

JUNE 27, 2012

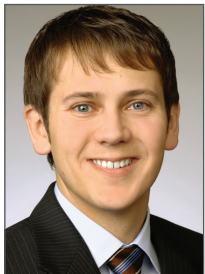
Radiologist-Physician EHR Connections: Avoiding Legal Pitfalls

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Radiologists and imaging centers are often asked to make the diagnostic studies they perform available to an ordering physician through the physician's electronic health records (EHR) system. The difficulty in accommodating these requests stems in part from the sheer variety of EHR and RIS/PACS systems. In most circumstances, some type of software interface, and possibly hardware, is required to connect the two systems. Someone has to purchase this hardware and software, of course.



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While it may make good business sense for an imaging center or radiology practice to provide and pay for software upgrades necessary for the RIS/PACS to interface with the EHR or to install hardware, such as viewing stations, in the ordering physician's office, these types of arrangements can raise significant regulatory issues. Federal and state laws prohibit radiologists and imaging centers from offering referring physicians something of value in return for ordering diagnostic tests.

Because software upgrades and computer hardware provide real value to ordering physicians, these types of arrangements should be carefully considered under the relevant federal and state law.

Many connectivity arrangements are capable of meeting an exception to the federal physician self-referral law, or "Stark law," allowing the radiologist or imaging center to fund and install the software interface. Under state and federal anti-kickback statutes, however, funding these systems on behalf of referring physicians raises more complex compliance issues. There are no safe harbors in the federal anti-kickback statute that explicitly protect such arrangements from scrutiny. Accordingly, the question becomes how to structure a connectivity arrangement in a way that adequately protects the parties from scrutiny under state and federal anti-kickback statutes.

Software Interfaces and Remuneration Under Stark

As a general rule, the Stark law, in the absence of an exception, prohibits physicians from referring Medicare and Medicaid patients to an imaging center for a diagnostic test if the physician has a direct or indirect financial relationship with the imaging center or interpreting radiologist.¹ For these reasons, determining whether IT services or assets constitute "financial relationship" under the Stark law is paramount.

According to the regulations, a "financial relationship" includes any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity providing designated health services. "Remuneration" is defined to include anything of value, in kind or in cash, but, importantly, the definition specifically excludes the "furnishing of items, devices, or supplies . . . used solely to order or communicate the results of tests or procedures for the entity."²

In many circumstances, a software interface is installed for the sole purpose of communicating the results of diagnostic tests by connecting the EHR to the RIS/PACS. Accordingly, many of the items required to establish connectivity are excluded from the definition of "remuneration," and, therefore, do not create a financial relationship between the referring physician and the radiologists or imaging center. If a financial relationship does not arise, radiologists and imaging centers may assist the ordering physician without implicating the Stark law.

CMS recognized this exception from the definition of "remuneration" in its Advisory Opinion CMS-AO-2008-01. Following the logic of this advisory opinion, radiologists and imaging centers may assist with the purchase and installation of a software interface without implicating the Stark law because the items and services provided do not create a "financial relationship."

Ins and Outs of the EHR Exemption

The EHR exception states that certain arrangements involving the donation of EHR technology and training services to a

physician by an entity to which the physician may refer Medicare and/or Medicaid patients do not create a financial relationship between the referring physician and that entity and, thus, would not violate the Stark law.

This exception applies to interface and translation software, connectivity services, maintenance services, and training and support services (for example, access to a help desk). CMS has specifically stated that a donation of software and services may not include hardware, storage devices, software with core functionality other than electronic health records (for example, payroll software), provision of staff to the physician's office, or items or services used by a physician primarily for non-practice business or reasons.

Thus, a radiologist or imaging center could possibly utilize this exception to donate software, connectivity, and access to the RIS/PACS. Radiologists and imaging centers could not, however, utilize this exception to donate hardware (for example, workstations, routers, modems, server for image storage) or space on a server for a physician to store patient records that belong to the ordering physician. If a radiologist or imaging center were to provide such hardware to a referring physician, it would need to do so either through a fair market value sale of such hardware to the physician or through a fair market value lease arrangement, in order to protect the arrangement under the separate "equipment rental" and/or "personal services" exceptions to the Stark law.

Thus, the EHR exception has limited use in typical connectivity arrangements between radiologists and referring physicians. To qualify for the EHR exception, the arrangement must meet each of 13 specific conditions. Typically, a connectivity arrangement where a radiologist or imaging center provides a software interface or viewing station to an ordering physician will not meet all of the conditions required for protection under the EHR exception. Specifically, the EHR exception is often not met because the software interface is not "interoperable" as defined in the Stark law regulations and the software interface is restricted to connecting the EHR to the RIS/PACS.

