I, §114(a)(1), July 15, 2008, 122 Stat. 2506; Pub. L. $111-148,\; title\; III,\; \S 3308(a),\; (b)(1),\; Mar.\; 23,\; 2010,\; 124$ Stat. 472, 474; Pub. L. 117-169, title I, §11201(d)(1), (2), (3)(C), Aug. 16, 2022, 136 Stat. 1888, 1890.)

Editorial Notes

AMENDMENTS

2022—Subsec. (a)(1)(A).Pub. L. 117-169, 11201(d)(1)(A)(i), inserted "or (8) (as applicable)" after 'paragraph (2)'

Subsec. (a)(2). Pub. L. 117–169, \$11201(d)(1)(A)(ii), substituted "Subject to paragraph (8), the base" for "The

base" in introductory provisions. Subsec. (a)(3)(A). Pub. L. 117–169, 11201(d)(2)(A), inserted "(or, for 2030 and each subsequent year, the percent specified under paragraph (9))" after "25.5 per-

Subsec. (a)(7)(B)(i). Pub. L. 117–169, §11201(d)(3)(C), inserted "(or, for 2030 and each subsequent year, the percent specified under paragraph (9))" after "25.5 percent" in subcls. (I) and (II).

Pub. 117-169 Subsec (a)(7)(B)(ii).L. 11201(d)(1)(A)(iii)(I), inserted "or (8) (as applicable)" after "paragraph (2)

Subsec. (a)(7)(E)(i). Pub. L. 117-169.§11201(d)(1)(A)(iii)(II), inserted "or (8) (as applicable)" after "paragraph (2)"

Subsec. (a)(8). Pub. L. 117-169, §11201(d)(1)(A)(iv), added par. (8).

Subsec. (a)(9). Pub. L. 117-169, §11201(d)(2)(B), added

Subsec. (b)(3)(A)(ii). Pub. L. 117–169, §11201(d)(1)(B), substituted "paragraph (2) or (8) of subsection (a) (as applicable)" for "subsection (a)(2)"

2010—Subsec. (a)(1)(F), (G). Pub. L. 111-148, §3308(b)(1), added subpar. (F), redesignated former subpar. (F) as (G), and substituted "(D), (E), and (F)" for "(D) and ' in subpar. (G).

Subsec. (a)(7). Pub. L. 111-148, §3308(a)(1), added par.

Subsec. (c)(1). Pub. L. 111–148, §3308(a)(2)(A), substituted "(2), (3), and (4)" for "(2) and (3)". Subsec. (c)(4). Pub. L. 111–148, §3308(a)(2)(B), added

par. (4).

2008—Subsec. (b)(8). Pub. L. 110–275 added par. (8).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110-275, title I, §114(b), July 15, 2008, 122 Stat. 2507, provided that: "The amendments made by this section [amending this section and section 1395w-114 of this title] shall apply to subsidies for months beginning with January 2009.

§ 1395w-114. Premium and cost-sharing subsidies for low-income individuals

(a) Income-related subsidies for certain individ-

(1) Individuals with certain low incomes

In the case of a subsidy eligible individual (as defined in paragraph (3)) who is determined to have income that is below 135 percent (or, with respect to a plan year beginning on or after January 1, 2024, 150 percent) of the poverty line applicable to a family of the size involved and who meets the resources requirement described in paragraph (3)(D) (or, with respect to a plan year beginning on or after January 1, 2024, paragraph (3)(E)) or who is covered under this paragraph under paragraph (3)(B)(i), the individual is entitled under this section to the following:

(A) Full premium subsidy

An income-related premium subsidy equal to 100 percent of the amount described in subsection (b)(1), but not to exceed the premium amount specified in subsection (b)(2)(B).

(B) Elimination of deductible

A reduction in the annual deductible applicable under section 1395w-102(b)(1) of this

(C) Continuation of coverage above the initial coverage limit

For a year preceding 2025, the continuation of coverage from the initial coverage limit (under paragraph (3) of section 1395w-102(b) of this title) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced cost-sharing described in subparagraph (D).

