

Health Law Alert

A report
for clients
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CMS and OIG Propose Protection for Electronic Prescribing and Electronic Health Records Support

On October 11, 2005, the Centers for Medicare & Medicaid Services ("CMS") of the U.S. Department of Health and Human Services ("HHS") proposed regulations for exceptions to the Stark Law regarding electronic prescribing and electronic health record support provided to physicians. 70 Fed. Reg. 59182. The same day, the HHS Office of Inspector General ("OIG") proposed Anti-Kickback Law safe harbor protection for electronic prescribing and electronic health records support. 70 Fed. Reg. 59015. Both the CMS- and OIG-proposed regulations for electronic prescribing were mandated by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "MMA").

Proposed Stark Law Exceptions

The Stark Law generally prohibits physicians from referring patients for certain "designated health services" to an entity with which the physician, or an immediate family member of the physician, has a financial relationship. 42 U.S.C. § 1395nn. The Stark Law also creates exceptions for certain financial relationships that do not pose a risk of program or patient abuse.

CMS has issued a proposed regulation with respect to the Stark Law that would broadly protect the provision to physicians of hardware, software, and support services necessary for electronic prescribing. As required by the MMA, the proposed regulation for electronic prescribing would implement a Stark exception for the provision to physicians of "non-

monetary remuneration (consisting of items and services in the form of hardware, software or information technology and training services) that is necessarily used solely to receive and transmit electronic prescription drug information."

The proposed regulations would extend protection more broadly than required by the MMA. Acting pursuant to its authority under the Stark Law, CMS has also proposed two additional Stark exceptions that would protect the provision to physicians of certain goods and services to enhance technology for electronic health records. The two proposed rules for electronic health records support cover, respectively, the periods before and after the development of a certificate of interoperability of such records by CMS. Importantly, once interoperative certification is established (CMS estimates within a year), then only technology so certified would be eligible for the exception.

The attached chart, provided by CMS, describes these three proposed Stark exceptions.

There are some important limitations to the use of the proposed Stark exceptions:

1. The transferred technology must be "necessary"; as a general rule, the technology cannot be duplicative of technology already available to the physicians.
2. Generally, the technology provided must be "used solely" for the supported purpose: electronic prescribing or electronic health records (in the pre-certification period). However, CMS did not include the "used solely" language for electronic health records in the post-interoperative certification period. Further, CMS is soliciting comments on an exception authorizing a "substantial use" standard for donated multi-functional hardware or connectivity services used in electronic prescribing. CMS is also considering

(and has requested comments on) a cap on the value of such support.

3. For electronic health records technology, the proposed regulatory exception for the post-interoperative certification period will only cover the provision of CMS-certified technology.
4. Only certain entities are authorized to make and receive such donations. Protected donations include those by hospitals to members of their medical staff, group practices to their physician members, and prescription drug plan sponsors and Medicare Advantage organizations to pharmacies, pharmacists, physicians, and other prescribing health care professionals. The regulatory definition of "group practice" does not appear to include a health plan, such as an individual practice association ("IPA"), unless the health plan's provision of the technology and services falls under another exception. (CMS notes this exclusion and proposes that existing exceptions may protect IPAs and others, but this is far from certain. In any event, CMS requests comments.)
5. The technology must be generally available for all patients and be used in compliance with the applicable electronic prescription drug program requirements under Medicare Part D.
6. Neither the physician nor the physician's practice will be permitted to make the technology donation a condition of doing business with the entity. Additionally, the eligibility of a physician to receive the relevant items and services, or the amount and nature of the items and services received, may not be determined in a manner that takes into account the value or volume of the physician's referrals to the donor or other business generated between the physician and the donor entity furnishing Stark-covered designated health services. (For example, such criteria could include the total number of prescriptions written by a physician, but could not include the volume of such prescriptions that are dispensed or paid by the donor of the electronic prescribing technology.)
7. The donor entity must not know or act in reckless disregard or deliberate ignorance of the fact that the physician already possessed the item or service.
8. The donor must not act to restrict or limit the physician's right to use the donated equipment for all patients.
9. Finally, each such arrangement must be in writing, specify the item or service being provided and the value

thereof, cover all such items or services, and contain a certification by the physician that the donated items or services are not technically or functionally equivalent to equipment the physician already owns or leases.

Further, in regard to the proposed Stark exception for electronic health records, the following additional requirements apply:

- (i) The donated items or services cannot include the provision of training staff for the physicians' offices. In the pre-interoperative certification period, the software cannot include billing, scheduling, or other general office management services or software. In the case of the proposed exception for post-interoperative electronic health records, the items and services may not be used solely to conduct personal affairs or business unrelated to the medical practice.
- (ii) The arrangement does not violate the Anti-Kickback Law or other Federal or State laws or regulations governing billing or claims submission.

