

June 2024

## 1. Who is a health care provider under the information blocking regulations?

For the purposes of information blocking, a health care provider is defined in <u>45 CFR 171.102</u>, which is the same definition of health care provider found in section 3000(3) of the Public Health Service Act (PHSA). For more information about who is considered a health care provider for information blocking, see this <u>resource</u>.

### 2. How will OIG decide which information blocking claims to investigate?

The 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking final rule states that OIG expects to use four priorities for enforcement when investigating information blocking practices by health care providers. OIG expects to prioritize practices that: (i) resulted in, are causing, or had the potential to cause patient harm; (ii) significantly impacted a provider's ability to care for patients; (iii) were of long duration; and (iv) caused financial loss to federal health care programs, or other government or private entities. OIG's expected priorities are informational only and are not binding on OIG decision making.

## 3. How will OIG determine that a health care provider has committed information blocking?

OIG will find that a practice (act or omission) by a health care provider constitutes information blocking if it finds that the health care 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" and the practice was neither required by law nor meets an <u>exception</u>.

# 4. How will a health care provider learn if they are subject to a disincentive following a determination of information blocking by OIG?

Following referral of a determination of information blocking by OIG, the final rule states that an appropriate agency that imposes a disincentive will 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.



### 5. Will the impact of a disincentive be the same for every provider?

Because the Cures Act requires disincentives to be established using authorities under applicable federal law, the impact of a disincentive will vary based on circumstances specific to each provider and their participation in the program under which a disincentive is imposed.

# 6. Are all health care providers included in the definition of health care provider for information blocking purposes impacted by the final rule?

No, some health care providers that are subject to the information blocking regulations are not impacted by the programs under which HHS has established disincentives in this final rule. This final rule is a first step that focuses on authorities which pertain to one set of health care providers that furnish a broad array of health care services to large numbers of Medicare beneficiaries and other patients.

### 7. Will additional disincentives for health care providers be established in the future?

HHS believes optimal deterrence of information blocking calls for imposing appropriate disincentives on all health care providers (as defined at 45 CFR 171.102) determined by the Office of the Inspector General (OIG) to have committed information blocking. The proposed rule requested information about the health care providers that HHS should prioritize when establishing additional disincentives, particularly disincentives that would apply to health care providers that are not impacted by the disincentives in this final rule, and disincentives for these health care providers that can be established using authorities under applicable federal law.

Many commenters provided input on the request for information, and HHS may consider these comments for future rulemaking. However, at this time, HHS has not established a target for when additional disincentives would be established.

### 8. Will other agencies besides CMS have disincentives?

While this final rule only establishes disincentives for health care providers using authorities for programs administered by CMS, other agencies could establish disincentives through future notice, public comment, and rulemaking.

### 9. Do any of the finalized policies differ from those proposed?

After considering public comments we finalized several modifications to the policies in the proposed rule:

• For the policies on transparency for information blocking determination, disincentives, and penalties, we have finalized modified language in 45 CFR 171.1101(a)(1)(iii) and 45 CFR 171.1101(b)(1)(iii) to clarify that the description of the practice includes when the practice occurred. We have also finalized a modification to the provision in 45 CFR



171.1101(a)(2) to add that information will not be posted prior to the completion of any administrative appeals process pursued by the health care provider.

- For the disincentive finalized under the Shared Savings Program, CMS has finalized incorporation of the alternative policy discussed in the proposed rule that CMS will consider an OIG information blocking determination in light of the relevant facts and circumstances before applying a disincentive such as 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), denying an ACO's application to participate in the Shared Savings Program if remedial action is not taken, or terminating an ACO's participation agreement with CMS. The relevant facts and circumstances 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, whether the provider was previously subject to a disincentive in another program, and other factors.
- We also finalized several minor modifications to language proposed for 45 CFR 171.102, 45 CFR 171.1000, 45 CFR 171.1001, for consistency with the final policies discussed in the rule.

### 10. When is the final rule effective?

The final rule states that OIG will not begin investigating health care providers until after the effective date of this final rule, and will exercise its enforcement discretion not to make any determinations regarding conduct occurring prior to the effective date of this final rule for information blocking disincentives. The policies in this final rule will be effective 30 days after the rule publishes in the Federal Register.