Except as specifically provided in section 411 of Pub. L. 100–360, amendment by section 411(e)(3), (k)(10)(B)(ii), (D) of Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

EFFECTIVE DATE OF 1987 AMENDMENT

Pub. L. 100–203, title IV, § 4118(e)(14), formerly § 4118(e)(3), Dec. 22, 1987, 101 Stat. 1330–155, as renumbered and amended by Pub. L. 100–360, title IV, § 411(k)(10)(B)(i), (D), July 1, 1988, 102 Stat. 794, 795, provided that: ''The amendments made by paragraph (1) [amending this section] shall apply to activities occurring before, on, or after the date of the enactment of this Act [Dec. 22, 1987].''

Amendment by Pub. L. 100–93 effective at end of fourteen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, except that amendment by section 3(a)(1) of Pub. L. 100–93 applicable to claims presented for services performed on or after date at end of fourteen-day period beginning Aug. 18, 1987, without regard to the date the physician's misrepresentation of fact was made, and amendment by section 3(f) of Pub. L. 100–93 effective Aug. 18, 1987, see section 15(a), (c)(3), and (d) of Pub. L. 100–93, set out as a note under section 1320a–7 of this title.

EFFECTIVE DATE OF 1986 AMENDMENT

Pub. L. 99–509, title IX, § 9313(c)(2), Oct. 21, 1986, 100 Stat. 2003, as amended by Pub. L. 100–203, title IV, § 4016, Dec. 22, 1987, 101 Stat. 1330–64; Pub. L. 101–239, title VI, § 6207(a), Dec. 19, 1989, 103 Stat. 2245, provided that: ''The amendments made by paragraph (1) [amending this section] shall apply to—

''(A) payments by hospitals occurring more than 6 months after the date of the enactment of this Act [Oct. 21, 1986], and

''(B) payments by eligible organizations or entities occurring on or after April 1, 1991.''

Pub. L. 99–509, title IX, § 9317(d)(1), (2), Oct. 21, 1986, 100 Stat. 2009, provided that:

''(1) The amendment made by subsection (a) [amending this section] shall take effect on the date of the enactment of this Act [Oct. 21, 1986], without regard to when the criminal conviction was obtained, but shall only apply to a conviction upon a plea of nolo contendere tendered after the date of the enactment of this Act.

''(2) The amendment made by subsection (b) [amending this section] shall apply to failures or misconduct occurring on or after the date of the enactment of this Act.''

EFFECTIVE DATE OF 1984 AMENDMENT

Amendment by section 2354(a)(3) of Pub. L. 98–369 effective July 18, 1984, but not to be construed as changing or affecting any right, liability, status, or interpretation which existed (under the provisions of law involved) before that date, see section 2354(e)(1) of Pub. L. 98–369, set out as a note under section 1320a–1 of this title.

EFFECTIVE DATE OF 1982 AMENDMENT

Amendment by Pub. L. 97–248 effective as if originally included as part of this section as this section was amended by the Omnibus Budget Reconciliation Act of 1981, Pub. L. 97–35, see section 137(d)(2) of Pub. L. 97–248, set out as a note under section 1396a of this title.

REGULATIONS

Pub. L. 105–277, div. J, title V, § 5201(e), Oct. 21, 1998, 112 Stat. 2681–917, provided that: ''The Secretary of Health and Human Services may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment, in order to implement the amendments made by this section [amending this section and section 1320a–7d of this title] in a timely manner.''

GAO STUDY AND REPORT ON IMPACT OF SAFE HARBOR ON MEDIGAP POLICIES

Pub. L. 105–277, div. J, title V, § 5201(b)(2), Oct. 21, 1998, 112 Stat. 2681–917, which provided that, if a permissible practice was promulgated under subsec. (n)(1)(A) of this section, the Comptroller General was to conduct a study comparing any disproportionate impact on specific issuers of medicare supplemental policies due to adverse selection in enrolling medicare ESRD beneficiaries before Aug. 21, 1996, and 1 year after the date of promulgation of such permissible practice under subsec. (n)(1)(A) of this section and was to submit a report to Congress on such study with recommendations concerning extension of the time limitation under subsec. (n)(1)(B), was repealed by Pub. L. 111–8, div. G, title I, § 1301(c), Mar. 11, 2009, 123 Stat. 829.

