

New E-Prescribing and EHR Exceptions and Safe Harbors

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I. INTRODUCTION AND BACKGROUND

On August 8, 2006, the Department of Health and Human Services (DHHS) published final regulations in the *Federal Register* that created two new exceptions to the federal physician self-referral law (Stark Law) and two new safe harbors under the federal healthcare anti-kickback statute involving e-prescribing and electronic health records. These new regulations are the result of a call by both Congress and the President for greater use of technology in the healthcare arena.

In April 2004, President Bush called for widespread adoption of interoperable electronic medical records for most Americans within the next ten years. To implement this mandate, the Office of the National Coordinator for Health Information Technology (ONC) was created to advise the Secretary of DHHS on the development, application, and use of health information technology (HIT); to coordinate DHHS' policies and programs with those of other relevant executive branch agencies; and to develop and direct implementation of a strategic plan for nationwide implementation of interoperable HIT. President Bush's initiative to increase the use of information technology followed the adoption of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA),¹ which amended the Social Security Act to establish a prescription drug benefit in the Medicare program. As part of the new drug benefit, Congress directed the Secretary of DHHS to establish standards for electronic prescribing in order to improve patient safety, quality of care, and efficiency in the delivery of care.

It stands to reason that much of the electronic prescribing technology, as well as the electronic health record (EHR) technology, that makes its way into the practices

of physicians and other healthcare providers will be donated by hospitals or other groups. Such arrangements in which electronic prescribing or EHR technology is directly or indirectly funded by a hospital, health system, or physician group for a physician or other healthcare providers, through full or partial donation, may create a financial relationship that is subject to either or both of the Stark Law prohibition or the anti-kickback statute. For this reason, the MMA directed the creation of an exception to the Stark Law and a safe harbor to the anti-kickback statute to permit certain entities to provide non-monetary assistance to physicians and other providers to encourage their use of electronic prescribing technology. DHHS went beyond this directive and created a second exception under the Stark Law and a second anti-kickback safe harbor in an effort to also encourage the adoption and use of EHR software or information technology and training services.

To fully understand the exceptions and safe harbors, it is helpful to know the basic prohibitions under the Stark Law and the anti-kickback statute and the differences between these two regulatory schemes. The Stark Law, which is enforced by the Centers for Medicare and Medicaid Services (CMS), prohibits a physician (or immediate family member) who has a financial relationship with an entity from making a referral to the entity for the provision of designated health services for which payment may be made under Medicare or Medicaid. Additionally, the entity may not present or cause to be presented a claim to any individual, third-party payor, or other entity for designated health services furnished pursuant to a prohibited referral. Since virtually any exchange of remuneration with a physician could potentially create a financial relationship, the law and regula-

tions published pursuant to the statute establish a number of exceptions and DHHS has the authority to create additional regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. An arrangement must meet all requirements of a physician self-referral exception or it violates the law. The final rule creates two new exceptions to the Stark Law. One exception protects certain arrangements involving the donation by hospitals, group practices, and certain other organizations of non-monetary remuneration (hardware, software or information technology, and training services) necessary and used solely to receive and transmit electronic prescription information in accordance with electronic prescribing standards to prescribing physicians. The second exception protects certain arrangements involving the donation of electronic health records software or information technology and training services.

The anti-kickback statute, which is enforced by the Office of Inspector General (OIG), provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under any federal healthcare program. While the Stark Law applies only to referrals from physicians, the anti-kickback statute applies more broadly. Because of the broad reach of the statute, the OIG has developed safe harbor provisions to specify various payment and business practices that are not treated as criminal offenses under the statute. The safe harbor regulations are evolving in nature and are updated periodically to reflect changing business practices and technologies in the healthcare industry. The final rule promulgates two new safe harbors to the anti-kickback statute. They are virtually identical to the two new Stark Law exceptions. However, complying with a safe harbor under the anti-kickback statute is voluntary, whereas meeting the requirements for an exception under the Stark law is mandatory. Arrangements that do not comply with a safe harbor may not necessarily violate the anti-kickback statute but are subject to a case-by-case review.

