American College of Radiology™

January 2, 2024

Submitted via Regulations.gov

Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building, Mail Stop: 7033A
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Washington, DC 20201

Subject: (RIN 0955–AA05) 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking; Comments of the American College of Radiology

The American College of Radiology (ACR)—a professional association representing over 41,000 diagnostic radiologists, interventional radiologists, nuclear medicine physicians, radiation oncologists, and medical physicists—appreciates the opportunity to provide comments to the U.S. Department of Health and Human Services (HHS) Office of the National Coordinator for Health IT (ONC) and Centers for Medicare and Medicaid Services (CMS) on the November 1, 2023, proposed rule, "21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking" (RIN 0955–AA05; FR Doc. 2023-24068).

The ACR supports appropriate access, exchange, and use of electronic health information (EHI) by providers and patients. The ACR has previously provided input into the legislative and regulatory policies of Sec. 4004 of the 21st Century Cures Act (Pub. L. 114–255, Dec. 13, 2016) and HHS' Information Blocking regulations under 45 CFR §171.

OIG Investigations and Referrals
The statutory definition of "information blocking" by a provider-actor type requires that actor to know the practice is both unreasonable as well as a likely interference, prevention, or materially discouragement of EHI access, exchange, or use. Pursuant to the law, the ACR recommends that HHS leverage enforcement discretion to focus HHS Office of Inspector General (OIG) investigations and application of provider disincentives on clearly intentional, repetitive, and objectively anticompetitive "bad faith" behaviors by major actors. HHS should prioritize the following circumstances:

- **The blocking was perpetrated by a major actor with significant influence on regional provider-to-provider EHI access, exchange, or use**. Large systems and major institutions typically influence EHI access, exchange, and use within a given region or facility more so than individual physicians, physician practices/departments, or smaller provider facilities. Accordingly, OIG and CMS should generally prioritize investigations of, and disincentives for, such systems and institutions rather than physicians, practices, and smaller providers.

- **The blocking was objectively unreasonable/bad faith.** The ONC-defined "exceptions" under 45 CFR §171.200 and §171.300 do not account for all reasonable interferences. For example, a provider may withhold access to output EHI from a medical device/algorithm until a physician can review and verify its accuracy, unknowingly implicating Information Blocking despite having medically appropriate cause for doing so. Therefore, OIG investigations and CMS disincentives should focus on obviously *unreasonable* practices, such as egregiously anticompetitive systematic interferences with provider-to-provider exchange intended to restrict access to, or the capabilities of, competing providers.
- **The blocking caused harm.** Examples include physical harm (e.g., via medical errors), negative financial impacts on patients, and demonstrable negative financial effects on competing providers (e.g., unreasonable connectivity fees).

CMS Proposed Disincentives

The ACR agrees that the "Promoting Interoperability" program for eligible hospitals, and the related performance category in the Merit-based Incentive Payment System (MIPS) for MIPS eligible clinicians, are the most appropriate HHS regulatory mechanisms for applying Information Blocking provider disincentives in accordance with the statute. However, we reiterate that individual physicians generally do not have substantial influence on data-sharing policies and procedures and thus should rarely be a priority target for Information Blocking investigations and disincentives. The ACR also supports CMS' proposal to not affect the status or MIPS scoring of "non-patient facing" and "hospital-based" MIPS eligible clinicians, or other MIPS eligible clinicians automatically reweighted from the "Promoting Interoperability" performance category.

Finally, the ACR recommends that CMS leverage enforcement discretion to "hold harmless" providers—in particularly smaller providers and individual physicians—for first-time violations and those with violations despite acting in good faith. Instead, HHS agencies should provide a warning and follow-up information on how to come into compliance with regulatory requirements. Such flexibility/warnings should also be available to providers with first-time violations resulting in multiple claims about the same instance/practice/policy. The ACR's experience is that most physicians and practices are either unfamiliar with 45 CFR §171 or have an incomplete or inaccurate understanding of the rules and compliance expectations.

The ACR appreciates consideration of these recommendations by CMS, OIG, and ONC. For questions, please contact Gloria Romanelli, JD, ACR Senior Director, Legislative and Regulatory Relations, at gromanelli@acr.org; or Michael Peters, ACR Senior Government Affairs Director, at mpeters@acr.org.

Sincerely,

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