March 15, 2021

Submitted via regulations.gov

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

Subject: (RIN: 0945-AA00; Docket ID: HHS-OCR-0945-AA00) Proposed Modifications to the HIPAA Privacy Rule to Support, and Remove Barriers to, Coordinated Care and Individual Engagement NPRM; Comments of the American College of Radiology

The American College of Radiology—a professional association representing more than 40,000 diagnostic radiologists, interventional radiologists, nuclear medicine physicians, radiation oncologists, and medical physicists—appreciates the opportunity to comment on the notice of proposed rulemaking (NPRM) from the U.S. Department of Health and Human Services (HHS) Office of Civil Rights (OCR) published in the January 21, 2021 *Federal Register* on "Proposed Modifications to the HIPAA Privacy Rule To Support, and Remove Barriers to, Coordinated Care and Individual Engagement" (RIN: 0945-AA00; Docket ID: HHS-OCR-0945-AA00).

While the ACR concurs with the stated greater goals of "empowering patients with greater access to their health information" and "lifting unnecessary regulations weighing down the health care industry," we are concerned that in including such a complex topic in the Agency's Regulatory Sprint to Coordinated Care, the NPRM has not been afforded the thorough and deliberative development and vetting process appropriate to such an important topic. Rather than addressing each topic in the NPRM that raises concerns, the following comments present some overarching observations, while focusing on two topics we perceive as being particularly problematic.

General Concerns Regarding NPRM Content

As a general comment, ACR has extensive concerns that the current proposal is underdeveloped and lacks sufficient clarity to measurably reduce the regulatory burden felt by health care providers; in fact, the ambiguity of new proposals, on balance, would seem to negate the intended regulatory relief. We note the unusual release of the NPRM via HHS prior to its formal release on the Public Inspection Desk and in the Federal Register. We also note the expansive list of request for comments throughout the

NPRM that are more akin to the scope of questions addressed in a "request for information" than a notice of proposed rulemaking. Numerous statements throughout the NPRM inaccurately presume an understanding of the real-world impact proposed policies would have on medical providers and practices. We urge the new Administration to utilize the comments received in response to this NPRM to reassess and rework the proposed rule and seek additional public input on a more detailed and concise NPRM.

Should HHS decide to proceed to a final rule on this NPRM, ACR strongly urges that the final rule clearly delineate safe harbors to relieve covered entities of the burden of interpreting poorly defined and ambiguous regulatory constructs.

As an example of the ambiguity contributing to health care provider burden, in the **Requests for Access** section of the NPRM the Department proposes to modify the Privacy Rule to expressly prohibit a covered entity from imposing "unreasonable measures" on an individual exercising the right of access that create a barrier to or "unreasonably delay" the individual from obtaining access. While an entity may still require individuals to make requests for access in writing, it would not be permitted to do so in a "way that impedes access". To help define "unreasonable measures" for covered entities, the Department proposes to include, in regulatory text, non-exhaustive specific examples of reasonable and unreasonable measures that some covered entities have imposed or may be likely to impose. While such examples can be helpful with respect to situations clearly addressed by regulatory text, the onus is on covered entities to presume how OCR might interpret "unreasonable measures" for practices not addressed by the regulatory text.

As another example, the discussion on the strengthened "Right to Inspect" provision at 45 CFR 164.524 requires Covered Entities to provide access to records "after arranging a mutually convenient time and place" for the individual to inspect their PHI in a designated record set. As written, the provision is unclear as to the covered entity's obligation to accommodate patient requests to access records outside the practice location and outside normal business hours.

Proposed Effective date and compliance dates

ACR does not believe the 180-day compliance period is generally sufficient for covered entities and business associates to revise existing policies and practices, renegotiate hundreds to thousands of Business Associate Agreements, complete training and begin implementation. The size of provider practices vary greatly. Although some larger entities may have the in-house expertise to come into compliance with new requirements, many practices do not. Moreover, most practices have experienced workload and financial stresses related to COVID-19 and are ill-equipped to take on the financial and resource-intensive efforts required to come into compliance within the proposed timeframe. A compliance period of at least 18 months is recommended.

Proposed Expansion of the "Request" Definition Per Right to Access

The ACR is concerned by the proposed expansion of the "request" definition in the Right to Access to include electronically executed or internet-based methods. This proposal could conceivably classify automated electronic queries from third-party personal health applications of unknown provenance the same as explicit written or verbal requests for PHI from patients. The NPRM also discussed—but did not propose—the similarly problematic concept of automated "broadcast queries" from exchange networks substituting for patient requests.

While the ACR is a staunch advocate for health information exchange and interoperability, we believe provider compliance with the expanded "request" definition in the context of HIPAA Right to Access regulatory paradigm would be overly broad and ambiguous, and thus impractical. Additionally, it would be even more problematic if this expanded definition of a patient request were applied to non-HIPAA regulatory policies that reference HIPAA Right to Access rules, such as the Information Blocking Provision (21st Century Cures Act, Section 4004).

Whenever HHS regulations require a provider's timely response to a patient's request, the request triggering the response requirements must be clear, conspicuous, and specific so that it is easily identifiable and documentable as such by the provider. This approach would better facilitate regulatory compliance by providers as well as enable consistent enforcement by HHS.

To that end, the ACR recommends that patient requests subject to HIPAA Right to Access rules be limited to written or verbal requests directly from the patient. Written requests could be delivered to the provider through patient-authored email or other provider-designated electronic means (for example, a patient's completion of an online PHI request form on the provider's website). Within these written or verbal requests, patients could clearly state their desire, per HIPAA Right to Access and Information Blocking rules, for access to the ePHI via their preferred personal health application (which the provider would then satisfy in the 15-day timeframe, if technically feasible). This recommended approach would enable providers to readily identify patient PHI requests and comply with HIPAA Right to Access requirements, while also enabling patients to specify within the requests their preferred means of PHI access.

Proposed Strengthening of the Right to Inspect

The preamble discussion in the NPRM regarding the strengthened "Right to Inspect" seems to describe it as a separated concept with different timeframes and information access requirements as compared to the Right of Access. As proposed, the Right to Inspect would have an immediate timeframe for in-office inspection of any available PHI, whereas the Right to Access would have a maximum 15-day compliance timeframe for all permissible PHI.

The ACR recommends further clarification around the form and format of how PHI should be made available for immediate, onsite inspection within provider facilities under this strengthened Right to Inspect concept. This clarification should more clearly differentiate the immediate, onsite Right to Inspect from the far broader Right to Access. To that end, we recommend that the required means of the Right to Inspect onsite be explicitly limited to patients' own notetaking and photography of any PHI readily presentable for immediate inspection.

Additionally, providers must not be penalized by HHS/OCR for accidental or intentional oversharing by patients of inspected PHI; for example, if a patient shared on social media a photograph with any visible PHI obtained while the patient was exercising their HIPAA Right to Inspect.

The American College of Radiology welcomes further discussion with HHS about this NPRM and any other issues of shared interest. For questions or outreach, please contact Gloria Romanelli, JD, ACR Senior Director of Legislative and Regulatory Relations and Legal Counsel, Quality and Safety; and,

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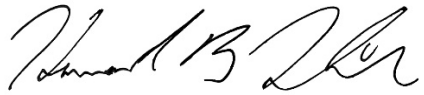
Sincerely,



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