



**SOCIAL SECURITY ACT
Section 1877**

**Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III) – Final Rule
Summary as Pertains to Electronic Healthcare Records**

By: Dr. Gary Crouch

Fall 2007 HIMSS Government Relations Intern, George Washington University

Phase III of the Stark Law, the “Final Rule”, issued by CMS for interpretation and clarification of the physician self-referral law provide for two exceptions to the Stark Law, which applies to physicians, permitting the donation of health information technology items, under certain circumstances and restrictions, for the support of electronic prescribing and electronic health records.

The Final Rule should be considered along with the safe harbor status of electronic health information technology provided under the Anti-Kickback Statute from the Office of the Inspector General (OIG) which is broader in its scope and applies to more than physicians. The Final Rule’s exceptions and the Statute’s safe harbors are intended to promote the use of health information technology to improve patient safety, quality of healthcare, and improve efficiency. The five key points from the new regulation include:

- These regulations apply to donation by allowed entities of **electronic prescribing technology** to physicians and other entities in the form of hardware, software or information technology and training services that are necessary and used solely to receive and transmit electronic prescription information are allowed.
- Under these regulations, permissible donors and recipients do not apply to pharmaceutical companies, device manufacturers or vendors, durable medical equipment manufacturers or vendors, or health information technology vendors.
- **Electronic health records** (EHR) items and services in the form of software or information technology and training services that are necessary and used predominately to create, maintain, transmit, or receive EHR can be furnished to allowed parties by allowed donors.
- Hardware and staff donations are not allowed for EHR, the software and services offered for EHR do not have to be “solely used” for this purpose, and that the recipient of EHR donations must provide 15% of the cost prior to receipt of the donations. Donated EHR software and services must support electronic prescribing services and be interoperable.
- The exceptions and safe harbors allowed by these regulations will sunset on December 31, 2013.

Background on Stark Regulation

The Centers for Medicare & Medicaid Services (CMS) issued part three (and final) of the interpretations and clarifications of regulations implementing the rules regarding physician self-referral prohibition (Stark). This final rule was published in the Federal Register on August 27, 2007, with a date of September 5, 2007, Vol. 72, No. 171, pp. 51012-51099.¹ The rule reflects the final interpretation of Section 1877 of the Social Security Act (known as the “physician self-referral law” or “Stark law”)² by the Secretary of the Department of Health and Human Services (DHHS), Michael Leavitt, and is effective on December 4, 2007.³ As the third part of the enactment of this law, Phase III is meant to be interpreted in light of Phase I (enforced as of January 1, 1995) and Phase II (enforced as of July 26, 2004).³ This civil law was established for two main purposes:

- 1) “Prohibits a physician from making referrals for certain “designated health services” (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies”³
- 2) “Prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those services”³

In Section 1877 of the Social Security Act (the Act), 11 services are designated as DHS:⁴

- Clinical laboratory services
- Physical therapy services
- Occupational therapy services
- Radiology services, including magnetic resonance imaging, computerized axial tomography, and ultrasound services
- Radiation therapy services and supplies
- Durable medical equipment and supplies
- Parenteral and enteral nutrients, equipment, and supplies
- Prosthetics, orthotics, and prosthetic devices and supplies
- Home health services
- Outpatient prescription drugs
- Inpatient and outpatient hospital services⁴

The intent of this law is to prevent unnecessary services to CMS beneficiaries and charges to CMS by physicians due to financial incentives for ordering excess tests and services. The Stark law is applicable to physicians, but when applying its rules to business practices, care should be taken to comply with the Federal anti-kickback statute (section 1128B(b) of the Act) which applies more broadly and includes both civil and criminal penalties for violations.⁵

Exceptions to the referral prohibitions of the Stark law are found in paragraph 411.357 of the CMS Federal Register document. Section U. of Stark III of the exemptions addresses

¹ Federal Register, Wednesday September 5, 2007, 42 CFR Parts 411 and 424, Vol. 72, No. 171.

