Proposed Rule

21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking

Office of the National Coordinator for Health Information Technology (ONC)

The Centers for Medicare & Medicaid (CMS)

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Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking: Public Comment Period Open

- Proposed Rule published in the Federal Register on November 1, 2023.
- Available for public comment for 60 days. To be assured consideration, written or electronic comments must be received via the Federal Register no later than 11:59 p.m. ET on January 2, 2024.
- You may submit public comments at the following link: https://www.federalregister.gov/documents/2023/11/01/2023-24068/21st-century-cures-act-establishment-of-disincentives-for-health-care-providers-that-have-committed

What Is the Purpose of the Proposed Rule?

The Proposed Rule…

- Implements the HHS Secretary's authority under section 4004 of the 21st Century Cures Act (Cures Act).
- Establishes disincentives for health care providers that commit information blocking as determined through an investigation by OIG.
- Complements OIG's "Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules" published in July 2023 which established civil money penalties authorized for other actors that have committed information blocking.

Proposed Rule Background

Background

- Section 4004 of the Cures Act identified health information technology developers, exchanges or networks, and health care providers in the definition of information blocking.
- If conducted by a health care provider, such provider **knows** that a practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.
- Section 4004 of the Cures Act requires OIG to refer **health care providers** that OIG determines to have committed information blocking 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."
- Section 4004 of the Cures Act gives the HHS Secretary the authority to impose civil monetary penalties of up to $1 million per violation on **health IT developers** and **health information networks and exchanges** that OIG determines to have committed information blocking.

Health Care Providers

- For the purposes of information blocking, a health care provider is defined in 45 CFR 171.102, which is the definition of health care provider found in section 3000(3) of the Public Health Service Act (PHSA), finalized in the ONC Cures Act Final Rule. For more information see: https://www.healthit.gov/sites/default/files/page2/202008/Health_Care_Provider_Definitions_v3.pdf
- The 45 CFR 171.102 health care provider definition includes:

- hospital
- skilled nursing facility
- nursing facility
- home health entity or other long term care facility
- health care clinic
- community mental health center (as defined in section 300x–2(b)(1) of this title)
- renal dialysis facility
- blood center
- ambulatory surgical center described in section 1395l(i) of this title,
- emergency medical services provider
- federally qualified health center
- group practice
- a pharmacist
- a pharmacy
- a laboratory
- a physician (as defined in section 1395x(r) of this title)
- a practitioner (as described in section 1395u(b)(18)(C) of this title)
- a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5301 et seq.]), tribal organization, or urban Indian organization (as defined in section 1603 of title 25)
- a rural health clinic
- a covered entity under section 256b of this title,
- an ambulatory surgical center described in section 1395l(i) of this title,
- a therapist (as defined in section 1395w–4(k)(3)(B)(iii) of this title), and
- any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.

What Proposals Does the Proposed Rule Include?

Relevant Statutory Terms and Provisions

PHSA 3022(b)(2)(B): “PROVIDERS.—Any individual or entity described in subparagraph (B) of paragraph (1) determined by the Inspector General 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.”

- Proposes to define “appropriate agency” in 45 CFR 171.102 to mean a government agency that has established disincentives for health care providers that OIG determines have committed information blocking.
- Proposes to define the term “disincentive” in 45 CFR 171.102 to mean a condition that may be imposed by an appropriate agency on a health care provider that OIG determines has committed information blocking and is specifically identified in 45 CFR 171.1001(a).
- Under this proposal, an appropriate disincentive for a health care provider that OIG has determined to have committed information blocking may be any condition, established through notice and comment rulemaking, that would, in our estimation, deter information blocking practices among health care providers subject to the information blocking regulations.

Relevant Statutory Terms and Provisions

PHSA 3022(b)(2)(B): “PROVIDERS.—Any individual or entity described in subparagraph (B) of paragraph (1) determined by the Inspector General 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.”

- Proposes to interpret “authorities under applicable Federal law” to mean that an appropriate agency may only subject a health care provider to a disincentive established using authorities that could apply to information blocking by a health care provider subject to the authority, such as health care providers participating in a program supported by the authority.
- Proposes that a health care provider would be subject to each appropriate disincentive that an agency has established through notice and comment rulemaking and is applicable to the health care provider.

