Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General's Civil Money Penalty Rules

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Summary of Proposed Rule

On April 24, 2020, the Office of the Inspector General (OIG) of the Department of Health and Human Services (HHS) published in the *Federal Register* (85 FR 22979) a proposed rule that would amend its civil money penalty (CMP) rules to (1) incorporate new authorities provided for CMPs, assessments, and exclusions related to HHS grants, contracts, other agreements; (2) incorporate new CMP authorities for information blocking; and (3) increase the maximum penalties for certain CMP violations. The proposal regulations would generally be effective 30 days after the final rule is published; different effective dates and alternatives are proposed and discussed for the information blocking provisions. **Comments on the proposed rule are due by June 23, 2020.**

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I. Background

The mission of the HHS OIG is to protect the integrity of HHS programs and the health and welfare of program beneficiaries. It focuses on efforts to fight waste, fraud and abuse in Medicare, Medicaid, and other HHS programs. Among its authorities, the OIG may impose CMPs, as provided by Section 1128A of the Social Security Act ("the Act"), the Public Health Service Act (PHSA), and set forth in existing regulations at 42 CFR Parts 1003 and 1005.

This proposed rule would implement provisions of the 21st Century Cures Act ("Cures Act") (P.L. 114-255) and the Bipartisan Budget Act of 2018 (BBA 2018) (P.L 115-123) which modified OIG authority regarding CMPs.

- Section 5003 of the Cures Act clarifies and expands the OIG authority (under section 1128A of the Act) to use CMPs, assessments, and exclusions in cases of HHS grant or contract fraud. CMPs of between $10,000 and $50,000 are authorized for each incident,

including where false claims are presented; applications, bids, proposals, or other documents are falsified or mispresented, or false information is provided; or the entity fails to grant timely access to the OIG for purposes of audits, investigations, and evaluations.

- Section 4004 of the Cures Act added section 3022 of the PHSA, which defines information blocking and provides authority for the OIG to investigate claims of information blocking and to impose CMPs of up to $1 million per violation.
- Section 50412 of the BBA 2018 doubled maximum CMPs under section 1128A(a) of the Act to a range of $20,000 to $100,000 from a range of $10,000 to $50,000 and also increased maximum penalties under section 1128A(b) to a range of $5,000 to $10,000 from a range of $2,000 to $5,000. These increases are effective for acts committed after February 9, 2018 (enactment of the BBA 2018).

II. Civil Money Penalty Assessment and Exclusion Authorities under 42 CFR Part 1003

A. Subpart A – General Provisions

1. Definitions

OIG proposes to add several statutory definitions to the regulatory definitions at §1003.100. Specifically, definitions are added for the terms "Department," "obligation," "other agreement," "program beneficiary," "recipient," "specified claim," and "specified State agency." These follow statutory definitions except for changes to reflect internal regulatory citations. In the case of "recipient," OIG proposes to clarify that the term means all persons (excluding program beneficiaries as currently defined in §1003.110) directly or indirectly receiving money or property under a grant, contract, or other agreement funded in whole or in part by the Secretary, including subrecipients and subcontractors. It believes that this proposed definition is consistent with Congressional intent.

2. Assessments

The regulations at §1003.130 would be amended to explicitly state that assessments are in lieu of damages sustained by HHS, a state agency, or a *specified state agency* because of the violation. The addition of "specified state agency" reflects the new statutory definition (as the agency that administers or supervises a grant, contract or other agreement funded in whole or in part by the Secretary) proposed above for addition to the regulation, and which differs from the statutory definition under section 1128A of "state agency" (as the agency administering the state plan for Medicaid, Title V or Title XX).

3. Technical Changes

Technical changes to regulatory text at §1003.140 are proposed to correct errors. In addition, footnotes that appear throughout part 1003[1] would be eliminated and replaced by a new

[1] Footnotes 1-12 are found in §§1003.210, 1003.310, 1003.410, 1003.510, 1003.610, 1003.810, 1003.910, 1003.1010, 1003.1110, 1003.1210, and 1003.1310; they state that the penalty amounts in the section are updated

§1003.140(d)(5) that would state that penalty amounts under part 1003 are adjusted annually for inflation.

