''(i) 100 percent of the amount described in subsection (b)(1) of this section, but not to exceed the premium amount specified in subsection (b)(2)(B) of this section; plus

''(ii) 80 percent of any late enrollment penalties imposed under section 1395w–113(b) of this title for the first 60 months in which such penalties are imposed for that individual, and 100 percent of any such penalties for any subsequent month.''

Subsec. (a)(3)(B)(iv)(III). Pub. L. 110–275, § 117(a), added subcl. (III).

Subsec. (a)(3)(C)(i). Pub. L. 110–275, § 116(a)(1), inserted ''and except that support and maintenance furnished in kind shall not be counted as income'' after ''section 1396a(r)(2) of this title''.

Subsec. (a)(3)(D), (E)(i). Pub. L. 110–275, § 116(a)(2), (3), inserted ''subject to the life insurance policy exclusion provided under subparagraph (G)'' after ''program'' in introductory provisions.

Subsec. (a)(3)(G). Pub. L. 110–275, § 116(a)(4), added subpar. (G).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, § 3302(b), Mar. 23, 2010, 124 Stat. 468, provided that: ''The amendment made by subsection (a) [amending this section] shall apply to premiums for months beginning on or after January 1, 2011.''

Amendment by section 3303(a) of Pub. L. 111–148 applicable to premiums for months, and enrollments for plan years, beginning on or after January 1, 2011, see section 3303(c) of Pub. L. 111–148, set out as a note under section 1395w–101 of this title.

Pub. L. 111–148, title III, § 3304(b), Mar. 23, 2010, 124 Stat. 470, provided that: ''The amendment made by subsection (a) [amending this section] shall take effect on January 1, 2011.''

EFFECTIVE DATE OF 2008 AMENDMENT

Amendment by section 114(a)(2) of Pub. L. 110–275 applicable to subsidies for months beginning with Jan. 2009, see section 114(b) of Pub. L. 110–275, set out as a note under section 1395w–113 of this title.

Pub. L. 110–275, title I, § 116(b), July 15, 2008, 122 Stat. 2507, provided that: ''The amendments made by this section [amending this section] shall take effect with respect to applications filed on or after January 1, 2010.''

Pub. L. 110–275, title I, § 117(b), July 15, 2008, 122 Stat. 2507, provided that: ''The amendments made by subsection (a) [amending this section] shall take effect as if included in the enactment of section 101 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 [Pub. L. 108–173].''

CONSTRUCTION OF 2022 AMENDMENT

Nothing in amendment by section 11401(b) of Pub. L. 117–169 to be construed as limiting coverage under this part for vaccines that are not recommended by the Advisory Committee on Immunization Practices, see section 11401(d) of Pub. L. 117–169, set out as a note under section 1395w–102 of this title.

GAO STUDY REGARDING IMPACT OF ASSETS TEST FOR SUBSIDY ELIGIBLE INDIVIDUALS

Pub. L. 108–173, title I, § 107(e), Dec. 8, 2003, 117 Stat. 2171, provided that:

''(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the extent to which drug utilization and access to covered part D drugs under part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.] by subsidy eligible individuals differs from such utilization and access for individuals who would qualify as such subsidy eligible individuals but for the application of section 1860D–14(a)(3)(A)(iii) of such Act [42 U.S.C. 1395w–114(a)(3)(A)(iii)].

''(2) REPORT.—Not later than September 30, 2007, the Comptroller General shall submit a report to Congress on the study conducted under paragraph (1) that includes such recommendations for legislation as the Comptroller General determines are appropriate.''

§ 1395w–114a. Medicare coverage gap discount program

(a) Establishment

Subject to subsection (h), the Secretary shall establish a Medicare coverage gap discount program (in this section referred to as the ''program'') by not later than January 1, 2011. 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)(1). The Secretary shall establish a model agreement for use under the program by not later than 180 days after March 23, 2010, in consultation with manufacturers, and allow for comment on such model agreement.

(b) Terms of agreement

(1) In general

(A) Agreement

An agreement under this section shall require the manufacturer to provide applicable beneficiaries access to discounted prices for applicable drugs of the manufacturer.

(B) Provision of discounted prices at the point-of-sale

Except as provided in subsection (c)(1)(A)(iii), such discounted prices shall be provided to the applicable beneficiary at the pharmacy or by the mail order service at the point-of-sale of an applicable drug.

