

New Stark Exceptions and Anti-Kickback Safe Harbors for Electronic Prescribing and Electronic Health Records

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The Office of Inspector General of the Department of Health and Human Services (“OIG”) and the Centers for Medicare and Medicaid Services (“CMS”) recently took important steps in facilitating the growth of electronic prescribing and electronic health records (“EHR”) technology. On Aug. 8, 2006, OIG and CMS issued final safe harbors under the anti-kickback statute and a final exception under the Stark law protecting donations of this technology to health care entities and physicians with which the donor may have a referral relationship. 71 Fed. Reg. 45110 (Aug. 8, 2006) (final anti-kickback safe harbors); 71 Fed. Reg. 45140 (Aug. 8, 2006) (final Stark exceptions).

This article will briefly discuss the competing policies underlying these new regulations, some background of the anti-kickback statute and the Stark law, and the specific requirements of the new regulations. Finally, this article will discuss some practical issues that may affect implementation of these regulations.

Policy Background

The health care industry has been moving for some time toward electronic health records (“EHR”) and electronic methods for prescribing and ordering services. This push has been spurred by the federal government’s recent emphasis on developing a pay-for-performance methodology for reimbursing services provided to federal health care program patients.

Technological innovation, however, is expensive, and can be beyond the means of physicians, especially those in small practices. One way that physician practices have sought to address that problem is by asking other health care entities, such as hospitals, to provide this technology either free of charge or at a substantial discount.

Unfortunately, the federal anti-kickback statute and Stark law arguably limit the ability of entities that have a referral relationship to share this technology. Congress, recognizing this limitation, mandated that CMS and OIG provide regulatory relief facilitating the spread of electronic prescribing technology. These agencies proposed rules on

Oct. 11, 2006, 70 Fed. Reg. 59015 (Oct. 11, 2005) (proposed anti-kickback safe harbors); 70 Fed. Reg. 59182 (Oct. 11, 2005) (proposed Stark exceptions), and released final rules on Aug. 8, 2006. The new rules provide regulatory protection for the donation of electronic health care technology, subject to certain restrictions.

In this rulemaking, the government is attempting to balance two competing and significant government policies. The first is to encourage the proliferation of electronic prescribing technology and EHR. The major goal of this governmental effort is to enhance the quality of care provided to patients and improve patient safety. The industry and the government are generally in agreement that use of these technologies will foster patient safety by helping to ensure that patients receive the correct drugs in the correct dosages and that complete, up-to-date information on patients is readily accessible. The government has also begun moving toward a pay-for-performance methodology for the reimbursement of physician services, which may be facilitated by greater access to electronic records.

The government’s competing interest is its long-standing concern over the provision of free or discounted items or services from one health care provider to another, where the recipient is in a position to refer federal health care program patients to the donor. The government generally believes that the provision of such items or services can increase utilization inappropriately by functioning as an inducement or reward for referrals of federal health care program patients. The new regulations should be understood as the government’s effort to walk the tightrope between these competing concerns.

New Stark Exceptions

CMS has promulgated two new exceptions under the Stark law: an exception for items and services related to electronic prescribing, and an exception for EHR items and services. Each exception has specific requirements. However, in order to understand that exceptions fully, it is important to remember the fundamentals of the Stark law.

The Stark law prohibits physicians from referring Medicare and Medicaid patients for certain designated health services to entities with which the referring physician (or a family member of the referring physician) has a financial relationship, unless an exception applies. 42 U.S.C. § 1395nn(a)(1)(A); 42 C.F.R. § 411.353(a). The law also prohibits any provider of designated health services from billing any person for designated health services furnished pursuant to a prohibited referral. 42 U.S.C. § 1395nn(a)(1)(B); 42 C.F.R. § 411.353(b). Sanctions under the Stark law include denial of payment, required refunds, civil money penalties and exclusion for knowing and willful submission of claims that should not be paid, and civil money penalties for circumvention schemes. 42 U.S.C. § 1395nn(g); 42 C.F.R. § 411.353(c) and (d).

The donation by a hospital or other entity of free or discounted electronic prescribing or EHR equipment to a physician or physician practice would, under most circumstances, create a financial relationship between the entities that could taint referrals under the Stark law. Unfortunately, the existing exceptions under the Stark law have been viewed as inadequate for the proposed donation of this technology.

The first new exception protects non-monetary remuneration consisting of items and services in the form of hardware, software, or information technology and training services necessary and used solely to receive and transmit electronic prescription information. *Id.* § 411.357(v). For purposes of this exception, “necessary” means that the donated items and services are not duplicative of any existing items and services at the donee practice. For example, if the donated hardware takes the form of a handheld device, the new handheld device may not be duplicative of existing handheld devices owned by the practice. “Used solely” in this context means that the donated hardware and software can have no other function than to transmit electronic prescribing information. In other words, hardware and software that could be used for electronic prescribing but also

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for billing or general e-mail communications would not be protected under the exception. 71 Fed. Reg. 45140, 45145.

