AMERICA'S ESSENTIAL HOSPITALS

December 22, 2023

Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Ref: RIN 0955–AA05: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Proposed Rule

Dear Secretary Becerra:

Thank you for the opportunity to comment on the above-captioned proposed rule. America's Essential Hospitals appreciates the Department of Health and Human Services' (HHS') work to promote interoperability and facilitate the access, exchange, and use of electronic health information. Essential hospitals are committed to using health information technology (IT) to improve the lives of their patients, including through population health efforts, telehealth to reach patients who face transportation barriers, and electronic health record (EHR) data to reduce unnecessary readmissions and improve outcomes. Despite progress on this front, burdensome regulatory requirements drain staff time and resources that hospitals could better spend on delivering high-quality, patient-centered care. HHS proposes financial disincentives that would apply to health care providers engaging in information blocking. While we support the underlying goal of encouraging information exchange, we strongly oppose the steep penalties. These penalties would damage essential hospitals and undermine HHS goals by decreasing the resources available to hospitals to make appropriate investments in their IT infrastructure they can leverage to share information.

America's Essential Hospitals is the leading association and champion for hospitals dedicated to equitable, high-quality care for all, including those who face social and financial barriers to care. Our more than 300 member hospitals fill a vital role in their communities. They provide a disproportionate share of the nation's uncompensated care (UC), providing an aggregate $9 billion in UC and, on average, five times as much UC as the average hospital.[1] This disproportionate UC burden reflects their heavily public and uninsured payer mix—three-quarters of their patients are uninsured or covered by Medicare or Medicaid.[2] Essential hospitals provide state-of-the-art, patient-centered care while operating on narrow margins significantly lower than the rest of acute-care hospitals: –8.6 in aggregate compared with –1.4

[1] Ramiah K, Taylor, J, et al. Essential Data: *Our Hospitals, Our Patients—Results of America's Essential Hospitals 2021 Annual Member Characteristics Survey*. America's Essential Hospitals. October 2023. https://essentialdata.info. Accessed December 5, 2023.
[2] Ibid.

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percent for all hospitals nationwide.[3] These narrow operating margins result in minimal reserves and low cash on hand, circumstances exacerbated by financial pressures related to COVID-19, rising workforce costs and shortages, rising supply costs, and supply shortages.

Given this backdrop of financial and operational challenges, we urge the agency to implement information blocking provisions in a way that provides maximum transparency to health care providers being investigated and crafts disincentives proportional to the violation in question. This will ensure stability for hospitals serving marginalized patients and promoting health equity. As we explain in our comments, the provisions outlined in the rule would subject providers to harsh penalties while not affording them with an adequate opportunity to respond to allegations of information blocking. HHS must reevaluate its proposals, engage in provider education, and develop adequate procedural safeguards before finalizing information blocking disincentives. HHS should not finalize any proposals in the rule until it has worked with stakeholders to better understand how the rule would impact providers. HHS can use this additional time to incorporate in a new proposed rule the recommendations we outline below and the input it has received from stakeholders.

1. HHS should not finalize its proposed disincentives for health care providers who are found liable for information blocking because these disincentives would be premature, excessive, and not proportional to the underlying violations.

HHS should not finalize its proposed disincentives for health care providers. While essential hospitals are firmly onboard with the need to seamlessly share information across the health care system, the proposed disincentives are excessively punitive and come at a time when health care providers continue to be in a precarious financial position. Furthermore, as we outline below, these disincentives are premature, because there is still significant confusion about the types of conduct that would constitute information blocking.

The 21st Century Cures Act codified a definition of information blocking that applied to health IT developers, exchanges, or networks; and a separate definition that applies to health care providers. The Cures Act also tasked the Office of the National Coordinator for Health IT (ONC) with issuing regulations defining information blocking, while authorizing the HHS Office of Inspector General (OIG) to investigate and enforce claims of information blocking. The Cures Act instructs OIG to impose civil monetary penalties (CMPs) of up to $1 million per violation on health IT developers, exchanges, and networks, but states that for health care providers, the OIG is to refer the provider to the "appropriate agency to be subject to appropriate disincentives using authorities under applicable Federal law, as the Secretary sets forth through notice and comment rulemaking."[4] Earlier this year, the OIG finalized a rule describing the investigation, appeals, and penalty process for health IT developers, exchanges, and networks.

