February 12, 2019

Roger Severino
U.S. Department of Health and Human Services
Office of Civil Rights
Hubert H. Humphrey Building
Room 509F
200 Independence Avenue SW
Washington, D.C. 20201

RE: Request for Information: RIN 0945-AA00: Modifying HIPAA Rules to Improve Coordinated Care; (Vol. 83, No. 240, Dec. 14, 2018) Docket No.: HHS-OCR-0945-AA00

Submitted electronically to: www.regulations.gov

Dear Mr. Severino:

On behalf of the Premier healthcare alliance (Premier) serving approximately 4,000 leading hospitals and health systems, hundreds of thousands of clinicians and 165,000 other provider organizations, we appreciate the opportunity to submit comments to the U.S. Department of Health and Human Services (HHS) Office of Civil Rights' (OCR) Request for Information (RFI) on modifying the Health Insurance Portability and Accountability Act of 1996 (HIPAA) rules to improve coordinated care. Premier, a 2006 Malcolm Baldrige National Quality Award recipient, plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Our comments reflect the concerns of our owner hospitals and health systems which, as service providers, have a vested interest in ensuring that HHS reduces provider and clinician administrative and reporting burdens.

Premier supports efforts to encourage value-based healthcare delivery that emphasizes integrated and coordinated care for patients, as well as to make the administrative aspect of healthcare delivery, such as information exchange for treatment, payment or healthcare operations purposes, more efficient. Premier also advocates for meaningful privacy and security rights for the protected health information (PHI) of our patients. We appreciate the opportunity to submit comments on identifying areas for improvement or modernization of the HIPAA Rules and related regulations. The primary goal is to ensure provider access to accurate health information at the point of care to inform healthcare decisions and achieve best patient outcomes. This must be accomplished in a manner that minimizes administrative burdens on providers.

We agree with OCR that it is appropriate to review and assess the HIPAA rules at this time given the rapid evolution of healthcare delivery and the rise of value-based care and advanced payment models. However, we believe that several of the barriers discussed in the RFI would be better addressed through additional and enhanced OCR guidance and education rather than through regulation.

REDUCING BURDEN ON PROVIDERS

Premier appreciates that the OCR seeks public input on identifying ways to modify the HIPAA privacy and security regulations to remove regulatory obstacles and decrease regulatory burdens in order to facilitate efficient care coordination or case management and to promote the transformation to value-based healthcare, while preserving the privacy and security of PHI. We share that vision, and support HHS's efforts to reduce unnecessary regulatory reporting and administrative burdens and costs for providers and clinicians, which can pose obstacles to the delivery of high-quality, safe and efficient care.

Timing requirements. **Premier believes that OCR should retain the current timing requirements for providing individuals with access to their Designated Record Sets, as covered entities need time to accommodate situations where it is difficult and more time consuming to retrieve information requested by the individual.** Shortening the time frame within which covered entities must provide PHI in response to an individual's request, as suggested in the RFI, is unrealistic and would be burdensome on providers. Premier believes that while typical requests can usually be met within the current 30-day requirement, in some situations it is difficult and more time consuming to retrieve information requested by the individual. For example, there are situations where an individual requests medical records from legacy electronic systems that are only accessible through remotely stored physical back-up tapes. In other situations, an individual may not just ask for copies of information within his or her medical record, but also may request any e-mail correspondence among healthcare providers about the patient's case. Covered entities need additional time in order to process these access requests fully and accurately. Shortening the time frame for all requests would be inappropriate and could jeopardize the accurate processing of the requests.

Accounting of disclosures. **Premier commends the OCR for indicating that it will not finalize the 2011 proposed rule concerning the accounting of disclosures requirement and encourages the OCR to consider whether consumer demand and technology support any expansion of the accounting of disclosures requirement**. Premier believes that the 2011 access log proposal was overly burdensome to covered entities and was unworkable with existing technology. Furthermore, electronic health record (EHR) technology has not yet reached a point where it could support the granularity of the access report as proposed. The OCR should be cautious about establishing any new accounting of disclosures requirements that could increase healthcare providers' costs and administrative burdens without providing a true benefit to patients.

If OCR seeks to rely on EHR technology for this purpose or for other aspects of sharing PHI, it should first work with the Office of the National Coordinator for Health IT (ONC) and the Centers for Medicare & Medicaid Services (CMS) to modify the standards and requirements for the Certified EHR Technology (CEHRT) program and related criteria for the Promoting Interoperability programs. In that way, the EHR vendors providing technology to healthcare providers would be required to adopt the necessary data elements, standards and functionality required to provide an accounting of disclosures. Otherwise it is not reasonable to expect providers to have access to EHR technology that includes the capabilities required to meet the accounting of disclosures obligations. EHR vendors should be required to support any accounting of disclosures requirements before requiring providers to comply with new regulations.

