

**(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.

**§ 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 1395// 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, and<sup>1</sup> 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

Revenue Code of 1986 with respect to the manufacturer.

##### (d) Definition of manufacturer

In this section, the term “manufacturer” has the meaning given such term in section 1395w-114a(g)(5) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, §1860D-43, as added Pub. L. 111-148, title III, §3301(a), Mar. 23, 2010, 124 Stat. 461; amended Pub. L. 111-152, title I, §1101(b)(1), Mar. 30, 2010, 124 Stat. 1037; Pub. L. 117-169, title I, §§11001(b)(1)(G)(i), 11201(e)(7), Aug. 16, 2022, 136 Stat. 1853, 1892.)

#### Editorial Notes

##### REFERENCES IN TEXT

Section 5000D(c)(1) of the Internal Revenue Code of 1986, referred to in subsec. (c)(2), is classified to section 5000D(c)(1) of Title 26, Internal Revenue Code.

##### AMENDMENTS

2022—Subsec. (a)(1). Pub. L. 117-169, §11201(e)(7)(A)(i), added par. (1) and struck out former par. (1) which read as follows: “participate in the Medicare coverage gap discount program under section 1395w-114a of this title;”.

Subsec. (a)(2). Pub. L. 117-169, §11201(e)(7)(A)(ii), added par. (2) and struck out former par. (2) which read as follows: “have entered into and have in effect an agreement described in subsection (b) of such section with the Secretary; and”.

Subsec. (a)(3). Pub. L. 117-169, §11201(e)(7)(A)(iii), substituted “section 1395w-114a of this title” for “such section”.

Subsec. (b). Pub. L. 117-169, §11201(e)(7)(B), added subsec. (b) and struck out former subsec. (b). Prior to amendment, text read as follows: “Subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011.”

Subsec. (c). Pub. L. 117-169, §11001(b)(1)(G)(i), designated existing provisions as par. (1) and inserted heading, substituted “Subject to paragraph (2), subsection” for “Subsection” in introductory provisions, redesignated former pars. (1) and (2) as subpars. (A) and (B), respectively, of par. (1), and added par. (2).

2010—Subsec. (b). Pub. L. 111-152, §1101(b)(1)(A), substituted “January 1, 2011” for “July 1, 2010”.

Subsec. (c)(2). Pub. L. 111-152, §1101(b)(1)(B), substituted “January 1, 2011, and December 31, 2011,” for “July 1, 2010, and ending on December 31, 2010,”.

#### § 1395w-154. Improved Medicare prescription drug plan and MA-PD plan complaint system

##### (a) In general

The Secretary shall develop and maintain a complaint system, that is widely known and easy to use, to collect and maintain information on MA-PD plan and prescription drug plan complaints that are received (including by telephone, letter, e-mail, or any other means) by the Secretary (including by a regional office of the Department of Health and Human Services, the Medicare Beneficiary Ombudsman, a subcontractor, a carrier, a fiscal intermediary, and a Medicare administrative contractor under section 1395kk-1 of this title) through the date on which the complaint is resolved. The system shall be able to report and initiate appropriate interventions and monitoring based on substantial complaints and to guide quality improvement.

##### (b) Model electronic complaint form

The Secretary shall develop a model electronic complaint form to be used for reporting

<sup>1</sup> So in original. Probably should be followed by “ending on”.