



January 2, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Micky Tripathi, PhD, MPP
National Coordinator for Health Information Technology
Attention: RIN 0955-AA05
Department of Health and Human Services
330 C Street NW #7033A
Washington, DC 20201

Re: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers
That Have Committed Information Blocking Proposed Rule [RIN 0955-AA05]

Dear Administrator Brooks-LaSure and National Coordinator Tripathi,

On behalf of the over 84,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) *21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking* proposed rule published in the *Federal Register* on November 1, 2023. This proposed rule would establish disincentives to be applied to certain health care providers who have committed information blocking as determined by the Department of Health & Human Services (HHS) Office of Inspector General (OIG).

The ACS is a scientific and educational association of surgeons founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Health information technology (health IT) and other digital tools continue to be an important part of the healthcare delivery landscape. Given this, the ACS recognizes that sharing healthcare data without barriers is essential to providing high quality care to patients and is dedicated to ensuring that these data are being leveraged in ways that offer value and support to surgeons' practices and their patients. The ACS appreciates the opportunity to provide feedback on these important issues.

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The ACS has strongly opposed information blocking and sees these activities as a threat to an integrated, collaborative health care system, creating a barrier to the delivery of safe, efficient, and timely patient care. We have long advocated for open-source standards and platform solutions that support high-quality, patient-centric care delivery; informed improvement cycles; and efficient, effective communications across all members of the care team. We recognize that data sharing and the ability to leverage longitudinal information about patients is integral to the modern care model, regardless of where patients receive care or who administers it.

This proposed rule would implement the 21st Century Cures Act (Cures Act) provision that tasks the HHS OIG with referring a health care provider (individual or entity) who has committed information blocking to the appropriate agency to be subject to appropriate disincentives using authorities under applicable federal law. Information blocking is defined in the Cures Act as a practice that, except where required by law or specified by the HHS Secretary pursuant to rulemaking, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI). The Cures Act tasked OIG with investigating information blocking claims against health IT developers of certified health IT or other entities offering certified health IT, health information exchanges (HIEs), and health information networks (HINs), and authorized the imposition of civil money penalties not to exceed \$1 million per violation. When an information blocking claim is made against a healthcare provider, the Cures Act authorizes ONC, the HHS Office for Civil Rights (OCR), and OIG (the agencies) to consult, refer, and coordinate to resolve claims of information blocking.

In May 2020, ONC published a final rule titled *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* (ONC Cures Act Final Rule) that offered additional details on reasonable and necessary activities that would not constitute information blocking and defined the four classes of individuals and entities covered by the statutory information blocking provision (or “actors”). Actors include health care providers, health IT developers of certified health IT, HINs, and HIEs. This proposed rule focuses on disincentives for those who fall under the health care provider class, which can include an individual health care provider, hospital/healthcare system, or Accountable Care Organization (ACO).

Approach to Determination of Information Blocking and Application of Disincentives

In the proposed rule, the agencies discuss the process by which a health care provider that has committed information blocking would be subject to appropriate disincentives for information blocking. It also shares that OIG expects to use the following four priorities when investigating information blocking claims:

1. Resulted in, are causing, or have the potential to cause patient harm;
2. Significantly impacted a provider’s ability to care for patients;
3. Were of long duration; and
4. Caused financial loss to federal health care programs, or other government or private entities.

The agencies also state that OIG may evaluate allegations and prioritize investigations based in part on the volume of claims relating to the same (or similar) practices by the same entity or individual. OIG will conduct an investigation and, should they determine a healthcare provider has committed information blocking, will make a referral of this determination to an appropriate agency. Upon confirmation and referral of the information blocking activities, the healthcare provider would be subject to disincentives.

The ACS appreciates the steps that ONC, CMS, and OIG have taken to facilitate interoperable data exchange through the implementation of these information blocking provisions. While we understand the intent of this proposed rule, many areas of the rule lack clarity, especially how OIG will prioritize and make information blocking determinations with regard to health care providers.

When the Cures Act and associated regulations were first introduced, the intent was to make data more interoperable from electronic health record (EHR) to EHR, EHR to HIE/HIN, health care provider to patient, health care provider to health care provider, etc. The original intent of sharing information about patients focused on exchanges across the points of care, involving clinical staff and the patients directly. With time, the potential to leverage health information for better has begun to transform simple exchange into a nest of information that comes from clinical algorithms in new forms of shared knowledge. These include clinical performance, population health, quality metrics, clinical trial data, and more.

With the growth of the knowledge management environment and the implementation of Qualified Health Information Networks (QHINs) via the Trusted Exchange Framework and Common Agreement (TEFCA), alongside the increased capabilities of EHRs, diverse information systems used in healthcare facilities, and much more, the data sharing intersects have become a complex web of activity. Yet, the priorities stated in the proposed rule are ill-defined and lack actionable information, which leaves much to interpretation. **Given this, we ask that the agencies develop a framework that includes detailed information regarding the determination process, how health care providers would be notified that they are under investigation for information blocking, and the process through which they will investigate information blocking claims. We also recommend that the agencies develop and share clear examples of scenarios where a healthcare provider would be investigated and subject to the proposed disincentives.** Health care providers, developers of certified health IT, HIEs, and others would benefit from resources that outline potential scenarios of information blocking and where disincentives would be applied based on relationships between actors, the actions of each actor, the complaint, etc. This should not be limited to how disincentives are applied but should also provide more comprehensive details about the definition of information blocking and how exceptions are applied. We understand that at this time, ONC does not have the authority to issue binding advisory opinions on whether a specific practice would constitute information blocking. Given this, **we urge the agencies to work with Congress to provide ONC with the authority to issue binding advisory opinions. This would allow ONC to provide actors with assurances that if they received a favorable advisory opinion, they would be protected from HHS penalties and disincentives for information blocking.**

Since these provisions have been in effect without penalty to date, it is important that prior to applying a penalty the agencies take steps to address any ambiguity around who would be subject to an information blocking penalty.

