

# Donating Health Information Technology: Final Regulations Compete with H.R. 4157 for Public Policy Control

October 2006

# Table of Contents

Brief Summary of Law	3
Final Regulation	3
H.R. 4157	5
Detailed Analysis and Commentary	6
Covered Technology	6
Interoperability And Other Required Technical Elements	8
Permissible Donors And Recipients	9
Conditioning Referrals On Donations And Discrimination Among Potential Recipients Based On The Volume Or Value Of Referrals	10
Mandatory Cost Sharing	12
Pre-Emption Of State Law	13
Sunsets And Reports To Congress	13
Conclusions	13

# Donating Health Information Technology: Final Regulations Compete with H.R. 4157 for Public Policy Control

This *White Paper* summarizes, analyzes and comments on the recently published final anti-kickback safe harbors and Stark regulatory exceptions for donation (or below-market transfer) of health information technology and related services (HIT) to referral sources (the final regulations).<sup>1</sup> This *White Paper* also considers the statutory kickback safe harbor and Stark exception currently proposed in the Health Information Technology Promotion Act of 2006 (H.R. 4157) recently passed by the U.S. House of Representatives, and how they compare to the final regulations. Additionally, recent federal register notices concerning the interoperability standards and the recognition of certifying bodies are incorporated into the discussion.

## Introduction

Congress recognized that proliferation of e-prescribing technology important to the Medicare Part D program could not occur without an anti-kickback safe harbor and Stark law exception for donations of electronic prescribing (e-prescribing) technology to prescribing practitioners and others in a position to steer Medicare Part D business to particular plans. Thus, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) required the Secretary of the U.S. Department of Health and Human Services (HHS) to adopt such a safe harbor and Stark law exception. However, Congress directed the Secretary to limit the exceptions to technology *necessary* to and *used solely* for e-prescribing. Under the statutory approach Congress previously adopted, a physician practice could not use the donated technology for other health information purposes, such as use with an electronic health record (EHR) system in connection with the delivery of day-to-day patient care.

Recognizing the need for an exception to address donation of EHR technology as well as e-prescribing technology by hospitals and health plans, in October 2005, the Office of Inspector General (OIG) proposed a safe harbor for e-prescribing arrangements and the concepts (but not the language) for a safe harbor for EHR arrangements. On the same date, the Centers for Medicaid and Medicare Services (CMS) proposed a new Stark exception for both EHR and e-prescribing arrangements (collectively the OIG and CMS proposals are called the proposed rules). The proposed rules, published for comment by OIG and CMS (the agencies), were widely criticized as too narrow to effectively encourage widespread adoption of EHR systems.

As a result, the health care industry welcomed the introduction of H.R. 4157 as a possible way out of the conundrum created by these two laws. H.R. 4157 would create exceptions from the anti-kickback statute and Stark law for donations or below-market transfers of HIT that are much broader and easier to comply with than those the proposed rules addressed. Only days after the U.S. House of Representatives passed H.R. 4157 and sent it to the Conference Committee for reconciliation with the Wired for Health Care Quality Act (S. 1418) (which contains no anti-kickback or Stark law exceptions), the agencies published the final regulations, effective October 10, 2006. As discussed below, the final regulations are much simpler and more flexible than the proposed rules. Nonetheless, they create issues for donors. Donors should act only after careful consideration of their donation and their relationship with the targeted recipient to avoid explicit or implicit violations of the law.

## Brief Summary of Law

### FINAL REGULATIONS

The final regulations provide Stark exceptions and anti-kickback safe harbors that are designed to permit specified individuals or entities to donate e-prescribing and EHR items and services to referral sources. In comments released with the rules, CMS and OIG have emphasized that they will work to ensure that the new donation rules do not foster illegal remuneration. Provisions have been written into the rules to prevent program or patient abuse.

---

<sup>1</sup> See 71 Fed. Reg. at 45110 (anti-kickback safe harbors) and at 45140 (Stark exceptions) (August 8, 2006).

The new Stark exceptions identify parties that can donate e-prescribing or EHR software, information technology and training services to physicians in specified relationships with the donor. Hardware donations are allowed only for e-prescribing purposes. Conditions for donation of e-prescribing items and services include:

- The donation must be part of or be used to access an electronic prescription drug program that meets Medicare Part D standards<sup>2</sup> at the time of donation
- The donor cannot restrict the use or compatibility of the donation with other e-prescribing or EHR systems
- The donor cannot limit the physician's right to use the donation with any patient when the donation can be used for any patient without regard to payor status
- The donor cannot take into account the volume or value of referrals or other business between the parties when determining eligibility for, or amount or nature of, donations
- The donation must be documented in a signed agreement that specifies the items and services to be provided and the donor's cost and covers all the items and services that the donor will provide
- The donation cannot duplicate capabilities that the recipient already possesses
- The recipient cannot make the donation a condition of doing business with the donor

Conditions for donation of EHR items and services add all of the following requirements:

- The EHR software must have an e-prescribing component that meets Medicare Part D standards at the time of donation
- Donated software must be interoperable at the time it is provided
- The donor cannot restrict interoperability of the items and services with other e-prescribing or EHR systems
- The recipient must share 15 percent of the donor's cost
- The donor cannot directly take the volume or value of referrals or other business between the parties into account when determining eligibility or the amount or nature of a donation
- Donations cannot include staffing the physician's office or items and services primarily used to conduct personal business or business unrelated to the physician's medical practice
- The transfers must be completed and all conditions satisfied by December 31, 2013

The new anti-kickback safe harbor is essentially identical to the Stark exception except that it addresses donations to other recipients in addition to physicians. Note the final regulations do not preclude donations of HIT that comply with other safe harbors and exceptions.<sup>3</sup>

---

<sup>2</sup> The Medicare Part D foundation standards require that the e-prescribing application comply with the National Council for Prescription Drug Programs SCRIPT Standard for communicating prescriptions between prescribers and dispensers for selected transactions, the Accredited Standards Committee X12N 270/271 Health Care Benefit Inquiry and Response for eligibility communications between prescribers and Part D sponsors, and the National Council for Prescription Drug Program Telecommunication Standard Specification for eligibility communications between dispensers and Part D sponsors.

<sup>3</sup> The prepaid plan exception provides that Stark designated health services furnished to enrollees of a Medicare Advantage (MA) and other specified risk plans are exempt from the Stark law's prohibitions. Thus, financial relationships arising from HIT donations by MA organizations to referring physicians should not trigger the Stark prohibitions and need not use the new donation exception. However, stand-alone Medicare prescription drug plans (PDP) do not qualify for the Stark pre-paid plan

## H.R. 4157

On July 27, 2006, the U.S. House of Representatives voted to approve H.R. 4157, which is aimed at promoting health information technology through coordination between the public and private sectors. Among other things, H.R. 4157 created a safe harbor under the federal anti-kickback law and an exception under the Stark regulations allowing hospitals and other health care providers (providers) to (a) provide health information technology and related training services, including hardware, software, license rights, intellectual property and equipment, to physicians and (b) prescribe conditions under which the technology and training would not be considered a prohibited payment made as an inducement to reduce or limit services. The safe harbor and exception would require that any such arrangement be in writing and that any remuneration be given without conditions that:

- Limit the use of the technology to services provided by the physician to individuals receiving services at the provider
- Limit the use of the technology in conjunction with other health information technology
- Take into account the volume or value of referrals (or other business generated) by the physician to the provider

H.R. 4157 also includes provisions unrelated to the Stark exception and anti-kickback safe harbors intended to promote the use of health information technology.<sup>4</sup>

---

exception. Nevertheless, there is a reasonable argument that prescribing physicians do not refer patients *to* a PDP, but, rather, the patient self-refers to a PDP after consulting various sources of information produced by pharmacies, AARP, Medicare and a myriad of other organizations. If the physician writing the prescription does not direct or steer the patient to a particular PDP, any HIT donations by the PDP sponsor to that physician should not present a problem under the Stark law.

The fact that Congress mandated a Stark exception for donations of e-prescribing technology and that the CMS has promulgated Stark exceptions for donations of e-prescribing and EHR technology by MA organizations and PDPs suggests to some that Congress and the CMS do not believe that the Stark pre-paid plan exception protects donations by these organizations. However, on numerous occasions the CMS has acknowledged that more than one Stark exception may apply to a particular financial arrangement, and the CMS has in published statements taken the position that a physician order for a Stark designated health service without steerage to a particular entity for the service is not a referral *to* an entity. Absent such referral *to* an entity, the Stark law is not implicated.

The creation of these new Stark exceptions should not mean that MA organizations cannot rely on the existing pre-paid plan exception or that PDP sponsors necessarily need, in the first instance, a Stark exception for their donations to physicians that prescribe drugs payable by the PDP. However, every situation warrants a fact-specific analysis under applicable provisions of the Stark law.

<sup>4</sup> Other components of H.R. 4157 include the following:

The creation of a permanent Office of the National Coordinator for Health Information Technology within HHS to coordinate federal government activities relating to health information technology and oversee a nationwide strategic plan for implementation of interoperable health information technology in the public and private sectors

Directing the Secretary of HHS to study and report on the continuity of federal and state laws on confidentiality and security of health information technology culminating in a report to Congress within 18 months on whether there should be a single federal set of standards

Directing the Secretary of HHS to promulgate a final rule for upgrading specified Accredited Standards Committee X12 (ASC X12) and National Council for Prescription Drug Programs (NCPDP) telecommunications standards for transactions occurring on or after April 1, 2009, and for upgrading International Statistical Classification of Diseases and Related Health Problems, 9th Revision (ICD-9) to ICD-10 codes by October 1, 2010

## Detailed Analysis and Commentary

### COVERED TECHNOLOGY

#### *E-Prescribing Technology*

As in the proposed rules, the e-prescribing exceptions and safe harbors in the final regulations restrict the donation of HIT to hardware, software, or information technology and training services *necessary* and *used solely* to receive and transmit electronic prescription information. Donated HIT is also protected only if it is provided as part of, or is used to access, an electronic prescription drug program that meets applicable standards under Medicare Part D at the time of the donation. While not wanting to create a laundry list of covered technology, the agencies indicated the following items and services are covered if *used solely* to receive and transmit e-prescribing information:

- Operating software
- Interfaces between the donor's e-prescribing technology and the physician's existing prescribing technology
- Licenses, rights to use and intellectual property
- Upgrades
- Educational and support services (including help desk and maintenance services)

The agencies explicitly exclude billing, scheduling, administrative and other general office software in the e-prescribing rules as they are not *used solely* for e-prescribing purposes. (However, the agencies do include these components in the EHR technology exceptions.)