(D) Reduction in cost-sharing below out-ofpocket threshold

(i) Institutionalized individuals

In the case of an individual who is a fullbenefit dual eligible individual and who is an institutionalized individual or couple (as defined in section 1396a(q)(1)(B) of this title) or, effective on a date specified by the Secretary (but in no case earlier than January 1, 2012), who would be such an institutionalized individual or couple, if the full-benefit dual eligible individual were not receiving services under a home and community-based waiver authorized for a State under section 1315 of this title or subsection (c) or (d) of section 1396n of this title or under a State plan amendment under subsection (i) of such section or services provided through enrollment in a medicaid managed care organization with a contract under section 1396b(m) of this title or under section 1396u-2 of this title, the elimination of any beneficiary coinsurance described in section 1395w-102(b)(2) of this title (for all amounts through the total amount of expenditures at which benefits are available under section 1395w-102(b)(4) of this title).

(ii) Lowest income dual eligible individuals

Subject to paragraph (6), in the case of an individual not described in clause (i) who is a full-benefit dual eligible individual and whose income does not exceed 100 percent of the poverty line applicable to a family of the size involved, the substitution for the beneficiary coinsurance described in section 1395w-102(b)(2) of this title (for all amounts through the total amount of expenditures at which benefits are available under section 1395w-102(b)(4) of this title) of a copayment amount that does not exceed \$1 for a generic drug or a preferred drug that is a multiple source defined in (as 1396r-8(k)(7)(A)(i) of this title) and \$3 for any other drug, or, if less, the copayment amount applicable to an individual under clause (iii).

(iii) Other individuals

Subject to paragraph (6), in the case of an individual not described in clause (i) or (ii), the substitution for the beneficiary coinsurance described in section 1395w-102(b)(2) of this title (for all amounts through the total amount of expenditures at which benefits are available under section 1395w-102(b)(4) of this title) of a copayment amount that does not exceed the copayment amount specified under section 1395w-102(b)(4)(A)(i)(I)(aa) of this title for the drug and year involved. For plan year 2023 and subsequent plan years, the copayment amount applicable under the preceding sentence to a month's supply of a covered insulin product (as defined in section 1395w-102(b)(9)(C) of this title) dispensed to the individual may not exceed the applicable copayment amount for the product under the prescription drug plan or MA-PD plan in which the individual is

(E) Elimination of cost-sharing above annual out-of-pocket threshold

For a year preceding 2024, the elimination of any cost-sharing imposed under section 1395w-102(b)(4)(A) of this title or under section 1395w-102(b)(9) of this title in the case of a covered insulin product (as defined in subparagraph (C) of such section).

(2) Other low-income individuals

With respect to a plan year beginning before January 1, 2024, in the case of a subsidy eligible individual who is not described in paragraph (1), the individual is entitled under this section to the following:

(A) Sliding scale premium subsidy

An income-related premium subsidy determined on a linear sliding scale ranging from 100 percent of the amount described in paragraph (1)(A) for individuals with incomes at or below 135 percent of such level to 0 percent of such amount for individuals with incomes at 150 percent of such level.

(B) Reduction of deductible

Subject to paragraphs (8) and (9) of section 1395w-102(b) of this title, a reduction in the annual deductible applicable under section 1395w-102(b)(1) of this title to \$50.

(C) Continuation of coverage above the initial coverage limit

The continuation of coverage from the initial coverage limit (under paragraph (3) of section 1395w-102(b) of this title) for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4) of such section, subject to the reduced coinsurance described in subparagraph (D).

(D) Reduction in cost-sharing below out-ofpocket threshold

Subject to paragraph (6), the substitution for the beneficiary coinsurance described in section 1395w-102(b)(2) of this title (for all amounts above the deductible under subparagraph (B) through the total amount of expenditures at which benefits are available under section 1395w-102(b)(4) of this title) of coinsurance of "15 percent" instead of coin-

surance of "25 percent" in section 1395w-102(b)(2) of this title. For plan year 2023, the amount of the coinsurance applicable under the preceding sentence to a month's supply of a covered insulin product (as defined in section 1395w-102(b)(9)(C) of this title) dispensed to the individual may not exceed the applicable copayment amount for the product under the prescription drug plan or MA-PD plan in which the individual is enrolled.

