ConnectedHealthInitiative

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, Maryland 21244

Micky Tripathi, PhD
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C Street Southwest, Floor 7
Washington, District of Columbia 20201

RE: Comments of the Connected Health Initiative to the Centers for Medicare & Medicaid Services (CMS) and Office of the National Coordinator for Health Information Technology (ONC) on *21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking* (HHS-ONC-2023-0007; 88 FR 23746)

The Connected Health Initiative (CHI) appreciates the opportunity to provide input on the Centers for Medicare & Medicaid Services (CMS) and Office of the National Coordinator for Health Information Technology (ONC) proposed rule to implement the provision of the 21st Century Cures Act specifying that a health care provider determined by the HHS Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives set forth through notice and comment rulemaking, and establishing for such health care providers a set of appropriate disincentives using authorities under applicable Federal law.[1]

CHI is the leading effort, driven by consensus that spans the healthcare ecosystem, to drive policies that enable the responsible deployment and use of digital health tools throughout the continuum of care to improve individual patient outcomes, reduce costs, augment population health, and streamline the clinician experience. For more information, see www.connectedhi.com.

The effectiveness of the technology tools needed to improve patient outcomes, advance precision medicine and population health, and save costs is dependent in large part on the availability of massive data sets. The free and secure flow of information, and interoperability, are central to improving outcomes for all patients, and CHI is committed to advancing health data interoperability throughout the continuum of care. Building on

[1] 88 FR 74947.

our community's consensus, and our previous detailed comments provided to CMS and ONC on health data flows both in the contexts of illegal information blocking[2] and meaningful use,[3] we provide detailed views on a range of ONC's proposals below.

A truly interoperable healthcare ecosystem must be inclusive and welcoming of data from a range of sources through open application programming interfaces (APIs) that allow the safe and secure introduction of patient-generated health data (PGHD) into electronic health records (EHRs). Data stored in standardized and structured formats (with interoperability facilitated by APIs) supports real-time analytics and alerting capabilities and the use of platforms for data streams from multiple and diverse sources, helping to eliminate information silos, data blocking, and deficient patient engagement.

CHI reiterates its support for ONC's efforts to prevent illegal information blocking and to facilitate greater data access throughout the care continuum, as well as CMS and ONC efforts to resolve ambiguities in its requirements. While ONC's rules have been in place for several years, the lack of enforcement makes it difficult to operationalize ONC information blocking rules as HHS' Office of the Inspector General only finalized its rules implementing the civil monetary penalty (CMP) component of the information blocking rules in mid-2023. Despite these developments, CHI members continue to experience flagrant information blocking practices explicitly addressed by CMS and ONC rules based on either a lack of awareness or willful violation enabled by a lack of enforcement. We urge CMS, ONC, the Office of the Inspector General (OIG), and others to take all steps practicable to operationalize and enforce rules to prevent information blocking as soon as possible while also scaling its enforcement measures to the severity of identified misconduct.

CHI initially offers the following general recommendations to CMS and ONC:

- CMS and ONC should prioritize ongoing education for all within, and impacted by, the information blocking rules, including an HHS-centralized online resource with easy-to-understand explainers using different modalities (written, video, etc.), a "frequently asked questions"-style portal that allows for responses to key/common questions, and clear contacts at both CMS and ONC for stakeholders to reach out to for non-adversarial discussions about compliance. CHI recognizes the important work that ONC has done to provide such a resource already, on which we encourage CMS and ONC to build (along with other key actors including HHS' Office of the Inspector General).
- Across the groups of stakeholders considered within scope of the information blocking rules, we urge CMS, ONC, and others within HHS to ensure that there is an opportunity for corrective action by good-faith actors, particularly those who are resource constrained. Such an approach, coordinated across HHS, will enable those good faith actors to develop corrective action plans in collaboration

[2] https://www.regulations.gov/comment/HHS-ONC-2019-0002-1608.

[3] E.g., https://www.regulations.gov/comment/CMS-2018-0076-13689.

with HHS, which is an optimal means of advancing responsible health data information sharing, and in supporting participation in the Medicare program.

