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

(a) Establishment

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 \( \frac{1}{3} \) 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.

(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 beneficiary 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 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 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.

**Footnotes**

1 So in original. Second “not later than” probably should not appear.


**Amendments**


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. (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”.

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