
*At What Cost?
An Evaluation of the Health and Human
Services Proposed Rule,
“Proposed Modifications to the HIPAA
Privacy Rule to Support, and Remove Barriers
to, Coordinated Care and Individual
Engagement”*

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As a final act of the Trump administration, the Office for Civil Rights (OCR) within the U.S. Department of Health and Human Services (HHS or the Department) proposed a deregulatory rule entitled, “Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement” (HHS 2021). OCR announced the proposed changes on December 10, 2020, and it was published in the Federal Register on January 21, 2021. While the Biden administration has withdrawn or proposed modifications to other last-minute Trump administration notices, it has taken no action to date on this proposed rulemaking. During the public comment period, which closed on May 6, 2021, I filed a comment on this proposal (Kaufman 2021). This article is based on my publicly submitted evaluation of the Department’s proposed rule.

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INTRODUCTION

The stated goal of the proposed rule is to advance the transformation of the health care system from fee-for-service care to value-based care (a system wherein fees are assessed based on the *outcomes* of the care received rather than the *quantity*) by reducing the regulatory burdens and barriers to coordinated care and care management. The Department's proposal (HHS 2021) aimed to meet these goals by modifying provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule to increase permissible disclosures of protected health information (PHI) in the following ways:

1. Define the terms electronic health record (EHR) and personal health application;
2. Modify individual's access to their own PHI:
 - a. Strengthen individuals' right to inspect their PHI in person;
 - b. Shorten covered entities' response times to 15 days instead of 30 days;
 - c. Clarify format of responding to individuals' requests for their PHI;
 - d. Require that covered entities inform individuals about their rights to obtain or pass along their PHI if just a summary is provided;
 - e. Reduce the identity verification burden;
 - f. Create a way for individuals to share their PHI among covered health care providers;
 - g. Require covered providers and plans to respond to records requests from other covered entities when directed by individuals;
 - h. Limit to EHR the individual right to direct their PHI transmission to a third party
 - i. Specify when electronic PHI must be provided to the individual without charge;
 - j. Amend permissible fee structure for responding to requests to direct records to a third party;
 - k. Require covered entities to post estimated fee schedules;
3. Amend the definition of health care operations to clarify scope of care coordination and case management;
4. Create an exception to the "minimum necessary" standard for individual-level care coordination and case management uses and disclosures;
5. Clarify the scope of covered entities' abilities to disclose PHI to health-related third parties;
6. Expand the permissiveness of PHI disclosure standards by replacing "professional judgment" with a "good faith belief" standard for covered entities;
7. Expand the ability of covered entities to disclose PHI when a harm is "serious or reasonably foreseeable" instead of "serious and imminent";
8. Eliminate the requirement to obtain an individual's written acknowledgement of receipt of a Notice of Privacy Practices;
9. Expressly permit disclosures to communications assistants for persons who are deaf, hard of hearing, deaf-blind, or have a speech disability; and
10. Expand the Armed Forces permission to disclose PHI to all uniformed services.

While many of these proposed modifications do seem likely to lower barriers to coordinated care, such as by allowing patients easier access to and distribution of their own PHI, my evaluation narrowly focuses on several important shortcomings of the proposal:

1. The Department's failure to establish how its proposed changes would address a compelling public need for value-based care;
2. The Department's failure to offer a plan for evaluating ex-post regulatory outcomes;
3. The Department's failure to conduct an adequate cost benefit analysis, instead basing it on narrow and unexplained uncertainty ranges without a threshold analysis for non-quantified costs;
4. The Department's failure to address distributional effects; and
5. The Department's failure to adequately address privacy loss for individual patients when expanding the permissiveness of PHI disclosure standards by replacing "professional judgment" with a "good faith belief" standard.

This article offers recommendations to improve the case for the proposed regulation in light of an administration change and suggests an alternative solution to the proposed replacement of the "professional judgment" standard.

COMPELLING PUBLIC NEED FOR VALUE-BASED CARE

Issued by President Bill Clinton in 1993, Executive Order 12866 states that federal agencies should only promulgate regulations if they are needed to interpret or abide by law or are made necessary by compelling public need (Clinton 1993). President Biden explicitly reaffirmed this order along with President Obama's Executive Order 13563 (Biden 2021a). Although the Department established a need to remove barriers to care coordination, it did not establish a compelling public need for value-based care, nor did it produce evidence to link the proposed modifications with this overarching goal.

