DechertOnPoint

August 2006 / Issue 6

A legal update from Dechert's Health Law Group

Final Rules Ease Barriers to Electronic Health Records Systems

On August 8, 2006, the Centers for Medicare and Medicaid Services (CMS) and the Department of Health and Human Services Office of Inspector General (OIG) published final rules that provide exceptions to the federal physician self-referral (Stark) law, and safe harbors under the federal health care anti-kickback statute intended to promote physician adoption of electronic prescribing and electronic health records (EHR) technology. The rules finalize the exceptions and safe harbors initially published in the Federal Register on October 11, 2005 (the Proposed Rules).

These final rules have been modified considerably from those initially proposed. The rules become effective October 10, 2006. In announcing the final regulations, Health and Human Services Secretary Mike Leavitt stated, "By removing barriers, these regulation changes will help physicians get these systems in place and working for patients faster."[1]

This update will focus on the Final Rules as they pertain to EHR.

Background

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a prescription drug benefit in the Medicare program. As part of the MMA, Congress directed the Secretary of Health and Human Services to establish standards for electronic prescribing to improve the quality of care, enhance patient safety, and streamline the delivery of health care.

Congress mandated the Secretary, in consultation with the Attorney General, to create an exception to Stark and a safe harbor under the anti-kickback statute which would allow entities to provide non-monetary assistance to physicians to encourage the use of electronic prescribing. As mandated, CMS created an electronic prescribing exception under Stark published in the Federal Register on August 8. Consistent with their regulatory authority under Section 1877(b)(4) of the Social Security Act, CMS carved out an additional exception for EHR arrangements under certain conditions.

The OIG created a final rule that is similar to the CMS rule published in the Federal Register on August 8. Consistent with their regulatory authority under Section 1128B(b)(3)(E) of the Social Security Act, OIG carved out an additional safe harbor for EHR arrangements. The OIG states that the safe harbor will "protect beneficial arrangements that would eliminate perceived barriers to the adoption of EHR without creating undue risk that the arrangements might be used to induce or reward" referrals.[2]

At the outset we highlight a significant difference in the statutory schemes of Stark and the anti-kickback statute—complying with a safe harbor under the anti-kickback statute is voluntary, whereas fitting in an exception under section 1877 of the Act is mandatory. Arrangements that do not comply with a safe harbor may not necessarily violate the anti-kickback statute, but they are subject to a case-by-case review under the statute. If an arrangement fails to meet all requirements of a physician self-referral exception, however, it

[1] United Stated Department of Health and Human Services News Release, "New Regulations to Facilitate Adoption of Health Information Technology" (August 1, 2006).

[2] 71 Fed. Reg. 45110, 45111 (August 8, 2006).

violates Stark. Another important distinction is that Stark applies only to referrals from physicians, while the anti-kickback statute applies more broadly.

Stark Law – Physician Self-Referral

Under section 1877 of the Social Security Act, physicians are prohibited from referring Medicare patients to entities for certain designated health services (DHS) if the physician has a financial relationship with the entity, unless an exception applies. In addition, the entity may not present or cause to be presented a claim pursuant to a referral prohibited under this law. The law is triggered by the mere fact that a financial relationship exists. Intent is not considered when the physician makes a referral.

Hospitals face significant financial exposure unless their financial relationships with referring physicians fit squarely in a statutory or regulatory exception to the statute. As noted above, an entity may not submit a claim for a DHS if the referral of the DHS comes from a physician with whom the entity has a prohibited financial relationship. This is true even if the prohibited financial relationship is the result of inadvertence or error. Violations of the statute are punishable by denial of payment for all CHS claims, refund of amounts collected for DHS claims, civil money penalties for knowing violations, and, in some cases, exclusion from participation in the federal health care programs. The donation of electronic technology may create a financial relationship that is subject to the physician self-referral prohibition.