(E) Reduction of cost-sharing above annual out-of-pocket threshold

Subject to paragraph (6) of this subsection and subsection (c), the substitution for the cost-sharing imposed under section 1395w-102(b)(4)(A) of this title of a copayment or coinsurance not to exceed the copayment or coinsurance amount specified under section 1395w-102(b)(4)(A)(i)(I)(aa) of this title for the drug and year involved. For plan year 2023, the amount of the copayment or coinsurance applicable under the preceding sentence to a month's supply of a covered insulin product (as defined in section 1395w-102(b)(9)(C) of this title) dispensed to the individual may not exceed the applicable copayment amount for the product under the prescription drug plan or MA-PD plan in which the individual is enrolled.

(3) Determination of eligibility

(A) Subsidy eligible individual defined

For purposes of this part, subject to subparagraph (F), the term "subsidy eligible individual" means a part D eligible individual who—

- (i) is enrolled in a prescription drug plan or MA-PD plan;
- (ii) has income below 150 percent of the poverty line applicable to a family of the size involved; and
- (iii) meets the resources requirement described in subparagraph (D) or (E).

(B) Determinations

(i) In general

The determination of whether a part D eligible individual residing in a State is a subsidy eligible individual and whether the individual is described in paragraph (1) shall be determined under the State plan under subchapter XIX for the State under section 1396u–5(a) of this title or by the Commissioner of Social Security. There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this subparagraph.

(ii) Effective period

Determinations under this subparagraph shall be effective beginning with the month in which the individual applies for a determination that the individual is a subsidy eligible individual and shall remain in effect for a period specified by the Secretary, but not to exceed 1 year.

(iii) Redeterminations and appeals through medicaid

Redeterminations and appeals, with respect to eligibility determinations under

clause (i) made under a State plan under subchapter XIX, shall be made in accordance with the frequency of, and manner in which, redeterminations and appeals of eligibility are made under such plan for purposes of medical assistance under such subchapter.

(iv) Redeterminations and appeals through Commissioner

With respect to eligibility determinations under clause (i) made by the Commissioner of Social Security—

- (I) redeterminations shall be made at such time or times as may be provided by the Commissioner;
- (II) the Commissioner shall establish procedures for appeals of such determinations that are similar to the procedures described in the third sentence of section 1383(c)(1)(A) of this title; and
- (III) judicial review of the final decision of the Commissioner made after a hearing shall be available to the same extent, and with the same limitations, as provided in subsections (g) and (h) of section 405 of this title.

(v) Treatment of medicaid beneficiaries

Subject to subparagraph (F), the Secretary—

(I) shall provide that part D eligible individuals who are full-benefit dual eligible individuals (as defined in section 1396u-5(c)(6) of this title) or who are recipients of supplemental security income benefits under subchapter XVI shall be treated as subsidy eligible individuals described in paragraph (1); and

(II) may provide that part D eligible individuals not described in subclause (I) who are determined for purposes of the State plan under subchapter XIX to be eligible for medical assistance under clause (i), (iii), or (iv) of section 1396a(a)(10)(E) of this title are treated as being determined to be subsidy eligible individuals described in paragraph (1).

Insofar as the Secretary determines that the eligibility requirements under the State plan for medical assistance referred to in subclause (II) are substantially the same as the requirements for being treated as a subsidy eligible individual described in paragraph (1), the Secretary shall provide for the treatment described in such subclause.

(vi) Special rule for widows and widowers

Notwithstanding the preceding provisions of this subparagraph, in the case of an individual whose spouse dies during the effective period for a determination or redetermination that has been made under this subparagraph, such effective period shall be extended through the date that is 1 year after the date on which the determination or redetermination would (but for the application of this clause) otherwise cease to be effective.

(C) Income determinations

For purposes of applying this section—

- (i) in the case of a part D eligible individual who is not treated as a subsidy eligible individual under subparagraph (B)(v), income shall be determined in the manner described in section 1396d(p)(1)(B) of this title, without regard to the application of section 1396a(r)(2) of this title and except that support and maintenance furnished in kind shall not be counted as income; and
- (ii) the term "poverty line" has the meaning given such term in section 9902(2) of this title, including any revision required by such section.

Nothing in clause (i) shall be construed to affect the application of section 1396a(r)(2) of this title for the determination of eligibility for medical assistance under subchapter XIX.