OIG Investigation and Referral

Overview

- Information in the rule regarding OIG's anticipated approach to information blocking investigations of health care providers is not a regulatory proposal and is provided for information purposes only.
- The Information Blocking Disincentives NPRM summarizes elements of the July 2023 OIG final rule. Please refer to the OIG final rule for more information.

Anticipated Priorities

- For investigations of health care providers, OIG expects to focus on practices that: (i) resulted in, are causing, or have the potential to cause patient harm; (ii) significantly impacted a provider’s ability to care for patients; (iii) were of long duration; and (iv) caused financial loss to Federal health care programs, or other government or private entities.
- OIG requests comment on these priorities.

Coordination with Other Agencies

OIG Investigation and Referral

Anticipated Approach to Referral

- During an investigation of information blocking by a health care provider, but prior to making a referral, OIG will coordinate with the appropriate agency to which OIG plans to refer its determination of information blocking.
- Once OIG has concluded its investigation and is prepared to make a referral, it will send information to the appropriate agency indicating that the referral is made pursuant to the statutory requirement.
- As part of the referral, OIG will provide information to explain its determination, which may include:
  - The dates when OIG has determined the information blocking violation(s) occurred;
  - Analysis to explain how the evidence demonstrates the health care provider committed information blocking (for instance, that the health care provider's "practice" meets each element of the information blocking definition);
  - Copies of evidence collected during the investigation (regardless of whether it was collected by subpoena or voluntarily provided to OIG); and
  - Additional information as part of its referral based on consultation with the appropriate agency, to the extent permitted by applicable law.

General Provisions for Application of Disincentives

- Proposes to list disincentives established for health care providers that commit information blocking in 45 CFR 171.1001(a).

- Proposes that an appropriate agency that imposes a disincentive or disincentives would send a notice (using usual methods of communication) to the health care provider subject to the disincentive or disincentives. This notice would 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 or disincentives 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.

- Notes that a health care provider may have the right to appeal administratively a disincentive if the authority used to establish the disincentive provides for such an appeal.

Transparency for Information Blocking Determinations, Disincentives, and Penalties

- Proposes transparency provisions for all actors, including health care providers, covered by the information blocking regulations, building on information already available on ONC's website about claims of information blocking.
- Proposes to include on ONC's website information about information blocking determinations by OIG, including identifying the information blocking practices, actors who committed information blocking, and any settlements of liability, civil money penalties levied, and disincentives administered.
- Publicly posting information about actors that have been determined by OIG to have committed information blocking is important for providing transparency into how and where information blocking is occurring within and impacting the broader nationwide health information technology infrastructure.

Proposed Disincentive: Medicare Promoting Interoperability Program

- Proposes that an eligible hospital or critical access hospital (CAH) would not be a meaningful EHR user in a calendar year if OIG, during the calendar year of the EHR reporting period, refers a determination that the eligible hospital or CAH committed information blocking.
    - The impact on eligible hospitals would be the loss of 75 percent of the annual market basket increase; for CAHs, payment would be reduced to 100 percent of reasonable costs instead of 101 percent.
- If the eligible hospital or CAH is already not a meaningful EHR user during the applicable EHR reporting period due to its performance in the Medicare Promoting Interoperability Program, imposition of the proposed disincentive would result in no additional impact.
- Regardless of whether multiple information blocking violations were identified as part of OIG's determination (including over multiple years), each referral of an information blocking determination by OIG would only affect an eligible hospital's or CAH's status as a meaningful EHR user in a single EHR reporting period.

Proposed Disincentive: Quality Payment Program

- Proposes that a MIPS eligible clinician would not be a meaningful EHR user in a performance period if OIG, during the calendar year of the performance period, refers a determination that the MIPS eligible clinician committed information blocking.
    - Proposes that the determination by OIG would result in a MIPS eligible clinician that is required to report on the MIPS Promoting Interoperability performance category not earning a score in the performance category (a zero score), which is typically a quarter of the total final score.
- If a MIPS eligible clinician is already not a meaningful EHR user in a performance period, imposition of the proposed disincentive would result in no additional impact.
- Proposes that if data for the MIPS Promoting Interoperability performance category is submitted as a group or virtual group then the application of the disincentive would be made at that level.
- Regardless of whether multiple information blocking violations were identified as part of OIG's determination (including over multiple years), each referral of an information blocking determination by OIG would only affect a MIPS eligible clinician's status as a meaningful EHR user in a single performance period.

