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HHS Extends Safe Harbor for EHR Donations through 2021

Other Significant but Less Publicized Changes Also Contained in Final Rules

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In a prior article by this author on recent developments involving the tax and compliance aspects of electronic health systems ("The Good, the Bad and the Ugly: Addressing Tax and Compliance Issued Posed by Electronic Health Systems," which appeared in the July-August 2013 issue of *JHCC*), reference was made to the likely extension of the federal exemptions as to donated electronic health record (EHR) systems beyond their then scheduled December 31, 2013 expiration date.

As expected, in final rules published on December 27, 2013, the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services (HHS) extended the December 31, 2013 expiration date of these exemptions until December 31, 2021. The April 2013 previously proposed revisions by CMS and the OIG would have extended the expiration date of the expiring rules only through December 31, 2016.

The extended expiration date coincides with the end of the Medicaid Electronic Health Record Incentive Program that was adopted as part of the American Recovery and Reinvestment Act. Under this program, CMS was authorized to pay up to $44,000 per eligible provider (hospitals, physicians, and other types of health care providers) that adopted and demonstrated "meaningful use" of such systems before 2013. In the April 2013 EHR rules proposal, CMS and the OIG had solicited comments as to the possibility of a later sunset date (such as December 31, 2021).

Under the prior rules that were first adopted by CMS and the OIG in 2006 but had been scheduled to expire at the end of 2013, exemptions under the federal anti-kickback and federal physician self-referral laws allowed a donor to "donate" EHR technology and services to persons who were in a position to refer business to the donor. The expiring rules imposed several conditions

to these exemptions. For example, the recipient of the donated technology was required to pay at least 15 percent of the donor's cost of the EHR technology and services before receipt of same. By taking advantage of these exemptions, a hospital could transfer an EHR system to a practice group that refers patients to the hospital at a deeply discounted "purchase price." This would enable the practice group to acquire the EHR systems without any risk of legal exposure under the federal anti-kickback or Stark laws.

The final rules extended the expiration date for an additional five years (from 2016 to 2021) from those contained in the April 2013 EHR rules proposal. In addition, the final rules addressed and modified in at least one additional instance several significant but less publicized changes contained in the EHR rules proposal.

Relaxation of EHR Certification Requirement

Under the EHR rules proposal, a condition to the exemptions was that the donated EHR be certified as interoperable within a year prior to the donation. In the final rules, this requirement was replaced by one that requires only that the EHR meet the then current EHR certification criteria as of the date of donation. This is consistent with changes in certification criteria made from time to time by each certifying agency.

Elimination of E-Prescribing Functionality Requirements

Under the EHR rules proposal, contrary to the expiring rules, the donated EHR was *not* required to include electronic prescribing functionality. Under the final rules, as provided in the EHR rules proposal, this requirement is discontinued. In explaining the rationale for this change, CMS and the OIG concluded that this capability did not contribute to the interoperability of the EHR.

Laboratories Are Not Eligible Donors

As was indicated on page 26 of the prior article, CMS and the OIG invited comments in the EHR rules proposal as to whether donations of EHR by ancillary providers such as clinical laboratories should be prohibited. Based on several comments received, the final rules prohibit clinical laboratories from making donations of EHR to physicians. This change was largely based on the lobbying efforts of smaller clinical testing laboratories which could not afford to compete with their larger competitors by donating EHR to physicians at the time that reference testing agreements were entered into.

In the preamble to the final rules, CMS and the OIG indicated that larger laboratories had required that physician groups enter into reference testing agreements (some with referral requirements and even quotas as to the number of referred specimens) as a condition to the donation of EHR to physician groups. Moreover, these agencies noted that as solicited in the EHR rules proposal, they had received comments to the effect that physician groups had selected clinical laboratory testing companies for reference testing based in large part on which testing laboratory gave the groups the most lucrative proposal for the donation of EHR systems.

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