(1) To resolve a hold, if an article of food is held under paragraph (b) of this section because it is from a foreign facility that is not registered, the facility must be registered, and a valid registration number must be obtained and submitted to the FDA Division of Food Defense Targeting within 30 calendar days from the date the notice of hold was issued.

* * * * *

Dated: October 26, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2023–24086 Filed 10–31–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 414, 425, and 495

Office of the Secretary

45 CFR Part 171

RIN 0955–AA05

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

AGENCY: Centers for Medicare & Medicaid Services (CMS) and Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement the provision of the 21st Century Cures Act specifying that a health care provider determined by the HHS Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives set forth through notice and comment rulemaking. In particular, this rulemaking would establish for such health care providers a set of appropriate disincentives using authorities under applicable Federal law.

DATES: To be assured consideration, written or electronic comments must be received at one of the addresses provided below, no later than 5 p.m. on January 2, 2024.

ADDRESSES: You may submit comments, identified by RIN 0955–AA05, by any of the following methods (please do not submit duplicate comments). Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

- *Federal eRulemaking Portal:* Follow the instructions for submitting comments. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word. *https://www.regulations.gov.*
- *Regular, Express, or Overnight Mail:* Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, Attention: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking Proposed Rule, Mary E. Switzer Building, Mail Stop: 7033A, 330 C Street SW, Washington, DC 20201. Please submit one original and two copies.
- *Inspection of Public Comments:* All comments received before the close of the comment period will be available for public inspection, including any personally identifiable or confidential business information that is included in a comment. Please do not include anything in your comment submission that you do not wish to share with the general public. For example, people typically do not wish to, and generally should not, share with the general public information such as: any person's social security number; date of birth; driver's license number; state identification number or foreign country equivalent; passport number; financial account number; credit or debit card number; individually identifiable health information; or any business information that could be considered proprietary. We will post all comments that are received before the close of the comment period at *https://www.regulations.gov.*
- *Docket:* For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Alexander Baker, Office of Policy, Office of the National Coordinator for Health Information Technology (ONC), (202) 690–7151, for general issues.

Elizabeth Holland, Centers for Medicare & Medicaid Services (CMS), (443) 934–2532, for issues related to the Promoting Interoperability Program and the Promoting Interoperability performance category of the Merit-Based Incentive Payment System.

Aryanna Abouzari, Centers for Medicare & Medicaid Services (CMS), (415) 744–3668 or *SharedSavingsProgram@cms.hhs.gov,* for issues related to the Medicare Shared Savings Program.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of Regulatory Action

This proposed rule would implement the 21st Century Cures Act (Cures Act) provision for referral of a health care provider (individual or entity) determined by the HHS Office of Inspector General (OIG) 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'' (42 U.S.C. 300jj–52(b)(2)(B), Public Health Service Act (PHSA) section 3022(b)(2)(B), as added by section 4004 of the Cures Act (Pub. L. 114–255, Dec. 13, 2016)). The proposals in this rule would establish disincentives for certain health care providers (as defined in 45 CFR 171.102) that are also Medicare-enrolled providers or suppliers.

B. Summary of Major Provisions

This proposed rule would establish disincentives applicable to certain health care providers (as defined in 45 CFR 171.102) determined by OIG to have committed information blocking (as defined in 45 CFR 171.103) that are also Medicare-enrolled providers or suppliers. The proposed rule also provides information related to OIG's investigation of claims of information blocking and referral of a health care provider to an appropriate agency to be subject to appropriate disincentives. Finally, the rule proposes to establish a process by which information would be shared with the public about health care providers that OIG determines have committed information blocking.

Although the proposals in this rule would not establish disincentives for all of the health care providers included in the 45 CFR 171.102 definition, the health care providers to whom these disincentives would apply furnish a broad array of services to a significant number of both Medicare beneficiaries and other patients. Thus, this set of disincentives would directly advance HHS priorities for deterring information blocking, while also advancing appropriate sharing of electronic health information (EHI) by health care providers [1] to support safer, more coordinated care for all patients.

We believe it is important to establish appropriate disincentives that account for all health care providers that fall within the definition of health care provider (45 CFR 171.102). While effective deterrence of information blocking can benefit patients by reducing the degree to which health care providers engage in this practice, fewer patients will benefit from these deterrent effects if disincentives have not been established for all of the health care providers within the definition of health care provider at 45 CFR 171.102. In section IV. of this proposed rule, we request information on how we can build on the proposals in this rule to establish disincentives for other health care providers, particularly those health care providers not participating in the CMS programs identified in this rule.

Consistent with PHSA section 3022(b)(2)(B), the proposals in this rule to establish disincentives use authorities under applicable Federal law, as follows:

- Under the authority for the Medicare Promoting Interoperability Program in the Social Security Act (SSA), at sections 1886(b)(3)(B)(ix) and 1886(n) for eligible hospitals, and at section 1814(l)(4) for critical access hospitals (CAHs), CMS proposes that an eligible hospital or CAH would not be a meaningful electronic health record (EHR) user in an EHR reporting period if OIG refers, during the calendar year of the reporting period, a determination that the eligible hospital or CAH committed information blocking as defined at 45 CFR 171.103. As a result, an eligible hospital subject to this disincentive would not be able to earn the three quarters of the annual market basket increase associated with qualifying as a meaningful EHR user, while a CAH subject to this disincentive would have its payment reduced to 100 percent of reasonable costs, from the 101 percent of reasonable costs it might have otherwise earned, in an applicable year.
- Under the authority in SSA sections 1848(o)(2)(A) and (D) and 1848(q)(2)(A)(iv) and (B)(iv), for the Promoting Interoperability performance category of the Merit-based Incentive Payment System (MIPS), CMS proposes that a health care provider defined in 45 CFR 171.102 that is a MIPS eligible clinician (as defined in 42 CFR 414.1305 and including groups) would not be a meaningful EHR user in a performance period if OIG refers, during the calendar year of the reporting period, a determination that the MIPS eligible clinician committed information blocking as defined at 45 CFR 171.103. CMS also proposes that the determination by OIG that a MIPS eligible clinician committed information blocking would result in the MIPS eligible clinician, if required to report on the Promoting Interoperability performance category of MIPS, not earning a score in the performance category (a zero score), which is typically a quarter of the total final composite performance score (a ''final score'' as defined at 42 CFR 414.1305). CMS proposes to codify this proposal under the definition of meaningful EHR user for MIPS at 42 CFR 414.1305 and add it to the requirements for earning a score for the MIPS Promoting Interoperability performance category at 42 CFR 414.1375(b).
- Under the authority in SSA section 1899(b)(2)(G) for the Medicare Shared Savings Program (Shared Savings Program), CMS proposes that a health care provider as defined in 45 CFR 171.102 that is an accountable care organization (ACO), ACO participant, or ACO provider/supplier, if determined by OIG to have committed information blocking as defined at 45 CFR 171.103, would be barred from participating in the Shared Savings Program for at least 1 year. This may result in a health care provider being removed from an ACO or prevented from joining an ACO; and in the instance where a health care provider is an ACO, this would prevent the ACO's participation in the Shared Savings Program.

C. Costs and Benefits

Executive Order 12866 on Regulatory Planning and Review and Executive Order 13563 on Improving Regulation and Regulatory Review direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866, as amended by Executive Order 14094, defines a ''significant regulatory action'' as an action that is likely to result in a rule that may: (1) have an annual effect on the economy of $200 million or more (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive Order, as specifically authorized in a timely manner by the Administrator of OIRA in each case. The Office of Management and Budget (OMB) has determined that this proposed rule is not a significant regulatory action, as the potential costs associated with this proposed rule would not be greater than $200 million per year and it does not meet any of the other requirements to be a significant regulatory action.

[1] Except if or as necessitated by the specific terminology of a particular statutory authority or CFR section, we use in this rule ''health care provider,'' ''provider,'' and ''provider type'' as inclusive of individuals and entities that may be characterized for purposes of Medicare enrollment or particular reimbursement policies as providers or suppliers—or both across different contexts such as specific services furnished in particular settings.

II. Background

A. Statutory Basis

The Cures Act was enacted on December 13, 2016, ''[t]o accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.'' Section 4004 of the Cures Act added section 3022 to the PHSA. Section 3022(a)(1) of the PHSA defines information blocking as 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. If the practice is conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information. If the practice is conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information. Section 3022(a)(3) of the PHSA further provides that the Secretary shall, through rulemaking, identify reasonable and necessary activities that do not constitute information blocking. Section 3022(a)(4) of the PHSA states that the term ''information blocking'' does not include any practice or conduct occurring prior to the date that is 30 days after December 13, 2016 (the date of the enactment of the Cures Act).[2] Section 3022(a)(2) of the PHSA describes certain practices that may constitute information blocking.

Section 3022(b)(1) of the PHSA authorizes OIG to investigate information blocking claims. Section 3022(b)(1)(B) of the PHSA authorizes OIG to investigate claims that ''a health care provider engaged in information blocking.'' Section 3022(b)(2)(B) of the PHSA provides that any health care provider 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. Sections 3022(b)(1)(A) and (C) of the PHSA authorize OIG to investigate health information technology (IT) developers of certified health IT or other entities offering certified health IT, health information exchanges, and health information networks. Section 3022(b)(2)(A) of the PHSA authorizes the imposition of civil money penalties (CMPs)[3] not to exceed $1 million per violation on those individuals and entities set forth in sections 3022(b)(1)(A) and (C) of the PHSA.

PHSA section 3022 also authorizes ONC, the HHS Office for Civil Rights (OCR), and OIG to consult, refer, and coordinate to resolve claims of information blocking. PHSA section 3022(b)(3)(A) authorizes OIG to refer claims of information blocking to OCR if OIG determines a consultation regarding the health privacy and security rules promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (42 U.S.C. 1320d–2 note) will resolve such claims. PHSA section 3022(d)(1) specifies that the National Coordinator may serve as a technical consultant to OIG and the Federal Trade Commission (FTC) for purposes of carrying out section 3022 and may share information related to claims or investigations of information blocking with the FTC for purposes of such investigations, in addition to requiring the National Coordinator to share information with OIG, as required by law.

PHSA section 3022(d)(4) requires the Secretary, in carrying out section 3022 and to the extent possible, to ensure that information blocking penalties do not duplicate penalty structures that would otherwise apply with respect to information blocking and the type of individual or entity involved as of the day before the date of enactment of the Cures Act. Section 3022(a)(7) of the PHSA states that, in carrying out section 3022, the Secretary shall ensure that health care providers are not penalized for the failure of developers of health information technology or other entities offering health information technology to such providers to ensure that such technology meets the requirements to be certified under Title XXX of the PHSA.

We address the statutory basis for each proposed disincentive in greater detail in section III.C. of this proposed rule.

B. Regulatory History

1. ONC Cures Act Final Rule

On March 4, 2019, a proposed rule titled ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (ONC Cures Act Proposed Rule) appeared in the **Federal Register** (84 FR 7424). The rule proposed to implement certain provisions of the Cures Act to advance interoperability and support the access, exchange, and use of electronic health information. The ONC Cures Act Proposed Rule included a request for information regarding potential disincentives for health care providers that have committed information blocking and asked whether modifying disincentives already available under existing Department programs and regulations would provide for more effective deterrence (84 FR 7553).

On May 1, 2020, a final rule titled ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (ONC Cures Act Final Rule) appeared in the **Federal Register** (85 FR 25642). The final rule identified eight reasonable and necessary activities that do not constitute information blocking, consistent with the requirement in PHSA section 3022(a)(3). Such reasonable and necessary activities are often referred to as ''exceptions'' to the definition of information blocking, or ''information blocking exceptions,'' as specified in 45 CFR part 171.

The ONC Cures Act Final Rule finalized definitions that are necessary to implement the statutory information blocking provision in PHSA section 3022, including definitions related to the four classes of individuals and entities covered by the statutory information blocking provision: health care providers, health IT developers, health IT networks, and health IT exchanges.

As the term ''health care provider'' is not explicitly defined in section 3022 of the PHSA as added by section 4004 of the Cures Act, the ONC Cures Act Final Rule adopted in 45 CFR 171.102 the definition of health care provider in section 3000(3) of the PHSA[4] for

[2] As January 12, 2017, was the thirtieth day after December 13, 2016, conduct occurring on or after January 13, 2017, that otherwise meets the PHSA section 3022(a) definition of ''information blocking,'' would be included in that definition.

[3] ONC uses the term ''civil money penalty'' here, rather than ''civil monetary penalty'' as used in PHSA section 3022(b)(2)(A) for consistency with OIG's usage in the OIG CMP Final Rule (88 FR 42820).

[4] As defined in 42 U.S.C 300–jj, the term ''health care provider'' includes a 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

Continued

purposes of the information blocking regulations in 45 CFR part 171. ONC noted that the definitions listed in section 3000 of the PHSA apply ''[i]n this title,'' which refers to Title XXX of the PHSA (85 FR 25795). Section 3022 of the PHSA is included in Title XXX. Since adopting a definition of health care provider in the ONC Cures Act Final Rule, the Secretary has not proposed to modify the definition for purposes of the information blocking regulations.

The ONC Cures Act Final Rule also established in 45 CFR 171.102 regulatory definitions for ''health information network or health information exchange'' and ''health IT developer of certified health IT,'' [5] among other terms.[6] The preamble text of the ONC Cures Act Final Rule makes clear that an individual or entity could meet both the definition of a health care provider and the definition of a health IT developer of certified health IT (85 FR 25798 through 25799) or could meet both the definition of a health care provider and a health information exchange or network (85 FR 25801). We mention these potential scenarios so that health care providers are aware that they would not necessarily only be subject to the disincentives proposed in this rule (should they be finalized), but depending on the specific facts and circumstances, they could meet the definition of a health information network or exchange, and therefore be subject to civil money penalties, if found by OIG to have committed information blocking.

On November 4, 2020, an interim final rule with comment period titled ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency'' (ONC Cures Act Interim Final Rule) appeared in the **Federal Register** (85 FR 70064). The ONC Cures Act Interim Final Rule extended certain compliance dates and timeframes adopted in the ONC Cures Act Final Rule to offer the healthcare system additional flexibilities in furnishing services to combat the COVID–19 pandemic, including extending the applicability date for the information blocking provisions to April 5, 2021 (85 FR 70068). The ONC Cures Act Interim Final Rule also extended from May 2, 2022, to October 6, 2022, the date on which electronic health information as defined in 45 CFR 171.102 for purposes of the information blocking definition in 45 CFR 171.103 would no longer be limited to the subset of EHI that is identified by data elements represented in the United States Core Data for Interoperability (USCDI) standard adopted in 45 CFR 170.213 (85 FR 70069).[7] On and after October 6, 2022, practices likely to interfere with access, exchange, or use of any information falling within the definition of EHI in 45 CFR 171.102 may constitute information blocking as defined in 45 CFR 171.103.

