

## § 1001.101

(3) Is the only source of specialized services in a reasonably defined service area where services by a non-specialist could not be substituted for the source without jeopardizing the health or safety of beneficiaries.

*State health care program* means:

(a) A State plan approved under title XIX of the Act (Medicaid),

(b) Any program receiving funds under title V of the Act or from an allotment to a State under such title (Maternal and Child Health Services Block Grant program), or

(c) Any program receiving funds under title XX of the Act or from any allotment to a State under such title (Block Grants to States for Social Services).

*State Medicaid Fraud Control Unit* means a unit certified by the Secretary as meeting the criteria of 42 U.S.C. 1396b(q) and § 1002.305 of this chapter.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46686, Sept. 2, 1998; 64 FR 39426, July 22, 1999]

### Subpart B—Mandatory Exclusions

#### § 1001.101 Basis for liability.

The OIG will exclude any individual or entity that—

(a) Has been convicted of a criminal offense related to the delivery of an item or service under Medicare or a State health care program, including the performance of management or administrative services relating to the delivery of items or services under any such program;

(b) Has been convicted, under Federal or State law, of a criminal offense related to the neglect or abuse of a patient, in connection with the delivery of a health care item or service, including any offense that the OIG concludes entailed, or resulted in, neglect or abuse of patients (the delivery of a health care item or service includes the provision of any item or service to an individual to meet his or her physical, mental or emotional needs or well-being, whether or not reimbursed under Medicare, Medicaid or any Federal health care program);

(c) Has been convicted, under Federal or State law, of a felony that occurred after August 21, 1996, relating to fraud, theft, embezzlement, breach of fidu-

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ciary responsibility, or other financial misconduct—

(1) In connection with the delivery of a health care item or service, including the performance of management or administrative services relating to the delivery of such items or services, or

(2) With respect to any act or omission in a health care program (other than Medicare and a State health care program) operated by, or financed in whole or in part, by any Federal, State or local government agency; or

(d) Has been convicted, under Federal or State law, of a felony that occurred after August 21, 1996 relating to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance, as defined under Federal or State law. This applies to any individual or entity that—

(1) Is, or has ever been, a health care practitioner, provider or supplier;

(2) Holds, or has held, a direct or indirect ownership or control interest (as defined in section 1124(a)(3) of the Act) in an entity that is a health care provider or supplier, or is, or has ever been, an officer, director, agent or managing employee (as defined in section 1126(b) of the Act) of such an entity; or

(3) Is, or has ever been, employed in any capacity in the health care industry.

[63 FR 46686, Sept. 2, 1998, as amended at 67 FR 11932, Mar. 18, 2002]

#### § 1001.102 Length of exclusion.

(a) No exclusion imposed in accordance with § 1001.101 will be for less than 5 years.

(b) Any of the following factors may be considered to be aggravating and a basis for lengthening the period of exclusion—

(1) The acts resulting in the conviction, or similar acts, that caused, or were intended to cause, a financial loss to a Government program or to one or more entities of \$5,000 or more. (The entire amount of financial loss to such programs or entities, including any amounts resulting from similar acts not adjudicated, will be considered regardless of whether full or partial restitution has been made);