

NEGOTIATED RULEMAKING FOR RISK-SHARING
EXCEPTION

Pub. L. 104-191, title II, §216(b), Aug. 21, 1996, 110 Stat. 2007, provided that:

“(1) ESTABLISHMENT.—

“(A) IN GENERAL.—The Secretary of Health and Human Services (in this subsection referred to as the ‘Secretary’) shall establish, on an expedited basis and using a negotiated rulemaking process under subchapter 3 [III] of chapter 5 of title 5, United States Code, standards relating to the exception for risk-sharing arrangements to the anti-kickback penalties described in section 1128B(b)(3)(F) of the Social Security Act [42 U.S.C. 1320a-7b(3)(F)], as added by subsection (a).

“(B) FACTORS TO CONSIDER.—In establishing standards relating to the exception for risk-sharing arrangements to the anti-kickback penalties under subparagraph (A), the Secretary—

“(i) shall consult with the Attorney General and representatives of the hospital, physician, other health practitioner, and health plan communities, and other interested parties; and

“(ii) shall take into account—

“(I) the level of risk appropriate to the size and type of arrangement;

“(II) the frequency of assessment and distribution of incentives;

“(III) the level of capital contribution; and

“(IV) the extent to which the risk-sharing arrangement provides incentives to control the cost and quality of health care services.

“(2) PUBLICATION OF NOTICE.—In carrying out the rulemaking process under this subsection, the Secretary shall publish the notice provided for under section 564(a) of title 5, United States Code, by not later than 45 days after the date of the enactment of this Act [Aug. 21, 1996].

“(3) TARGET DATE FOR PUBLICATION OF RULE.—As part of the notice under paragraph (2), and for purposes of this subsection, the ‘target date for publication’ (referred to in section 564(a)(5) of such title) shall be January 1, 1997.

“(4) ABBREVIATED PERIOD FOR SUBMISSION OF COMMENTS.—In applying section 564(c) of such title under this subsection, ‘15 days’ shall be substituted for ‘30 days’.

“(5) APPOINTMENT OF NEGOTIATED RULEMAKING COMMITTEE AND FACILITATOR.—The Secretary shall provide for—

“(A) the appointment of a negotiated rulemaking committee under section 565(a) of such title by not later than 30 days after the end of the comment period provided for under section 564(c) of such title (as shortened under paragraph (4)), and

“(B) the nomination of a facilitator under section 566(c) of such title by not later than 10 days after the date of appointment of the committee.

“(6) PRELIMINARY COMMITTEE REPORT.—The negotiated rulemaking committee appointed under paragraph (5) shall report to the Secretary, by not later than October 1, 1996, regarding the committee’s progress on achieving a consensus with regard to the rulemaking proceeding and whether such consensus is likely to occur before one month before the target date for publication of the rule. If the committee reports that the committee has failed to make significant progress toward such consensus or is unlikely to reach such consensus by the target date, the Secretary may terminate such process and provide for the publication of a rule under this subsection through such other methods as the Secretary may provide.

“(7) FINAL COMMITTEE REPORT.—If the committee is not terminated under paragraph (6), the rulemaking committee shall submit a report containing a proposed rule by not later than one month before the target publication date.

“(8) INTERIM, FINAL EFFECT.—The Secretary shall publish a rule under this subsection in the Federal Reg-

ister by not later than the target publication date. Such rule shall be effective and final immediately on an interim basis, but is subject to change and revision after public notice and opportunity for a period (of not less than 60 days) for public comment. In connection with such rule, the Secretary shall specify the process for the timely review and approval of applications of entities to be certified as provider-sponsored organizations pursuant to such rules and consistent with this subsection.

“(9) PUBLICATION OF RULE AFTER PUBLIC COMMENT.—The Secretary shall provide for consideration of such comments and republication of such rule by not later than 1 year after the target publication date.”

ANTI-KICKBACK REGULATIONS

Pub. L. 100-93, §14(a), Aug. 18, 1987, 101 Stat. 697, provided that: “The Secretary of Health and Human Services, in consultation with the Attorney General, not later than 1 year after the date of the enactment of this Act [Aug. 18, 1987] shall publish proposed regulations, and not later than 2 years after the date of the enactment of this Act shall promulgate final regulations, specifying payment practices that shall not be treated as a criminal offense under section 1128B(b) of the Social Security Act [42 U.S.C. 1320a-7b(b)] and shall not serve as the basis for an exclusion under section 1128(b)(7) of such Act. Any practices specified in regulations pursuant to the preceding sentence shall be in addition to the practices described in subparagraphs (A) through (C) of section 1128B(b)(3).”