² CMS Press Releases, Details for: “CMS issues final rule prohibiting physician self-referral”, <http://www.cms.hhs.gov/apps/media/press>, 9/20/2007.

³ Federal Register, Wednesday September 5, 2007, 42 CFR Parts 411 and 424, Vol. 72, No. 171, p. 51012.

⁴ Compilation of the Social Security Laws, Section 1877 Limitation on Certain Physician Referrals, http://www.ssa.gov/OP_Home/ssact/title18/1877.htm.

⁵ Federal Register, Wednesday September 5, 2007, 42 CFR Parts 411 and 424, Vol. 72, No. 171, p. 51013.

Community-Wide Health Information Systems. This section explains that the exception for community-wide health information system was made in Phase II of the Stark Law and that Phase III does not change this exception. This regulatory exception to the Stark law corresponds to safe harbors in the anti-kickback statute. Two of these exemptions include exceptions for providing electronic prescribing and electronic health records technology to physicians. These exemptions are covered under separate regulations as described in 70 FR 59182 and 71 FR 45140.⁵

Stark III and the Electronic Health Record

According to the Federal Register, exceptions for electronic prescribing and electronic health records are allowed if certain conditions are met. It is permissible to compensate physicians “in the form of items or services of information technology provided by an entity to a physician that allow access to, sharing of, electronic health care records and any complementary drug information systems, general health information, medical alerts, and related information for patients served by community providers and practitioners, in order to enhance the community’s overall health.”⁶ DHHS is “requiring compliance with criteria designed to safeguard against program and patient abuse”, but “both exceptions provide that neither the donor nor any person on the donor’s behalf may take any action to limit or restrict the use, compatibility or interoperability of the items or services. The electronic health records exception...requires interoperability **at the time the remuneration is provided to the physician**. Neither exception requires community-wide application.”⁶ DHHS will monitor the use of the electronic health record as an exception under the current rule and make changes in the future if needed because of misuse or need of clarification.

The following definitions are identified in Section 411.351:

- **Electronic health records** are 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”.⁷
- **Interoperable** is defined as “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”.⁷

Requirements for the exception of health information systems

- For **electronic prescribing** items and services used solely to receive and transmit electronic prescription information (non-monetary):⁸
 - May consist of items and services in the form of hardware, software, or information technology and training services
- Must meet all of the following
 - Items and services are provided by:
 - A hospital to a physician member of the medical staff

⁶ Federal Register, Wednesday September 5, 2007, 42 CFR Parts 411 and 424, Vol. 72, No. 171, p. 51068.

⁷ Federal Register, Wednesday September 5, 2007, 42 CFR Parts 411 and 424, Vol. 72, No. 171, p. 51080.

⁸ Federal Register, Wednesday September 5, 2007, 42 CFR Parts 411 and 424, Vol. 72, No. 171, p. 51097-51098.

- A group practice to a physician member of the group
- PDP (prescription drug plan) sponsor or MA (Medicare Advantage) organization to a prescribing physician
- Items and services are used with an electronic prescribing drug system that meets Medicare Part D standards.
- The donor does not limit or restrict the use of the items with other electronic prescription or health record systems.
- The donor permits the use of the items regardless of patient.
- The physician or physician practice cannot make the donation of the items a condition for doing business with the donor.
- The eligibility of the physician for the donation cannot in any way be attributed to the volume or value of the business between the two parties.
- Agreement between parties must be written.
- Donor does not provide items or services that the physician already possesses.