(D) Resource standard applied to full low-income subsidy to be based on three times SSI resource standard

The resources requirement of this subparagraph is that an individual's resources (as determined under section 1382b of this title for purposes of the supplemental security income program subject to the life insurance policy exclusion provided under subparagraph (G)) do not exceed—

- (i) for 2006 three times the maximum amount of resources that an individual may have and obtain benefits under that program; and
- (ii) for a subsequent year the resource limitation established under this clause for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any resource limitation established under clause (ii) that is not a multiple of \$10 shall be rounded to the nearest multiple of \$10.

(E) Alternative resource standard

(i) In general

The resources requirement of this subparagraph is that an individual's resources (as determined under section 1382b of this title for purposes of the supplemental security income program subject to the life insurance policy exclusion provided under subparagraph (G)) do not exceed—

- (I) for 2006, \$10,000 (or \$20,000 in the case of the combined value of the individual's assets or resources and the assets or resources of the individual's spouse); and
- (II) for a subsequent year the dollar amounts specified in this subclause (or subclause (I)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any dollar amount established under subclause (II) that is not a multiple of \$10 shall be rounded to the nearest multiple of

(ii) Use of simplified application form and process

The Secretary, jointly with the Commissioner of Social Security, shall—

(I) develop a model, simplified application form and process consistent with clause (iii) for the determination and verification of a part D eligible individual's assets or resources under this subparagraph; and

(II) provide such form to States.

(iii) Documentation and safeguards

Under such process-

(I) the application form shall consist of an attestation under penalty of perjury regarding the level of assets or resources (or combined assets and resources in the case of a married part D eligible individual) and valuations of general classes of assets or resources;

(II) such form shall be accompanied by copies of recent statements (if any) from financial institutions in support of the application; and

(III) matters attested to in the application shall be subject to appropriate methods of verification.

(iv) Methodology flexibility

The Secretary may permit a State in making eligibility determinations for premium and cost-sharing subsidies under this section to use the same asset or resource methodologies that are used with respect to eligibility for medical assistance for medicare cost-sharing described in section 1396d(p) of this title so long as the Secretary determines that the use of such methodologies will not result in any significant differences in the number of individuals determined to be subsidy eligible individuals.

(F) Treatment of territorial residents

In the case of a part D eligible individual who is not a resident of the 50 States or the District of Columbia, the individual is not eligible to be a subsidy eligible individual under this section but may be eligible for financial assistance with prescription drug expenses under section 1396u–5(e) of this title.

(G) Life insurance policy exclusion

In determining the resources of an individual (and the eligible spouse of the individual, if any) under section 1382b of this title for purposes of subparagraphs (D) and (E) no part of the value of any life insurance policy shall be taken into account.

(4) Indexing dollar amounts

(A) Copayment for lowest income dual eligible individuals

The dollar amounts applied under paragraph (1)(D)(ii)—

(i) for 2007 shall be the dollar amounts specified in such paragraph increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year; or

(ii) for a subsequent year shall be the dollar amounts specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any amount established under clause (i) or (ii), that is based on an increase of \$1 or \$3, that is not a multiple of 5 cents or 10 cents, respectively, shall be rounded to the nearest multiple of 5 cents or 10 cents, respectively.

(B) Reduced deductible

The dollar amount applied under paragraph (2)(B)—

(i) for 2007 shall be the dollar amount specified in such paragraph increased by the annual percentage increase described in section 1395w-102(b)(6) of this title for 2007; or

(ii) for a subsequent year shall be the dollar amount specified in this clause (or clause (i)) for the previous year increased by the annual percentage increase described in section 1395w-102(b)(6) of this title for the year involved.

Any amount established under clause (i) or (ii) that is not a multiple of \$1 shall be rounded to the nearest multiple of \$1.

(5) Waiver of de minimis premiums

The Secretary shall, under procedures established by the Secretary, permit a prescription drug plan or an MA-PD plan to waive the monthly beneficiary premium for a subsidy eligible individual if the amount of such premium is de minimis. If such premium is waived under the plan, the Secretary shall not reassign subsidy eligible individuals enrolled in the plan to other plans based on the fact that the monthly beneficiary premium under the plan was greater than the low-income benchmark premium amount.

