ASSOCIATION CHAIR OF THE BOARD
Everett E. Vokes, MD, FASCO

ASSOCIATION TREASURER
Brian Edward Persing, MD

ASSOCIATION DIRECTORS
Lisa A. Carey, MD, FASCO
Tara O. Henderson, MD, MPH, FASCO
Elizabeth R. Plimack, MD, MS
Lynn M. Schuchter, MD, FASCO
Enrique Soto Pérez de Celis, MD, MSc, PhD, FASCO
Piyush Srivastava, MD, FASCO
Eric P. Winer, MD, FASCO
Robin T. Zon, MD, FACP, FASCO

NON-VOTING DIRECTOR
Chief Executive Officer
Clifford A. Hudis, MD, FACP, FASCO

December 20, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services

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
Mail Stop: 7033A
330 C Street, SW
Washington, DC 20201

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

Submitted electronically via www.regulations.gov

Dear Administrator Brooks-LaSure and Dr. Tripathi,

I am pleased to submit these comments on behalf of the Association for Clinical Oncology (ASCO) in response to the Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Proposed Rule [RIN 0955-AA05] that was published in the Federal Register on November 1, 2023.

ASCO is a national organization representing nearly 50,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are dedicated to conducting research that leads to improved patient outcomes, and we are committed to ensuring that evidence-based practices for the prevention, diagnosis, and treatment of cancer are available to all Americans.

On October 30, 2023, the Department of Health and Human Services (HHS) issued a proposed rule that would establish disincentives for providers who do not comply with the information blocking requirements established by the 21st Century Cures Act. The rule proposes 1) penalties for providers who the HHS Office of Inspector General (OIG) determines have committed information blocking and 2) a process by which information would be shared with the public

about health care providers that OIG determines have committed information blocking.

Under the proposal, clinicians who commit information blocking and who participate in the Merit-based Incentive Payment System (MIPS)—and are thereby required to report on the Promoting Interoperability performance category—would receive a zero in that category.

If OIG determines that a health care provider who participates in the Medicare Shared Savings Program (MSSP) committed information blocking, that provider would be barred from participating in the MSSP for at least one year. This may result in a health care provider being removed from an MSSP ACO or prevented from joining such an ACO. In addition, providers that have been found to have committed information blocking would be listed on a public website.

* * * * * *

Information sharing holds great promise for improving and enhancing patient care, especially in the realm of care coordination and quality improvement. To further enhance healthcare quality, ASCO supports moving towards realizing the vision of seamlessly integrated health information, easily and securely accessible to all patients and their care team.

ASCO is highly committed to working with the Agency to improve information sharing in efforts to improve quality care; however, we are concerned with several provisions in the proposed rule, and we would ask the Agency address these in the final rule.

When the OIG determines that information blocking has occurred, it will refer the claim, all evidence, and an analysis to explain how the evidence demonstrates the health care provider committed information blocking to CMS, which will impose the disincentives. Unlike similar rules for information technology (IT) vendors, the OIG did not establish a separate appeals process for health care providers directly to OIG who is making the determination, nor has CMS proposed to allow health care providers to submit a corrective action plan before imposing penalties.

ASCO is extremely concerned with the lack of an appeals process directly to OIG—the authority making the information blocking determination. Instead, in the Proposed Rule, HHS appears to take the position that any appeal rights would apply *only to the application of the disincentive itself*, meaning that the provider would be able to challenge only how the disincentive was calculated and applied. Although the 21st Century Cures Act does not expressly state that an appeals process must be established and available to providers, we believe that most due process rights would require such a step and that it would be reasonable, appropriate, and necessary for the OIG to establish one. We are extremely concerned that, as provided, physicians and other providers would have different appeal rights and much less of an opportunity to refute an allegation compared to health IT vendors/health information exchanges and networks. **Accordingly, we urge the Agencies 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 a disincentive.**

As noted in the rule, the OIG will make information blocking determinations on a case-by-case basis, and it is possible that errors will be made, interpretations will be misconstrued, or evidence may be missing or not presented. As physicians will shoulder a large burden of the responsibility for ensuring that a response to a request for electronic health information (EHI) is handled appropriately—taking into consideration the requestor, nature of the request, and patient privacy and data security concerns—clinical judgement will play a significant role in a physician's behaviors, and they should have the opportunity to explain their reasoning. The rule, however, fails to detail the process for OIG investigation and if there are explicit differences between that for health IT vendors and providers. Importantly, the rule does not clarify when investigation and enforcement will begin. OIG explicitly provided in its final rule that there would be no retroactive enforcement for vendors, which we would argue is not only appropriate but potentially more so for the physician and provider context. Additionally, the rule contemplates situations where information blocking could also be referred to other agencies, such as the Office of Civil Rights (OCR) given the potential relevance to privacy and security concerns. Appeals processes are in place for physicians found to have committed HIPAA violations when patient safety is the primary concern as it is in these rules. **Before finalizing this rule, we believe that HHS must provide additional detail on the full enforcement process, how it will coordinate across different agencies and authorities, and establish a more meaningful opportunity for appeals.**

We do not believe that it would be appropriate or reasonable for the Agency, in this case CMS, to administer the appeals process as it did not decide to review the initial complaint, analyze the evidence, or make the initial decision that a provider committed information blocking. Placing the appeals process on the appropriate agency, instead of OIG, would create inefficiencies and cause unnecessary burden on the system.

