Editorial Notes

AMENDMENTS

2014—Subsecs. (d), (e). Pub. L. 113–188 redesignated subsec. (e) as (d) and struck out former subsec. (d) which required annual reports from the directors of Department medical centers and from the Secretary.

2001—Subsec. (d)(1). Pub. L. 107–14, §8(a)(15)(A), struck out ''(beginning in 1992)'' after ''each year''.

Subsec. (d)(2). Pub. L. 107–14, §8(a)(15)(B), struck out ''(beginning in 1993)'' after ''each year''.

Subsec. (d)(3). Pub. L. 107–14, §8(a)(15)(C), struck out par. (3) which read as follows: ''Not later than February 1 of each year from 1989 through 1992, the Secretary shall submit to the Committees on Veterans' Affairs of the Senate and the House of Representatives a report on the experience in carrying out this section during the preceding fiscal year. The first such report shall contain information showing the percentage (measured by cost) of the total of all health-care items procured by the Department during fiscal year 1988 that were procured through local contracts. The other reports under this paragraph shall contain information showing the percentage (measured by cost) of the total of all health-care items procured by the Department, and by each Department medical center, during the fiscal year covered by the report that were purchased through local contracts and, in the case of each medical center at which the percentage was greater than 20 percent, an explanation of the reasons why that occurred.''

1992—Subsec. (b)(1)(B)(ii). Pub. L. 102–405 substituted ''Under Secretary for Health'' for ''Chief Medical Director''.

1991—Pub. L. 102–40 renumbered section 5025 of this title as this section.

Subsec. (a). Pub. L. 102–83, §4(b)(1), (2)(E), substituted ''Secretary'' for ''Administrator''.

Subsec. (b). Pub. L. 102–83, §4(b)(1), (2)(E), substituted ''Secretary'' for ''Administrator'' in two places in par. (3)(C).

Pub. L. 102–83, §4(a)(3), (4), substituted ''Department'' for ''Veterans' Administration'' wherever appearing.

Subsec. (c). Pub. L. 102–83, §4(a)(3), (4), substituted ''Department'' for ''Veterans' Administration''.

Subsecs. (d), (e). Pub. L. 102–83, §4(b)(1), (2)(E), substituted ''Secretary'' for ''Administrator'' wherever appearing.

Pub. L. 102–83, §4(a)(3), (4), substituted ''Department'' for ''Veterans' Administration'' wherever appearing.

1988—Subsec. (d)(1). Pub. L. 100–687, §1507(b)(1), inserted ''(beginning in 1992)'' after ''of each year''.

Subsec. (d)(2). Pub. L. 100–687, §1507(b)(2), inserted ''(beginning in 1993)'' after ''of each year''.

Subsec. (d)(3). Pub. L. 100–687, §1507(b)(3), added par. (3).

Subsec. (e)(1). Pub. L. 100–687, §1507(c), substituted ''65 or 66'' for ''65, 66, or 73'' and inserted after first sentence ''Effective December 1, 1992, such term also includes any item listed in, or (as determined by the Administrator) of the same nature as an item listed in, Federal Supply Classification (FSC) Group 73.''

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Pub. L. 100–322, title IV, §403(b), May 20, 1988, 102 Stat. 545, as amended by Pub. L. 100–687, div. B, title XV, §1507(a), Nov. 18, 1988, 102 Stat. 4136, provided that:

''(1) Subsections (a), (b)(1), and (b)(2) of section 5025 [now 8125] of title 38, United States Code (as added by subsection (a)), shall take effect one year after the date of the enactment of this Act [May 20, 1988].

''(2) Subsection (b)(3) of such section shall apply to health-care items procured for use by the Veterans' Administration [now Department of Veterans Affairs] after September 30, 1990.''

MEDICAL SURGICAL PRIME VENDOR PROGRAM

Pub. L. 115–407, title VII, §703, Dec. 31, 2018, 132 Stat. 5381, provided that:

''(a) VENDORS.—In procuring certain medical, surgical, and dental supplies or laboratory supplies for medical centers of the Department of Veterans Affairs, the Secretary of Veterans Affairs shall carry out the Medical Surgical Prime Vendor program, or successor program, in a manner that—

''(1) requires the Secretary to award contracts to multiple regional prime vendors instead of a single nationwide prime vendor; and

''(2) prohibits a prime vendor from solely designing the formulary of such supplies.

