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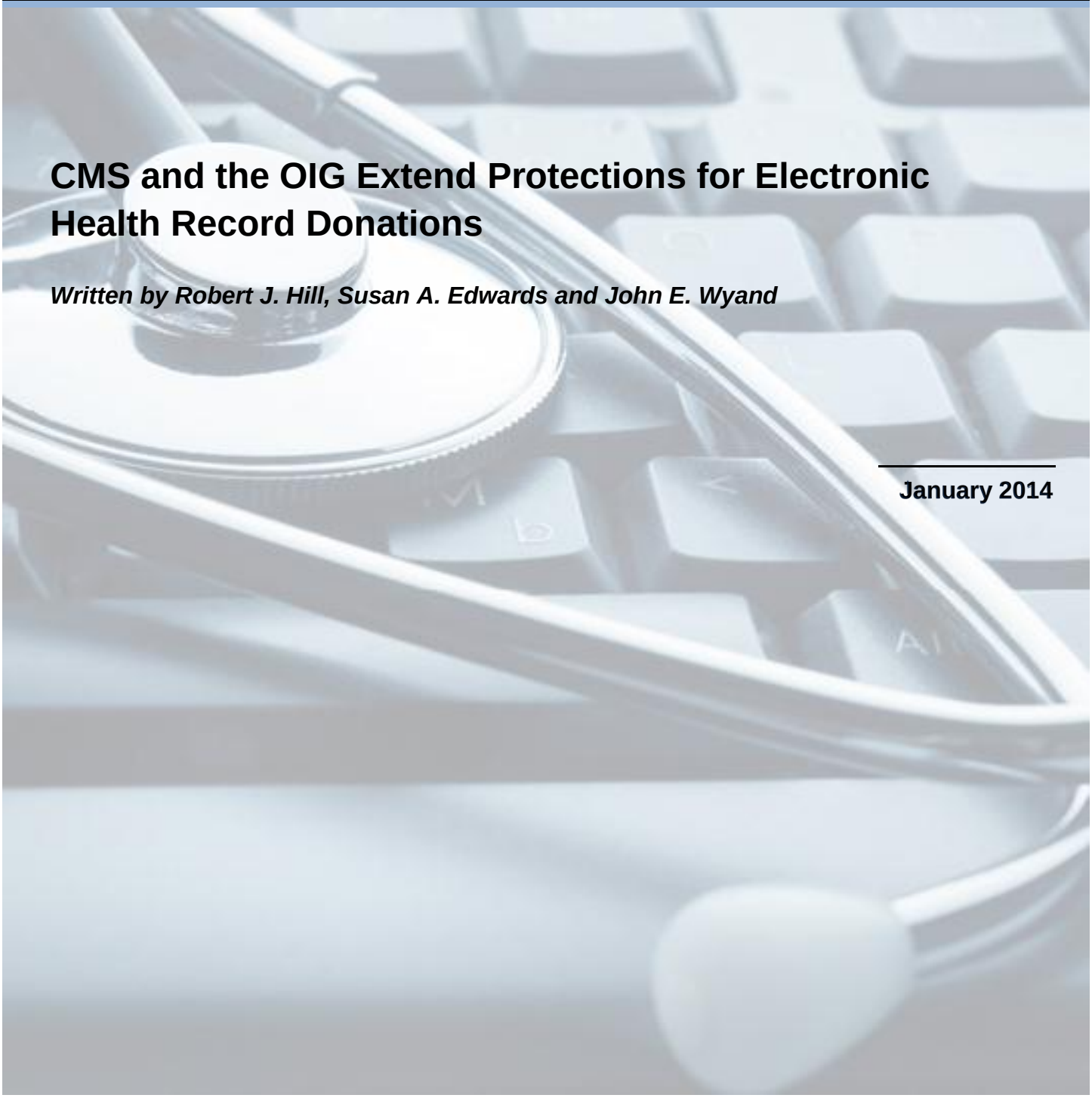

CMS and the OIG Extend Protections for Electronic Health Record Donations

Written by Robert J. Hill, Susan A. Edwards and John E. Wyand

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Brief Overview of Final Rules

On December 27, 2013, the Office of Inspector General ("OIG") and the Centers for Medicare & Medicaid Services ("CMS") each published, in the *Federal Register*, a final rule that amends regulations under the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b), and the federal physician self-referral law ("Stark Law"), 42 U.S.C. § 1395nn, permitting certain arrangements involving the donation of interoperable electronic health record ("EHR")[1] software or information technology and training services.[2] The final rules modify the Stark Law's EHR exception ("EHR Exception"), 42 C.F.R. § 411.357(w), and the AKS EHR safe harbor ("EHR Safe Harbor"), 42 C.F.R. § 1001.952(y), in a few important ways.