2. Office of Inspector General (OIG) Civil Money Penalties (CMP) Final Rule

On April 24, 2020, a proposed rule titled ''Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Revisions to the Office of Inspector General's Civil Money Penalty Rules'' (OIG CMP Proposed Rule) appeared in the **Federal Register** (85 FR 22979). The OIG CMP Proposed Rule set forth proposed regulations to incorporate new CMP authority for information blocking and related procedures at PHSA sections 3022(b)(2)(A) and (C) (88 FR 42825). Specific to information blocking, OIG also provided information on—but did not propose regulations for—expected enforcement priorities, the investigation process, and OIG's experience with investigating conduct that includes an intent element (88 FR 42822).

OIG subsequently addressed these proposals in a final rule, ''Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules,'' which appeared in the **Federal Register** on July 3, 2023 (OIG CMP Final Rule) (88 FR 42820). This rulemaking addressed imposition of CMPs for information blocking by health IT developers or other entities offering certified health IT, health information exchanges, and health information networks. The OIG CMP Final Rule did not establish appropriate disincentives for health care providers that OIG has determined have committed information blocking.

As mentioned above, a health care provider that also meets the definition of health IT developer of certified health IT, or health information network or health information exchange, or both, under 45 CFR 171.102, may be subject to information blocking CMPs (88 FR 42828). OIG has stated that as part of its assessment of whether a health care provider is a health information network or exchange that could be subject to civil money penalties for information blocking, OIG anticipates engaging with the health care provider to better understand its functions and to offer the provider an opportunity to explain why it is not a health information network or exchange (88 FR 42828).

III. Provisions of the Proposed Regulation

A. Relevant Statutory Terms and Provisions

In this section, we discuss certain statutory terms and provisions in PHSA sections 3022(a) and (b) related to the establishment of appropriate disincentives for health care providers as defined in 45 CFR 171.102. For brevity, we refer to PHSA section 3022(b)(2)(B), which states that health care providers that OIG has determined 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,'' as the ''disincentives provision'' throughout this section.

section 1395x(r) of the title), a practitioner (as described in section 1395u(b)(18)(C) of the 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 5), 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 the title), and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary. See also this guidance document: *https://www.healthit.gov/sites/default/files/page2/2020-08/Health_Care_Provider_Definitions_v3.pdf.*

[5] In the ONC Cures Act Final Rule, ONC defined the term ''health IT developer of certified health IT'' in 45 CFR 171.102, instead of using the term that appears in PHSA 3022(a)(1): ''health IT developer.'' ONC explained that, because title XXX of the PHSA does not define ''health information technology developer,'' ONC interpreted section 3022(a)(1)(B) in light of the specific authority provided to OIG in section 3022(b)(1)(A) and (b)(2). ONC noted that section 3022(b)(2) discusses developers, networks, and exchanges by referencing any individual or entity described in section 3022(b)(1)(A) or (C). Section 3022(b)(1)(A) states, in relevant part, that OIG may investigate any claim that *a health information technology developer of certified health information technology* or other entity offering certified health information technology engaged in information blocking (85 FR 25795, emphasis added).

[6] In 2023, ONC has proposed to establish a definition of what it means to ''offer'' certified health IT, and to make a corresponding update to the health IT developer of certified health IT definition. These proposals are part of a proposed rule titled ''Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing'' (88 FR 23746) (HTI–1 Proposed Rule). The comment period on the HTI–1 Proposed Rule ended June 20, 2023. Public Comments are posted as part of docket HHS–ONC–2023–0007, see *https://www.regulations.gov/docket/HHS-ONC-2023-0007/comments.*

[7] For more information about the USCDI, see *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

1. Appropriate Agency

The disincentives provision states that an individual or entity that is a health care provider determined by OIG to have committed information blocking shall be referred to the ''appropriate agency'' to be subject to appropriate disincentives. Accordingly, we propose 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. We note that, under the disincentives provision, an ''agency'' may be any component of HHS that has established a disincentive or disincentives on behalf of the Secretary of HHS, including any of the Staff or Operating Divisions of HHS. For example, the disincentives proposed in section III.C. of this proposed rule are proposed under authorities held by CMS, which is an Operating Division of HHS. Under our proposals, CMS would be the ''appropriate agency'' to which OIG would refer a health care provider to be subject to disincentives.

We invite public comments on our proposed definition of ''appropriate agency.''

2. Authorities Under Applicable Federal Law

We propose to interpret the phrase ''authorities under applicable Federal law'' in the disincentives provision 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. In section III.C. of this proposed rule, CMS identifies the authority under which each disincentive is proposed.

3. Appropriate Disincentives

The Cures Act does not specify or provide illustrations for the types of disincentives that should be established. As such, we propose 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). In section III.B.2 of this proposed rule, we propose to identify in 45 CFR 171.1001(a) those disincentives that have been established pursuant to the statute for the express purpose of deterring information blocking practices.

The term ''appropriate'' for disincentives is likewise not defined in PHSA section 3022, nor are illustrations provided. Under this proposal, a 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. In section III.C. of this proposed rule, we describe the potential impact that each proposed disincentive would have on a health care provider.

We note that the disincentives provision does not limit the number of disincentives that an appropriate agency can impose on a health care provider. Accordingly, we propose 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. Imposing cumulative disincentives, where applicable, would further deter health care providers from engaging in information blocking.

We invite public comments on our proposals to establish disincentives in section III.C. of this proposed rule.

B. Approach To Determination of Information Blocking and Application of Disincentives

In this section we provide additional detail about the process by which a health care provider that has committed information blocking would be subject to appropriate disincentives for information blocking. We begin with a discussion of an OIG investigation of a claim of information blocking, which may result in OIG determining that the health care provider committed information blocking. We then discuss how OIG would refer the health care provider to an appropriate agency. Next, we address certain general issues related to the application of a disincentive by an appropriate agency. Finally, we propose an approach to make information available to the public about health care providers that have been subject to an appropriate disincentive for information blocking, and about health information networks/health information exchanges and health IT developers of certified health IT that have been determined by OIG to have committed information blocking.

1. OIG Investigation and Referral

The following information 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. This preamble discussion of investigation priorities for health care provider information blocking claims is not binding on OIG and HHS. It does not impose any legal restrictions related to OIG's discretion to choose which health care provider information blocking complaints to investigate.

a. Anticipated Priorities

As with other conduct that OIG has authority to investigate, OIG has discretion to choose which information blocking complaints to investigate. To maximize efficient use of resources, OIG generally focuses on selecting cases for investigation that are consistent with its enforcement priorities and intends to apply that rationale to its approach for selecting information blocking complaints for investigation. In the OIG CMP Final Rule, OIG described its enforcement priorities for health IT developers of certified health IT or other entities offering certified health IT, health information exchanges, and health information networks that have committed information blocking and are subject to CMPs. OIG stated that its information blocking CMP enforcement priorities will include 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; (iv) caused financial loss to Federal healthcare programs, or other government or private entities; or (v) were performed with actual knowledge. OIG stated that it expected these priorities will evolve as it gains more experience investigating information blocking (88 FR 42822).

For investigations of health care providers, OIG expects to use four of these priorities: (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. Again, although not a regulatory proposal, OIG welcomes comments on these priorities, including comments on whether other issues specific to information blocking by health care providers should warrant changing these priorities or adding others.

OIG emphasizes that information blocking, as defined in PHSA section 3022(a)(1) and in 45 CFR 171.103, includes an element of intent. The standard of intent for health care providers was established by the Cures Act in PHSA section 3022(a)(1)(B)(ii): ''if conducted by a health care provider,

such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.'' This is different from the standard of intent in PHSA section 3022(a)(1)(B)(i): ''if conducted by a health information technology developer, exchange, or network, such developer, exchange, or network knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange, or use of electronic health information.'' The different intent standard for information blocking by a health care provider is why OIG does not expect to use ''actual knowledge'' as an enforcement priority. OIG has significant experience and expertise investigating and determining whether to take an enforcement action based on other laws that are intent-based (for example, the Federal anti-kickback statute, and Civil Monetary Penalties Law, 42 U.S.C. 1320a–7b(b) and 1320a–7a). This history will inform the use of OIG's discretion to investigate health care providers that OIG believes may have the requisite intent.

As noted in the OIG CMP Final Rule (88 FR 42822), explanation of OIG's priorities can provide the public with a better understanding of how OIG anticipates allocating its resources for information blocking enforcement. Applicable to this proposed rule, explanation of OIG's priorities can provide the public with a better understanding of how OIG anticipates allocating its resources to investigate claims that health care providers engaged in information blocking. Prioritization ensures OIG can effectively allocate its resources to target information blocking claims that have more negative effects on patients, providers, and healthcare programs. OIG's enforcement priorities will inform its decisions about which information blocking allegations to pursue, but these priorities are not dispositive. Each allegation will present unique facts and circumstances that must be assessed individually. Each allegation will be assessed to determine whether it implicates one or more of the enforcement priorities, or otherwise merits further investigation and potential enforcement action. Although OIG's anticipated priorities are framed around individual allegations, OIG may evaluate allegations and prioritize investigations based in part on the volume of claims relating to the same (or similar) practices by the same entity or individual (for example, a health care provider or health information network). There is no specific formula OIG can apply to every allegation that allows it to effectively evaluate and prioritize which claims merit investigation.

b. Coordination With Other Agencies

In this section we summarize the discussion in the OIG CMP Final Rule of the ways ONC, OCR, and OIG will consult, refer, and coordinate on information blocking claims as permitted by the Cures Act (88 FR 42823).

PHSA section 3022(d)(1) states that the National Coordinator may serve as a technical consultant to the Inspector General. OIG will accordingly consult with ONC throughout the investigative process. Additionally, PHSA section 3022(b)(3)(A) provides the option for OIG to refer claims of information blocking to OCR when a consultation regarding the health privacy and security rules promulgated under section 264(c) of HIPAA will resolve such claims. Depending on the facts and circumstances of the claim, OIG will exercise this statutory discretion as appropriate to refer information blocking claims to OCR for resolution. There is no set of facts or circumstances that will always be referred to OCR. OIG will work with OCR to determine which claims should be referred to OCR under the authority provided in PHSA section 3022(b)(3)(A). In addition to section 3022(b)(3)(A), OIG may request technical assistance from OCR during an information blocking investigation. It is important to note that while section 3022(b)(3)(A) of the PHSA specifically provides OIG with the authority to refer information blocking claims to OCR, OIG's statutory authority to refer to OCR allegations of violations of the HIPAA Privacy, Security, or Breach Notification Rules [8] is not solely based on PHSA section 3022(b)(3)(A). Thus, OIG's authority to refer to OCR such allegations against health care providers is not limited to claims of information blocking.

Finally, OIG stated that it anticipates coordinating with other HHS agencies to avoid duplicate penalties as identified in section 3022(d)(4) of the PHSA. Depending on the facts and circumstances, OIG stated that it might also consult or coordinate with a range of other government agencies, including CMS, FTC, or others (88 FR 42824).

c. 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. This coordination will ensure that the appropriate agency is aware of a potential referral and that OIG provides the information the agency needs to take appropriate action. OIG's referral to the appropriate agency will explain its determination that a health care provider committed information blocking, including meeting the requirements of the intent element of PHSA section 3022(a)(1)(B)(ii).

We note that PHSA section 3022 authorizes OIG to investigate claims of information blocking and requires OIG to refer health care providers to an appropriate agency when it determines a health care provider has committed information blocking, to be subject to appropriate disincentives. 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 in PHSA section 3022(b)(2)(B). 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'' [9] 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); copies of transcripts and video recordings (if applicable) of any witness and affected party testimony; and copies of documents OIG relied upon to make its determination that information blocking occurred. OIG may provide additional information as part of its referral based on consultation with the appropriate agency, to the extent permitted by applicable law.

2. General Provisions for Application of Disincentives

Following an investigation through which OIG determines a health care provider has committed information blocking, and OIG's referral of this determination to an appropriate agency, the health care provider would be subject to disincentives that have been

[8] 45 CFR parts 160 and 164, subparts A, C, D, and E.

[9] *Practice,* as defined in 45 CFR 171.102, means an act or omission by an actor (health care provider, health IT developer of certified health IT, health information network or health information exchange).

established under applicable Federal law through notice and comment rulemaking. In this section, we include general proposals and information related to the application of disincentives. For information on the specific disincentives proposed in this rule and further discussion about how each disincentive would be applied, we refer readers to section III.C.

We propose to add a new subpart J to 45 CFR part 171, entitled ''Disincentives for Information Blocking by Health Care Providers.'' As proposed in 45 CFR 171.1000, this subpart would set forth disincentives that an appropriate agency would impose on a health care provider based on a determination of information blocking referred to that agency by OIG, and certain procedures related to those disincentives. We propose in 45 CFR 171.1001(a) that health care providers that commit information blocking would be subject to the following disincentives from an appropriate agency based on a determination of information blocking referred by OIG, where applicable. The disincentives proposed for inclusion in 45 CFR 171.1001(a)(1) through (3) correspond to the appropriate disincentives proposed in section III.C. of this proposed rule, which include:

- An eligible hospital or CAH as defined in 42 CFR 495.4 is not a meaningful EHR user as also defined in that section;
- A MIPS eligible clinician as defined in 42 CFR 414.1305, who is also a health care provider as defined in 45 CFR 171.102, is not a meaningful EHR user for MIPS as also defined in 42 CFR 414.1305; and
- ACOs who are health care providers as defined in 45 CFR 171.102, ACO participants, and ACO providers/supplies will be removed from, or denied approval to participate, in the Medicare Shared Savings Program as defined in 42 CFR part 425 for at least 1 year.

In the future, if we propose to establish additional disincentives, we intend to add such disincentives to the disincentives listed in 45 CFR 171.1001(a).

We propose in 45 CFR 171.1002(a) through (d) that an appropriate agency that imposes a disincentive or disincentives in § 171.1001(a) would send a notice (using usual methods of communication for the program or payment system) 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.

The information in this notice would be based upon the authority used to establish the disincentive and policy finalized by the agency establishing the disincentive. For instance, the notice may contain specific information regarding when a disincentive would be imposed, which may be contingent on both the authority used to establish the disincentive and the specific policy under which the disincentive is established. We note that, where a health care provider that has been determined to have committed information blocking is subject to multiple disincentives established by an appropriate agency, nothing in this proposal would prevent the appropriate agency from combining these notices into a single communication.

Following the application of a disincentive, a health care provider, as defined in 45 CFR 171.102, may have the right to appeal administratively a disincentive if the authority used to establish the disincentive provides for such an appeal. We note that PHSA section 3022(b)(2)(C) requires that the imposition of CMPs that apply to health IT developers of certified health IT, and health information networks or health information exchanges, that have committed information blocking, follow the procedures of SSA section 1128A, which includes procedures for appeals. However, the Cures Act did not provide similar instruction regarding appeals of disincentives for health care providers established under PHSA section 3022(b)(2)(B). Therefore, any right to appeal administratively a disincentive, if available, would be provided under the authorities used by the Secretary to establish the disincentive through notice and comment rulemaking.

