

(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.)

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.

§ 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 de-

velop 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.)

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 1395f of this title.

AMENDMENTS

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

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

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 the Medicare coverage gap discount program under section 1395w-114a of this title;

(2) have entered into and have in effect an agreement described in subsection (b) of such section 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 such section.

(b) Effective date

Subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011.

(c) Authorizing coverage for drugs not covered under agreements

Subsection (a) shall not apply to the dispensing of a covered part D drug if—

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

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

(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.

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