

Donating e-Prescribing Equipment and Services

Two proposed rules offer practitioners some protection

by Marie C. Infante, Esq., and Stephen R. Bentfield, Esq.

In October 2005, the Centers for Medicare & Medicaid Services (CMS) and the U.S. Department of Health and Human Services Office of Inspector General (OIG) proposed two rules to protect certain entities that donate software and services used for electronic prescription (e-prescription) systems.¹ The rules are intended to protect donation by certain designated entities of non-monetary items and services necessary for and used solely to receive and transmit e-prescription information to certain categories of individuals.

When enacting Medicare Part D, Congress directed the HHS Secretary, in consultation with the Attorney General, to create an exception to the physician self-referral prohibition, the so-called Stark Law, and a safe harbor under the anti-kickback statute to protect donation of "non-monetary remuneration" for e-prescription systems used for Part D transactions.² Unless an exception applies, the Stark Law prohibits physicians from making referrals for certain health services payable by Medicare to an entity with which they have a financial relationship, and the entity from submitting claims to Medicare for those referred services. Similarly, the federal anti-kickback statute protects against the provision of free or reduced price goods or services to existing or potential referral sources in an effort to disguise or confer an unlawful payment for referrals of Federal healthcare program business. Congress was concerned that donation of hardware and/or services to assist in the operation of e-prescribing systems would run afoul of these laws.

The two proposed rules have similar structure and language, an intentional effort by CMS and the OIG to promote consistency in application and implementation under the two distinct legal schemes. The rules include several key features.

First, the donated item or service

must be necessary to the operation of an e-prescribing program. Necessary items can include hardware, software, broadband or wireless Internet connectivity, training, information technology support service, or other items used in connection with e-prescribing. Recipients must certify that donated items or services are not technically or functionally equivalent to items or services owned.

Second, the proposed protections are intended to cover items or services used solely for an e-prescribing program. CMS and the OIG have expressed concern regarding multifunctional devices or services that have additional value attributable to uses other than e-prescribing (e.g., personal computers, bundled software programs). Items or services with functionality beyond e-prescription systems would not fall within the proposed protections; however, recipients would not be precluded from purchasing such non-covered items at fair market value. In other words, the value of the multifunctional device would be apportioned between the covered and non-covered functions, while the protections of the proposed rules applicable to covered e-prescription function.

The Stark Law applies only to physicians, so the proposed exception applies only to physicians. In contrast, the anti-kickback safe harbor applies to physicians, other prescribing health professionals (e.g., nurse practitioners), pharmacies, and pharmacists. With that difference in mind, the proposed rules protect the following relationships:

- Donations by hospitals to individuals who routinely furnish services at that hospital.
- Donations by group practice organizations to its members and/or employees.
- Donations by Prescription Drug Plan (PDP) sponsors and Medicare Advantage (MA) organizations to

prescribing professionals (limited to physicians under the Stark exception), participating pharmacies, and participating pharmacists.

The proposed rules include other important limitations. Recipients may not make the donation of qualifying e-prescription item or service from donors a condition of doing business with the donor. Also, neither the eligibility of the recipient to receive the items or services, nor the amount or nature of the items or services, may be determined in a manner that takes into account the volume or value of the recipient's referrals or other business generated between the parties. CMS and the OIG are also exploring whether to limit the aggregate value of the qualifying e-prescription technology.

Currently, the agencies are reviewing public comments about proposed provisions protecting arrangements and items beyond those used for e-prescribing under Medicare Part D. These additional provisions, though not based upon the MMA, rely upon other legal authority to promote the adoption of e-prescription and EMR technology. Final rules are expected to be published later this year. ❏

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References

¹ See generally, Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships; Exemptions for Certain Electronic Prescribing and Electronic Health Records Arrangements, 70 Fed. Reg. 59,182 (Oct. 11, 2005) (proposed rule); and Safe Harbor for Certain Electronic Prescribing Arrangements Under the Anti-Kickback Statute, 70 Fed. Reg. 59,015 (Oct. 11, 2005) (proposed rule).

² 42 U.S.C. § 1395w-104(e)(6) (§ 1860D-4(e)(6) of the Social Security Act (SSA)).