More specifically, the final rules:

- Extend the "sunset" date of the EHR Exception and the EHR Safe Harbor from December 31, 2013 to December 31, 2021
- Exclude laboratory companies from the types of entities that may donate EHR items and services
- Update the provisions under which an EHR donor or recipient can ascertain, with certainty, that EHR is interoperable pursuant to the exception and safe harbor (the "deeming provisions")
- Remove the requirements that donated EHR include an electronic prescribing capability
- Clarify the requirement prohibiting any action that limits or restricts the use, compatibility, or interoperability of donated items or services

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[1] For the purposes of the EHR Safe Harbor and EHR Exception, "electronic health record" is defined 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." 42 C.F.R. § 411.351; note to 42 C.F.R. § 1001.952(y).

[2] 78 Fed. Reg. 78,751 (Dec. 27, 2013) (the final EHR Exception rule); 78 Fed. Reg. 79,202 (Dec. 27, 2013) (the final EHR Safe Harbor rule).

With the exception of the amendments to the sunset provisions, which went into effect December 31, 2013, the amended regulations will be effective March 27, 2014.

In explaining the modifications to the EHR Safe Harbor and the EHR Exception, the final rules' preamble discussions provide helpful insights into OIG's and CMS' views regarding interoperability, the importance of EHR adoption, and data and referral "lock-in." Because the final rules contain largely parallel modifications, and the preamble discussion for each rule generally mirrors the other, our summary below is a combined discussion of both the final EHR Exception rule and the final EHR Safe Harbor rule. For your reference, during this summary, we point out a few differences in OIG's and CMS' preamble discussions, and at the end of this summary, we provide a side-by-side comparison of the EHR Safe Harbor and the EHR Exception, highlighting the recent revisions.

Background Information Regarding EHR Safe Harbor and EHR Exception

The OIG and CMS initially published the final rules creating the EHR Safe Harbor and EHR Exception, respectively, in the August 8, 2006 *Federal Register*.[3] In accordance with the 2006 final rules, the EHR Safe Harbor and EHR Exception went into effect October 10, 2006.

The EHR Safe Harbor provides that, for purposes of the AKS, "'remuneration' does not include nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records," if all of the conditions of the EHR Safe Harbor are satisfied.[4]

The EHR Exception states that a compensation arrangement involving "[n]onmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records" does not constitute a financial relationship pursuant to the Stark Law if all of the conditions of the EHR Exception are satisfied.[5]

In essence, the EHR Safe Harbor and the EHR Exception protect non-monetary donations of EHR "software, information technology and training services" between certain donors and certain recipients, if all of the conditions

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[3] 71 Fed. Reg. 45,119 (Aug. 8, 2006) (the final 2006 EHR Safe Harbor rule); 71 Fed. Reg. 45,140 (Aug. 8, 2006) (the final 2006 EHR Exception rule).

[4] 42 C.F.R. § 1001.952(y).

[5] 42 C.F.R. § 411.357(w).

of the safe harbor or exception are met. The government previously indicated that "software, information technology and training services" does *not* include computer or information technology hardware, but does include the following:

- 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 services)
- Maintenance services
- Secure messaging (e.g., permitting physicians to communicate with patients through electronic messaging)
- Training and support services (such as access to help desk services)[6]

The OIG and CMS created the EHR Safe Harbor and EHR Exception, respectively, at the same time it promulgated the regulations for the e-prescribing safe harbor, 42 C.F.R. 1001.952(x), and e-prescribing exception, 42 C.F.R. 411.357(v). However, unlike the e-prescribing safe harbor and exception, which was mandated by Congress in the Medicare Prescription Drug, Improvement and Modernization Act of 2005,[7] the EHR Safe Harbor and EHR Exception were created using OIG's and CMS' discretionary authority to establish safe harbors and exceptions under the AKS and Stark Law. Stating the government's desire "to encourage the adoption of electronic health records technology consistent with the ultimate goal of achieving fully interoperable electronic health records for all patients," OIG created the EHR Safe Harbor and CMS created the EHR Exception.[8]

The EHR Safe Harbor and EHR Exception are unique in that they protect a financial relationship that otherwise would likely be highly suspect under the AKS and would potentially violate the Stark Law: the provision of free or deeply discounted goods to recipients chosen utilizing selective criteria. In finalizing the EHR Safe Harbor in 2006, the OIG commented on the unique nature of the EHR Safe Harbor, stating:

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[6] 71 Fed. Reg. 45,119, 45,125 (Aug. 8, 2006); 71 Fed. Reg. 45,140, 45,151 (Aug. 8, 2006).

