

(b)(1)(i) With respect to any exclusion based on liability for a penalty or assessment under §1003.102 (a), (b)(1), or (b)(4), the OIG will consider an application from a State agency for a waiver if the person is the sole community physician or the sole source of essential specialized services in a community. With respect to any exclusion imposed under §1003.105(a)(1)(ii), the OIG will consider an application from a State agency for a waiver if the physician's exclusion from the State health care program would deny beneficiaries access to medical care or would otherwise cause hardship to beneficiaries.

(ii) If a waiver is granted, it is applicable only to the State health care program for which the State requested the waiver.

(iii) If the OIG subsequently obtains information that the basis for a waiver no longer exists, or the State agency submits evidence that the basis for the waiver no longer exists, the waiver will cease and the person will be excluded from the State health care program for the remainder of the period that the person is excluded from Medicare.

(iv) The OIG notifies the State agency whether its request for a waiver has been granted or denied.

(v) The decision to deny a waiver is not subject to administrative or judicial review.

(2) For purposes of this section, the definitions contained in §1001.2 of this chapter for "sole community physician" and "sole source of essential specialized services in a community" apply.

(c) When the Inspector General proposes to exclude a nursing facility from the Medicare and Medicaid programs, he or she will, at the same time he or she notifies the respondent, notify the appropriate State licensing authority, the State Office of Aging, the long-term care ombudsman, and the State Medicaid agency of the Inspector General's intention to exclude the facility.

[59 FR 32125, June 22, 1994, as amended at 64 FR 39429, July 22, 1999; 65 FR 24416, Apr. 26, 2000; 65 FR 35584, June 5, 2000]

§ 1003.106 Determinations regarding the amount of the penalty and assessment.

(a) *Amount of penalty.* (1) In determining the amount of any penalty or assessment in accordance with §1003.102(a), (b)(1), (b)(4) and (b)(9) through (b)(14) of this part, the Department will take into account—

(i) The nature of the claim, referral arrangement or other wrongdoing;

(ii) The degree of culpability of the person against whom a civil money penalty is proposed;

(iii) The history of prior offenses of the person against whom a civil money penalty is proposed;

(iv) The financial condition of the person against whom a civil money penalty is proposed;

(v) The completeness and timeliness of the refund with respect to §1003.102(b)(9);

(vi) The amount of financial interest involved with respect to §1003.102(b)(12);

(vii) The amount of remuneration offered or transferred with respect to §1003.102(b)(13); and

(viii) Such other matters as justice may require.

(2) In determining the amount of any penalty in accordance with §§1003.102 (b)(5) and (b)(6), the Department will take into account—

(i) The nature and circumstances of the failure to properly report information, or the improper disclosure of information, as required;

(ii) The degree of culpability of the person in failing to provide timely and complete data or in improperly disclosing, using or permitting access to information, as appropriate;

(iii) The materiality, or significance of omission, of the information to be reported, or the materiality of the improper disclosure of, or use of, or access to information, as appropriate;

(iv) Any prior history of the person with respect to violations of these provisions; and

(v) Such other matters as justice may require.

(3)(i) In determining the amount of any penalty in accordance with

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§ 1003.102(b)(7), the OIG will take into account—

(A) The nature and objective of the advertisement, solicitation or other communication, and the degree to which it has the capacity to deceive members of the public;

(B) The degree of culpability of the individual, organization or entity in the use of the prohibited words, letters, symbols or emblems;

(C) The frequency and scope of the violation, and whether a specific segment of the population was targeted;

(D) The prior history of the individual, organization or entity in its willingness or refusal to comply with informal requests to correct violations;

(E) The history of prior offenses of the individual, organization or entity in its misuse of Departmental and program words, letters, symbols and emblems;

(F) The financial condition of the individual, organization or entity involved with the violation; and

(G) Such other matters as justice may require.