§ 1320a-7c. Fraud and abuse control program

(a) Establishment of program

(1) In general

Not later than January 1, 1997, the Secretary, acting through the Office of the Inspector General of the Department of Health and Human Services, and the Attorney General shall establish a program—

(A) to coordinate Federal, State, and local law enforcement programs to control fraud and abuse with respect to health plans,

(B) to conduct investigations, audits, evaluations, and inspections relating to the delivery of and payment for health care in the United States,

(C) to facilitate the enforcement of the provisions of sections 1320a-7, 1320a-7a, and 1320a-7b of this title and other statutes applicable to health care fraud and abuse, and

(D) to provide for the modification and establishment of safe harbors and to issue advisory opinions and special fraud alerts pursuant to section 1320a-7d of this title.

(2) Coordination with health plans

In carrying out the program established under paragraph (1), the Secretary and the Attorney General shall consult with, and arrange for the sharing of data with representatives of health plans.

(3) Guidelines

(A) In general

The Secretary and the Attorney General shall issue guidelines to carry out the program under paragraph (1). The provisions of sections 553, 556, and 557 of title 5 shall not apply in the issuance of such guidelines.

(B) Information guidelines

(i) In general

Such guidelines shall include guidelines relating to the furnishing of information

by health plans, providers, and others to enable the Secretary and the Attorney General to carry out the program (including coordination with health plans under paragraph (2)).

(ii) Confidentiality

Such guidelines shall include procedures to assure that such information is provided and utilized in a manner that appropriately protects the confidentiality of the information and the privacy of individuals receiving health care services and items.

(iii) Qualified immunity for providing information

The provisions of section 1320c-6(a) of this title (relating to limitation on liability) shall apply to a person providing information to the Secretary or the Attorney General in conjunction with their performance of duties under this section.

(4) Ensuring access to documentation

The Inspector General of the Department of Health and Human Services is authorized to exercise such authority described in paragraphs (3) through (9) of section 6¹ of the Inspector General Act of 1978 (5 U.S.C. App.) as necessary with respect to the activities under the fraud and abuse control program established under this subsection.

(5) Authority of Inspector General

Nothing in this chapter shall be construed to diminish the authority of any Inspector General, including such authority as provided in the Inspector General Act of 1978 (5 U.S.C. App.).

(b) Additional use of funds by Inspector General

(1) Reimbursements for investigations

The Inspector General of the Department of Health and Human Services is authorized to receive and retain for current use reimbursement for the costs of conducting investigations and audits and for monitoring compliance plans when such costs are ordered by a court, voluntarily agreed to by the payor, or otherwise.

(2) Crediting

Funds received by the Inspector General under paragraph (1) as reimbursement for costs of conducting investigations shall be deposited to the credit of the appropriation from which initially paid, or to appropriations for similar purposes currently available at the time of deposit, and shall remain available for obligation for 1 year from the date of the deposit of such funds.

(c) "Health plan" defined

For purposes of this section, the term "health plan" means a plan or program that provides health benefits, whether directly, through insurance, or otherwise, and includes—

- (1) a policy of health insurance;
- (2) a contract of a service benefit organization; and
- (3) a membership agreement with a health maintenance organization or other prepaid health plan.

(Aug. 14, 1935, ch. 531, title XI, §1128C, as added Pub. L. 104-191, title II, §201(a), Aug. 21, 1996, 110 Stat. 1992; amended Pub. L. 111-148, title VI, §6403(c), Mar. 23, 2010, 124 Stat. 766.)

REFERENCES IN TEXT

The Inspector General Act of 1978, referred to in subsec. (a)(4), (5), is Pub. L. 95-452, Oct. 12, 1978, 92 Stat. 1101, which is set out in the Appendix to Title 5, Government Organization and Employees. Paragraphs (3) through (9) of section 6 of the Act probably mean paragraphs (3) through (9) of section 6(a) of the Act, which set out various activities authorized to be performed by Inspectors General.

AMENDMENTS

2010—Subsec. (a)(1)(C) to (E). Pub. L. 111-148 inserted "and" at end of subpar. (C), substituted period for "and" at end of subpar. (D), and struck out subpar. (E) which read as follows: "to provide for the reporting and disclosure of certain final adverse actions against health care providers, suppliers, or practitioners pursuant to the data collection system established under section 1320a-7e of this title."

EFFECTIVE DATE OF 2010 AMENDMENT

Amendment by Pub. L. 111-148 effective on the first day after the final day of the transition period defined in section 6403(d)(5) of Pub. L. 111-148, see section 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

¹ See References in Text note below.