3. Transparency for Information Blocking Determinations, Disincentives, and Penalties

We believe that it is important to promote transparency about how and where information blocking is impacting the nationwide health information technology infrastructure. Publicly releasing information, including applicable public settlements, penalties, and disincentives, about actors that have been determined by OIG to have committed information blocking can inform the public about how and where information blocking is occurring within the broader health information technology infrastructure.

PHSA section 3001(c)(4) requires that the National Coordinator maintain an internet website ''to ensure transparency in promotion of a nationwide health information technology infrastructure.'' We believe this provision provides the National Coordinator with the authority to post information on ONC's website if that information has an impact on issues relating to transparency in the promotion of a nationwide health information technology infrastructure. We propose to add a new subpart K to 45 CFR part 171, entitled ''Transparency for Information Blocking Determinations, Disincentives, and Penalties.'' As proposed in 45 CFR 171.1100, this subpart would set forth the information that would be publicly posted on ONC's website about actors that have been determined by OIG to have committed information blocking.

We propose in 45 CFR 171.1101 that, in order to provide insight into how and where information blocking conduct is impacting the broader nationwide health information technology infrastructure, ONC would post on its public website information about actors that have been determined by OIG to have committed information blocking. For health care providers that are subject to a disincentive, we propose in 45 CFR 171.1101(a)(1) that the following information would be posted: health care provider's name, business address (to ensure accurate provider identification), the practice found to have been information blocking, the disincentive(s) applied, and where to find additional information, where available, about the determination of information blocking that is publicly available via HHS or another part of the U.S. Government. We propose in 45 CFR 171.1101(a)(2) that the information specified in 45 CFR 171.1101(a)(1) would not be posted prior to a disincentive being imposed and would not include information about a disincentive that has not been applied. We also recognize that under the authorities for the disincentives proposed in section III.C. of this proposed rule, an appropriate agency may have other obligations related to release of information about a participant that is a health care provider (as defined in 45 CFR 171.102) in programs under that authority. For instance, under SSA section 1848(q)(9)(C), MIPS eligible clinicians have a right to review information about their performance in MIPS prior to having this information publicly posted

on the Compare Tool in accordance with 42 CFR 414.1395. Therefore, we propose in 45 CFR 171.1101(a)(3) that posting of the information about health care providers that have been determined to have committed information blocking and have been subject to a disincentive would be conducted in accordance with existing rights to review information that may be associated with a disincentive specified in 45 CFR 171.1001. For instance, where a health care provider, as defined in 45 CFR 171.102, has a statutory right to review performance information, this existing right would be exercised prior to public posting of information regarding information blocking on the website described above.

In order to provide insight into how and where information blocking conduct is impacting the broader nationwide health information technology infrastructure, we also propose in 45 CFR 171.1101(b)(1) to post on ONC's public website information specified in 45 CFR 171.1101(b)(1) about health information networks (HINs)/health information exchanges (HIEs) and health IT developers of certified health IT that have been determined by OIG to have committed information blocking and have either resolved their civil money penalty (CMP) liability with OIG or had a CMP imposed by OIG for information blocking under subpart N of 42 CFR part 1003. To ensure accurate identification of actors, we propose in 45 CFR 171.1101(b)(1) to post the type of actor (*e.g.,* HIN/HIE or health IT developers of certified health IT) and the actor's legal name, including any alternative or additional trade name(s) under which the actor operates.

The last information we propose to post on our public website, for all actors, would be the two types of information mentioned above regarding health care providers. First, in 45 CFR 171.1101(a)(1)(iii) and (b)(1)(iii), we propose to post, a description of the practice, as the term is defined in 45 CFR 171.102 and referenced in 45 CFR 171.103, found to have been information blocking. In the case of a resolved CMP liability, we would post the practice alleged to be information blocking. This information will help provide transparency into how information blocking conduct is impacting the nationwide health information technology infrastructure, and in particular, specific practices that are impacting the infrastructure. Second, in 45 CFR 171.1101(a)(1)(v) and (b)(1)(iv), we propose to post where to find additional information about the determination (or resolution of CMP liability) of information blocking that is publicly available via HHS or, where applicable, another part of the U.S. Government. This information could include hyperlinks and other information, to help interested persons find any additional information about the determination, settlement, penalty, or disincentive that has been made publicly available by the U.S. Government. Such publicly available information would include any summaries or media releases that may be posted by OIG, or another part of HHS, on their internet website(s). It could also include additional information that may be made publicly available about the determination by or other parts of the U.S. Government. For example, if an actor who has exhausted applicable administrative appeal procedures and brought action in a Federal court for review of the decision that has become final, we could post information on our website about the existence of the court action and where or how to access information about the determination, or resulting court action, that has been made publicly available by the court. This information would provide additional context for how information blocking conduct is impacting the nationwide health information technology infrastructure.

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 conduct is occurring within and impacting the broader nationwide health information technology infrastructure. Between April 5, 2021, and September 30, 2023, we received over 800 claims of information blocking through the Report Information Blocking Portal.[10] We have publicly posted information about these claims, which we update monthly. Beyond posting the number of claims, the posted information includes claim counts by type of claimant and claim counts by potential actor.[11] While OIG has not necessarily evaluated whether these claims qualify as information blocking, this information provides transparency about how participants in the nationwide health IT infrastructure perceive actions by actors that are part of the same infrastructure, which is intended to support the access, exchange, and use of EHI. A natural progression of the posting of such information is the posting of information about actual information blocking determinations by OIG, including any settlements of liability, civil money penalties, and disincentives. This information can help the public understand how the information blocking regulations, which seek to prevent and address practices that unreasonably or unnecessarily interfere with lawful access, exchange, or use of EHI through the nationwide health IT infrastructure, are being enforced. It would also provide clarity regarding how and where actors are engaging in information blocking practices within the nationwide health IT infrastructure. Based on this information, participants in the nationwide health IT infrastructure and the public can confirm or dispel perceptions of information blocking within that infrastructure. Additionally, the combined transparency of the processes Congress authorized and instructed HHS to implement (*i.e.,* ONC implementing a claims reporting process, as well as civil money penalties and disincentives for applicable actors found to have committed information blocking by OIG) would foster public confidence in the information blocking enforcement framework and potentially encourage public participation in that framework, whether by submitting a claim of information blocking or participating in an OIG information blocking investigation. We invite public comments on these proposals, including comments on whether we should publicly post additional information (and why) about health care providers, health IT developers, or health information networks/health information exchanges that have been determined by OIG to have committed information blocking.

C. Appropriate Disincentives for Health Care Providers

In this section (III.C.), we propose to establish a set of disincentives for health care providers that have committed information blocking. These disincentives would be imposed following a referral of a determination of information blocking by OIG. Each of the proposed disincentives is being established using authorities under applicable Federal law, consistent with PHSA section 3022(b)(2)(B).

1. Background

a. Impacted Health Care Providers

The disincentives proposed in this section would apply to a subset of the individuals and entities meeting the information blocking regulations'

[10] See ''Information Blocking Claims: By the Numbers,'' *https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers.*

[11] *https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers.*

definition of health care provider at 45 CFR 171.102. Specifically, the proposals in this rule would provide disincentives for health care providers (as defined in 45 CFR 171.102) that are also eligible to participate in certain Federal programs: the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category (previously the EHR Incentive Programs); and the Medicare Shared Savings Program.

We recognize that the disincentives proposed in this rule would only apply to certain health care providers and that the information blocking regulations are also applicable to health care providers that are not eligible to participate in these programs. However, this proposed rule is a first step that focuses on authorities which pertain to certain health care providers that furnish a broad array of health care services to large numbers of Medicare beneficiaries and other patients. We believe optimal deterrence of information blocking calls for imposing appropriate disincentives on all health care providers (as defined at 45 CFR 171.102) determined by OIG to have committed information blocking. In section IV. of this proposed rule, we request public comment on establishing disincentives, using applicable Federal law, that could be imposed on a broader range of health care providers.

b. Impact of Disincentives

We believe the disincentives proposed in this rule would deter information blocking by health care providers. However, we recognize that the actual monetary impact resulting from the application of the disincentives proposed in this section may vary across health care providers subject to the disincentive.

For example, the disincentive proposed in section III.C.3. of this proposed rule for the MIPS Promoting Interoperability performance category would result in an adjustment to payments under Medicare Part B to MIPS eligible clinicians (as defined in 42 CFR 414.1305). This disincentive would reduce to zero the Promoting Interoperability performance category score of any MIPS eligible clinician that has been determined by OIG to have committed information blocking (as defined at 45 CFR 171.103) during the calendar year (CY) of the referral of a determination from OIG. However, the actual financial impact experienced by a health care provider as a result of this proposed disincentive being applied in MIPS would vary. For example, Part B payments to the MIPS eligible clinician are subject to a MIPS payment adjustment factor, which CMS determines based on the MIPS eligible clinician's final score. In determining each MIPS eligible clinician's final score, CMS takes into account the assigned weight of, and the MIPS eligible clinician's performance in, the four MIPS performance categories, including the Promoting Interoperability performance category. The MIPS eligible clinician's final score then determines whether the eligible clinician earns a negative, neutral, or positive payment adjustment factor that will be applied to the amounts otherwise paid to the MIPS eligible clinician under Medicare Part B for covered professional services during the applicable MIPS payment year.

In the interest of addressing this variability, we considered whether we could propose an alternative approach under which we would tailor the monetary impact of a disincentive imposed on a health care provider to the severity of the conduct in which the health care provider engaged. However, we do not believe it would be feasible to develop such an approach for the disincentives we propose for health care providers. Because disincentives must be established using authorities under applicable Federal law, the statute under which a disincentive is being established would need to specifically authorize or provide sufficient discretion for an appropriate agency to be able to adjust the monetary impact of the disincentive to fit the gravity or severity of the information blocking the health care provider has been determined to have committed. Based on our review of potential authorities under which to establish disincentives, we believe many authorities do not provide discretion to adjust the monetary impact of a potential disincentive in this fashion. For instance, in section III.C.2. of this proposed rule, CMS proposes to establish a disincentive through the Medicare Promoting Interoperability Program utilizing authority in SSA section 1886. Under this authority, CMS, as specified in section 1886(b)(3)(B)(ix)(I) of the SSA, adjusts payments for eligible hospitals by a fixed proportion, on the basis of whether or not an eligible hospital (as defined in section 1886(n)(6)(B) of the SSA) is a meaningful EHR user.

2. Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs)

a. Background

We intend to use existing Medicare Promoting Interoperability Program authority concerning the meaningful use of certified EHR technology (CEHRT) to impose disincentives on eligible hospitals and CAHs that OIG determines have committed information blocking (defined in 45 CFR 171.103) where OIG refers a determination that the eligible hospital or CAH committed information blocking. Under section 1886(n)(3)(A) of the SSA, an eligible hospital or CAH [12] is treated as a meaningful EHR user for the EHR reporting period for a payment year if it demonstrates to the satisfaction of the Secretary, and among other requirements, that during the EHR reporting period: (1) the eligible hospital used CEHRT in a meaningful manner; and (2) the CEHRT is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information. As discussed further in section III.C.2.b. of this proposed rule, these requirements for an eligible hospital or CAH to be a meaningful EHR user would be substantially undermined and frustrated if the eligible hospital or CAH commits information blocking, such that application of an appropriate disincentive is warranted.

Under section 1886(b)(3)(B)(ix) of the SSA, if an eligible hospital does not demonstrate that it has met the requirements to be a meaningful EHR user under section 1886(n)(3)(A), CMS will reduce the eligible hospital's payment by three quarters of the applicable percentage increase in the market basket update or rate-of-increase for hospitals. Under section 1814(l)(4) of the SSA, if the Secretary determines that a CAH has not been a meaningful EHR user for a given EHR reporting period, CMS will pay that CAH 100 percent of its reasonable costs, instead of 101 percent of reasonable costs, which is the amount that the CAH would have received as a meaningful EHR user under the Medicare Promoting Interoperability Program.

HHS has authority to apply disincentives to both eligible hospitals and CAHs. PHSA section 3022(b)(2)(B) authorizes HHS to apply disincentives to health care providers OIG determines have committed information blocking. As discussed in section II.B.1 of this proposed rule, HHS has adopted, for purposes of the information blocking regulations in 45 CFR part 171, the definition of health care provider in section 3000(3) of the PHSA, which includes health care providers that are eligible for participation in the Medicare Promoting Interoperability Program. The

[12] Section 1814(l)(3) of the SSA applies to critical access hospitals the standard for determining a meaningful EHR user in section 1886(n)(3).

definition of ''health care provider'' in section 3000(3) of the PHSA includes ''hospital'' as a health care provider. Section 1886(n)(6)(B) of the SSA defines the term ''eligible hospital'' for the purposes of the Medicare Promoting Interoperability Program (75 FR 44316 through 44317) as ''a hospital that is a subsection (d) hospital or a subsection (d) Puerto Rico hospital.'' Eligible hospitals are located in one of the fifty States or the District of Columbia (75 FR 44448). Hospitals in Puerto Rico became eligible hospitals for the Medicare Promoting Interoperability Program with the passage of the Consolidated Appropriations Act of 2016 (Pub. L. 114–113, Dec. 18, 2015). A CAH is defined in section 1861(mm) of the SSA as ''a facility that has been certified as a critical access hospital under section 1820(e).'' ''Hospital'' is not further defined under the PHSA definition in section 3000(3). Therefore, CMS interprets the term ''hospital'' in section 3000(3) of the PHSA to include both eligible hospitals and CAHs that can participate in the Medicare Promoting Interoperability Program.

b. The Medicare Promoting Interoperability Program as an Appropriate Disincentive for Information Blocking Under the PHSA

As discussed previously, the requirements under SSA section 1886(n)(3)(A) that an eligible hospital or CAH must meet to a be meaningful EHR user, particularly the first two requirements under SSA section 1886(n)(3)(A)(i) and (ii), would be substantially undermined and frustrated if the eligible hospital or CAH commits information blocking, such that application of an appropriate disincentive is warranted. To be considered a meaningful EHR user under section 1886(n)(3)(A) of the SSA, an eligible hospital or CAH must, in brief: (1) demonstrate to the satisfaction of the Secretary the use of CEHRT in a meaningful manner, (2) demonstrate to the satisfaction of the Secretary that their CEHRT is connected in a manner that provides for electronic exchange of health information to improve the quality of health care, and (3) use CEHRT to submit information concerning quality measures and other measures as specified. With respect to the electronic exchange of health information requirement in SSA section 1886(n)(3)(A)(ii), an eligible hospital or CAH must demonstrate to the satisfaction of the Secretary that its CEHRT is ''connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care, such as promoting care coordination, and . . . demonstrates . . . that the hospital has not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the certified EHR technology.'' Two examples of the CMS requirements for health information exchange include the requirement for eligible hospitals and CAHs to report on the Health Information Exchange Objective and the Provider to Patient Exchange Objective, both of which are part of the requirements for demonstrating the meaningful use of CEHRT, in accordance with SSA section 1886(n)(3).

