

(2) For each of fiscal years 2014, 2015, 2016, 2017, 2018, and 2019, an amount equal to \$2 multiplied by the average number of individuals entitled to benefits under part A, or enrolled under part B, of subchapter XVIII during such fiscal year.

(b) Adjustments for increases in health care spending

In the case of any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a)(2) for such fiscal year shall be equal to the sum of such dollar amount for the previous fiscal year (determined after the application of this subsection), plus an amount equal to the product of—

(1) such dollar amount for the previous fiscal year, multiplied by

(2) the percentage increase in the projected per capita amount of National Health Expenditures, as most recently published by the Secretary before the beginning of the fiscal year.

(Aug. 14, 1935, ch. 531, title XI, §1183, as added Pub. L. 111-148, title VI, §6301(d), Mar. 23, 2010, 124 Stat. 741.)

Editorial Notes

REFERENCES IN TEXT

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

§ 1320e-3. Information exchange with payroll data providers

(a) In general

The Commissioner of Social Security may enter into an information exchange with a payroll data provider for purposes of—

(1) efficiently administering—

(A) monthly insurance benefits under subsections (d)(1)(B)(ii), (d)(6)(A)(ii), (d)(6)(B), (e)(1)(B)(ii), and (f)(1)(B)(ii) of section 402 of this title and subsection (a)(1) of section 423 of this title; and

(B) supplemental security income benefits under subchapter XVI; and

(2) preventing improper payments of such benefits without the need for verification by independent or collateral sources.

(b) Notification requirements

Before entering into an information exchange pursuant to subsection (a), the Commissioner shall publish in the Federal Register a notice describing the information exchange and the extent to which the information received through such exchange is—

(1) relevant and necessary to—

(A) accurately determine entitlement to, and the amount of, benefits described under subparagraph (A) of subsection (a)(1);

(B) accurately determine eligibility for, and the amount of, benefits described in subparagraph (B) of such subsection; and

(C) prevent improper payment of such benefits; and

(2) sufficiently accurate, up-to-date, and complete.

(c) Definitions

For purposes of this section:

(1) Payroll data provider

The term “payroll data provider” means payroll providers, wage verification companies, and other commercial or non-commercial entities that collect and maintain data regarding employment and wages, without regard to whether the entity provides such data for a fee or without cost.

(2) Information exchange

The term “information exchange” means the automated comparison of a system of records maintained by the Commissioner of Social Security with records maintained by a payroll data provider.

(Aug. 14, 1935, ch. 531, title XI, §1184, as added Pub. L. 114-74, title VIII, §824(a), Nov. 2, 2015, 129 Stat. 607.)

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE

Section effective one year after Nov. 2, 2015, see section 824(e) of Pub. L. 114-74, set out as an Effective Date of 2015 Amendment note under section 425 of this title.

REGULATIONS

Pub. L. 114-74, title VIII, §824(d), Nov. 2, 2015, 129 Stat. 610, provided that: “Not later than 1 year after the date of the enactment of this Act [Nov. 2, 2015], the Commissioner of Social Security shall prescribe by regulation procedures for implementing the Commissioner’s access to and use of information held by payroll providers, including—

“(1) guidelines for establishing and maintaining information exchanges with payroll providers, pursuant to section 1184 of the Social Security Act [42 U.S.C. 1320e-3];

“(2) beneficiary authorizations;

“(3) reduced wage reporting responsibilities for individuals who authorize the Commissioner to access information held by payroll data providers through an information exchange; and

“(4) procedures for notifying individuals in writing when they become subject to such reduced wage reporting requirements and when such reduced wage reporting requirements no longer apply to them.”