REPEAL OF 1988 EXPANSION OF MEDICARE PART B BENEFITS

Pub. L. 101–234, title II, § 201(a), Dec. 13, 1989, 103 Stat. 1981, provided that:

''(1) GENERAL RULE.—Except as provided in paragraph (2), sections 201 through 208 of MCCA [sections 201 to 208 of Pub. L. 100–360, enacting section 1395w–3 of this title, amending this section and sections 1320c–3, 1395h, 1395k, 1395*l*, 1395m, 1395n, 1395u, 1395w–2, 1395x, 1395y, 1395z, 1395aa, 1395bb, 1395cc, 1395mm, 1396a, 1396b, and 1396n of this title, and enacting provisions set out as notes under sections 1320c–3, 1395b–1, 1395k, 1395m, 1395u, 1395x, 1395*ll*, and 1395ww of this title] are repealed and the provisions of law amended or repealed by such sections are restored or revived as if such sections had not been enacted.

''(2) EXCEPTION.—Paragraph (1) shall not apply to subsections (g) and (m)(4) of section 202 of MCCA [amending section 1395u of this title and enacting provisions set out as a note under section 1395u of this title.]''

STUDY AND REPORT ON INCENTIVE ARRANGEMENTS OFFERED TO PHYSICIANS

Pub. L. 99–509, title IX, § 9313(c)(3), Oct. 21, 1986, 100 Stat. 2003, directed Secretary of Health and Human Services to report to Congress, not later than Jan. 1, 1988, concerning incentive arrangements offered by health maintenance organizations and competitive medical plans to physicians.

§ 1320a–7b. Criminal penalties for acts involving Federal health care programs

(a) Making or causing to be made false statements or representations

Whoever—

(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program (as defined in subsection (f)),

(2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment,

(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment ei-

ther in a greater amount or quantity than is due or when no such benefit or payment is authorized,

(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,

(5) presents or causes to be presented a claim for a physician's service for which payment may be made under a Federal health care program and knows that the individual who furnished the service was not licensed as a physician, or

(6) for a fee knowingly and willfully counsels or assists an individual to dispose of assets (including by any transfer in trust) in order for the individual to become eligible for medical assistance under a State plan under subchapter XIX, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1396p(c) of this title,

shall (i) in the case of such a statement, representation, concealment, failure, or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be made under the program, be guilty of a felony and upon conviction thereof fined not more than $100,000 or imprisoned for not more than 10 years or both, or (ii) in the case of such a statement, representation, concealment, failure, conversion, or provision of counsel or assistance by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $20,000 or imprisoned for not more than one year, or both. In addition, in any case where an individual who is otherwise eligible for assistance under a Federal health care program is convicted of an offense under the preceding provisions of this subsection, the administrator of such program may at its option (notwithstanding any other provision of such program) limit, restrict, or suspend the eligibility of that individual for such period (not exceeding one year) as it deems appropriate; but the imposition of a limitation, restriction, or suspension with respect to the eligibility of any individual under this sentence shall not affect the eligibility of any other person for assistance under the plan, regardless of the relationship between that individual and such other person.

(b) Illegal remunerations

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(3) Paragraphs (1) and (2) shall not apply to—

(A) a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program;

(B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services;

(C) any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program if—

(i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and

(ii) in the case of an entity that is a provider of services (as defined in section 1395x(u) of this title), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity;

(D) a waiver of any coinsurance under part B of subchapter XVIII by a Federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act [42 U.S.C. 201 et seq.];

(E) any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 or in regulations under section 1395w–104(e)(6)[1] of this title;

(F) any remuneration between an organization and an individual or entity providing

[1] See References in Text note below.

items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1395mm of this title or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide;