Further, it is not clear whether changing CEHRT requirements in this way will ultimately be meaningful. It is our understanding that patients do not frequently request an accounting of disclosures. Therefore, requiring covered entities to implement special, costly technology and to implement related processes in order to accommodate a small number of requests is inconsistent with the goals of the OCR and HHS more broadly to remove regulatory obstacles and decrease regulatory burden in order to facilitate efficient care coordination and case management.

Notice of privacy practices. **Premier supports the removal of the requirement that healthcare providers obtain an acknowledgement from patients of their receipt of the Notice of Privacy Practices upon the patient's first visit and supports efforts by the OCR to make the notice more understandable and meaningful to individuals**.

The OCR acknowledges that some patients may not fully read or understand the contents of the Notice of Privacy Practices provided to them by healthcare providers and health plans, and Premier supports efforts by the OCR to simplify the notice requirement. If the OCR establishes a safe harbor to confirm that the Model Notice of Privacy Practices meets HIPAA's implementation specifications, healthcare providers and health plans will have added flexibility in designing simpler, easier to understand notices.

The HIPAA Model Notice provides an easy-to-understand overview of patients' rights and permitted and required disclosures of PHI, but the format does not encourage differentiation between healthcare providers and health plans. We believe OCR should focus additional efforts to educate individuals on how HIPAA protects their PHI, and the rights granted to individuals under HIPAA.

In addition to the Privacy Rule, the OCR should review potential regulatory burdens in the Security Rule that may be inhibiting the exchange of PHI for care coordination, case management and value-based payment programs. Currently there is significant confusion concerning the requirements for conducting a risk analysis and mitigating identified risks. As a result, covered entities and business associates are reluctant to disclose PHI to entities that are either not subject to the HIPAA Security Rule requirements, or do not appear to be sufficiently aware of them. Additional guidance or safe harbors for compliance with the HIPAA Security Rule would help assure covered entities and their business associates that they are meeting the OCR's expectations from a security perspective.

Interaction with state laws. **In assessing provider burden, the OCR should consider the interaction between HIPAA and non-preempted state and federal laws. Compliance by covered entities is challenging because of the vast array of state laws pertaining to the handling of health information.** Some states require healthcare providers to obtain consent before disclosing any health information, including for treatment, payment and healthcare operations purposes. Other states are less restrictive but require consent before any disclosure of sensitive categories of information, such as mental health, HIV testing results, genetic information, and information about sexually transmitted diseases. States define the information in these sensitive categories differently, making it challenging and cumbersome for covered entities to develop compliance strategies, particularly when disclosing health information across state lines.

In order to manage these complex state and federal legal requirements that are not pre-empted by HIPAA, some healthcare providers and health plans default to always requiring a consent or authorization prior to disclosing PHI – even for treatment, payment and healthcare operations purposes. Privacy laws that are not pre-empted by HIPAA thus create barriers to the seamless sharing of PHI for case management and care coordination, and the implementation of value-based payment models. We believe patients, beneficiaries, their families and caregivers would benefit if HIPAA's framework globally applied to all PHI and pre-empted laws.

Disclosure of PHI between covered entities. **Premier supports efforts to clarify to covered entities that they *may* disclose PHI to other covered entities for treatment, case management and care coordination purposes without first obtaining an authorization from the patient**. We urge OCR to provide more guidance and education on this topic. Patients should not be burdened with unnecessary authorization requests when providers need to share medical records for treatment, payment and healthcare operations. **However, we would not support a policy to *require* such disclosures, which e believe would create privacy risks**. Currently, covered entities can exercise professional judgment in deciding whether a request for disclosure from another covered entity is legitimate and from someone with a legitimate relationship with the patient. If these disclosures were mandatory, covered entities may be in the position of balancing the timing requirement with the requirement to adequately verify the identity of the requestor and the appropriateness of the request.

Further, **we would not support the policy of providing patients an "opt-out" from disclosures between covered entities, as this would result in additional administrative burdens, would likely require new technologies or functions, and the costs would be significant for the covered entities**. Providers would need to present patients a choice to opt-out of sharing PHI, document the opt-out requests in writing or in the healthcare provider's EHR, and check the opt-out status before sharing any PHI for treatment, payment, case management or care coordination purposes. Moreover, some patients may choose the opt-out without truly understanding that this would make it difficult for their

healthcare providers to collaborate in order to provide quality, efficient, coordinated and comprehensive care.

