

(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

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whom they are sharing a common abode as part of a single family unit, including domestic employees and others who live together as a family unit. A roomer or boarder is not considered a member of household.

Ownership interest means an interest in:

(i) The capital, the stock or the profits of the entity, or

(ii) Any mortgage, deed, trust or note, or other obligation secured in whole or in part by the property or assets of the entity.

(b) *Length of exclusion.* (1) Except as provided in §1001.3002(c), exclusions under this section will be for the same period as that of the individual whose relationship with the entity is the basis for this exclusion, if the individual has been or is being excluded.

(2) If the individual was not excluded, the length of the entity's exclusion will be determined by considering the factors that would have been considered if the individual had been excluded.

(3) An entity excluded under this section may apply for reinstatement at any time in accordance with the procedures set forth in §1001.3001(a)(2).

[57 FR 3330, Jan. 29, 1992, as amended at 64 FR 39427, July 22, 1999]

§ 1001.1051 Exclusion of individuals with ownership or control interest in sanctioned entities.

(a) *Circumstance for exclusion.* The OIG may exclude any individual who—

(1) Has a direct or indirect ownership or control interest in a sanctioned entity, and who knows or should know (as defined in section 1128A(i)(6) of the Act) of the action constituting the basis for the conviction or exclusion set forth in paragraph (b) of this section; or

(2) Is an officer or managing employee (as defined in section 1126(b) of the Act) of such an entity.

(b) For purposes of paragraph (a) of this section, the term “sanctioned entity” means an entity that—

(1) Has been convicted of any offense described in §§ 1001.101 through 1001.401 of this part; or

(2) Has been terminated or excluded from participation in Medicare, Medicaid and all other Federal health care programs.

(c) *Length of exclusion.* (1) If the entity has been excluded, the length of the individual's exclusion will be for the same period as that of the sanctioned entity with which the individual has the prohibited relationship.

(2) If the entity was not excluded, the length of the individual's exclusion will be determined by considering the factors that would have been considered if the entity had been excluded.

(3) An individual excluded under this section may apply for reinstatement in accordance with the procedures set forth in §1001.3001.

[63 FR 46689, Sept. 2, 1998]

§ 1001.1101 Failure to disclose certain information.

(a) *Circumstance for exclusion.* The OIG may exclude any entity that did not fully and accurately, or completely, make disclosures as required by section 1124, 1124A or 1126 of the Act, and by part 455, subpart B and part 420, subpart C of this title.

(b) *Length of exclusion.* The following factors will be considered in determining the length of an exclusion under this section—

(1) The number of instances where full and accurate, or complete, disclosure was not made;

(2) The significance of the undisclosed information;

(3) Whether the individual or entity has a documented history of criminal, civil or administrative wrongdoing (The lack of any prior record is to be considered neutral);

(4) Any other facts that bear on the nature or seriousness of the conduct;

(5) The availability of alternative sources of the type of health care services provided by the entity; and

(6) The extent to which the entity knew that the disclosures made were not full or accurate.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46689, Sept. 2, 1998]

§ 1001.1201 Failure to provide payment information.

(a) *Circumstance for exclusion.* The OIG may exclude any individual or entity that furnishes items or services for which payment may be made under Medicare or any of the State health care programs and that: