American College of Physicians
Leading Internal Medicine, Improving Lives

February 11, 2019

Roger Severino
Director, Office of Civil Rights
U.S. Department of Health and Human Services
Attention: RFI, RIN 045-AA00
Hubert H. Humphrey Building, Room 509F
200 Independence Avenue SW
Washington DC 20201

Re: Request for Information on Modifying HIPAA Rules to Improve Coordinated Care

Dear Mr. Severino:

On behalf of the American College of Physicians (ACP), I am pleased to share our comments regarding the Request for Information on Modifying HIPAA Rules to Improve Coordinated Care. The College is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 154,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

Thank you for the opportunity to provide feedback regarding the HIPAA Privacy and Security Rules. Both of these rules were written substantially before the widespread adoption of EHRs, before the iPhone, Apple Watch, or FitBit existed, and before Meaningful Use and MIPS. While paper still exists, in an integrated electronic environment, the transfer of information between covered entities (CEs) is less burdensome than it was in the paper world, but both paper and EHR requests still require staff and clinician time to process. Over the years, HIPAA, while protecting patient privacy and the security of personal health information (PHI), has resulted in more burden than benefits to the patients and the provision of high quality, efficient care.

ACP recognizes this as an opportunity to improve rules to allow for more seamless treatment, care coordination, and case management of patients while still ensuring the protection of patient information from inappropriate or unauthorized uses and disclosures. However, any regulatory changes to HIPAA could result in a number of unintended consequences. The HIPAA regulations are extremely complex and ingrained in the current system, thus any reform could take years to get right. **ACP strongly urges the Office of Civil Rights (OCR), prior to making any**

regulatory changes to the Privacy or Security Rules, to gather all necessary stakeholders and engage in a comprehensive review of the issues. In the meantime, clarification and guidance could serve to modernize HIPAA. ACP suggests that most, if not all, of this clarification could be accomplished by publishing frequently asked questions (FAQs) that address many of the everyday situations that CEs encounter from patients or other CEs, updating definitions, and providing supplemental guidance and educational outreach. Rulemaking might produce unintended consequences and increase burden when the goal is to reduce administrative burden while still protecting patient privacy.

ACP offers the following insights and general areas of concern for OCR to consider as they gather information regarding updates to HIPAA:

Overall:

- Information Sharing for Treatment and Care Coordination – Requests for PHI are a perceived barrier by patients and many practices. Some medical offices and facilities have their own additional requirements for authorization, even when the requests are for treatment, payment, or operations (TPO) purposes despite the fact that HIPAA rules do not require authorization for TPO purposes. Some individual staff at healthcare organizations may incorrectly interpret that they are not allowed to release some or any information to patients or healthcare organizations for treatment without specific written authorization, which results in unnecessary delays.
    - Clarification is needed regarding releases of PHI for (1) TPO, which is regulated by HIPAA but often misunderstood; and (2) patients, who have a right to their own PHI but not necessarily their families or caregivers. Current rules require that records be provided to patients within 30 days and providing the record is often perceived as permitted, but not required. Another common misperception is that written authorization is required for releases, including those for TPO. The reality is that capabilities of EHRs, staff time required, and organizational understanding of what is required versus what is permitted vary greatly, creating delays in sharing information necessary for treatment, care coordination, and case management. **ACP recommends that the Agency consider less prescriptive time requirements for treatment and care coordination purposes. ACP also recommends greater clarity regarding when specific written authorization is needed. The College would be pleased to work with the agency, as well as other key stakeholders, in order to determine the most appropriate time requirements or time ranges for release of PHI—and when written vs. verbal authorization is appropriate—and recommends that the regulation not be revised until the feedback from these collaborative discussions can be taken into account.**

Release of Information to Clinicians and Health Care Organizations:

- Requirements for paper versus electronic should not differ from each other. Clinician to clinician or clinician to other healthcare provider requests generally do have priority over patient requests in terms of time required to accomplish the exchange of PHI. Requests typically are readily processed within Certified EHR Technology (CEHRT) systems; however there is still no standard format or method to ensure this is the case. Therefore, the same standard should apply to all records that are less than 2 years old. Older or inactive records may take longer to retrieve.
- The current rule does not specify time requirements for release of PHI for TPO purposes – CE to CE (clinician to clinician or clinician to facility), including care coordination and case management. The rule also does not require release of information to non-covered entities (e.g. small providers or social service providers). The amount of effort varies depending on how each EHR system is set up and whether and how paper records are stored, thus a specific time requirement is not practical. Guidance is needed regarding releases to CEs as well as to families and caregivers and other non-covered entities. **It should be clarified that the release of PHI to other clinicians or healthcare provider organizations for TPO (which includes care coordination and case management) purposes should be required within a reasonable time frame.**
- Minimum necessary – Regarding whether OCR should expand the minimum necessary standard such as for case management, care coordination, claims management, and utilization reviews, all of which are related to TPO: yes, minimum necessary standards should be exempted for TPO. **CEs should be allowed to use their professional judgment on what information is needed for whom based on what is best for patients for treatment, care coordination, or case management.**
- Notice of Privacy Practices (NPP) – Many practices have incorporated the NPP into their workflows for new patients and is not undue burden by itself. However, most of the burden is related to a lack of understanding of what is in the NPP and "what does it mean to me?" particularly as many NPPs are several pages long.
    - **Written acknowledgement of receipt of the NPP should not be required** because it is not relevant to patient care and it is an unnecessary workflow. Rather, CEs could post it on web sites, in waiting rooms, and make printed or electronic copies available upon request.
    - CEs already use checklists but it would be helpful if OCR would continue to provide the NPP templates for use by CEs.

