

(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 noncompliance 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 applicable, 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 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.

(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