The Department made its case for a compelling public need to remove barriers to coordinated care by claiming that the "efficient care coordination and care management" that the HIPAA Privacy Rule is meant to facilitate is lacking with current standards (HHS 2021, 6489). HHS asserted that the existing PHI privacy standards impede care coordination and case management communications between and among individuals and covered entities. This argument was mainly based on responses to a 2018 Request for Information (RFI) that indicated covered entities and individuals currently face too great an administrative burden to share information (HHS 2018). Respondents stated that lowering this burden would improve efficiency and allow for more coordinated health care and case management, which the proposed rule aims to accomplish.

However, the Department did not explain the need to convert the US healthcare system from fee-for-service to value-based care nor how the proposed modifications would serve to reach that goal. HHS did not specifically describe the need for or benefit of value-based care in its proposal or regulatory impact analysis (RIA) beyond stating that former HHS Secretary Alex Azar identified it as among his top priorities (HHS 2021, 6448). While attempting to demonstrate government motivation to address the supposed need, the Department gives significant weight to his words and to other outdated sources such as the agency's 2018 Regulatory Sprint to Coordinated Care initiative, which the Biden administration has not stated will be continued, and two of President Trump's Executive Orders (13771 and 13777) that were revoked one day prior to the posting of the proposed rule (White House 2021).

Indeed, there is little evidence to support the claim that transitioning to value-based care within the United States' current system would be beneficial. In 2014, HHS sponsored a RAND Corporation evaluation of existing healthcare value-based purchasing (VBP) systems and how they could be implemented on a larger scale (Damberg et al. 2014). Their findings indicate that measuring the success of these programs is extremely difficult given the lack of clear, quantifiable goals—which the Department has not explicitly stated. The RAND researchers also found that VBP was not associated with significant improvements in studies with more rigorous methodologies. Another review of VBP programs conducted in 2016 found that the impacts of VBP were marginal despite increasing adoption, furthering doubts that this approach would be beneficial (Chee et al. 2016).

The Department's argument for compelling public need would be stronger if it had identified a clear problem with fee-for-service healthcare and recognized this problem as a failure of government or market function. If data remain inconclusive, the Department could also demonstrate the more bipartisan (and likely longer-lasting) commitment to VBP established by the 2015 Medicare Access and CHIP Reauthorization Act (MACRA), which made clear the role of VBP in Medicare (CMMS, n.d.). Many private insurance companies are also following suit (Chee et al. 2016).

More concerning is the lack of a clear link between the Department's proposed modifications and its overarching goal of a transition to value-based care. The Department's only attempt to explain this link in the proposal comes in the form of a rather vague quote about the value of coordination in care from former HHS Deputy Secretary Eric D. Hargan: "It's about coordination... Regulations are impeding coordination among providers that can provide better, lower cost patient care" (HHS 2021, 6448–49). Though the Department explores existing problems with coordination and access and explains the benefits of improving those through Privacy Rule modifications in the cost-benefit analysis, the path to the stated goal of the program—advancing the transformation to value-based care—is not present in the proposal or RIA.

The general goal of VBP is to increase care coordination, not necessarily for care coordination to enhance VBP. For example, a 2018 brief funded by the Melville Charitable Trust examined ways that VBP could be used to help integrate substance abuse disorder treatment with primary care (Schulman et al. 2018). In 2019, a webinar by the Integrated Care Resource Center looked at the role of VBP for improving coordination of care (ICRC 2019). It is unclear how much benefit VBP provides for the public if coordination can (and must) be first achieved through other means. The onus is on the Department to clarify how the proposed modifications, aimed at improving care coordination and management, would support a transition to value-based care.

EVALUATING EX-POST REGULATORY OUTCOMES

The Biden administration has stated a commitment to evidence-based "policy, program, budget, operational, and management decision-making" (OMB, n.d.). To provide evidence that the modifications have their intended effect after their implementation, the Department should include a provision to evaluate ex-post regulatory outcomes (i.e., outcomes based on actual events rather than predictions). Evidence-based decision-making depends on the completion of these

evaluations, and it is prudent for the Department to consider these during the initial rulemaking process.

If the Department is to determine the ex-post effectiveness of the proposals, clear and measurable goals will need to be laid out first—particularly as they relate to a transition to value-based healthcare. The difficulty that evaluators such as RAND have had in determining the true goals of VBP programs exemplifies the need for clarity on this point. Measurable goals such as improved patient safety and cost reductions could then be used to determine whether the regulation led to the desired outcomes.

