

FINAL RULE

21st Century Cures Act:

Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking

JULY 11, 2024

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

The Centers for Medicare & Medicaid Services (CMS)



Please Note:

- The materials contained in this presentation about the “21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking” final rule are based on the document published in the Federal Register on July 1, 2024.
- This communication is produced and disseminated at U.S. taxpayer expense.

Background

- Section 4004 of the Cures Act added section 3022 of the Public Health Service Act (PHSA).
- PHSA 3022 defines information blocking for several types of actor including health care providers.
- 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.
- PHSA 3022 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.”
- PHSA 3022 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.

Disincentives Final Rule Overview

- The 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking final rule published in the Federal Register on July 1, 2024 (89 FR 54662).
- The final rule effective date is 30 days after it is published in the Federal Register (July 31, 2024).
- Continues implementation of section 4004 of the 21st Century Cures Act (2016) and builds on ONC's 21st Century Cures Act Final Rule (2020) and OIG's "Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules" (2023).

Health Care Providers

- For the purposes of information blocking, “health care provider” is defined in [45 CFR 171.102](#) as it is in section 3000 of the Public Health Service Act (PHSA).
- 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 clinical pharmacy
- a laboratory
- renal dialysis facility
- blood center
- emergency medical services provider
- federally qualified health center
- group practice
- a pharmacist
- a physician (as defined 42 U.S.C 1395x(r))
- a practitioner (as described in 42 U.S.C 1395u(b)(18)(C))
- community mental health center (as defined in 42 U.S.C. 300x–2(b)(1))
- ambulatory surgical center described in 42 U.S.C. 1395l(i)
- 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 25 U.S.C. 1603)
- a rural health clinic
- a covered entity under section 42 U.S.C 256b
- an ambulatory surgical center described in 42 U.S.C. 1395l(i)
- a therapist (as defined in 42 U.S.C. 1395w–4(k)(3)(B)(iii)), and
- any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.

For more information see: https://www.healthit.gov/sites/default/files/page2/202008/Health_Care_Provider_Definitions_v3.pdf

Definitions

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.”

- Finalizes that the term “appropriate agency” in 45 CFR 171.102 means a government agency that has established disincentives for health care providers that OIG determines to have committed information blocking.
- Finalizes that the term “disincentive” in 45 CFR 171.102 means a condition specified in § 171.1001(a) that is imposed by an appropriate agency on a health care provider that OIG determines has committed information blocking, for the purpose of deterring information blocking practices.
 - 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.”

- “Authorities under applicable Federal law” means 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.
- A health care provider may be subject to each appropriate disincentive that an agency has established through notice and comment rulemaking and is applicable to the health care provider.
 - This policy was modified from the proposed rule to account for scenarios in which an appropriate agency may exercise discretion to not impose a disincentive.

OIG Investigation and Referral

- Information in the rule regarding OIG's anticipated approach to information blocking investigations of health care providers is not a regulatory provision and is provided for information purposes only.
 - The Information Blocking Disincentives final rule summarizes elements of the July 2023 OIG final rule.
- The final rule states that OIG will not begin investigating health care providers until after the effective date of the final rule, and will exercise its enforcement discretion not to make any determinations regarding conduct occurring prior to the effective date of the rule for information blocking disincentives.
 - This means that no disincentives finalized in this final rule will be applied to conduct occurring before the effective date of this final rule.
- 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 Investigation and 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

- Finalizes specification of disincentives established for health care providers that commit information blocking in 45 CFR 171.1001.
- Finalizes that the appropriate agency that imposes a disincentive or disincentives shall send a notice (using usual methods of communication) to the health care provider subject to the disincentive or disincentives. This 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 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.
- 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

- Finalizes transparency provisions for all actors, including health care providers, subject to the information blocking regulations.
- Finalizes that ONC will publicly post information about actors that have been determined by OIG to have committed information blocking, including identifying the information blocking practices, actors who committed information blocking, disincentives applied (for health care providers), and where to find any other information available about the determination from U.S. government source.
- 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.
- Based on recommendations from the public, ONC modified the transparency provision to clarify that posting of information about a disincentive will not occur until after any available administrative appeals has been completed.

Medicare Promoting Interoperability Program Disincentive

- Finalizes that an eligible hospital or critical access hospital (CAH) that commits information blocking will not be a meaningful EHR user during the calendar year of the EHR reporting period in which OIG refers its determination to CMS.
 - The impact on an eligible hospital will be the loss of 75 percent of the annual market basket increase; for a CAH, payment will 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 disincentive will 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 will only affect an eligible hospital's or CAH's status as a meaningful EHR user in a single EHR reporting period.

Quality Payment Program Disincentive

- Finalizes that a MIPS eligible clinician (including a group practice) that commits information blocking will not be a meaningful EHR user during the calendar year of the performance period in which OIG refers its determination to CMS.
 - The impact on a MIPS eligible clinician that is required to report on the MIPS Promoting Interoperability performance category will be 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 disincentive will result in no additional impact.
- CMS finalizes that only the individual that has committed information blocking will be subject to a disincentive, even if the individual reports as part of a group, modifying the proposed rule policy.
- 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 will only affect a MIPS eligible clinician's status as a meaningful EHR user in a single performance period.

Medicare Shared Savings Program ("Shared Savings Program") Disincentive

- Finalizes revisions to the Shared Savings Program regulations to establish disincentives for health care providers, including ACOs, ACO participants, and ACO providers/suppliers, that engage in information blocking.
- CMS will 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 a Shared Savings Program participant for the period of at least 1 year.
- In the case of an ACO applicant that is a health care provider, CMS may deny the ACO's application to participate in the Shared Savings Program for the upcoming performance year. For ACOs that are already participating in the Shared Savings Program, CMS may terminate the ACO's participation agreement.
- CMS finalizes the alternative policy discussed in the proposed rule to consider an OIG information blocking determination in light of the relevant facts and circumstances (such as 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, whether the provider was previously subject to a disincentive in another program, and other factors) before applying a disincentive.
- Restricting the ability of health care providers to participate in the Shared Savings Program for at least one year will result in these health care providers potentially not receiving revenue that they might otherwise would have earned if they had participated in the Shared Savings Program.
- CMS will determine if it would be appropriate for the period to exceed 1 year if OIG has made any subsequent determinations of information blocking.

Request for Information

- The disincentives finalized in this rule would only apply to a subset of health care providers. However, HHS believes it is important to establish appropriate disincentives that would apply to all health care providers as defined in 45 CFR 171.102.
- The proposed rule requested information from the public on additional appropriate disincentives to 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 in this rule.
 - Encouraged 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.
 - Requested information about the health care providers that HHS should prioritize when establishing additional disincentives.
- HHS will continue to explore establishment of additional disincentives through future rulemaking.

Resources Available

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

Questions



Contact ONC

For general issues regarding the final rule:

Alexander.Baker@hhs.gov



Phone: 202-690-7151



Health IT Feedback Form:

<https://www.healthit.gov/form/healthit-feedback-form>



Twitter: [@onc_healthIT](https://twitter.com/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