PART E—PRICE NEGOTIATION PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS

§ 1320f. Establishment of program

(a) In general

The Secretary shall establish a Drug Price Negotiation Program (in this part referred to as the “program”). Under the program, with respect to each price applicability period, the Secretary shall—

(1) publish a list of selected drugs in accordance with section 1320f-1 of this title;

(2) enter into agreements with manufacturers of selected drugs with respect to such period, in accordance with section 1320f-2 of this title;

(3) negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs, in accordance with section 1320f-3 of this title;¹

(4) carry out the publication and administrative duties and compliance monitoring in ac-

¹ So in original. Probably should be followed by “and”.

cordance with sections 1320f-4 and 1320f-5 of this title.

(b) Definitions relating to timing

For purposes of this part:

(1) Initial price applicability year

The term “initial price applicability year” means a year (beginning with 2026).

(2) Price applicability period

The term “price applicability period” means, with respect to a qualifying single source drug, the period beginning with the first initial price applicability year with respect to which such drug is a selected drug and ending with the last year during which the drug is a selected drug.

(3) Selected drug publication date

The term “selected drug publication date” means, with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year.

(4) Negotiation period

The term “negotiation period” means, with respect to an initial price applicability year with respect to a selected drug, the period—

(A) beginning on the sooner of—

(i) the date on which the manufacturer of the drug and the Secretary enter into an agreement under section 1320f-2 of this title with respect to such drug; or

(ii) February 28 following the selected drug publication date with respect to such selected drug; and

(B) ending on November 1 of the year that begins 2 years prior to the initial price applicability year.

(c) Other definitions

For purposes of this part:

(1) Manufacturer

The term “manufacturer” has the meaning given that term in section 1395w-3a(c)(6)(A) of this title.

(2) Maximum fair price eligible individual

The term “maximum fair price eligible individual” means, with respect to a selected drug—

(A) in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a prescription drug plan under part D of subchapter XVIII or an MA-PD plan under part C of such subchapter if coverage is provided under such plan for such selected drug; and

(B) in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under part B of subchapter XVIII, including an individual who is enrolled in an MA plan under part C of such subchapter, if payment may be made under part B for such selected drug.

(3) Maximum fair price

The term “maximum fair price” means, with respect to a year during a price applicability period and with respect to a selected drug (as

defined in section 1320f-1(c) of this title) with respect to such period, the price negotiated pursuant to section 1320f-3 of this title, and updated pursuant to section 1320f-4(b) of this title, as applicable, for such drug and year.

(4) Reference product

The term “reference product” has the meaning given such term in section 262(i) of this title.

(5) Total expenditures

The term “total expenditures” includes, in the case of expenditures with respect to part D of subchapter XVIII, the total gross covered prescription drug costs (as defined in section 1395w-115(b)(3) of this title). The term “total expenditures” excludes, in the case of expenditures with respect to part B of such subchapter, expenditures for a drug or biological product that are bundled or packaged into the payment for another service.

(6) Unit

The term “unit” means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.

(d) Timing for initial price applicability year 2026

Notwithstanding the provisions of this part, in the case of initial price applicability year 2026, the following rules shall apply for purposes of implementing the program:

(1) Subsection (b)(3) shall be applied by substituting “September 1, 2023” for “, with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year”.

(2) Subsection (b)(4) shall be applied—

(A) in subparagraph (A)(ii), by substituting “October 1, 2023” for “February 28 following the selected drug publication date with respect to such selected drug”; and

(B) in subparagraph (B), by substituting “August 1, 2024” for “November 1 of the year that begins 2 years prior to the initial price applicability year”.

(3) Section 1320f-1 of this title shall be applied—

(A) in subsection (b)(1)(A), by substituting “during the period beginning on June 1, 2022, and ending on May 31, 2023” for “during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available”; and

(B) in subsection (d)(1)(A), by substituting “during the period beginning on June 1, 2022, and ending on May 31, 2023” for “during the most recent period for which data are available of at least 12 months prior to the selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date), with respect to such year”.²

²So in original. Probably should read as follows: “during the most recent 12-month period for which data are available prior

(4) Section 1320f-2(a) of this title shall be applied by substituting “October 1, 2023” for “February 28 following the selected drug publication date with respect to such selected drug”.