(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under part D of subchapter XVIII, if the conditions described in clauses (i) through (iii) of section 1320a–7a(i)(6)(A) of this title are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1395w–114(a)(3) of this title), section 1320a–7a(i)(6)(A) of this title shall be applied without regard to clauses (ii) and (iii) of that section);

(H) any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1395w–23(a)(4) of this title;

(I) any remuneration between a health center entity described under clause (i) or (ii) of section 1396d(*l*)(2)(B) of this title and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity;

(J) a discount in the price of an applicable drug (as defined in paragraph (2) of section 1395w–114a(g) of this title) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1395w–114a of this title; and

(K) an incentive payment made to a Medicare fee-for-service beneficiary by an ACO under an ACO Beneficiary Incentive Program established under subsection (m) of section 1395jjj of this title, if the payment is made in accordance with the requirements of such subsection and meets such other conditions as the Secretary may establish.

(4) Whoever without lawful authority knowingly and willfully purchases, sells or distributes, or arranges for the purchase, sale, or distribution of a beneficiary identification number or unique health identifier for a health care provider under subchapter XVIII, subchapter XIX, or subchapter XXI shall be imprisoned for not more than 10 years or fined not more than $500,000 ($1,000,000 in the case of a corporation), or both.

(c) False statements or representations with respect to condition or operation of institutions

Whoever knowingly and willfully makes or causes to be made, or induces or seeks to induce the making of, any false statement or representation of a material fact with respect to the conditions or operation of any institution, facility, or entity in order that such institution, facility, or entity may qualify (either upon initial certification or upon recertification) as a hospital, critical access hospital, skilled nursing facility, nursing facility, intermediate care facility for the mentally retarded, home health agency, or other entity (including an eligible organization under section 1395mm(b) of this title) for which certification is required under subchapter XVIII or a State health care program (as defined in section 1320a–7(h) of this title), or with respect to information required to be provided under section 1320a–3a of this title, shall be guilty of a felony and upon conviction thereof shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(d) Illegal patient admittance and retention practices

Whoever knowingly and willfully—

(1) charges, for any service provided to a patient under a State plan approved under subchapter XIX, money or other consideration at a rate in excess of the rates established by the State (or, in the case of services provided to an individual enrolled with a medicaid managed care organization under subchapter XIX under a contract under section 1396b(m) of this title or under a contractual, referral, or other arrangement under such contract, at a rate in excess of the rate permitted under such contract), or

(2) charges, solicits, accepts, or receives, in addition to any amount otherwise required to be paid under a State plan approved under subchapter XIX, any gift, money, donation, or other consideration (other than a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to the patient)—

(A) as a precondition of admitting a patient to a hospital, nursing facility, or intermediate care facility for the mentally retarded, or

(B) as a requirement for the patient's continued stay in such a facility,

when the cost of the services provided therein to the patient is paid for (in whole or in part) under the State plan,

shall be guilty of a felony and upon conviction thereof shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(e) Violation of assignment terms

Whoever accepts assignments described in section 1395u(b)(3)(B)(ii) of this title or agrees to be a participating physician or supplier under section 1395u(h)(1) of this title and knowingly, willfully, and repeatedly violates the term of such assignments or agreement, shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $4,000 or imprisoned for not more than six months, or both.

(f) "Federal health care program" defined

For purposes of this section, the term ''Federal health care program'' means—

(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5); or

(2) any State health care program, as defined in section 1320a–7(h) of this title.

(g) Liability under subchapter III of chapter 37 of title 31

In addition to the penalties provided for in this section or section 1320a–7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31.

(h) Actual knowledge or specific intent not required

With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.

