sumer price index for all urban consumers (United States city average) for the first month of such applicable period.

(6) Average manufacturer price

The term ''average manufacturer price'' has the meaning, with respect to a part D rebatable drug of a manufacturer, given such term in section 1396r–8(k)(1) of this title, with respect to a covered outpatient drug of a manufacturer for a rebate period under section 1396r–8 of this title.

(7) Applicable period

The term ''applicable period'' means a 12-month period beginning with October 1 of a year (beginning with October 1, 2022).

(h) Implementation for 2022, 2023, and 2024

The Secretary shall implement this section for 2022, 2023, and 2024 by program instruction or other forms of program guidance.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D–14B, as added Pub. L. 117–169, title I, § 11102(a), Aug. 16, 2022, 136 Stat. 1871.)

§ 1395w–114c. Manufacturer discount program

(a) Establishment

The Secretary shall establish a manufacturer discount program (in this section referred to as the ''program''). Under the program, the Secretary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance of the duties described in subsection (c).

(b) Terms of agreement

(1) In general

(A) Agreement

An agreement under this section shall require the manufacturer to provide, in accordance with this section, discounted prices for applicable drugs of the manufacturer that are dispensed to applicable beneficiaries on or after January 1, 2025.

(B) Clarification

Nothing in this section shall be construed as affecting—

(i) the application of a coinsurance of 25 percent of the negotiated price, as applied under paragraph (2)(A) of section 1395w–102(b) of this title, for costs described in such paragraph; or

(ii) the application of the copayment amount described in paragraph (4)(A) of such section, with respect to costs described in such paragraph.

(C) Timing of agreement

(i) Special rule for 2025

In order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2025, and ending on December 31, 2025, the manufacturer shall enter into such agreement not later than March 1, 2024.

(ii) 2026 and subsequent years

In order for an agreement with a manufacturer to be in effect under this section with respect to plan year 2026 or a subsequent plan year, the manufacturer shall enter into such agreement not later than a calendar quarter or semi-annual deadline established by the Secretary.

(2) Provision of appropriate data

Each manufacturer with an agreement in effect under this section shall collect and have available appropriate data, as determined by the Secretary, to ensure that it can demonstrate to the Secretary compliance with the requirements under the program.

(3) Compliance with requirements for administration of program

Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary, as applicable, for purposes of administering the program, including any determination under subparagraph (A) of subsection (c)(1) or procedures established under such subsection (c)(1).

(4) Length of agreement

(A) In general

An agreement under this section shall be effective for an initial period of not less than 12 months and shall be automatically renewed for a period of not less than 1 year unless terminated under subparagraph (B).

(B) Termination

(i) By the Secretary

The Secretary shall provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

(ii) By a manufacturer

A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

(I) if the termination occurs before January 31 of a plan year, as of the day after the end of the plan year; and

(II) if the termination occurs on or after January 31 of a plan year, as of the day after the end of the succeeding plan year.

(iii) Effectiveness of termination

Any termination under this subparagraph shall not affect discounts for applicable drugs of the manufacturer that are due under the agreement before the effective date of its termination.

(5) Effective date of agreement

An agreement under this section shall take effect at the start of a calendar quarter or another date specified by the Secretary.

(c) Duties described

The duties described in this subsection are the following:

(1) Administration of program

Administering the program, including—

(A) the determination of the amount of the discounted price of an applicable drug of a manufacturer;

(B) the establishment of procedures to ensure that, not later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—

(i) the negotiated price of the applicable drug; and

(ii) the discounted price of the applicable drug;

(C) the establishment of procedures to ensure that the discounted price for an applicable drug under this section is applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of applicable beneficiaries as specified by the Secretary; and

(D) providing a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, prescription drug plans and MA–PD plans, and the Secretary.

(2) Monitoring compliance

The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under this section.

(3) Collection of data from prescription drug plans and MA–PD plans

The Secretary may collect appropriate data from prescription drug plans and MA–PD plans in a timeframe that allows for discounted prices to be provided for applicable drugs under this section.

(d) Administration

(1) In general

Subject to paragraph (2), the Secretary shall provide for the implementation of this section, including the performance of the duties described in subsection (c).

(2) Limitation

In providing for the implementation of this section, the Secretary shall not receive or distribute any funds of a manufacturer under the program.