The items and services must be donated by (1) a hospital to a physician who is a member of its medical staff; (2) a group practice (as defined under the Stark regulations) to a physician who is a member of the group (also as defined under the Stark regulations) or (3) a prescription drug plan sponsor or Medicare advantage organization to a prescribing physician. 42 C.F.R. § 411.357(v)(1). Note that this is an extremely restrictive list. The recipients are limited to physicians and group practices, which is consistent with the Stark law's application to physician referrals. However, the donors exclude some important industry groups, such as pharmacies and pharmaceutical companies.

The items and services must be provided as part of or used to access an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided. *Id.* § 411.357(v)(2). The first set of standards was finalized in November of 2005. See 71 Fed. Reg. at 45146-7.

The donor (or any person on the donor's behalf) must not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or EHR systems. 42 C.F.R. § 411.357(v)(3). This limitation is intended to promote interoperability. If the technology is interoperable in its basic form (in other words, the information it creates or stores may be shared among many different types of information systems), the donor may not modify the technology to limit the systems to which information may be transmitted. CMS's rationale for this restriction is that if a hospital were in a position to donate a system that only communicated with its information system, and with no other, the donation of that technology might encourage physicians to refer only to that hospital.

For items or services that may be used without regard to the patient's payor status, the donor will take no action to restrict or limit the use of the items or services for any patient. *Id.* § 411.357(v)(4). This limitation furthers the policy goal of fostering the spread of this technology generally, and not simply with respect to a limited number of patients.

Neither the physician nor the physician practice may make the receipt of items or services a condition of continued referrals to the donor. *Id.* § 411.357(v)(5). In effect, this regulation prevents physicians from using referrals as a bargaining chip to gain technology.

Neither the eligibility of the physician for 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 referrals or other business generated between the parties. *Id.* § 411.357(v)(6). This restriction is simply the converse of the foregoing restriction; just as physicians may not hold patients for ransom, neither may hospitals or other entities attempt to reward physicians for their referrals with donated technology.

The arrangement must be set forth in a written agreement that is signed by the parties, specifies

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the items and services being provided, the donor's cost of the items and services, and covers all of the electronic prescribing items and services to be provided by the donor. This requirement can be met through separate agreements, so long as the separate agreements incorporate each other by reference, or cross-reference a master centralized list of all items and equipment being provided. *Id.* § 411.357(v)(7).

Finally, the donor must not have actual knowledge of nor act in reckless disregard or deliberate ignorance of the fact that the recipient physician or physician group possesses or has obtained items or services equivalent to those provided by the donor. *Id.* § 411.357(v)(8). In the proposed regulation, CMS considered requiring a certification from the physician that the physician did not have equivalent equipment at the time of the donation. However, CMS dropped the certification requirement, and instead promulgated this provision to help ensure compliance with the statutory “used solely” language.

The second Stark exception is for EHR items and services. It covers non-monetary remuneration consisting of items and services in the form of software or information technology and training

services necessary and used predominantly to create, maintain, transmit, or receive EHR. *Id.* § 411.357(w). An important distinction between the EHR exception and the electronic prescribing exception is that under the EHR exception, hardware is not covered. However, the software and training services provided need not be “used solely” for EHR, but rather must be “used predominantly” for EHR. In this context, “used predominantly” means that the core functionality of the software is for the creation, maintenance, and transmission of EHR; however, “used predominantly” does not preclude the donation of software packages that include ancillary features, such as billing and scheduling. 71 Fed. Reg. at 45151.

The items and services must be provided by an entity that furnishes designated health services (as that term is defined under the Stark law) to a physician. 42 C.F.R. § 411.357(w)(1). The software must be interoperable at the time it is provided to the physician and the donor must not take any action to restrict or limit the software's interoperability. *Id.* § 411.357(w)(2), (3). For purposes of this requirement, software that has been certified by a certifying body recognized by the Secretary no more than 12 months prior to the date it is provided to the physician will be deemed to be interoperable. *Id.* The donor must not take any action to restrict or limit the interoperability of the software. *Id.* § 411.357(w)(3).

The physician must pay 15 percent of the cost of the technology before receipt of the technology. The donor may not finance this cost in any way. *Id.* § 411.357(w)(4). CMS believes that this provision will help safeguard against abusive arrangements, and also will tend to limit the likelihood that physicians will obtain duplicative software by forcing physicians to pay for a portion of the software.

Neither the physician nor the physician's practice may condition referrals on the receipt of the software. *Id.* § 411.357(w)(5). Neither the eligibility of the physician nor the amount or nature of the items or services may be determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. *Id.* § 411.357(w)(6). However, unlike with the electronic prescribing exception, CMS provides specific safe harbors that can be used by a donor to prioritize the list of potential EHR recipients. Those safe harbors include determinations based on (1) the total number of prescriptions written by the physician, but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program; (2) the size of the physician's medical prac-

tice (for example, total patients, total patient encounters, or total relative value units); (3) the total number of hours that the physician practices medicine; (4) the physician's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor); (5) whether the physician is a member of the donor's medical staff, if the donor has a formal medical staff; (6) the level of uncompensated care provided by the physician or (7) any reasonable and verifiable prioritization method that does not directly take into account the volume or value of referrals or other business generated between the parties. *Id.*

CMS intended these provisions to allow donors to provide the software to practices that are likely to use it, while not establishing a direct link between the software provided and the number of referrals between the parties.