(Aug. 14, 1935, ch. 531, title XI, § 1128B, formerly title XVIII, § 1877(d), and title XIX, § 1909, as added and amended Pub. L. 92–603, title II, §§ 242(c), 278(b)(9), Oct. 30, 1972, 86 Stat. 1419, 1454; Pub. L. 95–142, § 4(a), (b), Oct. 25, 1977, 91 Stat. 1179, 1181; Pub. L. 96–499, title IX, § 917, Dec. 5, 1980, 94 Stat. 2625; Pub. L. 98–369, div. B, title III, § 2306(f)(2), July 18, 1984, 98 Stat. 1073; renumbered title XI, § 1128B, and amended Pub. L. 100–93, §§ 4(a)–(d), 14(b), Aug. 18, 1987, 101 Stat. 688, 689, 697; Pub. L. 100–203, title IV, §§ 4039(a), 4211(h)(7), Dec. 22, 1987, 101 Stat. 1330–81, 1330–206; Pub. L. 100–360, title IV, § 411(a)(3)(A), (B)(i), July 1, 1988, 102 Stat. 768; Pub. L. 101–239, title VI, § 6003(g)(3)(D)(ii), Dec. 19, 1989, 103 Stat. 2153; Pub. L. 101–508, title IV, §§ 4161(a)(4), 4164(b)(2), Nov. 5, 1990, 104 Stat. 1388–94, 1388–102; Pub. L. 103–432, title I, § 133(a)(2), Oct. 31, 1994, 108 Stat. 4421; Pub. L. 104–191, title II, §§ 204(a), 216(a), 217, Aug. 21, 1996, 110 Stat. 1999, 2007, 2008; Pub. L. 105–33, title IV, §§ 4201(c)(1), 4704(b), 4734, Aug. 5, 1997, 111 Stat. 373, 498, 522; Pub. L. 108–173, title I, § 101(e)(2), (8)(A), title II, § 237(d), title IV, § 431(a), Dec. 8, 2003, 117 Stat. 2150, 2152, 2213, 2287; Pub. L. 111–148, title III, § 3301(d)(1), title VI, § 6402(f), Mar. 23, 2010, 124 Stat. 468, 759; Pub. L. 114–115, § 8, Dec. 28, 2015, 129 Stat. 3134; Pub. L. 115–123, div. E, title III, § 50341(b), title IV, § 50412(a)(2), (b), Feb. 9, 2018, 132 Stat. 208, 220.)

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (b)(3)(D), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended, which is classified generally to chapter 6A (§ 201 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

Section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987, referred to in subsec. (b)(3)(E), is section 14(a) of Pub. L. 100–93, which is set out below.

Section 1395w–104(e)(6) of this title, referred to in subsec. (b)(3)(E), was in the original ''section 1860D–3(e)(6)'', and was translated as reading ''section 1860D–4(e)(6)'' to reflect the probable intent of Congress, because section 1860D–3, which is classified to section 1395w–103 of this title, does not contain a subsec. (e), and section 1395w–104(e)(6) relates to regulations.

CODIFICATION

Prior to redesignation by Pub. L. 100–93, subsecs. (a) to (d) of this section were subsecs. (a) to (d) of section 1909 of act Aug. 14, 1935, which was classified to section 1396h of this title, and subsec. (e) of this section was subsec. (d) of section 1877 of act Aug. 14, 1935, which was classified to section 1395nn of this title.

AMENDMENTS

2018—Subsec. (a). Pub. L. 115–123, § 50412(a)(2)(A), (b)(1), in concluding provisions, substituted ''$100,000'' for ''$25,000'', ''not more than 10 years or both, or (ii)'' for ''not more than five years or both, or (ii)'', and ''$20,000'' for ''$10,000''.

Subsec. (b)(1). Pub. L. 115–123, § 50412(a)(2)(B)(i), (b)(2)(A), in concluding provisions, substituted ''$100,000'' for ''$25,000'' and ''not more than 10 years'' for ''not more than five years''.

Subsec. (b)(2). Pub. L. 115–123, § 50412(a)(2)(B)(ii), (b)(2)(B), in concluding provisions, substituted ''$100,000'' for ''$25,000'' and ''not more than 10 years'' for ''not more than five years''.

Subsec. (b)(3)(K). Pub. L. 115–123, § 50341(b), added subpar. (K).

Subsec. (c). Pub. L. 115–123, § 50412(a)(2)(C), (b)(3), substituted ''$100,000'' for ''$25,000'' and ''not more than 10 years'' for ''not more than five years''.

