APPENDIX O. ANTI-KICKBACK STATUTE EHR SAFE HARBOR REGULATION

This appendix provides a summary of the anti-kickback statute EHR safe harbor regulation, which is available to many providers, including certain ineligible providers. Below is an overview of the anti-kickback statute EHR safe harbor and its applicability to providers not eligible for the EHR Incentive Programs, followed by a table containing the safe harbor regulatory text. At the time this report was written, we were unable to identify any ineligible providers that received donations via arrangements protected by the EHR safe harbor. The last section of the appendix identifies a proposal advanced by two stakeholder groups to extend the anti-kickback statute EHR safe harbor.

Overview of Anti-Kickback Statute EHR Safe Harbor and Possible Donations to Providers Ineligible for the EHR Incentive Programs

HITECH and Health Care Reform create a key business imperative for EHs and EPs to partner with LTPAC providers to support HIE. Depending on the particular facts, certain arrangements between such parties may implicate the anti-kickback statute. In order to have assurances that their arrangements will not be subject to liability under this law, parties may seek to structure their arrangements to fit within a the safe harbor.[1] To encourage the adoption of electronic health records technology consistent with the ultimate goal of achieving fully interoperable electronic health records for all patients, the Office of Inspector General (OIG) promulgated (August 2006) a safe harbor to the anti-kickback statute for certain arrangements involving the donation of interoperable EHR software or information technology and training services. See Table O1. Refer to: AKS: 42 CFR 1001.952(y).

The EHR safe harbor protects arrangements under which certain individuals and entities make donations (and cover up to 85 percent of cost) of EHR software or information technology and training services to health care providers (including those who are not eligible for the EHR Incentive Programs) if certain conditions are met (see Table O1). For example, a Medicare hospital could donate EHR software and training services to a nursing home, covering 85 percent of the cost, and receive safe harbor protection if all of the safe harbor conditions are met. Per regulation (see Table O1), the safe harbor requires that donated software be "interoperable" and provides that such software will be "deemed to be interoperable if a certifying body recognized by the Secretary has certified the software no more than 12 months prior to the date it is provided to the recipient." The safe harbor is scheduled to sunset at the end of 2013.

[1] 42 CFR Sec. 1001.952. http://www.gpo.gov/fdsys/pkg/CFR-2010-title42-vol5/pdf/CFR-2010-title42-vol5-sec1001-952.pdf.

***NOTE**: There are many important conditions in the EHR safe harbor, all of which MUST be met in order to receive protection. Those seeking to avail themselves of protection under this safe harbor should consult their legal counsel.*

Proposals to Extend the Anti-Kickback Statute EHR Safe Harbor

The National Association for Home Care and Hospice (NAHC) asserts that the delivery of quality home health care and hospice services is very dependent upon the collaboration and exchange of health information across the continuum of care with physician and hospital systems. NAHC and its affiliated technology association, the Home Care Technology Association of America (HCTAA) have described their interest in strengthening the relationships of home health care agencies to both receive technologies from hospitals and other groups as well as to provide EHR technologies and services to physician partners under the EHR Safe Harbor provision. Towards that end, NAHC and HCTA have described:[2]

- Described the need to extend the safe harbor provision that is scheduled to expire on December 31, 2013, and suggested aligning the EHR Safe Harbor provision with the EHR Incentive Programs to further encourage adoption of Certified Electronic Health Records by physicians.

- Requested clarification regarding how the EHR Safe Harbor provision protects "other health care providers".

[2] HCTA Comment Letter EHR Safe Harbor: February 26, 2013. https://www.nahc.org/assets/1/7/4_HCTAA_SafeHarborProvisionsEHRs.docx.

TABLE O1. Anti-Kickback Statute EHR Safe Harbor 42 CFR Sec. 1001.952(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 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 an individual or entity engaged in the delivery of health care by-- (i) An individual or entity 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 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 the date it is provided to the recipient.
(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.
(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.
(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 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 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 recipient practices medicine; (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 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 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.
(6) The arrangement is set forth in a written agreement that-- (i) Is signed by the parties; (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 (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.
(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.
(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.
(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 the recipient's clinical practice or clinical operations.
(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.
(11) Before receipt of the items and services, the recipient pays 15% 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.
(12) The donor does not shift the costs of the items or services to any federal health care program.
(13) The transfer of the items and services occurs, and all conditions in this paragraph (y) have been satisfied, on or before December 31, 2013.
Note to paragraph (y): For purposes of paragraph (y) of this section, *health plan* shall have the meaning set forth at §1001.952(l)(2); *interoperable* shall mean 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; and *electronic health record* shall mean a repository of consumer health status information in computer processable form used for clinical diagnosis and treatment for a broad array of clinical conditions.

EHR PAYMENT INCENTIVES FOR PROVIDERS INELIGIBLE FOR PAYMENT INCENTIVES AND OTHER FUNDING STUDY

Files Available for This Report

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