2011'' for ''July 1, 2010, and ending on December 31, 2010''.

Subsec. (g)(1). Pub. L. 111–152, § 1101(b)(2)(E)(i), substituted ''a covered part D drug'' for ''an applicable drug'' in introductory provisions.

Subsec. (g)(1)(C) to (E). Pub. L. 111–152, § 1101(b)(2)(E)(ii)–(iv), inserted ''and'' at end of subpar. (C), redesignated subpar. (E) as (D), and struck out former subpar. (D) which read as follows: ''is not subject to a reduction in premium subsidy under section 1395r(i) of this title; and''.

§ 1395w–114b. Manufacturer rebate for certain drugs with prices increasing faster than inflation

(a) Requirements

(1) Secretarial provision of information

Not later than 9 months after the end of each applicable period (as defined in subsection (g)(7)), subject to paragraph (3), the Secretary shall, for each part D rebatable drug, report to each manufacturer of such part D rebatable drug the following for such period:

(A) The amount (if any) of the excess annual manufacturer price increase described in subsection (b)(1)(A)(ii) for each dosage form and strength with respect to such drug and period.

(B) The rebate amount specified under subsection (b) for each dosage form and strength with respect to such drug and period.

(2) Manufacturer requirements

For each applicable period, the manufacturer of a part D rebatable drug, for each dosage form and strength with respect to such drug, not later than 30 days after the date of receipt from the Secretary of the information described in paragraph (1) for such period, shall provide to the Secretary a rebate that is equal to the amount specified in subsection (b) for such dosage form and strength with respect to such drug for such period.

(3) Transition rule for reporting

The Secretary may, for each rebatable covered part D drug, delay the timeframe for reporting the information and rebate amount described in subparagraphs (A) and (B) of such paragraph for the applicable periods beginning October 1, 2022, and October 1, 2023, until not later than December 31, 2025.

(b) Rebate amount

(1) In general

(A) Calculation

For purposes of this section, the amount specified in this subsection for a dosage form and strength with respect to a part D rebatable drug and applicable period is, subject to subparagraph (C), paragraph (5)(B), and paragraph (6), the estimated amount equal to the product of—

(i) subject to subparagraph (B) of this paragraph, the total number of units of such dosage form and strength for each rebatable covered part D drug dispensed under this part during the applicable period; and

(ii) the amount (if any) by which—

(I) the annual manufacturer price (as determined in paragraph (2)) paid for such dosage form and strength with respect to such part D rebatable drug for the period; exceeds

(II) the inflation-adjusted payment amount determined under paragraph (3) for such dosage form and strength with respect to such part D rebatable drug for the period.

(B) Excluded units

For purposes of subparagraph (A)(i), beginning with plan year 2026, the Secretary shall exclude from the total number of units for a dosage form and strength with respect to a part D rebatable drug, with respect to an applicable period, units of each dosage form and strength of such part D rebatable drug for which the manufacturer provides a discount under the program under section 256b of this title.

(C) Reduction or waiver for shortages and severe supply chain disruptions

The Secretary shall reduce or waive the amount under subparagraph (A) with respect to a part D rebatable drug and an applicable period—

(i) in the case of a part D rebatable drug that is described as currently in shortage on the shortage list in effect under section 356e of title 21 at any point during the applicable period;

(ii) in the case of a generic part D rebatable drug (described in subsection (g)(1)(C)(ii)) or a biosimilar (defined as a biological product licensed under section 262(k) of this title), when the Secretary determines there is a severe supply chain disruption during the applicable period, such as that caused by a natural disaster or other unique or unexpected event; and

(iii) in the case of a generic Part[1] D rebatable drug (as so described), if the Secretary determines that without such reduction or waiver, the drug is likely to be described as in shortage on such shortage list during a subsequent applicable period.

