



# G-2

# Compliance

# Report



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## For Hospitals, Laboratories and Physician Practices

### Electronic Health Record Donations: Best Practices to Minimize Liability

In 2006, the government made its first real effort to promote the adoption and use of electronic health records (EHR) through the promulgation of rules that allow entities to provide nonmonetary assistance to physicians installing EHR systems without running afoul of the federal physician self-referral law (the Stark law)<sup>1</sup> or the federal health care anti-kickback statute.<sup>2</sup> At the time, the government's stated purpose was to "lower perceived barriers to the adoption of health information technology" by promoting "the adoption of open, interconnected, interoperable electronic record systems."<sup>3</sup>

Today, the push for EHR adoption has taken on greater urgency as part of the wider health reform effort. While there are divergent views on the need for health reform, both sides of the aisle generally agree on the benefits associated with EHR adoption and the potential it holds to reduce medical errors, increase quality of care, improve efficiency, and enhance coordination and information management among providers. Both parties want to reduce the redundancy, errors, and administrative overhead created by paper records, making the national goal of fully interoperable health records by 2014 a real possibility.

The EHR initiative gained additional momentum on Feb. 17, 2009 when President Obama signed into law the \$787 billion American Recovery and Reinvestment Act of 2009 (ARRA).<sup>4</sup> The ARRA established \$19 billion in incentives for hospitals and physicians to replace manual patient record systems with EHR systems. The government hopes that these incentives, in combination with the existing Stark law exception and anti-kickback statute safe harbor, will contribute to widespread EHR adoption and use.

Notwithstanding the many benefits associated with EHR use, there are a number of legal risks involved in implementing, managing, and maintaining EHR systems. Among other things, providers must ensure the privacy and security of patient information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA).<sup>5</sup> This obligation recently became even more complex with the passage of the ARRA, which strengthened HIPAA's privacy and security standards, including the penalties for noncompliance and the requirements associated with breach notifications. This article will focus on the legal risks associated with EHR adoption under the Stark law and anti-kickback statute, offer best practices to avoid liability, and consider the future utility of such provisions in light of the ARRA.

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<sup>1</sup> 42 U.S.C. § 1395nn.

<sup>2</sup> 42 U.S.C. § 1320a-7b(b).

<sup>3</sup> Statement of Lewis Morris, chief counsel to the inspector general, U.S. Department of Health and Human Services, testimony before the Subcommittee on Health of the House Committee on Ways and Means, April 6, 2006.

<sup>4</sup> Pub. L. No. 111-5.

<sup>5</sup> 42 U.S.C. § 1320d through d-8.

## EHR Exception and Safe Harbor

In 2006, the Centers for Medicare and Medicaid Services (CMS) and the Office of Inspector General (OIG) for the Department of Health and Human Services simultaneously published final rules intended to promote physician adoption of EHR technology.<sup>6</sup> Before promulgation of these rules, CMS and OIG viewed a donation of EHR technology to a potential or actual referral source as a possible inducement prohibited by the anti-kickback statute, and also as a likely violation of the Stark law.<sup>7</sup> However, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)<sup>8</sup> required the creation of exceptions and safe harbors that would allow entities to provide nonmonetary assistance to physicians to encourage the adoption of EHRs, thereby promoting the government's ultimate goal of achieving fully interoperable EHRs for all patients.

Both the EHR safe harbor and the EHR exception expire on Dec. 31, 2013. The OIG and CMS chose this date because it is consistent with the government's goal of full adoption of EHR technology by 2014 and because the agencies expect that the need for donations of EHR technology will diminish over time. Considering that the OIG and CMS declined to limit the value of donated technology and also allowed remuneration to be linked to some degree to volume or value of referrals, the sunset provision offers an additional safeguard against potentially abusive arrangements.

Since promulgation of the EHR safe harbor and exception, neither the OIG nor CMS has provided any significant guidance regarding best practices for EHR donations. In the preamble to the final EHR safe harbor, the OIG expressed concerns about inappropriate cost-shifting, abusive schemes involving free or deeply discounted goods, and abuse of the safe harbor by ancillary providers, but noted throughout that the totality of the safe harbor's conditions, such as the cost-sharing and sunset provisions, should address these issues.<sup>9</sup> The OIG further indicated that the benefit from interoperable EHRs is so significant that safe harbor protection is warranted for a limited period of time despite its concerns regarding abusive arrangements. In light of this lack of guidance, donors and recipients must carefully review their covered arrangements to ensure compliance.