Unlike other exceptions and safe harbors developed primarily to protect against fraud and abuse, the e-prescribing and EHR exceptions as well as the safe harbors are designed to promote improved healthcare quality and efficiency through widespread adoption of interoperable electronic health records.² For this reason, both CMS and the OIG worked to develop regulations that would eliminate perceived barriers to the adoption of electronic health records without creating a risk that such arrangements would be used as a mechanism to reward or induce referrals. The two agencies also attempted to ensure as much consistency as possible between the safe harbors and the exceptions and to draw as many bright lines as

possible. However, as with seemingly all healthcare regulations, there are provisions that create uncertainty and may require further clarification from the regulators.

II. ANALYSIS

A. The E-Prescribing Exception and Safe Harbor

The framework for the e-prescribing exception and safe harbor are contained in the MMA, which allows for the provision of nonmonetary remuneration (in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information. Specifically, the exception and safe harbor set forth conditions under which hospitals, group practices, Prescription Drug Program (PDP) Sponsors, and Medicare Advantage (MA) Organizations can provide such technological remuneration to certain healthcare professionals and pharmacies.

1. The E-Prescribing Exception. To fall within the Stark e-prescribing exception, a donation can include hardware, software, or information training and services provided these items are necessary for and used solely to receive or remit electronic prescription information and are provided or used as part of an electronic prescription drug program that meets the applicable standards under the Medicare Part D program at the time the items or services are provided.³ These donations are unlimited in value and can relate to any item or service normally ordered by prescription, such as laboratory tests and durable medical equipment; they need not be limited only to prescriptions for drugs. There is also a wide array of items that fall within the definition of hardware, software, and information training. Items such as connectivity services, including broadband and wireless internet services, interface and translation software, maintenance services, and access to help desk services, are a few examples. However, the technology donated may not include office function capabilities, such as scheduling or billing services, as the donation would no longer be used solely for prescription information. Further, products or services that duplicate what a physician already has available in his or her office are not protected donations as these items would not be considered necessary. In fact, the regulation specifies that donors not have actual knowledge or act in reckless disregard or deliberate ignorance of the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.⁴ Upgrades of equipment or software that enhance the functionality of an item or service are not considered duplicative, however, and are protected.⁵

There are also limitations on who may give and who may receive donations of e-prescribing hardware and software. Acceptable donors and recipients are: (1) a hospital to a

physician member of its medical staff; (2) a group practice to a physician member of the group; or (3) a PDP Sponsor or MA Organization to a prescribing physician.⁶ Selection criteria, such as the number of prescriptions written, may be adopted but the volume or value of referrals or other business generated between the parties may not be a selection criterion.⁷ Donors may not take any action to limit or restrict the use or compatibility of the items or services with other systems or the physician's right or ability to use the items or services for any patient, regardless of payor source.⁸ Conversely, physicians and their practices may not make the receipt, value, or nature of an item or service a condition of doing business with the donor.⁹ Finally, the arrangement for the receipt of items or services must be set out in a written agreement that: (a) is signed by the parties; (b) specifies the items or services being provided and the donor's cost; and (c) covers all of the items and services to be provided by the donor. This last requirement will be considered met if all separate agreements between the donor and the physician or immediate family member incorporate each other by reference or are cross-referenced on a master list that is maintained and updated centrally and kept in a manner that preserves the historical record of the agreements.¹⁰

2. E-Prescribing Safe Harbor. The e-prescribing safe harbor very closely mirrors the requirements for the e-prescribing exception to the Stark Law. However, because the anti-kickback statute applies to all healthcare providers, not just physicians, the e-prescribing safe harbor is somewhat more expansive in its scope. For example, eligible recipients include prescribing healthcare professionals (not just physicians) who are members of a group practice as well as pharmacies and pharmacists receiving items and services from a PDP sponsor or MA organization.¹¹ However, it must be noted that only physician members of a medical staff may receive items or services from a hospital.¹²