(2) Determination of annual manufacturer price

The annual manufacturer price determined under this paragraph for a dosage form and strength, with respect to a part D rebatable drug and an applicable period, is the sum of the products of—

(A) the average manufacturer price (as defined in subsection (g)(6)) of such dosage form and strength, as calculated for a unit of such drug, with respect to each of the calendar quarters of such period; and

(B) the ratio of—

(i) the total number of units of such dosage form and strength reported under section 1396r–8 of this title with respect to each such calendar quarter of such period; to

(ii) the total number of units of such dosage form and strength reported under section 1396r–8 of this title with respect to such period, as determined by the Secretary.

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

(3) Determination of inflation-adjusted payment amount

The inflation-adjusted payment amount determined under this paragraph for a dosage form and strength with respect to a part D rebatable drug for an applicable period, subject to paragraph (5), is—

(A) the benchmark period manufacturer price determined under paragraph (4) for such dosage form and strength with respect to such drug and period; increased by

(B) the percentage by which the applicable period CPI–U (as defined in subsection (g)(5)) for the period exceeds the benchmark period CPI–U (as defined in subsection (g)(4)).

(4) Determination of benchmark period manufacturer price

The benchmark period manufacturer price determined under this paragraph for a dosage form and strength, with respect to a part D rebatable drug and an applicable period, is the sum of the products of—

(A) the average manufacturer price (as defined in subsection (g)(6)) of such dosage form and strength, as calculated for a unit of such drug, with respect to each of the calendar quarters of the payment amount benchmark period (as defined in subsection (g)(3)); and

(B) the ratio of—

(i) the total number of units reported under section 1396r–8 of this title of such dosage form and strength with respect to each such calendar quarter of such payment amount benchmark period; to

(ii) the total number of units reported under section 1396r–8 of this title of such dosage form and strength with respect to such payment amount benchmark period.

(5) Special treatment of certain drugs and exemption

(A) Subsequently approved drugs

In the case of a part D rebatable drug first approved or licensed by the Food and Drug Administration after October 1, 2021, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term ''payment amount benchmark period'' were defined under subsection (g)(3) as the first calendar year beginning after the day on which the drug was first marketed and subparagraph (B) of paragraph (3) shall be applied as if the term ''benchmark period CPI–U'' were defined under subsection (g)(4) as if the reference to ''January 2021'' under such subsection were a reference to ''January of the first year beginning after the date on which the drug was first marketed''.

(B) Treatment of new formulations

(i) In general

In the case of a part D rebatable drug that is a line extension of a part D rebatable drug that is an oral solid dosage form, the Secretary shall establish a formula for determining the rebate amount under paragraph (1) and the inflation adjusted payment amount under paragraph (3) with respect to such part D rebatable drug and an applicable period, consistent with the formula applied under subsection (c)(2)(C) of section 1396r–8 of this title for determining a rebate obligation for a rebate period under such section.

(ii) Line extension defined

In this subparagraph, the term ''line extension'' means, with respect to a part D rebatable drug, a new formulation of the drug, such as an extended release formulation, but does not include an abuse-deterrent formulation of the drug (as determined by the Secretary), regardless of whether such abuse-deterrent formulation is an extended release formulation.

(C) Selected drugs

In the case of a part D rebatable drug that is a selected drug (as defined in section 1320f–1(c) of this title) with respect to a price applicability period (as defined in section 1320f(b)(2) of this title), in the case such drug is no longer considered to be a selected drug under section 1320f–1(c) of this title, for each applicable period (as defined under subsection (g)(7)) beginning after the price applicability period with respect to such drug, subparagraphs (A) and (B) of paragraph (4) shall be applied as if the term ''payment amount benchmark period'' were defined under subsection (g)(3) as the last year beginning during such price applicability period with respect to such selected drug and subparagraph (B) of paragraph (3) shall be applied as if the term ''benchmark period CPI–U'' were defined under subsection (g)(4) as if the reference to ''January 2021'' under such subsection were a reference to ''January of the last year beginning during such price applicability period with respect to such drug''.

(6) Reconciliation in case of revised information

The Secretary shall provide for a method and process under which, in the case where a PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan submits revisions to the number of units of a rebatable covered part D drug dispensed, the Secretary determines, pursuant to such revisions, adjustments, if any, to the calculation of the amount specified in this subsection for a dosage form and strength with respect to such part D rebatable drug and an applicable period and reconciles any overpayments or underpayments in amounts paid as rebates under this subsection. Any identified underpayment shall be rectified by the manufacturer not later than 30 days after the date of receipt from the Secretary of information on such underpayment.

