

6403(d)(6) of Pub. L. 111-148, set out as a Transition Process; Regulations; Effective Date of 2010 Amendment note under section 1320a-7e of this title.

§ 1320a-7d. Guidance regarding application of health care fraud and abuse sanctions

(a) Solicitation and publication of modifications to existing safe harbors and new safe harbors

(1) In general

(A) Solicitation of proposals for safe harbors

Not later than January 1, 1997, and not less than annually thereafter, the Secretary shall publish a notice in the Federal Register soliciting proposals, which will be accepted during a 60-day period, for—

- (i) modifications to existing safe harbors issued pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 (42 U.S.C. 1320a-7b note);
- (ii) additional safe harbors specifying payment practices that shall not be treated as a criminal offense under section 1320a-7b(b) of this title and shall not serve as the basis for an exclusion under section 1320a-7(b)(7) of this title;
- (iii) advisory opinions to be issued pursuant to subsection (b); and
- (iv) special fraud alerts to be issued pursuant to subsection (c).

(B) Publication of proposed modifications and proposed additional safe harbors

After considering the proposals described in clauses (i) and (ii) of subparagraph (A), the Secretary, in consultation with the Attorney General, shall publish in the Federal Register proposed modifications to existing safe harbors and proposed additional safe harbors, if appropriate, with a 60-day comment period. After considering any public comments received during this period, the Secretary shall issue final rules modifying the existing safe harbors and establishing new safe harbors, as appropriate.

(C) Report

The Inspector General of the Department of Health and Human Services (in this section referred to as the “Inspector General”) shall, in an annual report to Congress or as part of the year-end semiannual report required by section 5 of the Inspector General Act of 1978 (5 U.S.C. App.), describe the proposals received under clauses (i) and (ii) of subparagraph (A) and explain which proposals were included in the publication described in subparagraph (B), which proposals were not included in that publication, and the reasons for the rejection of the proposals that were not included.

(2) Criteria for modifying and establishing safe harbors

In modifying and establishing safe harbors under paragraph (1)(B), the Secretary may consider the extent to which providing a safe harbor for the specified payment practice may result in any of the following:

- (A) An increase or decrease in access to health care services.

(B) An increase or decrease in the quality of health care services.

(C) An increase or decrease in patient freedom of choice among health care providers.

(D) An increase or decrease in competition among health care providers.

(E) An increase or decrease in the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

(F) An increase or decrease in the cost to Federal health care programs (as defined in section 1320a-7b(f) of this title).

(G) An increase or decrease in the potential overutilization of health care services.

(H) The existence or nonexistence of any potential financial benefit to a health care professional or provider which may vary based on their decisions of—

- (i) whether to order a health care item or service; or
- (ii) whether to arrange for a referral of health care items or services to a particular practitioner or provider.

(I) Any other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs (as so defined).

(b) Advisory opinions

(1) Issuance of advisory opinions

The Secretary, in consultation with the Attorney General, shall issue written advisory opinions as provided in this subsection.

(2) Matters subject to advisory opinions

The Secretary shall issue advisory opinions as to the following matters:

(A) What constitutes prohibited remuneration within the meaning of section 1320a-7b(b) of this title or section 1320a-7a(i)(6) of this title.

(B) Whether an arrangement or proposed arrangement satisfies the criteria set forth in section 1320a-7b(b)(3) of this title for activities which do not result in prohibited remuneration.

(C) Whether an arrangement or proposed arrangement satisfies the criteria which the Secretary has established, or shall establish by regulation for activities which do not result in prohibited remuneration.

(D) What constitutes an inducement to reduce or limit services to individuals entitled to benefits under subchapter XVIII or subchapter XIX within the meaning of section 1320a-7a(b) of this title.

(E) Whether any activity or proposed activity constitutes grounds for the imposition of a sanction under section 1320a-7, 1320a-7a, or 1320a-7b of this title.

(3) Matters not subject to advisory opinions

Such advisory opinions shall not address the following matters:

(A) Whether the fair market value shall be, or was paid or received for any goods, services or property.

(B) Whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

(4) Effect of advisory opinions**(A) Binding as to Secretary and parties involved**

Each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion.

(B) Failure to seek opinion

The failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections¹ 1320a-7, 1320a-7a, or 1320a-7b of this title.