HEALTHCARE CLEARINGHOUSES

Premier does not support the suggestion in the RFI that healthcare clearinghouses be treated as a covered entity. The PHI provided to a healthcare clearinghouse or most other business associates originates with a healthcare provider or a payer, and these entities are responsible for protecting privacy of patient PHI. Individuals do not participate in the selection of clearinghouses or other business associates and must rely on their healthcare providers and health plans to select service providers that will protect their PHI. The business associate agreement requirement allows healthcare providers and health plans to hold healthcare clearinghouses accountable for how they use, disclose and secure patients' and beneficiaries' PHI. **Changes to the status of clearinghouse would not improve patient care, care coordination or care management**. Furthermore, **data integrity, provenance and patient privacy would be jeopardized if OCR revised or eliminated the requirement for healthcare clearinghouses to enter into business associate agreements with covered entities.**

Business associates can play an important role in facilitating provider and patient access to PHI. Premier supports policies that allow individuals to receive access to their PHI directly from business associates that aggregate PHI from multiple providers. However, **Premier believes healthcare clearinghouses should remain bound by their business associate agreements with covered entities**; these agreements have been negotiated over time and with the specific intent of safeguarding patient PHI. **We do not think it is appropriate to afford clearinghouses special rights to PHI in their possession beyond those given to other covered entities or their business associates.**

Premier, does not support efforts to eliminate the requirement for healthcare providers and payers to enter into business associate agreements with clearinghouses. Neither healthcare clearinghouses nor other business associates should be provided rights to use and disclose PHI beyond those given to covered entities. Business associates do not have a direct relationship with patients or beneficiaries and instead receive PHI on behalf of covered entities. While we agree that business associates should be permitted to respond directly to an individual's request for access to their PHI and provide the individual an aggregate view of information maintained by the business associate (when available), existing contract terms between clearinghouses, healthcare providers and health plans should not be reversed or invalidated by changes to the HIPAA Privacy Rule.

The restrictions on healthcare clearinghouses in these contracts have been negotiated by healthcare providers and health plans to protect the PHI of patients and beneficiaries. **Premier does not support providing health care clearinghouses special rights not afforded to other covered entities**, such as granting clearinghouses a waiver from having to notify individuals directly in the event of a breach of unsecured PHI and the ability to charge individuals "fair market value" to respond to access requests.

Premier supports efforts to improve patient access to health information in a manner that makes it easier for providers and patients to aggregate PHI from multiple providers. Section 4006 of the 21st Century Cures Act (Cures) modified the HITECH Act to permit Business Associates to provide electronic access to PHI directly to individuals when the individual requests access to such information directly from the Business Associate. In our view, Congress's goal in including this provision in Cures was to allow Business Associates who maintain PHI electronically on behalf of a Covered Entity – such as an EHR vendor, healthcare clearinghouse or health information exchange – to respond directly to individuals' requests for access to their PHI if they so choose.

Modifications to the HIPAA Privacy Rule consistent with section 4006 of the 21st Century Cures Act should suffice in addressing the concerns raised by healthcare clearinghouses and other Business

Associates about providing PHI to individuals directly while avoiding the downsides of some options considered in the RFI.

OCR should undertake increased and enhanced public outreach and education on existing provisions of the HIPAA Privacy Rule that permit uses and disclosures of PHI for care coordination and management. We urge OCR to expedite and regularly update guidance to further clarify what disclosures and activities are and are not permitted. We also encourage OCR to facilitate greater and improved stakeholder education, especially for patients and their caregivers regarding the provisions of HIPAA that permit uses and disclosures of PHI.

42 CFR PART 2 AND INFORMATION SHARING AMONG PROVIDERS OF PATIENT MEDICAL RECORDS ON SUBSTANCE ABUSE [1] [2] [3] [4]

Premier appreciates OCR's questions about how to address the opioid epidemic. Premier has previously submitted comments about the need to align HIPAA and Part 2. **We again, strongly recommend that Part 2 requirements should be aligned fully with the HIPAA requirements that allow the use and disclosure of patient information for treatment, payment, and health care operations (TPO).** Access to a patient's entire medical record, including addiction records, ensures that certain providers and organizations, when medically necessary, have all the information necessary for safe, effective, high quality treatment and care coordination that addresses all of a patient's health needs. Failure to integrate services and supports can lead to risks and dangers to individual patients, such as contraindicated prescription medicines and problems related to medication adherence. Obtaining multiple consents from a patient is challenging and creates barriers to whole-person, integrated approaches to care that have proven to produce the best outcomes for our patients. [5]