B. Subpart B – CMPs, Assessments, and Exclusions for False or Fraudulent Claims or Other Similar Misconduct

§§1003.210 and 1003.310 would be modified to reflect the new maximum penalty amounts provided under the BBA 2018 for conduct occurring after February 9, 2018. The proposed changes in the maximum amounts are summarized in the following table.

		Maximum Penalty	
Proposed Regulation	**Violation**	**Conduct on or before 2/9/2018**	**Conduct after 2/9/2018**
§1003.210(a)(1)	All violations not otherwise specified	$10,000	$20,000
§1003.210(a)(2)	False or misleading information under §1003.200(b)(2) – "An item or service for which the person knew, or should have known, that the claim was false or fraudulent"	$15,000	$30,000
§1003.210(a)(3)	Prohibited relationship under §1003.200(b)(3)) – "An item or service furnished during a period in which the person was excluded from participation in the Federal health care program to which the claim was presented"	$10,000 per day	$20,000 per day
§1003.210(a)(4)	Billing by excluded individual or entity under §1003.200(b)(4)	$10,000 per item or service	$20,000 per item or service
§1003.210(a)(6)	False statement, omission or misrepresentation of material fact under §1003.200(b)(7) – "….in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program, including contracting organizations, and entities that apply to participate as providers of services or suppliers in such contracting organizations"	$50,000 for each statement, omission, or misrepresentation	$100,000 for each statement, omission, or misrepresentation

annually, and published at 45 CFR part 102.

		Maximum Penalty	
Proposed Regulation	**Violation**	**Conduct on or before 2/9/2018**	**Conduct after 2/9/2018**
§1003.210(a)(7)	Under §1003.200(b)(9) -- False record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program.	$50,000 for each false record or statement	$100,000 for each false record or statement
§1003.210(a)(8)	Under §1003.200(b)(8) -- Overpayment that is not reported and returned	$10,000 for each related item or service	$20,000 for each related item or service
§1003.210(a)(9)	Failure to grant timely access to records, documents, and other material or data requested by the OIG for audits, investigations, or other statutory functions in violation of §1003.200(b)(10).	$15,000 per day	$30,000 per day
§1003.210(a)(10)	Under §1003.200(c), false certification by a physician falsely certifying that a Medicare beneficiary requires home health services when the physician knows that the beneficiary does not meet the eligibility requirements	Greater of $5,000 or 3 times the amount of home health payments made under the false certification.	Greater of $10,000 or 3 times the amount of home health payments made under the false certification.
§1003.310(a)(3)	Under §1003.300(d) – "…unlawfully offering, paying, soliciting, or receiving remuneration to induce or in return for the referral of business paid for, in whole or in part, by Medicare, Medicaid, or other Federal health care programs."	$50,000 for each offer, payment, solicitation, or receipt of remuneration	$100,000 for each offer, payment, solicitation, or receipt of remuneration

C. Subpart G-- CMPs, Assessments, and Exclusions for False or Fraudulent Claims or Similar Conduct Related to Grants, Contracts and Other Agreements

OIG proposes to add a new subpart G that codifies the new authority granted it under the Cures Act to impose CMPs, assessments and exclusions for fraud, false claims, and similar conduct related to HHS grants, contracts, and other agreements.

