

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-

utable 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

(ii) with respect to covered part D drugs that are not applicable drugs (as so defined), an amount equal to 40 percent of such allowable reinsurance costs 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.

(2) Allowable reinsurance costs

(A) In general

Subject to subparagraph (B), for purposes of this section, the term “allowable reinsurance costs” means, with respect to gross covered prescription drug costs under a prescription drug plan offered by a PDP sponsor or an MA-PD plan offered by an MA organization, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization or by (or on behalf of) an enrollee under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were standard prescription drug coverage.

(B) Inclusion of manufacturer discounts on applicable drugs

For purposes of applying subparagraph (A), the term “allowable reinsurance costs” shall include the portion of the negotiated price (as defined in section 1395w-114c(g)(6) of this title) of an applicable drug (as defined in section 1395w-114c(g)(2) of this title) that was paid by a manufacturer under the manufacturer discount program under section 1395w-114c of this title.

(3) Gross covered prescription drug costs

Subject to paragraph (2)(B), for purposes of this section, the term “gross covered prescription drug costs” means, with respect to a part D eligible individual enrolled in a prescription drug plan or MA-PD plan during a coverage year, the costs incurred under the plan, not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year and costs relating to the deductible. Such costs shall be determined whether they are paid by the individual or under the plan (or, with respect to 2025 and subsequent years, in the case of an applicable drug, as defined in section 1395w-114c(g)(2) of this title, by a manufacturer), regardless of whether the coverage under the plan exceeds basic prescription drug coverage.

(4) Coverage year defined

For purposes of this section, the term “coverage year” means a calendar year in which covered part D drugs are dispensed if the claim for such drugs (and payment on such claim) is made not later than such period after the end of such year as the Secretary specifies.

(c) Adjustments relating to bids

(1) Health status risk adjustment

(A) Establishment of risk adjustors

The Secretary shall establish an appropriate methodology for adjusting the standardized bid amount under subsection (a)(1)(A) to take into account variation in costs for basic prescription drug coverage among prescription drug plans and MA-PD plans based on the differences in actuarial risk of different enrollees being served. Any such risk adjustment shall be designed in a manner so as not to result in a change in the aggregate amounts payable to such plans under subsection (a)(1) and through that portion of the monthly beneficiary prescription drug premiums described in subsection (a)(1)(B) and MA monthly prescription drug beneficiary premiums.

(B) Considerations

In establishing the methodology under subparagraph (A), the Secretary may take into account the similar methodologies used under section 1395w-23(a)(3) of this title to adjust payments to MA organizations for benefits under the original medicare fee-for-service program option.

(C) Data collection

In order to carry out this paragraph, the Secretary shall require—

(i) PDP sponsors to submit data regarding drug claims that can be linked at the individual level to part A and part B data and such other information as the Secretary determines necessary; and

(ii) MA organizations that offer MA-PD plans to submit data regarding drug claims that can be linked at the individual level to other data that such organizations are required to submit to the Secretary and such other information as the Secretary determines necessary.

(D) Publication

At the time of publication of risk adjustment factors under section 1395w-23(b)(1)(B)(i)(II) of this title, the Secretary shall publish the risk adjusters established under this paragraph for the succeeding year.

(2) Geographic adjustment

(A) In general

Subject to subparagraph (B), for purposes of section 1395w-113(a)(1)(B)(iii) of this title, the Secretary shall establish an appropriate methodology for adjusting the national average monthly bid amount (computed under section 1395w-113(a)(4) of this title) to take into account differences in prices for covered part D drugs among PDP regions.

(B) De minimis rule

If the Secretary determines that the price variations described in subparagraph (A) among PDP regions are de minimis, the Secretary shall not provide for adjustment under this paragraph.

(C) Budget neutral adjustment

Any adjustment under this paragraph shall be applied in a manner so as to not result in a change in the aggregate payments made under this part that would have been made if the Secretary had not applied such adjustment.

(d) Payment methods**(1) In general**

Payments under this section shall be based on such a method as the Secretary determines. The Secretary may establish a payment method by which interim payments of amounts under this section are made during a year based on the Secretary's best estimate of amounts that will be payable after obtaining all of the information.

