1860D–31 of the Social Security Act [42 U.S.C. 1395w–141] to prescription drug benefits under subpart 1 of part D of title XVIII of such Act [42 U.S.C. 1395w–101 et seq.].''

STATE PHARMACEUTICAL ASSISTANCE TRANSITION COMMISSION

Pub. L. 108–173, title I, § 106, Dec. 8, 2003, 117 Stat. 2168, provided that:

''(a) ESTABLISHMENT.—

''(1) IN GENERAL.—There is established, as of the first day of the third month beginning after the date of the enactment of this Act [Dec. 8, 2003], a State Pharmaceutical Assistance Transition Commission (in this section referred to as the 'Commission') to develop a proposal for addressing the unique transitional issues facing State pharmaceutical assistance programs, and program participants, due to the implementation of the voluntary prescription drug benefit program under part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.], as added by section 101.

''(2) DEFINITIONS.—For purposes of this section:

''(A) STATE PHARMACEUTICAL ASSISTANCE PROGRAM DEFINED.—The term 'State pharmaceutical assistance program' means a program (other than the medicaid program) operated by a State (or under contract with a State) that provides as of the date of the enactment of this Act [Dec. 8, 2003] financial assistance to medicare beneficiaries for the purchase of prescription drugs.

''(B) PROGRAM PARTICIPANT.—The term 'program participant' means a low-income medicare beneficiary who is a participant in a State pharmaceutical assistance program.

''(b) COMPOSITION.—The Commission shall include the following:

''(1) A representative of each Governor of each State that the Secretary [of Health and Human Services] identifies as operating on a statewide basis a State pharmaceutical assistance program that provides for eligibility and benefits that are comparable or more generous than the low-income assistance eligibility and benefits offered under section 1860D–14 of the Social Security Act [42 U.S.C. 1395w–114].

''(2) Representatives from other States that the Secretary identifies have in operation other State pharmaceutical assistance programs, as appointed by the Secretary.

''(3) Representatives of organizations that have an inherent interest in program participants or the program itself, as appointed by the Secretary but not to exceed the number of representatives under paragraphs (1) and (2).

''(4) Representatives of Medicare Advantage organizations, pharmaceutical benefit managers, and other private health insurance plans, as appointed by the Secretary.

''(5) The Secretary (or the Secretary's designee) and such other members as the Secretary may specify.

The Secretary shall designate a member to serve as Chair of the Commission and the Commission shall meet at the call of the Chair.

''(c) DEVELOPMENT OF PROPOSAL.—The Commission shall develop the proposal described in subsection (a) in a manner consistent with the following principles:

''(1) Protection of the interests of program participants in a manner that is the least disruptive to such participants and that includes a single point of contact for enrollment and processing of benefits.

''(2) Protection of the financial and flexibility interests of States so that States are not financially worse off as a result of the enactment of this title [see Tables for classification].

''(3) Principles of medicare modernization under this Act [see Tables for classification].

''(d) REPORT.—By not later than January 1, 2005, the Commission shall submit to the President and Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate.

''(e) SUPPORT.—The Secretary shall provide the Commission with the administrative support services necessary for the Commission to carry out its responsibilities under this section.

''(f) TERMINATION.—The Commission shall terminate 30 days after the date of submission of the report under subsection (d).''

CONFLICT OF INTEREST STUDY

Pub. L. 108–173, title I, § 110, Dec. 8, 2003, 117 Stat. 2174, provided that:

''(a) STUDY.—The Federal Trade Commission shall conduct a study of differences in payment amounts for pharmacy services provided to enrollees in group health plans that utilize pharmacy benefit managers. Such study shall include the following:

''(1) An assessment of the differences in costs incurred by such enrollees and plans for prescription drugs dispensed by mail-order pharmacies owned by pharmaceutical benefit managers compared to mail-order pharmacies not owned by pharmaceutical benefit managers, and community pharmacies.

''(2) Whether such plans are acting in a manner that maximizes competition and results in lower prescription drug prices for enrollees.

''(b) REPORT.—Not later than 18 months after the date of the enactment of this Act [Dec. 8, 2003], the Commission shall submit to Congress a report on the study conducted under subsection (a). Such report shall include recommendations regarding any need for legislation to ensure the fiscal integrity of the voluntary prescription drug benefit program under part D of title XVIII [42 U.S.C. 1395w–101 et seq.], as added by section 101, that may be appropriated as the result of such study.

''(c) EXEMPTION FROM PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to the collection of information under subsection (a).''

§ 1395w–102. Prescription drug benefits

(a) Requirements

(1) In general

For purposes of this part and part C, the term ''qualified prescription drug coverage'' means either of the following:

(A) Standard prescription drug coverage with access to negotiated prices

Standard prescription drug coverage (as defined in subsection (b)) and access to negotiated prices under subsection (d).

(B) Alternative prescription drug coverage with at least actuarially equivalent benefits and access to negotiated prices

Coverage of covered part D drugs which meets the alternative prescription drug coverage requirements of subsection (c) and access to negotiated prices under subsection (d), but only if the benefit design of such coverage is approved by the Secretary, as provided under subsection (c).

(2) Permitting supplemental prescription drug coverage

(A) In general

Subject to subparagraph (B), qualified prescription drug coverage may include supplemental prescription drug coverage consisting of either or both of the following:

(i) Certain reductions in cost-sharing

(I) In general

A reduction in the annual deductible, a reduction in the coinsurance percentage

or, for a year preceding 2025, an increase in the initial coverage limit with respect to covered part D drugs, or any combination thereof, insofar as such a reduction or increase increases the actuarial value of benefits above the actuarial value of basic prescription drug coverage.

(II) Construction

Nothing in this paragraph shall be construed as affecting the application of subsection (c)(3).

(ii) Optional drugs

Coverage of any product that would be a covered part D drug but for the application of subsection (e)(2)(A).

(B) Requirement

A PDP sponsor may not offer a prescription drug plan that provides supplemental prescription drug coverage pursuant to subparagraph (A) in an area unless the sponsor also offers a prescription drug plan in the area that only provides basic prescription drug coverage.

(3) Basic prescription drug coverage

For purposes of this part and part C, the term ''basic prescription drug coverage'' means either of the following:

(A) Coverage that meets the requirements of paragraph (1)(A).

(B) Coverage that meets the requirements of paragraph (1)(B) but does not have any supplemental prescription drug coverage described in paragraph (2)(A).

(4) Application of secondary payor provisions

The provisions of section 1395w–22(a)(4) of this title shall apply under this part in the same manner as they apply under part C.

(5) Construction

Nothing in this subsection shall be construed as changing the computation of incurred costs under subsection (b)(4).