The final regulations for e-prescribing still require that the HIT be *necessary*, but the agencies clarify that this standard is not meant to preclude upgrades that enhance functionality, make software more user-friendly or current or standardize systems among donors and recipients.

However, the term *necessary* does exclude donations of HIT that the physician already possesses. While the proposed rules required a written certification by the recipient that the donation does not duplicate the technology the recipient already possesses, the final regulations eliminated that requirement. Instead, the donation is not protected if the donor knows or acts in reckless disregard or deliberate ignorance of the fact that the recipient possesses equivalent HIT. The agencies counsel that prudent donors may want to make reasonable inquiries of donors regarding existing HIT and document such communications, but they do not provide guidance concerning the types of facts and circumstances that are relevant to determining whether HIT the recipient possesses is equivalent (*e.g.*, a comparison of features and functions, the technology platform or architecture).

Finally, the agencies interpret *prescribing information* broadly to include information about prescriptions for drugs or any other item or service normally accomplished through a written prescription. However, since the literal language of the Stark regulations already protects the provision of *items, devices or supplies used solely* to order and receive results of tests and procedures, the benefits of this broad interpretation appear to be limited to managing the anti-kickback risk raised by hospital and laboratory donations of computerized order entry systems.

As a practical matter, the utility of the e-prescribing exceptions and safe harbors will be limited given the narrow definitions of *necessary* and *used solely* imposed by the MMA and reflected in the final regulations. As the commentary to the final regulations suggests, qualified donors will rely primarily on the EHR protections for providing the software and other services needed by physicians. Recipients are not likely to need or want hardware to be *used solely* for e-prescribing purposes, particularly when they can receive the more useful multi-functional software, which includes e-prescribing capability, under the EHR exceptions and safe harbors.

## *EHR Technology*

The proposed rules for EHR technology included a requirement that the technology be *necessary* and *used solely* for the transmission, receipt and maintenance of patients' electronic health records and electronic prescription drug information, and directly related training services. The final regulations for EHR technology broaden the scope of the covered technology substantially, now protecting software or information technology and training services *necessary* and *used predominantly* to create, maintain, transmit or receive electronic health records.<sup>5</sup> In contrast to the final regulations for e-prescribing, the final regulations for EHR arrangements extend protection to software packages that include, for example, patient administration, scheduling functions, billing, clinical support software or other software or functionality directly related to the care and treatment of patients. The final regulations also require that EHR technology contains e-prescribing capability that meets the applicable standards under Part D. This can be accomplished either through an e-prescribing component to the software, or by the software's ability to interface with the recipient's existing e-prescribing system.

Further, the agencies interpret the final regulations for EHR arrangements to protect:

- Interface and translation software
- Rights, licenses and intellectual property related to EHR software
- Connectivity services (including broadband and wireless internet services)
- Clinical support and information services related to patient care (but not separate research or marketing support)
- Maintenance services
- Secure messaging
- Training and support services

The agencies explicitly excluded hardware (including routers or modems), staffing (*e.g.*, to migrate data), and items and services used primarily to conduct personal business or business unrelated to the physician's medical practice.

Like the final regulations for e-prescribing arrangements, the EHR regulations retain the requirement that the HIT be *necessary* and not duplicative of HIT already possessed by the recipient. However, the agencies have clarified that this standard does not preclude upgrades that enhance functionality or achieve greater standardization between donors and recipients (provided the HIT is interoperable). Again, the term *necessary* is intended to exclude donations of HIT that the recipient already possesses. Although a certification by the recipient is no longer required, the exception turns on whether the donor knows or should know that the recipient has equivalent HIT. Again, the agencies counsel that prudent donors may want to make reasonable inquiries of donors regarding existing HIT and document such communications, but they do not provide guidance concerning the types of facts and circumstances that are relevant to determining whether the recipient possesses equivalent (*e.g.*, a comparison of features and functions, the technology platform or architecture).

This reasonable inquiry requirement leaves room for disagreement as to whether the donor exercised care in determining whether the recipients own duplicative HIT. It is not clear whether a representation by a recipient that he or she does not own such HIT will be sufficient. If it is not, the donor is presented with the question of whether a physical inspection of the recipient's premises is required and, if so, whether the inspection must be conducted by someone with enough technical knowledge to determine whether the recipient's existing HIT has the same functionality as the technology to be donated. Given the uncertainty surrounding this requirement, donors may tend to be more conservative when determining if the donation will be duplicative.

---

<sup>5</sup> The agencies define *electronic health record* as "a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions." 71 Fed. Reg. 45136 (anti-kickback safe harbors) and 45169 (Stark exceptions) (August 8, 2006).

