

CLIENT ALERT

HHS Proposes Anti-Kickback Safe Harbor and Stark Exceptions For The Donation of E-Prescribing & Electronic Health Record Technology

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The U.S. Department of Health and Human Services (HHS) published on October 11, 2005, two proposed rules that would protect certain donations of electronic prescribing (e-prescribing) and electronic health record (EHR) items and services from scrutiny under the Federal anti-kickback statute and physician self-referral (Stark) law. The proposed rules are important not only as a reflection of HHS' belief that the implementation of e-prescribing and EHR technology will help minimize fraud and abuse, but also as a crystallization of HHS' ongoing effort to encourage investment in interoperable technologies as a replacement of paper-based health records. As HHS stated:

The promise of a secure and seamless information exchange that reduces medical errors, improves the quality of patient care, and improves efficiency will be realized only when we have a standardized system that is open, adaptable, interoperable and predictable.

Nonetheless, the proposed rules demonstrate the tension between stimulating such investment and preventing fraud and abuse. Moreover, given the timing of the rules' publication, the regulations may risk incentivizing, in the near term, proprietary technologies that are not interoperable.

Background of the Stark Law and the Proposed Exceptions

The Stark law prohibits physicians from making referrals for certain designated health services payable by Medicare to entities in which the physicians (or their immediate family members) have a financial relationship. See 42 USC §1395nn. If such financial relationships are not structured to comply with at least one of the several statutory and regulatory exceptions, both the physicians and entities to which they refer can be subject to civil monetary penalties and potential liability under the civil False Claims Act. Congress, via the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, P.L. 108-173 (MMA) expressly required HHS to promulgate an additional exception to the Stark Law that would protect certain donations of e-prescribing technology items and services. See 42 U.S.C. §1395w-104(e)(6). Acting on this mandate, HHS' Centers for Medicare & Medicaid Services (CMS) has proposed to add not one, but three new regulatory exceptions protecting not only the donation of e-prescribing technology items and services, but also EHR technology items and services. These exceptions would be codified at 42 CFR §411.357(v)-(x).

The Proposed Exception for Donations of E-Prescribing Technology

Who is Covered?

The proposed Stark exception would apply to e-prescribing technology items and services donated:

- by a hospital to physicians who are members of its medical staff;
- by a group practice to physicians who are members of the group practice; and
- by a Medicare Part D Prescription Drug Plan (PDP) sponsor or Medicare Advantage (MA) organization to prescribing physicians.

The excepted categories of recipients is narrower in focus than the categories provided under the MMA (which would have applied to any prescribing professional, e.g., pharmacists), because the Stark Law, by definition, only applies to improper referrals made by certain physicians.

What is covered?

Through the MMA, Congress not only dictated which donors and recipients should be protected by the new exception, but also dictated the type of e-prescribing technology that may be permissibly donated. Specifically, the MMA provided that it should be permissible to donate “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 in accordance with the [e-prescribing] standards [to be] promulgated [by HHS] under [the Medicare Part D program].” CMS' proposed Stark Law exception adopts this language, and cites as examples of potentially protected technology “broadband or wireless Internet connectivity” and “hand-held device[s] capable of transmitting electronic prescribing information.”

However, CMS highlights two limitations within the MMA language. First, CMS' interpretation of “necessary” is not only technology-specific, but also recipient-specific. Thus, the proposed exception would not protect the donation of e-prescribing technology that is “technically or functionally equivalent to items and services [the recipient] already possesses or has obtained.” HHS is also mindful that practitioners, knowing donated technology is on the way, may divest themselves of the equipment they already own in order to free up and shift costs to a donor. Therefore, recipients of donated technology must certify in writing that they do not possess functionally equivalent technology, and the donor of such technology cannot act in reckless disregard or deliberate ignorance of the recipients' existing e-prescribing technology.