(c) Rebate deposits

Amounts paid as rebates under subsection (b) shall be deposited into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund established under section 1395t of this title.

(d) Information

For purposes of carrying out this section, the Secretary shall use information submitted by—

(1) manufacturers under section 1396r–8(b)(3) of this title;

(2) States under section 1396r–8(b)(2)(A) of this title; and

(3) PDP sponsors of prescription drug plans and MA organization offering MA–PD plans under this part.

(e) Civil money penalty

If a manufacturer of a part D rebatable drug has failed to comply with the requirement under subsection (a)(2) with respect to such drug for an applicable period, the manufacturer shall be subject to a civil money penalty in an amount equal to 125 percent of the amount specified in subsection (b) for such drug for such period. The provisions of section 1320a–7a of this title (other than subsections (a) (with respect to amounts of penalties or additional assessments) 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) Limitation on administrative or judicial review

There shall be no administrative or judicial review of any of the following:

(1) The determination of units under this section.

(2) The determination of whether a drug is a part D rebatable drug under this section.

(3) The calculation of the rebate amount under this section.

(g) Definitions

In this section:

(1) Part D rebatable drug

(A) In general

Except as provided in subparagraph (B), the term ''part D rebatable drug'' means, with respect to an applicable period, a drug or biological described in subparagraph (C) that is a covered part D drug (as such term is defined under section 1395w–102(e) of this title).

(B) Exclusion

(i) In general

Such term shall, with respect to an applicable period, not include a drug or biological if the average annual total cost under this part for such period per individual who uses such a drug or biological, as determined by the Secretary, is less than, subject to clause (ii), $100, as determined by the Secretary using the most recent data available or, if data is not available, as estimated by the Secretary.

(ii) Increase

The dollar amount applied under clause (i)—

(I) for the applicable period beginning October 1, 2023, shall be the dollar amount specified under such clause for the applicable period beginning October 1, 2022, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period beginning with October of 2023; and

(II) for a subsequent applicable period, shall be the dollar amount specified in this clause for the previous applicable period, increased by the percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period beginning with October of the previous period.

Any dollar amount specified under this clause that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(C) Drug or biological described

A drug or biological described in this subparagraph is a drug or biological that, as of the first day of the applicable period involved, is—

(i) a drug approved under a new drug application under section 355(c) of title 21;

(ii) a drug approved under an abbreviated new drug application under section 355(j) of title 21, in the case where—

(I) the reference listed drug approved under section 355(c) of title 21, including any ''authorized generic drug'' (as that term is defined in section 355(t)(3) of title 21), is not being marketed, as identified in the Food and Drug Administration's National Drug Code Directory;

(II) there is no other drug approved under section 355(j) of title 21 that is rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of ''Approved Drug Products with Therapeutic Equivalence Evaluations'') and that is being marketed, as identified in the Food and Drug Administration's National Drug Code Directory;

(III) the manufacturer is not a ''first applicant'' during the ''180-day exclusivity period'', as those terms are defined in section 355(j)(5)(B)(iv) of title 21; and

(IV) the manufacturer is not a ''first approved applicant'' for a competitive generic therapy, as that term is defined in section 355(j)(5)(B)(v) of title 21; or

(iii) a biological licensed under section 262 of this title.

(2) Unit

The term ''unit'' means, with respect to a part D rebatable drug, the lowest dispensable amount (such as a capsule or tablet, milligram of molecules, or grams) of the part D rebatable drug, as reported under section 1396r–8 of this title.

(3) Payment amount benchmark period

The term ''payment amount benchmark period'' means the period beginning January 1, 2021, and ending in the month immediately prior to October 1, 2021.

(4) Benchmark period CPI–U

The term ''benchmark period CPI–U'' means the consumer price index for all urban consumers (United States city average) for January 2021.

(5) Applicable period CPI–U

The term ''applicable period CPI–U'' means, with respect to an applicable period, the con-

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.