(b) Standard prescription drug coverage

For purposes of this part and part C, the term ''standard prescription drug coverage'' means coverage of covered part D drugs that meets the following requirements:

(1) Deductible

(A) In general

Subject to paragraphs (8) and (9), the coverage has an annual deductible—

(i) for 2006, that is equal to $250; or

(ii) for a subsequent year, that is equal to the amount specified under this paragraph for the previous year increased by the percentage specified in paragraph (6) for the year involved.

(B) Rounding

Any amount determined under subparagraph (A)(ii) that is not a multiple of $5 shall be rounded to the nearest multiple of $5.

(2) Benefit structure

(A) 25 percent coinsurance

Subject to subparagraphs (C), (D), and (E) and paragraphs (8) and (9), the coverage has coinsurance (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3) for a year preceding 2025 and for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2025 and each subsequent year) that is—

(i) equal to 25 percent; or

(ii) actuarially equivalent (using processes and methods established under section 1395w–111(c) of this title) to an average expected payment of 25 percent of such costs.

(B) Use of tiers

Nothing in this part shall be construed as preventing a PDP sponsor or an MA organization from applying tiered copayments under a plan, so long as such tiered copayments are consistent with subparagraphs (A)(ii), (C), and (D).

(C) Coverage for generic drugs in coverage gap

(i) In general

Except as provided in paragraphs (4), (8), and (9), for a year preceding 2025, the coverage for an applicable beneficiary (as defined in section 1395w–114a(g)(1) of this title) has coinsurance (for costs above the initial coverage limit under paragraph (3) and below the out-of-pocket threshold) for covered part D drugs that are not applicable drugs under section 1395w–114a(g)(2) of this title that is—

(I) equal to the generic-gap coinsurance percentage (specified in clause (ii)) for the year; or

(II) actuarially equivalent (using processes and methods established under section 1395w–111(c) of this title) to an average expected payment of such percentage of such costs for covered part D drugs that are not applicable drugs under section 1395w–114a(g)(2) of this title.

(ii) Generic-gap coinsurance percentage

The generic-gap coinsurance percentage specified in this clause for—

(I) 2011 is 93 percent;

(II) 2012 and each succeeding year before 2020 is the generic-gap coinsurance percentage under this clause for the previous year decreased by 7 percentage points; and

(III) 2020 through 2024 is 25 percent.

(D) Coverage for applicable drugs in coverage gap

(i) In general

Except as provided in paragraphs (4), (8), and (9), for a year preceding 2025, the coverage for an applicable beneficiary (as defined in section 1395w–114a(g)(1) of this title) has coinsurance (for costs above the initial coverage limit under paragraph (3) and below the out-of-pocket threshold) for the negotiated price (as defined in section 1395w–114a(g)(6) of this title) of covered part D drugs that are applicable drugs

under section 1395w–114a(g)(2) of this title that is—

(I) equal to the difference between—

(aa) the applicable gap percentage (specified in clause (ii) for the year); and

(bb) the discount percentage specified in section 1395w–114a(g)(4)(A) of this title for such applicable drugs (or, in the case of each of years 2019 through 2024, 50 percent); or

(II) actuarially equivalent (using processes and methods established under section 1395w–111(c) of this title) to an average expected payment of such percentage of such costs, for covered part D drugs that are applicable drugs under section 1395w–114a(g)(2) of this title.

(ii) Applicable gap percentage

The applicable gap percentage specified in this clause for—

(I) 2013 and 2014 is 97.5 percent;

(II) 2015 and 2016 is 95 percent;

(III) 2017 is 90 percent;

(IV) 2018 is 85 percent; and

(V) each of years 2019 through 2024 is 75 percent.

(E) Maximum monthly cap on cost-sharing payments

(i) In general

For plan years beginning on or after January 1, 2025, each PDP sponsor offering a prescription drug plan and each MA organization offering an MA–PD plan shall provide to any enrollee of such plan, including an enrollee who is a subsidy eligible individual (as defined in paragraph (3) of section 1395w–114(a) of this title), the option to elect with respect to a plan year to pay cost-sharing under the plan in monthly amounts that are capped in accordance with this subparagraph.

(ii) Determination of maximum monthly cap

For each month in the plan year for which an enrollee in a prescription drug plan or an MA–PD plan has made an election pursuant to clause (i), the PDP sponsor or MA organization shall determine a maximum monthly cap (as defined in clause (iv)) for such enrollee.

(iii) Beneficiary monthly payments

With respect to an enrollee who has made an election pursuant to clause (i), for each month described in clause (ii), the PDP sponsor or MA organization shall bill such enrollee an amount (not to exceed the maximum monthly cap) for the out-of-pocket costs of such enrollee in such month.

(iv) Maximum monthly cap defined

In this subparagraph, the term ''maximum monthly cap'' means, with respect to an enrollee—

(I) for the first month for which the enrollee has made an election pursuant to clause (i), an amount determined by calculating—

(aa) the annual out-of-pocket threshold specified in paragraph (4)(B) minus the incurred costs of the enrollee as described in paragraph (4)(C); divided by

(bb) the number of months remaining in the plan year; and

(II) for a subsequent month, an amount determined by calculating—

(aa) the sum of any remaining out-of-pocket costs owed by the enrollee from a previous month that have not yet been billed to the enrollee and any additional out-of-pocket costs incurred by the enrollee; divided by

(bb) the number of months remaining in the plan year.

(v) Additional requirements

The following requirements shall apply with respect to the option to make an election pursuant to clause (i) under this subparagraph:

(I) Secretarial responsibilities

The Secretary shall provide information to part D eligible individuals on the option to make such election through educational materials, including through the notices provided under section 1395b–2(a) of this title.

(II) Timing of election

An enrollee in a prescription drug plan or an MA–PD plan may make such an election—

(aa) prior to the beginning of the plan year; or

(bb) in any month during the plan year.

(III) PDP sponsor and MA organization responsibilities

Each PDP sponsor offering a prescription drug plan or MA organization offering an MA–PD plan—

(aa) may not limit the option for an enrollee to make such an election to certain covered part D drugs;

(bb) shall, prior to the plan year, notify prospective enrollees of the option to make such an election in promotional materials;

(cc) shall include information on such option in enrollee educational materials;

(dd) shall have in place a mechanism to notify a pharmacy during the plan year when an enrollee incurs out-of-pocket costs with respect to covered part D drugs that make it likely the enrollee may benefit from making such an election;

(ee) shall provide that a pharmacy, after receiving a notification described in item (dd) with respect to an enrollee, informs the enrollee of such notification;

(ff) shall ensure that such an election by an enrollee has no effect on the amount paid to pharmacies (or the timing of such payments) with respect

to covered part D drugs dispensed to the enrollee; and

(gg) shall have in place a financial reconciliation process to correct inaccuracies in payments made by an enrollee under this subparagraph with respect to covered part D drugs during the plan year.