By establishing a disincentive for information blocking under the Medicare Promoting Interoperability Program, we are using an authority under applicable Federal law as required in section 3022(b)(2)(B) of the PHSA. Health care providers OIG determines have committed information blocking, and for which OIG refers its determination to CMS, would be subject to a disincentive under applicable law as they are participating in the Medicare Promoting Interoperability Program authorized by that applicable law. In addition, the Medicare Promoting Interoperability Program already requires eligible hospitals and CAHs to engage in practices that encourage the access, exchange, and use of electronic health information to avoid a downward payment adjustment. The requirements an eligible hospital or CAH must meet to be treated as a meaningful EHR user in section 1886(n)(3)(A)(i) and (ii) of the SSA specify that an eligible hospital or CAH must demonstrate that it meets these requirements ''to the satisfaction of the Secretary.'' CMS believes these provisions authorize the Secretary to interpret these requirements through rulemaking as necessary to ensure that an eligible hospital or CAH satisfies the requirements to be a meaningful EHR user as defined by the Secretary. Specifically, CMS believes it is appropriate for the Secretary to interpret these requirements through rulemaking to determine that an eligible hospital or CAH that has committed information blocking, and for which OIG refers its determination of information blocking to CMS, has not met the definition of a meaningful EHR user. This proposal is consistent with the goals of the Medicare Promoting Interoperability Program, which include the advancement of CEHRT utilization, focusing on interoperability and data sharing (81 FR 79837). Information blocking by eligible hospitals and CAHs would frustrate both these goals.

CMS also believes the proposed disincentive under the Medicare Promoting Interoperability Program would be an appropriate disincentive that would similarly deter information blocking by other eligible hospitals and CAHs, consistent with the discussion in section III.A.3. of this proposed rule. While the exact monetary impact of the disincentive would vary based on the specific eligible hospital, CMS believes a reduction of three quarters of the annual market basket update would deter eligible hospitals from engaging in information blocking because it would reduce the inpatient prospective payment system (IPPS) payment that an eligible hospital could have earned had it met other requirements under the Medicare Promoting Interoperability Program. Similarly, though the exact dollar amount would vary based on the specific CAH, CMS believes that receiving 100 percent of reasonable costs instead of the 101 percent of reasonable costs that a CAH may have earned for successful participation in the Medicare Promoting Interoperability Program would deter information blocking by CAHs because it would reduce the reimbursement a CAH could have received had it met other requirements under the Medicare Promoting Interoperability Program.

HHS analyzed the range of potential disincentive amounts an eligible hospital could be subject to if the proposed disincentive was imposed, in order to illustrate the degree to which this disincentive could deter eligible hospitals from engaging in information blocking. We used payment data for IPPS eligible hospitals from the CMS Medicare Inpatient Hospitals dataset for 2021, the latest year of publicly available data.[13] We considered the Medicare total payment amounts for each hospital, which consist of several variables, including Base, Medicare Severity Diagnosis Related Groups (MS–DRG), and adjustments such as Indirect Medical Education (IME)/Graduate Medical Education (GME), disproportionate share hospital (DSH), and outlier payments. We attempted to estimate the portion of hospitals' total payments subject to the market basket increase by excluding adjustments not subject to the increase, using data from CMS Hospital Cost Reports to subtract out DSH and IME/GME payments, which account for a large portion of

[13] Available at *https://data.cms.gov/provider-summary-by-type-of-service/medicare-inpatient-hospitals/medicare-inpatient-hospitals-by-provider.*

these adjustments.[14] Since we did not account for other adjustments such as outlier payments, the remaining payment amount may overestimate the payment subject to the market basket increase.

We then conducted a simulation that applied the proposed disincentive amount to a market basket adjustment factor. We simulated a hypothetical scenario of a 3.2 percent market basket increase and a reduction of three quarters of that percentage increase if the proposed information blocking disincentive were applied.[15] Under this scenario, a hospital that lost three quarters of the market basket increase due to the proposed information blocking disincentive would be left with a 0.8 percent market basket increase. Based on this calculation, we estimated a median disincentive amount of $394,353, and a 95 percent range of $30,406 to $2,430,766 across eligible hospitals. The value of the reduction in the market basket increase would be larger in dollar terms for hospitals with greater base IPPS payments.

c. Proposals

CMS is proposing to revise the definition of ''Meaningful EHR User'' in 42 CFR 495.4 to state that an eligible hospital or CAH is not a meaningful EHR user in a calendar year if OIG refers a determination that the eligible hospital or CAH committed information blocking, as defined at 45 CFR 171.103, during the calendar year of the EHR reporting period. As a result of the proposal, CMS would apply a downward payment adjustment under the Medicare Promoting Interoperability Program to any such eligible hospital or CAH because the eligible hospital or CAH would not be a meaningful EHR user, as required under SSA sections 1886(b)(3)(B)(ix) and 1814(l)(4). For eligible hospitals, CMS would apply the downward adjustment to the payment adjustment year that occurs 2 years after the calendar year when the OIG referral occurs. For CAHs, CMS would apply the downward adjustment to the payment adjustment year that is the same as the calendar year when the OIG referral occurs.

As a result of these proposals, an eligible hospital or CAH that otherwise fulfilled the required objectives and measures to demonstrate that it is a meaningful EHR user for an EHR reporting period would nevertheless not be a meaningful EHR user for that EHR reporting period if OIG refers a determination of information blocking to CMS during the calendar year in which the EHR reporting period falls. CMS considered applying this proposed disincentive based on the date that the eligible hospital or CAH committed the information blocking as determined by OIG, instead of the date OIG refers its determination to CMS. However, a significant period of time could pass between the date when the eligible hospital or CAH is determined to have committed information blocking, and the date when OIG makes a referral to CMS, due to the time required for OIG to fully investigate a claim of information blocking. Such delay between the date the information blocking occurred and OIG's referral could complicate the application of the disincentive and would likely necessitate reprocessing of a significant number of claims. Therefore, CMS proposes to use the date of the OIG referral instead of the date of the information blocking occurrence to apply the proposed disincentive. Accordingly, CMS would apply the proposed disincentive to the payment adjustment year associated with the calendar year in which the OIG referred its determination to CMS.

CMS further notes that if an eligible hospital or CAH received the applicable downward payment adjustment because CMS had already determined the eligible hospital or CAH had otherwise not been 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 on the eligible hospital or CAH during that payment adjustment year. Finally, CMS clarifies that, even if multiple information blocking violations were identified as part of OIG's determination (including over multiple years) and referred to CMS, 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 during the calendar year when the determination of information blocking was referred by OIG. Unless OIG makes an additional referral of an information blocking determination in the subsequent calendar year, an eligible hospital or CAH would again be able to qualify as a meaningful EHR user starting in the subsequent EHR reporting period.

CMS invites public comment on these proposals, particularly on its approach to the application of a disincentive for OIG determinations that found that information blocking occurred in multiple years and whether there should be multiple disincentives for such instances (for example, disincentives in multiple calendar years/reporting periods compared to only the calendar year/reporting period in which OIG made the referral).

d. Notification and Application of the Disincentive

After OIG has determined that a health care provider has committed information blocking and referred that health care provider to CMS, CMS would notify the eligible hospital or CAH that OIG determined that the eligible hospital or CAH committed information blocking as defined under 45 CFR 171.103, and thus the eligible hospital or CAH was not a meaningful EHR user for the EHR reporting period in the calendar year when OIG referred its information blocking determination to CMS. This notice would be issued in accordance with the notice requirements proposed at 45 CFR 171.1002, as discussed in section III.B.2 of this proposed rule.

As a result of our proposal to modify the definition of meaningful EHR user in 42 CFR 495.4, the application of the disincentive would result in a downward payment adjustment for eligible hospitals 2 years after the OIG referral of a determination of information blocking to CMS. Based upon the existing regulation at 42 CFR 495.4, the downward payment adjustment would apply 2 years after the year of the referral and the EHR reporting period in which the eligible hospital was not a meaningful EHR user. For CAHs, the downward payment adjustment would apply to the payment adjustment year in which the OIG referral was made.

CMS invites public comment on these proposals.

3. Promoting Interoperability Performance Category of the Medicare Merit-Based Incentive Payment System (MIPS)

a. Background

MIPS requires that MIPS eligible clinicians use CEHRT, as defined at SSA section 1848(o)(4) and 42 CFR 414.1305,[16] in a meaningful manner, in

[14] Available at *https://www.cms.gov/research-statistics-data-and-systems/downloadable-public-use-files/cost-reports.*

[15] The hypothetical 3.2 percent market basket increase used in this simulation was based on the 2023 Medicare Trustees Report, which assumes a 3.2 percent annual market basket increase.

[16] For MIPS, SSA section 1848(o)(4) defines CEHRT as a qualified electronic health record (as defined in PHSA section 3000(13)) that is certified by ONC pursuant to PHSA section 3001(c)(5) as meeting standards adopted under PHSA section 3004 that are applicable to the type of record involved, as determined by the Secretary. CMS has

Continued

accordance with SSA sections 1848(q)(2)(A)(iv) and (B)(iv) and 1848(o)(2) and 42 CFR 414.1375, to earn a score for the MIPS Promoting Interoperability performance category. We intend to use this existing authority, requiring the meaningful use of CEHRT, to impose disincentives on MIPS eligible clinicians that OIG determines to have committed information blocking as defined at 45 CFR 171.103.

(1) MIPS Overview—Scoring and Payment Calculations

Authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015), the Quality Payment Program is a payment incentive program, by which the Medicare program rewards MIPS eligible clinicians who provide high-value, high-quality services in a cost-efficient manner. The Quality Payment Program includes two participation tracks for clinicians providing services under the Medicare program: MIPS and Advanced Alternative Payment Models (APMs). The statutory requirements for MIPS are set forth in SSA sections 1848(q) and (r).

For the MIPS participation track, MIPS eligible clinicians are subject to a MIPS payment adjustment (positive, negative, or neutral) based on their performance in four performance categories (cost, quality, improvement activities, and Promoting Interoperability) compared to the established performance threshold for that performance period/MIPS payment year. CMS assesses each MIPS eligible clinician's total performance according to established performance standards with respect to the applicable measures and activities specified in each of these four performance categories during a performance period to compute a final composite performance score (a ''final score'' as defined at 42 CFR 414.1305) in accordance with our policies set forth in 42 CFR 414.1380.

In calculating the final score, CMS must apply different weights for the four performance categories, subject to certain exceptions, as set forth in SSA section 1848(q)(5) and at 42 CFR 414.1380. Unless CMS assigns a different scoring weight pursuant to these exceptions, for the CY 2024 performance period/2026 MIPS payment year, the scoring weights 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 (SSA section 1848(q)(5)(E); 42 CFR 414.1380(c)(1)).

To calculate the payment adjustment factor that will be applied to the amounts otherwise paid to MIPS eligible clinicians under Medicare Part B for covered professional services during the applicable MIPS payment year, CMS then compares the final score to the performance threshold CMS has established for that performance period/MIPS payment year at 42 CFR 414.1405(b). The MIPS payment adjustment factors specified for a year must result in differential payments such that MIPS eligible clinicians with final scores above the performance threshold receive a positive MIPS payment adjustment factor, those with final scores at the performance threshold receive a neutral MIPS payment adjustment factor, and those with final scores below the performance threshold receive a negative MIPS payment adjustment factor. As further specified in SSA section 1848(q)(6)(F) and 42 CFR 414.1405, CMS also applies a scaling factor to determine the MIPS payment adjustment factor for each MIPS eligible clinician, and CMS must ensure that the estimated aggregate increases and decreases in payments to all MIPS eligible clinicians as a result of MIPS payment adjustment factors are budget neutral for that MIPS payment year. As provided in SSA sections 1848(q)(6)(A) and (B)(iv) and 42 CFR 414.1405(c), the 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.

(2) MIPS Promoting Interoperability Performance Category

For MIPS eligible clinicians, SSA section 1848(q)(2)(A)(iv) includes the meaningful use of CEHRT as one of the four performance categories by which a MIPS eligible clinician is assessed to determine a MIPS payment adjustment factor, as discussed previously. CMS refers to this performance category as the Promoting Interoperability performance category. SSA section 1848(q)(2)(B)(iv) provides that the requirements set forth in SSA section 1848(o)(2) for determining whether a MIPS eligible clinician is a meaningful user of CEHRT also apply to our assessment of MIPS eligible clinicians' performance on measures and activities with respect to the MIPS Promoting Interoperability performance category. Also, SSA section 1848(o)(2)(D) generally provides that the requirements for being a meaningful EHR user under section 1848(o)(2) continue to apply for purposes of MIPS.

A MIPS eligible clinician that is not a meaningful user of CEHRT in accordance with SSA section 1848(o)(2)(A) cannot satisfy the requirements of the MIPS Promoting Interoperability performance category and, therefore, would earn a score of zero for this performance category. Applying the weights for the performance categories under 42 CFR 414.1380(c)(1), a score of zero for the Promoting Interoperability performance category would mean that the maximum final score a MIPS eligible clinician could achieve, if they performed perfectly in the three remaining performance categories, would be 75 points.

To be a meaningful EHR user under SSA section 1848(o)(2)(A) (and therefore meet the requirements of the MIPS Promoting Interoperability performance category under SSA section 1848(q)(2)(B)(iv)), a MIPS eligible clinician must meet three requirements related to the meaningful use of CEHRT during a performance period for a MIPS payment year. In brief, the MIPS eligible clinician must (1) demonstrate to the satisfaction of the Secretary the use of CEHRT in a meaningful manner; (2) demonstrate to the satisfaction of the Secretary that their CEHRT is connected in a manner that provides for electronic exchange of health information to improve the quality of care; and (3) use CEHRT to submit information concerning quality measures and other measures as specified.

More specifically, for the first requirement under SSA section 1848(o)(2)(A)(i), a MIPS eligible clinician must demonstrate, to the satisfaction of the Secretary, that during the relevant performance period, the MIPS eligible clinician is ''using certified EHR technology in a meaningful manner.'' For the second requirement under SSA section 1848(o)(2)(A)(ii), a MIPS eligible clinician must demonstrate, to the satisfaction of the Secretary, that during the relevant period CEHRT is ''connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of care, such as promoting care coordination'' and the MIPS eligible clinician demonstrates, through ''a process specified by the Secretary, such as the use of an attestation'' that the MIPS eligible clinician ''has not knowingly and willfully taken action

codified the definition of CEHRT, including additional criteria it must be certified as meeting, that MIPS eligible clinicians must use at 42 CFR 414.1305.