### *H.R. 4157 Exceptions*

If signed into law in the form passed by the U.S. House of Representatives, H.R. 4157 would amend the federal anti-kickback and Stark laws to protect donations of health information technology or related installation, maintenance, support or training services. *Health information technology* is defined as follows:

hardware, software, license, right, intellectual property, equipment or other information technology (including new versions, upgrades, and connectivity) designed or provided primarily for the electronic creation, maintenance, or exchange of health information to better coordinate care or improve health care quality, efficiency, or research.<sup>6</sup>

The qualification that the HIT must be *designed or provided primarily for* the creation, maintenance or exchange of health information would appear to accommodate donations of both e-prescribing and EHR software, including software packages that include software and functionality directly related to patient services, *e.g.*, billing, patient scheduling and clinical support software (since such value-added components are not the primary purpose of the package).

As drafted, H.R. 4157 would provide a simple and broad description of the permitted scope and use of the donated technology. The only limitation on the HIT's scope is that the HIT and related health information be intended to better coordinate care or improve health care quality, efficiency or research. Presumably, this limitation would only exclude HIT that is duplicative or intended for personal business or business unrelated to the provision of health care or medical research. Although it is certainly possible that the agencies would interpret the law more narrowly, the language of H.R. 4157 would seem to permit HIT that is not permitted under the final regulations, namely hardware for EHR arrangements. Therefore, H.R. 4157 may have the best chance of overcoming the greatest obstacle to the proliferation of HIT—physician cost-sensitivity.

### INTEROPERABILITY AND OTHER REQUIRED TECHNICAL ELEMENTS

#### *Interoperability in EHR Donations*

One of the more controversial elements in the final EHR technology exceptions is the requirement that the donated software be interoperable.<sup>7</sup> The final regulations define *interoperability* as follows:

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 exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered.<sup>8</sup>

In the words of OIG, “software will not be considered interoperable if it is capable of communicating or exchanging data only within a limited health care system or community.” This is a stringent standard, and donors and recipients will, as a practical matter, need to rely on evolving interoperability standards and criteria *recognized by the Secretary of HHS*, or avail themselves of the regulations’ *deemed interoperable* provision. Software is considered *interoperable* if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date of the donation.

Donors are unlikely to accept the risk of performing their own interoperability assessment, but it is not completely clear that software that is *deemed interoperable* is truly interoperable. On August 4, 2006, the Secretary recognized certain interoperability and other certification criteria for ambulatory EHR established by the Certification Commission for Healthcare Information Technology (CCHIT).<sup>9</sup> At present, the only interoperability criterion cited by CCHIT for 2006 is the capacity to receive

---

<sup>6</sup> H.R. 4157, 109th Cong. § 301 (2006).

<sup>7</sup> A key structural change to the EHR technology donation exceptions in the final regulations is the elimination of the distinction between pre- and post-interoperable HIT that was in the proposed rules. The agencies no longer believe that a bifurcated approach is necessary, in light of the industry’s considerable progress in developing certification criteria for EHR products. The final regulations apply a uniform interoperability requirement to all donations as of the effective date of the final regulations.

<sup>8</sup> 71 Fed. Reg. 45137 (anti-kickback safe harbors) and 45169 (Stark exceptions) (August 8, 2006).

<sup>9</sup> At present, no body is currently recognized by the Secretary as a certifying body since regulations concerning the criteria for these organizations were not published until August 4, 2006 after publication of the final regulations. Nevertheless, because CCHIT is and has been a recognized government contractor, by all accounts it is expected that CCHIT will be recognized by the Secretary as a certifying body in the very near future.

laboratory results.<sup>10</sup> Vendors seeking CCHIT certification could satisfy this criterion through a self-attestation. CCHIT cites numerous additional criteria for interoperability for 2007 and 2008, including “sending orders” and sending “documents to repository: RHIO functionality.” Some of the proposed criteria reference interface standards. Clearly, interoperability criteria and meaningful compliance testing will evolve slowly over the next several years and, at least initially, have as much to do with software functionality as they do with interface standards. However, the current standards appear to do little to address the final regulations’ robust definition of *interoperability*.

Notably, CCHIT has certified more than 20 ambulatory EHR products to date, subject to the vendors for these products returning for interoperability inspections as required by CCHIT. However, in light of the fact that CCHIT was not a certifying body recognized by the Secretary at the time of its certification, the very limited interoperability criteria in place, and the apparent need for CCHIT-certified products to undergo future interoperability inspections, it is not completely clear whether CCHIT certification *currently*, at least as a technical matter, confers interoperable status on a vendor’s product.

The final regulations’ interoperability standard for donated EHR systems is only problematic if in the future CCHIT, other certifying bodies and Secretary-approved certification criteria impose interface and other certification standards that the industry cannot meet. However, if the CCHIT interoperability criteria approved by the Secretary are any positive indication, the Secretary recognizes the need for an incremental industry-driven approach. This approach should make compliance with the agencies’ interoperability standard much less daunting than the agencies’ more expansive interoperability definition would suggest. However, one of the questions that remains is whether, after qualifying for the exception under one interoperability standard, one must upgrade to a subsequent version in order to continue to qualify.