As for the shorter-term, non-quantifiable goals of increased coordinated care and care management, decreased regulatory burden, and improved patient access to PHI, HHS should include a provision for stakeholder outreach and health outcome data collection. Because an RFI conducted in 2018 was the main source of data indicating a need for the proposed changes, soliciting feedback from the public and from relevant stakeholders would be beneficial for a cost-effective evaluation of the outcomes of the regulation. The same questions posed in the RFI should be asked again, as appropriate, for the sake of comparability to see whether any improvement can be measured in the responses. Though a similar response bias would occur in both RFIs, this method is likely the most feasible option to solicit public feedback on such a wide-reaching proposal.

COST-BENEFIT ANALYSIS

Under the definition provided by 3(f)(1) of Executive Order 12866, the Office of Management and Budget (OMB) has determined that the proposed rule is economically significant. Therefore, HHS provided an analysis of the costs and benefits associated with the proposed modifications. The Department estimated that the proposed rule would result in net cost savings of \$3.2 billion over the first five years of its implementation, with cost savings benefiting all HIPAA covered entities (including hospitals, physicians, other health care providers, payors, and insurers) at an approximate average net savings of \$1,065 per entity over the same time (HHS 2021).

UNCERTAINTY ANALYSIS

Estimates always involve some degree of uncertainty, and it is critical that this uncertainty is recognized in any RIA (Dudley et al. 2017; OMB 2003). The former administrator of the Office of Information and Regulatory Affairs recommends that RIAs include a sensitivity analysis that examines various scenarios to “see how changes in key assumptions (or combinations of assumptions) influence estimated outcomes” (Dudley et al. 2017). HHS does include an uncertainty analysis to this effect, but only the mid-range figure of \$3.2 billion in savings over the first five years is truly considered in the proposal beyond the small section of the RIA calculating uncertainty (HHS 2021, 6488; HHS, 2021, 6520).

HHS also likely underestimated costs in its calculations, particularly when considering burden hours. For example, the Department calculated a difference of only one hour between the low and high ranges for updating training content (HHS 2021, 6520). This estimate does not seem

to consider the increased caution and time when applying modifications, even on at the highest range, that seem likely given the Department’s admission that “covered entities remain fearful of incurring HIPAA penalties” despite existing outreach efforts (HHS 2021, 6523). The Department did not clearly explain how it estimated these ranges or the baselines for the assumptions made in its uncertainty analysis.

Even as calculated, if costs are at or higher than mid- to high-range and savings are on the low- to mid-range, then the costs are estimated to outweigh the benefits. This alternative, but equally likely, calculation calls into question the true quantifiable cost savings of the proposed modifications. OMB’s guidance to agencies regarding uncertainty analyses suggests that “if the value of net benefits changes from positive to negative (or vice versa) or if the relative ranking of regulatory options changes with alternative plausible assumptions, you should conduct further analysis to determine which of the alternative assumptions is more appropriate” (OMB 2003). Again, the assumptions HHS made are often unclear and unsupported by crucial information from stakeholders—and the assumption that the mid-range figure is the most probable has large impacts on the net benefits calculated by the Department.

HHS must obtain the requested information from affected parties before making assumptions that could have large implications for the net costs and benefits of the proposed changes. HHS should request comments from covered entities and providers about the quantifiable burden hours or costs, quantify the estimated costs and benefits for individuals wherever possible, and consider these costs more significantly in its net calculations.

THRESHOLD ANALYSIS

In addition, OMB instructs agencies to include a threshold analysis to evaluate the significance of non-quantifiable benefits and costs (OMB 2003). Because the non-quantifiable benefits and costs make up the majority of the goals and risks for this proposed rule, the lack of a threshold analysis (in which the value of non-quantifiable benefits or costs that would lead to net-zero benefits is calculated) is notable. Benefits that fall into this category include “improved care coordination and case management, resulting in better health outcomes” and “improved access to PHI,” while non-quantifiable costs include “potential increased complaints to OCR from individuals who did not want their PHI used or disclosed” and “potential to chill some individuals’ willingness to access care” (HHS 2021, 6519).

These non-quantifiable costs and benefits—essentially privacy versus care coordination—are at the heart of the proposed rule and should be more fully considered within the analysis. A threshold analysis should be included in the RIA so that a truer estimation of costs and cost savings can be made.

