

Mr. Roger Severino  
Director of the Office for Civil Rights  
United States Department of Health & Human Services

10 February 2019

Re: Department of Health and Human Services, Office for Civil Rights RIN 0945-AA00  
Request for Information (RFI) on Modifying HIPAA Rules To Improve Coordinated Care  
(Clarified in the RFI as limited to “the Privacy, Security, and Breach Notification Rules”)

submitted via: <http://www.regulations.gov>

Dear Mr. Severino,

Thank you for accepting public comment during this Request for Information (RFI) comment period. The comments below reflect a response to the following verbiage in the RFI:

*OCR seeks public input on ways to modify the HIPAA Rules to remove regulatory obstacles and decrease regulatory burdens in order to facilitate efficient care coordination and/or case management and to promote the transformation to value-based health care, while preserving the privacy and security of PHI. Specifically, OCR seeks information on the provisions of the HIPAA Rules that may present obstacles to, or place unnecessary burdens on, the ability of covered entities and business associates to conduct care coordination and/or case management, or that may inhibit the transformation of the health care system to a value-based health care system. (underlining added for emphasis)*

After the passage of the Health Insurance Portability and Accountability Act (HIPAA) in 1996, I participated in the rulemaking process as a member of the public engaging with the National Committee on Vital and Health Statistics for several rules from the late 1990s through the early 2000s. I was dismayed to see inaccuracies about HIPAA used as a weapon from the very beginning to block the lawful purposes HIPAA intended. In the years since, your Office for Civil Rights (OCR) has progressively improved the available guidance about HIPAA and increasingly taken a public stand against violations with steep penalties. These efforts have led to some improvements, but it is clear from the material reprinted above and the 54 questions being asked in the RFI, that more needs to be done.

There is broad agreement that our healthcare system must continue to move toward one that optimizes value. There is also broad agreement that sharing clinical data can improve care outcomes and reduce health system costs. It is therefore not surprising that OCR is embarking on this effort to determine what OCR might do to facilitate our national efforts during this time of transformation.

As mentioned above, HIPAA has been inappropriately used to block appropriate sharing of individually identifiable Protected Health Information (PHI) for at least 15 years. This is not a new problem, but it now has a new urgency to resolve. OCR has made progress on this challenge, but with the added urgency, it is understandable that OCR may now view an urgent response is also needed. At the same time, OCR does not exist as the lone entity able to impact the current barriers to timely data sharing. The Health and Human Services Office of Inspector General (OIG) has been tasked with the responsibility of enforcing the Information Blocking Rule (IBR) currently being prepared by the Office of the National Coordinator for Health Information Technology (ONC).

In this context, I propose that OCR consider taking the following four actions:

- Seek additional resources to expand enforcement activities and improve response time.
- Provide new guidance in areas where the questions posed in the RFI permit.
- Rescind the data sharing exception for deidentified PHI.
- Coordinate efforts with ONC and OIG to ensure that the IBR will effectively resolve data sharing concerns, and only modify HIPAA in harmonized ways that solve what the IBR does not.

As a health strategist and policy adviser, my contribution to this RFI is focused on key principles that I believe will lead to the best policy outcome with the fewest new unintended consequences, least costs for government implementation and industry compliance, and least confusion. The primary principle is to do the minimum necessary. Each new change brings a risk as well as an intended benefit. As such, if education will suffice, do not issue new guidance or change HIPAA. If enforcement will suffice, do not change HIPAA. If the IBR addresses data blocking adequately, do not change HIPAA.

What follows is a deeper explanation of the reasons for the four recommendations made above.

**1) Seek additional resources to expand enforcement activities and improve response time.**

This is the first and perhaps most important action that OCR should undertake. If OCR had additional resources to respond to requests from Covered Entities (CEs), perhaps even in real time, the misuse of HIPAA to block appropriate sharing of PHI would decline over time.

Imagine that OCR has no increase in resources. If HIPAA or the IBR, or both are implemented to require data sharing and OCR is underfunded, enforcement will be restricted by budget and very little will change. It remains true that behavior does not change if rules are not enforced. Data originating CEs will continue to decline to share PHI "because of HIPAA" in the future unless OCR has the available resources to adjudicate complaints from data receiving CEs trying unsuccessfully to get PHI. OCR needs additional resources whether changes are made to HIPAA or not. In this time of urgency, there may be an understanding and acceptance that those resources must be provided.

