OCHIN

A driving force for health equity

Submitted via regulations.gov

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Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Micky Tripathi, PhD, MPP
National Coordinator for Health Information Technology
Department of Health and Human Services
Office of the National Coordinator for Health Information Technology
Mary E. Switzer Building
330 C Street SW, Washington, DC 20201

Re: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking

Dear Administrator Brooks-LaSure and National Coordinator Tripathi,

On behalf of OCHIN, I appreciate the opportunity to provide comments on the *Proposed 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking (Proposed Rule)*. OCHIN is a national nonprofit health information technology innovation and research network that supports nearly 2,000 community health care sites with 25,000 providers in 40 states, reaching more than 5 million patients. OCHIN strongly supports efforts to advance the secure exchange of properly consented patient health information and interoperability to support safer and improved coordinated care for patients and patient access to their medical records. OCHIN also applauds national, uniform data and technical standards for data collection and exchange as these reduce both cost and complexity as well as administrative burdens that fall heaviest on providers in underserved communities and their patients. This proposed rule is an important step forward to advance both though we urge the various U.S. Department of Health & Human Services agencies with jurisdiction to coordinate further with each other as well as states that are imposing variations on federal requirements related to health information exchange.

BACKGROUND

This proposed rule implements the statutorily required referral of a health care provider "to the appropriate agency to be subject to appropriate disincentives" if determined by the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) to have committed information blocking. The Office of the National Coordinator for Health Information Technology (ONC) finalized regulations defining the practice of information blocking, which went into effect in April 2021. The OIG finalized regulations for investigating information blocking claims and imposing civil money penalties

(CMPs) on specific non-provider "actors" determined to have committed information blocking, which went into effect in September 2023. This current proposed rule identifies an enforcement mechanism that applies to a subset of health care providers participating in three Centers for Medicare and Medicaid Services (CMS) programs. Specifically, the proposed rule would apply to providers in:

- the Merit Based Incentive-Payment System (MIPS) (which affects eligible clinicians),
- the Medicare Promoting Interoperability Program (which affects eligible hospitals), and
- the Medicare Shared Savings Program (which affects eligible Accountable Care Organizations (ACOs) and their participants).

We appreciate that ONC and CMS are seeking recommendations on additional disincentives for other providers. Interoperability cannot be achieved without adequate support for modernization of health IT systems, technical assistance, ongoing education on programmatic requirements, and disincentives commensurate with scale, scope, and culpability. We urge OIG, ONC, and CMS to host targeted stakeholder discussions on the regulatory interplay of the 21st Century regulations as well as related state level activity.

RECOMMENDATIONS

There are several issues that we urge CMS and ONC to address in coordination with OIG:

- Additional Guidance and Educational Content. Community-based providers are facing significant resource challenges and limits on clinical and staff able to develop educational content related to prohibitions on information blocking and health information exchange. We strongly encourage ONC and CMS to coordinate with OIG to offer a comprehensive education campaign which includes informational material toolkits, FAQs, and fact patterns and vignettes. These examples should provide specific examples that differentiate information blocking and the application of exceptions that may apply. Specifically, prior to finalizing an enforcement mechanism for providers, HHS should work with stakeholders to more clearly define practices that fall under ONC's definition of information blocking, and to develop a more detailed framework for how OIG would investigate claims and how CMS would apply disincentives.

- Addressing State Level Data Segmentation Requirements. Specific guidance is needed on state level activities requiring data segmentation for sensitive health information (for example, related to reproductive health and gender affirming care). To ensure that non-compliance is accurately identified, providers need clarity on what steps they must to take to avoid inadvertently violating information blocking prohibitions while adhering in some states to requirements to segment sensitive data (meaning block the exchange of such information). Because the technical capabilities do not currently exist—and would require EHR developer code level modifications—a broad category of sensitive patient health information cannot be exchanged in states such as California or Maryland, for example. This can include medication lists and medical history in addition to diagnosis and procedure codes.

- Structural Inequity in Design of the Penalties. The proposed disincentives disparately impact less resourced providers in underserved communities that must allocate relatively a higher percentage of resources to achieve compliance than better funded health systems and providers that may engage in information blocking with a relatively smaller consequence. By considering

the relative impact of alternative disincentives, CMS and ONC could create a penalty system that holds all actors accountable regardless of their size. In short, the proposed rule does not have a provision for scaling penalties based on the consequences and harm caused from information blocking, the frequency of violations, and degree of severity. This is a form of structural inequity.

- Corrective Action Opportunity. For providers in underserved communities, OIG, ONC, and CMS should consider providing a warning period for providers to introduce and execute a corrective plan of action prior to the finding of information blocking and implementation of penalties.

- Identification of Factors to Establish Level of Accountability. OIG and CMS should more clearly delineate how they would determine the level of accountability among associated providers and should limit practitioner or practice level accountability when information blocking is conducted by larger, affiliated institutions.

- Appeals Process Prior to Imposition of CMPs. Providers should have the ability to appeal information blocking determinations prior to OIG referring such determinations to CMS for imposition of an appropriate disincentive. Providers should have an opportunity to appeal OIG determinations directly through OIG, prior to CMS involvement. This is particularly important of providers with minimal resources in underserved communities.

Please contact me at stollj@ochin.org if we can provide any additional information or we could be of further assistance.

Sincerely,

Jennifer Stoll
Executive Vice President
External Affairs