(IV) Failure to pay amount billed

If an enrollee fails to pay the amount billed for a month as required under this subparagraph—

(aa) the election of the enrollee pursuant to clause (i) shall be terminated and the enrollee shall pay the cost-sharing otherwise applicable for any covered part D drugs subsequently dispensed to the enrollee up to the annual out-of-pocket threshold specified in paragraph (4)(B); and

(bb) the PDP sponsor or MA organization may preclude the enrollee from making an election pursuant to clause (i) in a subsequent plan year.

(V) Clarification regarding past due amounts

Nothing in this subparagraph shall be construed as prohibiting a PDP sponsor or an MA organization from billing an enrollee for an amount owed under this subparagraph.

(VI) Treatment of unsettled balances

Any unsettled balances with respect to amounts owed under this subparagraph shall be treated as plan losses and the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids.

(3) Initial coverage limit

(A) In general

Except as provided in paragraphs (2)(C), (2)(D), (4), (8), and (9), for a year preceding 2025, the coverage has an initial coverage limit on the maximum costs that may be recognized for payment purposes (including the annual deductible)—

(i) for 2006, that is equal to $2,250; or

(ii) for each of years 2007 through 2024, that is equal to the amount specified in this paragraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

(B) Rounding

Any amount determined under subparagraph (A)(ii) that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

(4) Protection against high out-of-pocket expenditures

(A) In general

(i) In general

Subject to paragraphs (8) and (9), the coverage provides benefits, after the part D eligible individual has incurred costs (as described in subparagraph (C)) for covered part D drugs in a year equal to the annual out-of-pocket threshold specified in subparagraph (B), with cost-sharing that is equal to—

(I) for a year preceding 2024, the greater of—

(aa) a copayment of $2 for a generic drug or a preferred drug that is a multiple source drug (as defined in section 1396r–8(k)(7)(A)(i) of this title) and $5 for any other drug; or

(bb) coinsurance that is equal to 5 percent; and

(II) for 2024 and each succeeding year, $0.

(ii) Adjustment of amount

For a year after 2006, the dollar amounts specified in clause (i)(I)(aa) shall be equal to the dollar amounts specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved. Any amount established under this clause that is not a multiple of a 5 cents shall be rounded to the nearest multiple of 5 cents. The Secretary shall continue to calculate the dollar amounts specified in clause (i)(I)(aa), including with the adjustment under this clause, after 2023 for purposes of section 1395w–114(a)(1)(D)(iii) of this title.

(B) Annual out-of-pocket threshold

(i) In general

For purposes of this part, the ''annual out-of-pocket threshold'' specified in this subparagraph—

(I) for 2006, is equal to $3,600;

(II) for each of years 2007 through 2013, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved;

(III) for 2014 and 2015, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved, minus 0.25 percentage point;

(IV) for each of years 2016 through 2019, is equal to the amount specified in this subparagraph for the previous year, increased by the lesser of—

(aa) the annual percentage increase described in paragraph (7) for the year involved, plus 2 percentage points; or

(bb) the annual percentage increase described in paragraph (6) for the year;

(V) for 2020, is equal to the amount that would have been applied under this subparagraph for 2020 if the amendments made by section 1101(d)(1) of the Health Care and Education Reconciliation Act of 2010 had not been enacted;

(VI) for each of years 2021 through 2024, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage in-

crease described in paragraph (6) for the year involved;

(VII) for 2025, is equal to $2,000; or

(VIII) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase described in paragraph (6) for the year involved.

(ii) Rounding

Any amount determined under clause (i) that is not a multiple of $50 shall be rounded to the nearest multiple of $50.

(C) Application

Except as provided in subparagraph (E) or subparagraph (F), in applying subparagraph (A)—

(i) incurred costs shall only include costs incurred with respect to covered part D drugs for the annual deductible described in paragraph (1), for cost-sharing described in paragraph (2), and, for a year preceding 2025, for amounts for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3), but does not include any costs incurred for covered part D drugs which are not included (or treated as being included) in the plan's formulary;

(ii) subject to clause (iii), such costs shall be treated as incurred only if they are paid by the part D eligible individual (or by another person, such as a family member, on behalf of the individual) and the part D eligible individual (or other person) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement (other than under such section or such a Program) for such costs; and

(iii) such costs shall be treated as incurred and shall not be considered to be reimbursed under clause (ii) if such costs—

(I) are borne or paid——[1]

(aa) under section 1395w–114 of this title;

(bb) under a State Pharmaceutical Assistance Program;

(cc) by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 1603 of title 25);

(dd)[2] under an AIDS Drug Assistance Program under part B of title XXVI of the Public Health Service Act [42 U.S.C. 300ff–21 et seq.]; or

(dd)[2] under section 1395w–115(h) of this title; or

(II) for 2025 and subsequent years, are reimbursed through insurance, a group health plan, or certain other third party payment arrangements, but not including the coverage provided by a prescription drug plan or an MA–PD plan that is basic prescription drug coverage (as defined in subsection (a)(3)) or any payments by a manufacturer under the manufacturer discount program under section 1395w–114c of this title.

(D) Information regarding third-party reimbursement

(i) Procedures for exchanging information

In order to accurately apply the requirements of subparagraph (C)(ii), the Secretary is authorized to establish procedures, in coordination with the Secretary of the Treasury and the Secretary of Labor—

(I) for determining whether costs for part D eligible individuals are being reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement; and

(II) for alerting the PDP sponsors and MA organizations that offer the prescription drug plans and MA–PD plans in which such individuals are enrolled about such reimbursement arrangements.

(ii) Authority to request information from enrollees

A PDP sponsor or an MA organization may periodically ask part D eligible individuals enrolled in a prescription drug plan or an MA–PD plan offered by the sponsor or organization whether such individuals have or expect to receive such third-party reimbursement. A material misrepresentation of the information described in the preceding sentence by an individual (as defined in standards set by the Secretary and determined through a process established by the Secretary) shall constitute grounds for termination of enrollment in any plan under section 1395w–21(g)(3)(B) of this title (and as applied under this part under section 1395w–101(b)(1)(B)(v) of this title) for a period specified by the Secretary.

(E) Inclusion of costs of applicable drugs under medicare coverage gap discount program

For each of years 2011 through 2024, in applying subparagraph (A), incurred costs shall include the negotiated price (as defined in paragraph (6) of section 1395w–114a(g) of this title) of an applicable drug (as defined in paragraph (2) of such section) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1395w–114a of this title, regardless of whether part of such costs were paid by a manufacturer under such program, except that incurred costs shall not include the portion of the negotiated price that represents the reduction in coinsurance resulting from the application of paragraph (2)(D).

(F) Inclusion of costs paid under maximum monthly cap option

In applying subparagraph (A), with respect to an enrollee who has made an election pursuant to clause (i) of paragraph (2)(E), costs shall be treated as incurred if such costs are

[1] So in original.