(2) Requirement for provision of information**(A) Requirement**

Payments under this section to a PDP sponsor or MA organization are conditioned upon the furnishing to the Secretary, in a form and manner specified by the Secretary, of such information as may be required to carry out this section.

(B) Restriction on use of information

Information disclosed or obtained pursuant to subparagraph (A) may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section.

(3) Source of payments

Payments under this section shall be made from the Medicare Prescription Drug Account.

(4) Application of enrollee adjustment

The provisions of section 1395w-23(a)(2) of this title shall apply to payments to PDP sponsors under this section in the same manner as they apply to payments to MA organizations under section 1395w-23(a) of this title.

(e) Portion of total payments to a sponsor or organization subject to risk (application of risk corridors)**(1) Computation of adjusted allowable risk corridor costs****(A) In general**

For purposes of this subsection, the term "adjusted allowable risk corridor costs" means, for a plan for a coverage year (as defined in subsection (b)(4))—

(i) the allowable risk corridor costs (as defined in subparagraph (B)) for the plan for the year, reduced by

(ii) the sum of (I) the total reinsurance payments made under subsection (b) to the sponsor of the plan for the year, and (II) the total subsidy payments made under section 1395w-114 of this title to the sponsor of the plan for the year.

(B) Allowable risk corridor costs

For purposes of this subsection, the term "allowable risk corridor costs" means, with respect to a prescription drug plan offered by a PDP sponsor or an MA-PD plan offered by an MA organization, the part of costs (not including administrative costs, but including costs directly related to the dispensing of covered part D drugs during the year) incurred by the sponsor or organization under the plan that are actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsor or organization under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were basic prescription drug coverage, or, in the case of a plan providing supplemental prescription drug coverage, if such coverage were basic prescription drug coverage taking into account the adjustment under section 1395w-111(c)(2) of this title. In computing allowable costs under this paragraph, the Secretary shall compute such costs based upon imposition under paragraphs (1)(D) and (2)(E) of section 1395w-114(a) of this title of the maximum amount of copayments permitted under such paragraphs.

(2) Adjustment of payment**(A) No adjustment if adjusted allowable risk corridor costs within risk corridor**

If the adjusted allowable risk corridor costs (as defined in paragraph (1)) for the plan for the year are at least equal to the first threshold lower limit of the risk corridor (specified in paragraph (3)(A)(i)), but not greater than the first threshold upper limit of the risk corridor (specified in paragraph (3)(A)(iii)) for the plan for the year, then no payment adjustment shall be made under this subsection.

(B) Increase in payment if adjusted allowable risk corridor costs above upper limit of risk corridor**(i) Costs between first and second threshold upper limits**

If the adjusted allowable risk corridor costs for the plan for the year are greater than the first threshold upper limit, but not greater than the second threshold upper limit, of the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between such adjusted allowable risk corridor costs and the first threshold upper limit of the risk corridor.

(ii) Costs above second threshold upper limits

If the adjusted allowable risk corridor costs for the plan for the year are greater than the second threshold upper limit of

the risk corridor for the plan for the year, the Secretary shall increase the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount equal to the sum of—

(I) 50 percent (or, for 2006 and 2007, 75 percent or 90 percent if the conditions described in clause (iii) are met for the year) of the difference between the second threshold upper limit and the first threshold upper limit; and

(II) 80 percent of the difference between such adjusted allowable risk corridor costs and the second threshold upper limit of the risk corridor.

(iii) Conditions for application of higher percentage for 2006 and 2007

The conditions described in this clause are met for 2006 or 2007 if the Secretary determines with respect to such year that—

(I) at least 60 percent of prescription drug plans and MA-PD plans to which this subsection applies have adjusted allowable risk corridor costs for the plan for the year that are more than the first threshold upper limit of the risk corridor for the plan for the year; and

(II) such plans represent at least 60 percent of part D eligible individuals enrolled in any prescription drug plan or MA-PD plan.

(C) Reduction in payment if adjusted allowable risk corridor costs below lower limit of risk corridor

(i) Costs between first and second threshold lower limits

If the adjusted allowable risk corridor costs for the plan for the year are less than the first threshold lower limit, but not less than the second threshold lower limit, of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization an amount) equal to 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit of the risk corridor and such adjusted allowable risk corridor costs.