[7] 42 U.S.C. § 1395w-104(e)(6).

[8] 71 Fed. Reg. 45,140, 45,149 (Aug. 8, 2006); 71 Fed. Reg. 45,119, 45,120 (Aug. 8, 2006).

> This approach is a deliberate departure from other safe harbors under the anti-kickback statute based on the unique public policy considerations surrounding electronic health records and the Department's goal of encouraging widespread adoption of interoperable electronic health records. We caution, however, that outside of the context of electronic health records, as specifically addressed in this final rule, both direct and indirect correlations between the provision of free or deeply discounted goods or services and the volume or value of referrals or other business generated between the parties are highly suspect under the anti-kickback statute (and may evidence outright violations) and do not meet the requirements of other safe harbors under the statute or § 1001.952.[9]

Overview of Modifications to EHR Safe Harbor and EHR Exception

The Deeming Provision

The EHR Safe Harbor and EHR Exception both require donated EHR software to be interoperable at the time such software is donated in order to satisfy the conditions of the EHR Exception and EHR Safe Harbor, respectively.[10] For the purposes of the EHR Safe Harbor and EHR Exception, "interoperable" means "able 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."[11] In addition, both the EHR Safe Harbor and EHR Exception include a "deeming provision" under which certain software is deemed interoperable for purposes of the rules.

The 2013 final rules modify the EHR Safe Harbor's and EHR Exception's "deeming provision" to deem software interoperable if, on the date it is provided to the recipient, it has been certified, by an Office of the National Coordinator for Health Information Technology ("ONC")-authorized certifying body, to any edition of EHR certification criteria that is identified in the then-applicable definition of certified EHR technology in 45 C.F.R. Part 170. This revision modified the previous requirement that the software be certified "within no more than 12 months prior to the date it is provided to the recipient" by a certifying body recognized by the Secretary, to conform to recent developments in the ONC certification program—most notably, the fact that ONC has released both 2011 and 2014 editions of EHR certification criteria, and intends to release further editions in the future. For

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[9] 71 Fed. Reg. 45,119, 45,130 (Aug. 8, 2006). CMS included a parallel discussion at 71 Fed. Reg. 45,119, 45,159 (Aug. 8, 2006).

[10] 42 C.F.R. § 411.357(w)(2); 42 C.F.R. § 1001.952(y)(2).

[11] 42 C.F.R. § 411.351; note to 42 C.F.R. § 1001.952(y).

example, since, for 2013, software certified to either the 2011 or 2014 editions is deemed "Certified EHR Technology" by ONC, such software would be deemed interoperable for purposes of the final rules if donated during 2013.

The OIG and CMS both reiterate that EHR software need not be certified to ONC standards in order to be considered interoperable for the purposes of the EHR Safe Harbor and EHR Exception, but instead the deeming provision offers certainty to the parties involved in an EHR donation.[12] Accordingly, while the ONC certification program currently focuses on certifying software as "Certified EHR Technology," as defined at 45 C.F.R. § 170.102, relating to the "EHR Incentive Programs" that provide payment incentives to certain types of providers (e.g., "meaningful use"), "[i]ndividuals and entities such as long term/post-acute care providers and non-physician behavioral health practitioners, while not eligible to participate in the EHR Incentive Programs, may receive donations that are protected by this safe harbor" if the software nevertheless meets the definition of "interoperable."[13]

The Electronic Prescribing Provision

The modifications to the EHR Safe Harbor and EHR Exception remove the electronic prescribing capability requirements found at 42 C.F.R. § 1001.952(y)(10) and 42 C.F.R. § 411.357(w)(11). According to the OIG and CMS, "since the 2006 Final Rule, several developments have occurred to make us conclude that it is no longer necessary to retain a requirement related to electronic prescribing capability in the electronic health records [safe harbor and exception]."[14] The government states that "[w]e do not want to undermine important public policy goals by requiring redundant and sometimes expensive software capabilities that may not contribute to the interoperability of a given system.[15]