''(b) CLINICALLY DRIVEN SOURCING.—

''(1) EXPERTISE.—In carrying out the formulary of supplies under the Medical Surgical Prime Vendor program, or successor program, the Secretary shall ensure that each employee of the Department of Veterans Affairs who conducts formulary analyses or makes decisions with respect to including items on the formulary has medical expertise relevant to the items for which the employee conducts such analyses or makes such decisions.

''(2) LISTS.—Not later than 30 days after the date of the enactment of this Act [Dec. 31, 2018], and every six months thereafter with respect to any updates, the Secretary shall submit to the Committees on Veterans' Affairs of the House of Representatives and the Senate a list of each employee described in paragraph (1) and the relevant medical expertise of the employee, listed by the categories of items in the formulary described in such paragraph.''

STANDARDIZATION OF MEDICAL AND PHARMACEUTICAL ITEMS

Pub. L. 100–322, title IV, §402, May 20, 1988, 102 Stat. 543, as amended by Pub. L. 100–687, div. B, title XV, §1508, Nov. 18, 1988, 102 Stat. 4137, directed Administrator, not later than Oct. 1, 1989, to develop and fully implement an agency-wide plan for cost-effective standardization of health-care items procured by Veterans' Administration.

§ 8126. Limitation on prices of drugs procured by Department and certain other Federal agencies

(a) Each manufacturer of covered drugs shall enter into a master agreement with the Secretary under which—

(1) beginning January 1, 1993, the manufacturer shall make available for procurement on the Federal Supply Schedule of the General Services Administration each covered drug of the manufacturer;

(2) with respect to each covered drug of the manufacturer procured by a Federal agency described in subsection (b) on or after January 1, 1993, that is purchased under depot contracting systems or listed on the Federal Supply Schedule, the manufacturer has entered into and has in effect a pharmaceutical pricing agreement with the Secretary (or the Federal agency involved, if the Secretary delegates to the Federal agency the authority to enter into such a pharmaceutical pricing agreement) under which the price charged during the one-year period beginning on the date on which the agreement takes effect may not exceed 76 percent of the non-Federal average manufacturer price (less the amount of any additional discount required under subsection (c)) during the one-year period ending one month before such date (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period are not available, during such period as the Secretary considers appropriate),

except that such price may nominally exceed such amount if found by the Secretary to be in the best interests of the Department or such Federal agencies;

(3) with respect to each covered drug of the manufacturer procured by a State home receiving funds under section 1741 of this title, the price charged may not exceed the price charged under the Federal Supply Schedule at the time the drug is procured; and

(4) unless the manufacturer meets the requirements of paragraphs (1), (2), and (3), the manufacturer may not receive payment for the purchase of drugs or biologicals from—

(A) a State plan under title XIX of the Social Security Act, except as authorized under section 1927(a)(3) of such Act,

(B) any Federal agency described in subsection (b), or

(C) any entity that receives funds under the Public Health Service Act.

(b) The Federal agencies described in this subsection are as follows:

(1) The Department.

(2) The Department of Defense.

(3) The Public Health Service, including the Indian Health Service.

(4) The Coast Guard.

(c) With respect to any covered drug the price of which is determined in accordance with a pharmaceutical pricing agreement entered into pursuant to subsection (a)(2), beginning on or after January 1, 1993, the manufacturer shall provide a discount in an amount equal to the amount by which the change in non-Federal price exceeds the amount equal to—

(1) the non-Federal average manufacturer price of the drug during the 3-month period that ends one year before the last day of the month preceding the month during which the contract for the covered drug goes into effect (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period is not available, during such period as the Secretary considers appropriate); multiplied by

(2) the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) between the last month of the period described in paragraph (1) and the last month preceding the month during which the contract goes into effect for which Consumer Price Index data is available.