(ii) The use of a disclaimer of affiliation with the United States Government, the Department or its programs will not be considered as a mitigating factor in determining the amount of penalty in accordance with § 1003.102(b)(7).

(4) In determining the amount of any penalty in accordance with § 1003.102(c), the OIG takes into account—

(i) The degree of culpability of the respondent;

(ii) The seriousness of the condition of the individual seeking emergency medical treatment;

(iii) The prior history of offenses of the respondent in failing to provide appropriate emergency medical screening, stabilization and treatment of individuals coming to a hospital's emergency department or to effect an appropriate transfer;

(iv) The respondent's financial condition;

(v) The nature and circumstances of the violation; and

(vi) Such other matters as justice may require.

(5) In determining the appropriate amount of any penalty in accordance

with § 1003.103(f), the OIG will consider as appropriate—

(i) The nature and scope of the required medically necessary item or service not provided and the circumstances under which it was not provided;

(ii) The degree of culpability of the contracting organization;

(iii) The seriousness of the adverse effect that resulted or could have resulted from the failure to provide required medically necessary care;

(iv) The harm which resulted or could have resulted from the provision of care by a person that the contracting organization is expressly prohibited, under section 1876(i)(6) or section 1903(p)(2) of the Act, from contracting with or employing;

(v) The harm which resulted or could have resulted from the contracting organization's expulsion or refusal to reenroll a Medicare beneficiary or Medicaid recipient;

(vi) The nature of the misrepresentation or fallacious information furnished by the contracting organization to the Secretary, State, enrollee or other entity under section 1876 or section 1903(m) of the Act;

(vii) The extent to which the failure to provide medically necessary services could be attributed to a prohibited inducement to reduce or limit services under a physician incentive plan and the harm to the enrollee which resulted or could have resulted from such failure. It would be considered an aggravating factor if the contracting organization knowingly or routinely engaged in any prohibited practice which acted as an inducement to reduce or limit medically necessary services provided with respect to a specific enrollee in the organization;

(viii) The history of prior offenses by the contracting organization or principals of the contracting organization, including whether, at any time prior to determination of the current violation or violations, the contracting organization or any of its principals were convicted of a criminal charge or were held liable for civil or administrative sanctions in connection with a program covered by this part or any other public or private program of payment for medical services; and

(ix) Such other matters as justice may require.

(b) *Determining the amount of the penalty or assessment.* As guidelines for taking into account the factors listed in paragraph (a)(1) of this section, the following circumstances are to be considered—

(1) *Nature and circumstances of the incident.* It should be considered a mitigating circumstance if all the items or services or incidents subject to a determination under §1003.102 included in the action brought under this part were of the same type and occurred within a short period of time, there were few such items or services or incidents, and the total amount claimed or requested for such items or services was less than \$1,000. It should be considered an aggravating circumstance if—

(i) Such items or services or incidents were of several types, occurred over a lengthy period of time;

(ii) There were many such items or services or incidents (or the nature and circumstances indicate a pattern of claims or requests for payment for such items or services or a pattern of incidents);

(iii) The amount claimed or requested for such items or services was substantial; or

(iv) The false or misleading information given resulted in harm to the patient, a premature discharge or a need for additional services or subsequent hospital admission.

(2) *Degree of culpability.* It should be considered a mitigating circumstance if corrective steps were taken promptly after the error was discovered. It should be considered an aggravating circumstance if—

(i) The respondent knew the item or service was not provided as claimed or if the respondent knew that the claim was false or fraudulent;

(ii) The respondent knew that the items or services were furnished during a period that he or she had been excluded from participation and that no payment could be made as specified in §§ 1003.102(a)(3) and 1003.102(b)(12), or because payment would violate the terms of an assignment or an agreement with a State agency or other agreement or

limitation on payment under §1003.102(b);

(iii) The respondent knew that the information could reasonably be expected to influence the decision of when to discharge a patient from a hospital; or

(iv) The respondent knew that the offer or transfer of remuneration described in §1003.102(b)(13) of this part would influence a beneficiary to order or receive from a particular provider, practitioner or supplier items or services reimbursable under Medicare or a State health care program.

