January 2, 2024

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Micky Tripathi
National Coordinator
Office of the National Coordinator for
Health Information Technology
Mary E. Switzer Building
330 C. Street, SW, 7th Floor
Washington, DC 20201

SUBJECT: RIN 0955–AA05, 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking, Proposed Rule, Federal Register (Vol 88, No 210), November 1, 2023

Dear Administrator Brooks-LaSure and National Coordinator Tripathi:

On behalf of our more than 400 hospitals and health systems, the California Hospital Association (CHA) appreciates the opportunity to provide comments on the proposed rule that would establish disincentives for health care providers that have committed information blocking as required by the 21st Century Cures Act.

California hospitals are committed to sharing health information that leads to better informed patients and promotes higher value, efficient, coordinated care. Hospitals and health systems have worked diligently since the information blocking final rule went into effect to improve their internal processes and technical capabilities so that health information can be easily shared among providers to improve care coordination, and with patients to fully engage them in their care and improve better health outcomes. In California, hospitals and health systems, clinicians, health plans, and health information exchange (HIE) networks are working together to support the exchange of health information across the state, under the state's Data Exchange Framework (DxF)[1].

[1] https://dxf.chhs.ca.gov/

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While CHA's members are committed to sharing health information, there are significant concerns about the impact of the penalties and their application only to certain health care providers. There also remains significant uncertainty regarding the information blocking regulations and the U.S. Office of Inspector General (OIG)'s investigation approach, and a period of enforcement discretion is needed to support educational efforts based on real-world scenarios that the OIG uncover in their investigations. CHA's more detailed comments are offered below.

Proposed Disincentives Are Arbitrary and Excessive

As required by the 21st Century Cures Act, the California Health and Human Services Agency OIG has the authority to investigate claims of information blocking. If a health information technology developer, exchange, or network is found to engage in information blocking, the OIG can impose civil monetary penalties (CMP) of up to $1 million per violation. Health care providers are not subject to CMPs; rather, the OIG is directed to refer the violation to "the appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law." In this proposed rule, the Office of the National Coordinator for Health Information Technology (ONC) proposes to establish the Centers for Medicare & Medicaid Services (CMS) as the appropriate agency, and the proposed disincentives would apply to health care providers that participate in the following federal programs:

- The Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs)
- The Promoting Interoperability Performance Category of the Medicare Merit-Based Incentive Payment System (MIPS)
- The Medicare Shared Savings Program (MSSP)

Under the proposed rule, hospitals would not be a meaningful electronic health record (EHR) user under the Promoting Interoperability Program in a calendar year if the OIG refers a determination that the eligible hospital or CAH committed information blocking during the calendar year of an EHR reporting period. For an eligible hospital, this would reduce the hospital's payment by three quarters of the applicable percentage increase in the market basket update or rate-of-increase for hospitals. For a CAH, this would result in a payment to the CAH of 100% of its reasonable costs rather than 101% of reasonable costs. **This proposed disincentive represents a significant financial impact that could far exceed the civil monetary penalties imposed by the other regulated actors without any regard to the relative severity of the violations.**

As noted in the proposed rule, the actual monetary impact resulting from the application of the proposed disincentive may vary across health care providers subject to the disincentive, depending on an individual hospital's market basket increase and payer mix. Medicare only covers 75% of the cost to provide care to Medicare beneficiaries. Therefore, hospitals that care for larger Medicare populations will be the most harmed by a disincentive structured in the manner proposed. While the proposed rule estimates a median disincentive amount of $394,353, and a 95% range of $30,406 to $2,430,766 across eligible hospitals, CHA is concerned that ONC and CMS have underestimated the potential negative impacts associated with the proposed approach for applying disincentives. **CHA urges CMS and ONC to provide detailed information about the impact analysis that was provided in the proposed rule.**

CHA analyzed annual payment updates for California hospitals from federal fiscal years 2020-2024 to estimate the impact of the proposed disincentive. On average, CHA estimates a median impact of

$555,073 for California hospitals, and a maximum average impact to a large academic medical center of $10,237,182. Because the impact would vary depending on the market-basket update and other factors in the payment year which the disincentive is applied, this same hospital could see impacts ranging from approximately $7 million to $13 million with no regard to the relative severity of a violation, and significantly higher than the $1 million maximum CMP for other regulated actors. CHA also found that if applied in federal fiscal year 2024, the maximum impact to a CAH in California would be $423,000. **The proposed disincentives could be devastating to hospitals, especially for safety net hospitals and CAHs who serve some of the most vulnerable patients, threatening the ability of hospitals to continue offering a full range of services, and even their ability to remain open for their communities.**

It is also worrying that health care providers could be subject to disincentives under more than one program for a violation of the information blocking provision. For example, a hospital that is a participant in a MSSP accountable care organization could be penalized with a reduction to the annual payment update under the Promoting Interoperability Program and lose the ability to participate in the MSSP for at least one year. **CHA strongly opposes these duplicative penalties.**

CHA is concerned that these significant penalties are only proposed for a subset of health care providers that are subject to the information blocking regulations. The information blocking regulations define the term "health care provider" broadly, but the proposed disincentives would only apply to hospitals and CAHs, clinicians participating in MIPS, or entities participating in the MSSP, leaving out a significant number of providers who are subject by law to the requirements, including laboratories, pharmacies, and post-acute care providers. This would imply that information blocking violations conducted by certain health care providers are less harmful than others, but the statute clearly does not contemplate such a notion. **CHA urges the agencies to reconsider this proposal and establish disincentives that do not arbitrarily apply only to subsets of health care providers as defined by law.**