(d) In the case of a covered drug of a manufacturer that has entered into a multi-year contract with the Secretary under subsection (a)(2) for the procurement of the drug—

(1) during any one-year period that follows the first year for which the contract is in effect, the contract price charged for the drug may not exceed the contract price charged during the preceding one-year period, increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) during the 12-month period ending with the last month of such preceding one-year period for which Consumer Price Index data is available; and

(2) in applying subsection (c) to determine the amount of the discount provided with respect to the drug during a year that follows the first year for which the contract is in effect, any reference in such subsection to ''the month during which the contract goes into effect'' shall be considered a reference to the first month of such following year.

(e)(1) The manufacturer of any covered drug the price of which is determined in accordance with a pharmaceutical pricing agreement entered into pursuant to subsection (a)(2) shall—

(A) not later than 30 days after the first day of the last quarter that begins before the agreement takes effect (or, in the case of an agreement that takes effect on January 1, 1993, not later than December 4, 1992), report to the Secretary the non-Federal average manufacturer price for the drug during the one-year period that ends on the last day of the previous quarter; and

(B) not later than 30 days after the last day of each quarter for which the agreement is in effect, report to the Secretary the non-Federal average manufacturer price for the drug during such quarter.

(2) The provisions of subparagraphs (B) and (C) of section 1927(b)(3) of the Social Security Act shall apply to drugs described in paragraph (1) and the Secretary in the same manner as such provisions apply to covered outpatient drugs and the Secretary of Health and Human Services under such subparagraphs, except that references in such subparagraphs to prices or information reported or required under ''subparagraph (A)'' shall be deemed to refer to information reported under paragraph (1).

(3) In order to determine the accuracy of a drug price that is reported to the Secretary under paragraph (1), the Secretary may audit the relevant records of the manufacturer or of any wholesaler that distributes the drug, and may delegate the authority to audit such records to the appropriate Federal agency described in subsection (b).

(4) Any information contained in a report submitted to the Secretary under paragraph (1) or obtained by the Secretary through any audit conducted under paragraph (3) shall remain confidential, except as the Secretary determines necessary to carry out this section and to permit the Comptroller General and the Director of the Congressional Budget Office to review the information provided.

(f) The Secretary shall supply to the Secretary of Health and Human Services—

(1) upon the execution or termination of any master agreement, the name of the manufacturer, and

(2) on a quarterly basis, a list of manufacturers who have entered into master agreements under this section.

(g)(1) Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on November 4, 1992.

(2) A manufacturer is deemed to meet the requirements of subsection (a) if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of this section (as in effect immediately after the en-

actment of this section), and would have entered into an agreement under this section (as such section was in effect at such time), but for a legislative change in this section after November 4, 1992.

(h) In this section:

(1) The term ''change in non-Federal price'' means, with respect to a covered drug that is subject to an agreement under this section, an amount equal to—

(A) the non-Federal average manufacturer price of the drug during the 3-month period that ends with the month preceding the month during which a contract goes into effect (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period is not available, during such period as the Secretary considers appropriate); minus

(B) the non-Federal average manufacturer price of the drug during the 3-month period that ends one year before the end of the period described in subparagraph (A) (or, in the case of a covered drug for which sufficient data for determining the non-Federal average manufacturer price during such period is not available, during such period preceding the period described in subparagraph (A) as the Secretary considers appropriate).

(2) The term ''covered drug'' means—

(A) a drug described in section 1927(k)(7)(A)(ii) of the Social Security Act, or that would be described in such section but for the application of the first sentence of section 1927(k)(3) of such Act;

(B) a drug described in section 1927(k)(7)(A)(iv) of the Social Security Act, or that would be described in such section but for the application of the first sentence of section 1927(k)(3) of such Act; or

(C) any biological product identified under section 600.3 of title 21, Code of Federal Regulations.

(3) The term ''depot'' means a centralized commodity management system through which covered drugs procured by an agency of the Federal Government are—

(A) received, stored, and delivered through—

(i) a federally owned and operated warehouse system, or

(ii) a commercial entity operating under contract with such agency; or

(B) delivered directly from the commercial source to the entity using such covered drugs.