Proposed new §1003.700 would set forth the five categories of offenses (as provided under the Cures Act) under which a penalty, assessment, or exclusion may be imposed on any person (including an organization, agency or other entity but excluding a program beneficiary) with

respect to a grant, contract, or other agreement. These categories are set forth in 1003.700(a)(1) through (a)(5) and involve:

- Presenting a false claim under the grant, contract, or agreement;
- Making a false statement, omission or misrepresentation of a material fact in an application, proposal, bid, progress report or other document required to be submitted in order to directly or indirectly receive or retain funds provided by the Secretary (in whole or in part) pursuant to the grant, contract or other agreement;
- Making a false record or statement material to a false or fraudulent claim under the grant, contract, or agreement;
- Making a false record or statement material to an obligation to pay or transmit funds or property to the Secretary with respect to a grant, contract, or agreement, or concealing and avoiding or decreasing such an obligation; and
- Failing to grant timely access upon reasonable request of the OIG for the purpose of audits, investigations, evaluations, or other statutory functions involving a grant, contract, or other agreement.

OIG notes that the statute applies to a wide array of HHS funding situations, and that in particular, "other agreements" is broadly defined. When it investigates potential misconduct under this statute, OIG intends to evaluate on a case-by-case basis whether the funding arrangement constitutes an "other agreement" and whether a violation has occurred.

The proposed new §1003.710 specifies the maximum penalties that may be imposed for violations under the five categories specified in §1003.700. The maximums are shown in the following table:

Proposed Regulation	**Violation**	**Maximum Penalty**
§1003.710(a)(1)	False claims under new §1003.700(a)(1)	$10,000 per claim*
§1003.710(a)(2)	False statement, omission, or misrepresentation in a document submitted to receive or retain funds under new §1003.700(a)(2)	$50,000 for each false statement, omission or misrepresentation**
§1003.710(a)(3)	False record or statement material to false or fraudulent claim under new §1003.700(a)(3)	$50,000 per false record or statement*
§1003.710(a)(4)	False record or statement material to an obligation to pay or transmit funds or property under new §1003.700(a)(4)	$50,000 per false record or statement or $10,000 for each day a person conceals, avoids or decreases an obligation to pay**
§1003.710(a)(5)	Failing to grant timely access to OIG under new §1003.700(a)(5)	$15,000 per day
* In addition, assessments on a person shall not exceed 3 times the amount claimed. ** In addition, assessments on a person shall not exceed 3 times the total amount of the funds (or value of the property) involved.		

Proposed new §1003.720 describes the aggravating and mitigating factors the OIG would consider in imposing penalties, assessments, and exclusions under the Cures Act authorities

regarding fraud and misconduct related to HHS grants, contracts, and other agreements. These are not all-inclusive and match the factors identified with respect to violations related to false healthcare claims at existing §1003.220. OIG says that based on its experience these factors provided a framework to aid it in assessing the severity of the conduct at issue when determining the size and scope of penalties, assessments, and exclusions to be imposed.

Specifically, the proposed rule would consider it a mitigating circumstance if all the violations included in the action were of the same type and occurred within a short period of time; there were few such violations; and the total amount claimed or requested or related to the violations was less than $5,000.

The non-exclusive list of aggravating circumstances include if the violations were of several types or occurred over a lengthy period of time; there were many such violations (or the nature and circumstances indicate a pattern of false or fraudulent specified claims, requests for payment, or a pattern of violations); the amount requested or claimed or related to the violations was $50,000 or more; or the violation resulted, or could have resulted, in physical harm to any individual.

OIG solicits comment on other aggravating or mitigating circumstances that it should consider when imposing penalties, assessments, and exclusions under its new authority pertaining to HHS grants, contracts, and other agreements.

D. Subpart J – CMPs, Assessments, and Exclusions for Beneficiary Inducement Violations

Existing §1003.1010 would be amended to reflect the increased maximum penalties provided under the BBA 2018 for violations of the prohibition on remuneration made to beneficiaries of Medicare or a state health care program (i.e., Medicaid, CHIP, Title V or Title XX) that are inducements for the individual to receive services from a particular provider or supplier under the program. Specifically, for conduct occurring after February 9, 2018, the penalty is increased from $10,000 to $20,000 for each item and service ordered or provided. The current provision additionally limiting an assessment on a person to no more than 3 times the amount claimed would be unchanged.