Subsec. (d). Pub. L. 115–123, § 50412(a)(2)(D), (b)(4), in concluding provisions, substituted ''$100,000'' for ''$25,000'' and ''not more than 10 years'' for ''not more than five years''.

Subsec. (e). Pub. L. 115–123, § 50412(a)(2)(E), substituted ''$4,000'' for ''$2,000''.

2015—Subsec. (b)(4). Pub. L. 114–115 added par. (4).

2010—Subsec. (b)(3)(G). Pub. L. 111–148, § 3301(d)(1)(A), struck out ''and'' at the end.

Subsec. (b)(3)(H). Pub. L. 111–148, § 3301(d)(1)(B), amended subpar. (H) relating to remuneration between a federally qualified health center and an MA organization by substituting a semicolon for the period at the end and realigning margins.

Subsec. (b)(3)(I). Pub. L. 111–148, § 3301(d)(1)(C)(i), (ii), redesignated subpar. (H) relating to remuneration between a health center entity and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity as (I) and realigned margins.

Subsec. (b)(3)(J). Pub. L. 111–148, § 3301(d)(1)(C)(iii), (D), added subpar. (J).

Subsecs. (g), (h). Pub. L. 111–148, § 6402(f), added subsecs. (g) and (h).

2003—Subsec. (b)(3)(E). Pub. L. 108–173, § 101(e)(8)(A), which directed the amendment of subpar. (C) by inserting ''or in regulations under section 1395w–104(e)(6) of this title'' after ''1987'', was executed by making the insertion in subpar. (E) to reflect the probable intent of Congress because ''1987'' does not appear in subpar. (C).

Subsec. (b)(3)(G). Pub. L. 108–173, § 101(e)(2), added subpar. (G).

Subsec. (b)(3)(H). Pub. L. 108–173, § 431(a), added subpar. (H) relating to remuneration between a health center entity and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity.

Pub. L. 108–173, § 237(d), added subpar. (H) relating to remuneration between a federally qualified health center and an MA organization.

1997—Subsec. (a). Pub. L. 105–33, § 4734(2), in cl. (ii) of concluding provisions, substituted ''failure, conversion, or provision of counsel or assistance by any other person'' for ''failure, or conversion by any other person''.

Subsec. (a)(6). Pub. L. 105–33, § 4734(1), added par. (6) and struck out former par. (6) which read as follows: ''knowingly and willfully disposes of assets (including

by any transfer in trust) in order for an individual to become eligible for medical assistance under a State plan under subchapter XIX of this chapter, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1396p(c) of this title,''.

Subsec. (c). Pub. L. 105–33, § 4201(c)(1), substituted ''critical access'' for ''rural primary care''.

Subsec. (d)(1). Pub. L. 105–33, § 4704(b), inserted ''(or, in the case of services provided to an individual enrolled with a medicaid managed care organization under subchapter XIX under a contract under section 1396b(m) of this title or under a contractual, referral, or other arrangement under such contract, at a rate in excess of the rate permitted under such contract)'' after ''by the State''.

1996—Pub. L. 104–191, § 204(a)(1), substituted ''Federal'' for ''Medicare or State'' in section catchline.

Subsec. (a). Pub. L. 104–191, § 204(a)(4), in concluding provisions, substituted ''a Federal health care program'' for ''a State plan approved under subchapter XIX of this chapter'' and ''the administrator of such program may at its option (notwithstanding any other provision of such program)'' for ''the State may at its option (notwithstanding any other provision of that subchapter or of such plan)''.

Subsec. (a)(1). Pub. L. 104–191, § 204(a)(2), substituted ''a Federal health care program (as defined in subsection (f))'' for ''a program under subchapter XVIII of this chapter or a State health care program (as defined in section 1320a–7(h) of this title)''.

Subsec. (a)(5). Pub. L. 104–191, § 204(a)(3), substituted ''a Federal'' for ''a program under subchapter XVIII of this chapter or a State''.

Subsec. (a)(6). Pub. L. 104–191, § 217, added par. (6).

Subsec. (b). Pub. L. 104–191, § 204(a)(5), substituted ''a Federal health care program'' for ''subchapter XVIII of this chapter or a State health care program'' wherever appearing.