- When disincentives are imposed, CHI requests that underlying background and circumstances—the scale, severity, and frequency of the misconduct and the resources available to the actor facing the imposition of disincentives—be considered. Such an approach will ensure that the penalty fits the crime, and that inappropriately large financial strains are not placed on a party.
- CHI encourages additional rulemakings by CMS and ONC to address the interaction of information blocking rules with other regulatory requirements on technology developers, health information exchanges (HIEs), health information networks (HINs), providers and others in as much detail as possible and in response to questions raised by CHI (and others) in this comment period. In addition to this proposed rule's development on the linkage between information blocking rules and CMS requirements on Medicare providers, other areas of ambiguity continue to present issues.

  For example, some further clarity should be provided with respect to HINs, including (1) the definition of a HIN to address how the extent that a technical infrastructure exists factors into whether an organization is considered an HIN and (2) how participation in an HIN impacts an organization's compliance with the information blocking rules.

  As a further example, there is still some uncertainty about the liabilities in releasing information to patients with respect to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and Federal Trade Commission requirements. While it is expected that HIPAA breaches may occur in a post-info blocking world, additional language is requested to advance the ecosystem's understanding of safeguards, best practices and exceptions may be deemed acceptable. CHI continues to experience confusion among healthcare professionals, clinical and IT staff, administrative and back-office personnel, compliance officers, consultants, attorneys, records release professionals, and technology vendors on implementing ONC's information blocking regulations. This lack of clarity contributes, in some instances, to oversharing information or, conversely, blocking information when entities are paralyzed by confusion. This rule, and a coordinated approach to stakeholder education, can and should do more to address such issues.
- CHI reiterates its request that CMS, ONC, and others across HHS prioritize minimizing administrative and compliance burdens for all subject to the information blocking rules.

Further, CHI offers the following in response to specific proposals in CMS' and ONC's proposed rule:

- <u>HHS Office of the Inspector General Referrals for, and Determinations of, Illegal Information Blocking:</u> While OIG has clear authority to impose, and has

now established its process for imposing, CMPs on certified health IT developers and health information networks (HINs) and health information exchanges (HIEs) that violate information blocking rules, CMS and ONC now propose some further details as to how OIG would serve in its role to refer others it deems to be engaging in information blocking to the appropriate agency to be subject to appropriate disincentives. Per CMS' and ONC's proposal, this referral would first be previewed as a potential referral to either CMS or ONC during OIG's investigation, and then officially transmitted with various details included once that investigation concludes. CMS and ONC also note OIG's stated information blocking priorities for healthcare providers, which are identical to OIG's priorities for health IT developers, HINs, and HIEs, except for the omission of needing actual knowledge in the case of healthcare providers, per statute. What is missing for the healthcare provider community, however, is detail from OIG on its investigative process (which OIG has elaborated on for health IT developers, HINs, and HIEs[4]). It is therefore vital that CMS, ONC, and OIG collaborate to provide details for those subject to this CMS and ONC proposed rule about how investigations will be conducted, how those providers facing an allegation of information blocking can provide evidence and explanations regarding their conduct (including with respect to exceptions to information blocking), how surrounding circumstances such as resource constraints will be considered, and the process by which a provider accused of illegal information blocking can appeal such a determination.

Under the Proposed Rule, providers would have differing appeal rights depending on the program through which the disincentive is imposed. If the disincentive's underlying program does not provide for appeal rights, providers subject to that disincentive would have no appeal rights at all. We are extremely concerned that providers would have different appeal rights that vary arbitrarily based on the disincentive being applied, and that many physicians would have no right to appeal a disincentive. Under the CMP construct, health IT developers and HINs/HIEs all have appeal rights. It is unfair and arbitrary that providers would not have the same or comparable appeal rights under the proposed disincentive construct. Accordingly, we urge CMS, ONC, and OIG to establish a meaningful appeals process that is available to all providers and that addresses both the underlying information blocking determination and the application of the disincentive.

Further, while CHI recognizes that HHS has clarified that Affordable Care Organization (ACO) appeals under Medicare Shared Savings Program (MSSP) rules do not extend to OIG's underlying information blocking determination, no further details are provided in this proposed rule for MSSP ACOs. CHI believes that it is vital that CMS, ONC, and OIG collaborate to

[4] https://oig.hhs.gov/reports-and-publications/featured-topics/information-blocking/process-info-blocking-enforcement-508.pdf.

produce guidance and insights into OIG investigations and the opportunities healthcare providers have to defend themselves before being subjected to disincentives as soon as possible (per the above a supplemental rulemaking on this topic is welcome).