E. Subpart N – CMPs for Information Blocking

1. Overview

As noted earlier, the Cures Act provides new authority for the OIG to impose penalties, assessments and exclusions with respect to information blocking; the information blocking provisions were added as section 3022 of the PHSA, and the related OIG authorities specifically at section 3022(b). OIG recognizes that information blocking is newly regulated conduct, and some individuals and entities subject to the information blocking CMPs may not be familiar with the OIG enforcement authorities. For those reasons, in this section of the preamble, OIG reviews its experience in investigating and imposing CMPs with respect to false claims made to health

care programs. It expects to use similar methods and techniques with respect to investigations of information blocking and exercise of discretion with respect to penalties.

Based on current expectations, OIG expects to prioritize investigations with respect to conduct that: (i) resulted in, is causing, or had the potential to cause patient harm; (ii) significantly impacted a provider's ability to care for patients; (iii) was of long duration; (iv) caused financial loss to federal health care programs, or other government or private entities; or (v) was performed with actual knowledge. OIG expects that its priorities will evolve as it gains experience with investigating information blocking.

OIG emphasizes that information blocking (as defined in section 3022(a)(1)(B)(i) and 45 CFR 171.103(b)) [2]includes an element of intent, and it will not bring enforcement actions against actors who it determines made innocent mistakes (i.e., lack the requisite intent for information blocking). It will use its experience with respect to other intent-based laws in using its discretion for taking action against individuals and entities. Note that with this statutory reference the OIG is referring to the intent standard that applies "to a health information technology developer, exchange, or network." As discussed in E.4 below, the OIG CMP authority applies only to these entities; health care providers are treated differently.

Further emphasis is given to the assessment of information blocking allegations based on the unique facts and circumstances presented. OIG will closely coordinate with the Office of the National Coordinator (ONC) for Health Information Technology given the ONC's authorities under the PHSA and expertise on information blocking.

Under section 3022(b)(3)(A) of the PHSA, OIG may refer an information claim to the HHS Office of Civil Rights if a consultation regarding health privacy and security under the Health Insurance Portability and Accountability Act (HIPAA) would resolve an information blocking claim. Depending on the facts and circumstances OIG may exercise its discretion for such referrals and intends to work closely with OCR in that regard.

The Secretary, under section 3022(d)(4), is required to ensure that information blocking penalties do not duplicate penalty structures that would otherwise apply to the individual or entity involved prior to enactment of the Cures Act. OIG will coordinate with ONC and OCR and other federal agencies such as the Department of Justice and the Federal Trade Commission and use its discretion to ensure that information blocking penalties are not duplicative of other penalties.

2. Proposed and Alternative Effective Dates

OIG proposes an effective date for the information blocking CMPs of 60 days after the effective date of the final rule associated with this proposed rule; it will begin enforcement against actors who engage in information blocking after that date. Although it points out that the statute (section 3022(b)) is self-implementing, OIG intends to use its enforcement discretion to impose CMPs only against actors who engaged in information blocking after the effective date of the

[2] In the CURES Act final rule, ONC restructured from the proposed rule its regulatory definition of information blocking at §171.103. The OIG's reference here to §171.103(b) is likely a reference to §171.103(a)(2).

OIG final rule. OIG notes that the ONC final rule[3] establishes a compliance date of November 2, 2020 for the information blocking provision, at which time individuals and entities are legally subject to the requirements. It believes that the time between that compliance date and the effective date of the OIG final rule will provide a reasonable amount of time for individuals to come into compliance with the ONC final rule.

An alternative effective date is under consideration by OIG. Under the alternative, OIG would specify an effective date – October 1, 2020 – for proposed new subpart N of part 1003 (described below), which would give entities a date certain for when OIG enforcement would begin. OIG says it has considered that it would have to issue the final rule before that date. It also says that at a minimum, enforcement would not begin before the compliance date of the ONC final rule.[4] **Comments are solicited on the two approaches for the effective date of the information blocking CMP regulations.** Alternative dates that are sooner or later than October 1, 2020 are being considered, and OIG is interested in comments on potential dates and why more or less time would be needed for compliance. The proposed effective dates would not apply to the other provisions of this proposed rule, which would be effective 30 days after publication of the final rule.