Subsec. (b)(3)(F). Pub. L. 104–191, § 216(a), added subpar. (F).

Subsec. (c). Pub. L. 104–191, § 204(a)(6), inserted ''(as defined in section 1320a–7(h) of this title)'' after ''a State health care program''.

Subsec. (f). Pub. L. 104–191, § 204(a)(7), added subsec. (f).

1994—Subsec. (b)(3)(B). Pub. L. 103–432, which directed substitution of ''1395m(j)(5)'' for ''1395m(j)(4)'' in subpar. (B) as amended by section 134(a) of Pub. L. 103–432, could not be executed because ''1395m(j)(4)'' does not appear in subpar. (B) and section 134(a) of Pub. L. 103–432 did not amend this section.

1990—Subsec. (b)(3)(D), (E). Pub. L. 101–508, § 4161(a)(4), added subpar. (D) and redesignated former subpar. (D) as (E).

Subsec. (c). Pub. L. 101–508, § 4164(b)(2), substituted ''health care program, or with respect to information required to be provided under section 1320a–3a of this title,'' for ''health care program''.

1989—Subsec. (c). Pub. L. 101–239 inserted ''rural primary care hospital,'' after ''hospital,''.

1988—Subsec. (c). Pub. L. 100–360 made technical correction to directory language of Pub. L. 100–203, § 4039(a), see 1987 Amendment note below.

Pub. L. 100–203, § 4211(h)(7)(A), substituted ''nursing facility, intermediate care facility for the mentally retarded'' for ''intermediate care facility''.

Subsec. (d)(2)(A). Pub. L. 100–203, § 4211(h)(7)(B), substituted ''nursing facility, or intermediate care facility for the mentally retarded'' for ''skilled nursing facility, or intermediate care facility''.

1987—Pub. L. 100–93, § 4(a)(1), substituted ''Criminal penalties for acts involving Medicare or State health care programs'' for ''Offenses and penalties'' in section catchline.

Subsec. (a). Pub. L. 100–93, § 4(a)(3), (4), in concluding provisions, substituted ''made under the program'' for ''made under this subchapter'', ''approved under subchapter XIX of this chapter'' for ''approved under this subchapter'', and ''provision of that subchapter'' for ''provision of this subchapter''.

Subsec. (a)(1). Pub. L. 100–93, § 4(a)(2), substituted ''a program under subchapter XVIII of this chapter or a State health care program (as defined in section 1320a–7(h) of this title)'' for ''a State plan approved under this subchapter''.

Subsec. (a)(5). Pub. L. 100–93, § 4(b), added par. (5).

Subsec. (b)(1)(A), (B), (2)(A), (B). Pub. L. 100–93, § 4(a)(5), substituted ''subchapter XVIII of this chapter or a State health care program'' for ''this subchapter''.

Subsec. (b)(3). Pub. L. 100–93, §§ 4(a)(5), (6), 14(b), substituted ''subchapter XVIII of this chapter or a State health care program'' for ''this subchapter'' in two places in subpar. (A) and added subpars. (C) and (D).

Subsec. (c). Pub. L. 100–203, § 4039(a), as amended by Pub. L. 100–360, substituted ''institution, facility, or entity'' for ''institution or facility'' wherever appearing and inserted ''(including an eligible organization under section 1395mm(b) of this title)'' after ''other entity''.

Pub. L. 100–93, § 4(a)(7), substituted ''home health agency, or other entity for which certification is required under subchapter XVIII or a State health care program'' for ''or home health agency (as those terms are employed in this subchapter)''.

Subsec. (d)(1), (2). Pub. L. 100–93, § 4(a)(8), substituted ''subchapter XIX'' for ''this subchapter''.

Subsec. (e). Pub. L. 100–93, § 4(c), redesignated subsec. (d) of section 1395nn of this title as subsec. (e) of this section.

1984—Subsec. (e). Pub. L. 98–369 inserted ''or agrees to be a participating physician or supplier under section 1395u(h)(1) of this title'' after ''section 1395u(b)(3)(B)(ii) of this title'', and substituted ''or agreement'' for ''specified in subclause (I) of such section''.