The EHR exception includes the same writing requirements, knowledge requirements with respect to duplicative software, and requirements with respect to patient's payor status as the electronic prescribing exception. *Id.* § 411.357(w)(7), (8), and (9). The protected items and services specifically exclude staffing of physician offices and may not be used primarily to conduct personal business or business unrelated to the physician's medical practice. *Id.* § 411.357(w)(10). The example that CMS provides in this context is that the donor may not supply staff to help convert paper records to electronic records.

The software must include electronic prescribing capability. *Id.* § 411.357(w)(11). The arrangement must not violate the anti-kickback statute. *Id.* § 411.357(w)(12).

Finally, the transfer of items and services meeting all conditions must be satisfied on or before Dec. 31, 2013. *Id.* § 411.357(w)(13). CMS included a sunset date in recognition of the likelihood that this technology will become pervasive, and, therefore, the need for regulatory exceptions will wane over time. In addition, CMS has concerns about open-ended arrangements where there is no cap on the maximum value that may be donated.

Anti-kickback Safe Harbors

The OIG adopted safe harbor regulations that are almost identical to the Stark exceptions, with some small differences that reflect the scope of the anti-kickback statute.

The anti-kickback statute prohibits any person from knowingly and willfully offering, paying, soliciting, or receiving direct or indirect remuneration, in cash or in kind, overt or covert, in return

for, or to induce, the referral of federal health care program patients, or the ordering of services for which a federal health care program may pay. 42 U.S.C. § 1320a-7b(b). The leading case interpreting the statute, which has been followed by most circuits, says that if "one purpose" of the payment is to induce referrals, the statute has been violated. *See U.S. v. Greber*, 720 F.2d 68 (3d Cir.), *cert. denied*, 474 U.S. 988 (1985). Violation of the statute is a felony, and penalties include up to five years imprisonment or \$25,000 in fines, or both. 42 U.S.C. § 1320a-7b(b). The government may also seek civil money penalties and exclusion. *Id.* § 1320a-7a(a)(7).

Because the statute has been construed so broadly, the OIG has promulgated "safe harbor" regulations protecting transactions that the government believes pose only limited risk of harm to the federal health care programs. However, there are no existing safe harbors that would fully protect the donation of a free or discounted electronic prescribing and EHR technology.

The safe harbor for electronic prescribing is virtually identical to the Stark exception for electronic prescribing, with the exception of the protected donors and recipients. 42 C.F.R. § 1001.952(x). The safe harbor protects donations by hospitals to members of their medical staffs and group practices to their physician members. However, in recognition of the broader scope of the anti-kickback statute, the safe harbor narrowly expands the permitted recipients by permitting prescription drug plan sponsors and Medicare advantage organizations to donate prescribing technology to *network pharmacists and pharmacies*, and to prescribing health care professionals. *Id.* § 1001.952(x)(1) (emphasis added).

As with the electronic prescribing safe harbor, the EHR safe harbor is nearly identical to the corresponding Stark exception. *Id.* § 1001.952(y). The only differences between the two regulations are with respect to the scope of covered donors and recipients, and with respect to cost-shifting.

The only donors protected by the safe harbor are individuals or entities that provide services covered by a federal health care program and that submit claims or request for payment either directly or by reassignment to the federal health care program, or health plans, as that term is defined elsewhere in the safe harbor regulations. *Id.* § 1001.952(y)(1). It is important to note that the safe harbor does not protect pharmaceutical companies or medical device manufacturers because they are typically not entities that bill federal health care programs either directly or through reassignment. Protected recipients include any individuals or entities engaged in the delivery of health care. *Id.*

Finally, the safe harbor requires that the donor not attempt to shift the costs of the donated technology to any federal health care program. *Id.* § 1001.952(y)(12).

Implementation Issues

As with many of the safe harbors and Stark exceptions, key implementation issues have been left unresolved by the text of the rules themselves. For example, it is not clear how donors and recipients are to calculate 15 percent of the donor's cost where the technology may have been acquired under vendor contracts that have financial incentives for bulk purchases. Furthermore, there is no bright line standard for functional equivalency for purposes of ensuring that a recipient is not receiving duplicative equipment. Similarly, in software packages that provide a variety of functions, it may be difficult to determine that the purpose of a software package is predominantly for EHR. Although the Certification Commission for Healthcare Information Technology, which is the first group to be recognized by the Department of Health and Human Services as a recognized certification body, has to date certified 33 outpatient and ambulatory EHRs, it still has not certified any inpatient or hospital EHRs or any systems that allow information to be exchanged between and among health care providers and institutions.

Conclusion

OIG and CMS have taken important strides forward in facilitating the spread of electronic prescribing and EHR technology through the anti-kickback safe harbors and related Stark exceptions. It will be interesting to see whether the health care industry is ready to take advantage of these opportunities. □

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