Although it appears the certification standards and process are developing and could evolve into a more complete system over the next two years, relief from the interoperability requirement may come through provisions proposed by H.R. 4157. Notably, H.R. 4157’s statutory safe harbor and Stark exceptions do not contain an interoperability standard. However, H.R. 4157 is still being reconciled with a Senate bill (S. 1418), and its final form and timing cannot be predicted with confidence. Even if it were to pass, it is not clear what effect regulations issued under 4157 would have on the final regulations.

We will continue to follow this issue and provide future updates.

#### *Non-Interference with Interoperability*

Like the proposed rules, the final regulations prohibit a donor from taking any action to limit or restrict the donated HIT’s use, compatibility or interoperability (in the case of donated EHR technology) with other e-prescribing or EHR systems. In the case of e-prescribing technology that can be used for any patient without regard to payor status, the donor is also prohibited from limiting the recipient’s right or ability to use the technology for any patient.

We do not interpret this non-interference requirement, however, as requiring donors to provide interfaces that a recipient wants for the purpose of connecting to a particular vendor or service. As long as the donated HIT is certified as meeting the interoperability standards established by the Secretary, the unwillingness of a donor to provide additional interfaces should not destroy the protection of the exceptions and safe harbors.

#### PERMISSIBLE DONORS AND RECIPIENTS

The final regulations for e-prescribing technology retain the statutory scope of permissible donors and recipients, *i.e.*, hospitals to medical staff members, group practices to physician members, and Prescription Drug Plans (PDPs) and Medicare Advantage (MA) organizations to network pharmacists, network pharmacies, and prescribing health care professionals.

The final Stark exception for donation of EHR technology extends the scope of permissible donors to *any* entity that is eligible for Medicare payment for Stark designated health services (with certain technical exceptions), and the scope of permissible recipients to *any* physician. Thus, for example, laboratories and long-term facilities will be permissible donors, and a physician who is not a member of a hospital’s medical staff or a donor group practice could receive an EHR system from such hospital or group practice if all other conditions of the exception are met.

---

<sup>10</sup> 71 Fed. Reg. 44295 (August 4, 2006).

Permissible donors under the final anti-kickback EHR exception are (i) any individual or entity that provides and submits claims for covered services paid for by a federal health care program and (ii) health plans. Any individual or entity engaged in the delivery of health care is an eligible recipient. The broader categories of permissible donors and recipients under the final Stark EHR exception may facilitate efforts by certain large urban hospitals and large, for-profit group practices to subsidize HIT adoption by smaller hospitals and medical practices. However, as discussed below with respect to the *volume/value* issue, such donors will still need to be careful about the criteria they use to determine which of these hospitals or medical practices will be eligible for assistance, and how much assistance will be granted.

The Stark regulations already permit laboratories and imaging suppliers to furnish ordering physicians with HIT *used solely* for ordering tests and receiving test results, but the agencies have a long-standing concern with donations of technology by laboratories that have an independent value to the practice. Thus, it is surprising to see the agencies expand the scope of permissible donors to include laboratories, in particular. It remains to be seen whether the large, national laboratories will see these final exceptions as an opportunity to expand the scope of HIT that they donate to practices, or whether medical practices will see this as an opportunity to solicit such donations. Presumably, the agencies felt that the volume/value standard and the prohibition on recipients making the receipt of technology a condition of doing business with the donor will prevent abuse.

Note that H.R. 4157 would permit the donation of HIT by any entity, which could include, for instance, Regional Health Information Organizations (RHIOs) or device manufacturers that are not protected under the final regulations.

#### CONDITIONING REFERRALS ON DONATIONS AND DISCRIMINATING AMONG POTENTIAL RECIPIENTS BASED ON THE VOLUME OR VALUE OF REFERRALS

##### *Non-Solicitation Standard*

The final regulations, like the proposed rules, will not protect either the donor or the recipient if the recipient, the recipient's practice or any affiliated individual or entity makes the donation or the amount or nature of the donation a condition of doing business with the donor. This is a fairly bright-line standard for donors and recipients; it seems to prohibit any explicit expression of bad intent by the recipient and imply that implicit expressions of intent through improper behavior, such as changed patterns of purchases or ordering, and not by any oral or written communication are also prohibited.

Much more complex is the requirement that neither eligibility for an HIT donation nor the amount or nature of the donated HIT can be determined in a manner that takes into account the volume or value of referrals or other business generated between the parties, or, in the case of the EHR exceptions, the eligibility cannot be determined in a manner that *directly* takes into account the volume or value of referrals or other business generated between the parties. The volume/value standards for e-prescribing and EHR eligibility criteria, respectively, are discussed below, followed by a discussion of how H.R. 4157 addresses this issue.

##### *Volume/Value Standard: E-Prescribing*

Read literally, the final regulations on e-prescribing arrangements would not permit a donor, such as a PDP sponsor or MA organization, to determine eligibility for a donation of e-prescribing technology in a manner that even *indirectly* takes into account the volume or value of prescriptions to the donor. For example, a PDP sponsor could not determine eligibility on the basis of the volume or value of the prescriptions that the practitioner writes if this criterion were a proxy for the volume or value of the prescriptions that the practitioner writes for enrollees in the PDP sponsor's plan.

