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Alerts

Two Early New Year's Gifts from CMS and the OIG Concerning the Donation of Electronic Health Records

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Health Care Alert

Background

In 2006, the Centers for Medicare and Medicaid Services (CMS) of the Department of Health and Human Services (DHHS) published a Final Rule that provided an exception to the Stark Physician Self-Referral Law (42 USC Section 1395nn, Section 1877 of the Social Security Act) for the donation of software and information technology and training services used to create, maintain, transmit or receive electronic health records (EHR) as long as certain requirements were met (the "Exception"). On the same date, the DHHS Office of Inspector General (OIG) published similar final regulations that provided for a safe harbor under the Federal Anti-Kickback Law (Section 1128B(b) of the Social Security Act, 42 U.S.C. 1320a–7b(b)) for donations of EHR (the "Safe Harbor"). Under the prior regulations, both the Stark Law Exception and the Anti-Kickback Law Safe Harbor were scheduled to expire on December 31, 2013.

The New Final Rules

On December 27, 2013, CMS and the OIG each issued Final Rules (available here and here), which extend the Exception and Safe Harbor for EHR donations until December 31, 2021, as long as certain requirements are met. These Final Rules make significant modifications in the requirements for protected donations and the types of donors whose donations will be covered by the Exception and Safe Harbor. Those changes are set forth below:

The definition of interoperability is updated. Under the prior rules, the donated software needed to be interoperable (able to communicate and exchange data based on certain standards) at the time of the donation. In order to avoid uncertainty, parties could use a "deeming" provision that provided that software was "deemed" interoperable if a certifying body recognized by the Secretary of DHHS certified the software within no more than 12 months prior to the date of the donation. *This provision has been modified to provide that software is deemed to be interoperable if, on the date that the software is provided to the recipient, it has been certified by a certifying body authorized by the Office of the National Coordinator for Health Information Technology (ONC) to an edition of the electronic health record certification criteria set forth in the version of 45 CFR part 170 in effect at the time of the donation.*

The requirement for electronic prescribing has been removed. Under the prior rules, in order to qualify for protection, the EHR was required to have electronic prescribing capability (either through an electronic prescribing component or the ability to interface with the physician's existing electronic prescribing system that met the applicable standards under Medicare Part D at the time the items and services are provided). *This requirement has been eliminated under the new Final Rules.*

Donations of EHR from laboratories do not qualify for protection. The prior rules provided that the donation could be made by any individual or entity that: (i) provided patients with health care items or services covered by a federal health care program; and (ii) submitted claims or payment requests for items or services to Medicare, Medicaid or another federal health care program. The new Final Rules provide that neither the Exception nor the Safe Harbor apply if the donation is made by a laboratory. *Thus, donations of EHR from laboratories will not meet either the Exception or the Safe Harbor.*

Restrictions on Donor Behavior to Limit the Use, Compatibility or Interoperability of the EHR. The prior rules prohibited donors from restricting the recipients' right or ability to use the items or services for any patient regardless of payor status. *The new Final Rules also provide that the donor may not take any action to limit or restrict the use, compatibility, or interoperability of the donated items or services.*

Expiration Date. *The new Final Rules extend the Exception and the Safe Harbor for eight years, or until December 31, 2021.*

The new Final Rules maintain a number of requirements from the old rules. Only software, information technology and training services qualify for protection. Hardware and operating software that enables the hardware to function is not covered. Also not covered is software whose core functionality is for uses other than electronic medical records, such as billing or practice management services. Under the new rules, as under the prior rules, the donation is protected only if the recipient pays at least 15 percent of the donor's cost of the donation. In addition, as under the prior rules, the donation arrangement must be documented in a written agreement.

The Effect of the New Final Rules

Under the new Final Rules, as long as the donation requirements are met and the donation is from an entity other than a laboratory, physicians and medical groups may continue to receive — and hospitals and other donors (other than laboratories) may continue to donate — EHR items and services to physicians and other providers until December 31, 2021, without the donor or the recipient violating the Stark Law or the Anti-Kickback Law for the donation. Given the complexity of these changes, and the effect on existing as well as future donation arrangements, it is important that providers who are parties to a donation arrangement or who are contemplating entering into such an arrangement consult with health care legal counsel experienced with these issues.

Tips for Reviewing Your Existing Donation Program or Entering into a Donation Arrangement

In reviewing your donation program or contemplating a new arrangement, issues that should be addressed with legal counsel include the following:

- Physicians and Medical Groups need to review their donation agreements and confirm that their donor is an approved donor under the new Final Rules. Physicians and medical groups who have arrangements with laboratories should consult their legal counsel to determine whether their agreements need to be terminated and determine what actions are necessary and the time frame for taking such actions to ensure that they are not accepting EHR software, IT services or training services from laboratories.
- Existing donors and recipients may wish to review the fair market value of the donation to determine if it meets the donation requirements or needs to be adjusted since the donor may only contribute 85 percent of the cost of the software and services and the recipient physician or medical group is responsible for the rest. Over time, the value of the donation may have gone down and the parties should review the existing agreements to determine whether an adjustment for ongoing services and software updates should be made.
- For parties contemplating entering into a donation arrangement, it is essential to understand the donation requirements, the requirements for the written donation agreement, the methods for valuing the technology, the new deeming requirements for interoperability, and the other requirements for protected donation arrangements.

Hinshaw is experienced in all aspects of EHR donation programs and requirements and is happy to help with any issues you may have.

Should you have any questions or need further information about EHR donations or about the application of the Stark Law or the Anti-Kickback Law, contact your regular Hinshaw attorney.

This alert has been prepared by Hinshaw & Culbertson LLP to provide information on recent legal developments of interest to our readers. It is not intended to provide legal advice for a specific situation or to create an attorney-client relationship.