[2] So in original. There are two items (dd).

paid by a PDP sponsor or an MA organization under the option provided under such paragraph.

(5) Construction

Nothing in this part shall be construed as preventing a PDP sponsor or an MA organization offering an MA–PD plan from reducing to zero the cost-sharing otherwise applicable to preferred or generic drugs.

(6) Annual percentage increase

The annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered part D drugs in the United States for part D eligible individuals, as determined by the Secretary for the 12-month period ending in July of the previous year using such methods as the Secretary shall specify.

(7) Additional annual percentage increase

The annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in the consumer price index for all urban consumers (United States city average) for the 12-month period ending in July of the previous year.

(8) Treatment of cost-sharing for adult vaccines recommended by the Advisory Committee on Immunization Practices consistent with treatment of vaccines under part B

(A) In general

For plan years beginning on or after January 1, 2023, with respect to an adult vaccine recommended by the Advisory Committee on Immunization Practices (as defined in subparagraph (B))—

(i) the deductible under paragraph (1) shall not apply; and

(ii) there shall be no coinsurance or other cost-sharing under this part with respect to such vaccine.

(B) Adult vaccines recommended by the Advisory Committee on Immunization Practices

For purposes of this paragraph, the term ''adult vaccine recommended by the Advisory Committee on Immunization Practices'' means a covered part D drug that is a vaccine licensed under section 351 of the Public Health Service Act [42 U.S.C. 262] for use by adult populations and administered in accordance with recommendations of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention.

(9) Treatment of cost-sharing for covered insulin products

(A) No application of deductible

For plan year 2023 and subsequent plan years, the deductible under paragraph (1) shall not apply with respect to any covered insulin product.

(B) Application of cost-sharing

(i) Plan years 2023 and 2024

For plan years 2023 and 2024, the coverage provides benefits for any covered insulin product, regardless of whether an individual has reached the initial coverage limit under paragraph (3) or the out-of-pocket threshold under paragraph (4), with cost-sharing for a month's supply that does not exceed the applicable copayment amount.

(ii) Plan year 2025 and subsequent plan years

For a plan year beginning on or after January 1, 2025, the coverage provides benefits for any covered insulin product, prior to an individual reaching the out-of-pocket threshold under paragraph (4), with cost-sharing for a month's supply that does not exceed the applicable copayment amount.

(C) Covered insulin product

In this paragraph, the term ''covered insulin product'' means an insulin product that is a covered part D drug covered under the prescription drug plan or MA–PD plan that is approved under section 355 of title 21 or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262] and marketed pursuant to such approval or licensure, including any covered insulin product that has been deemed to be licensed under section 351 of the Public Health Service Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and marketed pursuant to such section.

(D) Applicable copayment amount

In this paragraph, the term ''applicable copayment amount'' means, with respect to a covered insulin product under a prescription drug plan or an MA–PD plan dispensed—

(i) during plan years 2023, 2024, and 2025, $35; and

(ii) during plan year 2026 and each subsequent plan year, the lesser of—

(I) $35;

(II) an amount equal to 25 percent of the maximum fair price established for the covered insulin product in accordance with part E of subchapter XI; or

(III) an amount equal to 25 percent of the negotiated price of the covered insulin product under the prescription drug plan or MA–PD plan.

(E) Special rule for first 3 months of 2023

With respect to a month's supply of a covered insulin product dispensed during the period beginning on January 1, 2023, and ending on March 31, 2023, a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall reimburse an enrollee within 30 days for any cost-sharing paid by such enrollee that exceeds the cost-sharing applied by the prescription drug plan or MA–PD plan under subparagraph (B)(i) at the point-of-sale for such month's supply.

(c) Alternative prescription drug coverage requirements

A prescription drug plan or an MA–PD plan may provide a different prescription drug benefit design from standard prescription drug cov-

erage so long as the Secretary determines (consistent with section 1395w–111(c) of this title) that the following requirements are met and the plan applies for, and receives, the approval of the Secretary for such benefit design:

(1) Assuring at least actuarially equivalent coverage

(A) Assuring equivalent value of total coverage

The actuarial value of the total coverage is at least equal to the actuarial value of standard prescription drug coverage.

(B) Assuring equivalent unsubsidized value of coverage

The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage exceeds the actuarial value of the subsidy payments under section 1395w–115 of this title with respect to such coverage.

(C) Assuring standard payment for costs

The coverage is designed, based upon an actuarially representative pattern of utilization, to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (b)(3) for the year for a year preceding 2025 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the year for 2025 and each subsequent year, of an amount equal to at least the product of—

(i) the amount by which the initial coverage limit described in subsection (b)(3) for the year for a year preceding 2025 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the year for 2025 and each subsequent year exceeds the deductible described in subsection (b)(1) for the year; and

(ii) 100 percent minus the coinsurance percentage specified in subsection (b)(2)(A)(i).

(2) Maximum required deductible

The deductible under the coverage shall not exceed the deductible amount specified under subsection (b)(1) for the year.

(3) Same protection against high out-of-pocket expenditures

The coverage provides the coverage required under subsection (b)(4).

(4) Same maximum monthly cap on cost-sharing

The maximum monthly cap on cost-sharing payments shall apply to coverage with respect to an enrollee who has made an election pursuant to clause (i) of subsection (b)(2)(E) under the option provided under such subsection.

(5) Treatment of cost-sharing for adult vaccines recommended by the Advisory Committee on Immunization Practices

The coverage is in accordance with subsection (b)(8).

(6) Treatment of cost-sharing for covered insulin products

The coverage is provided in accordance with subsection (b)(9).

(d) Access to negotiated prices

(1) Access

(A) In general

Under qualified prescription drug coverage offered by a PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan, the sponsor or organization shall provide enrollees with access to negotiated prices used for payment for covered part D drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of a deductible or other cost-sharing or, for a year preceding 2025, an initial coverage limit (described in subsection (b)(3)).

(B) Negotiated prices

For purposes of this part, negotiated prices, subject to subparagraph (D), shall take into account negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, for covered part D drugs, and include any dispensing fees for such drugs.

(C) Medicaid-related provisions

The prices negotiated by a prescription drug plan, by an MA–PD plan with respect to covered part D drugs, or by a qualified retiree prescription drug plan (as defined in section 1395w–132(a)(2) of this title) with respect to such drugs on behalf of part D eligible individuals, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1396r–8(c)(1)(C) of this title.

(D) Application of maximum fair price for selected drugs

In applying this section, in the case of a covered part D drug that is a selected drug (as referred to 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), the negotiated prices used for payment (as described in this subsection) shall be no greater than the maximum fair price (as defined in section 1320f(c)(3) of this title) for such drug and for each year during such period plus any dispensing fees for such drug.

