

(e) Immediately after the ALJ's decision denying a request for a stay of the effective date under § 1005.22(b) of this title.

(f) If the ALJ grants a stay under § 1005.22(b) of this title, immediately after the judicial ruling is completed.

(g) Sixty days after the respondent receives the DAB's decision imposing a civil money penalty if the respondent has not requested a stay of the decision under § 1005.22(b) of this title.

§ 402.115 Collection of penalty or assessment.

(a) Once a determination by HHS has become final, CMS is responsible for the collection of any penalty or assessment.

(b) The General Counsel may compromise a penalty or assessment imposed under this part, after consultation with CMS or OIG, and the Federal government may recover the penalty or assessment in a civil action brought in the United States district court for the district where the claim was presented or where the respondent resides.

(c) The United States or a State agency may deduct the amount of a penalty and assessment when finally determined, or the amount agreed upon in compromise, from any sum then or later owing to the respondent.

(d) Matters that were raised or that could have been raised in a hearing before an ALJ or in an appeal under section 1128A(e) of the Act may not be raised as a defense in a civil action by the United States to collect a penalty under this part.

Subpart C—Exclusions

SOURCE: 72 FR 39752, July 20, 2007, unless otherwise noted.

§ 402.200 Basis and purpose.

(a) *Basis.* This subpart is based on the sections of the Act that are specified in § 402.1(e).

(b) *Purpose.* This subpart—

(1) Provides for the imposition of an exclusion from the Medicare and Medicaid programs (and, where applicable, other Federal health care programs) against persons that violate the provisions of the Act provided in § 402.1(e) (and further described in § 402.1(c)); and

(2) Sets forth the appeal rights of persons subject to exclusion and the procedures for reinstatement following exclusion.

§ 402.205 Length of exclusion.

The length of exclusion from participation in Medicare, Medicaid, and, where applicable, other Federal health care programs, is contingent upon the specific violation of the Medicare statute. A full description of the specific violations identified in the sections of the Act are cross-referenced in the regulatory sections listed in the table in paragraph (a) of this section.

(a) In no event will the period of exclusion exceed 5 years for violation of the following sections of the Act:

Social Security Act paragraph	Code of Federal Regulations section
1833(h)(5)(D) in repeated cases	§ 402.1(c)(1)
1833(q)(2)(B) in repeated cases	§ 402.1(c)(3)
1834(a)(11)(A)	§ 402.1(c)(4)
1834(a)(18)(B)	§ 402.1(c)(5)
1834(b)(5)(C)	§ 402.1(c)(6)
1834(c)(4)(C)	§ 402.1(c)(7)
1834(h)(3)	§ 402.1(c)(8)
1834(j)(4)	§ 402.1(c)(10)
1834(k)(6)	§ 402.1(c)(31)
1834(l)(6)	§ 402.1(c)(32)
1842(b)(18)(B)	§ 402.1(c)(11)
1842(k)	§ 402.1(c)(12)
1842(l)(3)	§ 402.1(c)(13)
1842(m)(3)	§ 402.1(c)(14)
1842(n)(3)	§ 402.1(c)(15)
1842(p)(3)(B) in repeated cases	§ 402.1(c)(16)
1848(g)(1)(B) in repeated cases	§ 402.1(c)(17)
1848(g)(3)(B)	§ 402.1(c)(18)
1848(g)(4)(B)(ii) in repeated cases	§ 402.1(c)(19)
1879(h)	§ 402.1(c)(23)

(b) For violation of the following sections, there is no maximum time limit for the period of exclusion.

Social Security Act paragraph	Code of Federal Regulations section
1834(a)(17)(c) for a pattern of contacts.	§ 402.1(e)(2)(i)
1834(h)(3) for a pattern of contacts	§ 402.1(e)(2)(ii)
1877(g)(5)	§ 402.1(c)(22)
1882(a)(2)	§ 402.1(c)(24)
1882(p)(8)	§ 402.1(c)(25)
1882(p)(9)(C)	§ 402.1(c)(26)
1882(q)(5)(C)	§ 402.1(c)(27)
1882(r)(6)(A)	§ 402.1(c)(28)
1882(s)(4)	§ 402.1(c)(29)
1882(t)(2)	§ 402.1(c)(30)

(c) For a person excluded under any of the grounds specified in paragraph (a) of this section, notwithstanding any

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other requirements in this section, reinstatement occurs—

(1) At the expiration of the period of exclusion, if the exclusion was imposed for a period of 5 years; or

(2) At the expiration of 5 years from the effective date of the exclusion, if the exclusion was imposed for a period of less than 5 years and the initiating agency did not receive the appropriate written request for reinstatement as specified in § 402.300.