Additional Clarity on Information Blocking Regulations Is Needed

CHA agrees that information blocking can be harmful to patients and the overall health care system, and hospitals are working to improve the exchange of health information daily. However, as acknowledged by the OIG in its final rule establishing CMPs, information blocking is a newly regulated conduct. Hospitals and health systems continue to lack clarity on what is and what is not considered information blocking. **CHA urges the ONC to provide more guidance – including illustrative examples of actions that it would consider information blocking versus those that are not – prior to referring providers for financial disincentives.**

The proposed rule references the OIG's anticipated four priorities for investigating claims of information blocking by health care providers, as cases that: (i) resulted in, are causing, or have the potential to cause patient harm; (ii) significantly impacted a provider's ability to care for patients; (iii) were of long duration; and (iv) caused financial loss to federal health care programs, or other government or private entities. As the OIG begins to investigate claims of information blocking, it should provide additional transparency on the decision-making process to pursue certain claims over others.

CHA appreciates that the OIG also emphasizes that the 21st Century Cures Act defined information blocking by providers to include a standard of intent. That is, the law defines information blocking committed by a provider differently than information blocking conducted by a health information

technology developer, exchange, or network, in that a health care provider "knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information," while the other regulated actor "knows, or should know," that their actions constituted information blocking. However, while the distinction is clear, what is not clear is how the OIG defines intent and actual knowledge versus actions that were a mistake or the result of a misunderstanding of the information blocking exceptions. **The OIG and the ONC should provide additional clarification on how intent will be determined in the course of information blocking investigations prior to finalizing disincentives for providers with such significant potential financial impacts.**

There also remains significant confusion about the enforcement timeline for OIG investigations. In its final rule establishing CMPs for developers, exchanges, and networks, the OIG established Sept. 1, 2023, as the date for which enforcement of the information blocking penalties would begin for these actors. While the OIG has stated that conduct occurring prior to Sept. 1, 2023, will not be subject to enforcement, this enforcement discretion does not preclude government agencies from assessing conduct prior to the information blocking enforcement date under other regulatory frameworks. However, the proposed rule is silent on when the OIG intends to begin investigating conduct of health care providers for information blocking but does note that more than 800 claims of information blocking had been received through the ONC Report Information Blocking Portal between April 5, 2021, and Sept. 30, 2023. It is unclear if OIG intends to investigate these existing claims for referral under the proposed provider disincentives. **CHA urges the agencies to establish a date for when the OIG will begin to investigate claims of information blocking by health care providers subject to appropriate disincentives that is at least 60 days after the effective date of the final rule.**

A Period of Enforcement Discretion and Additional Education is Needed

The information blocking regulations represent an important transformation in the framework under which health care providers, health information technology developers, vendors, exchanges, and networks capture and exchange highly sensitive health information. Hospitals and other health care providers remain committed to the exchange of health information, but there remains significant confusion about the requirements, including questions related to the broad definition of electronic health information and the application of information blocking exceptions.

CHA appreciates that on Dec. 13, 2023, ONC finalized additional changes to the information blocking regulations in its health data, technology, and interoperability (HTI-1) proposed rule. Many of these policies were responsive to stakeholder concerns, including a narrowed definition of "health IT developer of certified health IT," to better clarify that certain practices of hospitals and health systems will not inadvertently classify them as developers who would be subject to civil monetary policies rather than appropriate disincentives. CHA also appreciates that the ONC finalized several new or refined exceptions to what is considered information blocking under the infeasibility and manner exceptions, and the newly created exception for actors and requestors capable of exchange via the trusted exchange framework and common agreement (TEFCA). While the final rule provides some additional information on what is not considered information blocking, hospitals will need time to review and educate staff on the newly finalized exceptions.

Given the changing regulations and field uncertainty that remains, CHA asks that the ONC and the OIG conduct more substantial and in-depth outreach and education efforts prior to referring providers for financial disincentives. The regulations apply to a vast array of actors (the definition of health care provider alone is expansive) and there are differing needs for understanding expectations as they exchange electronic health information among themselves, patients, and other parties in compliance with the information blocking rule. Health care providers, in particular, receive a variety of requests for health information, and grapple with a complex regulatory environment where hospitals must balance the flow of patient data with patient privacy rights. **CHA believes that a significant period of enforcement discretion is required to ensure adequate time for all regulated actors to adapt to and understand what is required for compliance with this new framework.**

During an initial period of enforcement discretion, the OIG and ONC should offer providers who are part of the early cohort of investigations an opportunity for corrective action. The agencies could then take the lessons learned during this period to conduct expanded education and training efforts based on these real-world examples, bringing additional clarity to the field prior to the application of financial disincentives. **Following a period of enforcement discretion, CHA urges the OIG to continue to emphasize corrective action over financial disincentives, with the latter being reserved only for actors displaying a pattern of noncompliance or disregard of the information blocking rule that results in patient harm.**

CHA appreciates the opportunity to comment on the proposed rule. If you have any questions, please contact me at mhoward@calhospital.org or (202) 488-3742.

Sincerely,

/s/
Megan Howard
Vice President, Federal Policy