(6) No application of cost-sharing or deductible for adult vaccines recommended by the Advisory Committee on Immunization Practices

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 section 1395w-102(b)(8)(B) of this title)—

- (A) the deductible under section 1395w-102(b)(1) of this title shall not apply; and
- (B) there shall be no cost-sharing under this section with respect to such vaccine.

(b) Premium subsidy amount

(1) In general

The premium subsidy amount described in this subsection for a subsidy eligible individual residing in a PDP region and enrolled in a prescription drug plan or MA-PD plan is the low-income benchmark premium amount (as defined in paragraph (2)) for the PDP region in which the individual resides or, if greater, the amount specified in paragraph (3).

(2) Low-income benchmark premium amount defined

(A) In general

For purposes of this subsection, the term "low-income benchmark premium amount" means, with respect to a PDP region in which—

(i) all prescription drug plans are offered by the same PDP sponsor, the weighted average of the amounts described in subparagraph (B)(i) for such plans; or

(ii) there are prescription drug plans offered by more than one PDP sponsor, the weighted average of amounts described in subparagraph (B) for prescription drug plans and MA-PD plans described in section 1395w-21(a)(2)(A)(i) of this title offered in such region.

(B) Premium amounts described

The premium amounts described in this subparagraph are, in the case of—

(i) a prescription drug plan that is a basic prescription drug plan, the monthly beneficiary premium for such plan:

(ii) a prescription drug plan that provides alternative prescription drug coverage the actuarial value of which is greater than that of standard prescription drug coverage, the portion of the monthly beneficiary premium that is attributable to basic prescription drug coverage; and

(iii) an MA-PD plan, the portion of the MA monthly prescription drug beneficiary premium that is attributable to basic prescription drug benefits (described in section 1395w-22(a)(6)(B)(ii)¹ of this title) and determined before the application of the monthly rebate computed under section 1395w-24(b)(1)(C)(i) of this title for that plan and year involved and, in the case of a qualifying plan, before the application of the increase under section 1395w-23(o) of this title for that plan and year involved.

The premium amounts described in this subparagraph do not include any amounts attributable to late enrollment penalties under section 1395w-113(b) of this title.

(3) Access to 0 premium plan

In no case shall the premium subsidy amount under this subsection for a PDP region be less than the lowest monthly beneficiary premium for a prescription drug plan that offers basic prescription drug coverage in the region.

(c) Administration of subsidy program

(1) In general

The Secretary shall provide a process whereby, in the case of a part D eligible individual who is determined to be a subsidy eligible individual and who is enrolled in a prescription drug plan or is enrolled in an MA-PD plan—

(A) the Secretary provides for a notification of the PDP sponsor or the MA organization offering the plan involved that the individual is eligible for a subsidy and the amount of the subsidy under subsection (a);

- (B) the sponsor or organization involved reduces the premiums or cost-sharing otherwise imposed by the amount of the applicable subsidy and submits to the Secretary information on the amount of such reduction;
- (C) the Secretary periodically and on a timely basis reimburses the sponsor or organization for the amount of such reductions; and
- (D) the Secretary ensures the confidentiality of individually identifiable information.

In applying subparagraph (C), the Secretary shall compute reductions based upon imposition under subsections (a)(1)(D) and (a)(2)(E) of unreduced copayment amounts applied under such subsections.

(2) Use of capitated form of payment

The reimbursement under this section with respect to cost-sharing subsidies may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved.

(d) Facilitation of reassignments

Beginning not later than January 1, 2011, the Secretary shall, in the case of a subsidy eligible individual who is enrolled in one prescription drug plan and is subsequently reassigned by the Secretary to a new prescription drug plan, provide the individual, within 30 days of such reassignment, with—

(1) information on formulary differences between the individual's former plan and the plan to which the individual is reassigned with respect to the individual's drug regimens; and

(2) a description of the individual's right to request a coverage determination, exception, or reconsideration under section 1395w-104(g) of this title, bring an appeal under section 1395w-104(h) of this title, or resolve a grievance under section 1395w-104(f) of this title.

(e) Limited income newly eligible transition program

(1) In general

Beginning not later than January 1, 2024, the Secretary shall carry out a program to provide transitional coverage for covered part D drugs for LI NET eligible individuals in accordance with this subsection.