(4) The term ''manufacturer'' means any entity which is engaged in—

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(5) The term ''non-Federal average manufacturer price'' means, with respect to a covered drug and a period of time (as determined by the Secretary), the weighted average price of a single form and dosage unit of the drug that is paid by wholesalers in the United States to the manufacturer, taking into account any cash discounts or similar price reductions during that period, but not taking into account—

(A) any prices paid by the Federal Government; or

(B) any prices found by the Secretary to be merely nominal in amount.

(6) The term ''weighted average price'' means, with respect to a covered drug and a period of time (as determined by the Secretary) an amount equal to—

(A) the sum of the products of the average price per package unit of each quantity of the drug sold during the period and the number of package units of the drug sold during the period; divided by

(B) the total number of package units of the drug sold during the period.

(i)(1) If the Secretary modifies a multi-year contract described in subsection (d) to include a covered drug of the manufacturer that was not available for inclusion under the contract at the time the contract went into effect, the price of the drug shall be determined as follows:

(A) For the portion of the first contract year during which the drug is so included, the price of the drug shall be determined in accordance with subsection (a)(2), except that the reference in such subsection to ''the one-year period beginning on the date the agreement takes effect'' shall be considered a reference to such portion of the first contract year.

(B) For any subsequent contract year, the price of the drug shall be determined in accordance with subsection (d), except that each reference in such subsection to ''the first year for which the contract is in effect'' shall be considered a reference to the portion of the first contract year during which the drug is included under the contract.

(2) In this subsection, the term ''contract year'' means any one-year period for which a multi-year contract described in subsection (d) is in effect.

(Added Pub. L. 102–585, title VI, §603(a)(1), Nov. 4, 1992, 106 Stat. 4971; amended Pub. L. 103–18, §1(a), Apr. 12, 1993, 107 Stat. 53; Pub. L. 103–446, title XII, §1201(e)(27), (f)(6), Nov. 2, 1994, 108 Stat. 4686, 4687; Pub. L. 104–106, div. A, title VII, §737(a), Feb. 10, 1996, 110 Stat. 383; Pub. L. 105–115, title I, §125(b)(2)(E), Nov. 21, 1997, 111 Stat. 2325.)

Editorial Notes

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (a)(4)(A), (e)(2), (g)(1), and (h)(2)(A), (B), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended, which is classified generally to chapter 7 (§301 et seq.) of Title 42, The Public Health and Welfare. Title XIX of the Act is clas-

sified generally to subchapter XIX (§ 1396 et seq.) of chapter 7 of Title 42. Section 1927 of the Act is classified to section 1396r–8 of Title 42. For complete classification of this Act to the Code, see section 1305 of Title 42 and Tables.

The Public Health Service Act, referred to in subsec. (a)(4)(C), is act July 1, 1944, ch. 373, 58 Stat. 682, as amended, which is classified generally to chapter 6A (§ 201 et seq.) of Title 42. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

Enactment of this section, referred to in subsec. (g)(2), means enactment of Pub. L. 102–585, which enacted this section and was approved Nov. 4, 1992.

AMENDMENTS

1997—Subsec. (h)(2). Pub. L. 105–115 inserted ''or'' at end of subpar. (B), substituted a period for ''; or'' at end of subpar. (C), and struck out subpar. (D), which read as follows: ''insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.''

1996—Subsec. (b)(4). Pub. L. 104–106 added par. (4).

1994—Subsec. (e)(1)(A). Pub. L. 103–446, § 1201(e)(27)(A), (f)(6)(A), substituted ''December 4, 1992'' for ''30 days after the date of the enactment of this section'' and ''one-year period'' for ''1-year period''.

Subsec. (f)(2). Pub. L. 103–446, § 1201(e)(27)(B), substituted a period for '', and'' at end.

Subsec. (g)(1), (2). Pub. L. 103–446, § 1201(f)(6)(B), substituted ''November 4, 1992'' for ''the date of the enactment of this section''.

1993—Subsec. (a)(2). Pub. L. 103–18, § 1(a)(1), struck out ''preceding such date'' before ''as the Secretary considers appropriate''.

Subsec. (c). Pub. L. 103–18, § 1(a)(2), in introductory provisions, struck out ''for calendar quarters'' after ''subsection (a)(2),'', and in par. (1), struck out ''preceding the month during which the contract goes into effect'' after ''during such period'' and substituted ''multiplied by'' for ''increased by''.