Proposed Anti-Kickback Law Safe Harbors

The Federal Anti-Kickback Law (42 U.S.C. § 1320a-7b(b)) generally prohibits payments in any form made purposefully to induce or reward the referral, recommendation or generation of federal health care program business. As mandated by the MMA, the OIG has issued a proposed safe harbor under the Anti-Kickback Law for certain arrangements involving the provision of electronic prescribing technology.

Although the elements of the proposed Anti-Kickback safe harbor are not materially different from the elements of the proposed Stark exception for electronic prescribing, there are two important distinctions due to the differences between the two laws. First, electronic prescribing transactions are required to qualify for an exception to avoid strict liability under the Stark Law. However, compliance with the Anti-Kickback electronic prescribing safe harbor is voluntary because failure to qualify for an Anti-Kickback Law safe harbor does not necessarily indicate that a particular arrangement is unlawful. Secondly, the Stark exception would apply only to physician referrals, while the Anti-Kickback safe harbor would apply more broadly to other prescribing health care professionals.

The OIG is also soliciting comments on both an electronic health records safe harbor and a possible safe harbor for technology enabling physicians to participate in community-wide health information systems. The OIG has not proposed language for the electronic health records Anti-Kickback safe harbor at this time, but has stated that it would track the CMS-proposed Stark exception.

Conclusion

CMS has proposed extensive and potentially useful Stark exceptions that would benefit hospitals, group practices, and certain physicians. Potential technology donors should also take comfort from the OIG's solicitation of comments regarding its own broad proposed electronic prescribing and electronic health records Anti-Kickback safe harbors. Nevertheless, the requirements are, as usual, technical and not simple to meet. Care must be taken to assure a compliant program, and the advice of counsel should be sought in structuring transactions.

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Proposed Stark Law Exceptions (70 Fed. Reg. 59182)

	MMA-mandated electronic prescribing exception	Pre-interoperability electronic health records exception	Post-interoperability electronic health records exception
Authority for Proposed Exception ..	Section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.	Section 1877(b)(4) of the Social Security Act.	Section 1877(b)(4) of the Social Security Act.
Covered Technology	<i>Proposed:</i> <ul style="list-style-type: none"> • Items and services that are necessary and used solely to transmit and receive electronic prescription drug information. • Includes hardware, software, internet connectivity, and training and support services. 	<i>Proposed:</i> <ul style="list-style-type: none"> • Software used solely for the transmission, receipt or maintenance of electronic health records. • Directly-related training services. • Software <i>must</i> include an electronic prescribing component. 	<i>Proposed:</i> <ul style="list-style-type: none"> • <i>Certified</i> electronic health records software • Directly-related training services • Software <i>must</i> include an electronic prescribing component • Could include billing and scheduling software, provided that the core function of the software is electronic health records.
Standards With Which Donated Technology Must Comply	<i>Proposed:</i> <ul style="list-style-type: none"> • Foundation standards for electronic prescribing as adopted by the Secretary. 	<i>Proposed:</i> <ul style="list-style-type: none"> • Electronic prescribing component must comply with foundation standards for electronic prescribing as adopted by the Secretary. 	<i>Proposed:</i> <ul style="list-style-type: none"> • Product certification criteria adopted by the Secretary. • Electronic prescribing component must comply with foundation standards for electronic prescribing as adopted by the Secretary, to the extent these standards are not fully incorporated into the product certification criteria.
Permissible Donors	<i>Proposed:</i> <ul style="list-style-type: none"> • As required by statute, hospitals (to members of their medical staffs), group practices (to physician members), PDP sponsors and MA organizations (to Physicians). 	<i>Proposed:</i> <ul style="list-style-type: none"> • Hospitals to members of their medical staffs. • Group practices to physician members. • PDP sponsors. • MA organizations. 	<i>Proposed:</i> <ul style="list-style-type: none"> • Hospitals to members of their medical staffs. • Group practices to physician members. • PDP sponsors. • MA organizations.
Selection of Recipients	<i>Proposed:</i> <ul style="list-style-type: none"> • Donors may not take into account the volume or value of referrals from the recipient or other business between the parties. 	<i>Proposed:</i> <ul style="list-style-type: none"> • Donors may not take into account the volume or value of referrals from the recipient or other business between the parties. 	<i>Proposed:</i> <ul style="list-style-type: none"> • Donors may use criteria to select recipients that are not directly related to the volume or value of referrals or other business generated between the parties.
Value of Protected Technology	<i>Proposed:</i> <ul style="list-style-type: none"> • No specific dollar amount proposed for a cap on the value of protected technology. 	<i>Proposed:</i> <ul style="list-style-type: none"> • No specific dollar amount proposed for a cap on the value of protected items and services. 	<i>Proposed:</i> <ul style="list-style-type: none"> • No specific dollar amount proposed for a cap on the value of protected items and services. • May be greater than the cap on preinteroperability donations.