## Protected Donors and Recipients

The potential class of donors and recipients for EHR technology is very broad. Under the EHR safe harbor, "any individual or entity that provides covered services and submits claims or requests for payment, either directly or through reassignment, to any federal health care program, and health plans" may qualify as a protected donor or recipient.<sup>10</sup> With this definition, the OIG intended to focus on those individuals and entities that participate directly in the provision of health care to patients and are therefore in the best position to advance the implementation of EHR adoption through participation in interoperable EHR systems.

The OIG chose not to include pharmaceutical, device, and durable medical equipment manufacturers as protected donors. In doing so, the OIG noted its concern that such manufacturers' primary interest in offering technology to potential referral sources would be to market their products.<sup>11</sup> Under the EHR exception, "any entity that furnishes designated health services to any physician" may qualify as a protected donor and "any physician" may qualify as a protected recipient.<sup>12</sup>

When selecting a recipient, the donor cannot consider the volume or value of referrals or other business generated between the parties. Notwithstanding the

<sup>6</sup> See 42 C.F.R. §§ 411.357(w), 1001.952(y).

<sup>7</sup> The OIG enforces the anti-kickback statute while CMS is charged with enforcing the Stark law. Although the terms of the EHR safe harbor and the EHR exception are almost identical, the two applicable statutory schemes differ significantly. The anti-kickback statute is a criminal statute that requires proof of criminal intent. In contrast, the Stark law is a civil statute that has no intent requirement.

<sup>8</sup> Pub. L. 108-173.

<sup>9</sup> See e.g., 71 Fed. Reg. 45,110, 45,129 (Aug. 8, 2006).

<sup>10</sup> 42 C.F.R. § 1001.952(y)(1)(i).

<sup>11</sup> 71 Fed. Reg. 45,128.

<sup>12</sup> 42 C.F.R. § 411.351.

foregoing, the following six selection criteria are considered proper: (1) the size of the physician's practice, (2) the total number of prescriptions written by the physician, (3) the total number of hours that the physician practices medicine, (4) the physician's overall use of automated technology, (5) the amount of uncompensated care, or (6) whether the recipient is a member of the donor's medical staff.<sup>13</sup> It is therefore permissible for a donor to make a donation to a recipient from whom it receives a significant volume of business. This approach is a deliberate departure from other safe harbors under the anti-kickback statute and Stark law based on the unique public policy considerations surrounding EHR technology.

*Neither the OIG nor CMS has provided guidance on the standard for determining whether technology the recipient already possesses is "equivalent" to the proposed donation.*

### Protected Technology and Services

In practice, the permissible scope of donated EHR technology is often the most difficult piece of the safe harbor and exception for providers to navigate. Any software, information technology and training services that are "necessary and used predominantly to create, maintain, transmit, or receive electronic health records" may qualify for protection.<sup>14</sup> Donated software must be interoperable and must include e-prescribing capability, either as an electronic prescribing component or through the ability to interface with the recipient's existing e-prescribing system.<sup>15</sup>

❖ *The "Necessary" Requirement.* The "necessary" requirement of the exception and safe harbor means that the recipient may not already possess equivalent software or services, and the donor may not have any actual knowledge, or act in reckless disregard or deliberate ignorance of, a recipient's possession of EHR technology that is functionally or technically equivalent to that being donated.<sup>16</sup> From the government's perspective, the provision of equivalent items or services poses a heightened risk of abuse because such arrangements potentially confer independent value on the recipient unrelated to the need for electronic health records technology. For this reason, donors should make reasonable inquiries to potential recipients regarding their existing technology systems and document these communications. However, neither the OIG nor CMS has provided guidance on the standard for determining whether technology the recipient already possesses is "equivalent" to the proposed donation. For example, is the equivalence determination based on a comparison of features and functions, the technology platform, or specific system architecture? These questions remain unanswered and often make it difficult for donors to assess whether this requirement is met.