(2) LI NET eligible individual defined

For purposes of this subsection, the term "LI NET eligible individual" means a part D eligible individual who—

- (A) meets the requirements of clauses (ii) and (iii) of subsection (a)(3)(A); and
- (B) has not yet enrolled in a prescription drug plan or an MA-PD plan, or, who has so enrolled, but with respect to whom coverage under such plan has not yet taken effect.

(3) Transitional coverage

For purposes of this subsection, the term "transitional coverage" means with respect to an LI NET eligible individual—

(A) immediate access to covered part D drugs at the point of sale during the period that begins on the first day of the month

 $^{^1\}mathrm{So}$ in original. Section 1395w–22(a)(6) of this title does not contain a subpar. (B).

such individual is determined to meet the requirements of clauses (ii) and (iii) of subsection (a)(3)(A) and ends on the date that coverage under a prescription drug plan or MA-PD plan takes effect with respect to such individual; and

(B) in the case of an LI NET eligible individual who is a full-benefit dual eligible individual (as defined in section 1396u–5(c)(6) of this title) or a recipient of supplemental security income benefits under subchapter XVI, retroactive coverage (in the form of reimbursement of the amounts that would have been paid under this part had such individual been enrolled in a prescription drug plan or MA-PD plan) of covered part D drugs purchased by such individual during the period that begins on the date that is the later of

(i) the date that such individual was first eligible for a low-income subsidy under this part; or

(ii) the date that is 36 months prior to the date such individual enrolls in a prescription drug plan or MA-PD plan,

and ends on the date that coverage under such plan takes effect.

(4) Program administration

(A) Point of contact

The Secretary shall, as determined appropriate by the Secretary, administer the program under this subsection through a contract with a single program administrator.

(B) Benefit design

The Secretary shall ensure that the transitional coverage provided to LI NET eligible individuals under this subsection—

(i) provides access to all covered part D drugs under an open formulary;

(ii) permits all pharmacies determined by the Secretary to be in good standing to process claims under the program;

(iii) is consistent with such requirements as the Secretary considers necessary to improve patient safety and ensure appropriate dispensing of medication; and

(iv) meets such other requirements as the Secretary may establish.

(5) Relationship to other provisions of this subchapter; waiver authority

(A) In general

The following provisions shall not apply with respect to the program under this subsection:

(i) Paragraphs (1) and (3)(B) of section 1395w-104(a) of this title (relating to dissemination of general information; availability of information on changes in formulary through the internet).

(ii) Subparagraphs (A) and (B) of section

(ii) Subparagraphs (A) and (B) of section 1395w-104(b)(3) of this title (relating to requirements on development and application of formularies; formulary develop-

(iii) Paragraphs (1)(C) and (2) of section 1395w-104(c) of this title (relating to medication therapy management program).

(B) Waiver authority

The Secretary may waive such other requirements of subchapter XI and this sub-

chapter as may be necessary to carry out the purposes of the program established under this subsection.

(6) Contracting authority

The authority vested in the Secretary by this subsection may be performed without regard to such provisions of law or regulations relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the furtherance of the purpose of this subchapter.

(f) Relation to medicaid program

For special provisions under the medicaid program relating to medicare prescription drug benefits, see section 1396u–5 of this title.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D–14, as added Pub. L. 108–173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2107; amended Pub. L. 110–275, title I, §§114(a)(2), 116(a), 117(a), July 15, 2008, 122 Stat. 2506, 2507; Pub. L. 111–148, title III, §§3302(a), 3303(a), 3304(a), 3305, 3309, Mar. 23, 2010, 124 Stat. 468–470, 475; Pub. L. 111–152, title I, §1102(c)(4), Mar. 30, 2010, 124 Stat. 1045; Pub. L. 116–260, div. CC, title I, §118, Dec. 27, 2020, 134 Stat. 2950; Pub. L. 117–169, title I, §§11201(e)(3), 11401(b), 11404, 11406(b), Aug. 16, 2022, 136 Stat. 1891, 1897, 1899, 1903.)

Editorial Notes

AMENDMENTS

2022—Subsec. (a). Pub. L. 117–169, \$11404(1), substituted "certain individuals" for "individuals with income up to 150 percent of poverty line" in heading.

