CLIENT ALERT

HHS Issues Final Anti-Kickback Safe Harbors and Stark Exceptions for Donations of E-Prescribing & Electronic Health Record Technology

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The U.S. Department of Health and Human Services (HHS) has published final rules protecting eligible entities that provide electronic prescribing (e-prescribing) and electronic health record (EHR) items and services to eligible recipients. See 71 FR 45110 (anti-kickback safe harbors); 71 FR 45140 (Stark exceptions). The final rules, effective October 10, 2006, are substantially similar to the proposed rules promulgated in October 2005. As described below, however, there are important differences.

Of the two new safe harbors under the Federal anti-kickback statute, the EHR safe harbor has broader scope. The new paragraph (y) of 42 C.F.R. § 1001.952 applies to a wider range of potential donors than originally proposed, including health plans and any “individual or entity that provides services covered by a Federal health care program and submits claims or requests for payment ... to the Federal health care program.” This would include not only institutional and group practice providers, but also, e.g., pharmacies, laboratories, oncology centers, and dialysis facilities. Recipients, in turn, include any “individual or entity engaged in the delivery of health care.”

The EHR safe harbor protects donations of software or information technology and training services, but not hardware. Many of the other conditions for protection are the same as proposed last year, but not all. Perhaps most notably, the HHS Office of Inspector General (OIG) declined to implement two EHR safe harbors protecting “pre-interoperability” and “post-interoperability” donations. Rather, there is only one EHR safe harbor that protects donations of “interoperable” software, which is deemed as such if certified under HHS’ authority within the past year.

Other notable changes include the introduction of a requirement that the recipient pay 15% of the donor’s cost for the items and services, an amount that cannot be financed by the donor. (There is no 15% payment requirement for the e-prescribing safe harbor or Stark exception.) As a related matter, the rule requires reference to the donor’s “cost” – not the harder-to-calculate “value” of the items or services – to be included in the agreement between the parties. A recipient no longer must certify that the donated items and services are not equivalent to what the recipient possesses already, nor has OIG imposed a cap on the value of the donations. The safe harbor will sunset on December 31, 2013.

The e-prescribing safe harbor is, as proposed, largely reflective of the Congressional mandate requiring its implementation under the Medicare Modernization Act of 2003, P.L. 108-173. Unlike the EHR safe harbor, it has the advantage of protecting hardware as well as software; however it protects a narrower pool of donors and recipients. Changes in the final rule include introduction of a definition of “electronic health record” and – as in the EHR safe harbor – the elimination of the recipient certification requirement. This safe harbor does not include a requirement that the provider bear 15% of costs.
The final EHR and e-prescribing exceptions to the physician self-referral (Stark) law are very similar to the anti-kickback safe harbors, described above, while nevertheless accounting for the differences in the underlying statutes. For example, the EHR exception requires the receiving physician to pay 15% of the cost of the items or services, and the exception will sunset in 2013.

Notably, under both the EHR safe harbor and Stark exception, the donor is permitted to select a recipient and/or the nature of the items or services provided using factors that do not directly take into account the volume or value of referrals or other business generated between the parties. Examples of such factors set forth in the regulations include the total number of prescriptions written by the recipient/physician, the size of the recipient/physician’s medical practice, or whether the recipient/physician is a member of the donor’s medical staff. Selection may not be based on, e.g., the volume or value of prescriptions dispensed or paid by the donor or billed to a Federal health care program.

The final safe harbors and Stark exceptions improve on the proposed rules by simplifying some of the requirements and reducing unnecessary paperwork. The rules, however, may not prove as useful as some may have hoped, particularly to the extent that the EHR safe harbor and Stark exception protect software but not hardware. Impacted parties should carefully monitor developments in Congress to see whether the health information technology legislation currently under consideration will, by statute, introduce new protections that effectively supercede the new regulations.

Interestingly, in the 2003 Medicare Modernization, Prescription Drug and Improvements Act (“MMA”), Congress specifically authorized MA-PD plans to subsidize physician e-prescribing, but did not provide for similar recognition of such financial support for physician e-prescribing by prescription drug plans (PDPs). This may have reflected the notion that, in contrast to MA-PDs, PDPs would not generally be having financial dealings with physicians, since they do not typically have networks of contracting physicians. In any event, since the MMA also directed the issuance of the e-prescribing safe harbor and Stark exception that would cover PDPs, the MMA should not be an obstacle to PDPs interested in supporting e-prescribing activity by physicians.

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