(3) *Prior offenses.* It should be considered an aggravating circumstance if at any time prior to the incident or presentation of any claim or request for payment which included an item or service subject to a determination under §1003.102, the respondent 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 reimbursement for medical services.

(4) *Other wrongful conduct.* It should be considered an aggravating circumstance if there is proof that a respondent engaged in wrongful conduct, other than the specific conduct upon which liability is based, relating to government programs or in connection with the delivery of a health care item or service. The statute of limitations governing civil money penalty proceedings will not apply to proof of other wrongful conduct as an aggravating circumstance.

(5) *Financial condition.* In all cases, the resources available to the respondent will be considered when determining the amount of the penalty and assessment.

(6) *Other matters as justice may require.* Other circumstances of an aggravating or mitigating nature should be taken into account if, in the interests of justice, they require either a reduction of the penalty or assessment or an increase in order to assure the achievement of the purposes of this part.

(c) In determining the amount of the penalty and assessment to be imposed for every item or service or incident subject to a determination under §§ 1003.102(a), (b)(1) and (b)(4)—

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(1) If there are substantial or several mitigating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently below the maximum permitted by §§ 1003.103(a) and 1003.104, to reflect that fact.

(2) If there are substantial or several aggravating circumstances, the aggregate amount of the penalty and assessment should be set at an amount sufficiently close or at the maximum permitted by §§ 1003.103(a) and 1003.104, to reflect that fact.

(3) Unless there are extraordinary mitigating circumstances, the aggregate amount of the penalty and assessment should never be less than double the approximate amount of damages and costs (as defined in paragraph (f) of this section) sustained by the United States, or any State, as a result of claims or incidents subject to a determination under §§ 1003.102(a), (b)(1) and (b)(4).

(d) In considering the factors listed in paragraph (a)(4) of this section for violations subject to a determination under § 1003.103(e), the following circumstances are to be considered, as appropriate, in determining the amount of any penalty—

(1) *Degree of culpability.* It would be a mitigating circumstance if the respondent hospital had appropriate policies and procedures in place, and had effectively trained all of its personnel in the requirements of section 1867 of the Act and § 489.24 of this title, but an employee or responsible physician acted contrary to the respondent hospital's policies and procedures.

(2) *Seriousness of individual's condition.* It would be an aggravating circumstance if the respondent's violation(s) occurred with regard to an individual who presented to the hospital a request for treatment of a medical condition that was clearly an emergency, as defined by § 489.24(b) of this title.

(3) *Prior offenses.* It would be an aggravating circumstance if there is evidence that at any time prior to the current violation(s) the respondent was found to have violated any provision of section 1867 of the Act or § 489.24 of this title.

(4) *Financial condition.* In all cases, the resources available to the respondent

would be considered when determining the amount of the penalty. A respondent's audited financial statements, tax returns or financial disclosure statements, as appropriate, will be reviewed by OIG in making a determination with respect to the respondent's financial condition.

(5) *Nature and circumstances of the incident.* It would be considered a mitigating circumstance if an individual presented a request for treatment, but subsequently exhibited conduct that demonstrated a clear intent to leave the respondent hospital voluntarily. In reviewing such circumstances, the OIG would evaluate the respondent's efforts to—

(i) Provide the services required by section 1867 of the Act and § 489.24 of this title, despite the individual's withdrawal of the request for examination or treatment; and

(ii) Document any attempts to inform the individual (or his or her representative) of the risks of leaving the respondent hospital without receiving an appropriate medical screening examination or treatment, and obtain written acknowledgment from the individual (or his or her representative) prior to the individual's departure from the respondent hospital that he or she is leaving contrary to medical advice.