§ 402.208 Factors considered in determining whether to exclude, and the length of exclusion.

(a) *General factors.* In determining whether to exclude a person and the length of exclusion, the initiating agency considers the following:

(1) The nature of the claims and the circumstances under which they were presented.

(2) The degree of culpability, the history of prior offenses, and the financial condition of the person presenting the claims.

(3) The total number of acts in which the violation occurred.

(4) The dollar amount at issue (Medicare Trust Fund dollars or beneficiary out-of-pocket expenses).

(5) The prior history of the person insofar as its willingness or refusal to comply with requests to correct said violations.

(6) Any other facts bearing on the nature and seriousness of the person's misconduct.

(7) Any other matters that justice may require.

(b) *Criteria to be considered.* As a guideline for taking into account the general factors listed in paragraph (a) of this section, the initiating agency may consider any one or more of the circumstances listed in paragraphs (b)(1) and (b)(2) of this section, as applicable. The respondent, in his or her written response to the notice of intent to exclude (that is, the proposed exclusion), may provide information concerning potential mitigating circumstances.

(1) *Aggravating circumstances.* An aggravating circumstance may be any of the following:

(i) The services or incidents were of several types and occurred over an extended period of time.

(ii) There were numerous services or incidents, or the nature and circumstances indicate a pattern of claims or requests for payment or a pattern of incidents, or whether a specific segment of the population was targeted.

(iii) Whether the person was held liable for criminal, civil, or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for health care items or services at any time before the incident or whether the person presented any claim or made any request for payment that included an item or service subject to a determination under § 402.1.

(iv) There is proof that the person engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to government programs and in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings at section 1128A(c)(1) of the Act does not apply to proof of other wrongful conducts as an aggravating circumstance.

(v) The wrongful conduct had an adverse impact on the financial integrity of the Medicare program or its beneficiaries.

(vi) The person was the subject of an adverse action by any other Federal, State, or local government agency or board, and the adverse action is based on the same set of circumstances that serves as a basis for the imposition of the exclusion.

(vii) The noncompliance resulted in a financial loss to the Medicare program of at least \$5,000.

(viii) The number of instances for which full, accurate, and complete disclosure was not made as required, or provided as requested, and the significance of the undisclosed information.

(2) *Mitigating circumstances.* A mitigating circumstance may be any of the following:

(i) All incidents of noncompliance were few in nature and of the same type, occurred within a short period of time, and the total amount claimed or

requested for the items or services provided was less than \$1,500.

(ii) The claim(s) or request(s) for payment for the item(s) or service(s) provided by the person were the result of an unintentional and unrecognized error in the person's process for presenting claims or requesting payment, and the person took corrective steps promptly after the error was discovered.

(iii) Previous cooperation with a law enforcement or regulatory entity resulted in convictions, exclusions, investigations, reports for weaknesses, or civil money penalties against other persons.

(iv) Alternative sources of the type of health care items or services furnished by the person are not available to the Medicare population in the person's immediate area.

(v) The person took corrective action promptly upon learning of the non-compliance from the person's employee or contractor, or by the Medicare contractor.

(vi) The person had a documented mental, emotional, or physical condition before or during the commission of the noncompliant act(s) and that condition reduces the person's culpability for the acts in question.

(vii) The completeness and timeliness of refunding to the Medicare Trust Fund or Medicare beneficiaries any inappropriate payments.

(viii) The degree of culpability of the person in failing to provide timely and complete refunds.

(3) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature are taken into account if, in the interest of justice, those circumstances require either a reduction or increase in the sanction to ensure achievement for the purposes of this subpart.

(4) *Initiating agency authority.* Nothing in this section limits the authority of the initiating agency to settle any issue or case as provided by § 402.17, or to compromise any penalty and assessment as provided by § 402.115.

§ 402.209 Scope and effect of exclusion.

(a) *Scope of exclusion.* Under this title, persons may be excluded from the Medicare, Medicaid, and, where appli-

cable, any other Federal health care programs.

(b) *Effect of exclusion on a person(s).*

(1) Unless and until an excluded person is reinstated into the Medicare program, no payment is made by Medicare, Medicaid, and, where applicable, any other Federal health care programs for any item or service furnished by the excluded person or at the direction or request of the excluded person when the person furnishing the item or service knew or had reason to know of the exclusion, on or after the effective date of the exclusion as specified in the notice of exclusion.

