

HEALTH INDUSTRY ALERT

CMS AND OIG ISSUE PROPOSED RULES TO ACCELERATE ADOPTION OF HEALTH INFORMATION TECHNOLOGY



The Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General of the Department of Health and Human Services (OIG) have just released proposed rules that are intended to advance the Bush administration's initiative to accelerate the adoption of health information technology (HIT) by health care providers. Specifically, CMS released proposed exceptions to the federal physician self-referral prohibition (the Stark Law) that would allow qualified entities to donate electronic prescribing and electronic health records (EHR) technology to physicians and certain other entities. The OIG announced similar proposals for a safe harbor from the Anti-kickback Law related to electronic prescribing technology, and is also seeking comment about possible safe harbors regarding EHR technology and related training services.

These proposed rules both advance administration policy and fulfill a statutory obligation. In the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, Congress established a voluntary electronic prescribing program that would allow for the electronic transmission of prescription drug information between physicians, pharmacies and Medicare prescription drug plans. Congress also mandated the creation of a safe harbor from the Anti-kickback Law and an exception to the Stark Law for certain donations of the technology required to participate in this program. These proposed rules respond to that mandate and also contemplate protections that would extend beyond the electronic prescribing program to include donations of software and training related to EHR.

ANTI-KICKBACK LAW SAFE HARBORS

Electronic Prescribing

The Anti-kickback Law prohibits an entity from providing remuneration to any person in exchange for referring or recommending the purchase of an item or service that is reimbursable

by a federal health care program, such as Medicare. However, safe harbors exist in both the statute and the regulations that protect certain actions that could otherwise violate this law. To encourage the adoption and use of expensive electronic prescribing technology, Congress mandated the creation of a safe harbor that would allow certain entities to donate this technology to physicians and other parties.

Under the OIG's proposed rule, the donation of hardware, software, information technology training and other items and services "necessary" to "receive and transmit electronic prescription information" may qualify for protection from prosecution under the Anti-kickback Law. To be considered necessary, the donated technology must not be "technically or functionally equivalent" to items or services that the recipient already possesses.

By way of example, the OIG states that one may donate a hand-held device to a physician who has a desktop electronic prescribing system, but cannot donate a second device if the physician currently has a hand-held device that is sufficient to operate electronic prescribing software. Recognizing that the donor may not be aware of what technology the recipient may have, the proposed rule would require the recipient to certify that the items or services being donated are not technically or functionally equivalent to items or services the recipient already has. Additionally, the donor must not have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the recipient has items and services that are technically or functionally equivalent to those being donated. The OIG is seeking comment both on this requirement and on ways to ensure that potential recipients do not "divest themselves" of technology as a means to qualify for donated technology.

The technology must also be "used solely" for the transmission or receipt of electronic prescription information. For example, the technology cannot be bundled with general office management, billing, scheduling or other software that has a value to the recipient apart from the electronic prescribing component. The proposed safe harbor would allow, however, for the donation of certain limited hardware and connectivity services that are used for more than electronic prescribing, so long as "a substantial use" of the item or service is to receive or transmit electronic prescription information.

In mandating the creation of this safe harbor, Congress expressly enumerated the following entities and donations to which this protection would apply: a hospital donating to members of its medical staff, a group practice donating to members of the group, and Medicare prescription drug plan sponsors donating to prescribing health care professionals and to pharmacists and pharmacies participating in the sponsors' networks. Although in the proposed rule the OIG follows this direction and limits the safe harbor protections to the donors and situations described in the statute, the agency is also seeking comment on whether to expand the safe harbor to other donor entities.

The OIG is also seeking comment on whether and how it should impose a cap on the value of the technology a donor could provide under the safe harbor, and, specifically, on the methodology it should use to calculate any such cap (e.g., fixed dollar amount, percentage of the value of the donated technology).

Further, the OIG is proposing a requirement that the technology comply with the electronic prescribing standards currently under development by CMS and a prohibition that donors (or their agents) not limit the interoperability or compatibility of donated technology with other technology. Similarly, to the extent possible, the donated technology must be usable for all patients without regard to payor status. Finally, the donation must be reflected in a signed writing and cannot take into account the volume or value of referrals generated by the recipient of the technology, cannot be a condition of doing business with the donor, and cannot be used to induce the recipient to change loyalties from another provider or plan to the donor.

Electronic Health Records

With regard to possible safe harbors for donations of EHR technology, while the OIG is considering promulgating two safe harbors – one for donations that occur prior to the development and adoption of criteria for certifying EHR technology (the pre-certification safe harbor) and one for donations that occur after such criteria have been adopted (the post-certification safe harbor) – it does not believe it has sufficient information to draft safe harbor language, and does not include such language in the proposed rule. Nevertheless, the agency does seek comment on a number of issues it is considering incorporating into these safe harbors.

In particular, the OIG seeks comments regarding the definition of EHR, including the types of software that should be protected, the cost of such software and methods to define the scope of protected software. Additionally, the OIG is considering criteria for an EHR safe harbor that are similar to the criteria it proposes for the electronic prescribing safe harbor. For example, the safe harbor would protect EHR software and related training services, but not other types of technology that might be used to conduct other aspects of the recipient's business (e.g., scheduling, office management). Significantly, the EHR technology must contain an electronic prescribing component. The EHR safe harbor would apply to the same entities protected in the electronic prescribing safe harbor, although the OIG is also seeking comments on whether other categories of donors and recipients should be considered. Finally, the pre-certification safe harbor would expire when the post-certification safe harbor becomes effective.

The proposed rule is available at <http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-20315.pdf>, and comments are due to the OIG by December 12, 2005.

STARK LAW EXCEPTIONS

The Stark Law prohibits physicians from referring certain designated health services that are payable by Medicare to an entity with which they have a financial relationship, and also prohibits the submission of claims for the referred services, unless an exception applies. As pertinent here, a financial relationship includes any compensation arrangement, which could include non-monetary remuneration such as donations of technology.

CMS worked very closely with the OIG during the drafting of the proposed exceptions. Indeed, the issues raised for comment and the proposed regulatory language for the electronic prescribing Stark Law exception are nearly identical

to OIG’s proposed safe harbor. Unlike the OIG, however, CMS did propose specific regulatory language for a Stark Law exception for donations of EHR technology.

These proposed Stark Law exceptions would apply to the same donors and recipients protected by the Anti-kickback Law electronic prescribing safe harbor noted above. As with the electronic prescribing safe harbor, the donor (or its agent) cannot limit or restrict the interoperability or compatibility of donated technology, and cannot make the donation a condition of doing business with the donor. Further, the donor cannot condition the donation on the volume or value of referrals generated between the donor or the recipient, and the recipient must certify that the donated items are not technically or functionally equivalent to items or services the recipient already has. The donor also cannot have actual knowledge of, or act in reckless disregard or deliberate ignorance of, the fact that the recipient possesses technically or functionally equivalent items or services. Like the OIG, CMS proposes a pre-certification and post-certification exception under the Stark Law for EHR donations, with the pre-certification exception expiring upon the post-certification exception becoming effective.

The proposed rule is available at <http://a257.g.akamaitech.net/7/257/2422/01jan20051800/edocket.access.gpo.gov/2005/pdf/05-20322.pdf>, and comments are due by December 12, 2005. Notably, CMS is also planning to schedule an Open Door Forum early in the comment period to discuss the risks and benefits of donating electronic prescribing and EHR technology.

CONTACT INFORMATION

If you have any questions about these proposed rules, need assistance with the submission of comments or require counsel regarding other HIT matters, please contact:

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