(2) Disclosure

A PDP sponsor offering a prescription drug plan or an MA organization offering an MA–PD plan shall disclose to the Secretary (in a manner specified by the Secretary) the aggregate negotiated price concessions described in paragraph (1)(B) made available to the sponsor or organization by a manufacturer which are passed through in the form of lower subsidies, lower monthly beneficiary prescription drug premiums, and lower prices through pharmacies and other dispensers. The provisions of section 1396r–8(b)(3)(D) of this title

apply to information disclosed to the Secretary under this paragraph.

(3) Audits

To protect against fraud and abuse and to ensure proper disclosures and accounting under this part and in accordance with section 1395w–27(d)(2)(B) of this title (as applied under section 1395w–112(b)(3)(C) of this title), the Secretary may conduct periodic audits, directly or through contracts, of the financial statements and records of PDP sponsors with respect to prescription drug plans and MA organizations with respect to MA–PD plans.

(e) Covered part D drug defined

(1) In general

Except as provided in this subsection, for purposes of this part, the term ''covered part D drug'' means—

(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i), (A)(ii), or (A)(iii) of section 1396r–8(k)(2) of this title;

(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary); or

(C) for the period beginning on December 29, 2022, and ending on March 31, 2025, an oral antiviral drug that may be dispensed only upon a prescription and is authorized under section 360bbb–3 of title 21, on the basis of the declaration published in the Federal Register by the Secretary of Health and Human Services on April 1, 2020 (85 Fed. Reg. 18250 et seq.),

and such term includes a vaccine licensed under section 262 of this title (and, for vaccines administered on or after January 1, 2008, its administration) and any use of a covered part D drug for a medically accepted indication (as defined in paragraph (4)).

(2) Exclusions

(A) In general

Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1396r–8(d)(2) of this title, other than subparagraph (E) of such section (relating to smoking cessation agents), other than subparagraph (I) of such section (relating to barbiturates) if the barbiturate is used in the treatment of epilepsy, cancer, or a chronic mental health disorder, and other than subparagraph (J) of such section (relating to benzodiazepines), or under section 1396r–8(d)(3) of this title, as such sections were in effect on December 8, 2003. Such term also does not include a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration.

(B) Medicare covered drugs

A drug prescribed for a part D eligible individual that would otherwise be a covered part D drug under this part shall not be so considered if payment for such drug as so prescribed and dispensed or administered with respect to that individual is available (or would be available but for the application of a deductible) under part A or B for that individual.

(3) Application of general exclusion provisions

A prescription drug plan or an MA–PD plan may exclude from qualified prescription drug coverage any covered part D drug—

(A) for which payment would not be made if section 1395y(a) of this title applied to this part; or

(B) which is not prescribed in accordance with the plan or this part.

Such exclusions are determinations subject to reconsideration and appeal pursuant to subsections (g) and (h), respectively, of section 1395w–104 of this title.

(4) Medically accepted indication defined

(A) In general

For purposes of paragraph (1), the term ''medically accepted indication'' has the meaning given that term—

(i) in the case of a covered part D drug used in an anticancer chemotherapeutic regimen, in section 1395x(t)(2)(B) of this title, except that in applying such section—

(I) ''prescription drug plan or MA–PD plan'' shall be substituted for ''carrier'' each place it appears; and

(II) subject to subparagraph (B), the compendia described in section 1396r–8(g)(1)(B)(i)(III) of this title shall be included in the list of compendia described in clause (ii)(I) section 1395x(t)(2)(B) of this title; and

(ii) in the case of any other covered part D drug, in section 1396r–8(k)(6) of this title.

(B) Conflict of interest

On and after January 1, 2010, subparagraph (A)(i)(II) shall not apply unless the compendia described in section 1396r–8(g)(1)(B)(i)(III) of this title meets[3] the requirement in the third sentence of section 1395x(t)(2)(B) of this title.

(C) Update

For purposes of applying subparagraph (A)(ii), the Secretary shall revise the list of compendia described in section 1396r–8(g)(1)(B)(i) of this title as is appropriate for identifying medically accepted indications for drugs. Any such revision shall be done in a manner consistent with the process for revising compendia under section 1395x(t)(2)(B) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–2, as added Pub. L. 108–173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2075; amended Pub. L. 109–91, title

[3] So in original. Probably should be ''meet''.

I, §103(a), Oct. 20, 2005, 119 Stat. 2092; Pub. L. 109–432, div. B, title II, §202(b), Dec. 20, 2006, 120 Stat. 2986; Pub. L. 110–275, title I, §§175(a), 182(a)(1), July 15, 2008, 122 Stat. 2581, 2583; Pub. L. 111–148, title III, §§3301(c)(1), 3314(a), 3315, Mar. 23, 2010, 124 Stat. 467, 478, 479; Pub. L. 111–152, title I, §1101(a)(2), (b)(3), (d), Mar. 30, 2010, 124 Stat. 1037–1039; Pub. L. 115–123, div. E, title XII, §53116(a), Feb. 9, 2018, 132 Stat. 306; Pub. L. 117–169, title I, §§11001(b)(1)(D), 11201(a), (e)(1), 11202(a), (b), 11401(a), (c)(2), 11406(a), Aug. 16, 2022, 136 Stat. 1852, 1877, 1891, 1893, 1895, 1896, 1898, 1902; Pub. L. 117–328, div. FF, title IV, §4131, Dec. 29, 2022, 136 Stat. 5918; Pub. L. 118–158, div. C, title II, §3209, Dec. 21, 2024, 138 Stat. 1766.)

Editorial Notes

REFERENCES IN TEXT

Section 1101(d)(1) of the Health Care and Education Reconciliation Act of 2010, referred to in subsec. (b)(4)(B)(i)(V), is section 1101(d)(1) of Pub. L. 111–152, which amended this section.

The Public Health Service Act, referred to in subsec. (b)(4)(C)(iii)(I)(dd), is act July 1, 1944, ch. 373, 58 Stat. 682. Part B of title XXVI of the Act is classified generally to part B (§300ff–21 et seq.) of subchapter XXIV of chapter 6A of this title. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

Section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009, referred to in (b)(9)(C), is section 7002(e)(4) of Pub. L. 111–148, which is set out in a note under section 262 of this title.

AMENDMENTS

2024—Subsec. (e)(1)(C). Pub. L. 118–158 substituted ''March 31, 2025'' for ''December 31, 2024''.

2022—Subsec. (a)(2)(A)(i)(I). Pub. L. 117–169, §11201(e)(1)(A), substituted ''or, for a year preceding 2025, an increase in the initial'' for '', or an increase in the initial''.

Subsec. (b)(1)(A). Pub. L. 117–169, §11406(a)(1)(A), substituted ''paragraphs (8) and (9)'' for ''paragraph (8)'' in introductory provisions.