In this proposed rule, HHS now puts forth disincentives for information blocking that would apply to health care providers through various federal programs. Specifically:

- Eligible hospitals participating in the Medicare Promoting Interoperability (PI) program would not be a meaningful user of electronic health record (EHR) technology, resulting in a three-quarters reduction to the annual market basket update. The reduced payment would apply in the payment adjustment year two years after the

[3] Ibid.
[4] 21st Century Cures Act, Section 3022(b)(2)(B).

calendar year in which OIG refers the eligible hospital to the Centers for Medicare & Medicaid Services (CMS), which oversees the PI Program.

- Critical access hospitals (CAHs) participating in the PI program would not be a meaningful user and would be paid at 100 percent of reasonable costs instead of 101 percent of reasonable costs, in the same year in which OIG refers the CAH to CMS.
- Eligible clinicians participating in the Merit-based Incentive Payment System (MIPS) would not be a meaningful user, resulting in a zero score for the MIPS PI performance category in the performance year in which the OIG makes the referral to CMS. Any penalty would be imposed two years later, in the respective payment adjustment year.
- Medicare Shared Savings Program (MSSP) accountable care organizations (ACOs), ACO participants, and ACO providers/suppliers would be barred from participating in the MSSP in the performance year following the year in which OIG refers the ACO to CMS for an information blocking violation.

For essential hospitals, reducing the annual market basket payment update by three-quarters would be extremely harmful. Every year, CMS increases base Medicare payment rates to hospitals under the Inpatient Prospective Payment System (IPPS) by the market basket update, which is intended to measure the year-over-year price increase of goods and services hospitals purchase. Penalizing a hospital with a three-quarters reduction to its market basket update would eliminate most of its annual payment update and result in lower payments across the board for Medicare IPPS services. In the proposed rule, HHS provides an example of a year in which the market basket update is 3.2 percent. In this case, a hospital subject to a disincentive would receive only a 0.8 percent market basket increase. Depending on the hospital's Medicare inpatient volume and case mix, HHS estimates the reduction could be a median of $394,353 and nearly $2.5 million for a hospital at the 97.5 percentile.

The magnitude of the penalties would be even greater for essential hospitals, because they tend to be larger hospitals with high numbers of Medicare discharges and complex cases. On average, essential hospitals have more than 3,300 Medicare discharges each year, which is 63 percent higher than the average IPPS hospital. Essential hospitals' average Medicare case-mix index is 7 percent higher than other IPPS hospitals, representing the increased severity and complexity of essential hospitals' patients.[5] The higher volume of Medicare discharges and higher case complexity means an essential hospital subject to a disincentive would have the reduced market basket percentage apply to a larger number of complex cases for these hospitals, translating into larger payment reductions. This would be unsustainable for these hospitals, which already operate on deeply negative margins.

As America's Essential Hospitals has expressed in comment letters on the 2024 hospital payment regulations, the Medicare market basket updates in recent years have failed to keep pace with hospital workforce and input costs.[6] Hospitals continue to incur soaring costs as they recover from the COVID-19 pandemic, feel the effects of inflation, experience unprecedented increases in labor costs, and encounter supply chain issues and shortages. One analysis found

[5] Analysis of FY 2024 IPPS Final Rule Impact File data.
[6] See Siegel B, Letter to Chiquita Brooks-LaSure on the FY 2024 IPPS Proposed Rule. June 9, 2023. https://essentialhospitals.org/wp-content/uploads/2023/06/FINAL-AEH-FY-2024-IPPS-Comment-Letter-6-9-23.pdf. Siegel B, Letter to Chiquita Brooks-LaSure on the CY 2024 OPPS Proposed Rule. September 11, 2023. https://essentialhospitals.org/wp-content/uploads/2023/09/AEH-CY-2024-OPPS-Proposed-Rule-Comment-Letter-9-11-23-for-archive.pdf.

