CMS Proposed Rule on Information Blocking Disincentives for Health Care Providers

Background

On October 30, CMS issued a proposed rule implementing provisions of the 21st Century Cures Act to create disincentives for health care providers committing information blocking. Of note, CMS proposes ACOs who are health care providers as well as ACO providers/suppliers who are engaged in information blocking would be removed from or denied approval to participate in the Medicare Shared Savings Program (MSSP).In addition, CMS proposes other penalties for clinicians and hospitals who are engaged in information blocking..

This proposed rule complements the HHS Office of Inspector General (OIG) rule that established information blocking penalties for other actors identified by Congress such as health information technology (IT) developers of certified health IT, other entities offering certified health IT, health information exchanges., and health information networks.

NAACOS will submit comments in response to the proposed rule to advocate for more appropriate penalties for information blocking that do not impede the work of value-based care. Comments on these proposals will be accepted through January 2, 2024, and can be submitted electronically through Regulations.gov (refer to file code RIN 0955-AA05).

- Office of the National Coordinator for Health IT (ONC) webpage on information blocking
- CFR Information Blocking

What is Information Blocking

The Cures Act, enacted in 2016, was designed to accelerate the discovery, development, and delivery of 21st Century cures. Section 3022(a)(1) of the Public Health Service Act (PHSA) defines information blocking as a practice, that except as required by law or specified by the Secretary pursuant to rulemaking, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. Section 3022(a)(2) describes certain practices that may constitute information blocking. OIG is authorized to investigate claims that a health care provider engaged in information blocking. The PHSA also authorizes ONC, the HHS Office for Civil Rights (OCR), and OIG to consult, refer, and coordinate to resolve claims of information blocking.

As defined at 45 CFR 171.103, information blocking is a practice that:

1. Except as required by law or covered by an exception in subpart B or subpart C of this part, is likely to interfere with access, exchange, or use of electronic health information; and

2. If conducted by a health IT developer of certified health IT, health information network, or health information exchange, such developer, network, or exchange knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information; or
3. If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with access, exchange, or use of electronic health information.

Reasonable and necessary activities or exceptions to information blocking have been defined by ONC. NAACOS has developed a resource outlining the eight exceptions finalized to rules otherwise prohibiting information blocking (preventing harm, privacy, security, infeasibility, health IT performance, content/manner, fees, licensing). Actors will not be subject to civil monetary penalties or other enforcement actions if they satisfy at least one of the exceptions. More information on the exceptions is also provided in this ONC fact sheet. NAACOS also has a resource explaining these exceptions and other key definitions.

Given the very broad nature of this language, NAACOS is advocating for a clearer understanding and definitions for what constitutes information blocking.

Disincentives for Providers Determined by OIG to Have Committed Information Blocking

Hospitals

An eligible hospital or CAH under the Medicare Promoting Interoperability Program would not be a meaningful electronic health record (EHR) user for the applicable year if found to have committed information blocking. This would result in the loss of 75 percent of the annual market basket increase for hospitals and for CAHs, payment would be reduced to 100 percent of reasonable costs (as opposed to 101 percent).

CMS proposes to use the date of the OIG referral instead of the date of the information blocking occurrence to apply the disincentive. CMS will apply the disincentive to the payment adjustment year associated with the calendar year in which the OIG referred its determination to CMS. If an eligible hospital or CAH has already been determined to not be a meaningful EHR user during the applicable EHR reporting period due to its performance in the program, imposition of the disincentive would result in no additional impact on the hospital or CAH during that payment adjustment year. CMS also clarifies that even if multiple information blocking violations are identified as part of OIG's determination and referred to CMS, each referral would only affect an eligible hospital or CAH's status as a meaningful EHR user in a single EHR reporting period during the calendar year when the determination of information blocking was referred to OIG.

The application of the disincentive would result in a downward payment adjustment for eligible hospitals two years after the OIG referral of a determination of information blocking to CMS. For eligible hospitals, the downward adjustment would apply two years after the year of referral. For CAHs the downward adjustment would apply to the payment adjustment year in which the OIG referral was made.

Clinicians

An eligible clinician or group would not be a meaningful user of CEHRT under the MIPS PI performance category for the applicable performance year if found to have committed information blocking. This

would result in receiving a score of zero for the PI performance category, if required to report on that category. The PI performance category accounts for a portion of a MIPS eligible clinician's overall score.

CMS proposes that a MIPS eligible clinician (or group) would not be a meaningful EHR user in a performance period if OIG refers a determination that information blocking was committed at any time during the calendar year of the performance period. The MIPS payment year is two calendar years after the performance period. Therefore, CMS proposes if OIG referred its determination in calendar year 2025, then CMS would apply the disincentive for the 2027 MIPS payment year.

CMS clarifies that even if multiple information blocking violations were identified as part of OIG's determination and referred to CMS, each referral would only affect a MIPS eligible clinician's status as a meaningful EHR user in a single performance period during the calendar year when the determination of information blocking was referred by OIG.

MSSP ACOs

Under the MSSP, a health care provider would be deemed ineligible to participate in the program for a period of at least one year if found to have committed information blocking. This may result in a health care provider being removed from an ACO or prevented from joining an ACO. CMS notes its intent that by restricting the ability of health care providers to participate in the MSSP for at least one year, this would result in loss of potential revenue they might otherwise have earned through their participation in the program.

