

and proposing exclusions, as well as to Administrative Law Judges (ALJs), the Departmental Appeals Board (DAB), and federal courts in reviewing the imposition of exclusions by the OIG (and, where applicable, in imposing exclusions proposed by the OIG).

[57 FR 3330, Jan. 29, 1992, as amended at 58 FR 5618, Jan. 22, 1993; 64 FR 39426, July 22, 1999]

§ 1001.2 Definitions.

Controlled substance means a drug or other substance, or immediate precursor:

(a) Included in schedules I, II, III, IV or V of part B of subchapter I in 21 U.S.C. chapter 13, or

(b) That is deemed a controlled substance by the law of any State.

Convicted means that—

(a) A judgment of conviction has been entered against an individual or entity by a Federal, State or local court, regardless of whether:

(1) There is a post-trial motion or an appeal pending, or

(2) The judgment of conviction or other record relating to the criminal conduct has been expunged or otherwise removed;

(b) A Federal, State or local court has made a finding of guilt against an individual or entity;

(c) A Federal, State or local court has accepted a plea of guilty or *nolo contendere* by an individual or entity; or

(d) An individual or entity has entered into participation in a first offender, deferred adjudication or other program or arrangement where judgment of conviction has been withheld.

Exclusion means that items and services furnished, ordered or prescribed by a specified individual or entity will not be reimbursed under Medicare, Medicaid and all other Federal health care programs until the individual or entity is reinstated by the OIG.

Federal health care program means any plan or program providing health care benefits, whether directly through insurance or otherwise, that is funded directly, in whole or part, by the United States Government (other than the Federal Employees Health Benefits Program), or any State health care program as defined in this section.

HHS means Department of Health and Human Services.

Incarceration means imprisonment or any type of confinement with or without supervised release, including, but not limited to, community confinement, house arrest and home detention.

OIG means Office of Inspector General of the Department of Health and Human Services.

Patient means any individual who is receiving health care items or services, including any item or service provided to meet his or her physical, mental or emotional needs or well-being (including a resident receiving care in a facility as described in part 483 of this chapter), whether or not reimbursed under Medicare, Medicaid and any other Federal health care program and regardless of the location in which such item or service is provided.

QIO means Utilization and Quality Control Quality Improvement Organization as created by the Tax Equity and Fiscal Responsibility Act of 1982 (42 U.S.C. 1320c-3).

Professionally recognized standards of health care are Statewide or national standards of care, whether in writing or not, that professional peers of the individual or entity whose provision of care is an issue, recognize as applying to those peers practicing or providing care within a State. When the Department has declared a treatment modality not to be safe and effective, practitioners who employ such a treatment modality will be deemed not to meet professionally recognized standards of health care. This definition will not be construed to mean that all other treatments meet professionally recognized standards.

Sole community physician means a physician who is the only physician who provides primary care services to Federal or State health care program beneficiaries within a defined service area.

Sole source of essential specialized services in the community means that an individual or entity—

(1) Is the only practitioner, supplier or provider furnishing specialized services in an area designated by the Health Resources Services Administration as a health professional shortage

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area for that medical specialty, as listed in 42 part 5, appendices B–F;

(2) Is a sole community hospital, as defined in §412.92 of this title; or

(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 fiduciary 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