The usefulness of the e-prescribing exception and safe harbor is questionable. Since the guidelines for these regulations came directly from the MMA, neither CMS nor the OIG had the authority to broaden or otherwise change the limiting requirements. In determining if any donation or sale of e-prescribing technology is permitted, it must be noted that other exceptions and safe harbors that are broader than those relating to e-prescribing may be applicable, such as those relating to EHR (as discussed below), discounts, or employees. Finally, as acknowledged by the OIG, "In general, fair market value arrangements that are arm's length and do not take into account in any

manner the value or volume of Federal health care program business or arrangements that do not have as a purpose the generation of business payable by a Federal health care program should not raise concerns under the anti-kickback statute"¹³ Thus, the failure of an arrangement to fall squarely within the e-prescribing safe harbor may not preclude a planned donation of software and technology.

B. Electronic Health Records Exception and Safe Harbor

The exception and safe harbor for EHR are broader but more complicated than their e-prescribing counterparts. In adopting these regulations, CMS and the OIG did not have the same congressional restrictions as were imposed on the e-prescribing regulations and they are more clearly aimed at President Bush's goal of facilitating the widespread adoption of EHR by the year 2014. In fact, the protections offered by these regulations expire on December 31, 2013,¹⁴ thus discouraging delays in donations of technology beyond the ten-year timeframe proposed by the President. Further, while donations of hardware are not covered, EHR technology may be used for more than just the transmission, maintenance, and creation of EHR. Ancillary uses of the donated items and services are allowed provided these uses are secondary and not the predominate function of the donated items. There is also a cost sharing aspect of donations under the EHR exception not present in the exception for e-prescribing.

1. EHR Exception. Electronic health records are broadly defined to mean a "repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions."¹⁵ To qualify for protection under the EHR exception, donations must be from an entity to a physician for necessary software, information technology, and training services that are used predominately to create, maintain, transmit, or receive electronic health records.¹⁶ Additionally, the donated software must be interoperable at the time it is provided to a physician, meaning that the software is able to communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems.¹⁷ Software will be considered interoperable if it has been so certified by the Secretary no more than twelve months prior to the date it is provided to the physician.¹⁸ However, as discussed in more detail below, this requirement, at least initially, will provide little help to entities and physicians in determining whether software is interoperable. Although such standards and certifications are currently under development, it is unknown when they will be finalized.

As with the e-prescribing exception, neither a physician nor a staff member or an employee of the physician may make the receipt or nature of donated items and services a condition of doing business with the donor. Further, a physician may not receive products or services already available in his or her office. These items would not be considered necessary and, in fact, the regulations specify that donors not have actual knowledge or act in reckless disregard or deliberate ignorance of the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.¹⁹ Conversely, a donor may not limit or attempt to restrict the physician's right or ability to use the donated items for any patient, regardless of payor source.²⁰ Additionally, a donor may not determine eligibility for or determine the amount or nature of a donation in a manner that directly or indirectly takes into account the volume or value of referrals or other business generated between the parties.

Unlike other exceptions under Stark, however, a donor may establish criteria to determine which physicians receive donated items or services. It is considered acceptable practice for donors to base their donations on any of the following: (1) the number of prescriptions written by a physician (but not on the value or volume dispensed or paid by the donor); (2) the size of a physician's practice; (3) total number of hours a physician practices; (4) a physician's overall use of technology; (5) membership on the medical staff; and (6) the amount of uncompensated care provided.²¹ Further, a donor may make determinations to grant donations in any reasonable and verifiable manner that does not take into account the volume or value of referrals or other business generated between the parties.²² However, a donor may not take any action to limit or restrict the use, compatibility, or interoperability of the technology with other e-prescribing or EHR systems.²³

One of the major differences between the EHR exception and the e-prescribing exception is the cost-sharing requirement contained in the EHR exception. To fall within the EHR exception, a physician must pay 15% of the donor's cost for the items and services. CMS believes that the 15% requirement is high enough to encourage the purchase of appropriate technology that the physician will actually use, but not so high as to actually discourage the acceptance of donated items and services. A donor may not, however, finance or loan funds to the physician to pay for his or her co-payment amount. With regard to internally developed or adapted software, the parties may use any manner to determine the costs of this software provided the method is a reasonable and verifiable means of allocating costs. The parties also should maintain contemporaneous and accurate docu-

mentation as methods of cost allocations may come under careful scrutiny by CMS to ensure that physicians are not being provided inappropriate benefits. Finally, all donated software and technology is subject to the cost-sharing requirement. The 15% of cost sharing for items furnished at a later date, such as upgrades, updates, or modifications, must be assessed against physicians or other recipients if the cost of those items was not included in an initial donation.