(e) Civil money penalty

(1) In general

A manufacturer that fails to provide discounted prices for applicable drugs of the manufacturer dispensed to applicable beneficiaries in accordance with an agreement in effect under this section shall be subject to a civil money penalty for each such failure in an amount the Secretary determines is equal to the sum of—

(A) the amount that the manufacturer would have paid with respect to such discounts under the agreement, which will then be used to pay the discounts which the manufacturer had failed to provide; and

(B) 25 percent of such amount.

(2) Application

The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this subsection in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title.

(f) Clarification regarding availability of other covered part D drugs

Nothing in this section shall prevent an applicable beneficiary from purchasing a covered part D drug that is not an applicable drug (including a generic drug or a drug that is not on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in).

(g) Definitions

In this section:

(1) Applicable beneficiary

The term ''applicable beneficiary'' means an individual who, on the date of dispensing a covered part D drug—

(A) is enrolled in a prescription drug plan or an MA–PD plan;

(B) is not enrolled in a qualified retiree prescription drug plan; and

(C) has incurred costs, as determined in accordance with section 1395w–102(b)(4)(C) of this title, for covered part D drugs in the year that exceed the annual deductible specified in section 1395w–102(b)(1) of this title.

(2) Applicable drug

The term ''applicable drug'', with respect to an applicable beneficiary—

(A) means a covered part D drug—

(i) approved under a new drug application under section 355(c) of title 21 or, in the case of a biologic product, licensed under section 262 of this title; and

(ii)(I) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in;

(II) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

(III) is provided through an exception or appeal; and

(B) does not include a selected drug (as referred to under section 1320f–1(c) of this title) during a price applicability period (as defined in section 1320f(b)(2) of this title) with respect to such drug.

(3) Applicable number of calendar days

The term ''applicable number of calendar days'' means—

(A) with respect to claims for reimbursement submitted electronically, 14 days; and

(B) with respect to claims for reimbursement submitted otherwise, 30 days.

(4) Discounted price

(A) In general

The term ''discounted price'' means, subject to subparagraphs (B) and (C), with respect to an applicable drug of a manufacturer dispensed during a year to an applicable beneficiary—

(i) who has not incurred costs, as determined in accordance with section 1395w–102(b)(4)(C) of this title, for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B)(i) of this title for the year, 90 percent of the negotiated price of such drug; and

(ii) who has incurred such costs, as so determined, in the year that are equal to or exceed such threshold for the year, 80 percent of the negotiated price of such drug.

(B) Phase-in for certain drugs dispensed to LIS beneficiaries

(i) In general

In the case of an applicable drug of a specified manufacturer (as defined in clause (ii)) that is marketed as of August 16, 2022, and dispensed for an applicable beneficiary who is a subsidy eligible individual (as defined in section 1395w–114(a)(3) of this title), the term ''discounted price'' means the specified LIS percent (as defined in clause (iii)) of the negotiated price of the applicable drug of the manufacturer.

(ii) Specified manufacturer

(I) In general

In this subparagraph, subject to subclause (II), the term ''specified manufacturer'' means a manufacturer of an applicable drug for which, in 2021—

(aa) the manufacturer had a coverage gap discount agreement under section 1395w–114a of this title;

(bb) the total expenditures for all of the specified drugs of the manufacturer covered by such agreement or agreements for such year and covered under this part during such year represented less than 1.0 percent of the total expenditures under this part for all covered Part[1] D drugs during such year; and

(cc) the total expenditures for all of the specified drugs of the manufacturer that are single source drugs and biological products for which payment may be made under part B during such year represented less than 1.0 percent of the total expenditures under part B for all drugs or biological products for which payment may be made under such part during such year.

(II) Specified drugs

(aa) In general

For purposes of this clause, the term ''specified drug'' means, with respect to a specified manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the manufacturer.

(bb) Aggregation rule

All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this subparagraph. For purposes of making a determination pursuant to the previous sentence, an agreement under this section shall require that a manufacturer provide and attest to such information as specified by the Secretary as necessary.