Subsec. (a)(1). Pub. L. 117–169, §11404(2), substituted "Individuals with certain low incomes" for "Individuals with income below 135 percent of poverty line" in heading and, in introductory provisions, inserted "(or, with respect to a plan year beginning on or after January 1, 2024, 150 percent)" after "135 percent" and "(or, with respect to a plan year beginning on or after January 1, 2024, paragraph (3)(E))" after "the resources requirement described in paragraph (3)(D)".

Subsec. (a)(1)(C). Pub. L. 117-169, \$11201(e)(3)(A)(i), substituted "For a year preceding 2025, the continuation" for "The continuation".

Subsec. (a)(1)(D)(ii). Pub. L. 117-169, \$11401(b)(1), substituted "Subject to paragraph (6), in the case" for "In the case".

Subsec. (a)(1)(D)(iii). Pub. L. 117–169, §11406(b)(1)(A), inserted at end "For plan year 2023 and subsequent plan years, the copayment amount applicable under the preceding sentence to a month's supply of a covered insulin product (as defined in section 1395w–102(b)(9)(C) of this title) dispensed to the individual may not exceed the applicable copayment amount for the product under the prescription drug plan or MA-PD plan in which the individual is enrolled."

Pub. L. 117-169, \$11401(b)(1), substituted "Subject to paragraph (6), in the case" for "In the case".

Pub. L. 117-169, \$11201(e)(3)(A)(ii), substituted "1395w-102(b)(4)(A)(i)(I)(aa)" for "1395w-102(b)(4)(A)(i)(I)".

Subsec. (a)(1)(E). Pub. L. 117–169, §11406(b)(1)(B), inserted before period at end "or under section 1395w–102(b)(9) of this title in the case of a covered insulin product (as defined in subparagraph (C) of such section)".

Pub. L. 117-169, \$11201(e)(3)(A)(iii), substituted "For a year preceding 2024, the elimination" for "The elimination".

Subsec. (a)(2). Pub. L. 117–169, §11404(3), substituted "Other low-income individuals" for "Other individuals

with income below 150 percent of poverty line" in heading and "With respect to a plan year beginning before January 1, 2024, in the case of a subsidy" for "In the case of a subsidy" in introductory provisions.

Subsec. (a)(2)(B). Pub. L. 117-169, §11406(b)(2)(A), substituted "paragraphs (8) and (9) of section 1395w-102(b)" for "section 1395w-102(b)(8)"

Pub. L. 117–169, §11401(b)(2)(A), substituted "Subject to section 1395w-102(b)(8) of this title, a reduction" for "A reduction"

Subsec. (a)(2)(D). Pub. L. 117–169, §11406(b)(2)(B), inserted at end "For plan year 2023, the amount of the coinsurance applicable under the preceding sentence to a month's supply of a covered insulin product (as defined in section 1395w-102(b)(9)(C) of this title) dispensed to the individual may not exceed the applicable copayment amount for the product under the prescription drug plan or MA-PD plan in which the individual is enrolled.'

Pub. L. 117–169, §11401(b)(2)(B), substituted "Subject to paragraph (6), the substitution" for "The substitution".

Subsec. (a)(2)(E). Pub. L. 117-169, §11406(b)(2)(C), inserted at end "For plan year 2023, the amount of the copayment or coinsurance applicable under the preceding sentence to a month's supply of a covered insulin product (as defined in section 1395w-102(b)(9)(C) of this title) dispensed to the individual may not exceed the applicable copayment amount for the product under the prescription drug plan or MA-PD plan in which the individual is enrolled.'

Pub. L. 117-169, §11401(b)(2)(C), substituted "paragraph (6) of this subsection and subsection (c)" for "subsection (c)". Pub. L. 117–169,

§11201(e)(3)(B), substituted "1395w-102(b)(4)(A)(i)(I)(aa)""1395w-102(b)(4)(A)(i)(I)"

Subsec. (a)(6). Pub. L. 117-169, §11401(b)(3), added par.

