



December 21, 2023

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via: <http://www.regulations.gov>

Re: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking (RIN 0955-AA05)

Dear Administrator Brooks-LaSure:

On behalf of the American Society of Hematology (ASH), thank you for the opportunity to provide comments on the Centers for Medicare & Medicaid Services (CMS) *Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking* proposed rule. ASH recognizes the importance of the 21st Century Cures Act and information sharing provisions that have improved transparency for patients, aimed at empowering patients to make informed decisions in partnership with their physician. ASH urges CMS to consider how the proposed penalties for health care providers are implemented to ensure physicians, including hematologists, are best supported for information sharing that strengthens the patient-physician relationship and avoids unintended harm to patients and their relationship with physicians.

ASH represents more than 18,000 clinicians and scientists worldwide committed to studying and treating blood and blood-related diseases. These disorders encompass malignant hematologic disorders such as leukemia, lymphoma, and multiple myeloma, as well as classical (or non-malignant) conditions such as sickle cell disease, thalassemia, bone marrow failure, venous thromboembolism, and hemophilia. In addition, hematologists are pioneers in demonstrating the potential of treating various hematologic diseases and continue to be innovators in the fields of stem cell biology, regenerative medicine, transfusion medicine, and gene therapy. ASH membership is comprised of basic, translational, and clinical scientists, as well as physicians providing care to patients.

Health information technology has improved drastically since the initial passage of the 21st Century Cures Act, with the proliferation of information sharing through patient portals and various messaging services. ASH appreciates the role information sharing has had in improving transparency in health care and recognizes the intention of this proposed rule to ensure all health care professionals adhere to this standard of care. However, the limited guidance in the proposed rule may present challenges for physicians, including hematologists, to confirm their full adherence. ASH urges CMS to consider the following before finalizing policy of this proposed rule:

- Permit a delay in the delivery of sensitive health information, for example a malignant test result, to allow for appropriate physician review and action.

2023

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- Craft and implement a warning system to allow physicians time to understand what actions are expected of them to avoid penalties and allow the opportunity for corrective action before penalties are issued.
- Develop a scalable penalty system for the Promoting Interoperability performance category of the total Merit-based Incentive Payment System (MIPS) score for physicians who participate in the MIPS reimbursement program.
- Create a clear pathway to appeal an information blocking citation.

Allow the Delay of Delivering Sensitive Health Information

Although the proposed rule outlines four criteria to determine if information blocking occurred- the cost, the timeframe, the potential harm to the patient, and the impact on a physician's ability to provide care- the criteria are vague and create confusion about adherence vs. non-adherence. ASH members raised concerns about the lack of guidance around the noted criteria. Notably, the timeframe in which information is shared is especially important in hematology because complex health information and test results are often shared immediately with a patient via a patient portal or some other messaging system with limited context or support. For example, hematologists have cited instances of patients receiving seemingly alarming health information, such as a cancer diagnosis or lab results that might indicate one of many rare acquired classical hematologic conditions such as Paroxysmal Nocturnal Hemoglobinuria (PNH), over text or a phone call without access to a doctor to talk through the information or even the ability to schedule a follow up appointment.

Given the complexity and severity of diseases in hematology, the immediate release of certain health information or test results without context or support may cause unintended harm to patients; patients may misread or misinterpret high-risk health information, potentially causing anxiety around results or causing a patient to act without consulting their doctor, which may cause additional harm. ASH members raised that in instances of sharing high-risk health information, such as the above diagnoses, the harm of insufficient support or context for the information shared may outweigh the benefits of transparency.

ASH recommends a brief 72-hour hold on high-risk health information before it is released to the patient to allow physicians the ability to contextualize or personalize the information being shared. The Society also recommends that in future rulemaking or through the issuance of sub-regulatory guidance, a panel of experts should guide the development of a list of various types of information that could be briefly delayed. Our noted examples of a malignant diagnosis or test result that indicates a rare classical hematologic condition (e.g., PNH) would be the type of high-risk information that could be held for a specified period to allow a physician, including hematologists, adequate time to review the information and take any necessary actions prior to the information being shared with the patient. ASH is happy to work in collaboration with CMS and other medical specialty societies to develop and maintain a list of severe or complex diagnoses that would benefit from a 72-hour hold. ASH is supportive of transparency efforts with the consideration for thoughtful health information sharing.

Warning System to Support Adherence

The penalties physicians face in this proposed rule are stringent with limited guidance for how penalties will be rolled out; the proposed rule does not specify whether there will be a warning system or ramp up to implementation. While ASH supports CMS' efforts to improve transparency, the Society urges CMS to consider how the implementation of penalties may add to administrative burden, financial burden, psychological burden and may even contribute to burnout. ASH recommends that warnings become a part of the implementation process, allowing physicians the opportunity to take corrective action before a penalty is issued. This would allow physicians the time to better understand the criteria of information blocking and make necessary changes before incurring penalties.

Scalable Penalties

The proposed rule notes that a physician, operating under MIPS, who has been found to be an information blocker will receive a score of zero in the Promoting Interoperability (PI) performance category. The PI performance score is typically 25% of the physician's total MIPS score in a performance year. If a physician receives a score of zero in the PI performance category, then the physician would have to score perfectly in all other categories to qualify for a Medicare payment bonus under this program. A perfect score in all other categories is not reasonable and undermines

the physician's opportunity to earn a bonus payment. A zero score under the PI category is an unjust penalty, at least for first time offenders. Therefore, ASH recommends that if a penalty must be implemented at the MIPS scoring level, we encourage CMS to develop a scaled penalty system that assigns an appropriate penalty based on the severity of the infraction. For instance, a scaling factor could be applied to the calculation of the PI performance category, so that a physician would receive a percentage deduction rather than a score of zero, which would provide some flexibility for the physician to still earn a bonus payment.

Appeals Process

Lastly, the proposed rule does not provide a clear and cohesive path for physicians to challenge an information blocking citation. It is our understanding that the Office of the National Coordinator (ONC) may receive a complaint through the Report Information Blocking Portal, and ONC would then send the complaint to the Office of the Inspector General (OIG) to determine if information blocking had occurred. If OIG determined information blocking had in fact occurred, the penalty would apply under CMS programs, including MIPS and the Medicare Shared Savings Program (MSSP). Moreover, if a provider sought to appeal a decision, the appeal would be handled through CMS, and not the OIG, despite the fact that the OIG made the initial determination of an information blocking infraction. ASH believes that this cumbersome appeals process requires additional clarification and would benefit from a more streamlined process to allow physicians to appeal decisions without undue administrative burden.

Although the proposed rule aims to ensure all health care professionals meet a specified standard of care in providing health information to patients, it is important that physicians are supported to facilitate thoughtful information sharing and dialogue to make the most appropriate clinical care decisions with the patient. Furthermore, it is imperative that penalties do not place an undue burden on physicians or create potentially harmful, unintended consequences. ASH appreciates the opportunity to provide these comments. Please use ASH Manager for Health Care Access Policy, Carina Smith (casmith@hematology.org or 202-292-0264), as your point of contact if you have any questions or if we can provide additional information.

Sincerely,



Robert A. Brodsky, MD
President, 2023



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