

(i) A *receiving facility* is a hospital or other facility that provides emergency medical services.

(ii) An *ambulance provider* is a provider or supplier of ambulance transport services that provides emergency ambulance services. The term does not include a provider of ambulance transport services that provides only non-emergency transport services.

(iii) A *first responder* includes, but is not limited to, a fire department, paramedic service or search and rescue squad that responds to an emergency call (through 9–1–1 or other emergency access number) and treats the patient, but does not transport the patient to the hospital or other receiving facility.

(iv) An *emergency ambulance service* is a transport by ambulance initiated as a result of a call through 9–1–1 or other emergency access number or a call from another acute care facility unable to provide the higher level care required by the patient and available at the receiving facility.

(v) *Medical supplies* includes linens, unless otherwise provided.

[57 FR 3330, Jan. 29, 1992, as amended at 57 FR 52729, Nov. 5, 1992; 61 FR 2135, Jan. 25, 1996; 64 FR 63513, Nov. 19, 1999; 64 FR 63551, Nov. 19, 1999; 64 FR 71317, Dec. 21, 1999; 66 FR 62989, Dec. 4, 2001; 66 FR 63749, Dec. 10, 2001; 67 FR 11933, Mar. 18, 2002]

EFFECTIVE DATE NOTE: At 71 FR 45136, Aug. 8, 2006, §1001.952 was amended by republishing the introductory text, by adding and reserving paragraph (w), and by adding new paragraphs (x) and (y), effective Oct. 10, 2006. For the convenience of the user, the added text is set forth as follows:

**§ 1001.952 Exceptions.**

The following payment practices shall not be treated as a criminal offense under section 1128B of the Act and shall not serve as the basis for an exclusion:

\* \* \* \* \*

**(x) Electronic prescribing 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 hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information, if all of the following conditions are met:

(1) The items and services are provided by a—

(i) Hospital to a physician who is a member of its medical staff;

(ii) Group practice to a prescribing health care professional who is a member of the group practice; and

(iii) A PDP sponsor or MA organization to pharmacists and pharmacies participating in the network of such sponsor or organization and to prescribing health care professionals.

(2) The items and services are provided as part of, or are used to access, an electronic prescription drug program that meets the applicable standards under Medicare Part D at the time the items and services are provided.

(3) 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.

(4) 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.

(5) 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 recipient for the items or 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.

(7) The arrangement is set forth in a written agreement that—

(i) Is signed by the parties;

(ii) Specifies the items and services being provided and the donor’s cost of the items and services; and

(iii) Covers all of the electronic prescribing items and services to be provided by the donor (or affiliated parties). 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 recipient possesses or has obtained items or services equivalent to those provided by the donor.

NOTE TO PARAGRAPH (X): For purposes of paragraph (x) of this section, *group practice* shall have the meaning set forth at 42 CFR 411.352; *member of the group practice* shall mean all persons covered by the definition of

“member of the group or member of a group practice” at 42 CFR 411.351, as well as other prescribing health care professionals who are owners or employees of the group practice; *prescribing health care professional* shall mean a physician or other health care professional licensed to prescribe drugs in the State in which the drugs are dispensed; *PDP sponsor* or *MA organization* shall have the meanings set forth at 42 CFR 423.4 and 422.2, respectively; *prescription information* shall mean information about prescriptions for drugs or for any other item or service normally accomplished through a written prescription; 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.

(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 de-

termination 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 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.

(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(1)(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.

**§ 1001.1001 Exclusion of entities owned or controlled by a sanctioned person.**

(a) *Circumstance for exclusion.* (1) The OIG may exclude an entity if:

(i) A person with a relationship with such entity—

(A) Has been convicted of a criminal offense as described in sections 1128(a) and 1128(b) (1), (2) or (3) of the Act;

(B) Has had civil money penalties or assessments imposed under section 1128A of the Act; or

(C) Has been excluded from participation in Medicare or any of the State health care programs, and

(ii) Such a person—

(A)(1) Has a direct or indirect ownership interest (or any combination

thereof) of 5 percent or more in the entity;

(2) Is the owner of a whole or part interest in any mortgage, deed of trust, note or other obligation secured (in whole or in part) by the entity or any of the property assets thereof, in which whole or part interest is equal to or exceeds 5 percent of the total property and assets of the entity;

(3) Is an officer or director of the entity, if the entity is organized as a corporation;

(4) Is partner in the entity, if the entity is organized as a partnership;

(5) Is an agent of the entity; or

(6) Is a managing employee, that is, an individual (including a general manager, business manager, administrator or director) who exercises operational or managerial control over the entity or part thereof, or directly or indirectly conducts the day-to-day operations of the entity or part thereof, or

(B) Was formerly described in paragraph (a)(1)(ii)(A) of this section, but is no longer so described because of a transfer of ownership or control interest to an immediate family member or a member of the person's household as defined in paragraph (a)(2) of this section, in anticipation of or following a conviction, assessment of a CMP, or imposition of an exclusion.

(2) For purposes of this section, the term:

*Agent* means any person who has express or implied authority to obligate or act on behalf of an entity.

*Immediate family member* means, a person's husband or wife; natural or adoptive parent; child or sibling; step-parent, stepchild, stepbrother or step-sister; father-, mother-, daughter-, son-, brother- or sister-in-law; grandparent or grandchild; or spouse of a grandparent or grandchild.

*Indirect ownership interest* includes an ownership interest through any other entities that ultimately have an ownership interest in the entity in issue. (For example, an individual has a 10 percent ownership interest in the entity at issue if he or she has a 20 percent ownership interest in a corporation that wholly owns a subsidiary that is a 50 percent owner of the entity in issue.)

*Member of household* means, with respect to a person, any individual with