DISTRIBUTIONAL EFFECTS

OMB (2003) also guides agencies to include a separate description of the distributional effects of their proposed rule. Though HHS acknowledges in a footnote that the modifications would affect certain entities more than others and states that the “tables summarizing estimated costs and cost savings account for these differences,” HHS does not provide a separate section

explaining distributional effects. Because of the sheer number of affected entities, it is important that the Department describe the impact on smaller entities or those that cannot employ individuals to manage the changes that would be required due to the modifications, such as training requirements or decreased timeframes for delivery of PHI. Consequences may also be greater for these entities if they fail to comply with the new modifications.

HHS also does not provide a breakdown of distributional effects for members of the public. People with chronic illnesses requiring the involvement of multiple providers or people with easy access to online portals may benefit more from HHS's proposed modifications to existing practices, while people who have unhealthy or abusive relationships with family members may be more heavily impacted by modifications such as the good faith standard change (described below). Risks may also be greater for those in minority or marginalized groups, as the RAND study noted was sometimes an unintended effect in VBP programs (Damberg et al. 2014), and implicit bias could create disparities in care for certain groups, as will be discussed below.

In a separate section, the Department should provide a detailed description of these distributional effects and request comments. This separation and focus may be especially helpful considering the Biden administration's focus on distributional effects "to ensure that regulatory initiatives appropriately benefit and do not inappropriately burden disadvantaged, vulnerable, or marginalized communities" in his "Modernizing Regulatory Review" memo issued on his first day in office (Biden 2021b).

GOOD FAITH STANDARD

The Department asked for comment on the proposed change of PHI disclosure standard from "professional judgement" to "good faith belief" and to include a presumption of good faith. HHS notes that it believes this modification would improve outcomes, particularly given the opioid crisis, for people who are affected by a serious mental illness (SMI) or other substance use disorder (SUD), because it would facilitate the "increased disclosure of PHI by covered entities to persons who care about the individual and who need to be involved in the individual's care" (HHS 2021, 6501). The basis for this assumption is that increased familial support and involvement for these individuals has been shown to improve health outcomes.

The Department further supports this modification due to comments received that note reluctance on the part of some covered entities to disclose information to those involved with the patient's care, even when such a disclosure would be permitted under the current Privacy Rule (HHS 2021, 6479). HHS indicates that this concern would lessen as a result of the modification because a professional could be "assured that the Department would not second-guess the decision made for the patient's best interests by, for example, requiring the professional to prove that the decision was consistent with his or her professional training" (HHS 2021, 6481).

POSSIBLE CONSEQUENCES

HHS notes that this provision would be especially helpful for patients dealing with SMI or SUD. Because considerable stigma is attached to both disorders, however, making a change in these areas is potentially dangerous to patients. A covered entity cannot truly know whether a

person “care[s] about the individual” and “need[s] to be involved in the individual’s care” (HHS 2021, 6501). These decisions should be left to the patient to make whenever possible due to the real concerns noted by RFI commenters, who cited fears of discrimination, abuse, and retaliation if family members and employers were given access to this PHI information (HHS 2021, 6480). The Department’s support of this modification in spite of serious objections from RFI commenters, particularly from those who identified themselves as patients or privacy advocacy groups, appears to indicate a lack of consideration for the privacy consequences inherent in such a modification.

Knowing that providers may give out sensitive PHI or having previous experience with an unwanted disclosure could, according to the Department’s own analysis, discourage patients from seeking care for sensitive health problems. Healthcare providers who commented on the RFI expressed this concern in particular. According to many, the costs to patient privacy and trust in their providers’ discretion outweigh any benefit from disclosing PHI to individuals who may or may not be focused on the best interest of the patient. Disclosing PHI to a member of the patient’s family, for example, does not guarantee the support of that family member, and that disclosure could have a negative effect on the patient’s recovery if the disclosure were against the patient’s wishes.

By the Department’s own admission, this proposed modification would remove accountability from the process of PHI disclosure by assuming that providers are acting in “good faith.” “Good faith” is a broad and flexible term that is difficult to disprove, whereas “standards of professional judgment” are much more specific and concrete and can be proven using the ethical standards or teaching fundamentals of the provider’s professional training. HHS provides examples of “bad faith” disclosures, such as knowledge that the disclosure would be used to harm the patient, but it would be almost impossible to prove that a provider knew the intent of the person to whom the patient’s information was disclosed, and it would be similarly impossible to prove that a provider knew of the intent to harm.

Under this modification, the provider is effectively free to disclose PHI to any persons without fear of the consequences of violating the Privacy Rule. Though the Department’s goal is to lessen this fear, there should still be some degree of accountability in place so that unnecessary and unwanted disclosures that could harm patients’ well-being do not occur.