The Sunset Provision

In the 2006 EHR Safe Harbor and EHR Exception final rules, the OIG and CMS established a "sunset" date of December 31, 2013; donations of EHR items and services made after that date would not be eligible for protection under the safe harbor or the exception. In a modification welcomed by potential donors and recipients, the 2013 final rules extend the EHR Safe Harbor and EHR Exception until December 31, 2021. Note that this

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[12] 78 Fed. Reg. 79,202, 79,204 (Dec. 27, 2013); 78 Fed. Reg. 78,751, 78,765 (Dec. 27, 2013).

[13] 78 Fed. Reg. 79,202, 79,205 (Dec. 27, 2013).

[14] 78 Fed. Reg. 79,202, 79,218 (Dec. 27, 2013); 78 Fed. Reg. 78,751, 78,768 (Dec. 27, 2013).

[15] 78 Fed. Reg. 79,202, 79,206 (Dec. 27, 2013); 78 Fed. Reg. 78,751, 78,755 (Dec. 27, 2013).

was the latest sunset date the OIG and CMS specifically offered in their April 10, 2013 proposed rules.[16] As the OIG states in the EHR Safe Harbor final rule's preamble discussion, it believes that "a reasonable extension of the safe harbor strikes an appropriate balance between furthering the Department's electronic health record adoption goals and safeguarding against undue risks of abuse."[17]

The government based its extension of the sunset date upon its view that "although the industry has made great progress in the adoption and meaningful use of electronic health records technology, the use of such technology has not yet been adopted nationwide,"[18] and that "adoption of interoperable electronic health records technology remains a challenge for some providers and suppliers."[19]

Protected Donors

Because of "the concerns articulated by commenters and the wide-ranging support from the entire spectrum of the laboratory industry (from small, pathologist-owned laboratory companies to a national laboratory trade association that represents the industry's largest laboratory companies),"[20] the final EHR Safe Harbor and EHR Exception rules exclude laboratory companies as protected donors. However, with the exception of laboratory companies, the final EHR Safe Harbor rule continues to protect donors "that provide patients with health care items or services covered by a Federal health care program and submit claims or requests for payment to those programs directly or through reassignment,"[21] and the final EHR Exception rules continue to protect donors that are entities, as defined by 42 C.F.R. § 411.351, that are not laboratory companies.[22]

The OIG and CMS state that many commenters indicated that, "notwithstanding a clear prohibition in the safe harbor, laboratory companies are, explicitly or implicitly, conditioning donations of electronic health records items and services on the receipt of referrals from the recipients of those donations or establishing referral quotas and threatening to require the recipient to repay the cost of the donated items or services if the quotas are not

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[16] 78 Fed. Reg. 21,314, 21,318 (Apr. 10, 2013); 78 Fed. Reg. 21,308, 21,312 (Apr. 10, 2013).

[17] 78 Fed. Reg. 79,202, 79,207 (Dec. 27, 2013).

[18] *Id*.

[19] 78 Fed. Reg. 79,202, 79,207 (Dec. 27, 2013); 78 Fed. Reg. 78,751, 78,756 (Dec. 27, 2013).

[20] 78 Fed. Reg. 79,202, 79,208 (Dec. 27, 2013); 78 Fed. Reg. 78,751, 78,757 (Dec. 27, 2013).

[21] 42 C.F.R. § 1001.952(y)(1)(i).

[22] 42 C.F.R. 411.357(w)(1).

reached."[23] Commenters also "described arrangements involving laboratory companies and vendors that result in the vendor charging other laboratory companies high fees to interface with the donated technology or prohibiting other laboratory companies from purchasing the technology for donation to their own clients."[24] According to commenters, seven states have also prohibited or restricted donations of EHR technology by laboratory companies to address fraud and abuse concerns.[25]

In the context of their discussion of permitted donors, the OIG and CMS state that EHR donors are not required to offer a choice of EHR software or information technology to recipients as part of an EHR donation, but must offer interoperable EHR technology and may not impede the interoperability of EHR software offered, stating, "although physicians [and other recipients] remain free to choose any electronic health record technology that suits their needs, we do not require donors to facilitate that choice for purposes of the safe harbor."[26] The agencies state that "[e]xcluding potential competitors of the donors from interfacing with the donated items or services ... can result in data and referral lock-in.[27]