Although the certification requirement contained in the proposed regulations has been eliminated, any arrangement for the receipt of items or services must be set out in a written agreement that is: (a) signed by the parties; (b) specifies the items or services being provided and the donor's cost; and (c) covers all of the items and services to be provided by the donor. This last requirement will be considered met if all separate agreements between the donor and the physician or immediate family member incorporate each other by reference or are cross-referenced on a master list maintained and updated centrally and kept in a manner that preserves the historical record of the agreements. Further, any donated items or services must not violate the anti-kickback statute or any state or federal law governing billing or claims submission.²⁴ Whether this makes compliance with the anti-kickback safe harbor essentially mandatory remains to be seen. Finally, the EHR software must contain an electronic prescribing capability that meets the applicable standards under Medicare Part D at the time the items or services are provided.²⁵ This capability can be a component of the software or an interface with the physician's existing e-prescribing system.

2. EHR Safe Harbor. As was their intent, CMS and the OIG each drafted regulations that closely mirror each other. Again, however, as with the e-prescribing safe harbor, because the anti-kickback statute applies to all providers, not just physicians, the EHR safe harbor is slightly more expansive than the EHR exception. It applies to items and services provided to an individual or entity engaged in the delivery of healthcare by (1) an individual or entity that provides services covered by a federal healthcare program and that submits claims or requests for payment, either directly or through reassignment, to the federal healthcare program, or (2) a health plan.²⁶

C. H.R. 4157

On July 27, 2006, in an effort to encourage the dissemination and usefulness of HIT, the U.S. House of Representatives passed H.R. 4157, which sets forth conditions under which nonmonetary remuneration, in the form of HIT and related maintenance and training, may be made without being considered a prohibited pay-

ment.²⁷ As it stands, H.R. 4157 would amend the anti-kickback statute and the Stark Law to protect donations of HIT or related installation, maintenance, support, or training services. The bill's definition of HIT appears to cover both electronic prescribing and EHR software, including software that provides functions related to patient services such as billing and patient scheduling. Donations of software that include these types of patient services functions are not allowed under the DHHS EHR exceptions and are allowed under the safe harbors only if they are a secondary function of the donated items. One other significant difference between the final regulations and the H.R. 4157 equivalents is that the latter do not contain an interoperability standard. While it appears that H.R. 4157 could effectively undercut portions of the final regulations in place, the bill is currently being reconciled with Senate bill 1418 and its final outcome, as well as its effect on the final regulations, is unknown.

While the new e-prescribing and EHR exceptions and safe harbors seem to be a departure from existing Stark exceptions and anti-kickback safe harbors in that they allow more generous practices and attempt to further the EHR public policy goals, how useful they are remains to be seen. One reason is that, according to the new e-prescribing rules, hardware may be donated only if it is used solely for prescribing functions, which limits its usefulness in the grand scheme of technology integration in the healthcare arena. Another reason is that it is currently unknown as to exactly how the requirements that donated software and services be necessary and used predominantly for EHR will be applied. Further, what methodologies or documentation CMS will require to accurately determine the cost of donated items, particularly "home-grown" software also is unknown. The ultimate interpretations of both of these requirements by CMS may prove to be overly restrictive and burdensome. Additionally, the EHR rules require software to be interoperable or deemed certified by the Secretary, which limits both available products and investor confidence in their usefulness. However, the goal to establish and maintain EHR systems remains and these safe harbors and exceptions will likely have a significant impact in the achievement of these goals.