(6) *Other matters as justice may require.* (i) It would be considered a mitigating circumstance if the respondent hospital—

(A) Developed and implemented a corrective action plan;

(B) Took immediate appropriate action against any hospital personnel or responsible physician who violated section 1867 of the Act or § 489.24 of this title prior to any investigation of the respondent hospital by HCFA; or

(C) Is a rural or publicly-owned facility that is faced with severe physician staffing and financial deficiencies.

(ii) It would be considered an aggravating circumstance if an individual was severely harmed or died as a result, directly or indirectly, of the respondent's violation of section 1867 of the Act or § 489.24 of this title.

(iii) Other circumstances of an aggravating or mitigating nature will be taken into account if, in the interests

of justice, they require either a reduction of the penalty or an increase in order to assure the achievement of the purposes of this part.

(e) In considering the factors listed in paragraph (a)(5) of this section for violations subject to a determination under §1003.103(f), the following circumstances are to be considered, as appropriate, in determining the amount of any penalty—

(f)(1) The standards set forth in this section are binding, except to the extent that their application would result in imposition of an amount that would exceed limits imposed by the United States Constitution.

(2) The amount imposed will not be less than the approximate amount required to fully compensate the United States, or any State, for its damages and costs, tangible and intangible, including but not limited to the costs attributable to the investigation, prosecution and administrative review of the case.

(3) Nothing in this section will limit the authority of the Department to settle any issue or case as provided by §1003.126, or to compromise any penalty and assessment as provided by §1003.128.

[57 FR 3347, Jan. 29, 1992, as amended at 59 FR 32125, June 22, 1994; 59 FR 36086, July 15, 1994; 59 FR 48567, Sept. 22, 1994; 60 FR 16584, Mar. 31, 1995; 60 FR 58241, Nov. 27, 1995; 61 FR 13449, Mar. 27, 1996; 64 FR 39429, July 22, 1999; 65 FR 24416, Apr. 26, 2000]

§1003.107 Determinations regarding exclusion.

(a) In determining whether to exclude a person under this part and the duration of any exclusion, the Department considers the circumstances described in §1003.106(a).

(b) With respect to determinations to exclude a person under §§1003.102(a), (b)(1), (b)(4), (b)(12) or (b)(13) of this part, the Department considers those circumstances described in §1003.106(b). Where there are aggravating circumstances with respect to such determinations, the person should be excluded.

(c) The guidelines set forth in this section are not binding. Nothing in this section limits the authority of the De-

partment to settle any issue or case as provided by §1003.126 of this part.

[59 FR 32126, June 22, 1994, as amended at 65 FR 24418, Apr. 26, 2000]

§1003.108 Penalty, assessment, and exclusion not exclusive.

Penalties, assessments, and exclusions imposed under this part are in addition to any other penalties prescribed by law.

[59 FR 32126, June 22, 1994]

§1003.109 Notice of proposed determination.

(a) If the Inspector General proposes a penalty and, when applicable, assessment, or proposes to exclude a respondent from participation in a Federal health care program, as applicable, in accordance with this part, he or she must deliver or send by certified mail, return receipt requested, to the respondent written notice of his or her intent to impose a penalty, assessment and exclusion, as applicable. The notice includes—

(1) Reference to the statutory basis for the penalty, assessment and exclusion;

(2) A description of the claims, requests for payment, or incidents with respect to which the penalty, assessment and exclusion are proposed (except in cases where the Inspector General is relying upon statistical sampling in accordance with §1003.133 in which case the notice shall describe those claims and requests for payment comprising the sample upon which the Inspector General is relying and will also briefly describe the statistical sampling technique utilized by the Inspector General);

(3) The reason why such claims, requests for payments or incidents subject the respondent to a penalty, assessment and exclusion;

(4) The amount of the proposed penalty, assessment and the period of proposed exclusion (where applicable);

(5) Any circumstances described in §1003.106 that were considered when determining the amount of the proposed penalty and assessment and the period of exclusion;

(6) Instructions for responding to the notice, including—