Pub. L. 117–169, §11401(a)(1)(A), substituted ''Subject to paragraph (8), the coverage'' for ''The coverage'' in introductory provisions.

Subsec. (b)(2)(A). Pub. L. 117–169, §11406(a)(1)(B)(i), substituted ''paragraphs (8) and (9)'' for ''paragraph (8)'' in introductory provisions.

Pub. L. 117–169, §11401(a)(1)(B)(i), inserted ''and paragraph (8)'' after ''and (E)'' in introductory provisions.

Pub. L. 117–169, §11202(a)(1)(A), substituted '', (D), and (E)'' for ''and (D)'' in introductory provisions.

Pub. L. 117–169, §11201(a)(1)(A), inserted ''for a year preceding 2025 and for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2025 and each subsequent year'' after ''paragraph (3)'' in introductory provisions.

Subsec. (b)(2)(C)(i). Pub. L. 117–169, §11406(a)(1)(B)(ii), substituted '', (8), and (9)'' for ''and (8)'' in introductory provisions.

Pub. L. 117–169, §11401(a)(1)(B)(ii), substituted ''paragraphs (4) and (8)'' for ''paragraph (4)'' in introductory provisions.

Pub. L. 117–169, §11201(a)(1)(B)(i), inserted ''for a year preceding 2025,'' after ''paragraph (4),'' in introductory provisions.

Subsec. (b)(2)(C)(ii)(III). Pub. L. 117–169, §11201(a)(1)(B)(ii), substituted ''through 2024'' for ''and each subsequent year''.

Subsec. (b)(2)(D)(i). Pub. L. 117–169, §11406(a)(1)(B)(iii), substituted '', (8), and (9)'' for ''and (8)'' in introductory provisions.

Pub. L. 117–169, §11401(a)(1)(B)(iii), substituted ''paragraphs (4) and (8)'' for ''paragraph (4)'' in introductory provisions.

Pub. L. 117–169, §11201(a)(1)(C)(i)(I), inserted ''for a year preceding 2025,'' after ''paragraph (4),'' in introductory provisions.

Subsec. (b)(2)(D)(i)(I)(bb). Pub. L. 117–169, §11201(a)(1)(C)(i)(II), substituted ''each of years 2019 through 2024'' for ''a year after 2018''.

Subsec. (b)(2)(D)(ii)(V). Pub. L. 117–169, §11201(a)(1)(C)(ii), substituted ''each of years 2019 through 2024'' for ''2019 and each subsequent year''.

Subsec. (b)(2)(E). Pub. L. 117–169, §11202(a)(1)(B), added subpar. (E).

Subsec. (b)(3)(A). Pub. L. 117–169, §11406(a)(1)(C), substituted ''(8), and (9)'' for ''and (8)'' in introductory provisions.

Pub. L. 117–169, §11401(a)(1)(C), substituted ''(4), and (8)'' for ''and (4)'' in introductory provisions.

Pub. L. 117–169, §11201(a)(2)(A), inserted ''for a year preceding 2025,'' after ''and (4),'' in introductory provisions.

Subsec. (b)(3)(A)(ii). Pub. L. 117–169, §11201(a)(2)(B), substituted ''for each of years 2007 through 2024'' for ''for a subsequent year''.

Subsec. (b)(4)(A)(i). Pub. L. 117–169, §11406(a)(1)(D), substituted ''paragraphs (8) and (9)'' for ''paragraph (8)'' in introductory provisions.

Pub. L. 117–169, §11401(a)(1)(D), substituted ''Subject to paragraph (8), the coverage'' for ''The coverage'' in introductory provisions.

Pub. L. 117–169, §11201(a)(3)(A)(i), inserted dash after ''is equal to'' in introductory provisions, designated remainder of existing provisions as subcl. (I), inserted ''for a year preceding 2024,'' before ''the greater of—'', redesignated former subcls. (I) and (II) as items (aa) and (bb), respectively, of subcl. (I) and realigned margins, and added subcl. (II).

Subsec. (b)(4)(A)(ii). Pub. L. 117–169, §11201(a)(3)(A)(ii), substituted ''clause (i)(I)(aa) shall be'' for ''clause (i)(I) shall be'' and inserted at end ''The Secretary shall continue to calculate the dollar amounts specified in clause (i)(I)(aa), including with the adjustment under this clause, after 2023 for purposes of section 1395w–114(a)(1)(D)(iii) of this title.''

Subsec. (b)(4)(B)(i)(V). Pub. L. 117–169, §11201(a)(3)(B)(i)(I), struck out ''or'' at end.

Subsec. (b)(4)(B)(i)(VI). Pub. L. 117–169, §11201(a)(3)(B)(i)(II), substituted ''for each of years 2021 through 2024'' for ''for a subsequent year'' and semicolon for period at end.

Subsec. (b)(4)(B)(i)(VII), (VIII). Pub. L. 117–169, §11201(a)(3)(B)(i)(III), added subcls. (VII) and (VIII).

Subsec. (b)(4)(B)(ii). Pub. L. 117–169, §11201(a)(3)(B)(ii), substituted ''clause (i)'' for ''clause (i)(II)''.

Subsec. (b)(4)(C). Pub. L. 117–169, §11202(a)(2)(A), substituted ''subparagraph (E) or subparagraph (F)'' for ''subparagraph (E)'' in introductory provisions.

Subsec. (b)(4)(C)(i). Pub. L. 117–169, §11201(a)(3)(C)(i), substituted ''and, for a year preceding 2025, for amounts'' for ''and for amounts''.

Subsec. (b)(4)(C)(iii). Pub. L. 117–169, §11201(a)(3)(C)(ii), inserted dash after ''if such costs'' in introductory provisions, designated remainder of existing provisions as subcl. (I), redesignated former subcls. (I) to (IV) as items (aa) to (dd), respectively, of subcl. (I) and realigned margins, and added subcl. (II).

Subsec. (b)(4)(C)(iii)(I)(dd). Pub. L. 117–169, §11401(c)(2), added item (dd) referring to section 1395w–115(h) of this title.

Subsec. (b)(4)(E). Pub. L. 117–169, §11201(a)(3)(D), substituted ''For each of years 2011 through 2024, in applying'' for ''In applying''.

Subsec. (b)(4)(F). Pub. L. 117–169, §11202(a)(2)(B), added subpar. (F).

Subsec. (b)(8). Pub. L. 117–169, §11401(a)(1)(E), added par. (8).

Subsec. (b)(9). Pub. L. 117–169, §11406(a)(1)(E), added par. (9).

Subsec. (c)(1)(C). Pub. L. 117–169, §11201(e)(1)(B), struck out ''at initial coverage limit'' after ''payment for costs'' in heading and inserted ''for a year preceding 2025 or the annual out-of-pocket threshold specified in

subsection (b)(4)(B) for the year for 2025 and each subsequent year'' after ''subsection (b)(3) for the year'' in introductory provisions and in cl. (i).

