

(ii) the sum of such numbers for all States to which this paragraph applies.

(D) Continued availability of funds

Amounts made available to a State under this paragraph which are not used under this paragraph shall be added to the amount available to that State for purposes of carrying out section 1396u-5(e) of this title.

(k) Funding

(1) Establishment of Transitional Assistance Account

(A) In general

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

(B) Funds

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

(C) Separate from rest of Trust Fund

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

(2) Payments from account

(A) In general

The Managing Trustee shall pay from time to time from the Account such amounts as the Secretary certifies are necessary to make payments for transitional assistance provided under subsections (g) and (j)(2).

(B) Treatment in relation to part B premium

Amounts payable from the Account shall not be taken into account in computing actuarial rates or premium amounts under section 1395r of this title.

(3) Appropriations to cover benefits

There are appropriated to the Account in a fiscal year, out of any moneys in the Treasury not otherwise appropriated, an amount equal to the payments made from the Account in the year.

(4) For administrative expenses

There are authorized to be appropriated to the Secretary such sums as may be necessary to carry out the Secretary’s responsibilities under this section.

(5) Transfer of any remaining balance to Medicare Prescription Drug Account

Any balance remaining in the Account after the Secretary determines that funds in the Account are no longer necessary to carry out the program under this section shall be transferred and deposited into the Medicare Pre-

scription Drug Account under section 1395w-116 of this title.

(6) Construction

Nothing in this section shall be construed as authorizing the Secretary to provide for payment (other than payment of an enrollment fee on behalf of a transitional assistance eligible individual under subsection (g)(1)(A)) to a sponsor for administrative expenses incurred by the sponsor in carrying out this section (including in administering the transitional assistance provisions of subsections (f) and (g)).

(Aug. 14, 1935, ch. 531, title XVIII, §1860D-31, as added Pub. L. 108-173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2131.)

Editorial Notes

REFERENCES IN TEXT

The Internal Revenue Code of 1986, referred to in subsec. (f)(3)(B)(iii), is classified generally to Title 26, Internal Revenue Code.

Section 264(c) of the Health Insurance Portability and Accountability Act of 1996, referred to in subsec. (h)(6)(A), is section 264(c) of Pub. L. 104-191, which is set out as a note under section 1320d-2 of this title.

Statutory Notes and Related Subsidiaries

RULES FOR IMPLEMENTATION

Pub. L. 108-173, title I, §105(c), Dec. 8, 2003, 117 Stat. 2166, provided that: “The following rules shall apply to the medicare prescription drug discount card and transitional assistance program under section 1860D-31 of the Social Security Act [42 U.S.C. 1395w-141], as added by section 101(a):

“(1) In promulgating regulations pursuant to subsection (a)(2)(B) of such section 1860D-31 [42 U.S.C. 1395w-141(a)(2)(B)]—

“(A) section 1871(a)(3) of the Social Security Act (42 U.S.C. 1395hh(a)(3)), as added by section 902(a)(1), shall not apply;

“(B) chapter 35 of title 44, United States Code, shall not apply; and

“(C) sections 553(d) and 801(a)(3)(A) of title 5, United States Code, shall not apply.

“(2) Section 1857(c)(5) of the Social Security Act (42 U.S.C. 1395w-27(c)(5)) shall apply with respect to section 1860D-31 of such Act, as added by section 101(a), in the same manner as it applies to part C of title XVIII of such Act [42 U.S.C. 1395w-21 et seq.].

“(3) The administration of such program shall be made without regard to chapter 35 of title 44, United States Code.

“(4)(A) There shall be no judicial review of a determination not to endorse, or enter into a contract, with a prescription drug card sponsor under section 1860D-31 of the Social Security Act.

“(B) In the case of any order issued to enjoin any provision of section 1860D-31 of the Social Security Act (or of [sic] any provision of this section [amending sections 1395r, 1395t, and 1396r-8 of this title and sections 6103 and 7213 of Title 26, Internal Revenue Code]), such order shall not affect any other provision of such section (or of this section) and all such provisions shall be treated as severable.”

SUBPART 5—DEFINITIONS AND MISCELLANEOUS PROVISIONS

§ 1395w-151. Definitions; treatment of references to provisions in part C

(a) Definitions

For purposes of this part:

(1) Basic prescription drug coverage

The term “basic prescription drug coverage” is defined in section 1395w-102(a)(3) of this title.