(5) Section 1320f-3(b)(2) of this title shall be applied—

(A) in subparagraph (A), by substituting “October 2, 2023” for “March 1 of the year of the selected drug publication date, with respect to the selected drug”;

(B) in subparagraph (B), by substituting “February 1, 2024” for “the June 1 following the selected drug publication date”; and

(C) in subparagraph (E), by substituting “August 1, 2024” for “the first day of November following the selected drug publication date, with respect to the initial price applicability year”.

(6) Section 1320f-4(a)(1) of this title shall be applied by substituting “September 1, 2024” for “November 30 of the year that is 2 years prior to such initial price applicability year”.

(Aug. 14, 1935, ch. 531, title XI, §1191, as added Pub. L. 117-169, title I, §11001(a), Aug. 16, 2022, 136 Stat. 1833.)

Statutory Notes and Related Subsidiaries

IMPLEMENTATION FOR 2026 THROUGH 2028

Pub. L. 117-169, title I, §11001(c), Aug. 16, 2022, 136 Stat. 1854, provided that: “The Secretary of Health and Human Services shall implement this section [enacting this part and amending sections 1395w-3a, 1395w-22, 1395w-27, 1395w-102, 1395w-104, 1395w-111, 1395w-112, 1395w-115, 1395w-153, and 1396r-8 of this title], including the amendments made by this section, for 2026, 2027, and 2028 by program instruction or other forms of program guidance.”

§ 1320f-1. Selection of negotiation-eligible drugs as selected drugs

(a) In general

Not later than the selected drug publication date with respect to an initial price applicability year, in accordance with subsection (b), the Secretary shall select and publish a list of—

(1) with respect to the initial price applicability year 2026, 10 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 10) such negotiation-eligible drugs with respect to such year);

(2) with respect to the initial price applicability year 2027, 15 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year);

(3) with respect to the initial price applicability year 2028, 15 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1) with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year); and

to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date)“.

(4) with respect to the initial price applicability year 2029 or a subsequent year, 20 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1), with respect to such year (or, all (if such number is less than 20) such negotiation-eligible drugs with respect to such year).

Subject to subsection (c)(2) and section 1320f-3(f)(5) of this title, each drug published on the list pursuant to the previous sentence and subsection (b)(3) shall be subject to the negotiation process under section 1320f-3 of this title for the negotiation period with respect to such initial price applicability year (and the renegotiation process under such section as applicable for any subsequent year during the applicable price applicability period).

(b) Selection of drugs

(1) In general

In carrying out subsection (a), subject to paragraph (2), the Secretary shall, with respect to an initial price applicability year, do the following:

(A) Rank negotiation-eligible drugs described in subsection (d)(1) according to the total expenditures for such drugs under parts B and D of subchapter XVIII, as determined by the Secretary, during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available, with the negotiation-eligible drugs with the highest total expenditures being ranked the highest.

(B) Select from such ranked drugs with respect to such year the negotiation-eligible drugs with the highest such rankings.

(C) In the case of a biological product for which the inclusion of the biological product as a selected drug on a list published under subsection (a) has been delayed under subsection (f)(2), remove such biological product from the rankings under subparagraph (A) before making the selections under subparagraph (B).

(2) High spend part D drugs for 2026 and 2027

With respect to the initial price applicability year 2026 and with respect to the initial price applicability year 2027, the Secretary shall apply paragraph (1) as if the reference to “negotiation-eligible drugs described in subsection (d)(1)” were a reference to “negotiation-eligible drugs described in subsection (d)(1)(A)” and as if the reference to “total expenditures for such drugs under parts B and D of subchapter XVIII” were a reference to “total expenditures for such drugs under part D of subchapter XVIII”.

(3) Inclusion of delayed biological products

Pursuant to subparagraphs (B)(ii)(I) and (C)(i) of subsection (f)(2), the Secretary shall select and include on the list published under subsection (a) the biological products described in such subparagraphs. Such biological products shall count towards the required number of drugs to be selected under subsection (a)(1).