3. Regulatory Text

OIG proposes a new subpart N to part 1003 to implement the information blocking CMPs. The proposed regulatory text cross references to 45 CFR part 171 as established by the ONC final rule. That rule defines information blocking and identifies exceptions, (that is, activities that do not constitute information blocking). Under the proposal, OIG would use the ONC definitions and exceptions in assessing conduct of health information technology developers, entities offering certified health information technology, health information networks, health information exchanges, and health care providers.

4. Application of CMP Procedures and Appeals

The statute (at 3022(b)(2)(A) limits the application of CMPs to information technology developers or other entities offering certified health information technology or a health information exchange or network, and specifically excludes health care providers. Consistent with these provisions, if OIG determines that a health care provider has committed information blocking it will refer the provider to the "appropriate agency for appropriate disincentives." The appropriate agency and disincentives will be established by the Secretary in future rulemaking.

OIG notes that section 3022(b)(2)(C) of the PHSA requires that it apply existing CMP procedures under section 1128A for information blocking CMPs. By incorporating the

[3] The "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program," was put on public display ad the *Federal Register* on April 21, 2020 and is scheduled to be published in the *Federal Register* on May 1, 2020. Information is available at https://www.healthit.gov/curesrule/.
[4] The suggested October 1 alternative effective date is inconsistent with the OIG's statement that its enforcement would not begin before the effective date of the ONC final rule. It may be that this alternative was written prior to publication of the ONC final rule.

information blocking CMP rules into part 1003, the existing regulations on CMP procedures in subpart O and the appeals process set forth in part 1005 would apply. **OIG solicits comment on its proposal to incorporate the information blocking CMP rules into part 1003 and to apply existing CMP procedures and appeals to the information blocking CMPs.**

5. Maximum Penalty for Information Blocking

In a new §1003.1410, the proposed rule would codify the statutory maximum CMP for information blocking at $1 million per violation. The proposal would also define "violation" as a practice (defined in the ONC final rule at 45 CFR 171.102 as "one or more related acts or omissions by an actor") that constitutes information blocking. OIG believes this is necessary to clarify how it will determine the number of practices that might be penalized. For further explanation, OIG offers hypothetical examples as shown below. **OIG solicits comments on the proposed definition of "violation" for purposes of proposed subpart N.**

6. Hypothetical Examples of Information Blocking Violations

The following hypothetical examples are offered with an emphasis that they are illustrative and not exhaustive, and that the facts and circumstances of each case will determine what constitutes a violation of the information blocking provisions. The examples assume that the conduct meets all elements of the information blocking definition, such as the requisite level of statutory intent, are not required by law and do not meet any of the information blocking exceptions under the ONC final rule.

- Example 1. A health care provider notifies its health IT developer of its intent to switch to another electronic health record (EHR) system and requests a complete electronic export of its patients' electronic health information (EHI). The developer refuses to export any EHI without charging a fee. The refusal to export EHI without charging this fee would constitute a single violation.
- Example 2. A health IT developer (D1) connects to a health IT developer of certified health IT (D2) using a certified API. D2 decides to disable D1's ability to exchange information using the certified API. D1 requests EHI through the API for one patient of a health care provider for treatment. As a result of D2 disabling D1's access to the API, D1 receives an automated denial of the request. This would be considered a single violation.

