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Stark Choices

DHHS has proposed safe harbors that would allow hospitals and other entities to provide more funds to technology-hungry physicians.

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The U.S. Department of Health and Human Services (DHHS) has released two sets of proposed regulations regarding electronic prescribing and electronic health records (EHRs). If finalized and adopted, these regulations will offer protections to hospitals and physician practices that donate EHR technology and services to other providers.

Although the technology is currently available, hospitals and other entities have been slow to provide EHR systems to their medical staff because of concerns surrounding fraud and abuse laws. These new regulations are an attempt by DHHS to encourage providers to use EHRs.

Providing free software, hardware and training to doctors and others to implement EHR systems could counter to the federal anti-kickback statute which prohibits the giving of anything of value to a referral to induce patient referrals. In addition, there is the possibility that the Federal Physician Self-Referral Law (Stark) — which prohibits physicians from making referrals for certain Medicare or Medicaid services to an entity with which they (or an immediate family member) have a financial relationship — could be violated if the entity that receives referrals (e.g., a hospital) donates technology to a physician.

As mandated by the Medicare Modernization Act of 2003 (MMA), DHHS' Office of Inspector General has proposed a safe harbor to the anti-kickback statute that would protect certain arrangements involving hospitals, group practices, and certain other entities that provide hardware, software, training or other services necessary to receive and transmit e-prescribing drug information.

In addition, although not yet drafted, the Office of Inspector General has published its intention to adopt another set of rules for the provision of EHR technology. At the same time, the Centers for Medicare and Medicaid Services (CMS) published proposed exceptions to the Stark law for the provision of both e-

prescribing and EHR technology.



E-prescribing

To qualify for protection under the safe harbor and Stark exception, hospitals and physician practices that wish to provide e-prescribing technology will have to meet specific requirements pertaining to:

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The participants in the arrangement — As presently drafted, the proposed safe harbor and Stark except provide that hospitals would only be permitted to donate items or services to physicians on their medic staffs. The safe harbor permits group practices to donate to their group members (owners and employ who are prescribing professionals (e.g., nurse practitioners). Because the Stark law only pertains to physicians, the exception for group practices would only apply to member physicians.

The scope of the technology — The items or services donated must be “necessary” to conduct e-prescr transactions (e.g., hardware, software, Internet connectivity, training, support services) and “used sol the transmission or receipt of e -prescribing information.

Certification — Recipients would be required to attest in writing that the items or services received are technically or functionally equivalent to items or services already possessed. Moreover, to qualify for protection, the donor must not have actual knowledge of nor act in reckless disregard or deliberate ign of the fact that the recipient already possesses items or services equivalent to those donated. It is unc however, how far a donor must go to ascertain whether the recipient has functionally equivalent items.

Compatibility and Interoperability — The regulations would prohibit donors from taking any action to di or limit the interoperability of e-prescribing technology or from otherwise imposing barriers to compatil with other e-prescribing items, services or systems.

Value of Protected Technology — To minimize the potential for fraud and abuse, the aggregate moneta value of the e-prescribing technology that a donor could provide would be limited. However, the methc to be used to determine such a cap has not been decided.

Other conditions — DHHS' proposed regulations would prohibit recipients from making the donation of prescribing technology a condition of doing business with the donor; and donors from taking into accou volume or value of the recipients' referrals to the donor or other business generated between the parti determining the eligibility of a recipient. In addition, all agreements to provide e-prescribing technology be in writing, signed by the parties and identify with specificity the items or services provided and their values.

EHRs

DHHS believes that the provision of EHR technology to physicians poses a greater risk of fraud and abu than the provision of e-prescribing technology because it is “inherently more valuable to physicians in 1 of actual cost, avoided overhead and administrative expenses of an office practice.” However, adoption such technology is vital to a system that will allow health information to move from one point of care t another in a way that will satisfy patient concerns regarding confidentiality and security.

Both the Office of Inspector General and CMS expect to adopt an incremental approach in this area pro “pre-” and “post-interoperability” regulations that will depend on DHHS' adoption of product certificatio criteria, including criteria for interoperability, functionality, privacy and security. During the “pre- interoperability” phase, CMS proposes to only protect software that is essential to and used solely for t transmission, receipt or maintenance of patients' EHRs and that has an e-prescribing component. In th “post-operability” phase, CMS would expand the scope of donated software as long as the core functio remains e-prescribing and EHR.

Because of the importance and complexity of applying electronic information technology to the field of healthcare, the proposed regulations are certain to generate a large number of public comments and r to the safe harbor and Stark exception are assured. Thus, it is impossible to predict when these import regulations will become final.

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