(6). 2020—Subsecs. (e), (f). Pub. L. 116–260 added subsec. (e)

and redesignated former subsec. (e) as (f). 2010—Subsec. (a)(1)(D)(i). Pub. L. 111–148, §3309, inserted "or, effective on a date specified by the Secretary (but in no case earlier than January 1, 2012), who would be such an institutionalized individual or couple, if the full-benefit dual eligible individual were not receiving services under a home and community-based waiver authorized for a State under section 1315 of this title or subsection (c) or (d) of section 1396n of this title or under a State plan amendment under subsection (i) of such section or services provided through enrollment in a medicaid managed care organization with a contract under section 1396b(m) of this title or under section 1396u-2 of this title" after "1396a(q)(1)(B) of this title)".

Subsec. (a)(3)(B)(vi). Pub. L. 111-148, §3304(a), added

Subsec. (a)(5). Pub. L. 111–148, §3303(a), added par. (5). Subsec. (b)(2)(B)(iii). Pub. L. 111-152 substituted "and determined before the application of the monthly rebate computed under section 1395w-24(b)(1)(C)(i) of this title for that plan and year involved and, in the case of a qualifying plan, before the application of the increase under section 1395w-23(o) of this title for that plan and year involved" for ", determined without regard to any reduction in such premium as a result of any beneficiary rebate under section 1395w-24(b)(1)(C) of this title or bonus payment under section 1395w-23(n) of this

Pub. L. 111-148, §3302(a), inserted ", determined without regard to any reduction in such premium as a result of any beneficiary rebate under section 1854(b)(1)(C) or bonus payment

1395w-23(n) of this title' before period at end. Subsecs. (d), (e). Pub. L. 111-148, §3305, added subsec. (d) and redesignated former subsec. (d) as (e).

2008—Subsec. (a)(1)(A). Pub. L. 110–275, \$114(a)(2), substituted "equal to 100 percent of the amount described in subsection (b)(1), but not to exceed the premium amount specified in subsection (b)(2)(B)." for "equal

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

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

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

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

Subsect (a)(3)(D), (E)(1). Pub. L. 110-275, §116(a)(2), (3), inserted "subject to the life insurance policy exclusion provided under subparagraph (G)" after "program" in introductory provisions.

Subsec. (a)(3)(G). Pub. L. 110–275, $\S116(a)(4)$, added subpar. (G).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2010 AMENDMENT

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

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

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

EFFECTIVE DATE OF 2008 AMENDMENT

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

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

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

Construction of 2022 Amendment

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

GAO STUDY REGARDING IMPACT OF ASSETS TEST FOR SUBSIDY ELIGIBLE INDIVIDUALS

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

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

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

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

(a) Establishment

Subject to subsection (h), the Secretary shall establish a Medicare coverage gap discount program (in this section referred to as the "program") by not later than January 1, 2011. Under the program, the Secretary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance of the duties described in subsection (c)(1). The Secretary shall establish a model agreement for use under the program by not later than 180 days after March 23, 2010, in consultation with manufacturers, and allow for comment on such model agreement.

(b) Terms of agreement

(1) In general

(A) Agreement

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

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

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

(C) Timing of agreement

(i) Special rule for 2011

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

(ii) 2012 and subsequent years

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

(2) Provision of appropriate data

Each manufacturer with an agreement in effect under this section shall collect and have available appropriate data, as determined by the Secretary, to ensure that it can demonstrate to the Secretary compliance with the requirements under the program.

(3) Compliance with requirements for administration of program

Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary or a third party with a contract under subsection (d)(3), as applicable, for purposes of administering the program, including any determination under clause (i) of subsection (c)(1)(A) or procedures established under such subsection (c)(1)(A).

(4) Length of agreement

(A) In general

An agreement under this section shall be effective for an initial period of not less than 18 months and shall be automatically renewed for a period of not less than 1 year unless terminated under subparagraph (B).

(B) Termination

(i) By the Secretary

The Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

(ii) By a manufacturer

A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—

(I) if the termination occurs before January 30 of a plan year, as of the day after the end of the plan year; and

(II) if the termination occurs on or after January 30 of a plan year, as of the day after the end of the succeeding plan year.

(iii) Effectiveness of termination

Any termination under this subparagraph shall not affect discounts for applicable drugs of the manufacturer that are due under the agreement before the effective date of its termination.

(iv) Notice to third party

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

(c) Duties described and special rule for supplemental benefits

(1) Duties described

The duties described in this subsection are the following:

(A) Administration of program

Administering the program, including—

 $^{^1\}mathbf{So}$ in original. Second "not later than" probably should not appear.