Subsec. (c)(4). Pub. L. 117–169, §11202(b), added par. (4).

Subsec. (c)(5). Pub. L. 117–169, §11401(a)(2), added par. (5).

Subsec. (c)(6). Pub. L. 117–169, §11406(a)(2), added par. (6).

Subsec. (d)(1)(A). Pub. L. 117–169, §11201(e)(1)(C), substituted ''or, for a year preceding 2025, an initial'' for ''or an initial''.

Subsec. (d)(1)(B). Pub. L. 117–169, §11001(b)(1)(D)(i), inserted '', subject to subparagraph (D),'' after ''negotiated prices''.

Subsec. (d)(1)(D). Pub. L. 117–169, §11001(b)(1)(D)(ii), added subpar. (D).

Subsec. (e)(1)(C). Pub. L. 117–328 added subpar. (C).

2018—Subsec. (b)(2)(D)(i)(I). Pub. L. 115–123, §53116(a)(1), amended subcl. (I) generally. Prior to amendment, subcl. (I) read as follows: ''equal to the difference between the applicable gap percentage (specified in clause (ii) for the year) and the discount percentage specified in section 1395w–114a(g)(4)(A) of this title for such applicable drugs; or''.

Subsec. (b)(2)(D)(ii)(V), (VI). Pub. L. 115–123, §53116(a)(2), substituted ''2019'' for ''2020'' in subcl. (VI), redesignated subcl. (VI) as (V), and struck out former subcl. (V) which read as follows: ''2019 is 80 percent; and''.

2010—Subsec. (b)(2)(A). Pub. L. 111–152, §1101(b)(3)(A), substituted ''Subject to subparagraphs (C) and (D), the coverage'' for ''The coverage''.

Subsec. (b)(2)(B). Pub. L. 111–152, §1101(b)(3)(B), substituted ''subparagraphs (A)(ii), (C), and (D)'' for ''subparagraph (A)(ii)''.

Subsec. (b)(2)(C), (D). Pub. L. 111–152, §1101(b)(3)(C), added subpars. (C) and (D).

Subsec. (b)(3)(A). Pub. L. 111–152, §1101(b)(3)(D), substituted ''paragraphs (2)(C), (2)(D), and (4)'' for ''paragraph (4)''.

Pub. L. 111–148, §3315(1), which directed substitution of ''paragraphs (4) and (7)'' for ''paragraph (4)'' in introductory provisions, was repealed by Pub. L. 111–152, §1101(a)(2). See Construction of 2010 Amendment note below.

Subsec. (b)(4)(B)(i)(II) to (VI). Pub. L. 111–152, §1101(d)(1), added subcls. (II) to (V) and redesignated former subcl. (II) as (VI).

Subsec. (b)(4)(C). Pub. L. 111–148, §3314(a), in cl. (ii), substituted ''subject to clause (iii), such costs shall be treated as incurred only if'' for ''such costs shall be treated as incurred only if'' and struck out '', under section 1395w–114 of this title, or under a State Pharmaceutical Assistance Program'' after ''on behalf of the individual),'', and added cl. (iii).

Pub. L. 111–148, §3301(c)(1)(A), substituted ''Except as provided in subparagraph (E), in applying'' for ''In applying'' in introductory provisions.

Subsec. (b)(4)(E). Pub. L. 111–152, §1101(b)(3)(E), inserted before period at end '', except that incurred costs shall not include the portion of the negotiated price that represents the reduction in coinsurance resulting from the application of paragraph (2)(D)''.

Pub. L. 111–148, §3301(c)(1)(B), added subpar. (E).

Subsec. (b)(7). Pub. L. 111–152, §1101(d)(2), added par. (7).

Pub. L. 111–148, §3315(2), which directed addition of par. (7), was repealed by Pub. L. 111–152, §1101(a)(2). As enacted, text read as follows:

''(A) IN GENERAL.—For the plan year beginning on January 1, 2010, the initial coverage limit described in paragraph (3)(B) otherwise applicable shall be increased by $500.

''(B) APPLICATION.—In applying subparagraph (A)—

''(i) except as otherwise provided in this subparagraph, there shall be no change in the premiums, bids, or any other parameters under this part or part C;

''(ii) costs that would be treated as incurred costs for purposes of applying paragraph (4) but for the application of subparagraph (A) shall continue to be treated as incurred costs;

''(iii) the Secretary shall establish procedures, which may include a reconciliation process, to fully reimburse PDP sponsors with respect to prescription drug plans and MA organizations with respect to MA–PD plans for the reduction in beneficiary cost sharing associated with the application of subparagraph (A);

''(iv) the Secretary shall develop an estimate of the additional increased costs attributable to the application of this paragraph for increased drug utilization and financing and administrative costs and shall use such estimate to adjust payments to PDP sponsors with respect to prescription drug plans under this part and MA organizations with respect to MA–PD plans under part C; and

''(v) the Secretary shall establish procedures for retroactive reimbursement of part D eligible individuals who are covered under such a plan for costs which are incurred before the date of initial implementation of subparagraph (A) and which would be reimbursed under such a plan if such implementation occurred as of January 1, 2010.

''(C) NO EFFECT ON SUBSEQUENT YEARS.—The increase under subparagraph (A) shall only apply with respect to the plan year beginning on January 1, 2010, and the initial coverage limit for plan years beginning on or after January 1, 2011, shall be determined as if subparagraph (A) had never applied.''

See Construction of 2010 Amendment note below.

2008—Subsec. (e)(1). Pub. L. 110–275, §182(a)(1)(A), substituted ''(as defined in paragraph (4))'' for ''(as defined in section 1396r–8(k)(6) of this title)'' in concluding provisions.

Subsec. (e)(2)(A). Pub. L. 110–275, §175(a), inserted ''other than subparagraph (I) of such section (relating to barbiturates) if the barbiturate is used in the treatment of epilepsy, cancer, or a chronic mental health disorder, and other than subparagraph (J) of such section (relating to benzodiazepines),'' after ''agents),''.

Subsec. (e)(4). Pub. L. 110–275, §182(a)(1)(B), which directed amendment of subsec. (e)(1) in the matter following subpar. (B) by adding par. (4) at the end, was executed by adding par. (4) at end of subsec. (e), to reflect the probable intent of Congress.

2006—Subsec. (e)(1). Pub. L. 109–432 inserted ''(and, for vaccines administered on or after January 1, 2008, its administration)'' after ''section 262 of this title'' in concluding provisions.

