

# Government Proposes Extending Protections for Electronic Health Records Subsidies

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On April 10, 2013, the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) released almost identical proposed rules to update various aspects of the electronic health records (EHR) safe harbor to the [Anti-kickback statute \(42 C.F.R. §1001.952\(y\)\)](#) and [Stark Law exception \(42 C.F.R. §411.357\(w\)\)](#) and to extend the sunset date for the safe harbor and Stark Law exception to December 31, 2016. The following are some of the major aspects of the proposed rules.

## The “Deeming” Provision

CMS and OIG propose to update the provision under which EHR software is deemed interoperable. The EHR safe harbor and Stark Law exception specify that donated software must be interoperable at the time it is provided to the recipient. Software is deemed to be interoperable if a certifying body recognized by the Secretary of Health and Human Services has certified the software no more than 12 months prior to the date that it is provided to the physician.

The proposed rules update two aspects of the “deeming provision” of the EHR safe harbor and Stark Law exception. First, CMS and OIG propose to modify the provision to reflect that the Office of the National Coordinator for Health Information Technology (ONC) is responsible for certifying bodies. In order to become a certifying body recognized by the Secretary, the entity must complete an authorization process established by the ONC. Second, the proposed rules modify the 12-month requirement substituting a provision that is more in line with the ONC certification program that is anticipated to occur on a two-year regulatory interval.

## Electronic Prescribing

CMS and OIG propose to delete the electronic prescribing conditions found at 42 C.F.R. §1001.952(y)(10) and 42 C.F.R. §411.357(w)(11). Both CMS and OIG agree there are sufficient policy drivers supporting the adoption of electronic prescribing capabilities and removal of the electronic prescribing condition would not increase the risk of program or patient abuse for donations made under the EHR safe harbor and Stark Law exception.

## Extension of the EHR Safe Harbor/Exception

The EHR safe harbor and Stark Law exception are scheduled to sunset on December 31, 2013. The proposed rule extends the sunset date to December 31, 2016. As an alternative to the proposed extended sunset date, CMS and OIG are also considering extending the sunset date to December 31, 2021, which would correspond with the end of the EHR Medicaid incentives.

## Protected Donors

CMS and OIG propose to limit the scope of protected donors under the EHR exception and safe harbor to hospitals, group practices, prescription drug plan sponsors, and Medicare Advantage



organizations. Additionally, CMS and OIG are also considering retaining the current definition of protected donors, but excluding certain types of donors, such as laboratory companies, durable medical equipment suppliers and independent home health agencies.

## Data Lock-In and Exchange

The proposed rules intend to prevent the misuse of the EHR safe harbor and Stark Law exception in ways that result in data and referral lock-in. CMS and OIG are considering the inclusion of new or modified conditions in the safe harbor and exception as a way of limiting these risks.

## Covered Technology

CMS and OIG received questions about what items and services are within the scope of covered technology. In the proposed rules, the Agencies indicate that the current definition is sufficiently clear concerning the scope of covered technology; however, CMS and OIG are seeking public input regarding this issue.

Comments on the proposed rules must be received by June 10, 2013.

Squire Sanders lawyers have significant experience in advising clients on implementing EHRs and structuring EHR subsidy arrangements. We continue to monitor regulatory changes in this area and are available to counsel clients on these matters. For more information regarding how can assist you, please contact your principal Squire Sanders lawyer or one of the lawyers listed below.

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