Although Examples 1 and 2 each illustrate a single violation, OIG notes that in the first example it would consider the number of patients affected by the health IT developer's information blocking practice in determining the *penalty amount*. But for determining *the number of violations*, the important fact would be that the health IT developer engaged in one practice (charging a fee to the health care provider to perform an export of electronic health information for the purposes of switching health IT) that meets the elements of the information blocking definition. **OIG solicits comment on the examples of a single violation and what constitutes a single violation.**

- Example 3. A health IT developer's software license agreement with one customer prohibits the customer from disclosing to its IT contractors certain technical interoperability information (i.e. interoperability elements), without which the customer and the IT contractors cannot access and convert EHI for use in other applications. The health IT developer also chooses to perform maintenance on the health IT that it licenses to the customer at the most inopportune times because the customer has indicated its intention to switch its health IT to that of the developer's competitor. For this specific circumstance, one violation would be the contractual prohibition on disclosure of certain technical interoperability information and the second violation would be performing maintenance on the health IT in a discriminatory fashion. Each violation would be subject to a separate penalty.
- Example 4. A health IT developer requires vetting of third-party applications before the applications can access the health IT developer's product. The health IT developer denies applications based on the functionality of the application. There are multiple violations based on each instance the health IT developer vets a third-party application because each practice is separate and based on the specific functionality of each application. Each of the violations in this specific scenario would be subject to a penalty.

With respect to Examples 3 and 4 illustrating multiple violations, OIG notes that important facts in determining the number of violations under the proposed rule are the discrete practices that each meet the elements of the information blocking definition. In Example 3, the health IT developer engages in two separate practices: (1) prohibiting disclosure of certain technical interoperability information and (2) performing maintenance on the health IT in a discriminatory fashion. Each practice would meet the definition of information blocking separately. Therefore, it illustrates a scenario with two violations under the proposed rule. In Example 4, the health IT developer vets each third-party application separately and makes a separate decision for each application. For each denial of access to EHI based on the discriminatory vetting, there is a practice that meets the definition of information blocking. Thus, each denial of access would constitute a separate violation under the proposed rule.

7. Determinations Regarding the Penalty Amount

A new §1003.1420 would codify the factors that OIG must consider when imposing a CMP against an individual or entity for committing information blocking. The factors specified are the nature and extent of information blocking and the resulting harm including, where applicable, the number of patients affected, the number of providers affected, and the number of days the information blocking persisted. These factors are required under section 3022(b)(2)(A) of the PHSA and are similar to those found in other sections of part 1003 with respect to other CMP authorities of the OIG.

OIG notes that because regulation of information blocking conduct is new it has limited experience on which to inform a proposal for additional aggravating and mitigating circumstances to adjust the CMP penalties. For these reasons, it proposes only to implement the statutory factors. **OIG solicits comments on any additional factors it should consider in**

determining the amount of information blocking CMPs, including examples of specific conduct that should be subject to higher or lower penalty amounts.

F. Subpart O – Procedures for the Imposition of CMPs, Assessments, and Exclusions

Technical changes would be made to the regulatory text in subpart O to apply the Cures Act change to this section. These changes would add a reference to "specified claims" in the provision at §1003.1580 allowing it to use statistical sampling as evidence and §1003.1550 pertaining to collection of penalties and assessments. OIG says with respect to the latter that the change would permit the US to file suit in the US district court for the district in which the specified claim was presented.

III. Appeals of Exclusions, Civil Money Penalties, and Assessments under 42 CFR Part 1005

In order to capture its authority with respect to HHS grants, contracts and other agreements as well as information blocking, OIG proposes to amend the definition of "civil money penalty cases" to refer to all proceedings arising under any of the statutory bases for which it has been delegated authority to impose CMPs. The definition of "exclusion cases" would be similarly modified. Current language restricts these definitions to cases involving Medicare or the state health care programs.

IV. Regulatory Impact Statement

The proposed rule does not meet the threshold for a major rule ($100 million impact) that would trigger a regulatory impact analysis. OIG believes the benefits of the rule would be to deter conduct that negatively affects the integrity of HHS grants, contracts, and other agreements, and to deter information blocking conduct that interferes with effective health information exchange. OIG expects to incur some investigation and enforcement costs as a result of the proposed rule; it notes that the FY 2021 President's Budget proposes $5.3 million for OIG information blocking activities. Transfers resulting from CMPs and assessments cannot be quantified because they depend on the facts and circumstances of individual cases.