(5) Regulations**(A) In general**

Not later than 180 days after August 21, 1996, the Secretary shall issue regulations to carry out this section. Such regulations shall provide for—

- (i) the procedure to be followed by a party applying for an advisory opinion;
- (ii) the procedure to be followed by the Secretary in responding to a request for an advisory opinion;
- (iii) the interval in which the Secretary shall respond;
- (iv) the reasonable fee to be charged to the party requesting an advisory opinion; and
- (v) the manner in which advisory opinions will be made available to the public.

(B) Specific contents

Under the regulations promulgated pursuant to subparagraph (A)—

- (i) the Secretary shall be required to issue to a party requesting an advisory opinion by not later than 60 days after the request is received; and
- (ii) the fee charged to the party requesting an advisory opinion shall be equal to the costs incurred by the Secretary in responding to the request.

(6) Application of subsection

This subsection shall apply to requests for advisory opinions made on or after the date which is 6 months after August 21, 1996.

(c) Special fraud alerts**(1) In general****(A) Request for special fraud alerts**

Any person may present, at any time, a request to the Inspector General for a notice which informs the public of practices which the Inspector General considers to be suspect or of particular concern under the Medicare program under subchapter XVIII or a State health care program, as defined in section 1320a-7(h) of this title (in this subsection referred to as a “special fraud alert”).

(B) Issuance and publication of special fraud alerts

Upon receipt of a request described in subparagraph (A), the Inspector General shall

investigate the subject matter of the request to determine whether a special fraud alert should be issued. If appropriate, the Inspector General shall issue a special fraud alert in response to the request. All special fraud alerts issued pursuant to this subparagraph shall be published in the Federal Register.

(2) Criteria for special fraud alerts

In determining whether to issue a special fraud alert upon a request described in paragraph (1), the Inspector General may consider—

- (A) whether and to what extent the practices that would be identified in the special fraud alert may result in any of the consequences described in subsection (a)(2); and
- (B) the volume and frequency of the conduct that would be identified in the special fraud alert.

(Aug. 14, 1935, ch. 531, title XI, § 1128D, as added Pub. L. 104-191, title II, § 205, Aug. 21, 1996, 110 Stat. 2000; amended Pub. L. 105-33, title IV, § 4331(a)(1), Aug. 5, 1997, 111 Stat. 395; Pub. L. 105-277, div. J, title V, § 5201(c), Oct. 21, 1998, 112 Stat. 2681-917; Pub. L. 106-554, § 1(a)(6) [title V, § 543], Dec. 21, 2000, 114 Stat. 2763, 2763A-551.)

REFERENCES IN TEXT

Section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987, referred to in subsec. (a)(1)(A)(i), is section 14(a) of Pub. L. 100-93, which is set out as a note under section 1320a-7b of this title.

Section 5 of the Inspector General Act of 1978, referred to in subsec. (a)(1)(C), is section 5 of Pub. L. 95-452, Oct. 12, 1978, 92 Stat. 1103, as amended, which is set out in the Appendix to Title 5, Government Organization and Employees.

The Internal Revenue Code of 1986, referred to in subsec. (b)(3)(B), is classified generally to Title 26, Internal Revenue Code.

AMENDMENTS

2000—Subsec. (b)(6). Pub. L. 106-554 struck out “, and before the date which is 4 years after August 21, 1996” before period at end.

1998—Subsec. (b)(2)(A). Pub. L. 105-277 inserted “or section 1320a-7a(i)(6) of this title” before period at end. 1997—Subsec. (b)(2)(D). Pub. L. 105-33 substituted “section 1320a-7a(b)” for “section 1320a-7b(b)”.

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by Pub. L. 105-33 effective as if included in the enactment of the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, see section 4331(f) of Pub. L. 105-33, set out as a note under section 1320a-7e of this title.

§ 1320a-7e. Health care fraud and abuse data collection program**(a) In general**

The Secretary shall maintain a national health care fraud and abuse data collection program under this section for the reporting of certain final adverse actions (not including settlements in which no findings of liability have been made) against health care providers, suppliers, or practitioners as required by subsection (b), with access as set forth in subsection (d), and shall furnish the information collected under this section to the National Practitioner Data Bank established pursuant to the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11101 et seq.).

¹ So in original. Probably should be “section”.