(C) Timing of agreement

(i) Special rule for 2011

In order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2011, and ending on December 31, 2011, the manufacturer shall enter into such agreement not later than not later than[1] 30 days after the date of the establishment of a model agreement under subsection (a).

(ii) 2012 and subsequent years

In order for an agreement with a manufacturer to be in effect under this section with respect to plan year 2012 or a subsequent plan year, the manufacturer shall enter into such agreement (or such agreement shall be renewed under paragraph (4)(A)) not later than January 30 of the preceding year.

(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.

[1] So in original. Second ''not later than'' probably should not appear.

(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 or a third party with a contract under subsection (d)(3), as applicable, for purposes of administering the program, including any determination under clause (i) of subsection (c)(1)(A) or procedures established under such subsection (c)(1)(A).

(4) Length of agreement

(A) In general

An agreement under this section shall be effective for an initial period of not less than 18 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 may 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 30 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 30 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.

(iv) Notice to third party

The Secretary shall provide notice of such termination to a third party with a contract under subsection (d)(3) within not less than 30 days before the effective date of such termination.

(c) Duties described and special rule for supplemental benefits

(1) Duties described

The duties described in this subsection are the following:

(A) Administration of program

Administering the program, including—

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

(ii) except as provided in clause (iii), the establishment of procedures under which discounted prices are provided to applicable beneficiaries at pharmacies or by mail order service at the point-of-sale of an applicable drug;

(iii) in the case where, during the period beginning on January 1, 2011, and ending on December 31, 2011, it is not practicable to provide such discounted prices at the point-of-sale (as described in clause (ii)), the establishment of procedures to provide such discounted prices as soon as practicable after the point-of-sale;

(iv) 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;

(v) 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 the Secretary may specify;

(vi) the establishment of procedures to implement the special rule for supplemental benefits under paragraph (2); and

(vii) providing a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, applicable beneficiaries, and the third party with a contract under subsection (d)(3).

(B) Monitoring compliance

(i) In general

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

(ii) Notification

If a third party with a contract under subsection (d)(3) determines that the manufacturer is not in compliance with such agreement, the third party shall notify the Secretary of such noncompliance for appropriate enforcement under subsection (e).

(C) 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.

(2) Special rule for supplemental benefits

For plan year 2011 and each subsequent plan year, in the case where an applicable bene-

ficiary has supplemental benefits with respect to applicable drugs under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in, the applicable beneficiary shall not be provided a discounted price for an applicable drug under this section until after such supplemental benefits have been applied with respect to the applicable drug.

(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)(1).

(2) Limitation

(A) In general

Subject to subparagraph (B), in providing for such implementation, the Secretary shall not receive or distribute any funds of a manufacturer under the program.

(B) Exception

The limitation under subparagraph (A) shall not apply to the Secretary with respect to drugs dispensed during the period beginning on January 1, 2011, and ending on December 31, 2011, but only if the Secretary determines that the exception to such limitation under this subparagraph is necessary in order for the Secretary to begin implementation of this section and provide applicable beneficiaries timely access to discounted prices during such period.

(3) Contract with third parties

The Secretary shall enter into a contract with 1 or more third parties to administer the requirements established by the Secretary in order to carry out this section. At a minimum, the contract with a third party under the preceding sentence shall require that the third party—

(A) receive and transmit information between the Secretary, manufacturers, and other individuals or entities the Secretary determines appropriate;

(B) receive, distribute, or facilitate the distribution of funds of manufacturers to appropriate individuals or entities in order to meet the obligations of manufacturers under agreements under this section;

(C) provide adequate and timely information to manufacturers, consistent with the agreement with the manufacturer under this section, as necessary for the manufacturer to fulfill its obligations under this section; and

(D) permit manufacturers to conduct periodic audits, directly or through contracts, of the data and information used by the third party to determine discounts for applicable drugs of the manufacturer under the program.

(4) Performance requirements

The Secretary shall establish performance requirements for a third party with a contract under paragraph (3) and safeguards to protect the independence and integrity of the activities carried out by the third party under the program under this section.

(5) Implementation

The Secretary may implement the program under this section by program instruction or otherwise.

(6) Administration

Chapter 35 of title 44 shall not apply to the program under this section.