Although the safe harbor and exception do not include a separate requirement addressing divestiture of technology, the government remains concerned about the risk of recipients intentionally divesting themselves of technically or functionally equivalent technology that they already possess, or have previously obtained, in order to shift costs to the donor.<sup>17</sup> The government has indicated that such cost-shifting may occur in connection with ongoing maintenance and help desk support for EHR systems previously purchased by the recipient or the movement of previously purchased technology to other uses and replacement of such technology with equivalent new technology obtained from a donor.<sup>18</sup> As noted below, maintenance services may be included as part of a permissible EHR donation, but a donor may not offer to pay for maintenance services associated with EHR technology previously purchased by the recipient. The necessary requirement does not, however, preclude the donation of upgrades to EHR technology that enhance functionality, including upgrades that make software more user-friendly or current, or items and services that result in standardization of systems among donors and recipients.<sup>19</sup>

<sup>13</sup> *Id.* §§ 411.357(w)(6), 1001.952(y)(5).

<sup>14</sup> *Id.* §§ 411.357(w), 1001.952(y)(5).

<sup>15</sup> *Id.* §§ 411.357(2), 1001.952(y)(2).

<sup>16</sup> *Id.* §§ 411.357(w)(8), 1001.952(y)(7).

<sup>17</sup> See 71 Fed. Reg. 45,124.

<sup>18</sup> See *id.*

<sup>19</sup> See 71 Fed. Reg. 45,123.

❖ **The “Used Predominantly” Requirement.** The EHR functions of any donated software must be predominant. In other words, the core functionality of the technology must be the creation, maintenance, transmission, or receipt of individual patients’ EHRs. The safe harbor and exception do protect software packages that include other functionality related to the care and treatment of individual patients, such as patient administration, scheduling functions, billing, and clinical support that is commonly integrated with EHR software,<sup>20</sup> as long as those features are secondary to the EHR function.

#### **Cost-Sharing Requirement**

An arrangement between a donor and a recipient for EHR technology is only protected where the recipient pays for at least 15 percent of the cost of the donated technology,<sup>21</sup> and this cost-sharing requirement also applies to the technology as well as the related services, such as training, help-desk, and maintenance services. In addition, any updates, upgrades, or modifications to the donated technology that are not covered under the initial purchase price are subject to a separate cost-sharing obligation by the recipient if the donor incurs additional costs. This 15 percent cost-sharing must be paid at the time of, or prior to, receipt of the EHR technology. The donor may not finance the recipient’s cost-sharing obligation or loan funds to the recipient to pay for the recipient’s portion of the donated technology. There is no cap on the amount of protected technology that can be donated.

#### **Documentation Requirement**

Each EHR donation arrangement must be set forth in a written agreement between the donor and recipient.<sup>22</sup> The parties must enter into the written agreement prior to the donation, and the agreement must describe all of the donated technology, the donor’s costs, and the amount of the recipient’s contribution. The parties also should include in the agreement specific representations regarding their compliance with the safe harbor and exception. For example, the agreement should contain representations by the parties that:

- ❖ the donor has not restricted the software’s interoperability;
- ❖ the donation is not a condition of doing business between the parties;
- ❖ the donation is not based on the volume or value of referrals between the parties;
- ❖ the recipient does not possess equivalent software or services; and
- ❖ the recipient has not received any loans from the donor to finance the recipient’s cost-sharing obligation.

The parties may also wish to include provisions regarding ownership of the EHR technology and termination of the donation arrangement. In particular, the parties should consider what, if any, effect termination of the donation arrangement may have on the ownership of the EHR technology.

#### **Future of the EHR Safe Harbor and Exception**

As discussed above, the ARRA provided for \$19 billion in grants to promote the adoption of health information technology. Physicians and hospitals participating in the Medicare and Medicaid programs may qualify for grants to purchase certified EHR technology if they engage in “meaningful use” of EHR. Physicians may receive up to \$44,000 over a five-year period beginning in 2011, and hospitals may receive a \$2 million base amount, plus additional amounts beginning in 2011. In addition, physicians and hospitals that do not engage in meaningful use of EHR technology will be subject to reimbursement reductions beginning in 2015. Even though CMS has not yet published final regulations

<sup>20</sup> See *id.* at 45,125.

