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Centers for Medicare & Medicaid Services (CMS) and Office of Inspector General (OIG) Extend Sunset Dates for Electronic Health Records (EHR) Subsidy Rules

Article By:

Health Law

CMS and OIG Extend Sunset Dates for EHR Subsidy Rules

Health care entities that have subsidized physician purchases of **electronic health records (EHR)** items and services may breathe a sigh of relief: the government has adopted final rules extending sunset dates for the regulations governing such subsidies.

On December 23, the government posted two final rules to extend sunset dates for theStark exception and fraud and abuse safe harbor for subsidies paid for adoption ofelectronic health records (EHR). The new sunset date is December 31, 2021. The sunset dates for both rules had been December 31, 2013.

The Centers for Medicare and Medicaid Services' (CMS) amendment to the relevant Stark rule and the Office of Inspector General's (OIG) amendment to the relevant safe harbor rule mirror each other. Because the OIG made analogous changes to the safe harbor rule, this blog post will discuss only the CMS Stark rule, which:

- Extends the sunset date to December 31, 2021
- Prohibits laboratory companies from donating EHR items and services under the Stark EHR exception;
- Removes the electronic prescribing requirement;
- Updates the "deemed interoperable" provision of the rule; and
- Clarifies the prohibition against any action that limits or restricts the use, compatibility, or interoperability of donated items or services.

The sunset extensions take effect on December 31, 2013. The other provisions take effect 90 days after December 27, 2013, which is the date the new rules will be published in the Federal Register.

The original Stark EHR subsidy rule required that donated software contain electronic prescribing capabilities meeting Medicare Part D requirements. The new rule eliminates this requirement.

The original Stark EHR subsidy rule required that donated or subsidized software be "interoperable". The rule stated that software is interoperable if a certifying body recognized by the Secretary of the Department of Health and Human Services certified the software within 12 months of the time it was provided to a physician. The new CMS rule says software is deemed to be interoperable if, on the date it is provided to the physician, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of EHR certification criteria under 45 CFR Part 170 (addressing health information technology standards).

Addressing what CMS said were concerns about potential abusive donations, the agency excluded laboratory companies from the types of entities that may donate electronic items and services under the Stark exception.

In addition, one provision of the Stark EHR exception prohibits donors from taking any action to limit or restrict the use, compatibility, or interoperability of the donated items or services with other electronic prescribing or electronic records systems. By adding examples to this regulatory prohibition, CMS sought to make it clearer that this prohibition applies to any donor action that limits the use of donated software with "any other health information technology".

Any entity contemplating making use of the Stark EHR exception and the fraud and abuse safe harbor should carefully review the entire rules and structure any donation or subsidy to meet the precise terms of the rules.

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