



February 12, 2019

Secretary Alex M. Azar, II
Department of Health and Human Services
Office for Civil Rights
Attention: RFI, RIN 0945-AA00
Hubert Humphrey Building, Room 509F
200 Independence Ave., SW
Washington, DC 20201

Re: Request for Information on Modifying HIPAA Rules to Improve Coordinated Care [RIN 0945-AA00]

Dear Secretary Azar:

The Physicians Advocacy Institute (PAI) appreciates the opportunity to provide comments on the Request for Information (RFI) on Modifying HIPAA Rules to Improve Coordinated Care which seeks feedback on potential modifications that can help promote the transition to a system of value-based health care and encourage coordinated care between patients and hospitals, physicians, and payors while still preserving the privacy and security of individuals' protected health information (PHI).

PAI is a not-for-profit organization that was established to advance fair and transparent policies in the health care system to sustain the profession of medicine for the benefit of patients. As part of this mission, PAI seeks to better understand the challenges facing physicians and their patients and to educate policymakers about these challenges. PAI also develops tools to help physicians prepare for and respond to policies and marketplace trends that impact their ability to practice medicine. PAI's Board of Directors is comprised of CEOs and former CEOs from nine state medical associations: California Medical Association, Connecticut State Medical Society, Medical Association of Georgia, Nebraska Medical Association, Medical Society of the State of New York, North Carolina Medical Society, South Carolina Medical Association, Tennessee Medical Association, and Texas Medical Association, and a physician member from Kentucky. As a physician-based organization, PAI is equipped to provide comments and insight into many of the challenges and barriers facing the medical profession.

PAI strongly supports the Department of Health and Human Services' (HHS') efforts to modernize HIPAA and adopt policies that promote removal of regulatory obstacles and reduce regulatory burdens to facilitate care coordination and promote value-base health care transformation. We believe efforts to modernize HIPAA will enhance opportunities to improve the health care system with innovative approaches to

physician collaboration while taking into consideration the law's original goal to protect patients' privacies and rights to how and when their PHI is used and disclosed. Based on our members' extensive expertise, we provide comments and proposals in response to the RFI.

Overview

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), which was subsequently modified by the Health Information and Technology for Economic and Clinical Health (HITECH) Act of 2009, was enacted to protect individuals' medical records and other PHI. The HIPAA Privacy and Security Rules define when PHI can and cannot be shared, under what circumstances and by whom or which entity. The HIPAA Breach Notification Rule requires HIPAA covered entities to issue notifications when there are breaches of unsecured PHI. Collectively, the HIPAA Privacy, Security, and Breach Notification Rules are referred to as HIPAA Rules. While the HIPAA Rules were enacted with the intent to protect individuals' privacies and their rights to how and when their PHI is shared and used, they can create regulatory barriers and burdens to participation in patient-centered, value-based payment arrangements. Even with some exceptions that allow certain disclosures and use of PHI, the law is often considered an obstacle to participation in integrated delivery models, alternative payment models (APMs), and other value-based payment arrangements.

CMS has been encouraging physicians to bear more accountability for the total costs of their patients' care, both through APMs involving two-sided risk and through the Quality Payment Program (QPP). These programs and opportunities help limit the concerns that gave rise to compliance with HIPAA Rules. In order for these efforts to succeed, however, physicians need additional simplification of and clarification and education on the HIPAA Rules to coordinate their patients' care and manage their illnesses and their health effectively and efficiently.

As described in greater detail below, the existing HIPAA Rules inhibit participation in new financing and care delivery arrangements focused on care coordination and improving outcomes. Specifically, physicians can be hesitant to enter into certain types of practice arrangements that require any type of patient information sharing out of fear that they may implicate or violate HIPAA, even if the information may not necessarily be considered PHI. These factors can deter physicians from pursuing innovative and more coordinated care approaches. To address those constraints and promote the transition to and adoption of value-based arrangements, PAI proposes the following key priorities for consideration as HHS proceeds with modifying the HIPAA Rules:

1. Simplify the existing HIPAA Rules and provide greater education on the HIPAA Rules to reduce confusion, complexity, and encourage participation in care coordination models, with consideration and understanding of the costs and burdens for complying with the modified HIPAA Rules.
2. Modify the HIPAA Rules to encourage accurate, helpful, and timely exchange of PHI and other patient information to patients, physicians, and other providers that can impact care decisions and delivery of services.

3. Establish open standards for interoperable electronic transmission of clinical data developed with input from physicians and patients and allow for information exchange across state lines without triggering HIPAA.
4. Streamline standards across federal and state levels to ensure more consistency in definitions (e.g., of mental and behavioral health) and disclosure policies (e.g., those for opioids and other substance abuse disorders).

Additional details on each of these are provided below.

Simplify the HIPAA Rules and Provide Greater Education

Many physicians find the HIPAA Rules complex and difficult to navigate, particularly as they enter into value-based arrangements and APMs that rely on greater health information exchange for greater care coordination. There is confusion about what patient information can be exchanged, even when the information may not necessarily be PHI, and by whom and under what arrangements such information can be exchanged. This can be a barrier especially for smaller practices and solo physicians who are interested in participating in innovative approaches to care delivery but may lack resources or access to expert legal teams who can help them navigate these complex rules and regulations. This can prevent, stall, or delay collaborative approaches and partnerships, which can hinder the provision of high-quality, coordinated care, and patient access to and availability of necessary services.