  - Notably, CMS, ONC, and OIG should provide further details on the scope of conduct that will be considered in an investigation. For example, the period of time in the past being considered should be clarified, which CHI recommends be no longer than six (6) years from date of conduct.
  - CHI appreciates and supports CMS' and ONC's proposal to publicly disclose providers, health IT developers, HINs, and HIEs who have been determined to have engaged in illegal information blocking. This resource should build on existing resources created and maintained by ONC.[5] CHI strongly recommends that HHS only include those who have been found to have engaged in illegal information blocking (that is, an investigation has been concluded and appeals within OIG's to-be-determined investigation process for providers subject to this rule have been exhausted, and an informal corrective action process has failed). Whether providers, health IT developers, HINs, or HIEs, no good faith actor should be listed on this public resource when they are in the process of, or have completed, an informal corrective action process that has resolved the issue.

- Critical Access Hospitals: CHI appreciates the proposed use of existing Medicare Promoting Interoperability Program for the meaningful use of certified EHR technology to impose disincentives on eligible hospitals and critical access hospitals (CAHs). CHI agrees that the linkage between CMS rules for CAHs and the priority of improved responsible information flows/avoidance of illegal information blocking is an important linkage that should be made. Based on CMS' and ONC's estimates, the disincentive amount assessed to a CAH could be high, and we therefore urge CMS to develop targeted compliance educational materials and outreach to the CAH community on an ongoing basis.
- Medicare Physician Fee Schedule Clinicians: CMS and ONC propose that a clinician who participates in the Merit-based Incentive Payment System (MIPS) and is required to report on the Promoting Interoperability performance category would receive a zero score for the category if OIG refers a determination that the clinician committed information blocking during the calendar year of the clinician's reporting period. CHI appreciates the creation of a linkage between ONC's information blocking rules and MIPS, but also recognizes that the imposition of CMS' and ONC's proposed disincentive could be devastating to some providers in Medicare who are already operating on slim margins while they serve the country's most vulnerable

[5] https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers.

populations, and that their exclusion from the Medicare program writ large due to good faith information blocking misunderstandings are not in the public interest. Consistent with our above general recommendations, we strongly encourage CMS and ONC (and others in HHS) to prioritize education for this vital community of providers, to broadly consider the circumstances and frequency of misconduct when determining the appropriate disincentive to apply, and to permit corrective action before the imposition of a disincentive.

- Medicare Shared Savings Plan (MSSP): To address MSSP accountable care organizations (ACOs) not yet required to report under the Promoting Interoperability program, it is proposed that an ACO (or part of an ACO) that has committed information blocking would be barred from participating in the MSSP for at least one year if that actor is deemed by OIG to have engaged in illegal information blocking. Because such a disincentive would, practically, have the effect of removing a provider from an ACO, preventing them from joining an ACO, or preventing an ACO's participation in the MSSP, it will be important that CMS and ONC (and others in HHS) to prioritize education for this vital community of providers, to broadly consider the circumstances and frequency of misconduct when determining the appropriate disincentive to apply, and to permit corrective action before the imposition of a disincentive. Further, it is vital that assessments of information blocking are appropriately attributed to the actors within an ACO, not the entire practice group who may have nothing to do with the conduct at issue.
- Developing Further Disincentives for Actors not Within Scope of CMS' and ONC's Proposals: We appreciates CMS and ONC raising the possibility of additional appropriate disincentives that would apply to the healthcare providers excluded from the disincentive framework in this rulemaking. CHI looks forward to further engagement on these possibilities, and notes that any further disincentives should (1) align with CMS' and ONC's clear authority provided by Congress and (2) be based on real-world experiences and data collected from field (for which CHI is happy to again convene listening sessions to share this real-world experience).

CHI appreciates the opportunity to submit its comments to ONC and CMS. We look forward to realizing a technology-enabled care continuum that provides maximum value to patients at the lowest costs.

Sincerely,

Brian Scarpelli
Executive Director

Connected Health Initiative
1401 K St NW (Ste 501)
Washington, DC 20005