Release of Information to Patients, Families, and Caregivers:

- Again, regarding the release of information from clinician to clinician or health care organization above, requirements for paper versus electronic should not differ from each other**.** The multi-stakeholder discussions recommended above should consider whether patient or caregiver requests should have a different timeline than requests

related to clinical care. That said, in cases where practices have been able to establish their EHRs so that there are real-time or near real-time updates occurring, many patient requests can now be easily accommodated through patient portals. However, it is important to note that many patient portals do not offer ways in which users could print the information in a usable format, if at all. Further promotion and adoption of application programming interfaces (APIs) would allow EHR vendors or third-party app developers to create an automated process for PHI requests. To the extent that a patient requests PHI outside of a portal, processing paper or electronic requests requires staff time to designate what information to include to meet the minimum necessary for the request.

- HIPAA calls for making the "designated record set" available to the patient. This adds to the complexity of releasing PHI because much of the data is not stored in the typical EHR but across multiple systems in various entities. Collecting data from these sources is still largely a manual process, whether held in paper or digital formats. Thus, clarification or guidance is needed regarding what may or may not be included in the "designated record set" of any given CE.
- Clarification also is needed regarding access by caregivers and family as allowed by law. For example, state laws abound regarding privacy of minors and other family relationship situations, such as married couples and separated or divorced couples. Current rules require written authorization, which can be burdensome to obtain in a timely manner. For example, a patient may be unable to authorize access to PHI because of mental illness or physical or cognitive incapacity when the individual is not the designated personal representative. **Verbal authorization for permission for specific individuals or CEs to access PHI (as documented in the record) should substitute when written authorization is not practical.**
    - The Advanced Care Planning visit could include some of these elements as part of the discussion.

- Access to PHI - Patients should have the right and the ability to "tag" information that they do *not* want disclosed to others. For example, patients should be able to request that genetic information or certain types of tests be excluded from any releases unless specifically authorized. Patients should also be able to identify specific individuals who are not authorized to access PHI. Instead, patients should be able to find out if specific individuals (e.g., an ex-spouse) have had access or to request specific people be denied access or releases**. ACP recommends that CMS and the ONC encourage vendors to build in the ability to identify specific elements of PHI that can be excluded from disclosure without authorization.**

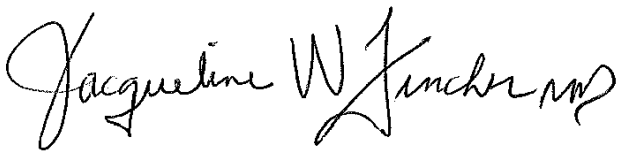
Accounting of Disclosures (AOD):

- Practices receive very few if any requests for an AOD, which are intended to determine whether PHI is being disclosed appropriately as part of receiving coordinated care. Thus the amount of effort to provide reports would far exceed the benefit.

- Most EHRs have an audit trail of individuals who have accessed a record or disclosed PHI for TPO purposes, but a report of non-TPO disclosures is a manual process. While many EHRs are able to identify who has accessed the record, they are not able to provide a reason for such access, nor can they provide a meaningful report. Patients with a long health record with multiple healthcare organizations involved in their care will have many individuals who have accessed their record legitimately. Such reports would be lengthy and could require significant staff time and/or supplies to provide. There is no standard way to provide an AOD, and often it is the staff of CEs (including ancillary staff) whom patients would have no way of identifying, and because very few patients ever request such accountings of disclosure, **ACP recommends that the requirement to provide an AOD be eliminated.**

Thank you again for the opportunity to provide input on this Request for Information on Modifying HIPAA Rules to Improve Coordinated Care. We hope that you will find value in our response. Should you have any questions, please contact Brian Outland, Director of Regulatory Affairs, at boutland@acponline.org.

Sincerely,



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