Second, CMS emphasizes the MMA mandate that the donated technology be “used solely” to transmit or receive e-prescribing information. Thus, the donation of “software that bundles valuable general office management, billing, scheduling, or other software with the electronic prescribing features” would not qualify for protection unless the bundled features are purchased at fair market value. That said, CMS indicated a willingness to use its rulemaking authority to expand protection to the donation of technology items and services “substantially used” to transmit or receive e-prescribing information, and has requested commentary on same. CMS did *not* include a finite cap on the dollar value of technology permitted to be donated, though it suggested that a cap likely will be included as a component of any final regulations. CMS specifically requested comment on cap-related issues, such as methodology, whether a cap should be reduced over time, and whether a cap inherently disadvantages smaller (or rural) entities with comparably fewer resources.

Additional terms

In addition to the terms described above, the proposed Stark exception includes further measures designed both to prevent fraud and abuse and to promote e-prescribing technological interoperability. For example, donors may not “limit or restrict

unnecessarily the use or compatibility of the items or services with other electronic prescription information items or services or electronic health information systems.” Moreover, where technologically possible, the items or services may not be limited to particular patients (*e.g.*, only to patients insured by a certain MA plan). Finally, the recipient may not make receipt of the items or services a condition of doing business with the donor, and the donor may not base donations on the volume or value of referrals or other business generated from the recipient.

The Proposed Stark Exceptions for Donations of EHR Technology

Although the MMA only authorized HHS to promulgate a Stark Law exception and anti-kickback safe harbor for the donation of certain e-prescribing technology items and services, CMS has used its regulatory authority to propose additional Stark exceptions for the donation of a broader category of technology items and services – namely, donations of technology that will stimulate the development of electronic health records (EHRs). In so doing, HHS stressed its interest in crafting

[C]onditions that would promote open, interconnected, interoperable electronic health records systems that help improve the quality of patient care and efficiency in the delivery of health care to patients, without protecting arrangements that serve as marketing platforms and mechanisms to influence inappropriate clinical decision making or tie physicians to particular providers or suppliers.

In this light, CMS proposed two Stark exceptions designed to protect donations of EHR technology (1) before and (2) after HHS' adoption of criteria for the interoperability, functionality, privacy and security of EHR technology, *i.e.*, “pre-interoperability” and “post-interoperability” exceptions. CMS indicated that HHS would adopt such criteria by October, 2006, and would consider phasing out the “pre-interoperability” exception once the criteria are adopted and the “post-interoperability” exception is effective.

Who is covered?

Both the proposed “pre-interoperability” and “post-interoperability” exceptions would apply to the same three categories of donors and recipients that would be protected by the e-prescribing exception, *i.e.*, EHR technology donated:

- by a hospital to physicians who are members of its medical staff;
- by a group practice to physicians who are members of the group practice; and
- by a Medicare Part D PDP sponsor or MA organization to prescribing physicians.

CMS declined to extend protection to other donors of EHR technology (such as ancillary service providers) because “hospitals, group practices, PDP sponsors, and MA organizations are potentially in a better position to promote widespread use of [EHR] technology that has the greatest degree of openness and interoperability.” CMS requested comment on whether additional individuals or entities should be protected as recipients.

Interestingly, in a carefully articulated departure from typical “volume or value” fraud and abuse verbiage, CMS indicated that the “post-interoperability” exception would allow donors of EHR technology to select their recipients on the basis of volume (*e.g.*, number of prescriptions written, size of recipient's medical practice), but not on the basis of value (*e.g.*, cost of drugs prescribed, type of patients).

What is Covered?

Both the proposed “pre-interopability” and “post-interopability” exceptions would protect donations of “non-monetary remuneration (consisting of items and services in the form of software or directly related training services) necessary and used solely to receive, transmit, and maintain electronic health records.” Note that, in contrast to the e-prescribing exception, neither EHR exception would protect the donation of “information technology” or hardware. Both exceptions require the donated EHR technology to also include e-prescribing technology.

Similar to the exception for donated e-prescribing technology, both the “pre-interopability” and “post-interopability” exceptions would require that the donated technology be “necessary” for EHR functions, as well as e-prescribing functions. Specifically, recipients of donated technology must certify in writing that they do not possess functionally equivalent technology, and donors cannot act in reckless disregard or deliberate ignorance of the recipients' existing technology.