Non-Monetary Compensation Exception

Another exception with limited use in most connectivity arrangements is the non-monetary compensation exception to the Stark law. This exception protects compensation in the form of items or services (excluding cash or cash equivalents) that does not exceed an aggregate of \$373 per calendar year, as annually adjusted for inflation, if all of the following conditions are satisfied:

- *The compensation is not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.*
- *The compensation may not be solicited by the physician or the physician's practice (including employees and staff members).*

- *The compensation arrangement does not violate the anti-kickback statute or any federal or state law or regulation governing billing or claims submission.*³

Because each requirement of the non-monetary compensation exception must be met, including the annual limitation in the total value of items and services provided, any IT or connectivity support or services provided to an ordering physician should be carefully tracked to ensure that the annual limit is not surpassed, taking into account all items or services provided in a calendar year.

Uncertainty Under the Anti-Kickback Statute

The federal anti-kickback statute penalizes anyone who knowingly and willingly offers or pays any remuneration, directly or indirectly, in cash or in kind, in return for referring an individual to a person for the provision of services reimbursable by Medicare.⁴ While there are numerous safe harbors under the federal anti-kickback statute that protect certain arrangements from liability, none of these safe harbors protect an arrangement where a radiologist or imaging center provides a software interface system or viewing station to an ordering physician. Unlike the Stark law, the federal anti-kickback statute does not exclude items and supplies used to order tests from the definition of "remuneration."

In 2006, the OIG developed a corresponding safe harbor for the donation of EHR items and services. The language of the safe harbor to the federal anti-kickback statute is essentially identical to that of the Stark law exception, with a few notable differences.

The safe harbor protects a slightly different scope of donors and recipients. The Stark exception only protects a donation by an "entity," which is essentially defined by Stark as an individual or entity that submits claims to the Medicare program for designated health services, whereas the safe harbor protects a donation by: (a) a health plan or (b) any individual or entity that submits claims to Medicare, Medicaid, or any other federal health care program for any services (not just designated health services) covered by such programs. In addition, the (Stark) EHR exception is only designed to protect donations to physicians, whereas the (anti-kickback law) safe harbor protects donations to any individual or entity that is "engaged in the delivery of health care."

Other than the distinctions discussed above, the requirements of the EHR safe harbor (and the ability of a radiologist or imaging center to potentially comply with those requirements) are largely the same as the requirements of the Stark exception. As with the EHR exception, an arrangement where a radiologist or imaging center provides a software interface or viewing station to an ordering physician is unlikely to satisfy all of the requirements of the EHR safe harbor. It is important to note that, unlike the EHR exception, compliance with a safe harbor

is not mandatory. The agency that promulgated the safe harbors, the OIG, has specifically stated that failure to qualify for a safe harbor does not make an arrangement unlawful. Nevertheless, it is prudent to take steps to ensure connectivity arrangements with ordering physicians are structured to meet as many of the requirements for the EHR safe harbor as possible in order to reduce the risk under the anti-kickback statute.

Conclusion

A radiology group or imaging center that donates software or IT services to a referring physician could potentially shield those donations from potential liability under the Stark law if the items donated are used solely to order or communicate the results of diagnostic tests. Any arrangement outside of this narrow scope must be structured to meet an exception to the Stark law such as the EHR exception or the non-monetary compensation exception.

Regardless of what may be permitted under the Stark law, radiologists and imaging centers should consider limiting their share of the total cost involved in installing and maintaining a software interface or other IT systems because the arrangement would still be subject to scrutiny under the federal

anti-kickback statute and unlikely to fit within a safe harbor. Arguably, the ordering physician shares in the benefit of this arrangement, and should be expected to share the costs.

In order to reduce the risk under the federal anti-kickback statute, any connectivity or other IT arrangement with ordering physicians should be in writing and not conditioned on the volume or value of referrals or other business generated between the parties. The framers of these arrangements also should consider the implications of state anti-kickback laws, as well as the appropriate protection of patient health information.

References

1. 42 U.S.C. § 1395nn.
2. 42 C.F.R. § 411.351 - Definition of remuneration.
3. 42 C.F.R. § 411.357(k).
4. See 42 U.S.C. § 1320a7-b(b)(2)(A).

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