(ii) Costs below second threshold lower limit

If the adjusted allowable risk corridor costs for the plan for the year are less than the second threshold lower limit of the risk corridor for the plan for the year, the Secretary shall reduce the total of the payments made to the sponsor or organization offering the plan for the year under this section by an amount (or otherwise recover from the sponsor or organization an amount) equal to the sum of—

(I) 50 percent (or, for 2006 and 2007, 75 percent) of the difference between the first threshold lower limit and the second threshold lower limit; and

(II) 80 percent of the difference between the second threshold upper limit

of the risk corridor and such adjusted allowable risk corridor costs.

(3) Establishment of risk corridors

(A) In general

For each plan year the Secretary shall establish a risk corridor for each prescription drug plan and each MA-PD plan. The risk corridor for a plan for a year shall be equal to a range as follows:

(i) First threshold lower limit

The first threshold lower limit of such corridor shall be equal to—

(I) the target amount described in subparagraph (B) for the plan; minus

(II) an amount equal to the first threshold risk percentage for the plan (as determined under subparagraph (C)(i)) of such target amount.

(ii) Second threshold lower limit

The second threshold lower limit of such corridor shall be equal to—

(I) the target amount described in subparagraph (B) for the plan; minus

(II) an amount equal to the second threshold risk percentage for the plan (as determined under subparagraph (C)(ii)) of such target amount.

(iii) First threshold upper limit

The first threshold upper limit of such corridor shall be equal to the sum of—

(I) such target amount; and

(II) the amount described in clause (i)(II).

(iv) Second threshold upper limit

The second threshold upper limit of such corridor shall be equal to the sum of—

(I) such target amount; and

(II) the amount described in clause (ii)(II).

(B) Target amount described

The target amount described in this paragraph is, with respect to a prescription drug plan or an MA-PD plan in a year, the total amount of payments paid to the PDP sponsor or MA-PD organization for the plan for the year, taking into account amounts paid by the Secretary and enrollees, based upon the standardized bid amount (as defined in section 1395w-113(a)(5) of this title and as risk adjusted under subsection (c)(1)), reduced by the total amount of administrative expenses for the year assumed in such standardized bid.

(C) First and second threshold risk percentage defined

(i) First threshold risk percentage

Subject to clause (iii), for purposes of this section, the first threshold risk percentage is—

(I) for 2006 and 2007, and¹ 2.5 percent;

(II) for 2008 through 2011, 5 percent; and

(III) for 2012 and subsequent years, a percentage established by the Secretary, but in no case less than 5 percent.

¹ So in original. The word "and" probably should not appear.

(ii) Second threshold risk percentage

Subject to clause (iii), for purposes of this section, the second threshold risk percentage is—

(I) for 2006 and 2007, 5 percent;

(II) for 2008 through 2011, 10 percent; and

(III) for 2012 and subsequent years, a percentage established by the Secretary that is greater than the percent established for the year under clause (i)(III), but in no case less than 10 percent.

(iii) Reduction of risk percentage to ensure 2 plans in an area

Pursuant to section 1395w-111(b)(2)(E)(ii) of this title, a PDP sponsor may submit a bid that requests a decrease in the applicable first or second threshold risk percentages or an increase in the percents applied under paragraph (2).

(4) Plans at risk for entire amount of supplemental prescription drug coverage

A PDP sponsor and MA organization that offers a plan that provides supplemental prescription drug benefits shall be at full financial risk for the provision of such supplemental benefits.

(5) No effect on monthly premium

No adjustment in payments made by reason of this subsection shall affect the monthly beneficiary premium or the MA monthly prescription drug beneficiary premium.

(f) Disclosure of information**(1) In general**

Each contract under this part and under part C shall provide that—

(A) the PDP sponsor offering a prescription drug plan or an MA organization offering an MA-PD plan shall provide the Secretary with such information as the Secretary determines is necessary to carry out this section; and

(B) the Secretary shall have the right in accordance with section 1395w-27(d)(2)(B) of this title (as applied under section 1395w-112(b)(3)(C) of this title) to inspect and audit any books and records of a PDP sponsor or MA organization that pertain to the information regarding costs provided to the Secretary under subparagraph (A).