Notably, because CMS believes that technological interoperability inherently reduces fraud and abuse, the “post-interopability” exception (which will necessarily only apply to interoperable technology meeting HHS criteria) is broader than the “pre-interopability” exception. The “pre-interopability” exception applies only to technology “used solely” for EHR and e-prescribing functions. Specifically, “the [donated] items or services [must] *not* include *any* billing, scheduling, or other similar general office management or administration software or services...” (emphasis added). The “post-interopability” exception, on the other hand, would be expansive enough to cover software where the “core function” is EHR and e-prescribing. The exception would merely require that “the items or services... not [be] used solely to conduct personal business or business unrelated to the physician's medical practice.”

Additional Terms

Under either the “pre-interopability” or “post-interopability” exception, donors may not “limit or restrict unnecessarily the use or compatibility of the items or services with other EHR items or services or electronic health information systems.” Further, the use of such items or services may not be limited to particular patients (*e.g.*, only to patients insured by a certain MA plan). The recipient of donated EHR technology may not make such receipt a condition of doing business with the donor, and the donor may not base donations on the volume or value of referrals or other business generated from the recipient. Finally, as with all exceptions promulgated under CMS' rulemaking authority, the donations must not violate the anti-kickback statute.

Background of the Anti-Kickback Statute and the Proposed Safe Harbor

Under the Federal anti-kickback statute, it is a crime to knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under certain Federal health care programs, including Medicare and Medicaid. *See* 42 USC §1320a-7b(b). In addition to a handful of statutory exceptions to this prohibition, HHS' Office of Inspector General (OIG) has also promulgated a series of rules that describe various payment and business practices that the Federal government will not treat as criminal offenses (the “safe harbor” provisions).

The MMA specifically required HHS not only to promulgate an exception to the Stark Law for the donation of e-prescribing technology (as discussed above), but also to promulgate a similar safe harbor under the anti-kickback statute. Acting on this mandate, the OIG proposed one new safe harbor for certain donated e-prescribing technology. Should the safe harbor be finalized, it would be codified at 42 CFR §1001.952(x). While OIG discussed the possibility of establishing other safe harbors

protecting the donation of certain EHR technology, it concluded (unlike CMS) that it “do[es] not have sufficient information at this time to draft appropriate safe harbor language.” Therefore, the only safe harbor for which OIG proposed terms is for the donation of certain e-prescribing technology.

The Proposed Safe Harbor for Donations of E-Prescribing Technology

Who is covered?

Similar to the Stark exception, the terms of the proposed safe harbor protecting donations of e-prescribing technology are also dictated significantly by the MMA. Thus, the OIG adopted virtually verbatim the MMA's mandated protection for e-prescribing technology items and services that are donated:

- by a hospital to physicians who are members of its medical staff;
- by a group practice to prescribing health care professionals who are members of the group practice; and
- by a Medicare Part D PDP sponsor or MA organization to (i) pharmacists and pharmacies participating in the networks of such a sponsor or organization; and to (ii) prescribing health care professionals.

Notably, a hospital would only be able to donate technology to physicians who “routinely” (*i.e.*, already) furnish services at the hospital; a hospital would not be able to donate technology in order to induce a physician to join its medical staff. The OIG has requested comment on whether other categories of recipients deserve protection. The OIG has indicated that it would be disinclined to expand its list of donors, considering its longstanding concern regarding the provision of free goods and services.

What is Covered?

The OIG proposes to shelter from anti-kickback scrutiny “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... [if] the items and services are donated as part, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D.” The OIG interprets “necessary” in the same manner as CMS, *i.e.*, the donation of e-prescribing technology that is “technically or functionally equivalent to items and services the recipient already possesses or has obtained” will not be immune from scrutiny. Similar to the Stark exception, recipients of donated technology must certify in writing that they do not possess functionally equivalent technology, and the donor of such technology cannot act in reckless disregard or deliberate ignorance of the recipients' existing e-prescribing technology.

