

Technology Donations to Physicians: New Health IT Rules in Play

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Solo physicians and small groups have been slow to adopt electronic health information based largely on the barrier of start-up costs. Health and Human Services (HHS) Secretary Mike Leavitt recently launched new exceptions to the Stark physician self-referral rules and safe harbors under the Antikickback statute that ease restrictions on health information technology (IT) provided to referring physicians if certain conditions are met.

Background

HHS has previously excluded from the Stark rule a hospital's provision of IT wholly dedicated to hospital services furnished to hospital patients. So, a treatment portal into a hospital's IT system is considered acceptable, but if this technology also has any independent functionality above and beyond patient treatment (e.g., physician billing functions), the physician would need to pay fair market value for the license. Interestingly, the new rule provides some additional guidance, outlining key areas that explicitly relate to patient treatment without independent value. These areas include transmitting test results, diagnosis codes, medical history and prescription information.

The new e-prescribing rules allow both software and hardware donations, but may have fairly limited utility due to the requirement that the technology be used solely to transmit and receive prescriptions. The new rules for electronic health records (EHR) allow health plans and entities that bill Medicare and federal health care programs for designated health services (DHS) to more easily provide EHR software that has value to the physician. Both sets of rules were effective October 10, 2006.

Eligible EHR Technology

First, the donated software must be necessary and used predominantly to create, maintain, transmit, or receive electronic health records and must include an electronic prescribing component. The software cannot duplicate equivalent technology the physician already possesses.

EHR software also must be interoperable at the time of donation, meaning data can be exchanged accurately, securely and consistently with other applications and networks in different settings such that the clinical or operational purpose and meaning of the data are preserved without alteration. Software is deemed interoperable if it has been certified by a body recognized by HHS.

Although industry standards for what is considered interoperable are amorphous and evolving, several things are clear: (i) the software package must communicate with products of other vendors, (ii) it must contain or interface with an E-prescribing component that meets Medicare Part D electronic standards, and (iii) donors cannot disable interoperability or impose barriers to compatibility with other e-prescribing or EHR systems — i.e., lock-in donor referrals through a closed system. Beyond that, HHS advises parties to consult industry standards to determine whether the software is "as interoperable as feasible given the prevailing state of technology" at the time of donation.

Certain related technology and training services may be donated as well, such as Internet connectivity (including broadband and wireless access), secure messaging, and training and help desk support services. While EHR functionality must predominate, the software can include ancillary administrative functions which relate to the care and treatment of individual patients (e.g., scheduling, billing, and clinical support). The EHR rules prohibit donations of hardware, storage devices, core functionality other than EHR, such as payroll packages or software that focuses primarily on billing and practice management, staffing to migrate hard copy to electronic formats, and software or items and services used primarily for personal business or unrelated to medical practice (separate research or marketing support).

Eligible Donors

Eligible donors under the safe harbor are health plans and those who deliver health care and bill federal health care programs, including hospitals and group practices, pharmacies, surgery centers, labs, dialysis and imaging centers, home health agencies and medical equipment suppliers, nursing facilities, and prescription drug plans. HHS declined to extend safe harbor protections to pharma and device manufacturers donations, preferring to rely on the facts and circumstances in an individual case over bright line rules.

Donors cannot select recipients or set the level of donation using criteria relating directly to the volume or value of referrals or other business between the parties. In a move demonstrating flexibility on the manner in which recipients are selected, HHS will allow donors to select eligible physicians on any reasonable and verifiable manner that indirectly relates to referrals, including such criteria as medical staff membership, size of the medical practice as measured through total patient encounters, RVUs, hours worked, or prescriptions written.

Conditions for Physician Participation:

So what must a physician do to be eligible for EHR donations? Before receiving a donation, the physician must pay at least 15% of the donor's cost, which could be a significant savings over paying the full price at retail or using existing exceptions that require a license at fair market value. Healthcare organizations are considering how to account for those costs on an incremental basis that appropriately considers physician use rather than an allocation methodology that attempts to fully load hospital system development costs in the license fees. The cost sharing amount for homegrown software and add-ons can be derived using a reasonable and verifiable cost allocation method, but the parties must document all costs and technology and the level of physician contribution in a written agreement.

Many donors will likely inquire of the physician as to existing technology utilized to document that the donation is not duplicative. This type of request is reasonable and protects both parties, but HHS does not expect the parties to hire technical experts here and allows for upgrades that enhance functionality or make the software more current and user friendly as not being duplicative. Finally, physicians cannot make the donation a condition of doing business with the donor, and donors cannot loan funds to a physician or finance physician payments.

The new rules sunset on December 31, 2013 — just in time to meet the President's ambitious goal of electronic health records that improve patient safety and quality care for all Americans by 2014. Despite vagueness in some aspects of the new rules, HHS is moving to remove financial impediments to IT adoption. Stay tuned as Congress debates further expansion and additional funding sources for this goal consistent with privacy and security principles.

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