(2) Restriction on use of information

Information disclosed or obtained pursuant to the provisions of this section may be used—

(A) by officers, employees, and contractors of the Department of Health and Human Services for the purposes of, and to the extent necessary in—

(i) carrying out this section or part E of subchapter XI; and

(ii) conducting oversight, evaluation, and enforcement under this subchapter;

(B) by the Attorney General and the Comptroller General of the United States for the purposes of, and to the extent necessary in, carrying out health oversight activities;

(C) by the Executive Director of the Medicare Payment Advisory Commission for pur-

poses of monitoring, making recommendations for, and analysis of the program under this subchapter and by the Executive Director of the Medicaid and CHIP Payment and Access Commission for purposes of monitoring, making recommendations for, and analysis of the Medicaid program established under subchapter XIX and the Children's Health Insurance Program under subchapter XXI; and

(D) by the Director of the Congressional Budget Office for the purposes of analysis of programs authorized under this chapter, as applicable, and the fulfillment of such Director's duties under the Congressional Budget and Impoundment Control Act of 1974.

(3) Additional restrictions on disclosure of information**(A) In general**

The Executive Directors described in paragraph (2)(C) shall not disclose any of the following information disclosed to such Executive Directors or obtained by such Executive Directors pursuant to such paragraph, with respect to a prescription drug plan offered by a PDP sponsor or an MA-PD plan offered by an MA organization:

(i) The specific amounts or the identity of the source of any rebates, discounts, price concessions, or other forms of direct or indirect remuneration under such prescription drug plan or such MA-PD plan.

(ii) Information submitted with the bid submitted under section 1395w-111(b) of this title by such PDP sponsor or under section 1395w-24(a) of this title by such MA organization.

(iii) In the case of such information from prescription drug event records, information in a form that would not be permitted under section 423.505(m) of title 42, Code of Federal Regulations, or any successor regulation, if released by the Centers for Medicare & Medicaid Services.

(B) Clarification

The restrictions on disclosures described in subparagraph (A) shall also apply to disclosures to individual Commissioners of the Medicare Payment Advisory Commission or of the Medicaid and CHIP Payment and Access Commission.

(g) Payment for fallback prescription drug plans

In lieu of the amounts otherwise payable under this section to a PDP sponsor offering a fallback prescription drug plan (as defined in section 1395w-111(g)(4) of this title²), the amount payable shall be the amounts determined under the contract for such plan pursuant to section 1395w-111(g)(5) of this title.

(h) Temporary retrospective subsidy for reduction in cost-sharing and deductible for adult vaccines recommended by the Advisory Committee on Immunization Practices and Insulin During 2023**(1) In general**

In addition to amounts otherwise payable under this section to a PDP sponsor of a pre-

² See References in Text note below.

scription drug plan or an MA organization offering an MA-PD plan, for plan year 2023, the Secretary shall provide the PDP sponsor or MA organization offering the plan subsidies in an amount equal to the aggregate reduction in cost-sharing and deductible by reason of the application of paragraph (8) or (9) of section 1395w-102(b) of this title for individuals under the plan during the year.

(2) Timing

The Secretary shall provide a subsidy under paragraph (1), as applicable, not later than 18 months following the end of the applicable plan year.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D-15, as added Pub. L. 108-173, title I, § 101(a)(2), Dec. 8, 2003, 117 Stat. 2113; amended Pub. L. 111-148, title VI, § 6402(b)(1), Mar. 23, 2010, 124 Stat. 756; Pub. L. 116-260, div. CC, title I, § 112(a), Dec. 27, 2020, 134 Stat. 2946; Pub. L. 117-169, title I, §§ 11001(b)(1)(H)(ii), 11201(b), (d)(3)(D), 11401(c)(1), 11406(c), Aug. 16, 2022, 136 Stat. 1853, 1879, 1891, 1897, 1904; Pub. L. 117-328, div. FF, title IV, § 4132, Dec. 29, 2022, 136 Stat. 5918.)

Editorial Notes

REFERENCES IN TEXT

This chapter, referred to in subsec. (f)(2)(D), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, was in the original “the Social Security Act”, which is classified generally to this chapter. For complete classification of the Social Security Act to the Code, see section 1305 of this title and Tables.