(III) Limitation

The term ''specified manufacturer'' shall not include a manufacturer described in subclause (I) if such manufacturer is acquired after 2021 by another manufacturer that is not a specified manufacturer, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

(iii) Specified LIS percent

In this subparagraph, the ''specified LIS percent'' means, with respect to a year—

(I) for an applicable drug dispensed for an applicable beneficiary described in clause (i) who has not incurred costs, as determined in accordance with section 1395w–102(b)(4)(C) of this title, for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B)(i) of this title for the year—

(aa) for 2025, 99 percent;
(bb) for 2026, 98 percent;
(cc) for 2027, 95 percent;
(dd) for 2028, 92 percent; and
(ee) for 2029 and each subsequent year, 90 percent; and

(II) for an applicable drug dispensed for an applicable beneficiary described in clause (i) who has incurred costs, as determined in accordance with section 1395w–102(b)(4)(C) of this title, for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B)(i) of this title for the year—

(aa) for 2025, 99 percent;
(bb) for 2026, 98 percent;
(cc) for 2027, 95 percent;
(dd) for 2028, 92 percent;
(ee) for 2029, 90 percent;
(ff) for 2030, 85 percent; and
(gg) for 2031 and each subsequent year, 80 percent.

[1] So in original. Probably should not be capitalized.

(C) Phase-in for specified small manufacturers

(i) In general

In the case of an applicable drug of a specified small manufacturer (as defined in clause (ii)) that is marketed as of August 16, 2022, and dispensed for an applicable beneficiary, the term ''discounted price'' means the specified small manufacturer percent (as defined in clause (iii)) of the negotiated price of the applicable drug of the manufacturer.

(ii) Specified small manufacturer

(I) In general

In this subparagraph, subject to subclause (III), the term ''specified small manufacturer'' means a manufacturer of an applicable drug for which, in 2021—

(aa) the manufacturer is a specified manufacturer (as defined in subparagraph (B)(ii)); and

(bb) the total expenditures under part D for any one of the specified small manufacturer drugs of the manufacturer that are covered by the agreement or agreements under section 1395w–114a of this title of such manufacturer for such year and covered under this part during such year are equal to or more than 80 percent of the total expenditures under this part for all specified small manufacturer drugs of the manufacturer that are covered by such agreement or agreements for such year and covered under this part during such year.

(II) Specified small manufacturer drugs

(aa) In general

For purposes of this clause, the term ''specified small manufacturer drugs'' means, with respect to a specified small manufacturer, for 2021, an applicable drug that is produced, prepared, propagated, compounded, converted, or processed by the manufacturer.

(bb) Aggregation rule

All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this subparagraph. For purposes of making a determination pursuant to the previous sentence, an agreement under this section shall require that a manufacturer provide and attest to such information as specified by the Secretary as necessary.

(III) Limitation

The term ''specified small manufacturer'' shall not include a manufacturer described in subclause (I) if such manufacturer is acquired after 2021 by another manufacturer that is not a specified small manufacturer, effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

(iii) Specified small manufacturer percent

In this subparagraph, the term ''specified small manufacturer percent'' means, with respect to a year—

(I) for an applicable drug dispensed for an applicable beneficiary who has not incurred costs, as determined in accordance with section 1395w–102(b)(4)(C) of this title, for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B)(i) of this title for the year—

(aa) for 2025, 99 percent;
(bb) for 2026, 98 percent;
(cc) for 2027, 95 percent;
(dd) for 2028, 92 percent; and
(ee) for 2029 and each subsequent year, 90 percent; and

(II) for an applicable drug dispensed for an applicable beneficiary who has incurred costs, as determined in accordance with section 1395w–102(b)(4)(C) of this title, for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B)(i) of this title for the year—

(aa) for 2025, 99 percent;
(bb) for 2026, 98 percent;
(cc) for 2027, 95 percent;
(dd) for 2028, 92 percent;
(ee) for 2029, 90 percent;
(ff) for 2030, 85 percent; and
(gg) for 2031 and each subsequent year, 80 percent.

(D) Total expenditures

For purposes of this paragraph, the term ''total expenditures'' includes, in the case of expenditures with respect to part D, 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, expenditures for a drug or biological that are bundled or packaged into the payment for another service.

(E) Special case for certain claims

(i) Claims spanning deductible

In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall above the annual deductible specified in section 1395w–102(b)(1) of this title for the year, the manufacturer of the applicable drug shall provide the discounted price under this section on only the portion of the negotiated price of the applicable drug that falls above such annual deductible.