(2) An excluded person may not take assignment of a Medicare beneficiary's claim on or after the effective date of the exclusion.

(3) An excluded person that submits, or causes to be submitted, claims for items or services furnished during the exclusion period is subject to civil money penalty liability under section 1128A(a)(1)(D) of the Act, and criminal liability under section 1128B(a)(3) of the Act. In addition, submission of claims, or the causing of claims to be submitted for items or services furnished, ordered, or prescribed, by an excluded person may serve as the basis for denying reinstatement to the Medicare program.

(c) *Exceptions.* (1) If a Medicare beneficiary or other person (including a supplier) submits an otherwise payable claim for items or services furnished by an excluded person, or under the medical direction or on the request of an excluded person after the effective date of the exclusion, CMS pays the first claim submitted by the beneficiary or other person and immediately notifies the claimant of the exclusion. CMS does not pay a beneficiary or other person (including a supplier) for items or services furnished by, or under, the medical direction of an excluded person more than 15 days after the date on the notice to the beneficiary or other person (including a supplier), or after the effective date of the exclusion, whichever is later.

(2) Notwithstanding the other provisions of this section, payment may be made for certain emergency items or services furnished by an excluded person, or under the medical direction or

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on the request of an excluded person during the period of exclusion. To be payable, a claim for the emergency items or services must be accompanied by a sworn statement of the person furnishing the items or services, specifying the nature of the emergency and the reason that the items or services were not furnished by a person eligible to furnish or order the items or services. No claim for emergency items or services is payable if those items or services were provided by an excluded person that, through employment, contractual, or under any other arrangement, routinely provides emergency health care items or services.

§ 402.210 Notices.

(a) *Notice of proposed determination to exclude.* When the initiating agency proposes to exclude a person from participation in a Federal health care program in accordance with this part, notice of the proposed determination to exclude must be given in writing, and delivered or sent by certified mail, return receipt requested. The written notice must include, at a minimum—

- (1) Reference to the statutory basis for the exclusion.
- (2) A description of the claims, requests for payment, or incidents for which the exclusion is proposed.
- (3) The reason why those claims, requests for payments, or incidents subject the person to an exclusion.
- (4) The length of the proposed exclusion.
- (5) A description of the circumstances that were considered when determining the period of exclusion.
- (6) Instructions for responding to the notice, including a specific statement of the person's right to submit documentary evidence and a written response concerning whether the exclusion is warranted, and any related issues such as potential mitigating circumstances. The notice must specify that—
 - (i) The person has the right to request an opportunity to meet with an official of the initiating agency to make an oral presentation; and
 - (ii) The request to make an oral presentation must be submitted within 30 days of the receipt of the notice of intent to exclude.

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(7) If a person fails, within the time permitted under § 402.212, to exercise the right to respond to the notice of proposed determination to exclude, the initiating agency may initiate actions for the imposition of the exclusion.

(b) *Notice of exclusion.* Once the initiating agency determines that the exclusion is warranted, a written notice of exclusion is sent to the person in the same manner as described in paragraph (a) of this section. The exclusion is effective 20 days from the date of the notice. The written notice must include, at a minimum, the following:

- (1) The basis for the exclusion.
- (2) The length of the exclusion and, when applicable, the factors considered in setting the length.
- (3) The effect of exclusion.
- (4) The earliest date on which the initiating agency considers a request for reinstatement.
- (5) The requirements and procedures for reinstatement.
- (6) The appeal rights available to the excluded person under part 1005 of this title.

(c) *Amendment to the notice of exclusion.* No later than 15 days before the final exhibit exchanges required under § 1005.8 of this title, the initiating agency may amend the notice of exclusion if information becomes available that justifies the imposition of a period of exclusion other than the one proposed in the original written notice.

§ 402.212 Response to notice of proposed determination to exclude.

(a) A person that receives a notice of intent to exclude (that is, the proposed determination) as described in § 402.210, may present to the initiating agency a written response stating whether the proposed exclusion is warranted, and may present additional supportive documentation. The person must submit this response within 60 days of the receipt of notice. The initiating agency reviews the materials presented and initiates a response to the person regarding the argument presented, and any changes to the determination, if appropriate.

(b) The person is also afforded an opportunity to make an oral presentation to the initiating agency concerning

whether the proposed exclusion is warranted and any related matters. The person must submit this request within 30 days of the receipt of notice. Within 15 days of receipt of the person's request, the initiating agency initiates communication with the person to establish a mutually agreed upon time and place for the oral presentation and discussion.

§ 402.214 Appeal of exclusion.