III. INTEROPERABILITY

One aspect of the EHR exception and safe harbor that is causing controversy and concern is the requirement that software donated pursuant to the rules be interoperable at the time it is donated.²⁸ Interoperable is defined as the ability "to communicate and exchange data accurately,

effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings; and the exchange data must be such that the clinical or operational purpose and meaning of the data are preserved and unaltered."²⁹ This is an imposing standard and both donors and recipients may be wary of making their own determination as to whether or not a particular software product meets the standard. There is another option available. According to both the Stark exception and the anti-kickback safe harbor, software is deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than twelve months prior to the date it is provided to the recipient.³⁰ The problem with this alternative is that, currently there are no EHR certification bodies certified by the Secretary of DHHS.

The situation may not be as dire as it seems on first blush, however. On August 4, 2006, the ONC published interim guidance regarding the recognition of certification bodies, which includes the process for application. The Certification Commission for Health Information Technology (CCHIT), a voluntary, private-sector organization established specifically to develop certification standards and certify HIT products, has applied for and expects to receive its RCB (Recognized Certification Body) status soon.

CMS recognizes that the interoperability component of EHR technology is evolving and that interoperability standards have not yet become a reality across systems. In the preamble to the exception and safe harbor rules, CMS states: "The industry has made considerable progress in developing certification criteria for electronic health records products within a very short time. In fact, one certification organization has already completed an initial set of certification criteria for ambulatory electronic health records."³¹ The certification agency CMS is referring to is CCHIT. In 2005, DHHS awarded CCHIT a three-year contract to develop and evaluate certification criteria and create an inspection process for HIT in three areas: (1) ambulatory EHRs for the office-based physician or provider; (2) inpatient EHRs for hospitals and health systems; and (3) network components through which they interoperate and share information. On August 4, 2006, the Secretary recognized the CCHIT-developed ambulatory certification criteria in the areas of functionality, interoperability, security, and reliability.³² While there is currently just one recognized criterion for interoperability—the ability to receive lab results—the CCHIT timeline available on CCHIT's website indicates there will

be more interoperability criteria coming as CCHIT updates the ambulatory EHR certification criteria.

In addition, CCHIT's inpatient EHR certification criteria for hospitals and other health systems scheduled to launch in the second quarter of 2007 and the certification interoperability criteria networks scheduled for the second quarter of 2008 will include increasing interoperability criteria. The development of interoperability standards will be continuous as new certification criteria are approved and certification for existing programs is updated. As long as CCHIT and any other certifying bodies eventually recognized by the Secretary move forward with establishing new criteria at a pace that meets the needs of the providers and as long as the criteria can reasonably be met by the industry, then interoperability requirements may not be a critical barrier to the donation of EHR systems.

To date, CCHIT has certified twenty-two ambulatory EHR programs offered by vendors for physician offices and other office-based providers, and there are at least fourteen more programs that have applied for CCHIT certification. Since CCHIT was not a certifying body recognized by the Secretary at the time it certified the first twenty-two products and because of the limited approved interoperability criteria, it is unclear, however, whether the CCHIT certification, as a technical matter, confer "deemed interoperable" status on a vendor's product.

While the new regulations do not require vendors who currently sell EHR products to periodically provide updates, including those allowing for greater interoperability, the market may offer incentives for vendors to do so. As certification criteria become established and recognized, vendors who do not offer updates or modifications will not survive if their competition provides these updates. These market incentives may offer some protection for providers who donate or receive software in the early days of the new exception and safe harbor. In addition, CCHIT requires that the products it certifies include updates. This should decrease reluctance to purchase systems now for fear that the systems will have to be replaced as new interoperability criteria are imposed.

As discussed above, the anti-kickback safe harbor and Stark Law exception provisions of proposed H.R. 4157 contain no interoperability requirements and, if passed as written, could trump the new regulations just published. Since H.R. 4157 is currently being debated and would have to be reconciled with its companion Senate bill, it is difficult to determine what impact the bill may have.

