health care." The HHS OCR has published a steady stream of settlements under the initiative across both the Trump and Biden Administrations, suggesting that the agency has no intentions on slowing down enforcement in the area.

Trump Administration

While the Trump and Biden Administrations are likely to find common ground under initiatives like Right of Access, there is some question about how the two administrations will differ in the handling of other health care priorities. Rubin, however, expects that there will not be significant changes in terms of data privacy enforcement. She suggested, "while the Biden Administration will certainly walk back the Trump Administration's efforts to weaken the Affordable Care Act, privacy and security initiatives have historically received bi-partisan support." For example, she noted that "both administrations appear to be aligned on the need to promote electronic data exchange among health care providers in order to improve the coordination and management of patient care." In that same vein, she expects "the Biden Administration will support the initiatives proposed by the Trump Administration as part of its "Regulatory Sprint to Coordinated Care initiative," including the widespread adoption of interoperable EHR and investment in other cybersecurity technology." Rubin thinks "both administrations would agree that data silos continue to fragment care, burden patients and providers, and drive up the cost of health care services."

Proposed Rule

There are some questions which remain outstanding about the future of data privacy enforcement. For example, on December 10, 2020, HHS (at that time still under the control of Secretary Azar and the Trump Administration) issued a notice of proposed rulemaking (NPRM) to modify certain provisions of the HIPAA Privacy Rule. The rule proposed a number of things, including: strengthening individuals' rights to access health information; improving



information sharing for care coordination; facilitating greater family and caregiver involvement; enhancing flexibilities for disclosures in emergencies, such as the opioid and COVID-19 public health emergencies; and reducing administrative burdens on HIPAA covered health care providers and health plans.

However, the rule went <u>unpublished</u> in the Federal Register through the end of the Trump Administration. Although the rule eventually published in the Federal Register on January 21, 2021—President Biden ordered a regulatory freeze on January 20, raising questions about the future of the proposal. Subsequently, on March 9, 2021, HHS <u>announced</u> a 45-day extension on the public comment period for the NPRM, moving the current deadline for public comment from March 22, 2021, to May 6, 2021. In a press release on the extension, Acting OCR Director Robinsue Frohboese illustrated the import of the proposal, noting: "OCR anticipates a high degree of public interest in providing input on the proposals because the HIPAA Privacy Rule affects nearly anyone who interacts with the health care system."

Brown suggested that while she is skeptical about significant legislative changes, agency rulemaking may move the needle. She explained that "modernization through rulemaking is likely faster than a legislative overhaul."

Looking Ahead

It appears that data privacy enforcement will not undergo the kind of policy swing sometimes seen in other areas following a change in administrations. While the Biden Administration has made clear that it will reverse the Trump Administration's course on things like the Affordable Care Act, there has not been much suggestion that the Biden Administration differs in policy on questions of how to enforce current rules regarding patients' access to medical records. However, if the December 2020 proposed rule is any indication, change may not come from a new kind of enforcement, but a change to the rules themselves.

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