AMERICA'S PHYSICIAN GROUPS

January 2, 2024

Chiquita Brooks-LaSure
Administrator, Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
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Submitted via https://www.federalregister.gov/documents/2023/11/01/2023-24068/21st-century-cures-act-establishment-of-disincentives-for-health-care-providers-that-have-committed#open-comment

I. Re: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking RIN 0955–AA05

Dear Administrator Brooks-LaSure and National Coordinator Tripathi:

America's Physician Groups (APG) appreciates the opportunity to respond to the proposed rule from the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC) on establishing disincentives for health care providers that have committed information blocking. APG welcomes your agencies' openness to stakeholder input and ongoing commitment to improving health care for all Americans.

Below, APG will first provide (I) a brief description of our organization, followed by (II) a summary

of CMS's and ONC's request for input, and then (III) our fuller comments and recommendations. Together they reflect the voice of our membership and our commitment to working with the agencies to ensure that all Americans have consistently accessible, high-quality, person-centered health care; that health care be equitable; and that the health care system provides for the responsible flow of electronic health information (EHI) that is required by the 21st Century Cures Act (Cures Act).

I. About America's Physician Groups

APG is a national association representing more than 360 physician groups that are committed to the transition to value, and that engage in the full spectrum of alternative payment models and Medicare Advantage (MA). APG members collectively employ or contract with approximately 195,000 physicians (as well as many nurse practitioners, physician assistants, and other clinicians), and care for approximately 90 million patients, including roughly 30 percent of all Medicare beneficiaries who are enrolled in MA.

Our motto, "Taking Responsibility for America's Health," underscores our members' preference for being in risk-based, accountable, and responsible relationships with all payers, including MA health plans, rather than being paid by plans on a fee-for-service basis. Delegation of risk from payers to providers creates the optimal incentives for our groups to provide integrated, coordinated care; make investments in innovations in care delivery; advance health equity; and manage our populations of patients in more constructive ways than if our members were merely compensated for the units of service that they provide.

II. CMS and ONC Proposed Rule

This proposed rule would implement an important Cures Act provision regarding health care providers – whether individuals or entities – who have been determined by the Department of Health and Human Services (HHS) Office of Inspector General (OIG) to have committed information blocking. As set forth through notice and comment rulemaking, these providers would be referred to the appropriate agency and be subject to appropriate disincentives using authorities under applicable federal law.

The Cures Act, enacted in 2016, established three key elements of prohibited information blocking. First, the Act defines information blocking as a practice that, except as required by law or specified by the Secretary of HHS pursuant to rulemaking, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. It also specifies that for a health care provider to be deemed to have engaged in information blocking, such provider must know that a practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI. Second, the Cures Act authorizes OIG to investigate information blocking claims. Third, the Act provides that any health care provider whom OIG determines to have committed information blocking shall be referred 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.

Subsequent rulemaking in 2020 finalized eight reasonable and necessary activities that do not constitute information blocking. Such reasonable and necessary activities are often referred to as

''exceptions.'' These eight exceptions are divided into two categories: 1) exceptions that involve not fulfilling requests to access, exchange, or use electronic health information; and 2) exceptions that involve procedures for fulfilling requests to access, exchange, or use electronic health information.[1] ONC provides information about the eight exceptions and other aspects of information blocking on the agency's website.[2]

In this proposed rule, CMS and ONC propose to establish specific disincentives for certain health care providers who have been determined by OIG to have committed information blocking and for which OIG refers its determination to CMS, including:

- hospitals and critical access hospitals,
- clinicians participating in the Merit-based Incentive Payment System (MIPS), and
- Medicare Shared Savings Program (MSSP) accountable care organizations (ACOs), health care providers who are ACO participants, and ACO providers and suppliers.

The proposed rule also includes OIG's anticipated priorities and proposed notification and transparency policies.