In their discussion regarding the exclusion of laboratory companies from protection as EHR Safe Harbor and Exception donors, the OIG and CMS also discuss their position with respect to the free provision of limited-use interfaces. The OIG explains that it has "long distinguished between free items and services that are integrally related to the offering provider's or supplier's services and those that are not," and that "[i]t is the lack of independent value to the recipient that takes the donation outside the scope of the anti-kickback statute's prohibition, not the mode of technology."[28] In its discussion, the OIG states that the "donation of free access to an interface used only to transmit orders for the donor's services to the donor and to receive the results of those services" would not implicate the AKS.[29] CMS approaches the same issue somewhat differently, explaining that the Stark Law's definition of ''remuneration'' does not include ''the provision of items, devices, or supplies that are used solely to: (i) collect, transport, process, or store specimens for the entity providing the item, device, or supply; or (ii) order or communicate the results of tests or procedures for such entity," and therefore, a laboratory

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[23] 78 Fed. Reg. 79,202, 79,208 (Dec. 27, 2013); 78 Fed. Reg. 78,751, 78,757 (Dec. 27, 2013).

[24] 78 Fed. Reg. 79,202, 79,209 (Dec. 27, 2013); 78 Fed. Reg. 78,751, 78,758 (Dec. 27, 2013).

[25] *Id.*

[26] 78 Fed. Reg. 79,202, 79,209 (Dec. 27, 2013); 78 Fed. Reg. 78,751, 78,758 (Dec. 27, 2013).

[27] 78 Fed. Reg. 79,202, 79,209 (Dec. 27, 2013); 78 Fed. Reg. 78,751, 78,758 (Dec. 27, 2013).

[28] 78 Fed. Reg. 79,202, 79,210 (Dec. 27, 2013).

[29] *Id*.

company's donation of a laboratory information system interface to a physician would not implicate the Stark Law.[30]

Data and Referral Lock-In

The final rule modifies 42 C.F.R. § 1001.952(y)(3) and 42 C.F.R. 411.357(w)(3) to state, "[t]he donor (or any person on the donor's behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems (including, but not limited to, health information technology applications, products, or services)."[31] The OIG states that "[w]e believe that any action taken by a donor (or any person acting on behalf of the donor, including the electronic health record vendor or recipient) to limit the use of the donated items or services by charging fees to deter non-recipient providers and suppliers and the donor's competitors from interfacing with the donated items or services would pose legitimate concerns that parties were improperly locking-in data and referrals and that the arrangement in question would not qualify for safe harbor protection."[32]

While the agencies had solicited comment on whether further modifications to the rules should be made to prevent data and referral lock-in, they declined to impose any further requirements.

Covered Technology

The OIG and CMS determined not to make any changes to the regulation text regarding the scope of technology covered by the EHR Safe Harbor and EHR Exception.

Implications for Providers and Suppliers

The final EHR Safe Harbor and EHR Exception rules published at the end of last month will allow for AKS and Stark Law protection for EHR donations over the next eight years under largely the same framework that such donations were permitted since 2006.

Notably, however, the preamble discussions to the final rules also provide some helpful clarifications. For example, certain preamble discussion may encourage EHR donations by and between providers other than hospitals and physicians, as the preamble discussion to the final EHR Safe Harbor rule specifically states, twice,

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[30] 78 Fed. Reg. 78,751, 78,759 (Dec. 27, 2013).

[31] 78 Fed. Reg. 78,769 (Dec. 27, 2013); 78 Fed. Reg. 79,220 (Dec. 27, 2013).

[32] 78 Fed. Reg. 79,202, 79,213 (Dec. 27, 2013).

that long-term care providers/post-acute providers are eligible to receive donations pursuant to the EHR Safe Harbor.

In addition, the final rules' preamble discussions touched upon recurring fees/services, which would be relevant to any arrangement where a donor continues to cover part of monthly licensing fees, for example. The preamble discussions state, "[a]nother commenter urged us to eliminate maintenance and service agreements from the scope of potentially protected donations under the safe harbor . . . [noting] concerns that donors may use ongoing donations of maintenance and service agreements to lock in referrals from recipients."[33] In response, the government refuses to make the requested changes, indicating that the ongoing donations of maintenance and service fees, in an arrangement that otherwise satisfies the conditions of the EHR Safe Harbor and EHR Exception, may be permissible.