(2) Covered part D drug

The term “covered part D drug” is defined in section 1395w-102(e) of this title.

(3) Creditable prescription drug coverage

The term “creditable prescription drug coverage” has the meaning given such term in section 1395w-113(b)(4) of this title.

(4) Part D eligible individual

The term “part D eligible individual” has the meaning given such term in section 1395w-101(a)(3)(A) of this title.¹

(5) Fallback prescription drug plan

The term “fallback prescription drug plan” has the meaning given such term in section 1395w-111(g)(4) of this title.

(6) Initial coverage limit

The term “initial coverage limit” means such limit as established under section 1395w-102(b)(3) of this title for a year before 2025, or, in the case of coverage that is not standard prescription drug coverage, the comparable limit (if any) established under the coverage for such year.

(7) Insurance risk

The term “insurance risk” means, with respect to a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect performance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitution.

(8) MA plan

The term “MA plan” has the meaning given such term in section 1395w-101(a)(3)(B) of this title.¹

(9) MA-PD plan

The term “MA-PD plan” has the meaning given such term in section 1395w-101(a)(3)(C) of this title.¹

(10) Medicare Prescription Drug Account

The term “Medicare Prescription Drug Account” means the Account created under section 1395w-116(a) of this title.

(11) PDP approved bid

The term “PDP approved bid” has the meaning given such term in section 1395w-113(a)(6) of this title.

(12) PDP region

The term “PDP region” means such a region as provided under section 1395w-111(a)(2) of this title.

(13) PDP sponsor

The term “PDP sponsor” means a non-governmental entity that is certified under this part as meeting the requirements and standards of this part for such a sponsor.

(14) Prescription drug plan

The term “prescription drug plan” means prescription drug coverage that is offered—

(A) under a policy, contract, or plan that has been approved under section 1395w-111(e) of this title; and

(B) by a PDP sponsor pursuant to, and in accordance with, a contract between the Secretary and the sponsor under section 1395w-112(b) of this title.

(15) Qualified prescription drug coverage

The term “qualified prescription drug coverage” is defined in section 1395w-102(a)(1) of this title.

(16) Standard prescription drug coverage

The term “standard prescription drug coverage” is defined in section 1395w-102(b) of this title.

(17) State Pharmaceutical Assistance Program

The term “State Pharmaceutical Assistance Program” has the meaning given such term in section 1395w-133(b) of this title.

(18) Subsidy eligible individual

The term “subsidy eligible individual” has the meaning given such term in section 1395w-114(a)(3)(A) of this title.

(b) Application of part C provisions under this part

For purposes of applying provisions of part C under this part with respect to a prescription drug plan and a PDP sponsor, unless otherwise provided in this part such provisions shall be applied as if—

(1) any reference to an MA plan included a reference to a prescription drug plan;

(2) any reference to an MA organization or a provider-sponsored organization included a reference to a PDP sponsor;

(3) any reference to a contract under section 1395w-27 of this title included a reference to a contract under section 1395w-112(b) of this title;

(4) any reference to part C included a reference to this part; and

(5) any reference to an election period under section 1395w-21 of this title were a reference to an enrollment period under section 1395w-101 of this title.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D-41, as added Pub. L. 108-173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2148; amended Pub. L. 117-169, title I, §11201(e)(6), Aug. 16, 2022, 136 Stat. 1892.)

Editorial Notes

REFERENCES IN TEXT

Section 1395w-101(a)(3) of this title, referred to in subsec. (a)(4), (8), (9), was in the original “section 1860D-1(a)(4)”, and was translated as meaning section 1860D-1(a)(3) of act Aug. 14, 1935, which is classified to section 1395w-101(a)(3) of this title, to reflect the probable intent of Congress, because section 1395w-101(a) of this title does not contain a par. (4) and par. (3) defines terms for purposes of this part.

AMENDMENTS

2022—Subsec. (a)(6). Pub. L. 117-169 inserted “for a year before 2025” after “1395w-102(b)(3) of this title” and “for such year” before period at end.

¹ See References in Text note below.

§ 1395w-152. Miscellaneous provisions**(a) Access to coverage in territories**

The Secretary may waive such requirements of this part, including section 1395w-103(a)(1) of this title, insofar as the Secretary determines it is necessary to secure access to qualified prescription drug coverage for part D eligible individuals residing in a State (other than the 50 States and the District of Columbia).