(such as to disable functionality) to limit or restrict the compatibility or interoperability of the certified EHR technology.'' For the third requirement under SSA section 1848(o)(2)(A)(iii), a MIPS eligible clinician currently must submit information via their CEHRT on ''such clinical quality measures and such other measures as selected by the Secretary'' in ''a form and manner specified by the Secretary,'' including measures focused on providing patients with electronic access to their electronic health information, sending electronic health information to other health care providers, and receiving and incorporating electronic health information from other health care providers.

As discussed further in section III.C.3.b. of this proposed rule, these three requirements for a MIPS eligible clinician to be determined to be a meaningful user of CEHRT, particularly the first two requirements under SSA section 1848(o)(2)(A)(i) and (ii), would be substantially undermined and frustrated if the MIPS eligible clinician commits information blocking, such that application of an appropriate disincentive is warranted.

b. The MIPS Promoting Interoperability Performance Category Requirements as an Appropriate Disincentive for Information Blocking Under the PHSA

As discussed previously, we believe that the requirements set forth in SSA sections 1848(q)(2)(B)(iv) and 1848(o)(2)(A) for the MIPS Promoting Interoperability performance category are an applicable Federal law for the purposes of establishing a disincentive for a health care provider that participates in MIPS and has been determined by OIG to have committed information blocking. First, the definitions of MIPS eligible clinician and health care provider under 45 CFR 171.102 and the PHSA generally are aligned. Second, committing information blocking not only violates the law and principles set forth in the Cures Act, but also undermines the goals and purpose of the MIPS Promoting Interoperability performance category. On such basis, CMS is proposing an appropriate disincentive for MIPS eligible clinicians that OIG determines have committed information blocking and for whom OIG refers its determination of information blocking to CMS, as discussed further in section III.C.3.c. of this proposed rule.

(1) Alignment of Definitions of MIPS Eligible Clinician and Health Care Provider Under the PHSA

CMS believes that the definitions of MIPS eligible clinician under the SSA and 42 CFR 414.1305 and health care provider under PHSA section 3000(3) and 45 CFR 171.102 generally are aligned. CMS believes this alignment will permit application of appropriate disincentives, as required by PHSA section 3022(b)(2)(B), to MIPS eligible clinicians, except for qualified audiologists. CMS proposes to codify this exception in the definition of Meaningful EHR User for MIPS at 42 CFR 414.1305.

Beginning with the 2024 MIPS payment year, a MIPS eligible clinician is defined in 42 CFR 414.1305 as including: (1) a physician (as defined in SSA section 1861(r)); (2) a physician assistant, nurse practitioner, and clinical nurse specialist (as defined in SSA 1861(aa)(5)); (3) a certified registered nurse anesthetist (defined in SSA section 1861(bb)(2)); (4) a physical therapist or occupational therapist; (5) a qualified speech-language pathologist; (6) a qualified audiologist (as defined in SSA section 1861(ll)(4)(B)); (7) a clinical psychologist (as defined by the Secretary for purposes of SSA section 1861(ii)); (8) a registered dietician or nutrition professional; (9) a clinical social worker (as defined in SSA section 1861(hh)(1)); (10) a certified nurse midwife (as defined in SSA section 1861(gg)(2)); and (11) a group, identified by a unique single taxpayer identification number (TIN), with two or more eligible clinicians, one of which must be a MIPS eligible clinician, identified by their individual national provider identifier (NPI) and who have reassigned their billing rights to the single group TIN. However, for a given performance period/MIPS payment year, a MIPS eligible clinician does not include an eligible clinician who meets one of the exclusions set forth in 42 CFR 414.1310(b), including being a Qualifying APM participant, Partial Qualifying APM Participant that does not elect to participate in MIPS, or does not exceed the low volume threshold (as these terms are defined in 42 CFR 414.1305).

Meanwhile, the definition of ''health care provider'' under PHSA section 3000(3) as implemented in 45 CFR 171.102, includes the following which are also considered MIPS eligible clinicians: (1) a ''group practice'' (which is not defined in the PHSA); (2) a physician (as defined in SSA section 1861(r)); (3) practitioners, as defined in SSA section 1842(b)(18)(C) to include: (a) a physician assistant, nurse practitioner, and clinical nurse specialist (as defined in SSA 1861(aa)(5)); (b) a certified registered nurse anesthetist (defined in SSA section 1861(bb)(2)); (c) a certified nurse-midwife (as defined in SSA section 1861(gg)(2)); (d) a clinical social worker (as defined in SSA section 1861(hh)(1)); (e) a clinical psychologist (as defined by the Secretary for purposes of SSA section 1861(ii)); and (f) a registered dietician or nutrition professional; (4) therapists, as defined in SSA section 1848(k)(3)(B)(iii) to include: (a) a physical therapist; (b) an occupational therapist; and (c) a qualified speech-language pathologist; and (5) ''any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.''

CMS notes that, at this time, only a qualified audiologist, included in the definition of MIPS eligible clinician in 42 CFR 414.1305 since the CY 2019 performance period/2021 MIPS payment year, is not identified as a health care provider under 45 CFR 171.102 and PHSA section 3000(3). Because qualified audiologists are not included in the PHSA definition of health care provider, CMS proposes that MIPS eligible clinicians who are qualified audiologists would not be subject to the disincentive proposed for the MIPS Promoting Interoperability performance category in this proposed rule.

As discussed previously in this section (III.C.3.b.(1)), groups and multispecialty groups (as defined in 42 CFR 414.1305) also are included in the definition of MIPS eligible clinician and therefore are subject to payment adjustments under MIPS based on the performance of MIPS eligible clinicians that are included in these groups, under different sets of regulations in 42 CFR part 414, subpart O. Meanwhile, as discussed previously, the definition of health care provider in PHSA section 3000(3) includes ''group practice,'' but does not define what this term means. Accordingly, CMS also believes that a group may be subject to the disincentive proposed for the MIPS Promoting Interoperability performance category in this proposed rule if the group has been determined by OIG to have committed information blocking, or if MIPS eligible clinicians included in the group have committed information blocking.

(2) Information Blocking Conduct Undermines the Goals and Purpose of the MIPS Promoting Interoperability Performance Category

Health care providers that engage in information blocking undermine and frustrate the purpose for requiring MIPS eligible clinicians to use CEHRT in a meaningful manner. Specifically, requiring MIPS eligible clinicians to use CEHRT is not limited to MIPS eligible clinicians adopting and implementing CEHRT for documenting clinical care in lieu of paper-based medical records. For use of CEHRT to be meaningful, SSA section 1848(o)(2)(A) requires that MIPS eligible clinicians use CEHRT to communicate with other treating providers, pharmacies, and oversight authorities regarding the patient's health information, including the MIPS eligible clinician's review and treatment of the patient's health. SSA sections 1848(o)(2)(A)(i) and (ii) require that MIPS eligible clinicians demonstrate that they are meaningfully using CEHRT's key functionalities, such as electronically prescribing, and ensuring that CEHRT is ''connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for the electronic exchange of health information to improve the quality of health care,'' such as ''promoting care coordination.'' SSA section 1848(o)(2)(A)(ii) further requires that the MIPS eligible clinician demonstrate that they have not ''knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability'' of CEHRT, which is similar to the directive to investigate and discourage information blocking under PHSA section 3022. Establishing an appropriate disincentive for information blocking under the MIPS Promoting Interoperability performance category would not only deter information blocking, but would strengthen an existing merit-based incentive payment system that already encourages health care providers to support the access, exchange, and use of electronic health information.

Furthermore, the requirements to be treated as a meaningful EHR user in SSA sections 1848(o)(2)(A)(i) and (ii) specify that a MIPS eligible clinician must demonstrate that they meet these requirements to the satisfaction of the Secretary. CMS believes these provisions authorize the Secretary to interpret these requirements through rulemaking as necessary to ensure that a MIPS eligible clinician satisfies the requirements to be a meaningful user of CEHRT as defined by the Secretary. Specifically, CMS believes it is appropriate for the Secretary to interpret these requirements through rulemaking to determine that a MIPS eligible clinician that has committed information blocking is not a meaningful EHR user. This proposal is consistent with the goals of the MIPS Promoting Interoperability performance category, which include promoting health care efficiency and encouraging widespread health information exchange (81 FR 77200 through 77202). Information blocking by MIPS eligible clinicians frustrates both these goals.

CMS believes a disincentive for information blocking associated with the MIPS Promoting Interoperability performance category would be an appropriate disincentive that would deter information blocking by other MIPS eligible clinicians, consistent with the discussion in section III.A.3. of this proposed rule. While the exact monetary impact of the disincentive may vary for each MIPS eligible clinician based on the various factors CMS considers when determining the MIPS payment adjustment factor, CMS believes the proposed disincentive would deter information blocking by other MIPS eligible clinicians. A MIPS eligible clinician who receives a score of zero in the MIPS Promoting Interoperability performance category under this proposed disincentive may not be able to earn a positive or neutral MIPS payment adjustment factor that they otherwise would have earned for their performance in MIPS.

To illustrate the degree to which this disincentive could deter information blocking, HHS analyzed the range of potential disincentive amounts MIPS eligible clinicians could be subject to if the proposed disincentive was imposed, using actual payment and MIPS data from 2021, the most recent year of publicly available data. The three data sets used were the Medicare Fee-For-Service Provider Utilization & Payment Data—Physician and Other Practitioners Dataset; the Clinician Public Reporting: Overall MIPS Performance Dataset and the Quality Payment Program Experience Dataset.[17] [18] [19] The Medicare Fee-For-Service Provider Utilization file contains actual payments to clinicians under Medicare Part B. We simulated disincentive amounts for all eligible clinicians on an individual basis by applying zero points for the Promoting Interoperability performance category portion of the MIPS score and using the MIPS scoring policies from the CY 2021 performance year. We estimated potential disincentive amounts for groups by multiplying estimated per-clinical disincentive amounts by the number of eligible clinicians in estimated group sizes.

We first assessed the overall payment to eligible clinicians as well as the portion of the payment that was based on a positive or negative adjustment based on their MIPS score. We then varied the MIPS score based on lower scores on the Promoting Interoperability performance category portion, determined the change in positive or negative adjustment amount, and recalculated the payment under Medicare Part B. The difference between the actual 2021 payment and the simulated payment under the lower score represents the disincentive amount calculated in the simulation for individual eligible clinicians. 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 across all eligible clinicians (including those who may have been in a group). Based on the median estimated disincentive amount of $686 and 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). In consideration of MIPS eligible clinicians that may be subject to higher-than-median disincentives, we also simulated estimates for a median-sized group of six clinicians and an estimated 75th percentile per-clinician disincentive amount of $1,798. Based on this, we estimated a disincentive of $10,788. We noted that the ranges of potential group disincentive amounts vary based on individual clinician payments and group sizes.

c. Proposals

Under the authority in SSA sections 1848(o)(2)(A) and (D), and 1848(q)(2)(A)(iv) and (B)(iv), for the MIPS Promoting Interoperability performance category, CMS proposes that a MIPS eligible clinician would not be a meaningful EHR user in a performance period if OIG refers a determination that the MIPS eligible clinician committed information blocking (as defined at 45 CFR 171.103)

[17] Provider Utilization and Payment Data available at *https://catalog.data.gov/dataset/medicare-physician-other-practitioners-by-provider-b297e.*

[18] Overall MIPS Performance Dataset available at *https://data.cms.gov/provider-data/dataset/a174-a962.*

[19] Quality Payment Program Experience Dataset available at *https://data.cms.gov/quality-of-care/quality-payment-program-experience/data.*

at any time during the calendar year of the performance period.[20] CMS also proposes that the determination by OIG that the MIPS eligible clinician committed information blocking 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. CMS proposes to codify this proposal under the definition of meaningful EHR user for MIPS at 42 CFR 414.1305 and amend the requirements for earning a score for the MIPS Promoting Interoperability performance category at 42 CFR 414.1375(b).

CMS considered applying this proposed disincentive based on the date that the MIPS eligible clinician committed the information blocking as determined by OIG, instead of the date OIG refers its determination to CMS. However, a significant period of time could pass between the date when the MIPS eligible clinician is determined to have committed information blocking, and the date when OIG makes a referral to CMS, due to the time required for OIG to fully investigate a claim of information blocking. Such delay between the date the information blocking allegedly occurred and OIG's referral could complicate our application of the disincentive and would likely necessitate reprocessing of a significant number of claims. Therefore, CMS decided to use the date of the OIG referral instead of the date of the information blocking occurrence to apply this proposed disincentive. Accordingly, CMS would apply the proposed disincentive to the MIPS payment year associated with the calendar year in which OIG referred its determination to CMS.

As provided in 42 CFR 414.1320, the applicable MIPS payment year is 2 calendar years after the performance period. This time period between the performance period and the MIPS payment year permits CMS to review each MIPS eligible clinician's performance to determine their final score and MIPS payment adjustment factor. Under our proposal, if OIG referred its determination that a MIPS eligible clinician committed information blocking in calendar year 2025, then CMS would apply the disincentive proposed herein for the 2027 MIPS payment year.

First, CMS proposes to amend the definition of ''meaningful EHR user for MIPS'' at 42 CFR 414.1305. The current definition of meaningful EHR user for MIPS definition states that a ''meaningful EHR user for MIPS means a MIPS eligible clinician who possesses CEHRT, uses the functionality of CEHRT, reports on applicable objectives and measures specified for the Promoting Interoperability performance category for a performance period in the form and manner specified by CMS, does not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT, and engages in activities related to supporting providers with the performance of CEHRT.'' CMS proposes to add to this definition that a MIPS eligible clinician is not a meaningful EHR user in a performance period if OIG refers a determination that the clinician committed information blocking (as defined at 45 CFR 171.103) during the calendar year of the performance period. CMS also proposes other minor technical changes to the language of the definition. In tandem with other proposals in this section, this proposed amendment to the definition in 42 CFR 414.1305 would result in a MIPS eligible clinician not being able to earn points associated with the Promoting Interoperability performance category they may otherwise have earned, potentially resulting in a negative or neutral payment adjustment. As such, this potential outcome likely would deter health care providers from engaging in information blocking.

Second, CMS proposes to amend our requirements for earning a score for the MIPS Promoting Interoperability performance category by adding a new requirement at 42 CFR 414.1375(b). Currently, 42 CFR 414.1375(b) provides that, to earn a score (other than zero) for the Promoting Interoperability performance category, the MIPS eligible clinician must meet certain requirements, including using CEHRT, reporting on the objectives and associated measures as specified by CMS, and attesting to certain statements and activities. CMS proposes to amend 42 CFR 414.1375(b) by adding that the MIPS eligible clinician must be a meaningful EHR user for MIPS as defined at 42 CFR 414.1305. In conjunction with our proposal to amend the definition of a meaningful EHR user for MIPS at 42 CFR 414.1305 discussed previously, CMS believes this proposal would establish a clear basis to apply a score of zero for the MIPS Promoting Interoperability performance category to a MIPS eligible clinician that fails to meet the definition of meaningful EHR user for MIPS during a performance period, specifically if OIG refers a determination of information blocking during the calendar year of the performance period.