If OCR receives the additional resources, then adjudication of complaints by receiving CEs can occur quickly. Originating CEs refusing to share data for erroneous HIPAA claims can be referred directly to OIG for data blocking after adjudication by OCR. After a series of public fines for erroneous use of HIPAA to block data sharing, the data blocking problem will begin to wane. The continued efforts by OCR to adjudicate complaints quickly will keep the data blocking challenge from returning.

**2) Provide new guidance in areas where the questions posed in the RFI permit.**

The RFI suggests that OCR is prepared to provide new guidance rather than modify HIPAA when such guidance will suffice. As I read through the questions being asked, I believe that many of the responses that OCR will receive can be addressed through educational efforts (website updates, webinars, conference presentations, etc.) or new guidance. While the challenges that individuals and health systems face in relation to HIPAA are real, a large part of some challenges appears to be either inadequate knowledge about HIPAA or uncertain interpretation about what HIPAA means. This is another area where additional resources (as described above) would be helpful to spread information widely (through information campaigns) and tackle several areas of guidance simultaneously to expedite positive change.

**3) Rescind the data sharing exception for deidentified PHI.**

Each individual values their identity to a degree that guides their view on personal privacy. Similarly, each individual values charity to a degree that guides how they share their resources. We do not uniformly tell every individual that they must share their resources, and yet privacy is often treated as though it is not a personal resource. HIPAA recognized the value of clinical data for research purposes and created an exception for the release of PHI if the data was deidentified, respecting that not all individuals would want their privacy breached for research. This was allowed at a time when the vast majority of clinical records were on paper, there was little social media, and there were no gargantuan data aggregators like Facebook or Google. This was a reasonable compromise to enable research without harming individual privacy.

Much has changed since then, including that Facebook and Google are working directly with health systems. Not only do they have massive amounts of data about most people on the planet, they have the computing and data resources to specifically identify individuals. This has been an important part of their business model to track people in order to support advertisers and advertising revenue.

The existing HIPAA deidentification exception allows patients to be reidentified, effectively forcing people to share their identity whether they choose to or not. While we have urgency on the data blocking side, we have a similar urgency on stopping the sharing of deidentified data. In order to protect patients, I would strongly urge OCR to convene a task force to determine a) if deidentification is still possible, and if so b) what would need to be changed in or excluded from PHI for sharing to occur safely. Effective as soon as is practical, I urge OCR to rescind the exception in HIPAA permitting sharing of PHI that has been deidentified until the task force can complete its work. In the interim, there is no policy or technical barrier to stop researchers from obtaining patient permission before using PHI. The circumstances around PHI have changed and patients should not be the only ones to pay the cost.

**4) Coordinate efforts with OIG to ensure that the IBR will effectively resolve data sharing concerns, and only modify HIPAA in harmonized ways that address what the IBR does not.**

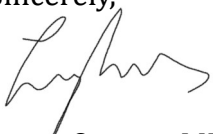
The IBR, while much delayed, has not been finalized. At a minimum, it would be premature to make specific recommendations to change HIPAA. Please minimize conflict in these two different regulations that bring differences of agency perspective and historical focus. OCR should develop a process to work with ONC and OIG to ensure that HIPAA does not need to be changed to require data sharing unless it must do so. As much as reasonably possible and legally permissible, OCR should share responses received from this RFI with ONC and OIG that relate to data sharing and data blocking.

If OCR is able to work with ONC and OIG to harmonize HIPAA and IBR, it will save both enforcers from potential conflicts of jurisdiction and it will ensure that health systems and providers know how to interpret the rules and which agency is responsible. These benefits will save both government agencies and CEs time, money, and other resources.

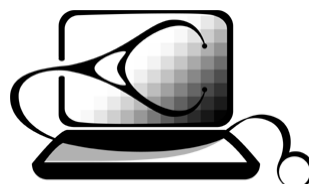
In addition, if OCR becomes responsible for enforcing new HIPAA rules that require sharing, it may negatively impact the ability of OCR to serve the needs of patients. HIPAA became law to support patients move from one health plan to another, sharing their PHI and protecting it. Adding HIPAA rules that are intended to make data sharing easier for CEs is a wholly new perspective and might create internal division within OCR. As such, allowing OIG to be the enforcer that supports CEs will allow OCR to continue to focus on HIPAA as it was intended to support patients. Please consider that the Office of Civil Rights is charged with supporting individual rights, not corporate rights.

Thank you again for the opportunity to share my thoughts and suggestions. I am available to answer any questions that may arise.

Sincerely,



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