

(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.

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(b) *Length of exclusion.* (1) Except as provided in paragraph (b)(2) of this section, an exclusion imposed in accordance with this section will not be for a period of time less than the period during which an individual's or entity's license is revoked, suspended, or otherwise not in effect as a result of, or in connection with, a State licensing agency action.

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

(i) The acts that resulted in the revocation, suspension or loss of the individual's or entity's license to provide health care had or could have had a significant adverse physical, emotional or financial impact on one or more program beneficiaries or other individuals;

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

(iii) The acts, or similar acts, had or could have had a significant adverse impact on the financial integrity of the programs; or

(iv) The individual or entity has been the subject of any other adverse action by any other 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 if any of the aggravating factors listed in paragraph (b)(2) of this section justifies a longer exclusion may a mitigating factor be considered as a basis for reducing the period of exclusion to a period not less than that set forth in paragraph (b)(1) of this section. Only the following factor may be considered mitigating: The individual's or entity's cooperation with a State licensing authority resulted in—

(i) The sanctioning of other individuals or entities, or

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

(4) When an individual or entity has been excluded under this section, the OIG will consider a request for reinstatement in accordance with §1001.3001 if:

(i) The individual or entity obtains the license in the State where the license was originally revoked, suspended, surrendered, or otherwise lost or

(ii) The individual meets the conditions for early reinstatement set forth in paragraph (c) of this section.

(c) *Consideration of early reinstatement.* (1) If an individual or entity that is excluded in accordance with this section fully and accurately discloses the circumstances surrounding the action that formed the basis for the exclusion to a licensing authority of a different State or to a different licensing authority in the same State and that licensing authority grants the individual or entity a new health care license or has decided to take no adverse action as to a currently held health care license, the OIG will consider a request for early reinstatement. The OIG will consider the following factors in determining whether a request for early reinstatement under this paragraph (c)(1) will be granted:

(i) The circumstances that formed the basis for the exclusion;

(ii) Whether the second licensing authority is in a state that is not the individual's primary place of practice;

(iii) Evidence that the second licensing authority was aware of the circumstances surrounding the action that formed the basis for the exclusion;

(iv) Whether the individual has demonstrated that he or she has satisfactorily resolved any underlying problem that caused or contributed to the basis for the initial licensing action;

(v) The benefits to the Federal health care programs and program beneficiaries of early reinstatement;

(vi) The risks to the Federal health care programs and program beneficiaries of early reinstatement;

(vii) Any additional or pending license actions in any State;

(viii) Any ongoing investigations involving the individual; and

(ix) All the factors set forth in §1001.3002(b).

(2) If an exclusion has been imposed under this section and the individual does not have a valid health care license of any kind in any State, that individual may request the OIG to consider whether he or she may be eligible

for early reinstatement. The OIG will consider the following factors in determining whether a request for early reinstatement under this paragraph (c)(2) will be granted:

(i) The length of time the individual has been excluded. The OIG will apply a presumption against early reinstatement under paragraph (c)(2) of this section if the person has been excluded for less than 3 years; however, if the revocation or suspension on which the exclusion is based was for a set period longer than 3 years, the presumption against early reinstatement will be coterminal with the period set by the licensing board;

(ii) The circumstances that formed the basis for the exclusion;

(iii) Whether the individual has demonstrated that he or she has satisfactorily resolved any underlying problem that caused or contributed to the basis for the initial licensing action;

(iv) The benefits to the Federal health care programs and program beneficiaries of early reinstatement;

(v) The risks to the Federal health care programs and program beneficiaries of early reinstatement;

(vi) Any additional or pending license actions in any State;

(vii) Any ongoing investigations involving the individual; and

(viii) All the factors set forth in § 1001.3002(b).

(3) Notwithstanding paragraphs (c)(1) and (2) of this section, if an individual's license revocation or suspension was for reasons related to patient abuse or neglect, the OIG will not consider an application for early reinstatement.

(4) Except for § 1001.3002(a)(1)(i), all the provisions of subpart F (§§ 1001.3001 through 1001.3005) apply to early reinstatements under this section.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46688, Sept. 2, 1998; 82 FR 4113, Jan. 12, 2017]

§ 1001.601 Exclusion or suspension under a Federal or State health care program.

(a) *Circumstance for exclusion.* (1) The OIG may exclude an individual or entity suspended or excluded from participation, or otherwise sanctioned, under—

(i) Any Federal program involving the provision of health care, or

(ii) A State health care program, for reasons bearing on the individual's or entity's professional competence, professional performance or financial integrity.

(2) The term “or otherwise sanctioned” in paragraph (a)(1) of this section is intended to cover all actions that limit the ability of a person to participate in the program at issue regardless of what such an action is called, and includes situations where an individual or entity voluntarily withdraws from a program to avoid a formal sanction.

(b) *Length of exclusion.* (1) An exclusion imposed in accordance with this section will not be for a period of time less than the period during which the individual or entity is excluded or suspended from a Federal or State health care program.

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

(i) The acts that resulted in the exclusion, suspension or other sanction under Medicare, Medicaid and all other Federal health care programs had, or could have had, a significant adverse impact on Federal or State health care programs or the beneficiaries of those programs or other individuals;

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

(iii) 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 if any of the aggravating factors listed in paragraph (b)(2) of this section justifies a longer exclusion may a mitigating factor be considered as a basis for reducing the period of exclusion to a period not less than that set forth in paragraph (b)(1) of this section. Only the following factor may be considered mitigating: The individual's or entity's cooperation with Federal or State officials resulted in—

(i) The sanctioning of other individuals or entities, or