hospitals' per-discharge labor costs increased 37 percent from 2019 to 2022.[7] The pressure on hospital input costs has continued into 2023, with one analysis of hospital finances citing increased material costs and increased labor costs attributable to persistent workforce shortages. This analysis shows a 5 percent increase in hospital expenses in October 2023 compared with October 2022 and a 20 percent increase in expenses so far in 2023 compared with 2020.[8]

These trends are not expected to abate anytime soon, with clinical labor costs expected to outpace inflation and increase by 6 to 10 percent over the next two years.[9] Essential hospitals have incurred considerable costs associated with hiring bonuses, retention bonuses, and increased salaries to recruit and retain nurses and other staff in short supply. These challenges have persisted even as COVID-19–related hospitalizations decrease and stabilize. Ongoing challenges from the protracted battle against COVID-19 and the consequential emotional toll on staff remain evident. The pandemic has led to burnout on an unprecedented scale, and essential hospitals have expended significant resources to recruit and retain clinical and nonclinical staff—a costly undertaking in the already competitive marketplace for health care workers.

In the context of historical inflation and workforce challenges, a reduction to the already insufficient market basket update would further diminish essential hospitals' fragile financial standing. Reduced Medicare payments would translate to fewer resources available to reinvest in health IT infrastructure, including investments in interoperability and information exchange. Ultimately, these reduced payments would exacerbate the challenges of already struggling hospitals and counteract HHS' goals of facilitating information exchange.

Compounding the difficulties posed by the stark disincentives is the variability inherent in the methodology CMS would use to calculate the disincentive. Because the exact reduction in payments is based on the market basket update, which varies annually, the actual impact on a hospital could be even higher in a year with a higher market basket update percentage. The exact amount a hospital could be penalized would depend not on the number or seriousness of the violations but instead would arbitrarily be based on what the market basket update is in the year OIG makes an information blocking finding. Such variability and uncertainty are yet more reasons for HHS to withdraw its proposed disincentive structure.

Finally, because of the way in which HHS has structured the penalties, a health care provider could be subject to multiple penalties in a year. For example, a hospital participating in the MSSP would be removed from the MSSP in the violation year and barred from MSSP participation the following year. This would be in addition to the market basket decrease applied through the PI program. And, HHS has stated in the rule and in previous rules that a health care provider that also meets the definition of a health IT developer, exchange, or network could receive both a disincentive through this proposed rule and a CMP of up to $1 million for each violation. Ultimately, due to the potential stacking of penalties, the harm to

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[7] Kaufman Hall. The Financial Effects of Hospital Workforce Dislocation. A Special Workforce Edition of the National Hospital Flash Report. May 2022. https://www.kaufmanhall.com/sites/default/files/2022-05/KH-NHFR-Special-Report-2.pdf. Accessed December 7, 2023.
[8] Kaufman Hall. National Hospital Flash Report. November 2023. https://www.kaufmanhall.com/sites/default/files/2023-11/November_NHFR-2023.pdf. Accessed December 7, 2023.
[9] Fleron A, Krishna A, Singhal S. The gathering storm: The transformative impact of inflation on the healthcare sector. McKinsey & Company. September 19, 2022. https://www.mckinsey.com/industries/healthcare/our-insights/the-gathering-storm-the-transformative-impact-of-inflation-on-the-healthcare-sector. Accessed December 7, 2023.

hospitals would be more pronounced. **For these reasons, we urge HHS to withdraw its proposed disincentives for health care providers.**

2. HHS should ensure information blocking disincentives are proportional to the number and scope of information blocking violations.

