

MEDICARE FACT SHEET

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Physician Self-Referral Exceptions for Electronic Prescribing and Electronic Health Records Technology

BACKGROUND: Section 1877 of the Social Security Act (the Act), commonly referred to as the “Stark” law, prohibits a physician from making referrals for certain “designated health services” (DHS) payable by Medicare to an entity with which the physician (or an immediate family member of the physician) has a financial relationship, unless an exception applies. Section 1877 of the Act also prohibits the entity from submitting claims to Medicare or anyone else for Medicare DHS that are furnished as a result of a prohibited referral. Violations of the statute are punishable by denial of payment for all DHS claims, refund of amounts collected for DHS claims, and civil money penalties for knowing violations of the prohibition.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended the Act to establish a prescription drug benefit in the Medicare program. As part of the new benefit, the Congress directed the Secretary to establish standards for electronic prescribing with the objective of improving patient safety, quality of care, and efficiency in the delivery of care. Because the donation of electronic prescribing technology may create a financial relationship that is subject to the physician self-referral prohibition, the MMA directed the Secretary, in consultation with the Attorney General, to create an exception to the physician self-referral prohibition to permit certain entities to provide non-monetary assistance to physicians to encourage their use of electronic prescribing technology. This final rule (CMS-1303-F) sets forth the terms and conditions of the MMA-mandated physician self-referral electronic prescribing exception and also sets forth the conditions for a new regulatory exception for arrangements involving the donation of electronic health records software or information technology and training services. The MMA mandated a similar safe harbor under the anti-kickback statute for donations of electronic prescribing technology made to physicians and certain other entities. The HHS Office of Inspector General (OIG) is simultaneously issuing a final rule regarding the MMA-mandated anti-kickback statute safe harbor for certain electronic prescribing arrangements, as well as a safe harbor for the donation of electronic health records software or information technology and training services. Information about the OIG regulations can be found on the OIG website at www.oig.hhs.gov.

Exception for Electronic Prescribing Arrangements

To qualify for the physician self-referral exception regarding donations of electronic prescribing technology and training services, the following criteria must be satisfied, as fully set forth at 42 CFR § 411.357(v):

- The items and services must consist of hardware, software, or information technology and training services that are necessary and used solely to receive and transmit electronic prescription information;
- The items and services must be provided by a hospital to a physician who is a member of its medical staff; by a group practice to a physician who is a member of the group; or by a prescription drug plan sponsor or Medicare Advantage organization to a prescribing physician; and
- The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets applicable standards under Medicare Part D at the time the items and services are provided.
- The donor (or any person on the donor's behalf) does not take any action to limit or restrict the use or compatibility of the items or services with other electronic prescribing or electronic health records systems;
- 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 physician's right or ability to use the items or services for any patient;
- 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.
- Neither the eligibility of a physician for the items and services, nor the amount or nature of the items or services, is determined in a manner that takes into account the volume or value of referrals or other business generated between the parties;
- The arrangement is in writing, is signed by the parties, specifies the items and services being provided, identifies the cost to the donor of the items and services, and covers all of the electronic prescribing items and services to be provided by the donor. This requirement will be 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 should be maintained in a manner that preserves the historical record of agreements.
- 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.

Exception for Electronic Health Records Arrangements

To qualify for the physician self-referral exception regarding donations of electronic health records software or information technology and training services, the arrangement is required to satisfy the following criteria, as fully set forth at 42 CFR § 411.357(w):

- The software and training services must be necessary and used predominantly to create, maintain, transmit, or receive electronic health records;
- The items and services are provided to a physician by a hospital or other entity that furnishes designated health care services;
- The software is interoperable (as defined at §411.351) at the time it is provided to the physician. For purposes of the exception, “interoperable” means that the software is able to (i) communicate and exchange data accurately, effectively, securely, and consistently with different information technology systems, software applications, and networks, in various settings, and (ii) exchange data such that the clinical or operational purpose and meaning of the data are preserved and unaltered. 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 the date it is provided to the physician.
- 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;
- 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.
- 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.
- Neither the eligibility of a physician for the items and services, nor the amount or nature of the items and 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 requirement, 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 physician (but not the volume or value of prescriptions dispensed or paid by the donor or billed to the 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);

(iii) The determination is based on the total number of hours that the physician 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);

(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;

(vi) The determination is based on the level of uncompensated care provided by the physician; 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.

- The arrangement is in writing; is signed by the parties; specifies the items and services being provided, the cost to the donor of the items and services, and the amount of the physician's contribution; and covers all of the electronic health records items and services to be provided by the donor. This requirement will be 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 should be maintained in a manner that preserves the historical record of agreements.
- 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;
- For items or services that are of a 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 physician's right or ability to use the items or services for any patient;
- 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 physician's medical practice;
- 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;

- The arrangement does not violate the anti-kickback statute or any Federal or State law or regulation governing billing or claims submission; and
- The transfer of the items or services occurs on or before December 31, 2013.