Weighing the Stark Law Exceptions

by Linda Howrey, EJD, CCS-P

Donations of software and services to physicians allowed under the anti-kickback exceptions are meant to spur health IT adoption, but evaluating the potential is a complex exercise for both donor and recipient.

Exceptions to the Stark Law and the anti-kickback statute enable hospitals and payers to donate IT software and services to physician practices. The exceptions are meant to promote the adoption of health IT in physician offices by lowering the cost barriers.

While the exceptions have introduced health IT into some physician practices in the past two years, they have not created a rush of donated services. The choice is a complex one for both donors and recipients.

Donors must calculate not only the cost of the services they cover, but also the cost of related management or administration they assume. Physicians must determine if the IT systems being offered are a match for their practices, and they must determine the full cost to themselves. Additionally, physicians must keep an eye on 2013, when the exceptions sunset and practices must choose whether to take on the full cost of the services or terminate the arrangement and get back their data.

What the Exceptions Allow

The physician self-referral law—commonly known as the Stark Law—prohibits physicians from referring Medicare patients for designated health services to an entity with which the physician or a member of the physician's immediate family has a financial relationship. The law also prohibits an entity from submitting a claim to any person for a service or item furnished as a result of a prohibited referral.

The anti-kickback statute makes it a crime to offer payment in return for a referral for any item or service paid for by any federally funded healthcare program. A hospital thus may not offer remuneration to a physician to induce the physician to make referrals to the hospital. The statute is broader and stronger than the Stark Law. It applies to any federally funded healthcare program, and violating it is a felony.

In 2006 the Centers for Medicare and Medicaid Services created exceptions to the Stark Law in response to the Medicare Modernization Act, which called for self-referral exceptions that would promote widespread physician adoption of e-prescribing and electronic health record software. In tandem, the Office of the Inspector General created a safe harbor to the anti-kickback statute. The exceptions took effect October 2006.

Under the exceptions, donors may provide electronic health record and practice management software licenses. The donations may cover connectivity and interfaces, training, maintenance, and help desk services.

To be eligible under the exceptions, donated systems must include e-prescribing capability through an e-prescribing component or they must have the ability to interface with EHR systems.

Donated systems must be interoperable, capable of exchanging data accurately, effectively, and securely across different IT systems. Software products certified by the Certification Commission for Healthcare Information Technology likely meet the requirements.

The donated system must be necessary and used predominately to create, maintain, transmit, or receive health records. It may include integrated practice management functionality, but the system may not be composed of practice management software

alone. The practice management software must integrate with the health record software, and the recipient must commit to implementing the health record software.

Hardware Not Included, Copayment Required

Not included in the exceptions are hardware, interfaces that connect the practice to competing organizations, and staff for abstracting, scanning, or other practice duties. Donors may not provide technology equivalent to any technology that the recipient already has. Upgrades are permissible if organizations do not qualify because they are already using comparable technology.

The donation may not exceed 85 percent of the donor's cost for the technology. The practice must pay the remaining 15 percent in advance. The donor may not finance the physician's payment. A written agreement is required.

A set of criteria governs how donors may select recipients. Recipients may not be selected based on the value or volume of referrals to the donor. They may not be selected by criteria such as the size of the practice (e.g., total patients or encounters) or whether the physicians are members of the donor's medical staff.

Donors and recipients must mind the provisions carefully. Violating the Stark Law can lead to civil fines and penalties up to $100,000 per violation. Violators may be excluded from federal healthcare programs. Violating the anti-kickback statute is a felony, and the punishments are accordingly higher, including possible jail time.

Evaluating the Opportunity

Clearly this is no free lunch. Rather, the exceptions offer 85 percent off certain items on the menu.

This is an important distinction. Paying 15 percent of the covered items and the full cost of any necessary hardware, new staffing, or additional services may still prove too costly for some practices. Practices must discover all costs to the best of their ability before entering into any agreement.