However, to accommodate the MMA mandate for e-prescribing exceptions to the anti-kickback and Stark laws and congressional intent, the agencies interpret the e-prescribing volume/value standard to allow a donor to select recipients based on the total number of prescriptions written by the recipient, regardless of the payors involved. The agencies do not extend this latitude, however, to determinations based on the total *value* of prescriptions written by the practitioner or pharmacy, or the volume or value of the practitioner's or pharmacy's prescriptions reimbursable by a federal health care program.

A potential problem for health plans is that the e-prescribing exceptions define an eligible recipient who is a *prescribing health care professional* as a physician or other health care professional licensed to prescribe drugs in the state in which the drugs are dispensed. Neither the exception nor the definition of *prescribing health care professional* mandates that the health plan donate e-prescribing technology to prescribing health care professionals in the plan's network. Unlike a hospital, which is restricted by the exception to donating e-prescribing technology to physicians on its medical staff and has a regulatory basis for discriminating against prescribing professionals who are not on its medical staff, an MA organization does not have an explicit regulatory basis

for discriminating against prescribing professionals who are not in its network of physicians and other health care professionals with prescribing authority. This seems to produce the absurd result of an MA organization, for example, which has established eligibility criteria based on the total volume of prescriptions written by a practice, having to donate the e-prescribing technology to all physicians with prescribing authority in the state who meet these criteria, not just those physicians or practices in its network of physicians. Restricting donations to network physicians only would indirectly take into account the volume or value of referrals or other business generated between the physicians and the plans, which, generally, is not permitted under the e-prescribing exception.

However, another reasonable inference to draw from the agencies' decision not to limit *prescribing health care professionals* to professionals in the plan's network is that, unlike MA organizations, PDP sponsors do not have networks of physicians, only networks of pharmacists and pharmacies. Consequently, it would not make sense to impose such a network limitation on PDP sponsors. While this analysis does not answer the question of whether an MA organization can restrict its HIT donations to physicians in the plan's network, it leaves open the possibility that the agencies' decision not to restrict plan donations to network physicians does not mean that the agencies believe that such a restriction would necessarily violate the volume/value standard of the e-prescribing exceptions. Unless this ambiguity is resolved favorably for MA organizations, those MA organizations wishing to restrict donations to network physicians may need to look to other Stark exceptions.

#### *Volume/Value Standard: EHR*

Unlike the final regulations on e-prescribing arrangements, the final regulations for EHR arrangements only prohibit the use of recipient selection criteria that *directly* take into account the volume or value of referrals or other business generated between the parties. Stated differently, the final regulations permit determinations of eligibility made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated. This was a big step for OIG in particular, as it believes that even an indirect relationship between the provision of free or deeply discounted services and items and the volume or value of business between the parties is "highly suspect" under the anti-kickback statute, and "may evidence outright violations . . ." <sup>11</sup> OIG took this approach due to the unique public policy considerations surrounding electronic health records and HHS' goal of encouraging widespread adoption of interoperable electronic health records. <sup>12</sup>

Further, in an effort to provide bright-line guidance on the volume/value standard, the final regulations on EHR arrangements set forth six criteria that a donor could use that would be *deemed* not to *directly* take into account the volume or value of business generation:

- The total number of prescriptions written by the physicians (but not the volume or value of prescriptions dispensed or paid by the donor or billed to a federal health care program)
- The size of the physician's medical practice, *e.g.*, total patients, total patient encounters, or total relative value units
- The total number of hours that the physician practices medicine
- The physician's overall use of automated technology in his or her medical practice (without reference to the use of technology in connection with referrals made to the donor)
- Membership on the member's medical staff
- The level of uncompensated care provided by the physician or other permitted recipient

Notwithstanding the agencies' apparent liberal approach and their efforts to provide bright-line guidance for the volume/value standard applicable to EHR technology donations, the *deeming* provisions actually create some ambiguity and uncertainty for donors. For example, it is unclear whether, under this standard, a hospital could stage a roll-out of HIT to its medical staff beginning with the medical specialty or department that accounts for the greatest utilization of the hospital. There are a number of good business, operational and clinical reasons for a hospital to take this approach; however, it is not at all clear under current guidance whether this approach would be sufficiently indirect to qualify for the EHR exception or safe harbor. Similarly, there

---

<sup>11</sup> 71 Fed. Reg. 45130 (anti-kickback safe harbors) (August 8, 2006).

<sup>12</sup> 71 Fed. Reg. 45130 (anti-kickback safe harbors) (August 8, 2006).

are legitimate reasons why a hospital might want to use criteria based on the physician's HIT utilization related to common patients, if only because this is relevant information that the hospital can readily access.

Consequently, just as the final regulations prevent a health plan from investing in HIT that will most support its network, *i.e.*, create connectivity and health information flow with those practitioners who most treat and prescribe for its enrollees, the final regulations' volume/value standard may similarly prevent a hospital from investing in HIT where it can most benefit the hospital and its patients.