Furthermore, the potential penalties and sanctions under the HIPAA Rules add to the compliance costs, which can often deter physicians and others from participating in value-based and patient-centered care models. The HIPAA Rules in and of themselves can often serve as “red lights” that deter even initial discussions into exploration of innovative payment arrangements for some physicians and practices.

PAI Recommendations

Taking those factors into account, modernization of the HIPAA Rules should focus on increased simplification and clarity, and decreased complexity and confusion. Additionally, changes should account for compliance costs and burdens. Less stringent standards should be provided that do not penalize unintentional errors that may occur as physicians, practices, and others are looking to experiment and learn through demonstration models and work towards identifying ideal care models. Furthermore, lack of understanding of the HIPAA Rules can be an obstacle to greater coordinated and higher-value care for patients, and so it is essential that greater focus be placed on education and training for different types of covered entities, physicians, and other providers.

However, as HHS considers potential modifications to the HIPAA Rules, we caution HHS to be aware of potential unintended consequences and any modifications. For example, in an effort to simplify and increase care coordination, the resulting increase in the number of PHI requests and other potential modifications could result in significantly increased administrative costs and burdens for providers. HHS should consider the compliance costs and burdens associated with both the existing HIPAA Rules as well as any potential modifications. Compliance costs, as mentioned above, can lead to higher legal fees or

deterrence of participation in value-based payment arrangements. There will also be costs and burdens associated with transitioning from the status quo and ensuring compliance under the new and modified HIPAA Rules. To help decrease these burdens and costs, PAI recommends that HHS understand the current workflow and processes of practices so that the rules and regulations are modified in a complementary manner that is not too prescriptive or burdensome. The HIPAA Rules should be modified with different types of physician practices and specialties in mind to help and allow them to provide more comprehensive, coordinated, and interdisciplinary care to their respective patient populations.

Modify the HIPAA Rules to Improve Information Exchange for Patients and Physicians

As noted above, many innovative care models and APMs require health information exchange for improved care coordination. Often times, these types of requirements can implicate the HIPAA Rules even though they promote holistic, patient-centered care. However, due to HIPAA limitations, patient information often is not shared or exchanged as quickly or efficiently as needed between all those who touch the patient. This can result in physicians and patients making care decisions based on a limited or incomplete data. For example, patient information may not be exchanged between medical and non-medical providers in the same community or state, or between physicians and providers in different states or hospital systems, or between different electronic health record (EHR) systems, etc.

PAI Recommendation

PAI believes that health information exchange needs to be improved at all levels, from the statutory and regulatory levels with modifying the HIPAA Rules, but also at the transactional, functional, and practice levels with the establishment of open standards for health information exchange and data flow across state lines and across EHR systems.

PAI believes that streamlining and establishing open data sharing standards would help reduce physician burden and contribute to the goal of greater coordinated care. However, these efforts should be done with stakeholder input, especially those who must enter the data and who must rely on the data for care delivery, and not in isolation. The delivery of health care services is a cross-sector model and it is important that the different requirements from each of the sectors be incorporated and aligned. PAI urges further clarification and additional guidance on HIPAA privacy requirements. Additional guidance on what information can be exchanged, what information can be used for patient care services as opposed to just monitoring, and who certain exceptions apply to would be extremely valuable and help facilitate greater use of and comfort with using EHRs.

Streamline Standards Across Federal and State Levels

There is often confusion about when and how the law and its waivers and exceptions apply, especially given inconsistent interpretations of permitted arrangements at both federal and state levels. Because of this inconsistency, physicians face burdensome compliance costs to meet sometimes divergent requirements. While the goals of the various federal and state programs and value-based models are often aligned, the variations and differences can often lead to fragmented and unaligned care with different outcomes.

PAI Recommendations

Modernization efforts should also ensure that the guiding laws and regulations at both the federal and state level are updated and keep pace with health care delivery system innovations and advancements. There should be alignment between federal and state self-referral policies to not create additional unnecessary complexities and confusion. Additionally, there should be standardization and more consistency across federal and state level definitions (e.g., of mental and behavioral health) and disclosure policies (e.g., those for opioids and other substance abuse disorders).

Conclusion

Overall, PAI supports the agency's efforts to address the complexities and obstacles currently created by the HIPAA Rules. The state medical associations represented on the PAI Board of Directors welcome the opportunity to work with HHS and its agencies to further modify existing policies and advance new policies. We look forward to exploring ways that allow physicians to provide higher quality, coordinated, integrated, and holistic care to their patients, while decreasing costs and increasing competition and choice in the health care market for patients and physicians alike. We reaffirm our belief that opportunities exist to improve the health care system and believe this should be done by enacting policies and modernizing antiquated regulations, which serve to foster innovative approaches to physician collaboration that will bring the benefits of competition to patients.

If you have any questions, please contact me at rseligson@ncmedsoc.org, or Kelly C. Kenney, PAI's Chief Executive Officer, at k2strategiesllc@gmail.com.

Sincerely,



Robert W. Seligson, MBA, MA
President, Physicians Advocacy Institute