

(iii) Alternative sources of the type of health care items or services furnished by the individual or entity are not available.

[57 FR 3329, Jan. 29, 1992; 57 FR 9669, Mar. 20, 1992; 63 FR 46687, Sept. 2, 1998; 64 FR 39426, July 22, 1999; 82 FR 4112, Jan. 12, 2017]

§ 1001.401 Conviction relating to controlled substances.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity convicted under Federal or State law of a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance, as defined under Federal or State law. This section applies to any individual or entity that—

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

(2) Holds, or held, a direct or indirect ownership or control interest in an entity that furnished or furnishes items or services or is or has ever been an officer, director, agent, or managing employee of such an entity; or

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

(b) For purposes of this section, the definition of *controlled substance* will be the definition that applies to the law forming the basis for the conviction.

(c) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will be for a period of 3 years, unless aggravating or mitigating factors listed in paragraphs (c)(2) and (3) of this section form a basis for lengthening or shortening that period.

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

(i) The acts that resulted in the conviction or similar acts were committed over a period of one year or more;

(ii) The acts that resulted in the conviction or similar acts had a significant adverse mental, physical or financial impact on program beneficiaries or other individuals or the Medicare, Medicaid or other Federal health care programs;

(iii) The sentence imposed by the court included incarceration;

(iv) Whether the individual or entity has a documented history of criminal, civil, or administrative wrongdoing;

(v) Whether the individual or entity has been convicted of other offenses besides those that formed the basis for the exclusion; or

(vi) Whether the individual or entity has been the subject of any other adverse action by any Federal, State, or local government agency or board if the adverse action is based on the same set of circumstances that serves as the basis for the imposition of the exclusion.

(3) Only the following factor may be considered to be mitigating and to be a basis for shortening the period of exclusion: The individual's or entity's cooperation with Federal or State officials resulted in—

(i) Others being convicted or excluded from Medicare, Medicaid, and any other Federal health care program;

(ii) Additional cases being investigated or reports being issued by the appropriate law enforcement agency identifying program vulnerabilities or weaknesses; or

(iii) The imposition of a civil money penalty against others.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46687, Sept. 2, 1998; 64 FR 39426, July 22, 1999; 82 FR 4113, Jan. 12, 2017]

§ 1001.501 License revocation or suspension.

(a) *Circumstance for exclusion.* The OIG may exclude an individual or entity that has—

(1) Had a license to provide health care revoked or suspended by any State licensing authority, or has otherwise lost such a license (including the right to apply for or renew such a license), for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity; or

(2) Has surrendered such a license while a formal disciplinary proceeding concerning the individual's or entity's professional competence, professional performance or financial integrity was pending before a State licensing authority.