HHS should consider scaling the information blocking disincentives so they are proportional to the magnitude of the information blocking conduct. As described in the previous section of this letter, the amount of the reduction in Medicare payment to an eligible hospital is variable and dependent on many factors, including the market basket update in the year in question and the hospital's Medicare inpatient volume and case mix that year. What is lacking in HHS' proposal is any nexus between the severity of the information blocking conduct and the disincentive. Therefore, regardless of the scope of the violation, a hospital with higher Medicare volume that is subject to a penalty in a year with a higher market basket update will receive a larger payment reduction than a hospital with lower Medicare volume that is subject to a penalty in a year with a lower market basket update. Thus, it is possible that a large hospital that engages in one isolated instance of information blocking could be subject to a higher penalty than another hospital that is systematically engaged in information blocking. If HHS' goal is to ultimately deter information blocking, it would be reasonable for the disincentive to be proportional to the violations that have occurred, both in terms of number and severity.

Such an approach would be consistent with the approach finalized by OIG in its CMPs rule for health IT developers, networks, and exchanges.[10] In that rule, OIG finalized penalties of up to $1 million per violation, allowing for multiple CMPs to be imposed for multiple violations. The amount of the CMP per violation is capped at $1 million but could be less, depending on the factors OIG will assess to determine the gravity of the information blocking violations. OIG finalized factors it will review, including the nature and extent of the information blocking conduct, as well as the harm resulting from the information blocking conduct. To inform its determination, OIG will look at the number of patients affected, the number of providers affected, and the number of days the information blocking persisted. HHS has not proposed similar factors that could be used in determining disincentive amounts for health care providers. **We urge HHS to ensure consistency across affected entities (health care providers and health IT developers, exchanges, and networks) by accounting for the severity and number of violations in determining a disincentive amount for health care providers.**

3. HHS should provide an enforcement grace period during which it can educate providers on information blocking violations.

Given the punitive nature of the information blocking provisions—which include not just financial disincentives for health care providers but also the public posting of information on entities that are referred for information blocking—HHS must delay enforcement and application of disincentives by two years from the publication of a final rule. During this interim period, HHS can investigate claims without referring them for disincentives and provide education about the types of information blocking claims that have been found to violate the information blocking prohibition.

[10] 88 Fed. Reg. 42820 (July 3, 2023).

ONC has begun compiling and publishing information about complaints it has received through its information blocking portal. To date, there are 923 complaints that have been filed, with the vast majority (719) of these complaints against health care providers. However, on the portal ONC states that the claims are allegations or suggestions and do not indicate whether an investigation occurred or whether an information blocking determination has been made. Before being subject to disincentives, providers should have the opportunity to learn from HHS about the types of conduct that OIG would refer to CMS for a disincentive to be applied.

America's Essential Hospitals is committed to an interoperable learning health system. Essential hospitals realize the need for patients' health information to be readily accessible by providers across the care continuum. However, there are many obstacles—most of which are outside of a hospital's control—that can prevent a hospital from seamlessly exchanging information. Providers governed by information blocking provisions have begun assessing their systems and updating their internal processes to comply with the information blocking provisions and the exceptions. Providers have been training their staff about the provisions of the 2020 ONC final rule and on how to determine whether a given activity qualifies for an information blocking exception. Providers also have been responsible for developing internal policies to capture and document relevant information to justify their use of an exception. Yet, there remains substantial uncertainty about which types of actions could constitute information blocking and which actions could qualify for one of the eight exceptions.