Under these proposals, a MIPS eligible clinician that OIG determines has committed information blocking would not be a meaningful EHR user, and therefore would be unable to earn a score (instead, earning a score of zero) for the MIPS Promoting Interoperability performance category. Because a MIPS eligible clinician that has committed information blocking would not be a meaningful EHR user for a given performance period, they would earn a zero for the Promoting Interoperability performance category for the calendar year of the applicable performance period in which the determination of information blocking was referred by OIG. For example, if OIG refers a determination that a MIPS eligible clinician committed information blocking to CMS in CY 2026, CMS would apply a score of zero for the Promoting Interoperability performance category for the CY 2028 MIPS payment year to the MIPS eligible clinician.

Under this proposed disincentive for information blocking, a score of zero for the MIPS Promoting Interoperability performance category would negatively impact 25 percent of the MIPS eligible clinician's final score such that it would likely result in a negative MIPS payment adjustment for the applicable MIPS payment year. For example, applying the weights for the performance categories under 42 CFR 414.1380(c)(1), a score of zero for the Promoting Interoperability performance category would mean that the maximum final score a MIPS eligible clinician could achieve, if they performed perfectly in the three remaining performance categories, would be 75 points.

Then, as discussed previously, to determine the MIPS payment adjustment factor, CMS compares the MIPS eligible clinician's final score to the established performance threshold for that MIPS payment year. In 42 CFR 414.1405(b)(9)(ii), CMS established that the performance threshold for the 2025

[20] As provided in 42 CFR 414.1320(h), for purposes of the 2024 MIPS payment year and each subsequent MIPS payment year, the performance period for the MIPS Promoting Interoperability performance category is a minimum of a continuous 90-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year. In 42 CFR 414.1305, CMS has defined the ''MIPS payment year'' as the calendar year in which the MIPS payment adjustment factor is applied to Medicare Part B payments. In the CY 2024 Physician Fee Schedule proposed rule, CMS proposed that, beginning with the 2026 MIPS payment year, the performance period for the MIPS Promoting Interoperability performance category is a minimum of a continuous 180-day period within the calendar year that occurs 2 years prior to the applicable MIPS payment year, up to and including the full calendar year (88 FR 52578 through 52579).

MIPS payment year is 75 points. If, under this example, a MIPS eligible clinician still achieved 75 points for their final score for the 2025 MIPS payment year matching the established performance threshold of 75 points, then they would receive a neutral MIPS payment adjustment factor.

However, in the CY 2024 Physician Fee Schedule proposed rule, CMS proposed that the performance threshold for the 2026 MIPS payment year would be 82 points (88 FR 52596 through 52601). If this performance threshold of 82 points is finalized for the 2026 MIPS payment year, or some other performance threshold higher than 75 points is finalized in a future MIPS payment year, then, under our example, a MIPS eligible clinician (that OIG determined committed information blocking and received a score of zero in the Promoting Interoperability performance category and therefore a final score of 75 points) would receive a negative MIPS payment adjustment factor. If CMS finalizes a performance threshold higher than 75 points in a future MIPS payment year, this proposed disincentive would likely to result in a MIPS eligible clinician that commits information blocking, as determined by OIG, receiving a negative payment adjustment, up to negative nine percent for a final score of zero as set forth in 42 CFR 414.1405(b)(2) and (c).

Under this proposal, a MIPS eligible clinician that otherwise fulfilled other requirements to demonstrate meaningful use for a performance period, and earned a score for the Promoting Interoperability performance category, would nevertheless not be a meaningful EHR user for that performance period if OIG refers a determination of information blocking during the calendar year of the performance period. CMS further notes that if a MIPS eligible clinician earned a score of zero for the Promoting Interoperability performance category for a given year because CMS had already determined the MIPS eligible clinician had otherwise not been a meaningful EHR user in that performance period due to its performance in the Promoting Interoperability performance category, imposition of the proposed disincentive would result in no additional impact on the MIPS eligible clinician during that MIPS payment year.

CMS clarifies that, even if multiple information blocking violations were identified as part of OIG's determination (including over multiple years) and referred to CMS, 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 during the calendar year when the determination of information blocking was referred by OIG. Barring an additional referral of an information blocking determination by OIG in the subsequent calendar year, a MIPS eligible clinician could be deemed a meaningful EHR user and earn a score for the Promoting Interoperability performance category in the following calendar year.

CMS invites public comment on these proposals. CMS particularly requests comment on its approach to the application of a disincentive for OIG determinations that found that information blocking occurred in multiple years and whether there should be multiple disincentives for such instances (for example, disincentives in multiple calendar years/performance periods compared to only one disincentive in the calendar year in which a referral from OIG is made).

(1) Groups and Virtual Groups

CMS also 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. CMS refers readers to our prior rulemaking governing groups and virtual groups (81 FR 77073 through 77077) and our regulations at 42 CFR 414.1305 (defining MIPS eligible clinicians as including groups as well as separately defining groups and virtual groups) and 414.1315 (governing virtual groups). MIPS eligible clinicians who submit data as a part of a group or virtual group and individually will be evaluated as an individual and as a group for all performance categories. Beginning with the CY 2021 performance period/2023 MIPS payment year, if a TIN/NPI has a virtual group final score associated with it, we will use the virtual group final score to determine the MIPS payment adjustment; if a TIN/NPI does not have a virtual group final score associated with it, we will use the highest available final score associated with the TIN/NPI to determine the MIPS payment adjustment (85 FR 84917 through 84919). CMS would apply the MIPS payment adjustment factor to the Medicare Part B claims during the MIPS payment year for the MIPS eligible clinicians in the group or virtual group. Thus, if CMS is calculating a final score and MIPS payment adjustment factor for a group or virtual group and OIG refers a finding of information blocking to CMS, CMS would apply the proposed disincentive to the whole group.

(2) Reweighting Policies

CMS has established policies that result in the reweighting of the Promoting Interoperability performance category for certain MIPS eligible clinicians at 42 CFR 414.1380(c)(2). These include but are not limited to hospital-based clinicians (81 FR 77238 through 77420, 82 FR 53684, and 82 FR 53686 through 53687) and Ambulatory Surgical Center-based clinicians (82 FR 53684). CMS is not proposing changes to its existing reweighting policies for MIPS eligible clinicians.

Starting with the CY 2022 performance period/2024 MIPS payment year performance period CMS automatically reweights small practices for the Promoting Interoperability performance category (86 FR 65485 through 65487; 42 CFR 414.1380(c)(2)(i)(C)(*9*)). CMS is not proposing changes to our existing policy for MIPS eligible clinicians in small practices.

CMS notes that if these MIPS eligible clinicians choose to submit data for the Promoting Interoperability performance category, their reweighting is canceled, and they could be subject to a disincentive if OIG refers a determination of information blocking to CMS.

d. Notification of the Disincentive

After OIG has determined that a health care provider has committed information blocking and referred that health care provider to CMS, CMS would notify the MIPS eligible clinician that OIG determined that the eligible clinician committed information blocking as defined under 45 CFR 171.103, and thus the MIPS eligible clinician was not a meaningful EHR user for the performance period in the calendar year when OIG referred its information blocking determination to CMS. CMS would apply the proposed disincentive to the MIPS payment year associated with the calendar year in which the OIG referred its determination to CMS. This notice would be issued in accordance with the notice requirements for disincentives proposed in 45 CFR 171.1002 (see also section III.B.2. of this proposed rule).

CMS invites public comment on this proposal.

4. Medicare Shared Savings Program

a. Background

(1) Statutory Authority for Disincentive

Section 3022 of the Patient Protection and Affordable Care Act (PPACA) (Pub.

L. 111–148, Mar. 23, 2010) added section 1899 to the Social Security Act (SSA) (42 U.S.C. 1395jjj), which established the Medicare Shared Savings Program (Shared Savings Program). In accordance with the statute, groups of providers of services and suppliers (referred to herein as ''ACO participants'') and their associated health care providers (referred to herein as ''ACO providers/suppliers'') meeting criteria specified by the Secretary may work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an ACO. ACOs that meet quality performance standards established by the Secretary are eligible to receive payments for shared savings the ACO generates for Medicare and to avoid sharing losses at the maximum level. One condition of participation required by the statute is for the ACO to define certain processes, including a mandate to ''define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies'' (Social Security Act section 1899(b)(2)(G)).

(2) Shared Savings Program Regulations

The Shared Savings Program regulations at 42 CFR part 425 set forth, among other things, requirements for ACO eligibility, quality reporting, and other program requirements and beneficiary protections.[21] The regulations at 42 CFR 425.116 require that an ACO, as a condition of participation in the Shared Savings Program, must effectuate an agreement with its ACO participants and ACO providers/suppliers (as defined at 42 CFR 425.20). This agreement must expressly require the ACO participant to agree, and to ensure that each ACO provider/supplier billing through the TIN of the ACO participant agrees, to participate in the Shared Savings Program and to comply with the requirements of the Shared Savings Program and all other applicable Federal laws and regulations including, but not limited to: (1) Federal criminal law; (2) The False Claims Act (31 U.S.C. 3729 *et seq.*); (3) The anti-kickback statute (42 U.S.C. 1320a–7b(b)); (4) The civil monetary penalties law (42 U.S.C. 1320a–7a); and (5) The physician self-referral law (42 U.S.C. 1395nn).

CMS has interpreted the requirement at section 1899(b)(1)(G) of the SSA that an ACO coordinates care for assigned beneficiaries using enabling technologies to require an ACO (and, by agreement, an ACO participant and ACO provider/supplier) to, among other things, define its methods and processes established to coordinate care across and among health care providers both inside and outside the ACO and have a written plan to ''encourage and promote use of enabling technologies for improving care coordination for beneficiaries'' (42 CFR 425.112(b)(4)(i) and (b)(4)(ii)(C)). Enabling technologies may include one or more of the following: electronic health records and other health IT tools; telehealth services, including remote patient monitoring; electronic exchange of health information; and other electronic tools to engage beneficiaries in their care. The ACO must ensure that ACO participants and ACO providers/suppliers comply with and implement the defined care coordination process, including the encouragement and promotion of enabling technologies, and the remedial processes and penalties (including the potential for expulsion) applicable to ACO participants and ACO providers/suppliers for failure to comply with and implement the required process (see 42 CFR 425.112(a)(3)). Sharing health information using enabling technologies across all health care providers engaged in a beneficiary's care (both inside and outside the ACO) for purposes of care coordination and quality improvement is an essential aspect of the ACO's activities. Moreover, this type of information sharing among health care providers (both inside and outside the ACO) supports quality measurement and quality reporting activities, which are necessary in order for the ACO to be eligible to share in savings and are also used in determining the amount of shared losses.

Before the start of an agreement period, before each performance year thereafter, and at such other times as specified by CMS, the ACO must submit to CMS an ACO participant list and an ACO provider/supplier list (see 42 CFR 425.118(a)). The ACO must certify the submitted lists annually. All Medicare-enrolled individuals and entities that have reassigned their right to receive Medicare payment to the TIN of the ACO participant must be included on the ACO provider/supplier list and must agree to participate in the ACO and comply with the requirements of the Shared Savings Program before the ACO submits the ACO participant list and the ACO provider/supplier list.

CMS may deny an ACO, ACO participant, and/or an ACO provider/supplier participation in the Shared Savings Program if the entity or individual has a history of program integrity issues (see 42 CFR 425.305(a)(2)). CMS screens ACOs, ACO participants, and ACO providers/suppliers during the Shared Savings Program application process and periodically thereafter (for example, during the annual certification of the ACO participant and ACO provider/supplier lists) with regard to their program integrity history (including any history of Medicare program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues) (see 42 CFR 425.305(a)(1)). In the Medicare Shared Savings Program Final Rule (76 FR 67802), CMS stated that the results of the screening would need to be considered in light of the relevant facts and circumstances. CMS did not draw a bright line regarding when an entity's history of program integrity issues justifies denial of a Shared Savings Program participation agreement. CMS stated instead that we would likely consider the nature of the applicant's program integrity issues (including the program integrity history of affiliated individuals and entities), the available evidence, the entity's diligence in identifying and correcting the problem, and other factors. CMS stated that we intended to ensure that ACOs, ACO participants, and ACO providers/suppliers would not pose a risk of fraud or abuse within the Shared Savings Program while recognizing that some program integrity allegations may not have been fully adjudicated.

CMS may terminate the participation agreement with an ACO when the ACO, its ACO participants, or its ACO providers/suppliers or other individuals or entities performing functions or services related to ACO activities fail to comply with any of the requirements of the Shared Savings Program under 42 CFR part 425 (§ 425.218(a) and (b)). This includes, but is not limited to, violations of the physician self-referral prohibition, CMP law, Federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to ACO operations. Similarly, CMS requires that the agreement the ACO effectuates with its ACO participants must permit the ACO to take remedial action against the ACO participant, and must require the ACO participant, in turn, to take remedial action against its ACO providers/suppliers, including

[21] Shared Savings Program regulations generally specify standards for an ACO, which is bound by its participation agreement to the standards. CMS generally specifies standards applicable to an ACO participant and ACO provider/supplier that is participating in the ACO through its regulation of the ACO.

imposition of a corrective action plan, denial of incentive payments, and termination of the ACO participant agreement, to address noncompliance with the requirements of the Shared Savings Program and other program integrity issues, including program integrity issues identified by CMS (42 CFR 425.116(a)(7)). Taken together, these regulations ensure that CMS may take appropriate enforcement actions when CMS' screening process or oversight of ACOs reveals a history of program integrity issues or when an ACO, an ACO participant or ACO provider/suppliers and other individuals or entities performing functions or services related to ACO activities fail to comply with the requirements of the Shared Savings Program, including failure to comply with other Federal laws that are relevant to the ACO's operations, such as the Cures Act's information blocking provision (PHSA section 3022).

b. Proposals

CMS proposes to revise the Shared Savings Program regulations to establish disincentives for health care providers, including ACOs, ACO participants, or ACO providers/suppliers, that engage in information blocking. Under this proposal, a health care provider that OIG determines has committed information blocking may not participate in the Shared Savings Program for a period of at least 1 year.

Information blocking runs contrary to the care coordination goals of the Shared Savings Program. ACO participants and their ACO providers/suppliers participating in an ACO in the Shared Savings Program use enabling technologies (such as electronic health records) to improve care coordination for beneficiaries. The ability of ACO providers/suppliers to exchange information between health care providers (both inside and outside the ACO) is essential for the operations of the ACO, including for effective coordination of care and quality improvement activities and services for assigned beneficiaries.