(a) The procedures in part 1005 of this title apply to all appeals of exclusions. References to the Inspector General in that part apply to the initiating agency.

(b) A person excluded under this subpart may file a request for a hearing before an administrative law judge (ALJ) only on the issues of whether—

(1) The basis for the imposition of the exclusion exists; and

(2) The duration of the exclusion is unreasonable.

(c) When the initiating agency imposes an exclusion for a period of 1 year or less, paragraph (b)(2) of this section does not apply.

(d) The excluded person must file a request for a hearing within 60 days from the receipt of notice of exclusion. The effective date of an exclusion is not delayed beyond the date stated in the notice of exclusion simply because a request for a hearing is timely filed (see paragraph (g) of this section).

(e) A timely filed written request for a hearing must include—

(1) A statement as to the specific issues or findings of fact and conclusions of law in the notice of exclusion with which the person disagrees.

(2) Basis for the disagreement.

(3) The general basis for the defenses that the person intends to assert.

(4) Reasons why the proposed length of exclusion should be modified.

(5) Reasons, if applicable, why the health or safety of Medicare beneficiaries receiving items or services does not warrant the exclusion going into or remaining in effect before the completion of an ALJ proceeding in accordance with part 1005 of this title.

(f) If the excluded person does not file a written request for a hearing as provided in paragraph (d) of this section, the initiating agency notifies the ex-

cluded person, by certified mail, return receipt requested, that the exclusion goes into effect or continues in accordance with the notice of exclusion. The excluded person has no right to appeal the exclusion other than as described in this section.

(g) If the excluded person files a written request for a hearing, and asserts in the request that the health or safety of Medicare beneficiaries does not warrant the exclusion going into or remaining in effect before completion of an ALJ hearing, then the initiating agency may make a determination as to whether the exclusion goes into effect or continues pending the outcome of the ALJ hearing.

§ 402.300 Request for reinstatement.

(a) An excluded person may submit a written request for reinstatement to the initiating agency no sooner than 120 days prior to the terminal date of exclusion as specified in the notice of exclusion. The written request for reinstatement must include documentation demonstrating that the person has met the standards set forth in § 402.302. Obtaining or reactivating a Medicare provider number (or equivalent) does not constitute reinstatement.

(b) Upon receipt of a written request for reinstatement, the initiating agency may require the person to furnish additional, specific information, and authorization to obtain information from private health insurers, peer review organizations, and others as necessary to determine whether reinstatement is granted.

(c) Failure to submit a written request for reinstatement or to furnish the required information or authorization results in the continuation of the exclusion, unless the exclusion has been in effect for 5 years. In this case, reinstatement is automatic.

(d) If a period of exclusion is reduced on appeal (regardless of whether further appeal is pending), the excluded person may request and apply for reinstatement within 120 days of the expiration of the reduced exclusion period. A written request for the reinstatement includes the same standards as noted in paragraph (b) of this section.

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§ 402.302 Basis for reinstatement.

(a) The initiating agency authorizes reinstatement if it determines that—

(1) The period of exclusion has expired;

(2) There are reasonable assurances that the types of actions that formed the basis for the original exclusion did not recur and will not recur; and

(3) There is no additional basis under title XVIII of the Act that justifies the continuation of the exclusion.

(b) The initiating agency does not authorize reinstatement if it determines that submitting claims or causing claims to be submitted or payments to be made by the Medicare program for items or services furnished, ordered, or prescribed, may serve as a basis for denying reinstatement. This section applies regardless of whether the excluded person has obtained a Medicare provider number (or equivalent), either as an individual or as a member of a group, before being reinstated.

(c) In making a determination regarding reinstatement, the initiating agency considers the following:

(1) Conduct of the excluded person occurring before the date of the notice of the exclusion, if that conduct was not known to the initiating agency at the time of the exclusion;

(2) Conduct of the excluded person after the date of the exclusion;

(3) Whether all fines and all debts due and owing (including overpayments) to any Federal, State, or local government that relate to Medicare, Medicaid, or, where applicable, any Federal, State, or local health care program are paid in full, or satisfactory arrangements are made to fulfill these obligations;

(4) Whether the excluded person complies with, or has made satisfactory arrangements to fulfill, all of the applicable conditions of participation or conditions of coverage under the Medicare statutes and regulations; and

(5) Whether the excluded person has, during the period of exclusion, submitted claims, or caused claims to be submitted or payment to be made by Medicare, Medicaid, and, where applicable, any other Federal health care program, for items or services furnished, ordered, or prescribed, and the

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conditions under which these actions occurred.