A provider education period will be critical, due to the complexity of the exceptions and ambiguity about which scenarios would qualify for an exception. Below, we outline a few illustrative fact patterns in which it is unclear whether a provider would be engaged in information blocking:

- A provider shields a note from a patient under the preventing harm exception. The provider notes in the record that, during the encounter, the patient said that they would kill themself if the provider diagnosed them with a mental health disorder. The provider includes a mental health diagnosis in the note and, thus, blocks the note, specifically under the preventing harm exception for endangering the life or physical safety of the patient or another person (to prevent potential harm to the patient, based on the note). The patient logs onto the patient portal the next day to review the visit notes, which do not display because the provider blocked the note. The patient could then submit a claim of information blocking.
- A provider delays the release of test results to the patient. Suppose a patient's test result is critical, and the provider wants to speak to the patient about the result and what it means before the patient sees the information displayed in their portal. Here, the patient could report to ONC that their provider blocked the test result or there was a delay. The provider might not have the opportunity to explain that it did not immediately release the result to protect the patient and ensure they had the information needed to interpret the critical test result.
- A health care system determines that certain note types related to research, as opposed to clinical decision-making, would be excluded from a medical records release because they are not part of the designated record set (DRS). The patient might not understand or recall that the information is related to research and, thus, report the provider for information blocking. Without the opportunity to respond, OIG might also not recognize the information was recorded and used for research and, thus, the health system could be subject to disincentives.
- A provider excludes records from the DRS in error. Using the previous example, the health care system inaccurately flagged a certain type of record as being research-

related when, in fact, it was not. Under the proposed rule, it is possible the disincentive is applied before the system is made aware of the issue, and, therefore, affects payment reimbursement for one or more years without notice.

In scenarios like these, it is unclear whether OIG would find a provider in violation of the information blocking prohibition because there is no precedent to which providers can turn to inform themselves about how OIG enforces the prohibition. **Therefore, HHS should provide an enforcement grace period during which it can work with providers to educate them about the types of conduct that would rise to the level of being subject to disincentives.**

4. HHS should clarify that OIG will not refer to CMS violations that arose from conduct before the effective date of a final rule.

In addition to delaying implementation of enforcement, when HHS issues a final rule, it should clarify that conduct before the effective date would not be subject to OIG investigation or disincentives. HHS does not specify in the proposed rule whether there would be a lookback period for OIG—that is, whether OIG would review conduct that occurred before the finalization of the final rule. While the ONC information blocking regulations went into effect on April 5, 2021, HHS has not proposed disincentives until now. Any conduct that occurred before the effective date of the final rule should be exempted from disincentives. In the final rule establishing CMPs for other entity types, OIG stated it will not investigate violations that occurred before the effective date of the final rule. **HHS should include a similar provision in the final rule on disincentives for health care providers.**

5. HHS should include procedural safeguards for health care providers, including adequate notice and the ability to appeal an information blocking determination.

To ensure transparency and accuracy in the investigation process, HHS must offer health care providers notice of an impending investigation, as well as an appeals process. In the proposed rule, HHS says health care providers may have the right to appeal a disincentive administratively if the authority used to establish the disincentive provides for such an appeal. However, HHS does not propose appeal rights for health care providers the OIG determines have committed information blocking. Furthermore, the rule outlines a process through which the agency imposing the disincentive would provide notice to the health care provider of the decision to impose a disincentive, the amount of the disincentive, the basis for application of the disincentive, and the effect of the disincentive. This notification process would take place after the decision to impose a disincentive is made, as opposed to before the start of an OIG investigation.

Because of the repercussions of an information blocking finding, it is imperative that health care providers have an opportunity to be notified of an investigation when it begins, to provide input and consult with OIG during the investigation process, and to appeal an adverse determination. As we outlined in section 3 above, providers might be privy to facts that would absolve them of an information blocking determination and should be able to present this information through an appropriate process. In the final rule on CMPs for health IT developers, exchanges, and networks, OIG finalized a detailed process, which includes an opportunity for

the entity to discuss OIG's ongoing investigation, as well as the ability to appeal the imposition of a penalty. **To ensure parity, HHS should outline a similar process for health care providers, which would include the ability to appeal an information blocking determination.**

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America's Essential Hospitals appreciates the opportunity to submit these comments. If you have questions, please contact Senior Director of Policy Erin O'Malley at 202-585-0127 or eomalley@essentialhospitals.org.

Sincerely,

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President and CEO