1980—Subsec. (b)(1), (2). Pub. L. 96–499 inserted ''knowingly and willfully'' after ''Whoever''.

1977—Subsec. (a). Pub. L. 95–142, § 4(b), designated existing provisions following par. (4) as cl. (ii) and, as so designated, inserted provisions relating to activities of other persons, and inserted provisions authorizing the State to limit, restrict, or suspend, the eligibility of any convicted persons for benefits, and added cl. (i). See Codification note above.

Subsec. (b). Pub. L. 95–142, § 4(b), redesignated existing provisions as par. (1), substituted provisions relating to solicitation or receiving of any remuneration in return for referring an individual to a person for the furnishing or arranging the furnishing of any item or service, or in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, etc., as constituting a felony punishable by a fine of not more than $25,000 and/or imprisonment for not more than five years, for provisions relating to furnishing items or services and soliciting, offering or receiving any kickback, bribe, or rebate in connection with furnishing, etc. items or services as constituting a misdemeanor punishable by a fine of not more than $10,000 and/or imprisonment for not more than one year, and added pars. (2) and (3). See Codification note above.

Subsec. (c). Pub. L. 95–142, § 4(b), substituted provisions setting forth felony nature of criminal activities with a fine of not more than $25,000, or imprisonment for not more than five years, or both, for provisions setting forth misdemeanor nature of criminal activities with a fine of not more than $2,000, or imprisonment for not more than six months, or both. See Codification note above.

Subsec. (d). Pub. L. 95–142, § 4(b), added subsec. (d). See Codification note above.

Subsec. (e). Pub. L. 95–142, § 4(a), added subsec. (e). See Codification note above.

1972—Subsec. (c). Pub. L. 92–603, § 278(b)(9), substituted ''skilled nursing facility'' for ''skilled nursing home''.

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, § 3301(d)(3), Mar. 23, 2010, 124 Stat. 468, provided that: ''The amendments made by this subsection [amending this section and 1396r–8 of this title] shall apply to drugs dispensed on or after July 1, 2010.''

EFFECTIVE DATE OF 2003 AMENDMENT

Pub. L. 108–173, title II, § 237(e), Dec. 8, 2003, 117 Stat. 2213, provided that: ''The amendments made by this section [amending this section and sections 1395*l*, 1395w–21, 1395w–23, and 1395w–27 of this title] shall apply to services provided on or after January 1, 2006, and contract years beginning on or after such date.''

EFFECTIVE DATE OF 1997 AMENDMENT

Amendment by section 4201(c)(1) of Pub. L. 105–33 applicable to services furnished on or after Oct. 1, 1997, see section 4201(d) of Pub. L. 105–33, set out as a note under section 1395f of this title.

Amendment by section 4704(b) of Pub. L. 105–33 effective Aug. 5, 1997, and applicable to contracts entered into or renewed on or after Oct. 1, 1997, see section 4710 of Pub. L. 105–33, set out as a note under section 1396b of this title.

EFFECTIVE DATE OF 1996 AMENDMENT

Pub. L. 104–191, title II, § 204(b), Aug. 21, 1996, 110 Stat. 2000, provided that: ''The amendments made by this section [amending this section] shall take effect on January 1, 1997.''

Pub. L. 104–191, title II, § 216(c), Aug. 21, 1996, 110 Stat. 2008, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to written agreements entered into on or after January 1, 1997, without regard to whether regulations have been issued to implement such amendments.''

Amendment by section 217 of Pub. L. 104–191 effective Jan. 1, 1997, except as otherwise provided, see section 218 of Pub. L. 104–191, set out as a note under section 1320a–7 of this title.

EFFECTIVE DATE OF 1994 AMENDMENT

Amendment by section 133(a)(2) of Pub. L. 103–432 applicable to items or services furnished on or after Jan. 1, 1995, see section 133(c) of Pub. L. 103–432, set out as a note under section 1395m of this title.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by section 4161(a)(4) of Pub. L. 101–508 applicable to services furnished on or after Oct. 1, 1991, see section 4161(a)(8) of Pub. L. 101–508, set out as a note under section 1395k of this title.

