graph (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 Register 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).''

Executive Documents

EX. ORD. NO. 13939. LOWERING PRICES FOR PATIENTS BY ELIMINATING KICKBACKS TO MIDDLEMEN

Ex. Ord. No. 13939, July 24, 2020, 85 F.R. 45759, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Purpose*. One of the reasons pharmaceutical drug prices in the United States are so high is because of the complex mix of payers and negotiators that often separates the consumer from the manufacturer in the drug-purchasing process. The result is that the prices patients see at the point-of-sale do not reflect the prices that the patient's insurance companies, and middlemen hired by the insurance companies, actually pay for drugs. Instead, these middlemen—health plan sponsors and pharmacy benefit managers (PBMs)—negotiate significant discounts off of the list prices, sometimes up to 50 percent of the cost of the drug. Medicare patients, whose cost sharing is typically based on list prices, pay more than they should for drugs while the middlemen collect large ''rebate'' checks. These rebates are the functional equivalent of kickbacks, and erode savings that could otherwise go to the Medicare patients taking those drugs. Yet currently, Federal regulations create a safe harbor for such discounts and preclude treating them as kickbacks under the law.

Fixing this problem could save Medicare patients billions of dollars. The Office of the Inspector General at the Department of Health and Human Services has found that patients in the catastrophic phase of the Medicare Part D program saw their out-of-pocket costs for high-price drugs increase by 47 percent from 2010 to 2015, from $175 per month to $257 per month. Narrowing the safe harbor for these discounts under the anti-kickback statute will allow tens of billions in dollars of rebates on prescription drugs in the Medicare Part D program to go directly to patients, saving many patients hundreds or thousands of dollars per year at the pharmacy counter.

SEC. 2. *Policy*. It is the policy of the United States that discounts offered on prescription drugs should be passed on to patients.

SEC. 3. *Directing Drug Rebates to Patients Instead of Middlemen*. The Secretary of Health and Human Services shall complete the rulemaking process he commenced seeking to:

(a) exclude from safe harbor protections under the anti-kickback statute, section 1128B(b) of the Social Security Act, 42 U.S.C. 1320a–7b[(b)], certain retrospective reductions in price that are not applied at the point-of-sale or other remuneration that drug manufacturers provide to health plan sponsors, pharmacies, or PBMs in operating the Medicare Part D program; and

(b) establish new safe harbors that would permit health plan sponsors, pharmacies, and PBMs to apply discounts at the patient's point-of-sale in order to lower the patient's out-of-pocket costs, and that would permit the use of certain bona fide PBM service fees.

SEC. 4. *Protecting Low Premiums*. Prior to taking action under section 3 of this order, the Secretary of Health and Human Services shall confirm—and make public such confirmation—that the action is not projected to increase Federal spending, Medicare beneficiary premiums, or patients' total out-of-pocket costs.

SEC. 5. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

§ 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 406(a) of title 5 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 chapter 4 of title 5.

(6) Public-private partnership for waste, fraud, and abuse detection

(A) In general

Under the program described in paragraph (1), there is established a public-private partnership (in this paragraph referred to as the ''partnership'') of health plans, Federal and State agencies, law enforcement agencies, health care anti-fraud organizations, and any other entity determined appropriate by the Secretary (in this paragraph referred to as ''partners'') for purposes of detecting and preventing health care waste, fraud, and abuse.

(B) Contract with trusted third party

In carrying out the partnership, the Secretary shall enter into a contract with a trusted third party for purposes of carrying out the duties of the partnership described in subparagraph (C).

(C) Duties of partnership

The partnership shall—

(i) provide technical and operational support to facilitate data sharing between partners in the partnership;

(ii) analyze data so shared to identify fraudulent and aberrant billing patterns;

(iii) conduct aggregate analyses of health care data so shared across Federal, State, and private health plans for purposes of detecting fraud, waste, and abuse schemes;

(iv) identify outlier trends and potential vulnerabilities of partners in the partnership with respect to such schemes;

(v) refer specific cases of potential unlawful conduct to appropriate governmental entities;

(vi) convene, not less than annually, meetings with partners in the partnership for purposes of providing updates on the partnership's work and facilitating information sharing between the partners;

(vii) enter into data sharing and data use agreements with partners in the partnership in such a manner so as to ensure the partnership has access to data necessary to identify waste, fraud, and abuse while maintaining the confidentiality and integrity of such data;

(viii) provide partners in the partnership with plan-specific, confidential feedback on any aberrant billing patterns or potential fraud identified by the partnership with respect to such partner;

(ix) establish a process by which entities described in subparagraph (A) may enter the partnership and requirements such entities must meet to enter the partnership;

(x) provide appropriate training, outreach, and education to partners based on the results of data analyses described in clauses (ii) and (iii); and

(xi) perform such other duties as the Secretary determines appropriate.