The OIG also interprets “used solely” in the same manner as CMS. Therefore, the full value of “software that bundles valuable general office management, billing, scheduling, or other software with the electronic prescribing features” will not qualify for protection under the proposed exception. Such additional features may be purchased at fair market value. However, the OIG is mindful that many people prefer to use one device for connectivity, and thus indicated a willingness to use its rulemaking authority to create another safe harbor affording protection to the donation of technology items and services “substantially used” to transmit or receive e-prescribing information. Specific terms of an additional, more expansive safe harbor were not proposed.

Additional terms

Similar to the proposed Stark exception, the proposed anti-kickback safe harbor would also include additional measures designed both to prevent fraud and abuse and to promote e-prescribing technological interoperability. For example, donors may not “limit or restrict unnecessarily the use or compatibility of the items or services with other electronic prescription information items or services.” Further, where technologically possible, the use of the items or services may not be limited to particular patients. Finally, the recipient may not make receipt of the items or services a condition of doing business with the donor, and the donor may not base donations on the volume or value of referrals or other business generated from the recipient.

Safe Harbors for Donations of Electronic Health Record Technology?

As discussed above, the OIG discussed but opted not to propose terms for anti-kickback safe harbors protecting the donation of EHR technology. The OIG reasoned, “the provision of EHR technology to physicians and others poses greater risk of fraud and abuse than the provision of electronic prescribing technology; EHR technology is inherently more valuable to physicians in terms of actual cost, avoided overhead, and administrative expenses of an office practice.” Notwithstanding these reservations, the OIG indicated that it would consider promulgating two additional safe harbors akin to the proposed “pre-interoperable” and “post-interoperable” Stark exceptions for EHR technology, and solicited public comment on the same. Tellingly, a table is included in the preamble to the proposed rule that reflects possible EHR safe harbor elements that indeed would be similar to the proposed Stark EHR exceptions.

Analysis and Conclusion

CMS and OIG indicate that they have tried to “ensure as much consistency as possible” between the proposed Stark exceptions and anti-kickback safe harbors. To a large extent, the proposed rules and the regulatory preambles reflect this endeavor. Some differences exist, however, as exhibited by OIG's reluctance to propose specific terms for an anti-kickback safe harbor protecting the donation of EHR technology. Moreover, the OIG would not protect hospital donations of e-prescribing technology to physicians as an inducement for the physicians to join the hospital's medical staff. This provision may be overly cautious, given physicians customary ability to join multiple medical staffs, and may also limit, to some degree, the adoption of e-prescribing technology in the physician sector. Furthermore, while the OIG has indicated its reluctance to protect technology donors other than hospitals, physician groups and certain PDP sponsors and MA organizations, it would seem reasonable, at a minimum, to consider protecting donations by other health plans that cover Medicare patients.

From CMS' perspective, its decision to propose Stark exceptions for the donation of EHR technology before the adoption of certification criteria has created a classic chicken-and-egg problem. As CMS itself notes, implementing an exception sooner (*i.e.*, before criteria are adopted) will help “recognize the innovative early adopters of [EHR] technology.” However, absent established criteria, “pre-interoperability... protection may have the unintended effect of impeding the beneficial spread of interoperable [EHR] systems by promoting closed or isolated systems that effectively tie physicians to particular providers or suppliers.” Perhaps certification criteria will be adopted before the “pre-interoperability” exceptions can be finalized.

It is important that CMS and OIG provide every indication that they will continue to work closely not only with each other to finalize these rules, but also with the various entities within HHS that are involved in the overall effort to increase adoption of e-prescribing and EHR technologies. Throughout the preambles to the proposed rules, both CMS and OIG welcome public comment on multiple topics, suggesting that HHS is open to making any number changes before the rules are finalized. Health care providers, health plans, and others who are in the various stages of implementing these technologies – and, thus, can practically assess the adequacy of these proposed rules – should consider the long-term advantage of submitting comments to

HHS before the December 12, 2005 deadline, as well as the practical implications of the proposed rules on current arrangements.

For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.