Amendment by section 4164(b)(2) of Pub. L. 101–508 applicable with respect to items or services furnished on or after Jan. 1, 1993, in the case of items or services furnished by a provider who, on or before Nov. 5, 1990, has furnished items or services for which payment may be made under part B of subchapter XVIII of this chapter or Jan. 1, 1992, in the case of items or services furnished by any other provider, see section 4164(b)(4) of Pub. L. 101–508, set out as an Effective Date note under section 1320a–3a of this title.

EFFECTIVE DATE OF 1988 AMENDMENT

Except as specifically provided in section 411 of Pub. L. 100–360, amendment by Pub. L. 100–360, as it relates to a provision in the Omnibus Budget Reconciliation Act of 1987, Pub. L. 100–203, effective as if included in the enactment of that provision in Pub. L. 100–203, see section 411(a) of Pub. L. 100–360, set out as a Reference to OBRA; Effective Date note under section 106 of Title 1, General Provisions.

EFFECTIVE DATE OF 1987 AMENDMENTS

Amendment by section 4211(h)(7) of Pub. L. 100–203 applicable to nursing facility services furnished on or after Oct. 1, 1990, without regard to whether regulations implementing such amendment are promulgated by such date, except as otherwise specifically provided in section 1396r of this title, with transitional rule, see section 4214(a), (b)(2) of Pub. L. 100–203, as amended, set out as an Effective Date note under section 1396r of this title.

Amendment by Pub. L. 100–93 effective at end of fourteen-day period beginning Aug. 18, 1987, and inapplicable to administrative proceedings commenced before end of such period, see section 15(a) of Pub. L. 100–93, set out as a note under section 1320a–7 of this title.

EFFECTIVE DATE OF 1977 AMENDMENT

Pub. L. 95–142, § 4(d), Oct. 25, 1977, 91 Stat. 1183, provided that: ''The amendments made by subsections (a) and (b) [amending this section] shall apply with respect to acts occurring and statements or representations made on or after the date of the enactment of this Act [Oct. 25, 1977].''

EFFECTIVE DATE

Pub. L. 92–603, title II, § 242(d), Oct. 30, 1972, 86 Stat. 1420, provided that: ''The provisions of amendments made by this section [enacting this section and section 1396h of this title and amending section 1395ii of this title] shall not be applicable to any acts, statements, or representations made or committed prior to the enactment of this Act [Oct. 30, 1972].''

RULEMAKING FOR EXCEPTION FOR HEALTH CENTER ENTITY ARRANGEMENTS

Pub. L. 108–173, title IV, § 431(b), Dec. 8, 2003, 117 Stat. 2287, provided that:

''(1) ESTABLISHMENT.—

''(A) IN GENERAL.—The Secretary [of Health and Human Services] shall establish, on an expedited basis, standards relating to the exception described in section 1128B(b)(3)(H) [now section 1128B(b)(3)(I)] of the Social Security Act [42 U.S.C. 1320a–7b(b)(3)(I)], as added by subsection (a), for health center entity arrangements to the antikickback penalties.

''(B) FACTORS TO CONSIDER.—The Secretary shall consider the following factors, among others, in establishing standards relating to the exception for health center entity arrangements under subparagraph (A):

''(i) Whether the arrangement between the health center entity and the other party results in savings of Federal grant funds or increased revenues to the health center entity.

''(ii) Whether the arrangement between the health center entity and the other party restricts or limits an individual's freedom of choice.

''(iii) Whether the arrangement between the health center entity and the other party protects a health care professional's independent medical judgment regarding medically appropriate treatment.

The Secretary may also include other standards and criteria that are consistent with the intent of Congress in enacting the exception established under this section.

''(2) DEADLINE.—Not later than 1 year after the date of the enactment of this Act [Dec. 8, 2003] the Secretary shall publish final regulations establishing the standards described in paragraph (1).''

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(b)(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 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).''

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 6[1] 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.).

(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

[1] See References in Text note below.