2005—Subsec. (e)(2)(A). Pub. L. 109–91, §103(a)(2), inserted at end ''Such term also does not include a drug when used for the treatment of sexual or erectile dysfunction, unless such drug were used to treat a condition, other than sexual or erectile dysfunction, for which the drug has been approved by the Food and Drug Administration.''

Pub. L. 109–91, §103(a)(1), inserted before period at end '', as such sections were in effect on December 8, 2003''.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111–148, title III, §3301(c)(2), Mar. 23, 2010, 124 Stat. 468, provided that: ''The amendments made by this subsection [amending this section] shall apply to costs incurred on or after July 1, 2010.''

Pub. L. 111–148, title III, §3314(b), Mar. 23, 2010, 124 Stat. 479, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to costs incurred on or after January 1, 2011.''

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110–275, title I, §175(b), July 15, 2008, 122 Stat. 2581, provided that: ''The amendments made by subsection (a) [amending this section] shall apply to prescriptions dispensed on or after January 1, 2013.''

Pub. L. 110–275, title I, §182(a)(2), July 15, 2008, 122 Stat. 2583, provided that: ''The amendments made by

this subsection [amending this section] shall apply to plan years beginning on or after January 1, 2009.''

EFFECTIVE DATE OF 2005 AMENDMENT

Pub. L. 109–91, title I, §103(c), Oct. 20, 2005, 119 Stat. 2092, provided that: ''The amendment made by subsection (a)(1) [amending this section] shall take effect as if included in the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) and the amendment made by subsection (a)(2) [amending this section] shall apply to coverage for drugs dispensed on or after January 1, 2007.''

CONSTRUCTION OF 2022 AMENDMENT

Pub. L. 117–169, title I, §11401(d), Aug. 16, 2022, 136 Stat. 1898, provided that: ''Nothing in this section [amending this section and sections 1395w–114 and 1395w–115 of this title and enacting provisions set out as a note below] shall be construed as limiting coverage under part D of title XVIII of the Social Security Act [42 U.S.C. 1395w–101 et seq.] for vaccines that are not recommended by the Advisory Committee on Immunization Practices.''

CONSTRUCTION OF 2010 AMENDMENT

Pub. L. 111–152, title I, §1101(a)(2), Mar. 30, 2010, 124 Stat. 1037, provided that: ''Section 3315 of the Patient Protection and Affordable Care Act [section 3315 of Pub. L. 111–148, amending this section] (including the amendments made by such section) is repealed, and any provision of law amended or repealed by such sections [sic] is hereby restored or revived as if such section had not been enacted into law.''

CONSTRUCTION

Pub. L. 109–91, title I, §103(b), Oct. 20, 2005, 119 Stat. 2092, provided that: ''Nothing in this section [amending this section and enacting provisions set out as a note under this section] shall be construed as preventing a prescription drug plan or an MA–PD plan from providing coverage of drugs for the treatment of sexual or erectile dysfunction as supplemental prescription drug coverage under section 1860D–2(a)(2)(A)(ii) of the Social Security Act (42 U.S.C. 1395w–102(a)(2)(A)(ii)).''

IMPLEMENTATION OF PUB. L. 117–169 FOR CERTAIN YEARS

Pub. L. 117–169, title I, §11201(f), Aug. 16, 2022, 136 Stat. 1892, provided that: ''The Secretary shall implement this section [enacting sections 1395w–114c and 1395w–114d of this title and amending this section and sections 1395w–24, 1395w–104, 1395w–111, 1395w–113, 1395w–114, 1395w–114a, 1395w–115, 1395w–116, 1395w–131, 1395w–132, 1395w–151, 1395w–153, and 1396r–8 of this title], including the amendments made by this section, for 2024, 2025, and 2026 by program instruction or other forms of program guidance.''

Pub. L. 117–169, title I, §11202(c), Aug. 16, 2022, 136 Stat. 1895, provided that: ''The Secretary shall implement this section [amending this section], including the amendments made by this section, for 2025 by program instruction or other forms of program guidance.''

Pub. L. 117–169, title I, §11401(e), Aug. 16, 2022, 136 Stat. 1898, provided that: ''The Secretary shall implement this section [amending this section and sections 1395w–114 and 1395w–115 of this title and enacting provisions set out as a note above], including the amendments made by this section, for 2023, 2024, and 2025, by program instruction or other forms of program guidance.''

Pub. L. 117–169, title I, §11406(d), Aug. 16, 2022, 136 Stat. 1904, provided that: ''The Secretary shall implement this section [amending this section and sections 1395w–114 and 1395w–115 of this title] for plan years 2023, 2024, and 2025 by program instruction or other forms of program guidance.''

PAYMENT FOR ADMINISTRATION OF PART D VACCINES IN 2007

Pub. L. 109–432, div. B, title II, §202(a), Dec. 20, 2006, 120 Stat. 2986, provided that: ''Notwithstanding any other provision of law, in the case of a vaccine that is a covered part D drug under section 1860D–2(e) of the Social Security Act (42 U.S.C. 1395w–102(e)) and that is administered during 2007, the administration of such vaccine shall be paid under part B of title XVIII of such Act [42 U.S.C. 1395j et seq.] as if it were the administration of a vaccine described in section 1861(s)(10)(B) of such Act (42 U.S.C. 1395w(s)(10)(B) [probably should be 1395x(s)(10)(B)]).''

§ 1395w–103. Access to a choice of qualified prescription drug coverage

(a) Assuring access to a choice of coverage

(1) Choice of at least two plans in each area

The Secretary shall ensure that each part D eligible individual has available, consistent with paragraph (2), a choice of enrollment in at least 2 qualifying plans (as defined in paragraph (3)) in the area in which the individual resides, at least one of which is a prescription drug plan. In any such case in which such plans are not available, the part D eligible individual shall be given the opportunity to enroll in a fallback prescription drug plan.

(2) Requirement for different plan sponsors

The requirement in paragraph (1) is not satisfied with respect to an area if only one entity offers all the qualifying plans in the area.

(3) Qualifying plan defined

For purposes of this section, the term ''qualifying plan'' means—

(A) a prescription drug plan; or

(B) an MA–PD plan described in section 1395w–21(a)(2)(A)(i) of this title that provides—

(i) basic prescription drug coverage; or

(ii) qualified prescription drug coverage that provides supplemental prescription drug coverage so long as there is no MA monthly supplemental beneficiary premium applied under the plan, due to the application of a credit against such premium of a rebate under section 1395w–24(b)(1)(C) of this title.

(b) Flexibility in risk assumed and application of fallback plan

In order to ensure access pursuant to subsection (a) in an area—

(1) the Secretary may approve limited risk plans under section 1395w–111(f) of this title for the area; and

(2) only if such access is still not provided in the area after applying paragraph (1), the Secretary shall provide for the offering of a fallback prescription drug plan for that area under section 1395w–111(g) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–3, as added Pub. L. 108–173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2081.)