(d) Reinstatement is not effective until the initiating agency grants the request and provides notices under § 402.304. Reinstatement is effective as provided in the notice.

(e) A determination for a denial of reinstatement is not appealable or reviewable except as provided in § 402.306.

(f) An ALJ may not require reinstatement of an excluded person in accordance with this chapter.

§ 402.304 Approval of request for reinstatement.

(a) If the initiating agency grants a request for reinstatement, the initiating agency—

(1) Gives written notice to the excluded person specifying the date of reinstatement; and

(2) Notifies appropriate Federal and State agencies, and, to the extent possible, all others that were originally notified of the exclusion, that the person is reinstated into the Medicare program.

(b) A determination by the initiating agency to reinstate an excluded person has no effect if Medicare, Medicaid, or, where applicable, any other Federal health care program has imposed a longer period of exclusion under its own authorities.

§ 402.306 Denial of request for reinstatement.

(a) If a request for reinstatement is denied, the initiating agency provides written notice to the excluded person. Within 30 days of the date of this notice, the excluded person may submit to the initiating agency:

(1) Documentary evidence and a written argument challenging the reinstatement denial; or

(2) A written request to present written evidence or oral argument to an official of the initiating agency.

(b) If a written request as described in paragraph (a)(2) of this section is received timely by the initiating agency, the initiating agency, within 15 days of receipt of the excluded person's request, initiates communication with the excluded person to establish a time and place for the requested meeting.

(c) After evaluating any additional evidence submitted by the excluded person (or at the end of the 30-day period described in paragraph (a) of this section, if no documentary evidence or written request is submitted), the initiating agency sends written notice to the excluded person either confirming the denial, or approving the reinstatement in the manner set forth in § 402.304. If the initiating agency elects to uphold its denial decision, the written notice also indicates that a subsequent request for reinstatement will not be considered until at least 1 year after the date of the written denial notice.

(d) The decision to deny reinstatement is not subject to administrative review.

§ 402.308 Waivers of exclusions.

(a) *Basis.* Section 1128(c)(3)(B) of the Act specifies that in the case of an exclusion from participation in the Medicare program based upon section 1128(a)(1), (a)(3), or (a)(4) of the Act, the individual may request that CMS present, on his or her behalf, a request to the OIG for a waiver of the exclusion.

(b) *Definitions.* For purposes of this section:

Excluded person has the same meaning as a “person” as defined in § 402.3 who meets for the purposes of this subpart, the definition of the term “exclusion” in § 402.3.

Hardship for purposes of this section means something that negatively affects Medicare beneficiaries and results from the imposition of an exclusion because the excluded person is the sole community physician or sole source of essential specialized services in the Medicare community.

Sole community physician has the same meaning as that term is defined § 1001.2 of this title.

Sole source of essential specialized services in the community has the same meaning as that term defined by the § 1001.2 of this title.

(c) *General rule.* If CMS determines that a hardship as defined in paragraph (b)(2) of this section results from exclusion of an affected person from the Medicare program, CMS may consider and may make a request to the Inspec-

tor General for waiver of the Medicare exclusion.

(d) *Submission and content of a waiver of exclusion request.* An excluded person must submit a request for waiver of exclusion in writing to CMS that includes the following:

(1) A copy of the exclusion notice from the OIG.

(2) A statement requesting that CMS present a waiver of exclusion request to the OIG on his or her behalf.

(3) A statement that he or she is the sole community physician or sole source of essential specialized services in the community.

(4) Documentation to support the statement in paragraph (d)(3) of this section.

(e) *Processing of waiver of exclusion requests.* CMS processes a request for a waiver of exclusion as follows:

(1) Notifies the submitter that the waiver of exclusion request has been received.

(2) Reviews and validates all submitted documents.

(3) During its analysis, CMS may require additional, specific information, and authorization to obtain information from private health insurers, peer review organizations (including, but not limited to, Quality Improvement Organizations), and others as necessary to determine validity.

(4) Makes a determination regarding whether or not to submit the waiver of exclusion request to the OIG based on review and validation of the submitted documents.

(5) If CMS elects to submit the waiver of exclusion request to the OIG, CMS copies the excluded person on the request.

(6) If CMS denies the request, then CMS notifies the excluded person of the decision and specifies the reason(s) for the decision.

(f) *Administrative or judicial review.* A determination rendered under paragraph (e)(4) of this section is not subject to administrative or judicial review.

PART 403—SPECIAL PROGRAMS AND PROJECTS

Subpart A [Reserved]