(b) Application of demonstration authority

The provisions of section 402 of the Social Security Amendments of 1967 (Public Law 90-248) shall apply with respect to this part and part C in the same manner it applies with respect to parts A and B, except that any reference with respect to a Trust Fund in relation to an experiment or demonstration project relating to prescription drug coverage under this part shall be deemed a reference to the Medicare Prescription Drug Account within the Federal Supplementary Medical Insurance Trust Fund.

(c) Coverage gap rebate for 2010**(1) In general**

In the case of an individual described in subparagraphs (A) through (D) of section 1395w-114a(g)(1) of this title who as of the last day of a calendar quarter in 2010 has incurred costs for covered part D drugs so that the individual has exceeded the initial coverage limit under section 1395w-102(b)(3) of this title for 2010, the Secretary shall provide for payment from the Medicare Prescription Drug Account of \$250 to the individual by not later than the 15th day of the third month following the end of such quarter.

(2) Limitation

The Secretary shall provide only 1 payment under this subsection with respect to any individual.

(d) Treatment of certain complaints for purposes of quality or performance assessment

In conducting a quality or performance assessment of a PDP sponsor, the Secretary shall develop or utilize existing screening methods for reviewing and considering complaints that are received from enrollees in a prescription drug plan offered by such PDP sponsor and that are complaints regarding the lack of access by the individual to prescription drugs due to a drug management program for at-risk beneficiaries.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D-42, as added Pub. L. 108-173, title I, §101(a)(2), Dec. 8, 2003, 117 Stat. 2149; amended Pub. L. 111-152, title I, §1101(a)(1), Mar. 30, 2010, 124 Stat. 1036; Pub. L. 114-198, title VII, §704(d), July 22, 2016, 130 Stat. 750.)

Editorial Notes

REFERENCES IN TEXT

Section 402 of the Social Security Amendments of 1967, referred to in subsec. (b), is section 402 of Pub. L. 90-248, title IV, Jan. 2, 1968, 81 Stat. 930, which enacted section 1395b-1 of this title and amended section 1395j of this title.

AMENDMENTS

2016—Subsec. (d). Pub. L. 114-198 added subsec. (d).

2010—Subsec. (c). Pub. L. 111-152 added subsec. (c).

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2016 AMENDMENT

Amendment by Pub. L. 114-198 applicable to prescription drug plans (and MA-PD plans) for plan years beginning on or after Jan. 1, 2019, see section 704(g)(1) of Pub. L. 114-198, set out as a note under section 1395w-101 of this title.

§ 1395w-153. Condition for coverage of drugs under this part**(a) In general**

In order for coverage to be available under this part for covered part D drugs (as defined in section 1395w-102(e) of this title) of a manufacturer, the manufacturer must—

(1) participate in—

(A) for 2011 through 2024, the Medicare coverage gap discount program under section 1395w-114a of this title; and

(B) for 2025 and each subsequent year, the manufacturer discount program under section 1395w-114c of this title;

(2) have entered into and have in effect—

(A) for 2011 through 2024, an agreement described in subsection (b) of section 1395w-114a of this title with the Secretary; and

(B) for 2025 and each subsequent year, an agreement described in subsection (b) of section 1395w-114c of this title with the Secretary; and

(3) have entered into and have in effect, under terms and conditions specified by the Secretary, a contract with a third party that the Secretary has entered into a contract with under subsection (d)(3) of section 1395w-114a of this title.

(b) Effective date

Paragraphs (1)(A), (2)(A), and (3) of subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011, and before January 1, 2025, and paragraphs (1)(B) and (2)(B) of such subsection shall apply to covered part D drugs dispensed under this part on or after January 1, 2025.

(c) Authorizing coverage for drugs not covered under agreements**(1) In general**

Subject to paragraph (2), subsection (a) shall not apply to the dispensing of a covered part D drug if—

(A) the Secretary has made a determination that the availability of the drug is essential to the health of beneficiaries under this part; or

(B) the Secretary determines that in the period beginning on January 1, 2011, and¹ December 31, 2011, there were extenuating circumstances.

(2) Exception

Paragraph (1)(A) shall not apply to a covered part D drug of a manufacturer for any period described in section 5000D(c)(1) of the Internal

¹ So in original. Probably should be followed by “ending on”.