

§ 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”.