The Congressional Budget and Impoundment Control Act of 1974, referred to in subsec. (f)(2)(D), is Pub. L. 93-344, July 12, 1974, 88 Stat. 297. For complete classification of this Act to the Code, see Short Title note set out under section 621 of Title 2, The Congress, and Tables.

Section 1395w-111(g)(4) of this title, referred to in subsec. (g), was in the original “section 1860D-3(c)(4)”, and was translated as reading “section 1860D-11(g)(4)”, meaning section 1860D-11(g)(4) of the Social Security Act, to reflect the probable intent of Congress, because section 1860D-3, which is classified to section 1395w-103 of this title, does not contain a subsec. (c), and section 1395w-111(g)(4) of this title defines “fallback prescription drug plan” for purposes of this part.

AMENDMENTS

2022—Subsec. (a). Pub. L. 117-169, § 11201(d)(3)(D)(i), inserted “(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)” after “74.5 percent” in introductory provisions.

Subsec. (a)(1)(B). Pub. L. 117-169, § 11201(d)(3)(D)(ii), substituted “paragraph (2) or (8) of section 1395w-113(a) of this title (as applicable)” for “paragraph (2) of section 1395w-113(a) of this title”.

Subsec. (b)(1). Pub. L. 117-169, § 11201(b)(1), inserted dash after “equal to”, designated remainder of existing provisions as subpar. (A), substituted “for a year preceding 2025, 80 percent” for “80 percent”, and added subpar. (B).

Subsec. (b)(2). Pub. L. 117-169, § 11201(b)(2), designated existing provisions as subpar. (A) and inserted heading, substituted “Subject to subparagraph (B), for purposes” for “For purposes”, and added subpar. (B).

Subsec. (b)(3). Pub. L. 117-169, § 11201(b)(3), substituted “Subject to paragraph (2)(B), for purposes” for “For purposes” and inserted “(or, with respect to 2025 and subsequent years, in the case of an applicable drug, as

defined in section 1395w-114c(g)(2) of this title, by a manufacturer)” after “by the individual or under the plan”.

Subsec. (f)(2)(A)(i). Pub. L. 117-169, § 11001(b)(1)(H)(ii), inserted “or part E of subchapter XI” after “this section”.

Subsec. (f)(2)(D). Pub. L. 117-328 added subpar. (D).

Subsec. (h). Pub. L. 117-169, § 11406(c)(1), inserted “and Insulin” after “Practices” in heading.

Pub. L. 117-169, § 11401(c)(1), added subsec. (h).

Subsec. (h)(1). Pub. L. 117-169, § 11406(c)(2), substituted “paragraph (8) or (9) of section 1395w-102(b) of this title” for “section 1395w-102(b)(8) of this title”.

2020—Subsec. (f)(2)(C). Pub. L. 116-260, § 112(a)(1), added subpar. (C).

Subsec. (f)(3). Pub. L. 116-260, § 112(a)(2), added par. (3).

2010—Subsec. (f)(2). Pub. L. 111-148 substituted “may be used—” for “may be used by officers, employees, and contractors of the Department of Health and Human Services only for the purposes of, and to the extent necessary in, carrying out this section.” in introductory provisions and added subpars. (A) and (B).

Statutory Notes and Related Subsidiaries

CONSTRUCTION OF 2022 AMENDMENT

Nothing in amendment by section 11401(c)(1) 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.

§ 1395w-116. Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund

(a) Establishment and operation of Account

(1) Establishment

There is created within the Federal Supplementary Medical Insurance Trust Fund established by section 1395t of this title an account to be known as the “Medicare Prescription Drug Account” (in this section referred to as the “Account”).

(2) Funding

The Account shall consist of such gifts and bequests as may be made as provided in section 401(i)(1) of this title, accrued interest on balances in the Account, and such amounts as may be deposited in, or appropriated to, such Account as provided in this part.

(3) Separate from rest of Trust Fund

Funds provided under this part to the Account shall be kept separate from all other funds within the Federal Supplementary Medical Insurance Trust Fund, but shall be invested, and such investments redeemed, in the same manner as all other funds and investments within such Trust Fund.

(b) Payments from Account

(1) In general

The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments to operate the program under this part, including—

(A) payments under section 1395w-114 of this title (relating to low-income subsidy payments);

(B) payments under section 1395w-115 of this title (relating to subsidy payments and payments for fallback plans);