#### *Volume/Value Standard: H.R.4157*

H.R. 4157 provides that the donation of HIT cannot involve "an agreement" or a "legal condition" that "conditions the provision of such remuneration on the referral of patients or business to the . . . [donor]." This could be a much brighter line than the volume/value standard articulated by the agencies for donation of EHR systems, and it seems to provide donors with significantly greater flexibility in determining eligibility criteria and the flexibility to discriminate among potential recipients based on rational business considerations. Under this standard, a hospital arguably could select practices for a donation of HIT based on the practices' historical volume of cases at the hospital, provided the donation is not pursuant to an agreement for referrals or conditioned on a legally binding commitment of referrals by the practice.

The volume/value standard of the final EHR exceptions, which reflects the agencies' core concern regarding the potential for HIT donations to facilitate fraud and abuse, could pose the greatest risk of liability for donors under the anti-kickback and the Stark laws. It may frustrate hospitals' attempts to begin funding HIT where it makes the most business sense—the physician offices that treat the most patients of that hospital. Whether the agencies will attempt to eliminate this flexibility through a narrow interpretation of the legislation in agency rulemaking remains to be seen. Further, the Conference Committee considering H.R. 4157 could amend the legislation to conform with or be in closer harmony with the agencies' volume/value standards.

#### **MANDATORY COST-SHARING**

The agencies jettisoned their original proposal to impose caps on the value of donated HIT. Instead, in the final regulations the agencies decided to require cost-sharing for donations of EHR technology. Recipients of donated EHR technology must pay 15 percent of the donor's cost prior to receipt of the technology, and neither the donor nor a related party may finance or loan money to the physician or other recipient to pay this cost-sharing amount. There is no cost-sharing requirement under the final regulations for e-prescribing donations or under H.R. 4157.

The agencies believe that cost-sharing will have the salutary effect of engaging potential recipients in the implementation and adoption of the technology. However, physicians nearing retirement, small or rural practices, and physicians with declining or stagnating incomes may be unwilling to pay even 15 percent of the cost of HIT adoption, especially since the final regulations also require that they bear the full cost of the hardware.

Further, it remains to be seen whether public and private grants will meet the need for HIT in those lower-income practices that can least afford to pay for the technology. Hospitals and large group practices will likely be instrumental to introducing HIT in rural and other underserved areas. The 15 percent cost-sharing obligation on small rural practices could restrict such outreach efforts. Although the donor or a related party may not finance or loan the recipient the 15 percent cost-sharing amount, presumably a public or charitable entity unrelated to the donor could loan or donate the cost-sharing amount to the physician. Such loans or grants could prevent the cost-sharing obligation from chilling HIT adoption by lower-income practices, but there is no guarantee that grants and loans will reach enough of these practices that will balk at the 15 percent cost-sharing obligation.

Due to the risk of abuse, pharmaceutical, device and durable medical equipment manufacturers have not been granted protected donor status. In some cases, manufacturers may be able to make donations under safe harbors other than the donation safe harbor or without safe harbor protection. However, the agencies were blunt in their assessment of past infractions by manufacturers and can be expected to scrutinize any such arrangement closely.

In addition, donors who are tax-exempt organizations must address whether providing HIT at an 85 percent discount is consistent with the private inurement and private benefit prohibitions of section 501(c)(3) of the Internal Revenue Code. While the final regulations provide a public policy argument that donations with 15 percent cost-sharing serve a community, rather than a private, purpose, it is not clear that the Internal Revenue Service will recognize the argument.

The agencies advise donors that they will scrutinize cost sharing arrangements, but they provide no guidance with respect to the calculation of *cost*. For example, it is unclear whether donors that have made significant fixed or capital investments in technology have to pass those charges along to recipients. In addition, technology is often purchased as a package, and donors may need to remove from the package cost certain items that they are either precluded from donating or items they do not want to donate. Donors are advised to structure their information technology contracts to explicitly list incremental charges for licenses and make the applicable costs as explicit as possible.

Finally, it is unclear whether the final regulations intend for the recipient's cost-sharing obligation to *be no more than 15 percent* or *at least 15 percent*. Recipients will assert that the former is the correct interpretation; donors the latter. As a practical matter, some hospital donors who desire to expand their medical staffs' EHR capabilities will be unable financially to donate HIT unless their physicians can shoulder more than 15 percent of the cost. Limiting the cost sharing percentage to *no more than 15 percent* seems inconsistent with the spirit of the Stark and anti-kickback laws in general, and we suspect that CMS and OIG may clarify this result.

#### PRE-EMPTION OF STATE LAW

The agencies declined requests to pre-empt state anti-kickback and physician self-referral laws that could be implicated by donations of HIT to physicians and other referral sources. This leaves organizations in states that have mini-Stark or state anti-kickback statutes in a grey zone, depending on the specifics of those statutes, only some of which track federal law. In contrast, H.R. 4157 pre-empts state law. If enacted, pre-emption will be very important to eliminating conflicting state law for donors attempting to donate HIT to recipients who reside in states with broad anti-kickback or physician self-referral laws.

#### SUNSETS AND REPORTS TO CONGRESS

The agencies' final regulations on EHR technology sunset on December 31, 2013. The e-prescribing regulations do not sunset. Under H.R. 4157, the Secretary is required to conduct studies to determine the impact of the statutory safe harbors and Stark exceptions on HIT adoption, the types of HIT provided under each exception, and the effect of the exceptions on the health care system or choices available to consumers. The Secretary is also required to study the impact of HIT adoption on health care quality, cost and access under the exceptions. Reports on the studies must be submitted to Congress within three years of the effective date of H.R. 4157.