Reed Smith lawyers have significant experience advising clients on EHR implementation issues under the Stark Law and AKS, and continue to monitor regulatory changes in this area. For more information these and other health care regulatory matters, please contact your principal Reed Smith lawyer or one of the lawyers listed in this publication.

Side-by-Side Comparison of EHR Exception and EHR Safe Harbor (with Revisions)[34]

This side-by-side comparison shows, in color, the revisions made to the EHR Exception and EHR Safe Harbor by the final rules published December 27, 2013. With the exception of the extension of the sunset date, these revisions are effective as of March 27, 2014. Deletions are featured in red; insertions are featured in blue.

EHR Exception—42 C.F.R. § 411.357(w)	**EHR Safe Harbor—42 C.F.R. §1001.952(y)**
(w) Electronic health records items and services. Nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used	(y) Electronic health records items and services. As used in section 1128B of the Act, "remuneration" does not include nonmonetary remuneration (consisting of items and services in the form of software or

[33] 78 Fed. Reg. 79,202, 79,217 (Dec. 27, 2013); 78 Fed. Reg. 78,751, 78,766 (Dec. 27, 2013).

[34] 42 C.F.R. § 411.357(w); 42 C.F.R. § 1001.952(y); 78 Fed. Reg. 79,202 (Dec. 27, 2013); 78 Fed. Reg. 78,751 (Dec. 27, 2013).

EHR Exception—42 C.F.R. § 411.357(w)	EHR Safe Harbor—42 C.F.R. §1001.952(y)
predominantly to create, maintain, transmit, or receive electronic health records, if all of the following conditions are met:	information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records, if all of the following conditions are met:
(1) The items and services are provided to a physician by an entity (as defined at § 411.351) ~~to a physician~~ that is not a laboratory company.	(1) The items and services are provided to an individual or entity engaged in the delivery of health care by—(i) An individual or entity, other than a laboratory company, that provides services covered by a Federal health care program and submits claims or requests for payment, either directly or through reassignment, to the Federal health care program; or (ii) A health plan.
(2) The software is interoperable (as defined ~~at~~ in § 411.351) at the time it is provided to the physician. For purposes of this paragraph, software is deemed to be interoperable if ~~a certifying body recognized by the Secretary has certified the software no more than 12 months prior to~~, on the date it is provided to the physician~~.~~, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170.	(2) The software is interoperable at the time it is provided to the recipient. For purposes of this subparagraph, software is deemed to be interoperable if ~~a certifying body recognized by the Secretary has certified the software within no more than 12 months prior to~~, on the date it is provided to the recipient~~.~~, it has been certified by a certifying body authorized by the National Coordinator for Health Information Technology to an edition of the electronic health record certification criteria identified in the then-applicable version of 45 CFR part 170.
(3) The donor (or any person on the donor~~'~~'s behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems (including, but not limited to, health information technology applications, products, or services).	(3) The donor (or any person on the donor~~'~~'s behalf) does not take any action to limit or restrict the use, compatibility, or interoperability of the items or services with other electronic prescribing or electronic health records systems (including, but not limited to, health information technology applications, products, or services).

EHR Exception—42 C.F.R. § 411.357(w)	EHR Safe Harbor—42 C.F.R. §1001.952(y)
(4) Before receipt of the items and services, the physician pays 15 percent of the donor's cost for the items and services. The donor (or any party related to the donor) does not finance the physician's payment or loan funds to be used by the physician to pay for the items and services.	**The EHR Safe Harbor provision parallel to the EHR Stark Exception provision to the left, 42 C.F.R. § 411.357(w)(4), is found at 42 C.F.R. §1001.952(y)(11). Therefore, for the benefit of a side-by-side comparison, the section below is intentionally out of order.** (11) Before receipt of the items and services, the recipient pays 15 percent of the donor's cost for the items and services. The donor (or any affiliated individual or entity) does not finance the recipient's payment or loan funds to be used by the recipient to pay for the items and services.
(5) Neither the physician nor the physician's practice (including employees and staff members) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.	(4) Neither the recipient nor the recipient's practice (or any affiliated individual or entity) makes the receipt of items or services, or the amount or nature of the items or services, a condition of doing business with the donor.
(6) Neither the eligibility of a physician for the items or services, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For purposes of this paragraph, the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:	(5) Neither the eligibility of a recipient for the items or services, nor the amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties. For the purposes of this paragraph (y)(5), the determination is deemed not to directly take into account the volume or value of referrals or other business generated between the parties if any one of the following conditions is met:
(i) The determination is based on the total number of	(i) The determination is based on the total number of