Donors face similar challenges in determining the full costs. This can make calculating the required 15 percent copayment difficult, as the donor may not be able to determine the complete cost up front, especially for large-scale implementations across many practices.

Practices do not get a choice of software; they are offered licenses for the software the hospital uses. However, physicians still must assess their needs and identify the type of system that will benefit their practices, just as they would if they were shopping for a system. Any new IT system requires an evaluation and modification of workflow. This can be a complex and time-consuming task that should not be underestimated.

Practices should evaluate donated software to ensure that it is an appropriate fit for the practice. If the practice cannot match the system to its needs—or is unwilling to adapt the practice to the system—the system won't work for it no matter how low the price.

The evaluation should include the practice's ability to manage the system once installed. For smaller practices with minimal IT and information management expertise on hand, a new system may require a new staff person.

Systems donated by hospitals usually offer the appropriate clinical and administrative functionality for physicians and interact smoothly with the hospital. This may not be the case with systems donated by payers. Practices must confirm that a system offered by a payer is interoperable with the hospital system; otherwise, the practice will find itself using two systems, neither of which works with the other.

Depending on the agreement, the practice may deal directly with the vendor or it may deal with the hospital. Hospitals that work directly with practices must be certain they are prepared to function as a vendor to the physicians. Underestimating the support required will generate frustration within both the hospital and the practices.

In exchange for discounted rates received through the donor, the practice will necessarily give up some levels of control and perhaps the ability to work directly with the vendor to resolve key issues. For example, a practice may not be able to make

upgrades or changes to the system if the hospital is not making the same changes.

Finally, even before the relationship begins, physicians must consider how it will end.

The safe harbor sunsets in 2013, and at that point donations cease and practices will be on the hook for the full cost of the software and services. The practice should confirm in advance that it can continue the relationship directly with the vendor once the donor steps out of the picture.

Practices should also determine what happens to their data if they choose to terminate the agreement. This issue exists in any agreement with an application service provider. Practices must confirm that they can get their data back from the vendor. They must also establish how the data will be returned—in a readily usable form or in a format that requires some IT intervention before it can be imported into a new system.

The opportunities offered by the exceptions are intriguing. The homework required is extensive. Legal counsel is essential in fully evaluating the safe harbor implications.

The View from Montana

by **Liz Lewis** , RN, MSN, JD, senior vice president of operations/legal, Bozeman Deaconess Hospital, MT

The rule was a gift to us. We are embarking on an enterprisewide system with our community physicians. We were heading down the path prior to the ruling and trying to figure out how it would be affordable to the small private practices pursuant to the fair market value regulations. The ability to donate up to 85 percent of the costs was great.

The pitfalls, since the rule is new, related to applying the regulations to reality (as usual). Issues included determining donor costs. It is difficult to define it in the IT world, and more difficult to explain it to physicians.

The most difficult part of the requirements have been:

- 411.357V(7)(iii). It sounds simple; however, it is difficult to do when you have multiple groups going live over a three-year period. You really do not know your total costs until the end of the ramp up.
- (w)(4). It is easy regarding the purchase of the software, but more difficult on monthly maintenance. We ended up requiring three months in advance so we would never have to worry about shutting off the service.

The criteria for determining the amount of the donation were easy to work with, as we were able to place community benefit standards as conditions of participation—such as taking unassigned calls in the emergency room, creation of a community-wide problem list, medication list, and allergy list in an easily accessible site.

The big issue is the sunset of the rule. The doctors are concerned they will not be able to afford 100 percent of the monthly costs if the donation cannot continue.

The other issue, not related to the Stark regulations, was how to treat the donation. We are issuing 1099s to the participants pending a ruling by the IRS on this topic. In addition, getting an agreement relating to ownership of the licenses, transfer of the licenses, ownership of data, warranties, limits of liability with over 100 docs was quite challenging.

But we are moving forward, and at this point have four clinics up and running and two more years to go to be fully implemented.

Resources

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