First, CMS proposes to amend 42 CFR 425.208(b) to include a specific reference to the Cures Act information blocking provision codified in the PHSA. The provision would be one of many laws with which ACOs (and by agreement, their ACO participants and ACO providers/suppliers) must comply.[22] In this case, compliance is required because a Medicare enrolled ''health care provider,'' to which an information blocking disincentive may apply, includes ACO providers/suppliers (See 42 CFR 400.202 and 425.20 and 45 CFR 171.102). The effect of adding a specific reference to the information blocking provision would be to require that, as a condition of participation in the Shared Savings Program, an ACO must specifically agree (and must require its ACO participants, ACO providers/suppliers, and other individuals or entities performing functions or services related to the ACO's activities to agree) to not commit information blocking as defined in PHSA section 3022(a).

Second, CMS proposes to revise 42 CFR 425.305(a)(1) to specify that the program integrity history on which ACOs, ACO participants, and ACO providers/suppliers are reviewed during the Shared Savings Program application process and periodically thereafter includes, but is not limited to, a history of Medicare program exclusions or other sanctions, noncompliance with the requirements of the Shared Savings Program, or violations of laws specified at 42 CFR 425.208(b). This revision would provide the basis for CMS to deny participation in the Shared Savings Program to a health care provider that is an ACO, an ACO participant, or an ACO provider/supplier when the health care provider has engaged in information blocking, as determined by OIG.

Third, CMS proposes to make a conforming modification to the provision related to the grounds for CMS to terminate an ACO at 42 CFR 425.218(b)(3) based on ''[v]iolations of the physician self-referral prohibition, civil monetary penalties (CMP) law, Federal anti-kickback statute, antitrust laws, or any other applicable Medicare laws, rules, or regulations that are relevant to ACO operations.'' CMS proposes to replace this language with ''[v]iolations of any applicable laws, rules, or regulations that are relevant to ACO operations, including, but not limited to, the laws specified at § 425.208(b).''

Pursuant to CMS' authority under 42 CFR 425.206(a)(1)(iii) to deny an ACO's participation in the Shared Savings Program, CMS' authority under 42 CFR 425.118(b)(1)(iii) to deny the addition of a health care provider to an ACO's participation list, and CMS' authority under 42 CFR 425.305(a) to screen for program integrity issues, 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 1 year. In the case of an ACO that is a health care provider, CMS proposes to deny the ACO's application to participate in the Shared Savings Program for the period of at least 1 year. If the ACO were to re-apply to participate in the Shared Savings Program in a subsequent year, then CMS would review whether OIG had made any subsequent determinations of information blocking with respect to the ACO as a health care provider as well as any evidence that indicated whether the issue had been corrected and appropriate safeguards had been put in place to prevent its reoccurrence, as part of the ACO's application process. CMS therefore proposes that, in cases where the result of the program integrity screening identifies that an ACO (acting as a health care provider), ACO participant, or ACO provider/supplier, has committed information blocking, as determined by OIG, CMS would take the following actions, as applicable:

- Pursuant to 42 CFR 425.118(b)(1)(iii), CMS would deny the request of the ACO to add an ACO participant to its ACO participant list on the basis of the results of the program integrity screening under 42 CFR 425.305(a).
- Pursuant to 42 CFR 425.116(a)(7) and (b)(7), CMS would notify an ACO currently participating in the Shared Savings Program 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.
- Pursuant to 42 CFR 425.305(a)(2), CMS would deny an ACO's Shared Savings Program application if the results of a program integrity screening under 42 CFR 425.305(a)(1) reveal a history of program integrity issues or other sanctions and affiliations with individuals or entities that have a history of program integrity issues.
- Pursuant to 42 CFR 425.218(a) and (b)(3), CMS would terminate an ACO participation agreement in the case of a failure to comply with requirements of the Shared Savings Program, including violations of any applicable laws, rules, or regulations that are relevant to ACO operations, including, but not limited to, the laws specified at 42 CFR 425.208(b).

Each of these actions would deter information blocking consistent with the discussion of an appropriate

[22] CMS notes that the list of laws included at 42 CFR 425.208(b) with which an ACO must comply is not an exclusive list. ACOs, ACO participants, and ACO providers/suppliers must continue to comply with all applicable Federal laws.

disincentive in section III.A.3. of this proposed rule. Restricting the ability for these entities to participate in the Shared Savings Program for at least 1 year would result in these health care providers potentially not receiving revenue that they might otherwise have earned if they had participated in the Shared Savings Program.

The period of time of the disincentive would be at least 1 performance year. 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 (for example, CMS would be unlikely impose a disincentive greater than 1 year if the information blocking occurred in the past and there was evidence that the information blocking had stopped) and whether safeguards have been put in place to prevent the information blocking that was the subject of OIG's determination. Prior to imposing any disincentive arising from an OIG determination of information blocking, CMS would provide a notice in accordance with the notice requirements proposed in 45 CFR 171.1002 (see section III.B.2 of this proposed rule) that would specify the disincentive would be imposed for at least 1 performance year.

CMS proposes to apply the disincentive no sooner than the first performance year after we receive a referral of an information blocking determination from OIG and in which the health care provider is to participate in the Shared Savings Program. CMS performs a program integrity screening of ACOs, ACO participants, and ACO providers/suppliers as part of the annual application/change request process for new and existing ACOs, which typically occurs between May and October during the performance year. In the case of the new addition of an ACO participant (TIN) to an ACO's participant list, CMS would prevent the TIN from joining the ACO as an ACO participant if the program integrity screening reveals that the TIN has engaged in information blocking, as determined by OIG. In the case of an existing ACO participant, CMS would notify the ACO that an ACO participant or an ACO provider/supplier had committed information blocking, as determined by OIG, so the ACO can remove the ACO participant or ACO provider/supplier from its ACO participant list or ACO provider/supplier list, as applicable. If the TIN were to remain on the ACO participant list or ACO provider/supplier list when the ACO certifies its ACO participant list for the next performance year, then CMS would issue a compliance action to the ACO. Continued noncompliance (for example, failure to remove the TIN) would result in termination of the ACO's participant agreement with CMS, as the ACO would have failed to enforce the terms of its ACO participant agreement.

Applying the disincentive prospectively is the most appropriate timing for the disincentive. It would be impractical and inequitable for CMS to apply the disincentive retrospectively or in the same year in which CMS received a referral from OIG. Applying the disincentive to a historical performance year or a performance year contemporaneous to the OIG's determination would unfairly affect other ACO participants that did not commit the information blocking and likely were not aware of the information blocking. CMS recognizes, however, that the prospective application of the disincentive means that it may be applied to a health care provider substantially after the information blocking occurred, during the provider's first attempt to participate in the Shared Savings Program, and after the provider was previously subject to a disincentive in another program, such as MIPS. As discussed in more detail below, CMS is contemplating an approach under which a health care provider could participate in the Shared Savings Program if a significant amount of time (for example, 3 to 5 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.

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 NPI on its ACO participant list or ACO provider/supplier list, as applicable, for a subsequent performance year, and CMS would approve the addition, assuming that all other Shared Savings Program requirements for adding a TIN or NPI are met, 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, however, 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.

In addition, CMS would notify ACOs about an ACO participant or ACO provider/supplier that had committed information blocking, as determined by OIG, so that the ACO could 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. ACOs are well-positioned to take remedial action against ACO participants and ACO providers/suppliers that have been found by OIG to have committed information blocking as a result of their ACO participant agreements, which provide for the ACO to take remedial action against the ACO participant, and require the ACO participant to take remedial action against its ACO providers/suppliers, including imposition of a corrective action plan, denial of incentive payments, and termination of the ACO participant agreement, to address noncompliance with the requirements of the Shared Savings Program and other program integrity issues.

By way of example, consider if in January 2025 OIG determined that an ACO participant has committed information blocking as recently as 2024 and referred this determination to CMS. Under CMS' proposal, the ACO participant would be able to remain on the ACO's certified participant list for the duration of the 2025 performance year. However, CMS would notify the ACO that an ACO participant had been determined to have committed information blocking by OIG and that CMS expected the ACO to take remedial action by removing the ACO participant from its ACO participant list for a specified period of time. To determine if removal was warranted for a period in addition to performance year 2026, CMS would consider whether there was any evidence to suggest that that information blocking was still occurring (for example, whether OIG had made a subsequent determination of information blocking) and whether safeguards had been put in place to prevent the information blocking that was the subject of the referral. Upon a review of these criteria, CMS may require the affected ACO to remove the ACO participant prior to recertification of the ACO participant list for additional performance years. If the ACO participant were to remain when the ACO certifies its ACO participant list for performance year 2026, CMS

would inform the ACO that it was obligated to take remedial action against the ACO participant by removing it from the ACO participant list for performance year 2026; if it failed to do so, CMS would remove the ACO participant from the ACO's participant list and take compliance action against the ACO up to terminating the ACO pursuant to 42 CFR 425.218(b)(1) and (3). In the case of a disincentive that was applied only for performance year 2026, if the ACO were to submit a change request to add the ACO participant for performance year 2027 or a subsequent year, then CMS would review whether OIG had made any subsequent determinations of information blocking with respect to the ACO participant as well as any evidence that indicated whether the issue had been corrected and appropriate safeguards had been put in place to prevent its reoccurrence, prior to approving the ACO participant to participate in the ACO for performance year 2027 or the subsequent year.

If an ACO applicant or a renewal ACO applicant that is itself a health care provider (for example, a large multi-specialty practice that forms a single participant ACO using its existing legal entity and governing body under 42 CFR 425.104) is the subject of an OIG information blocking determination, CMS would deny the ACO's application for participation in the Shared Savings Program for the upcoming performance year for which it was applying to participate. Should OIG make a determination of information blocking with respect to an ACO that is already participating in the Shared Savings Program and refer the determination to us for the application of a disincentive, CMS may terminate the ACO's participation agreement for the upcoming performance year. CMS would assess a subsequent application from an ACO to which the disincentive had been applied under the same criteria described for assessing the return of an ACO participant or ACO provider/supplier. The ACO may participate in the Shared Savings Program after the duration of the disincentive so long as OIG had not made a subsequent determination of information blocking applicable to the health care provider and whether there was evidence that the issue had been corrected and appropriate safeguards had been put in place to prevent its reoccurrence, prior to approving the ACO's application to participate in the Shared Savings Program in a subsequent performance year.

The Shared Savings Program is considering an alternative policy in which CMS would not apply a disincentive in certain circumstances despite an OIG information blocking determination. Under this alternative policy, the Shared Savings Program 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 the Shared Savings Program. 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, where prohibiting an ACO, ACO participant, or ACO provider/supplier from participating in the Shared Savings Program would distort participation incentives and therefore be less appropriate. We are particularly concerned about situations in which many years have passed since an ACO participant or ACO provider/supplier was found to be an information blocker and such an issue had long been remediated. In such a case, the ACO participant or ACO provider/supplier might be incentivized to apply to the Shared Savings Program for a year in which it did not actually intend to participate merely to avoid being barred from doing so at a future date when it did intend to participate, wasting the resources of the ACO and CMS. Such an alternative policy could allow a health care provider to participate in the Shared Savings Program if a significant amount of time had passed between the occurrence of the information blocking and the 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.

An ACO may be able to appeal the application of an information blocking disincentive in the Shared Savings Program. An ACO may appeal an initial determination that is not prohibited from administrative or judicial review under 42 CFR 425.800 by requesting a reconsideration review by a CMS reconsideration official (42 CFR 425.802(a)). To the extent it is not barred by 42 CFR 425.800, an ACO may appeal the removal or denial of a health care provider from an ACO participant list as a result of the referral by OIG of an ACO participant that OIG had determined to be an information blocker. Subject to the same limitation, an ACO applicant or ACO may appeal the denial of the ACO applicant's application or termination of the ACO's participation agreement as a result of the referral by OIG of the ACO applicant or ACO that the OIG had determined to be an information blocker. The underlying information blocking determination made by OIG, however would not be subject to the Shared Savings Program's reconsideration process. The OIG determination is not an initial determination made by CMS, but a determination made by another agency. The Shared Savings Program reconsideration process may not negate, diminish, or otherwise alter the applicability of determinations made by other government agencies (see 42 CFR 425.808(b)).

We remind all health care providers and ACOs that it is possible that a health care provider or any entity, such as an ACO, may meet the definition of a health information network or health information exchange, which is a functional definition, or the definition of a health IT developer of certified health IT, codified in 45 CFR 171.102. If it is found by OIG that such health care provider or entity meets either definition and, while under the same set of facts and circumstances, is also found by OIG to have committed information blocking, then the health care provider or entity would be subject to a different intent standard and civil money penalties administered by OIG (see generally 88 FR 42820; see 88 FR 42828 through 42829).

We invite public comment on these proposals and on whether additional actions should be taken.

IV. Request for Information

As discussed in section III.C.1. of this proposed rule, we recognize that the disincentives we propose would only apply to a subset of health care providers as defined in 45 CFR 171.102. However, we believe it is important for HHS to establish appropriate disincentives that would apply to all health care providers, as such providers are defined in 45 CFR 171.102. This would ensure that any health care provider, as defined in 45 CFR 171.102, that has engaged in information blocking would be subject to appropriate disincentives by an appropriate agency, consistent with the

disincentives provision at PHSA section 3022(b)(2)(B).

We request 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. We encourage 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. We also request information about the health care providers that HHS should prioritize when establishing additional disincentives.

V. Collection of Information Requirements

This document does not impose any new information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VI. Regulatory Impact Statement

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (Pub. L. 96–354, September 19, 1980), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999).

A. Executive Order 12866

Executive Order 12866, as amended by Executive Order 14094 published on April 6, 2023, directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulations are necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects; distributive impacts; and equity). A regulatory impact analysis must be prepared for major rules with significant effects (for example, $200 million or more in any given year). This is not a major rule as defined at 5 U.S.C. 804(2); it is not significant under section 3(f)(1) because it does not reach that economic threshold, nor does it meet the other criteria outlined in the Executive order.

This proposed rule would implement provisions of the Cures Act through changes to 45 CFR part 171 and 42 CFR parts 414, 425, and 495. We believe that the likely aggregate economic effect of these regulations would be significantly less than $200 million.

The expected benefits of this proposed rule would be to deter information blocking that interferes with effective health information exchange and negatively impacts many important aspects of healthcare. We refer readers to the impact analysis of the benefits of prohibiting and deterring information blocking in the ONC Cures Act Final Rule, which encompasses all anticipated benefits without differentiation among actors (85 FR 25936).