Proposed Disincentive: Medicare Shared Savings Program ("SSP")

- Proposes to revise the SSP regulations to establish disincentives for health care providers, including ACOs, ACO participants, and ACO providers/suppliers, that engage in information blocking.
- 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 as an SSP participant for the period of at least 1 year.
- In the case of an ACO applicant that is a health care provider, proposes to deny the ACO's application to participate in the SSP for the upcoming performance year. For ACOs that are already participating in the SSP, CMS may terminate the ACO's participation agreement for the upcoming performance year.
- Restricting the ability of health care providers to participate in the SSP for at least one year would result in these health care providers potentially not receiving revenue that they might otherwise have earned if they had participated in the SSP.
- CMS would determine if it would be appropriate for the period to exceed 1 year if OIG has made any subsequent determinations of information blocking.

Impact of Disincentives

- The actual monetary impact resulting from the application of the proposed disincentives may vary across health care providers subject to the disincentive.

- The proposed rule includes estimates to illustrate the potential impact of two proposed disincentives, including:
  - For eligible hospitals subject to a disincentive under the Medicare Promoting Interoperability Program, we estimated a median disincentive amount of $394,353, and a 95 percent range of $30,406 to $2,430,766 across eligible hospitals.[1]
  - For eligible clinicians subject to a disincentive under the MIPS Promoting Interoperability performance category, we estimated a median individual disincentive amount of $686 and a 95 percent range (the 2.5th to 97.5th percentile of estimated disincentive amounts) of $38 to $7,184.[2]
  - For an estimated median group size of six clinicians, we estimated a group disincentive of $4,116 and a range of $1,372 to $165,326 for group sizes ranging from two to 241 clinicians (the estimated 2.5th to 97.5th percentile of group sizes).[2]

[1]Available at https://www.cms.gov/research-statistics-data-and-systems/downloadable-public-use-files/cost-reports.
[2]2021 Provider Utilization and Payment Data available at https://catalog.data.gov/dataset/medicare-physician-other-practitioners-by-provider-b297e, Overall MIPS Performance Dataset available at https://data.cms.gov/provider-data/dataset/a174-a962, and
Quality Payment Program Experience Dataset available at https://data.cms.gov/quality-of-care/quality-payment-program-experience/data.

Request for Information

- While HHS believes it is important to establish appropriate disincentives that would apply to all health care providers, HHS recognizes that the disincentives proposed in this rule would only apply to a subset of health care providers as defined in 45 CFR 171.102.

- The proposed rule requests information from the public on additional appropriate disincentives that we should consider in future rulemaking, particularly disincentives that would apply to health care providers, as defined in 45 CFR 171.102, that are not implicated by the disincentives proposed in this rule.
  - Encourages commenters to identify specific health care providers (for example, laboratories, pharmacies, post-acute care providers, etc.) and associated potential disincentives using authorities under applicable Federal law.
  - Requests information about the health care providers that HHS should prioritize when establishing additional disincentives.

Resources Available

More information can be found at https://www.healthit.gov/disincentivesrule

> Please submit public comments no later than 11:59 p.m. ET on January 2, 2024.

Questions

Contact ONC

For general policy questions: Alexander.Baker@hhs.gov

Phone: 202-690-7151

Health IT Feedback Form: https://www.healthit.gov/form/healthit-feedback-form

Twitter: @onc_healthIT

LinkedIn: Office of the National Coordinator for Health Information Technology

YouTube: https://www.youtube.com/user/HHSONC

Subscribe to our weekly eblast at healthit.gov for the latest updates!

Contact CMS

For Promoting Interoperability Program & the Promoting Interoperability performance category of Merit-Based Incentive Payment System:

Elizabeth.Holland@cms.hhs.gov

or

Jessica.Warren@cms.hhs.gov

For issues related to the Medicare Shared Savings Program:

SharedSavingsProgram@cms.hhs.gov