For **electronic health records** items and services necessary and used predominately to create, maintain, transmit, or receive electronic health records (non-monetary):⁸

- May consist of items and services in the form of software or information technology and training services
- Must meet all of the following
 - Provided by an entity to a physician
 - The software is interoperable at the time it is provided to the physician
 - Deemed to be interoperable by a certifying body recognized by the Secretary of DHHS no more than 12 months prior to the date it is provided to the physician
 - The donor does not restrict the use, compatibility, or interoperability of the items with other electronic prescribing or health records
 - The physician must pay 15% of the donor's costs for the items and services prior to receipt and the donor cannot finance these costs
 - The physician or physician practice cannot make the donation of the items a condition for doing business with the donor
 - The eligibility of the physician for the donation cannot in any way be attributed to the volume or value of the business between the two parties
 - Agreement between parties must be written
 - Donor does not provide items or services that the physician already possesses
 - The donor permits the use of the items regardless of patient
 - Items and services cannot include staffing of the physician office and cannot be used primarily for personal or practice related business
 - Items and services are used have an electronic drug prescribing system component that meets Medicare Part D standards
 - No part of services or items can violate the anti-kickback statute
 - All items and services must meet the above conditions by December 31, 2013.⁸

Penalties for violations of the Stark law are civil in nature and range from \$15,000 for each improper claim for DHS, \$100,000 for each improper arrangement or circumvention scheme,

and \$10,000 for each day for failure to report on time.⁹ Physicians and healthcare organizations should be aware that the separate, but important anti-kickback statute could also apply in certain situations that demonstrate intent to commit fraud regarding the Social Security Act under Section 1128 and are punishable by exclusion from federal healthcare programs, criminal penalties of up to \$25,000 in fines or up to five years in jail (or both) and a \$50,000 civil money penalty for each violation.¹⁰

Conclusion

The exceptions and safe harbors created in the Final Rule and the Anti-Kickback Statute regarding electronic prescribing and electronic health record technologies create opportunities for furnishing technology items and services to physicians and other health care providers if certain limitations are followed. These regulations are consistent with public policy that seeks to promote the availability and use of electronic health information technology. There are restrictions on who are donors and recipients, and which donors can donate to which recipients. For instance, the exception for electronic prescribing technology under the Stark Law does not allow hospitals to furnish technology items to entire physician groups unless each member of the group is on the medical staff of the hospital. There are also restrictions on what can be donated and to what extent. An example is that hardware can not be provided for electronic health records, but can be provided for sole-use electronic prescribing technology. Donations of electronic health records have an additional restriction in that the recipient must cover 15% of the donor's costs for any "donated" software or services. While the new safe harbors and exceptions provide opportunities for investing in and expanding electronic health information technology, care must be taken in adhering to the requirements of these regulations by all health care providers, practitioners, and suppliers.

The inclusion of an organization name, product or service in this white paper should not be construed as a HIMSS endorsement of such organization, product or service, nor is the failure to include an organization name, product or service to be construed as disapproval.

Please note that this summary is for reference use only and does not replace the original rules and regulations discussed and referenced.

⁹ Compilation of the Social Security Laws, Section 1128 Exclusion of Certain Individuals and Entities from Participation in Medicare and State Health Care Programs, http://www.ssa.gov/OP_Home/ssact/title11/1128.htm.

¹⁰ "The Stark Truth about the Stark Law: Part I", Family Practice Management, <http://www.aafp.org/fpm/20031100/27thes.html>, 10/1/2007.

Citations

1) “Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III)”, *Federal Register* (Center for Medicare and Medicaid Studies) September 5, 2007, Vol. 72, No. 171, pp. 51012-51099

Online available at:

<http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/07-4252.htm>

2) “Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III)”, *Federal Register* (Center for Medicare and Medicaid Studies) September 5, 2007, Vol. 72, No. 171, pp. 51012-51099

Online available at:

<http://a257.g.akamaitech.net/7/257/2422/01jan20071800/edocket.access.gpo.gov/2007/07-4252.htm>

3) *Ibid*

4) *Ibid*

5) *Ibid*

6) *Ibid*

7) *Ibid*

8) *Ibid*

9) *Ibid*

10) *Ibid*

Copyright 2008 by the Healthcare Information and Management Systems Society (HIMSS).