

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 CMS; 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 pen-

alty 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; 67 FR 11935, Mar. 18, 2002]

#### **§ 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 Department 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;