IV. SUMMARY

Even with the new exceptions and safe harbors, there are many considerations for both recipients and donors in determining whether to commit to the implementation of an e-prescribing and/or EHR system. One consideration for recipients is whether the required minimum 15% of the cost to acquire much of the software and technology necessary to establish such a system is affordable, particularly since additional funds and time for implementation and staff training will be necessary to develop a fully functional EHR system. The potential return on this investment may be too far down the road to act as a current incentive. Another consideration for recipients is how to handle situations where two competing hospitals or healthcare networks have incompatible systems. Recipients may have to decide which hospital or healthcare network system is most important to them since they cannot maintain two separate e-prescribing or EHR systems.

A consideration for both recipients and donors is that, with interoperability still an issue, both may be reluctant to proceed as no one wants to invest in a Beta system. Hospitals also face roadblocks in making permissible donations. Many are undertaking the expense of implementing their own EHR systems and CMS has given no indication that it will make any funds available for these technology investments. For nonprofit and governmental hospitals, donations that are allowable under these safe harbors and exceptions may be prohibited under Internal Revenue Service guidelines or state laws and constitutions. Despite these many considerations, uncertainties and potential roadblocks, Congress and the President are likely to continue their call for greater implementation of technology in prescribing and medical record keeping and the implementation and use of the safe harbors and exceptions will be an important part of achieving this goal.

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END NOTES

¹ MMA § 1860D-4(e) (6), 42 U.S.C.A. §1395w-104(e) (6) (West Supp. 2006).

² 71 Fed. Reg. 45111 (Aug. 8, 2006).

³ 42 C.F.R. § 411.357(v), 42 C.F.R. § 411.357(v) (2). The final Stark Law exceptions and anti-kickback safe harbors and the accompanying commentary are set forth at 71 Fed. Reg. 45140 (Stark Law exceptions) and 71 Fed. Reg. 45110 (anti-kickback safe harbors). For ease, however, we have noted the appropriate cite to the Code of Federal Regulations throughout this article.

⁴ 42 C.F.R. § 411.357(v) (8).

⁵ 71 Fed. Reg. 45146 (Aug. 8, 2006).

⁶ 42 C.F.R. § 411.357(v) (1).

⁷ 42 C.F.R. § 411.357(v) (6).

⁸ 42 C.F.R. § 411.357(v) (3), (4).

⁹ 42 C.F.R. § 411.357(v) (5).

¹⁰ 42 C.F.R. § 411.357(v) (7).

¹¹ 42 C.F.R. § 1001.952(x) (1) (ii)-(iii).

¹² 42 C.F.R. § 1001.952(x) (1) (i).

¹³ 71 Fed. Reg. 45111 (Aug. 8, 2006).

¹⁴ 42 C.F.R. § 411.357(w) (13); 42 C.F.R. § 1001.952(y) (13).

¹⁵ 42 C.F.R. § 411.351.

¹⁶ 42 C.F.R. § 411.357(w).

¹⁷ 42 C.F.R. § 411.357(w) (2).

¹⁸ 42 C.F.R. § 411.357(w) (2).

¹⁹ 42 C.F.R. § 411.357(v) (8).

²⁰ 42 C.F.R. § 411.357(w) (9).

²¹ 42 C.F.R. § 411.357(w) (6) (i) – (vi).

²² 42 C.F.R. § 411.357(w) (6) (vii).

²³ 42 C.F.R. § 411.357(w) (3).

²⁴ 42 C.F.R. § 411.357(w) (12).

²⁵ 42 C.F.R. § 411.357(w) (11).

²⁶ 42 C.F.R. § 1001.952(y) (1).

²⁷ H.R. 4157, 109th Cong. Section 301 (2006).

²⁸ 42 C.F.R. § 411.357(w) (2) and 1001.952(y) (2).

²⁹ 42 C.F.R. §§ 411.351 and 1001.952(y).

³⁰ 42 C.F.R. §§ 411.357(w) (2) and 1001.952(y) (2).

³¹ 71 Fed. Reg. 45150 (Aug. 8, 2006).

³² “Recognized Ambulatory Electronic Health Record (EHR) Certification Criteria,” Department of Health and Human Services (2006).