HHS should certainly consider the distributional effects of this proposed modification. The proposed deregulation would make it easier for abusive or ill-intentioned family members to gain access to PHI even if the patient does not want this information revealed. This risk would be especially high with a provider who is new to the patient and not yet aware of the patient’s family situation. And unwanted disclosure could widen disparities in recovery between those with support systems and those without.

Implicit bias could also play a large role in a provider’s decision to disclose information. According to the National Academies of Sciences, in cases where providers have substantial discretion, PHI disclosure variability can occur depending on “the health care provider’s professional knowledge, familiarity with the family, personal attitudes, perceptions, and biases” (Schultz and Eden 2016). Although this type of bias no doubt exists with the current professional

judgment standard, it would again be more difficult to hold a provider accountable for a poor disclosure decision under the modified good faith standard.

For example, a provider might be more likely to assume that certain people are predisposed to have the best interest of the patient in mind. The provider or covered entity's own values or religious beliefs could also affect their decision, which could become more likely under a "good faith" standard rather than a "professional judgment" one. These biases could widen disparities in care between groups and increase the vulnerability of certain patients, especially those who live or work among populations with greater stigma toward SMI and SUD or those who are already reluctant to seek care.

ALTERNATIVE SOLUTION

Healthcare professionals who commented on the RFI noted that the current Privacy Rule is already flexible enough to allow for disclosures that address the opioid epidemic, and many believe that issuing further clarifying guidance is preferred to the proposed modification (HHS 2021, 6480). The existing standard for covered entities is appropriate to minimize the risk, both to providers and to individuals, of having PHI disclosed to an individual or entity who should not have access to that material.

The Department should follow the suggestions of RFI commenters and issue further guidance on the meaning of "professional judgment" and the nature of permissible disclosures without changing the standard itself, as this change would open the door to too many "bad faith" or incorrect disclosures as well as a lack of accountability when poor decisions are made by covered entities. This guidance would not expand the permissiveness of the standard—rather, it would help covered entities understand what is already acceptable, addressing commenters' concerns about providers failing to disclose information even when it was permissible.

HHS states that this alternative is not realistic because guidance has been issued in the past to little effect (HHS 2021, 6479). However, the acceptance of a "good faith" standard would also rely on the successful distribution of new guidance. Further guidance will thus be required regardless of whether the language is changed or remains the same, so this alternative does not place any additional burden beyond what is already proposed. If additional guidance does not change providers' behaviors, then it is doubtful that changing the wording would have a substantially greater effect. The main result of changing the standard would likely be a decrease in accountability when retroactively reviewing whether an action was acceptable, not an improvement in providers' decision-making in the moment.

The Department also considered applying a presumption of compliance to provisions rather than changing the standard, but it decided not to because it also wanted to broaden the circumstances in which disclosure can occur to help address the needs of those experiencing opioid use (HHS 2021, 6525). However, as discussed above, this modification could just as easily harm those experiencing SMI or SUD, both hindering their recovery and worsening the public health crisis by chilling patients' desire and ability to seek help.

CONCLUSION AND RECOMMENDATIONS

The Department's proposed rule offered many solutions to break down barriers to coordinated care and case management. Its efforts to increase patients' access to their own PHI and their ability to decide how it is distributed, for example, seem beneficial and pose a relatively low risk to privacy.

However, there are a few instances wherein HHS could improve its rule, and the current administration should take advantage of them:

1. Establish a compelling public need for value-based care and link the proposed modifications to this outcome, clearly articulating the problem with fee-for-service care that this proposed rule aims to solve;
2. Provide for an ex-post regulatory evaluation process to ensure that the regulation meets these goals in practice—laying out clear goals for the modification would enable this review;
3. Improve the cost-benefit analysis by further explaining its uncertainty ranges and including a threshold analysis for the non-quantifiable costs and benefits, which currently are not prominently featured in the cost-benefit analysis despite being central to the goals of the proposed rule;
4. Strongly consider the distributional effects of its proposed rule in a separate section based on engagement with stakeholders; and
5. Reconsider replacing the “professional judgment” standard and instead release further guidance about what the existing standard means for providers' ability to disclose patient information.

Many of these changes will rely on further comments from affected parties, which HHS rightfully requested within the proposed rule. The Department will need to review these comments and carefully consider how they change the RIA and the individual modifications. The recommendations set out here would substantially improve the proposed rule and its adherence to standards set forth by Executive Order 12866 (Clinton 1993) and by OMB Circular A-4 (OMB 2003).

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