EHR Exception—42 C.F.R. § 411.357(w)	EHR Safe Harbor—42 C.F.R. §1001.952(y)
prescriptions written by the physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the program);	prescriptions written by the recipient (but not the volume or value of prescriptions dispensed or paid by the donor or billed to a Federal health care program);
(ii) The determination is based on the size of the physician's medical practice (for example, total patients, total patient encounters, or total relative value units);	(ii) The determination is based on the size of the recipient's medical practice (for example, total patients, total patient encounters, or total relative value units);
(iii) The determination is based on the total number of hours that the physician practices medicine;	(iii) The determination is based on the total number of hours that the recipient practices medicine;
(iv) The determination is based on the physician's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);	(iv) The determination is based on the recipient's overall use of automated technology in his or her medical practice (without specific reference to the use of technology in connection with referrals made to the donor);
(v) The determination is based on whether the physician is a member of the donor's medical staff, if the donor has a formal medical staff;	(v) The determination is based on whether the recipient is a member of the donor's medical staff, if the donor has a formal medical staff;
(vi) The determination is based on the level of uncompensated care provided by the physician; or	(vi) The determination is based on the level of uncompensated care provided by the recipient; or
(vii) The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.	(vii) The determination is made in any reasonable and verifiable manner that does not directly take into account the volume or value of referrals or other business generated between the parties.
(7) The arrangement is set forth in a written agreement that—	(6) The arrangement is set forth in a written agreement that —

EHR Exception—42 C.F.R. § 411.357(w)	EHR Safe Harbor—42 C.F.R. §1001.952(y)
(i) Is signed by the parties;	(i) Is signed by the parties;
(ii) Specifies the items and services being provided, the donor's cost of the items and services, and the amount of the physician's contribution; and	(ii) Specifies the items and services being provided, the donor's cost of those items and services, and the amount of the recipient's contribution; and
(iii) Covers all of the electronic health records items and services to be provided by the donor. This requirement is met if all separate agreements between the donor and the physician (and the donor and any family members of the physician) incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list must be maintained in a manner that preserves the historical record of agreements.	(iii) Covers all of the electronic health records items and services to be provided by the donor (or any affiliate). This requirement will be met if all separate agreements between the donor (and affiliated parties) and the recipient incorporate each other by reference or if they cross-reference a master list of agreements that is maintained and updated centrally and is available for review by the Secretary upon request. The master list should be maintained in a manner that preserves the historical record of agreements.
(8) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the physician possesses or has obtained items or services equivalent to those provided by the donor.	(7) The donor does not have actual knowledge of, and does not act in reckless disregard or deliberate ignorance of, the fact that the recipient possesses or has obtained items or services equivalent to those provided by the donor.
(9) For items or services that are of the type that can be used for any patient without regard to payer status, the donor does not restrict, or take any action to limit, the physician's right or ability to use the items or services for any patient.	(8) For items or services that are of the type that can be used for any patient without regard to payor status, the donor does not restrict, or take any action to limit, the recipient's right or ability to use the items or services for any patient.
(10) The items and services do not include staffing of physician offices and are not used primarily to conduct personal business or business unrelated to the	(9) The items and services do not include staffing of the recipient's office and are not used primarily to conduct personal business or business unrelated to

EHR Exception—42 C.F.R. § 411.357(w)	EHR Safe Harbor—42 C.F.R. §1001.952(y)
physician's medical practice.	the recipient's clinical practice or clinical operations.
(11) ~~The electronic health records software contains electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the physician's existing electronic prescribing system that meets the applicable standards under Medicare Part D at the time the items and services are provided.~~[Reserved]	(10) ~~The electronic health records software contains electronic prescribing capability, either through an electronic prescribing component or the ability to interface with the recipient's existing electronic prescribing system, that meets the applicable standards under Medicare Part D at the time the items and services are provided.~~[Reserved]
(12) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.	N/A
(13) The transfer of the items or services occurs and all conditions in this paragraph (w) are satisfied on or before December 31, ~~2013.~~2021.	(13) The transfer of the items ~~or~~and services occurs, and all conditions in this paragraph (y) ~~are~~have been satisfied, on or before December 31, ~~2013.~~2021.
N/A	(12) The donor does not shift the costs of the items or services to any Federal health care program.