



VCU Medical Center

Office of Health Innovation

Proposed Rule: Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships; Exception for Certain Electronic Health Records

Description: This proposed rule would revise the exception to the physician self-referral prohibition for certain arrangements involving the donation of electronic health records items and services. Specifically, it would extend the sunset date of the exception, remove the electronic prescribing capability requirement, and update the provision under which electronic health records technology is deemed interoperable.

Major Provisions

Section 1877 of the Social Security Act (the Act), codified at 42 U.S.C. 1395nn, also known as the physician self-referral statute: (1) prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership interest or compensation arrangement), unless an exception applies; and (2) prohibits the entity from submitting claims to Medicare for those referred services, unless an exception applies.

In accordance with this authority, CMS published an exception to protect certain arrangements involving the provision of interoperable electronic health records software or information technology and training services. The purpose of this proposed rule is to update certain aspects of the electronic health records exception and to extend the sunset date.

This proposed rule would amend the current exception in at least three ways. First, the proposed rule would update the provision under which electronic health records software is deemed interoperable. Second, the proposed rule would remove the requirement related to electronic prescribing capability from the exception. Third, the proposed rule would extend the sunset date of the exception.

The Deeming Provision

The current electronic health records exception to the physician self-referral law specifies that the donated software must be interoperable at the time it is provided to the physician. For purposes of this exception, "interoperable" means "able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered."

The current provisions of the electronic health records exception state that for purposes of meeting this condition, "software is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the physician." CMS

proposes to update two aspects of this deeming provision to reflect the current Office of the National Coordinator for Health Information Technology (ONC) certification program for electronic health record technology.

1. To become a certifying body “recognized” by the Secretary, an entity must successfully complete an authorization process established by ONC. This authorization process constitutes Secretary’s recognition as a certifying body.
2. Currently, the electronic health records exception deeming provision requires that software must have been certified within no more than 12 months prior to the date of donation in order to ensure that products have an up-to-date certification. CMS proposes to modify this portion of the exception by removing the 12-month timeframe and substituting a provision that more closely tracks the current ONC certification program.

The Electronic Prescribing Provision

The current electronic health records exception specifies that the donated software must “contain . . . electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the physician’s existing electronic prescribing system that meets the applicable standards under Medicare Part D at the time the items and services are provided.” In light of recent developments, CMS proposes to delete the electronic prescribing condition.

The Sunset Provision

The electronic health records exception is scheduled to sunset on December 31, 2013. CMS proposes to extend the sunset date to December 31, 2016. This date was selected because it corresponds to the last year in which one may receive a Medicare electronic health record incentive payment and the last year in which one may initiate participation in the Medicaid electronic health record incentive program.

Additional Proposals and Considerations

Protected Donors: CMS proposes to limit the scope of protected donors under the electronic health records exception, with the continued goal of promoting adoption of interoperable electronic health record technology that benefits patient care while reducing the likelihood that donors would misuse electronic health record technology donations to secure referrals. In this regard, CMS is considering revising the exception to cover only the original MMA-mandated donors: hospitals, group practices, PDP sponsors, and MA organizations. CMS is considering, and seeking comments regarding, whether other individuals or entities with front-line patient care responsibilities across health care settings, such as safety net providers, should be included, and, if so, which ones.

Data Lock-In and Exchange: CMS is interested in new or modified conditions that would help achieve two related goals. The first goal is to prevent the misuse of the exception in a way that results in data and referral lock-in. The second, related goal is to encourage the free exchange of data (in accordance with protections for privacy). CMS is seeking comments on what new or modified conditions could be added to the exception for electronic health records to achieve these two goals and whether those

conditions, if any, should be in addition to, or in lieu of, the proposal to limit the scope of permissible donors.