We anticipate that OIG would incur some costs associated with investigation as authorized by the Cures Act. The Consolidated Appropriations Act, 2022 appropriates to OIG funding necessary for carrying out information blocking activities (Pub. L. 117–103, March 15, 2022). Additionally, investigated parties may incur some costs in response to an OIG investigation or in response to the application of a disincentive by an agency with the authority to impose a disincentive. Absent information about the frequency of prohibited practices, including the number of OIG determinations of information blocking in a given year that could be referred to an appropriate agency, we are unable to determine the potential costs of this regulation.

The monetary value of the disincentives proposed in this rule, if imposed on a health care provider by an appropriate agency, would be considered transfers. We are unable to reliably estimate the aggregate value of potential disincentive amounts because the value of the disincentive may vary based on other provisions specific to the authority under which the disincentive has been established, as discussed in section III.C.1. of this proposed rule. For instance, the value of a disincentive imposed on an eligible hospital under the disincentive proposed in section III.C.2. of this proposed rule would depend on the amount of IPPS payment received by the eligible hospital.

We invite public comment on potential impacts of the rulemaking.

B. Regulatory Flexibility Act

The RFA and the Small Business Regulatory Enforcement and Fairness Act of 1996, which amended the RFA, require agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and Government agencies.

The Department considers a rule to have a significant impact on a substantial number of small entities if it has an impact of more than 3 percent of revenue for more than 5 percent of affected small entities. This proposed rule would not have a significant impact on the operations of a substantial number of small entities, as these changes would not impose any new requirement on any party. We have concluded that this proposed rule likely would not have a significant impact on a substantial number of small entities and that a regulatory flexibility analysis is not required for this rulemaking. Additionally, the Secretary proposes to certify that this proposed rule would not have a significant impact on a substantial number of small entities.

In addition, section 1102(b) the SSA (42 U.S.C. 1302) requires us to prepare a regulatory impact analysis if a rule under Titles XVIII or XIX or section B of Title XI of the SSA may have a significant impact the operations of a substantial number of small rural hospitals. We have concluded that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals because these changes would not impose any requirement on any party. Therefore, a regulatory impact analysis under section 1102(b) of the SSA is not required for this rulemaking. Therefore, the Secretary has certified that this proposed rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

C. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995, Public Law 104–4, requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any 1 year by State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million, adjusted annually for inflation. There are no significant costs associated with these proposals that would impose mandates on State, local, or Tribal governments or the private sector resulting in an expenditure of $177 million in 2023 (after adjustment for inflation) or more in any given year. A full analysis under the Unfunded Mandates Reform Act is not necessary.

D. Executive Order 13132

Executive Order 13132, Federalism, establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has federalism implications. In reviewing this rule under the threshold criteria of Executive Order 13132, we have determined that this proposed rule would not significantly affect the rights, roles, and responsibilities of State or local governments. Nothing in this proposed rule imposes substantial direct requirements or costs on State and local governments, preempts State law, or otherwise has federalism implications. We are not aware of any State laws or regulations that are contradicted or impeded by any of the provisions in this proposed rule.

List of Subjects

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

45 CFR Part 171

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Healthcare, Health care provider, Health information exchange, Health information technology, Health information network, Health insurance, Health records, Hospitals, Privacy, Reporting and recordkeeping requirements, Public health, Security.

For the reasons set forth in the preamble, HHS proposes to amend 42 CFR chapter IV and 45 CFR part 171 as follows:

42 CFR Chapter IV

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 1. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 2. Amend § 414.1305 by revising the definition of ''Meaningful EHR user for MIPS'' to read as follows:

§ 414.1305 Definitions.

* * * * *

Meaningful EHR user for MIPS means a MIPS eligible clinician that possesses CEHRT, uses the functionality of CEHRT, reports on applicable objectives and measures specified for the Promoting Interoperability performance category for a performance period in the form and manner specified by CMS, does not knowingly and willfully take action (such as to disable functionality) to limit or restrict the compatibility or interoperability of CEHRT, and engages in activities related to supporting providers with the performance of CEHRT. In addition, a MIPS eligible clinician (other than a qualified audiologist) is not a meaningful EHR user for a performance period if the HHS Inspector General refers a determination that the MIPS eligible clinician committed information blocking as defined at 45 CFR 171.103 during the calendar year of the performance period.

* * * * *

■ 3. Amend § 414.1375 by revising paragraph (b) introductory text to read as follows:

§ 414.1375 Promoting Interoperability (PI) performance category.

* * * * *

(b) *Reporting for the Promoting Interoperability performance category.* To earn a performance category score for the Promoting Interoperability performance category for inclusion in the final score, a MIPS eligible clinician must be a meaningful EHR user for MIPS and:

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 4. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 5. Amend § 425.208 by adding paragraph (b)(6) to read as follows:

§ 425.208 Provisions of participation agreement.

* * * * *

(b) * * *

(6) The information blocking provision of the 21st Century Cures Act (42 U.S.C. 300jj–52).

* * * * *

■ 6. Amend § 425.218 by revising paragraph (b)(3) to read as follows:

§ 425.218 Termination of the participation agreement by CMS.

* * * * *

(b) * * *

(3) Violations of any applicable laws, rules, or regulations that are relevant to ACO operations, including, but not limited to, the laws specified at § 425.208(b).

* * * * *

■ 7. Amend § 425.305 by revising paragraph (a)(1) to read as follows:

§ 425.305 Other program safeguards.

(a) * * *

(1) ACOs, ACO participants, and ACO providers/suppliers are reviewed during the Shared Savings Program application process and periodically thereafter with regard to their program integrity history, including any history of Medicare program exclusions or other sanctions and affiliations with individuals or entities that have a history of program integrity issues. Program integrity history issues include, but are not limited to, a history of Medicare program exclusions or other sanctions, noncompliance with the requirements of the Shared Savings Program, or violations of laws specified at § 425.208(b).

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 8. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 9. Amend § 495.4 in the definition of ''Meaningful EHR user'' by revising paragraph (1) introductory text and adding paragraph (4) to read as follows:

§ 495.4 Definitions.

* * * * *

Meaningful EHR user * * *

(1) Subject to paragraphs (3) and (4) of this definition, an eligible professional, eligible hospital or CAH that, for an EHR reporting period for a payment year or payment adjustment year—

* * * * *

(4) An eligible professional, eligible hospital or CAH is not a meaningful

EHR user in a payment adjustment year if the HHS Inspector General refers a determination that the eligible hospital or CAH committed information blocking as defined at 45 CFR 171.103 during the calendar year of the EHR reporting period.

* * * * *

45 CFR Subtitle A

PART 171—INFORMATION BLOCKING

■ 10. The authority citation for part 171 continues to read as follows:

Authority: 42 U.S.C. 300jj–52; 5 U.S.C. 552.

■ 11. Amend § 171.102 by adding, in alphabetical order, the definition of ''Appropriate agency'' and ''Disincentive'' to read as follows:

§ 171.102 Definitions.

* * * * *

Appropriate agency means a government agency that has established disincentives for health care providers that the Office of Inspector General (OIG) determines have committed information blocking.

* * * * *

Disincentive means a condition specified in § 171.1001(a) that may be 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.

* * * * *

Subparts D through I [Added and Reserved]

■ 12. Add reserved subparts D through I.

■ 13. Add subpart J to read as follows:

Subpart J—Disincentives for Information Blocking by Health Care Providers

Sec.

§ 171.1000 Scope.

This subpart sets forth disincentives that an appropriate agency may impose on a health care provider based on a determination of information blocking referred to that agency by OIG, and certain procedures related to those disincentives.

§ 171.1001 Disincentives.

(a) Health care providers that commit information blocking are subject to the following disincentives from an appropriate agency based on a determination of information blocking referred by OIG:

(1) An eligible hospital or critical access hospital (CAH) as defined in 42 CFR 495.4 is not a meaningful electronic health record (EHR) user as also defined in 42 CFR 495.4.

(2) A Merit-based Incentive Payment System (MIPS) eligible clinician as defined in 42 CFR 414.1305, who is also a health care provider as defined in § 171.102, is not a meaningful EHR user for MIPS as defined in 42 CFR 414.1305.

(3) Accountable care organizations (ACOs) who are health care providers as defined in § 171.102, ACO participants, and ACO providers/suppliers will be removed from, or denied approval to participate, in the Medicare Shared Savings Program as defined in 42 CFR part 425 for at least 1 year.

(b) [Reserved]

§ 171.1002 Notice of disincentive.

Following referral of a determination of information blocking by OIG, an appropriate agency that imposes a disincentive or disincentives specified in § 171.1001(a) would send a notice to the health care provider subject to the disincentive or disincentives, via usual methods of communication for the program or payment system under which the disincentive is applied, that includes:

(a) A description of the practice or practices that formed the basis for the determination of information blocking referred by OIG;

(b) The basis for the application of the disincentive or disincentives being imposed;

(c) The effect of each disincentive; and

(d) Any other information necessary for a health care provider to understand how each disincentive will be implemented.

■ 14. Add subpart K to read as follows:

Subpart K—Transparency for Information Blocking Determinations, Disincentives, and Penalties

Sec.

§ 171.1100 Scope.

This subpart sets forth the information that will be posted on the Office of the National Coordinator for Health Information Technology's (ONC) public website about actors that have been determined by the HHS Office of Inspector General to have committed information blocking.

§ 171.1101 Posting of information for actors found to have committed information blocking.

(a) *Health care providers.* (1) ONC will post on its public website the following information about health care providers that have been subject to a disincentive in § 171.1001(a) for information blocking:

(i) Health care provider name;

(ii) Business address;

(iii) The practice, as the term is defined in § 171.102 and referenced in § 171.103, found to have been information blocking;

(iv) Disincentive(s) applied; and

(iv) Where to find any additional information about the determination of information blocking that is publicly available via HHS or, where applicable, another part of the U.S. Government.

(2) The information specified in paragraph (a)(1) of this section will not be posted prior to a disincentive being imposed and will not include information about a disincentive that has not been applied.

(3) Posting of the information specified in paragraph (a)(1) of this section will be conducted in accordance with existing rights to review information that may be associated with a disincentive specified in § 171.1001.

(b) *Health IT developers of certified health IT and health information networks or health information exchanges.* (1) ONC will post on its public website the following information, to the extent applicable, about health information networks/health information exchanges and health IT developers of certified health IT (actors) that have been determined by the HHS Office of Inspector General to have committed information blocking:

(i) Type of actor;

(ii) Actor's legal name, including any alternative or additional trade name(s) under which the actor operates;

(iii) The practice, as the term is defined in § 171.102 and referenced in § 171.103, found to have been information blocking or alleged to be information blocking in the situation specified in paragraph (b)(2)(i) of this section; and

(iv) Where to find any additional information about the determination (or resolution of information blocking as specified in paragraph (b)(2)(i) of this section) of information blocking that is publicly available via HHS or, where applicable, another part of the U.S. Government.

(2) The information specified in paragraph (b)(1) of this section will not be posted until one of the following occurs:

(i) OIG enters into a resolution of civil money penalty (CMP) liability; or

(ii) A CMP imposed under subpart N of 42 CFR part 1003 has become final consistent with the procedures in subpart O of 42 CFR part 1003.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–24068 Filed 10–30–23; 11:15 am]

BILLING CODE 4150–45–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1, 2, 4, 7, 10, 11, 12, 37, 39, and 52

[FAR Case 2021–019; Docket No. FAR–2021–0019; Sequence No. 1]

RIN 9000–AO35

Federal Acquisition Regulation: Standardizing Cybersecurity Requirements for Unclassified Federal Information Systems; Extension of Comment Period

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: DoD, GSA, and NASA issued a proposed rule on October 3, 2023, proposing to amend the Federal Acquisition Regulation (FAR) to partially implement an Executive Order to standardize cybersecurity contractual requirements across Federal agencies for unclassified Federal information systems, and a statute on improving the Nation's cybersecurity. The deadline for submitting comments is being extended from December 4, 2023, to February 2, 2024, to provide additional time for interested parties to provide comments on the proposed rule.

DATES: For the proposed rule published on October 3, 2023 (88 FR 68402), the deadline to submit comments is extended. Submit comments by February 2, 2024.

ADDRESSES: Submit comments in response to FAR Case 2021–019 to the Federal eRulemaking portal at *https://www.regulations.gov* by searching for ''FAR Case 2021–019''. Select the link ''Comment Now'' that corresponds with ''FAR Case 2021–019''. Follow the instructions provided on the ''Comment Now'' screen. Please include your name, company name (if any), and ''FAR Case 2021–019'' on your attached document. If your comment cannot be submitted using *https://www.regulations.gov,* call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite ''FAR Case 2021–019'' in all correspondence related to this case. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. Public comments may be submitted as an individual, as an organization, or anonymously (see frequently asked questions at *https://www.regulations.gov/faq*). To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: For clarification of content, Ms. Carrie Moore, Procurement Analyst, at 571–300–5917 or by email at *carrie.moore@gsa.gov.* For information pertaining to status, publication schedules, or alternate instructions for submitting comments if *https://www.regulations.gov* cannot be used, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite FAR Case 2021–019.

SUPPLEMENTARY INFORMATION:

I. Background

DoD, GSA, and NASA published a proposed rule in the **Federal Register** at 88 FR 68402 on October 3, 2023. The comment period is extended to February 2, 2024, to allow additional time for interested parties to develop comments on the rule.

List of Subjects in 48 CFR Parts 1, 2, 4, 7, 10, 11, 12, 37, 39, and 52

Government procurement.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2023–24026 Filed 10–31–23; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1, 2, 4, 7, 10, 11, 12, 39, and 52

[FAR Case 2021–017; Docket No. FAR–2021–0017; Sequence No. 1]

RIN 9000–AO34

Federal Acquisition Regulation: Cyber Threat and Incident Reporting and Information Sharing; Extension of Comment Period

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule; extension of comment period.

SUMMARY: DoD, GSA, and NASA issued a proposed rule on October 3, 2023, proposing to amend the Federal Acquisition Regulation (FAR) to implement an Executive order on cyber threats and incident reporting and information sharing for Federal contractors and to implement related cybersecurity policies. The deadline for submitting comments is being extended from December 4, 2023, to February 2, 2024, to provide additional time for interested parties to provide comments on the proposed rule.

DATES: For the proposed rule published on October 3, 2023 (88 FR 68055), the comment period is extended. Submit comments by February 2, 2024.

ADDRESSES: Submit comments in response to FAR Case 2021–017 to the Federal eRulemaking portal at *https://www.regulations.gov* by searching for ''FAR Case 2021–017''. Select the link ''Comment Now'' that corresponds with ''FAR Case 2021–017''. Follow the instructions provided on the ''Comment Now'' screen. Please include your name, company name (if any), and ''FAR Case 2021–017'' on your attached document. If your comment cannot be submitted using *https://www.regulations.gov,* call or email the points of contact in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Instructions: Please submit comments only and cite ''FAR Case 2021–017'' in all correspondence related to this case. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. Public comments