(e) Enforcement

(1) Audits

Each manufacturer with an agreement in effect under this section shall be subject to periodic audit by the Secretary.

(2) Civil money penalty

(A) In general

The Secretary shall impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with such agreement for each such failure in an amount the Secretary determines is commensurate with the sum of—

(i) 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

(ii) 25 percent of such amount.

(B) 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 paragraph 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;

(C) is not entitled to an income-related subsidy under section 1395w–114(a) of this title; and

(D) who—

(i) has reached or exceeded the initial coverage limit under section 1395w–102(b)(3) of this title during the year; and

(ii) has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B) of this title.

(2) Applicable drug

The term ''applicable drug'' means, with respect to an applicable beneficiary, a covered part D drug—

(A) approved under a new drug application under section 355(b) of title 21 or, in the case of a biologic product, licensed under section 262 of this title (other than, with respect to a plan year before 2019, a product licensed under subsection (k) of such section 262); and

(B)(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.

(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 50 percent (or, with respect to a plan year after plan year 2018, 30 percent) of the negotiated price of the applicable drug of a manufacturer.

(B) Clarification

Nothing in this section shall be construed as affecting the responsibility of an applicable beneficiary for payment of a dispensing fee for an applicable drug.

(C) Special case for certain claims

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 at or above the initial coverage limit under section 1395w–102(b)(3) of this title and below the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B) 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 at or above such initial coverage limit and below such annual out-of-pocket 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 in section 423.100 of title 42, Code of Federal Regulations (as in effect on March 23, 2010), except that such negotiated price shall not include any dispensing 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.

(h) Sunset of program

(1) In general

The program shall not apply with respect to applicable drugs dispensed on or after January 1, 2025, and, subject to paragraph (2), agreements under this section shall be terminated as of such date.

(2) Continued application for applicable drugs dispensed prior to sunset

The provisions of this section (including all responsibilities and duties) shall continue to apply on and after January 1, 2025, with respect to applicable drugs dispensed prior to such date.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–14A, as added Pub. L. 111–148, title III, §3301(b), Mar. 23, 2010, 124 Stat. 462; amended Pub. L. 111–152, title I, §1101(b)(2), Mar. 30, 2010, 124 Stat. 1037; Pub. L. 115–123, div. E, title XII, §§53113, 53116(b), Feb. 9, 2018, 132 Stat. 305, 307; Pub. L. 117–169, title I, §11201(c)(2), Aug. 16, 2022, 136 Stat. 1888.)

Editorial Notes

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–169, §11201(c)(2)(A), substituted ''Subject to subsection (h), the Secretary'' for ''The Secretary''.

Subsec. (h). Pub. L. 117–169, §11201(c)(2)(B), added subsec. (h).

2018—Subsec. (g)(2)(A). Pub. L. 115–123, §53113, inserted '', with respect to a plan year before 2019,'' after ''other than''.

Subsec. (g)(4)(A). Pub. L. 115–123, §53116(b), inserted ''(or, with respect to a plan year after plan year 2018, 30 percent)'' after ''50 percent''.

2010—Subsec. (a). Pub. L. 111–152, §1101(b)(2)(A), substituted ''January 1, 2011'' for ''July 1, 2010'' and ''180 days after March 23, 2010'' for ''April 1, 2010''.

Subsec. (b)(1)(C)(i). Pub. L. 111–152, §1101(b)(2)(B)(i), which directed the amendment of subpar. (C) by striking out ''2010 and'' in the heading, was executed by striking ''2010 and'' before ''2011'' in cl. (i) heading to reflect the probable intent of Congress.

Pub. L. 111–152, §1101(b)(2)(B)(ii), (iii), substituted ''January 1, 2011'' for ''July 1, 2010'' and ''not later than 30 days after the date of the establishment of a model agreement under subsection (a)'' for ''May 1, 2010''.

Subsec. (c)(1)(A)(iii). Pub. L. 111–152, §1101(b)(2)(C)(i), substituted ''January 1, 2011, and ending on December 31, 2011'' for ''July 1, 2010, and ending on December 31, 2011''.

Subsec. (c)(2). Pub. L. 111–152, §1101(b)(2)(C)(ii), substituted ''2011'' for ''2010''.

Subsec. (d)(2)(B). Pub. L. 111–152, §1101(b)(2)(D), substituted ''January 1, 2011, and ending on December 31,

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.

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