CMS proposes to revise the MSSP regulations to specify that the program integrity history on which ACOs, ACO participants, and ACO providers/suppliers are reviewed during the MSSP application process and periodically thereafter includes, but is not limited to, a history of Medicare program exclusions or other sanctions, noncompliance with MSSP requirements, or violations of law. This provides the basis for CMS to deny participation in MSSP to a health care provider that is an ACO, an ACO participant, or an ACO provider/supplier when they have engaged in information blocking as determined by the OIG.

CMS proposes to screen ACOs, ACO participants, and ACO providers/suppliers for an OIG determination of information blocking and deny the addition of such a health care provider to an ACO's participation list for the period of at least one year.

- If the ACO is a health care provider, CMS proposes to deny the ACO's application to participate in the MSSP for the period of at least one year. If the ACO reapplies in a subsequent year, CMS will review whether OIG had any subsequent determinations of information blocking, as well as any evidence that indicated whether the issue had been corrected and appropriate safeguards had been put in place to prevent reoccurrence, as part of the application process.
- CMS would notify an ACO currently participating in MSSP if one of its ACO participants or ACO providers/suppliers is determined by the OIG to have committed information blocking so the ACO can take remedial action (removing the ACO participant or provider/supplier from the ACO participant or provider/supplier list).

Timing and Notice

The period of time would be at least one performance year, it but could exceed one year if OIG has made any subsequent determinations of information blocking and whether safeguards have been put in place

to prevent the information blocking that was the subject of the OIG's determination. **CMS proposes to apply the disincentive no sooner than the first performance year after receiving a referral of an information blocking determination from OIG and in which the health care provider is to participate in the MSSP.**

- In the case of the new addition of an ACO participant Tax Identification Number (TIN) to an ACO's participant list, CMS would prevent the TIN from joining the ACO if the program integrity screening reveals the TIN has engaged in information blocking.
- In the case of an existing ACO participant, CMS would notify the ACO that the ACO participant or provider/supplier had committed information blocking so the ACO can remove them from its ACO participant list or ACO provider/supplier list. If the TIN remains on the participant or provider/supplier list when the ACO certifies its list for the next performance year, then CMS would issue a compliance action to the ACO. Continued noncompliance (failure to remove the TIN) would result in termination of the ACO's agreement with CMS.

CMS will provide this notice in accordance with program requirements. After the completion of the last performance year in which the disincentive was applied, an ACO may submit a change request to add the TIN or include the National Provider Identifier (NPI) on its ACO participant list or ACO provider/supplier list, as applicable, for a subsequent performance year, and CMS would approve the addition, so long as (1) OIG has not made any additional determinations of information blocking, and (2) the ACO provides assurances (in the form and manner required by CMS) that the information blocking is no longer ongoing and that the ACO has put safeguards in place to prevent the information blocking that was the subject of the referral. If the OIG made and referred an additional information blocking determination (that is either related or unrelated to the previous OIG referral) in a subsequent year or the ACO cannot provide assurance that the information blocking has ceased, then CMS would continue to deny participation.

An ACO may be able to appeal the application of an information blocking distinctive in the MSSP, if not prohibited from administrative or judicial review under 42 CFR 425.800, by requesting a reconsideration review by CMS. The MSSP reconsideration process may not negate, diminish, or alter the applicability of determinations made by other government agencies.

CMS notes all health care providers and ACOs may meet the definition of a health information network or health information exchange, or the definition of a health IT developer of certified health IT. If it is found by OIG that the health care provider or entity (such as an ACO) meets either definition, then they would be subject to a different intent standard and civil monetary penalties administered by the OIG (88 FR 42828).

Potential Alternative Proposal: CMS is contemplating an approach which would allow the health care provider to participate in MSSP if a significant amount of time, such as three to five years, has passed between the occurrence of information blocking and the OIG's determination, if 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 reoccurrence.

Enforcement

OIG has the discretion to choose which information blocking complaints to investigate. OIG notes in the rule that it generally focuses on selecting cases for investigations that are consistent with enforcement priorities, which will include:

1. Resulted in, are causing, or have the potential to cause patient harm;
2. Significantly impacted a provider's ability to care for patients;
3. Were of long duration;
4. Caused financial loss to federal health care programs or other government or private entities; or
5. Were performed with actual knowledge.

These priorities are expected to evolve as OIG gains more experience with investigating information blocking. OIG emphasizes that information blocking includes an element of intent. OIG emphasizes that information blocking, as defined in PHSA section 3022(a)(1) and in 45 CFR 171.103, includes an element of intent.

Notice

The appropriate agency imposing the disincentive(s) would send a notice, using usual methods of communication for the program or payment system, to the health care provider. The notice will include:

- A description of the practice or practices that formed the basis for the determination of information blocking referred by 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 implemented.

Appeals

Following the application of a disincentive, a health care provider may have the right to administratively appeal a disincentive. No additional information is provided in the rule regarding how to proceed with appeals.

Publication

ONC will publicly post information about actors that have been determined by OIG to have committed information blocking. Specifically, ONC plans to post the following:

- Health care provider's name, business address, practice of information blocking, disincentive(s) applied.

ONC will also post information about Health Information Networks (HINs), health information exchanges (HIEs) and health IT developers of certified health IT that have committed information blocking and have either resolved their civil monetary penalty (CMP) liability with OIG or had a CMP imposed, including the type of actor, legal name, and any alternative or additional trade names.