

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

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

(4) If the individual or entity is eligible to apply for reinstatement in accordance with §1001.3001 and the sole reason why the State or Federal health care program denied reinstatement to that program is the existing exclusion imposed by the OIG as a result of the original State or Federal health care program action, the OIG will consider a request for reinstatement.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46688, Sept. 2, 1998; 82 FR 4114, Jan. 12, 2017]

**§ 1001.701 Excessive claims or furnishing of unnecessary or substandard items and services.**

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

(1) Submitted, or caused to be submitted, bills or requests for payments under Medicare or any of the State health care programs containing charges or costs for items or services furnished that are substantially in excess of such individual's or entity's usual charges or costs for such items or services; or

(2) Furnished, or caused to be furnished, to patients (whether or not covered by Medicare or any of the State health care programs) any items or services substantially in excess of the patient's needs, or of a quality that fails to meet professionally recognized standards of health care.

(b) The OIG's determination under paragraph (a)(2) of this section—that the items or services furnished were excessive or of unacceptable quality—will be made on the basis of information, including sanction reports, from the following sources:

(1) The QIO for the area served by the individual or entity;

(2) State or local licensing or certification authorities;

(3) Fiscal agents or contractors, or private insurance companies;

(4) State or local professional societies; or

(5) Any other sources deemed appropriate by the OIG.

(c) Exceptions. An individual or entity will not be excluded for—

(1) Submitting, or causing to be submitted, bills or requests for payment that contain charges or costs substantially in excess of usual charges or costs when such charges or costs are due to unusual circumstances or medical complications requiring additional time, effort, expense or other good cause; or

(2) Furnishing, or causing to be furnished, items or services in excess of the needs of patients, when the items or services were ordered by a physician or other authorized individual, and the individual or entity furnishing the items or services was not in a position to determine medical necessity or to refuse to comply with the order of the physician or other authorized individual.

(d) *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 set forth in paragraphs (d)(2) and (d)(3) of this section form a basis for lengthening or shortening the period. In no case may the period be shorter than 1 year for any exclusion taken in accordance with paragraph (a)(2) of this section.

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

(i) The violations were serious in nature, and occurred over a period of one year or more;

(ii) The violations had a significant adverse physical, mental or financial impact on program beneficiaries or other individuals;

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

(iv) The violation resulted in financial loss to Medicare, Medicaid, or any other Federal health care program of \$15,000 or more; or

(v) 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.