This can also be done by creating a mechanism that can assess and advise health care providers on what actions would be considered information blocking. A tool that allows healthcare providers to ask questions and receive guidance would be extremely helpful in creating transparency around what constitutes information blocking. As such, assisting providers in determining systems that are trustworthy and secure would also remove burden from health care systems. From the ACS perspective, being able to trust the data coming into a system and ensuring trust in the technology that is accessing your data is foundational to successful, secure data sharing. This is recognized in the information blocking exceptions finalized by ONC, but without the proper resources and detailed definitions of information blocking activities, it can be difficult to understand. ONC may consider leveraging platforms or data sharing networks that already have an infrastructure that maintains security boundaries, standards, and governance, such as the QHINs, to use as an example or further advance these efforts.

Appropriate Disincentives for Health Care Providers

The agencies propose disincentives for eligible hospitals, critical access hospitals (CAH), individual providers, ACOs, and ACO participants. The proposed disincentives are summarized below:

- **Medicare Promoting Interoperability (PI) Program for Eligible Hospitals and CAHs**
Under the Medicare PI Program, CMS proposes that an eligible hospital or CAH would not be a meaningful EHR user in an EHR reporting period if OIG refers, during the calendar year of the reporting period, a determination that the eligible hospital or CAH committed information blocking. If an eligible hospital is confirmed to be an information blocker and subject to the disincentive, they would be able to earn the three quarters of the annual market basket increase associated with qualifying as a meaningful EHR user. A CAH subject to this disincentive would have its payment reduced to 100 percent of reasonable costs, from the 101 percent of reasonable costs that it might have otherwise earned, in an applicable year.
- **PI Performance Category of the Medicare Merit-based Incentive Payment System (MIPS)**
CMS proposes that a health care provider that is a MIPS eligible clinician would not be a meaningful EHR user in a performance period if OIG refers, during the calendar year of the reporting period, a determination that the MIPS eligible clinician committed information blocking. CMS also proposes that the determination by OIG that a MIPS eligible clinician committed information blocking would result in the MIPS eligible clinician, if required to report on the PI performance category of MIPS, not earning a score in the performance category (i.e., a zero score), which is typically a quarter of the total final composite performance score. In addition, CMS proposes that if a MIPS eligible clinician participates in MIPS as part of a group and data for the PI performance category is submitted as part of the group or virtual group, the

disincentive would be applied at the group level. This means the proposed disincentive would be applied to the whole group.

- **Medicare Shared Savings Program**

CMS proposes that a health care provider that is an ACO, ACO participant, or ACO provider/supplier, if determined by OIG to have committed information blocking, would be barred from participating in the Shared Savings Program for at least one year.

We echo the previously stated request for CMS to offer more clarity about how the disincentives will be applied to ensure individuals are not receiving duplicative penalties and that the actor who is actually driving the information blocking activities is penalized. The rule states that “the disincentive provision does not limit the number of disincentives that an appropriate agency can impose on a health care provider” and that a “health care provider would be subject to each appropriate disincentive that an agency has established through notice and comment rulemaking and is applicable to the health care provider.” Does this mean that if OIG determines that a physician, who is a MIPS eligible clinician and a participant in a Shared Savings Program ACO, is an information blocker that the physician could potentially be penalized under MIPS and also removed from the ACO for a year? Similarly, how will OIG and CMS determine levels of accountability among associated providers, particularly as the healthcare system undergoes increasing practice consolidation. For example, if the OIG determined that a hospital was an information blocker and CMS imposed a penalty under the Medicare PI Program, could the physicians practicing in or affiliated with that hospital (e.g., an outpatient clinic) also receive a penalty under MIPS? **It is critical that OIG and CMS develop clear criteria, subject to public comments, which outline how they will determine levels of accountability and which disincentive(s) to apply. We also suggest that CMS adopt policies that limit the number of disincentives it would apply to physicians.** Physicians practicing in or associated with a facility regularly encounter barriers to information exchange that are due to factors outside of their direct control. The OIG determination and subsequent CMS disincentive should focus on the true custodians of the data (e.g., the hospital) and/or the health IT platforms that control decisions about the movement of such data; not the physicians who are impacted by the downstream effects of these higher decisions.

Finally, the proposed rule discusses that an appeal process was established for actors subject to the imposition of civil money penalties (i.e., health IT developers of certified health IT, and HINs or HIEs). However, the Cures Act did not provide similar instruction regarding appeals of disincentives for health care providers. Instead, following the application of a disincentive, a health care provider may have the right to appeal under any process specified under the authority that the disincentive has been established (e.g., under the appeals processes established under MIPS or the Medicare Shared Savings Program). **Given the multitude of variables that are at play in an information blocking determination and the complexity of the various programs, the ACS recommends that the agencies develop an appeal process that gives a physician or other health care provider an opportunity to challenge an information blocking determination through OIG, not just the application of disincentive or associated penalty. Along the same lines, we feel that the agencies should offer pathways for education and improvement before taking steps to enforcements around information blocking. As**

such, we suggest that the agencies create a pathway that gives health care providers an opportunity to submit and implement a corrective action plan before receiving a disincentive.

The ACS appreciates the opportunity to provide feedback on this proposed rule and looks forward to continuing dialogue with the agencies on this important issue. If you have any questions about our comments, please contact Jill Sage, Chief of Quality Affairs, at jsage@facs.org.

Sincerely,



Patricia L. Turner, MD, MBA, FACS
Executive Director and CEO