III. Summary of APG's Recommendations

B. Recommendations Related to Notification and Transparency Policies

- **APG recommends that HHS incorporate expanded guidance on HealthIT.gov that explains how new policies interact with previously finalized information blocking regulations.**
- **APG recommends that HHS provide additional opportunities to provide more information and technical assistance to health care providers – for example, through HHS-hosted webinars and office hours.**
- **APG recommends that OIG notify entities that have been evaluated when OIG determines that actions taken do not rise to the level of an adverse determination but do signal areas of concerns that could be improved.**

C. Recommendations Related to Disincentives for MIPS-eligible Clinicians

- **APG recommends that CMS establish more than one disincentive option for MIPS-eligible clinicians who are referred by OIG to allow the agency flexibility in determining the disincentive appropriate for each case.**
- **APG recommends that CMS identify a single set of disincentives for ACO participants beginning in 2025, rather than subjecting them to two sets of disincentives – one under MIPS and one regarding MSSP participation. Such a circumstance would effectively**

[1] https://www.healthit.gov/sites/default/files/2022-07/InformationBlockingExceptions.pdf
[2] https://www.healthit.gov/topic/information-blocking

constitute double jeopardy.

D. Recommendations Related to Disincentives for MSSP ACOs, ACO Participants, and ACO Providers and Suppliers

- **APG recommends that CMS establish more than one disincentive option for MSSP ACOs, ACO Participants, and ACO Providers and Suppliers who are referred by OIG to allow the agency flexibility in determining the disincentive appropriate for each case.**

IV. APG's Detailed Comments and Recommendations

The proposed rule lays out two sequential steps for application of information blocking regulations that will be the responsibility of three HHS agencies: 1) ONC is to establish and maintain information blocking rules while OIG investigates entities for potential violations of these rules and issues determinations when these rules are violated; and 2) CMS, as the appropriate agency, determines and applies the appropriate disincentive or punishment for entitles determined by OIG to have engaged in information blocking.

A. OIG's Anticipated Priorities

The proposed rule reiterates the priorities that OIG anticipates will guide investigations and findings that were established in prior rulemaking. For investigations of health care providers, OIG expects to focus on practices in the following categories:

- They resulted in, are causing, or have the potential to cause patient harm;
- They significantly impacted a provider's ability to care for patients;
- They were of long duration; or
- They caused financial loss to federal health care programs or other government of private entities.

Although these anticipated priorities have already been established and thus are not subject to modification as part of this proposed rule, APG appreciates OIG's transparency in outlining these priorities and reiterating them. This clarity helps to address providers' confusion about information blocking and allay concerns that limited instances of misunderstanding or misapplication of information blocking rules could be cause for adverse findings.

B. Notification and Transparency Policies

HHS proposes to make new information blocking actions transparent, building on information already available on ONC's website about claims of information blocking. Specifically, HHS proposes to include information on ONC's website about OIG determinations, including identifying information

blocking practices, actors who committed information blocking, and any settlements, civil monetary penalties, and disincentives administered.

When disincentives are applied, HHS proposes that CMS send a notice to affected providers that would include the following:

- A description of the practice that formed the basis for the determination of information blocking referred by the OIG;
- The basis for the application of the disincentive being imposed;
- The effect of each disincentive; and
- Any other information necessary for a health care provider to understand how each disincentive will be effectuated.

APG appreciates the inclusion of a detailed description of the proposed notification and transparency policies and commends HHS for pursuing greater transparency. If finalized, these new policies will provide robust information on the nature of information blocking that has been determined to have taken place.

APG requests that HHS also consider providing more transparency and greater detail on how ONC defines information blocking; how OIG applies criteria for selecting potential cases for evaluation; and how the agency arrives at determinations. This guidance could be added to existing information that ONC has already made available on the HealthIT.gov website to explain previously finalized information blocking regulations.[3] APG further requests additional opportunities for transparency and technical assistance, for example through HHS-hosted webinars and office hours.

This expanded guidance could explain further how the new regulations, if finalized, would interact with existing rules and guidance. For example, providers would find it helpful to understand how the OIG's anticipated priorities interacted with the eight exceptions and how both interacted with state laws and regulations regarding the exchange of EHI.