(ii) Claims spanning out-of-pocket threshold

In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall en-

tirely below or entirely above the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B)(i) of this title for the year, the manufacturer of the applicable drug shall provide the discounted price—

(I) in accordance with subparagraph (A)(i) on the portion of the negotiated price of the applicable drug that falls below such threshold; and

(II) in accordance with subparagraph (A)(ii) on the portion of such price of such drug that falls at or above such threshold.

(5) Manufacturer

The term ''manufacturer'' means any entity which is engaged in 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. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) Negotiated price

The term ''negotiated price'' has the meaning given such term for purposes of section 1395w–102(d)(1)(B) of this title, and, with respect to an applicable drug, such negotiated price shall include any dispensing fee and, if applicable, any vaccine administration fee for the applicable drug.

(7) Qualified retiree prescription drug plan

The term ''qualified retiree prescription drug plan'' has the meaning given such term in section 1395w–132(a)(2) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–14C, as added Pub. L. 117–169, title I, §11201(c)(1), Aug. 16, 2022, 136 Stat. 1880.)

Editorial Notes

REFERENCES IN TEXT

Section 52 of the Internal Revenue Code of 1986, referred to in subsec. (g)(4)(B)(ii)(II)(bb), (C)(ii)(II)(bb), is classified to section 52 of Title 26, Internal Revenue Code.

§ 1395w–114d. Selected drug subsidy program

With respect to covered part D drugs that would be applicable drugs (as defined in section 1395w–114c(g)(2) of this title) but for the application of subparagraph (B) of such section, the Secretary shall provide a process whereby, in the case of an applicable beneficiary (as defined in section 1395w–114c(g)(1) of this title) who, with respect to a year, is enrolled in a prescription drug plan or is enrolled in an MA–PD plan, has not incurred costs that are equal to or exceed the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B)(i) of this title, and is dispensed such a drug, the Secretary (periodically and on a timely basis) provides the PDP sponsor or the MA organization offering the plan, a subsidy with respect to such drug that is equal to 10 percent of the negotiated price (as defined in section 1395w–114c(g)(6) of this title) of such drug.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–14D, as added Pub. L. 117–169, title I, §11201(c)(1), Aug. 16, 2022, 136 Stat. 1888.)

§ 1395w–115. Subsidies for part D eligible individuals for qualified prescription drug coverage

(a) Subsidy payment

In order to reduce premium levels applicable to qualified prescription drug coverage for part D eligible individuals consistent with an overall subsidy level of 74.5 percent (or, for each of 2024 through 2029, the percent applicable as a result of the application of section 1395w–113(a)(8) of this title, or, for 2030 and each subsequent year, 100 percent minus the percent specified under section 1395w–113(a)(9) of this title) for basic prescription drug coverage, to reduce adverse selection among prescription drug plans and MA–PD plans, and to promote the participation of PDP sponsors under this part and MA organizations under part C, the Secretary shall provide for payment to a PDP sponsor that offers a prescription drug plan and an MA organization that offers an MA–PD plan of the following subsidies in accordance with this section:

(1) Direct subsidy

A direct subsidy for each part D eligible individual enrolled in a prescription drug plan or MA–PD plan for a month equal to—

(A) the amount of the plan's standardized bid amount (as defined in section 1395w–113(a)(5) of this title), adjusted under subsection (c)(1), reduced by

(B) the base beneficiary premium (as computed under paragraph (2) or (8) of section 1395w–113(a) of this title (as applicable) and as adjusted under paragraph (1)(B) of such section).

(2) Subsidy through reinsurance

The reinsurance payment amount (as defined in subsection (b)).

This section constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this section.

(b) Reinsurance payment amount

(1) In general

The reinsurance payment amount under this subsection for a part D eligible individual enrolled in a prescription drug plan or MA–PD plan for a coverage year is an amount equal to—

(A) for a year preceding 2025, 80 percent of the allowable reinsurance costs (as specified in paragraph (2)) attributable to that portion of gross covered prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B) of this title; and

(B) for 2025 and each subsequent year, the sum of—

(i) with respect to applicable drugs (as defined in section 1395w–114c(g)(2) of this title), an amount equal to 20 percent of such allowable reinsurance costs attrib-