Published on *The National Law Review* https://natlawreview.com

HHS Publishes Proposed "Disincentives Rule" to Prevent Information Blocking by Health Care Providers

Article By:

Jennifer (Jenny) M. Nelson Carney

Karen Mandelbaum

Dennis A. Pangindian

Elizabeth Scarola

Patricia M. Wagner

The U.S. Department of Health and Human Services (HHS)—through the Centers for Medicare & Medicaid Services (CMS) and the Office of the National Coordinator for Health Information Technology (ONC)—recently published a proposed rule establishing disincentives[1] for certain health care providers[2] that the Office of Inspector General (OIG) determines have committed information blocking[3] (the "Proposed Disincentives Rule").

The Proposed Disincentives Rule is next in a series of rules implementing the 21st Century Cures Act (the "Cures Act") mandate for developers of certified health information technology (IT), health information exchanges/networks, and health care providers to share electronic health information (interoperability) and to avoid information blocking. **Comments on the Proposed Disincentives Rule are due no later than 5 p.m. on January 2, 2024.**

Key Takeaways

The Cures Act specifies that "health care providers" that commit "information blocking" should be subject to disincentives, while health IT developers or other entities offering certified health IT, health information exchanges, and health information networks would be subject to civil money penalties not to exceed $1 million per offense. The definition of "health care provider" in the Cures Act and in the ONC's May 1, 2020, final rule[4] is broad and arguably could encompass any category of health care facility, entity, practitioner, or clinician as determined appropriate by the Secretary of the HHS.

Nevertheless, this Proposed Disincentives Rule applies only to those health care providers that participate in certain CMS programs through which they are eligible to receive incentives for using certified electronic health record technology (CEHRT). As such, providers participating in CMS's

Merit-based Incentive Payment System (MIPS)[5] for eligible clinicians, the Medicare Promoting Interoperability (PI) Program[6] for eligible hospitals and critical access hospitals (CAHs), and participants in the Medicare Shared Savings Program (MSSP)[7] could be penalized with a disincentive that would result in a negative payment adjustment under the applicable program.

In evaluating complaints of information blocking, the OIG expects to use four priorities to assess whether the health care provider's practices "(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."[8] Regarding the priority related to patient harm, OIG previously clarified that "patient harm is not specific to individual harm, but rather may broadly encompass harm to a patient population, community, or the public."[9] Furthermore, OIG may prioritize investigations based, in part, on the amount of information blocking allegations "relating to the same (or similar) practices by the same entity or individual."[10] Although these priorities are 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 also "emphasizes" that information blocking "includes an element of intent" but notes that the standard for intent is different for health care providers than it is for a health IT developer, exchange, or network.[11]

This is only the beginning, as the Proposed Disincentives Rule preamble notes that further rulemaking to expand disincentives to other types of providers by other appropriate agencies is anticipated. It is important to note here that the disincentives provision in the Cures Act does not limit the number of disincentives that an appropriate agency can impose on a health care provider. As such, cumulative disincentives could be imposed on an eligible clinician to deter health care providers from engaging in information blocking. CMS has requested that commenters suggest specific types of health care providers that should be subject to disincentives and what those potential disincentives should be. Commenters might also want to voice their opinion during the comment period on whether or not to include additional providers at all.

How Did We Get Here?

The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 incentivized hospitals and providers to invest in CEHRT. The CMS EHR Incentive Program, originally called "Meaningful Use," offered health care providers that use CEHRT and that demonstrate meaningful use (e.g., "meaningful users") to be entitled to enhanced reimbursement or incentive payments. The purpose behind these incentive programs was to enable interoperability and to ensure access to patient information when and where it is needed to provide care, improve quality, and lower costs. Yet despite these investments, ONC reported to Congress that information blocking was frustrating the goals of the HITECH Act and undermining health reform.[12] In 2018, CMS changed the name and focus of the EHR Incentive Program to the PI Program, and to encourage interoperability, CMS began to integrate the use of CEHRT into the conditions of participation in CMS programs.

Impact

Hospitals

Under the Proposed Disincentives Rule, an eligible hospital or CAH would not be a meaningful user of CEHRT in an applicable EHR reporting period if the OIG determines that the eligible hospital committed information blocking. CMS estimated that an appropriate disincentive for eligible hospitals would be the loss of 75 percent of the annual market basket increase. For CAHs, CMS estimated that an appropriate disincentive would be that payment would be reduced to 100 percent of reasonable costs instead of 101 percent. Using data from previous years, CMS simulated the calculation for a disincentive to which an eligible hospital may be subject and estimated the median disincentive amount of $394,353, and a 95 percent range of between $30,406 and $2,430,766, that the hospital would receive in lower reimbursements.

Eligible Clinicians

CMS is proposing to codify an amendment to the criteria for an eligible clinician or group to earn a score in the PI category. The clinician or group must be a meaningful user of CEHRT. Since an OIG determination deems an eligible clinician or group to not be considered a meaningful user of CEHRT, the disincentive would automatically attach, and instead of receiving an increase or positive payment adjustment for that performance year, the eligible provider or group would be assessed a disincentive up to as much as a negative nine percent of Medicare reimbursements. The range of potential individual and group disincentive amounts will vary based on individual clinician payments and group sizes. However, CMS estimated the median disincentive amount for individual eligible providers to be $686 and the disincentive amount for a median group size of six clinicians to be $4,116 (although there is a range of $1,372 to $164,326 for groups with two to 241 providers). The Proposed Disincentives Rule also provides additional estimates for those MIPS-eligible providers that may be subject to a “higher than median” disincentive.