We also urge CMS to implement a warning or grace period for providers before applying any penalties. As proposed, CMS would have to send a notice to providers found to have committed information blocking that includes a description of the practice or practices that formed the basis for the determination, the effect of the provider actions, and the penalty(s). We strongly urge the Agency to use this notice not as a vehicle to implement the penalty, but as a mechanism to issue a warning to the provider. We urge the Agency to include in the notice guidance about how to correct the action and come into compliance within a reasonable timeframe. CMS implements similar warnings for other requirements regulated by CMS such as electronic prescribing of controlled substances, price transparency, and billing issues[1]; therefore, we believe it would be reasonable and appropriate to do the same for information blocking requirements. Information sharing is crucial to improving care coordination and promoting quality cancer care; CMS should not impose restrictions, penalties, or other limitations that may interfere with this progress without taking steps to support and promote compliance efforts.

[1] See e.g., https://www.cms.gov/data-research/monitoring-programs/improper-payment-measurement-programs/payment-error-rate-measurement-perm/corrective-action-plan-cap-process

Association for Clinical Oncology
2318 Mill Road, Suite 800, Alexandria, VA 22314 • T: 571-483-1300 • F: 571-366-9530 • asco.org

ASCO is also extremely concerned that the proposed penalties are not scaled as they are for other patient access and safety violations, such as HIPAA. Like HIPAA, the priority OIG considers when making an information blocking determination is whether it resulted in, caused, or has the potential to cause patient harm. Neither the severity of the violation, the consequences or patient harms resulting from information blocking, and frequency of the information blocking within a reporting period are considered when the penalty is applied. A provider who is found to have committed information blocking one time for one patient in a period will receive the same penalty as someone who is found to have committed information blocking multiple times during the same reporting period. ASCO does not believe this is appropriate and urges the Agency to reconsider the proposed penalties. Again, we strongly urge CMS to issue warning notices with an opportunity to make corrective actions prior to penalty implementation.

Under the proposed disincentives rule, if OIG determines that a health care provider who participates in the Medicare Shared Savings Program (MSSP) has committed information blocking, that provider or ACO would be barred from participating in the MSSP for at least one year. This may result in a health care provider being removed from an ACO or prevented from joining an ACO. In the instance where a health care provider is an ACO, this would prevent the ACO's participation in the MSSP.

ASCO has several concerns with this proposal and asks the Agency to consider and address our concerns in future notice-and-comment rulemaking. For example, some MSSP ACOs report under one tax identification number (TIN) and if one physician has been found to have committed information blocking, removing just one physician from the ACO TIN would not be feasible, or at a minimum extremely burdensome. The rule also does not address how patient attribution would be determined if a provider or TIN was removed from the program for information blocking. Without more detail on such issues, the entire revenue and shared savings of the MSSP ACO could be altered. Since the structure of the MSSP can vary, this essentially means that the disincentives will likewise depend not on the severity of the offense but on how the ACO is configured and arranged. We strongly disagree with this approach, which creates arbitrary penalties that are not based on the underlying information blocking concern. The uncertainty could also discourage providers from joining MSSP ACOs, significantly undercutting the Administration's stated goal of having all traditional Medicare beneficiaries in a care relationship with a provider who is accountable for their quality and total cost of care by 2030.

We are also concerned with the lag time that is likely to occur between when the OIG begins and ends an investigation of information blocking. As CMS mentions in the rule, it may take anywhere from three to five years for the OIG to fully investigate a claim of information blocking, during which time an individual may no longer participate in an MSSP ACO or report as a group in MIPS. We urge the Agency to clarify that should the OIG determine that an individual commits information blocking and is no longer a reporting under the same MIPS or ACO at the time of referral, then penalties will not apply to those remaining in the group.

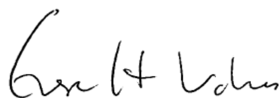
Under the proposed rule, a clinician who participates in MIPS and is required to report Promoting Interoperability will receive a zero score for the category if OIG refers, during the calendar year of the clinician's reporting period, a determination that the clinician committed information blocking. Since the Promoting Interoperability performance category is currently 25% of the total MIPS score, 75 would be the highest score that the clinician could earn and would likely result in a penalty based on the current MIPS performance threshold for 2024. Under this proposed penalty, a provider who is found to have committed information blocking one time will likely receive a negative payment adjustment to 100% of their Medicare payments for one year, unless they receive a perfect score in the three remaining categories. We ultimately believe this significant penalty, especially given the financial challenges facing the current Medicare physician fee schedule, could impact patient access to care. Furthermore, it is confusing that the penalty will then depend on the operations of the MIPS program, specifically the MIPS threshold. If CMS continues to increase the MIPS threshold, the same information blocking determination will have greater and greater penalties. The rule, however, fails to even contemplate this concern or that these are economically significant challenges for physicians. For these reasons, we disagree that this rulemaking is not economically significant.

Finally, HHS has not proposed disincentives that would govern health care providers who do not participate in Medicare. We are concerned that Medicare participation is once again being tied to additional financial penalties. The penalties also are more substantial for those providers with a larger portion of Medicare claims. For example, for those participating in MIPS, HHS explicitly outlines that the penalty will vary based on the health care professional's volume of FFS Medicare claims. Before moving forward with this approach, HHS should conduct more explicit assessments on the impact to clinicians and on patient access, which was not done as this rule was deemed economically insignificant. Again, we believe that potentially negative impacts on patient access and Medicare participation could be avoided if HHS began enforcement with corrective action, education, and activities that would improve compliance.

* * * * * *

We appreciate the opportunity to comment on the21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Proposed Rule. Please contact Gina Hoxie (gina.hoxie@asco.org) or Karen Hagerty (karen.hagerty@asco.org) with any questions or for further information.

Sincerely,



Everett Vokes, MD, FASCO

Chair of the Board
Association for Clinical Oncology