In summary:

- **APG recommends that HHS incorporate expanded guidance on HealthIT.gov that explains how new policies interact with previously finalized information blocking regulations.**
- **APG recommends that HHS provide additional opportunities to provide more information and technical assistance to health care providers – for example, through HHS-hosted webinars and office hours.**

APG also observes that existing and proposed policies regarding OIG's evaluation of potential information blocking appear to offer only one binary set of outcomes: reach either a finding that information blocking occurred or a finding that it did not. This approach may not be the best one if the goal is to reduce instances of information blocking. OIG should also consider interim outcomes – for example, notifying entities that have been evaluated when OIG determines that actions taken do not rise to the level of an adverse determination but do signal areas of concern. Providers would welcome this information and could take steps to further improve their exchange of electronic health

[3] https://www.healthit.gov/topic/information-blocking

information.

In summary:

- **APG recommends that OIG notify entities that have been evaluated when OIG determines that actions taken do not rise to the level of an adverse determination but do signal areas of concerns that could be improved.**

C. Disincentives for MIPS-eligible Clinicians

CMS proposes that an eligible hospital, critical access hospital, or Merit-based Incentive Payment System (MIPS)-eligible clinician would not qualify as a meaningful electronic health record (EHR) user in a calendar year of the performance period during which OIG refers a determination of information blocking. A MIPS-eligible clinician who is not a meaningful user of Certified EHR Technology (CEHRT) cannot satisfy the requirements of the MIPS Promoting Interoperability performance category and, therefore, would earn a score of zero for this performance category. CMS also proposes for MIPS-eligible clinicians that if data are submitted as a group or virtual group, then the disincentive would apply at this level.

CMS's planned MIPS scoring weights for the 2024 performance period/2026 payment year are as follows: 30 percent for the quality performance category; 30 percent for the cost performance category; 15 percent for the improvement activities performance category; and 25 percent for the Promoting Interoperability performance category. Given these weights for the performance categories, a score of zero for the Promoting Interoperability performance category would mean that the maximum final score that MIPS-eligible clinicians could achieve, if they performed perfectly in the three remaining performance categories, would be 75 points. The performance threshold for the 2026 MIPS payment year will also be 75 points.

These calculations mean that a MIPS-eligible clinician whom OIG determined committed information blocking and who received a score of zero in the Promoting Interoperability performance category would be eligible to receive no greater than a 0 percent MIPS payment adjustment factor. (A positive MIPS payment adjustment factor may be up to 9 percent for a final score of 100 and the negative MIPS payment adjustment factor may be up to negative 9 percent for a final score of zero.)

APG acknowledges CMS's responsibility to ensure that the Promoting Interoperability performance category accurately assesses MIPS-eligible clinicians' meaningful use of CEHRT. A Promoting Interoperability performance category score of zero and resulting MIPS payment adjustment factor of zero or less is an appropriate disincentive for MIPS-eligible clinicians found to have engaged in significant information blocking that was identified by OIG's anticipated priorities, including harm to patients and long duration.

However, as these proposed policies, if finalized, will be newly introduced to the program, it is not clear that all OIG findings of information blocking will be for significant instances. Given this uncertainty, CMS may wish to establish more than one disincentive option from which the agency could choose to apply to MIPS-eligible clinicians who are referred by OIG. For example, the Promoting Interoperability performance category score could be reduced, or the MIPS-eligible clinician could be subject to a corrective action plan. The authority for determining the appropriate disincentive would still reside with

the Secretary, but the flexibility to choose among more than one disincentive option, including the application of no disincentive, would allow the agency to gain experience with the new policies, and this experience could inform any needed revisions to the policies through future notice-and-comment rulemaking.

In summary:

- **APG recommends that CMS establish more than one disincentive option for MIPS-eligible clinicians who are referred by OIG to allow the agency flexibility in determining the disincentive appropriate for each case.**

Beginning in 2025, ACO participants will be required to report in the Promoting Interoperability performance category. As described below, CMS is proposing separate disincentives for MSSP ACO participants. APG requests that CMS clarify whether ACO participants will be subject to two sets of disincentives – one under MIPS and one regarding MSSP participation – beginning in 2025. APG urges CMS to select one set of disincentives so that ACO participants are not effectively subject to double jeopardy.