Final Rules – Stark Exception Pertaining to Electronic Medical Records

The final rules set forth the conditions for a new regulatory exception for arrangements involving the donation of EHR software or information technology and training services (but not hardware).[3] The software must be "interoperable," but CMS eliminated the pre and post interoperability standards found in the Proposed Rules which commenters referred to as "confusing" and contrary to the goal of achieving nationwide adoption of EHR. The preamble states that "the industry has made considerable progress in developing certification criteria" for EHR, making it unnecessary to bifurcate interoperability standards, provided software is interoperable at the time it is donated and no attempt is made to restrict or limit operability.[4]

The proposed rules required physicians to certify that they did not have software that was technically and functionally equivalent to the donated software. The final rules eliminate this requirement. Instead, the final rules require software and training services to be "necessary," and used predominantly to create, maintain, transmit, or receive EHR. CMS extrapolates that "software and services are [not] 'necessary'" if the physician recipient already possesses the equivalent software or services. The exception prohibits donation of items or services if there is actual knowledge of, or reckless disregard or deliberate ignorance of, the fact that the physician possesses or has such items or services equivalent to those provided.

Software and training services explicitly include internet connectivity and help desk support services, two services which were not included in the proposed exception. In addition, the final rule permits, under certain conditions, donated software to include various patient administration functions excluded from the proposed rule: scheduling, billing, and clinical support. However, the final rules do not allow donors to donate staffing to physician offices. Furthermore, the final rules include a cost-sharing component which requires the physician to pay 15% of the donor's cost for the items and services before the physician receives the items and services. The exception covers items and services that are provided to a physician by a hospital or other entity that furnishes DHS.

To qualify for the exception, certain additional conditions must be satisfied, including:

- The physician (or physician's practice) does not make the receipt of items or services, a condition of doing business with the donor.
- The donor does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or HER systems.

[3] 71 Fed. Reg. 45140 (August 8, 2006).

[4] "Interoperable" means that the software is able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered. Software is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the physician.

- Donors use selection criteria that are not directly related to the volume or value of referrals from the donor or other business generated between the parties. The exception provides a number of examples of permitted selection criteria which are geared to permit donation to physicians who are most likely to use it. Total number of prescriptions written (but not the value of such prescriptions), size of the physician's practice or total patient encounters, and total hours devoted to medical practice are listed as permissible criteria. Other permissible criteria include whether the physician is a member of the donor's medical staff, and 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).

- Arrangements are in writing, specify all the items and services being provided and the donor's cost of the items and services, and are signed by the parties.

- The use of the technology may not be limited by the donor with regard to payor status.

- EHR software contains electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the physician's existing electronic prescribing system, that meets the applicable standards under Medicare Part D at the time the items and services are provided.

- The arrangement does not violate the anti-kickback statute, or any Federal or State law or regulation governing billing or claims submission.

- This exception sunsets on December 31, 2013. This means that the transfer of items or services must occur and all conditions in the regulation must be satisfied on or before that date.

Anti-kickback Statute

Originally enacted in 1972, the anti-kickback statute criminalizes kickbacks in connection with the Medicare or Medicaid programs. Specifically, the statute prohibits the knowing and willful solicitation, offer, payment, or receipt, directly or indirectly, of any remuneration (including kickbacks, bribes, or rebates), whether in cash or in kind:

- In return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under Medicare or Medicaid program, or

- In return for purchasing, leasing, ordering, or arranging for or recommending the purchasing, leasing, or ordering of any good, facility, service, or item for which payment may be made in whole or in part under Medicare or a Medicaid program.

Violation of the anti-kickback statute constitutes a felony punishable by a $25,000 fine and/or imprisonment for up to 5 years.

Given the breadth of the anti-kickback statute, Congress directed the OIG to establish safe harbor regulations to protect from enforcement action legitimate business arrangements which would otherwise violate the statute. As noted above, the failure of a particular arrangement to fit squarely within a safe harbor does not mean the arrangement is illegal. However, meeting the requirements of an applicable safe harbor provides more certainty that the given arrangement is not illegal. The donation of electronic technology may create a financial relationship that is subject to the anti-kickback statute unless it fits within one of the safe harbors.

Final Rule – Electronic Health Records Safe Harbor

In accordance with the final rule released by the OIG, "remuneration" does not include 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, under conditions very similar to the criteria under the Stark exception, with few differences. In contrast to the Stark exception, which covers physicians, the EHR safe harbor is broader and includes the following recipients of the software: "individuals or entities engaged in the delivery of health care and health plans."

Like the Stark exception, there is no cap on value of donated items and services—rather, the physician

must pay 15% of donor cost for the items and services prior to receipt. Moreover, the donor is prohibited from shifting the costs of the items or services to any Federal health care program. The electronic medical records safe harbor parallels the Stark exception in many other respects.

Practice group contacts

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