Accountable Care Organizations

Under the Affordable Care Act, MSSP accountable care organizations (ACOs) must “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**” (emphasis added).

CMS further defines “enabling technologies” to include “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.” CMS has interpreted this to mean that ACOs are required to have a written plan that defines the methods and processes it uses to coordinate care across and among health care providers both inside and outside the ACO that “encourages and promotes the use of enabling technologies for improving care coordination for beneficiaries.”[13] As such, CMS is proposing that a failure to comply with the Cures Act information blocking provisions is a failure to comply with the conditions of participation in MSSP, and the offender (e.g., the ACO, an ACO participant, and/or an ACO participating provider/supplier)[14] would be ineligible to participate in the program for a period of at least one year.

These ACO disincentives can follow ACOs, ACO participants, and ACO providers/suppliers even after the penalty imposed has been satisfied and the information blocking behavior is fixed. The proposed disincentives for MSSP participants may have a particularly punitive effect on ACOs, ACO participants, and ACO providers/suppliers. Of note, the MSSP regulations include a screening process through which CMS can deny participation in the MSSP if the entity or individual has a history of program integrity issues, including committing information blocking. Designating information blocking as a “program integrity issue” puts a violation of the Interoperability Rules into the same

category of behaviors as fraud, waste, and abuse.

Missing from the discussion in the preamble is what might happen to Medicare beneficiaries who have been receiving their health care through an MSSP ACO, or from ACO providers/suppliers that get suspended or terminated from the program because of a determination by the OIG that a health care provider committed information blocking. While the patients may continue to receive care through that ACO or from the ACO participant, providers, and suppliers, this disincentive may result in Medicare beneficiaries going back into Original Medicare fee-for-service without the added benefit of the value-based care model. This potential result seemingly runs afoul of CMS's goal to increase the number of beneficiaries in a care relationship with accountability for quality and total cost of care. Since 2012, CMS has supported ACOs in their efforts to improve the delivery of care for their assigned beneficiary populations through model-specific learning systems that provide ACOs with a forum in which they can collaborate with and learn from one another. It would be reasonable to believe that MSSP ACO disincentives would be able to leverage those model-specific learning systems to resolve violations or allegations of information blocking rather than risk an MSSP ACO's otherwise successful participation in the program.

When Would Disincentives Be Recouped?

HHS is proposing that the disincentives for eligible providers, hospitals, and CAHs should be imposed during the year of OIG's determination of information blocking—as opposed to recouping an amount calculated based on the year or years during which the information blocking occurred. Assuming the offending behavior is remediated, once the disincentive is satisfied, the offender may resume participation in the program(s) supported by the authority of the "appropriate agency."[15]

Additional Penalties

Providers should note that, in addition to financial disincentives, the ONC also plans to publish publicly the names of actors found guilty of information blocking, along with any penalties they received, in what is referred to colloquially by the agency as a "wall of shame."

ENDNOTES

[1] HHS, 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking, 88 Fed. Reg. 74947 (Nov. 1, 2023), *available at* https://www.govinfo.gov/content/pkg/FR-2023-11-01/pdf/2023-24068.pdf. Under this proposed rule, "*[d]isincentive* means a condition specified in § 171.1001(a) that may be imposed by an appropriate agency on a health care provider that [the HHS Office of Inspector General] determines has committed information blocking for the purpose of deterring information blocking practices." HHS has requested feedback on this definition.

[2] See 45 C.F.R. 171.102, noting that a *health care provider* has the same meaning as "health care provider" in 42 U.S.C. 300jj, which states the following:

[T]he 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 section 1395x(r) of this title), a practitioner (as described in section 1395u(b)(18)(C) of this title), a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act [25 U.S.C. 5301 et seq.]), tribal organization, or urban Indian organization (as defined in section 1603 of title 25), a rural health clinic, a covered entity under section 256b of this title, an ambulatory surgical center described in section 1395l(i) of this title, a therapist (as defined in section 1395w–4(k)(3)(B)(iii) of this title), and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.

[3] See 45 C.F.R. §171.103. Information blocking is a practice by an "actor" that is likely to interfere with the access, exchange, or use of electronic health information, except as required by law or specified in an information blocking exception.

[4] HHS, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program, 85 Fed. Reg. 25642, May 1, 2020, *available at* https://www.govinfo.gov/content/pkg/FR-2020-05-01/pdf/2020-07419.pdf.

[5] The MIPS program as described in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).

[6] CMS, 2022 Medicare Promoting Interoperability Program Requirements, *available at* https://www.cms.gov/regulations-guidance/promoting-interoperability/2022-medicare-promoting-interoperability-program-requirements.

[7] See Medicare Shared Savings Program, 42 CFR Part 425, implementing Section 1899 of the Social Security Act.

[8] 88 Fed. Reg. 74947, 74951(Nov. 1, 2023).

[9] 88 Fed. Reg. 42820, 42823 (July 3, 2023).

[10] 88 Fed. Reg. 74947, 74952 (Nov. 1, 2023).

[11] *Id.*, at 74952.

[12] *See* ONC's *Report on Health Information Blocking*, Report to Congress, April 2015, *available at* https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf.

[13] 42 CFR 425.112(b)(4)(i) and (b)(4)(ii)(C).

[14] "ACO," "ACO participant," and "ACO provider/supplier" are defined at 42 CFR 425.20.

[15] HHS has proposed to define "appropriate agency" (at 45 CFR §171.102) to mean a government agency that has established disincentives for health care providers that OIG determines have committed information blocking.

National Law Review, Volumess XIII, Number 343