

(b) If the OIG proposes to exclude an individual or entity under the provisions of §1001.701 or §1001.801 of this part, in conjunction with the submission of documentary evidence and written argument, an individual or entity may request an opportunity to present oral argument to an OIG official.

(c) *Exception.* If the OIG proposes to exclude an individual or entity under the provisions of §§1001.1301, 1001.1401 or 1001.1501 of this part, paragraph (a) of this section will not apply.

(d) If an entity has a provider agreement under section 1866 of the Act, and the OIG proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice provided for in paragraph (a) of this section will so state.

[63 FR 46690, Sept. 2, 1998, as amended at 63 FR 57918, Oct. 29, 1998]

§ 1001.2002 Notice of exclusion.

(a) Except as provided in §1001.2003, if the OIG determines that exclusion is warranted, it will send a written notice of this decision to the affected individual or entity.

(b) The exclusion will be effective 20 days from the date of the notice.

(c) The written notice will state—

(1) The basis for the exclusion;

(2) The length of the exclusion and, where applicable, the factors considered in setting the length;

(3) The effect of the exclusion;

(4) The earliest date on which the OIG will consider a request for reinstatement;

(5) The requirements and procedures for reinstatement; and

(6) The appeal rights available to the excluded individual or entity.

(d) Paragraph (b) of this section does not apply to exclusions imposed in accordance with §1001.1301.

(e) No later than 15 days prior to the final exhibit exchanges required under §1005.8 of this chapter, the OIG may amend its notice letter if information comes to light that justifies the imposition of a different period of exclusion other than the one proposed in the original notice letter.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998]

§ 1001.2003 Notice of proposal to exclude.

(a) Except as provided in paragraph (c) of this section, if the OIG proposes to exclude an individual or entity in accordance with §§1001.901, 1001.951, 1001.1601 or 1001.1701, it will send written notice of this decision to the affected individual or entity. The written notice will provide the same information set forth in §1001.2002(c). If an entity has a provider agreement under section 1866 of the Act, and the OIG also proposes to terminate that agreement in accordance with section 1866(b)(2)(C) of the Act, the notice will so indicate. The exclusion will be effective 60 days after the receipt of the notice (as defined in §1005.2 of this chapter) unless, within that period, the individual or entity files a written request for a hearing in accordance with part 1005 of this chapter. Such request must set forth—

(1) The specific issues or statements in the notice with which the individual or entity disagrees;

(2) The basis for that disagreement;

(3) The defenses on which reliance is intended;

(4) Any reasons why the proposed length of exclusion should be modified; and

(5) Reasons why the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant the exclusion going into effect prior to the completion of an administrative law judge (ALJ) proceeding in accordance with part 1005 of this chapter.

(b)(1) If the individual or entity does not make a written request for a hearing as provided for in paragraph (a) of this section, the OIG will send a notice of exclusion as described in §1001.2002.

(2) If the individual or entity makes a timely written request for a hearing and the OIG determines that the health or safety of individuals receiving services under Medicare or any of the State health care programs does not warrant immediate exclusion, an exclusion will only go into effect, with the date of the ALJ's decision, if the ALJ upholds the decision to exclude.

(c) If, prior to issuing a notice of proposal to exclude under paragraph (a) of this section, the OIG determines that

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the health or safety of individuals receiving services under Medicare or any of the State health care programs warrants the exclusion taking place prior to the completion of an ALJ proceeding in accordance with part 1005 of this chapter, the OIG will proceed under §§ 1001.2001 and 1001.2002.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998; 65 FR 24414, Apr. 26, 2000]

§ 1001.2004 Notice to State agencies.

HHS will promptly notify each appropriate State agency administering or supervising the administration of each State health care program of:

(a) The facts and circumstances of each exclusion, and

(b) The period for which the State agency is being directed to exclude the individual or entity.

§ 1001.2005 Notice to State licensing agencies.

(a) HHS will promptly notify the appropriate State(s) or local agencies or authorities having responsibility for the licensing or certification of an individual or entity excluded (or directed to be excluded) from participation of the facts and circumstances of the exclusion.

(b) HHS will request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and will request that the State or local agency or authority keep the Secretary and the OIG fully and currently informed with respect to any actions taken in response to the request.

§ 1001.2006 Notice to others regarding exclusion.

(a) HHS will give notice of the exclusion and the effective date to the public, to beneficiaries (in accordance with § 1001.1901(c)), and, as appropriate, to—

(1) Any entity in which the excluded individual is known to be serving as an employee, administrator, operator, or in which the individual is serving in any other capacity and is receiving payment for providing services (The lack of this notice will not affect CMS's ability to deny payment for services);

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(2) State Medicaid Fraud Control Units;

(3) Utilization and Quality Control Quality Improvement Organizations;

(4) Hospitals, skilled nursing facilities, home health agencies and health maintenance organizations;

(5) Medical societies and other professional organizations;

(6) Contractors, health care prepayment plans, private insurance companies and other affected agencies and organizations;

(7) The State and Area Agencies on Aging established under title III of the Older Americans Act;

(8) The National Practitioner Data Bank.

(9) Other Departmental operating divisions, Federal agencies, and other agencies or organizations, as appropriate.

(b) In the case of an exclusion under § 1001.101 of this chapter, if section 304(a)(5) of the Controlled Substances Act (21 U.S.C. 824(a)(5)) applies, HHS will give notice to the Attorney General of the United States of the facts and circumstances of the exclusion and the length of the exclusion.

[57 FR 3330, Jan. 29, 1992, as amended at 63 FR 46690, Sept. 2, 1998]

§ 1001.2007 Appeal of exclusions.

(a)(1) Except as provided in § 1001.2003, an individual or entity excluded under this Part may file a request for a hearing before an ALJ only on the issues of whether:

(i) The basis for the imposition of the sanction exists, and

(ii) The length of exclusion is unreasonable.

(2) When the OIG imposes an exclusion under subpart B of this part for a period of 5 years, paragraph (a)(1)(ii) of this section will not apply.

(3) The request for a hearing should contain the information set forth in § 1005.2(d) of this chapter.

(b) The excluded individual or entity has 60 days from the receipt of notice of exclusion provided for in § 1001.2002 to file a request for such a hearing.

(c) The standard of proof at a hearing is preponderance of the evidence.

(d) When the exclusion is based on the existence of a criminal conviction or a civil judgment imposing liability