In summary:

- **APG recommends that CMS identify a single set of disincentives for ACO participants beginning in 2025, rather than subjecting them to two sets of disincentives – one under MIPS and one regarding MSSP participation. Such a circumstance would effectively constitute double jeopardy.**

D. Disincentives for MSSP ACOs, ACO Participants, and ACO Providers and Suppliers

CMS proposes to revise the MSSP regulations to establish disincentives for health care providers – including ACOs, ACO participants, or ACO providers/suppliers – that engage in information blocking. Under this proposal, CMS will screen ACOs, ACO participants, and ACO providers/suppliers for an OIG determination of information blocking and bar these actors from participation in MSSP for a period of at least one year. CMS could opt to bar participation for more than one year.

Specifically, CMS would take the following actions, as applicable:

- Deny the request of the ACO to add an ACO participant to its ACO participant list based on the results of the program integrity screening.
- Notify an ACO currently participating in MSSP if one of its ACO participants or ACO providers/suppliers is determined by OIG to have committed information blocking so that the ACO can take remedial action—removing the ACO participant from the ACO participant list or the ACO provider/supplier from the ACO provider/supplier list—as required by the ACO participant agreement.
- Deny an ACO's MSSP application if the results of a program integrity screening reveal a history of program integrity issues or other sanctions and affiliations with individuals or entities that have a history of program integrity issues.
- Terminate an ACO participation agreement in the case of a failure to comply with MSSP requirements, including violations of any applicable laws, rules, or regulations relevant to ACO operations.

An ACO might be able to appeal the application of an information blocking MSSP disincentive for an initial determination that is not prohibited from administrative or judicial review by requesting a reconsideration review by CMS. However, the underlying information blocking determination made by OIG would not be subject to the CMS reconsideration process.

CMS is contemplating an approach under which a health care provider could participate in MSSP if a significant amount of time (for example, three to five years) had passed between the occurrence of the information blocking and OIG's determination, and the provider had given assurances in the form and manner specified by CMS that the issue had been corrected and appropriate safeguards had been put in place to prevent its reoccurrence.

CMS is also considering an alternative approach in which the agency would not apply an MSSP disincentive in certain circumstances despite an OIG information blocking determination. Under this alternative policy, CMS would consider OIG's referral of an information blocking determination in light of the relevant facts and circumstances before denying the addition of an ACO participant to an ACO participant list (or an ACO provider/supplier to the ACO provider/supplier list), informing an ACO that remedial action should be taken against the ACO participant (or ACO provider/supplier), or denying an ACO's application to participate in MSSP.

The relevant facts and circumstances could include the nature of the health care provider's information blocking; the health care provider's diligence in identifying and correcting the problem; the time since the information blocking occurred; the time since the OIG's determination of information blocking; and other factors. This alternative policy would offer some flexibility in certain circumstances, in which prohibiting an ACO, ACO participant, or ACO provider/supplier from participating in MSSP would distort participation incentives and therefore be less appropriate. The agency is particularly concerned about situations in which many years have passed since an ACO participant or ACO provider/supplier was found to have engaged in information blocking and such an issue had long been remediated.

APG appreciates CMS's consideration of an alternative policy in which the agency would not apply an MSSP disincentive in certain circumstances despite an OIG information blocking determination. As noted above regarding disincentives for MIPS-eligible clinicians, APG supports establishing multiple potential disincentive options. Doing so would allow the agency flexibility to determine the appropriate disincentive, including no disincentive, to suit the relevant facts and circumstances of each case.

In summary:

- **APG recommends that CMS establish more than one disincentive option for MSSP ACOs, ACO Participants, and ACO Providers and Suppliers who are referred by OIG to allow the agency flexibility in determining the disincentive appropriate for each case.**

V. Conclusion

APG appreciates and welcomes the detailed descriptions of the proposed policies in this proposed rule and supports HHS's efforts to identify and curtail information blocking to ensure that all health care

providers support the appropriate exchange of EHI. APG encourages the agencies to consider modifications to the proposed policies to include flexibility for the agencies to choose among multiple potential responses rather than being locked into a binary set of options.

Sincerely,

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