<sup>21</sup> 42 C.F.R. §§ 411.357(w)(4), 1001.952(y)(11).

<sup>22</sup> *Id.* §§ 411.357(w)(7), 1001.952(y)(6).

PROTECTED	NOT PROTECTED
<input type="checkbox"/> Software with core functionality of creating, maintaining, transmitting, or receiving EHR	<input type="checkbox"/> Money
<input type="checkbox"/> Software with other functionality directly related to individual patient care and treatment (e.g., registration, scheduling, billing, clinical support software)	<input type="checkbox"/> Reimbursement for previously purchased technology
<input type="checkbox"/> Interface and translation software	<input type="checkbox"/> Software with core functionality other than EHR (e.g., human resources or payroll software)
<input type="checkbox"/> Rights, licenses, and intellectual property related to EHR software	<input type="checkbox"/> Hardware
<input type="checkbox"/> Information technology services	<input type="checkbox"/> Hardware support
<input type="checkbox"/> Connectivity services (including broadband and wireless Internet services)	<input type="checkbox"/> Technology that is duplicative of technology currently possessed by the recipient
<input type="checkbox"/> Maintenance services	<input type="checkbox"/> Items or services used by a recipient primarily to conduct business unrelated to the recipient's clinical practice or clinical operations
<input type="checkbox"/> Training and support services	<input type="checkbox"/> The provision of staff to recipients or their offices
<input type="checkbox"/> Help desk services (and other similar support)	<input type="checkbox"/> Support and information services unrelated to EHR or patient care (e.g., research or marketing support services)
<input type="checkbox"/> Clinical support and information services related to patient care (but not separate research or marketing support services)	
<input type="checkbox"/> Secure messaging (e.g., permitting physicians to communicate with patients through electronic messaging)	
<input type="checkbox"/> Data migration services (but not through the provision of staff to the recipient)	
<input type="checkbox"/> Upgrades and enhancements to existing technology to enhance functionality or to make the technology more current or user-friendly	

implementing this grant program, the OIG already has indicated that it will make scrutiny and enforcement in this area a top priority so providers should proceed with caution.

In light of the incentives available under the ARRA, some trade associations have called for the repeal of the anti-kickback statute safe harbor and Stark law exception for EHR donations.<sup>23</sup> In a letter to the OIG, the American Clinical Laboratory Association (ACLA) noted that the financial incentives available under the ARRA “make it possible for any physician or hospital that needs an EHR system to obtain it” and called into question the OIG’s “ultimate justification for adopting the EHR safe harbor.”<sup>24</sup> In light of the potential windfall available to physicians and hospitals, ACLA recommended either repeal of the safe harbor or the removal of laboratories from the list of permitted donors.

However, the ARRA contains no indication that providers who have already availed themselves of an EHR donation under the Stark law or anti-kickback statute may not also take advantage of the incentives available under the ARRA. In addition, repeal of the safe harbor or exception is unlikely because both already contain safeguards against fraud and abuse, such as the sunset provision, and because the Obama administration is prioritizing adoption of EHR technology.

In light of this fact, donors may wish to reconsider the scope and format of their donations. For example, a donor may require that the recipient apply for ARRA funds and

<sup>23</sup> See Letter from American Clinical Laboratory Association to Daniel R. Levinson, inspector general, Office of Inspector General, Department of Health and Human Services, March 19, 2009. Available at [www.clinical-labs.org/documents/ACLAOIGLetterEHRSafeHarbor\\_1.PDF](http://www.clinical-labs.org/documents/ACLAOIGLetterEHRSafeHarbor_1.PDF). See also Letter from College of American Pathologists to Daniel R. Levinson, inspector general, Office of Inspector General, Department of Health and Human Services, Feb. 17, 2009. Available at [www.cap.org/apps/docs/advocacy/comments/comments\\_levinson.pdf](http://www.cap.org/apps/docs/advocacy/comments/comments_levinson.pdf).

reimburse the donor if it receives such funds. Either way, EHR technology undoubtedly will continue to play a central role in the health care delivery system.

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