§ 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*ll* 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[1] 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''.

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 plan complaints under the system. Such form shall be prominently displayed on the front page of the Medicare.gov Internet website and on the Internet website of the Medicare Beneficiary Ombudsman.

(c) Annual reports by the Secretary

The Secretary shall submit to Congress annual reports on the system. Such reports shall include an analysis of the number and types of complaints reported in the system, geographic variations in such complaints, the timeliness of agency or plan responses to such complaints, and the resolution of such complaints.

(d) Definitions

In this section:

(1) MA–PD plan

The term ''MA–PD plan'' has the meaning given such term in section 1395w–151(a)(9) of this title.

(2) Prescription drug plan

The term ''prescription drug plan'' has the meaning given such term in section 1395w–151(a)(14) of this title.

(3) Secretary

The term ''Secretary'' means the Secretary of Health and Human Services.

(4) System

The term ''system'' means the plan complaint system developed and maintained under subsection (a).

(Pub. L. 111–148, title III, § 3311, Mar. 23, 2010, 124 Stat. 475.)

Editorial Notes

CODIFICATION

Section was enacted as part of the Patient Protection and Affordable Care Act, and not as part of the Social Security Act which comprises this chapter.

PART E—MISCELLANEOUS PROVISIONS

Editorial Notes

CODIFICATION

Pub. L. 108–173, title I, § 101(a)(1), Dec. 8, 2003, 117 Stat. 2071, redesignated part D of this subchapter as part E.

Pub. L. 105–33, title IV, § 4001, Aug. 5, 1997, 111 Stat. 275, redesignated part C of this subchapter as part D.

§ 1395x. Definitions

For purposes of this subchapter—

(a) Spell of illness

The term ''spell of illness'' with respect to any individual means a period of consecutive days—

(1) beginning with the first day (not included in a previous spell of illness) (A) on which such individual is furnished inpatient hospital services, inpatient critical access hospital services or extended care services, and (B) which occurs in a month for which he is entitled to benefits under part A, and

(2) ending with the close of the first period of 60 consecutive days thereafter on each of which he is neither an inpatient of a hospital or critical access hospital nor an inpatient of a facility described in section 1395i–3(a)(1) of this title or subsection (y)(1).