H.R. 4157 would assure that donors have the flexibility to make upgrades and other enhancements well into the next decade. The sunset of the EHR exceptions could chill the proliferation of next-generation systems, even if the cost of the technology comes down significantly. Further, it could incentivize unnecessary expenditures immediately prior to the sunset date.

## Conclusions

The differences between the final regulations and H.R. 4157 result from the agencies' delegated responsibility to implement and enforce the federal anti-kickback and Stark laws. Consequently, the agencies can only go so far in providing the industry with relief. Because the drafters of H.R. 4157 are not under such constraints, they have offered broader exceptions and struck a balance between public policy concerns regarding fraud and abuse and the public benefits of HIT adoption that is more favorable toward HIT donations.

The future of H.R. 4157 is uncertain. In the absence of this or similar legislation, the final regulations offer a significantly more liberal approach to donors of HIT and may ultimately provide the industry with sufficient protection. As the final regulations, H.R. 4157, S. 1418 and the certification system evolve, we will continue to analyze and report on developments.

## Authors

*Stephen W. Bernstein* is a partner in the Health Department of McDermott Will & Emery Boston office. He chairs the Firm's HIPAA Practice Group and co-chairs the Firm's Health Transactions Group. He specializes in e-health, deployment of electronic health record systems, health related matters impacted by the internet, and HIPAA, as well as mergers, acquisitions, affiliations and joint ventures in the hospital and physician areas.

*Bernadette M. Broccolo* is a partner in the law firm of McDermott Will & Emery based in its Chicago office. Bernadette is a member of the Health Department, and has been advising health industry organizations for more than 25 years on legal and regulatory compliance matters, information technology acquisition and health information privacy. She is particularly experienced in federal taxation of exempt organizations; health industry joint ventures; corporate governance and restructurings; hospital-physician relationships; and clinical research compliance counseling.

*Heidi Y. Echols* is a partner in the law firm of McDermott Will & Emery based in the Firm's Chicago office. As a member of the Health Department, Heidi's practice focuses on information technology (IT) transactions, counseling, and privacy and security issues. Heidi is chair of the Firm's Health Information Technology Affinity Group and a member of the Firm's e-Business Group.

*John D. Healey* is an associate in the law firm of McDermott Will & Emery based in the Chicago office. As a member of the Health Department, John's practice focuses on information technology for clients in the health industry. He has more than 20 years of experience working with information technology vendors, primarily in the health industry. Prior to joining the Firm, John grew a start-up company from initial product launch to more than \$12 million in recurring annual revenue. He performed multiple functions, including contract reviews, Medicare/HIPAA compliance, information technology security planning, and product feature, capacity and security testing.

*Daniel H. Melvin* is a partner in the law firm of McDermott Will & Emery resident in the Firm's Chicago office. As a member of the Health Department, Daniel's practice is focused on regulatory compliance and payment issues for the health care industry, including hospitals, health systems, medical device manufacturers, group practices and freestanding ambulatory care facilities. He has substantial experience counseling clients on fraud and abuse, physician self-referral and Medicare reimbursement, and compliance issues, as well as modeling of clinical joint ventures and other collaborative arrangements involving physicians.

*William H. Roach, Jr.* is a partner in the law firm of McDermott Will & Emery based in the Firm's Chicago office. He is a member of the Health Department. Bill's experience includes the formation of regional and national hospital systems; mergers and acquisitions; affiliations and dispositions; joint sponsorship of faith-based health care facilities and systems; corporate reorganizations; health industry joint ventures; creation and implementation of corporate compliance plans; and medical staff organization, credentialing and contracts.

For more information about McDermott Will & Emery, visit [www.mwe.com](http://www.mwe.com)

IRS Circular 230 Disclosure: To comply with requirements imposed by the IRS, we inform you that any U.S. federal tax advice contained herein (including any attachments), unless specifically stated otherwise, is not intended or written to be used, and cannot be used, for the purposes of (i) avoiding penalties under the Internal Revenue Code or (ii) promoting, marketing or recommending to another party any transaction or matter herein.

The material in this publication may not be reproduced, in whole or part without acknowledgement of its source and copyright. *Donating Health Information Technology: Final Regulations Compete with H.R. 4157 for Public Policy Control* is intended to provide information of general interest in a summary manner and should not be construed as individual legal advice. Readers should consult with their McDermott Will & Emery lawyer or other professional counsel before acting on the information contained in this publication.

© 2006 McDermott Will & Emery. The following legal entities are collectively referred to as "McDermott Will & Emery," "McDermott" or "the Firm": McDermott Will & Emery LLP, McDermott Will & Emery/Stambridge LLP, McDermott Will & Emery Rechtsanwälte Steuerberater LLP, MWE Steuerberatungsgesellschaft mbH, McDermott Will & Emery Studio Legale Associato and McDermott Will & Emery UK LLP. These entities coordinate their activities through service agreements. These entities coordinate their activities through service agreements. This communication may be considered advertising under the rules regulating the legal profession.