Subsec. (d)(1). Pub. L. 103–18, § 1(a)(3), amended par. (1) generally. Prior to amendment, par. (1) read as follows: ''during any one-year period that follows the first year for which the contract is in effect, the price charged may not exceed the price charged during the preceding one-year period, increased by the percentage increase in the Consumer Price Index for all urban consumers (U.S. city average) between the last months of such one-year periods for which Consumer Price Index data is available; and''.

Subsec. (i). Pub. L. 103–18, § 1(a)(4), added subsec. (i).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 1996 AMENDMENT

Pub. L. 104–106, div. A, title VII, § 737(b), Feb. 10, 1996, 110 Stat. 383, provided that: ''The amendment made by subsection (a) [amending this section] shall take effect as if included in the enactment of section 603 of the Veterans Health Care Act of 1992 (Public Law 102–585; 106 Stat. 4971).''

EFFECTIVE DATE OF 1993 AMENDMENT

Pub. L. 103–18, § 1(b), Apr. 12, 1993, 107 Stat. 54, provided that: ''The amendments made by subsection (a) [amending this section] shall take effect as if included in the enactment of section 603 of the Veterans Health Care Act of 1992 [Pub. L. 102–585].''

TRANSFER OF FUNCTIONS

For transfer of authorities, functions, personnel, and assets of the Coast Guard, including the authorities and functions of the Secretary of Transportation relating thereto, to the Department of Homeland Security, and for treatment of related references, see sections 468(b), 551(d), 552(d), and 557 of Title 6, Domestic Security, and the Department of Homeland Security Reorganization Plan of November 25, 2002, as modified, set out as a note under section 542 of Title 6.

§ 8127. Small business concerns owned and controlled by veterans: contracting goals and preferences

(a) CONTRACTING GOALS.—(1) In order to increase contracting opportunities for small business concerns owned and controlled by veterans and small business concerns owned and controlled by veterans with service-connected disabilities, the Secretary shall—

(A) establish a goal for each fiscal year for participation in Department contracts (including subcontracts) by small business concerns owned and controlled by veterans who are not veterans with service-connected disabilities in accordance with paragraph (2); and

(B) establish a goal for each fiscal year for participation in Department contracts (including subcontracts) by small business concerns owned and controlled by veterans with service-connected disabilities in accordance with paragraph (3).

(2) The goal for a fiscal year for participation under paragraph (1)(A) shall be determined by the Secretary.

(3) The goal for a fiscal year for participation under paragraph (1)(B) shall be not less than the Government-wide goal for that fiscal year for participation by small business concerns owned and controlled by veterans with service-connected disabilities under section 15(g)(1) of the Small Business Act (15 U.S.C. 644(g)(1)).

(4) The Secretary shall establish a review mechanism to ensure that, in the case of a subcontract of a Department contract that is counted for purposes of meeting a goal established pursuant to this section, the subcontract was actually awarded to a business concern that may be counted for purposes of meeting that goal.

(b) USE OF NONCOMPETITIVE PROCEDURES FOR CERTAIN SMALL CONTRACTS.—Except as provided in subsection (d)(2), for purposes of meeting the goals under subsection (a), and in accordance with this section, in entering into a contract with a small business concern owned and controlled by veterans or a small business concern owned and controlled by veterans with service-connected disabilities for an amount less than the simplified acquisition threshold (as defined in section 134 of title 41), a contracting officer of the Department may use procedures other than competitive procedures.

(c) SOLE SOURCE CONTRACTS FOR CONTRACTS ABOVE SIMPLIFIED ACQUISITION THRESHOLD.—Except as provided in subsection (d)(2), for purposes of meeting the goals under subsection (a), and in accordance with this section, a contracting officer of the Department may award a contract to a small business concern owned and controlled by veterans or a small business concern owned and controlled by veterans with service-connected disabilities using procedures other than competitive procedures if—

(1) such concern is determined to be a responsible source with respect to performance of such contract opportunity;

(2) the anticipated award price of the contract (including options) will exceed the simplified acquisition threshold (as defined in section 134 of title 41) but will not exceed $5,000,000; and