(D) Substance use disorder treatment analysis

Not later than 2 years after December 27, 2020, the trusted third party with a contract in effect under subparagraph (B) shall perform an analysis of aberrant or fraudulent billing patterns and trends with respect to providers and suppliers of substance use disorder treatments from data shared with the partnership.

(E) Executive board

(i) Executive board composition

(I) In general

There shall be an executive board of the partnership comprised of representa-

tives of the Federal Government and representatives of the private sector selected by the Secretary.

(II) Chairs

The executive board shall be co-chaired by one Federal Government official and one representative from the private sector.

(ii) Meetings

The executive board of the partnership shall meet at least once per year.

(iii) Executive board duties

The duties of the executive board shall include the following:

(I) Providing strategic direction for the partnership, including membership criteria and a mission statement.

(II) Communicating with the leadership of the Department of Health and Human Services and the Department of Justice and the various private health sector associations.

(F) Reports

Not later than January 1, 2023, and every 2 years thereafter, the Secretary shall submit to Congress and make available on the public website of the Centers for Medicare & Medicaid Services a report containing—

(i) a review of activities conducted by the partnership over the 2-year period ending on the date of the submission of such report, including any progress to any objectives established by the partnership;

(ii) any savings voluntarily reported by health plans participating in the partnership attributable to the partnership during such period;

(iii) any savings to the Federal Government attributable to the partnership during such period;

(iv) any other outcomes attributable to the partnership, as determined by the Secretary, during such period; and

(v) a strategic plan for the 2-year period beginning on the day after the date of the submission of such report, including a description of any emerging fraud and abuse schemes, trends, or practices that the partnership intends to study during such period.

(G) Funding

The partnership shall be funded by amounts otherwise made available to the Secretary for carrying out the program described in paragraph (1).

(H) Transitional provisions

To the extent consistent with this subsection, all functions, personnel, assets, liabilities, and administrative actions applicable on the date before December 27, 2020, to the National Fraud Prevention Partnership established on September 17, 2012, by charter of the Secretary shall be transferred to the partnership established under subparagraph (A) as of December 27, 2020.

(I) Nonapplicability of FACA

The provisions of the Federal Advisory Committee Act shall not apply to the partnership established by subparagraph (A).

(J) Implementation

Notwithstanding any other provision of law, the Secretary may implement the partnership established by subparagraph (A) by program instruction or otherwise.

(K) Definition

For purposes of this paragraph, the term ''trusted third party'' means an entity that—

(i) demonstrates the capability to carry out the duties of the partnership described in subparagraph (C);

(ii) complies with such conflict of interest standards determined appropriate by the Secretary; and

(iii) meets such other requirements as the Secretary may prescribe.

(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; Pub. L. 116–260, div. CC, title I, § 124(a), Dec. 27, 2020, 134 Stat. 2957; Pub. L. 117–286, § 4(b)(78), Dec. 27, 2022, 136 Stat. 4351.)

Editorial Notes

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (a)(6)(I), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, which was set out in the Appendix to Title 5, Government Organization and Employees, and was substantially repealed and restated in chapter 10 (§ 1001 et seq.) of Title 5 by Pub. L. 117–286, §§ 3(a), 7, Dec. 27, 2022, 136 Stat. 4197, 4361. For disposition of sections of the Act into chapter 10 of Title 5, see Disposition Table preceding section 101 of Title 5.

AMENDMENTS

2022—Subsec. (a)(4). Pub. L. 117–286, § 4(b)(78)(A), substituted ''paragraphs (3) through (9) of section 406(a) of title 5'' for ''paragraphs (3) through (9) of section 6 of the Inspector General Act of 1978 (5 U.S.C. App.)''.

Subsec. (a)(5). Pub. L. 117–286, § 4(b)(78)(B), substituted ''chapter 4 of title 5.'' for ''the Inspector General Act of 1978 (5 U.S.C. App.).''

2020—Subsec. (a)(6). Pub. L. 116–260 added par. (6).

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.''

Statutory Notes and Related Subsidiaries

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 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 405 of title 5, 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).

(3) Consideration of safe harbor for certain contingency management interventions

(A) In general

Not later than one year after December 29, 2022, the Inspector General shall conduct a review on whether to establish a safe harbor described in paragraph (1)(A)(ii) for evidence-based contingency management incentives and the parameters for such a safe harbor. In conducting the review under the previous sentence, the Inspector General shall consider the extent to which providing such a safe harbor for evidence-based contingency management incentives may result in any of the factors described in paragraph (2).

(B) Report

Not later than two years after December 29, 2022, the Secretary and the Inspector General shall submit to Congress recommendations, including based on the re-