Any OCR efforts about the merits of updating HIPAA privacy and security regulations in order to improve care coordination among patients and healthcare providers must include the regulations of the Substance Abuse and Mental Health Services Administration (SAMHSA) related to confidentiality of substance use disorder information in medical records at 42 CFR Part 2. **Statutory and regulatory reform of the Part 2 regulations is needed to make substance use data more readily available to providers who are already subject to HIPAA patient privacy protection regulations. Although SAMHSA recently released two final rules to modernize Part 2, additional changes to Part 2 are needed to effectively deal with the opioid epidemic.**

The Part 2 regulations impose substantial restrictions and barriers on the sharing of patient health information relating to substance use disorders (SUD) by requiring patient consent for providers to access SUD and addiction records from federally funded substance use treatment programs. Patients are required to give multiple consents, creating a barrier for integration and coordination of healthcare. A lack of access to the full scope of medical information for each patient can result in the inability of providers and organizations to deliver safe, high-quality treatment and care coordination. The barriers presented by Part 2 can result in the failure to integrate services and can lead to potentially dangerous medical situations for patients.[6]

This frustrates and compromises the ability of providers to make informed decisions about patient care; this is especially problematic where those providers are part of ACOs and other value-based healthcare delivery reform models that emphasize integrated care. Timely access to that information is essential for providers to understand the totality of a patient's care needs and to provide safe, effective and coordinated treatment. In the case of substance use disorder, these barriers may also unknowingly endanger a person's recovery and life.

As an example, in the context of the coordinated care programs under Medicare, including ACOs and alternative payment models, CMS currently does not make records on SUD available across all the files furnished to providers. Claims are redacted where a principle diagnosis of SUD applies; claims are also

redacted when a secondary diagnosis of SUD is coded. This inhibits providers from being able to make informed clinical decisions. This policy also skews research by systematically removing certain types of claims for a subset of patients and prohibits researchers from doing analyses on the SUD trends such as the opioid epidemic.

Finally, **the different state and federal laws on privacy of a patient's PHI should be harmonized to the greatest extent possible to increase clarity and reduce burden on providers**. To the extent the Part 2 regulations conflict with the HIPAA Privacy Rule requirements, changes should be made to harmonize requirements using the HIPAA Privacy Rule standards for privacy and security of PHI.

CONCLUSION

In closing, Premier appreciates the opportunity to submit these comments in response to the Request for Information on Modifying HIPAA Rules to Improve Coordinated Care. Premier supports efforts to transform healthcare through value-based integrated care models. This is facilitated when providers and clinicians can communicate patient information expeditiously to make informed healthcare decisions with their patients while protecting patient privacy interests in their medical records. Care coordination is also improved when providers and clinicians dedicate their time to patient care as opposed to meeting burdensome and occasionally duplicative administrative requirements that do not advance care or privacy interests. Premier hopes our comments are helpful as you continue to assess and revise regulatory and operational aspects of the HIPAA Privacy Rules, the 42 CFR Part 2 regulations, and other federal privacy and security programs, and reduce associated clinician and provider burdens.

If you have any questions regarding our comments or need more information, please contact Meryl Bloomrosen, Senior Director, Federal Affairs, at meryl_bloomrosen@premierinc.com or 202.879.8012.

Sincerely,

Blair Childs
Senior vice president, Public Affairs
Premier healthcare alliance

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[1] Journal of American Medical Association: Ten Steps the Federal Government Should Take Now to Reverse the Opioid Addiction Epidemic https://jamanetwork.com/journals/jama/article-abstract/2657452
[2] The New England Journal of Medicine: Protection or Harm? Suppressing Substance-Use Data https://www.nejm.org/doi/full/10.1056/NEJMp1501362
[3] The American Journal of Accountable Care: Treating Behavioral Health Disorders in an Accountable Care Organization https://www.ajmc.com/journals/ajac/2016/2016-vol4-n4/treating-behavioral-health-disorders-in-an-accountable-care-organization
[4] Milliman: Economic Impact of Integrated Medical-Behavioral Healthcare, Implications for Psychiatry http://www.milliman.com/insight/2018/Potential-economic-impact-of-integrated-medical-behavioral-healthcare-Updated-projections-for-2017/
[5] http://www.helpendopioidcrisis.org/wp-content/uploads/2018/09/Partnership-to-Amend-42-CFR-Part-2-7.23.18.pdf
[6] http://www.helpendopioidcrisis.org/wp-content/uploads/2018/11/Stakeholder-Letter-in-Favor-of-H.R.-6082.pdf