

(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”.

(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.)

AMENDMENTS

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.)

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

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).

(b) Inpatient hospital services

The term “inpatient hospital services” means the following items and services furnished to an inpatient of a hospital and (except as provided in paragraph (3)) by the hospital—

(1) bed and board;

(2) such nursing services and other related services, such use of hospital facilities, and such medical social services as are ordinarily furnished by the hospital for the care and treatment of inpatients, and such drugs, biologicals, supplies, appliances, and equipment, for use in the hospital, as are ordinarily furnished by such hospital for the care and treatment of inpatients; and

(3) such other diagnostic or therapeutic items or services, furnished by the hospital or by others under arrangements with them made by the hospital, as are ordinarily furnished to inpatients either by such hospital or by others under such arrangements;

excluding, however—

(4) medical or surgical services provided by a physician, resident, or intern, services described by subsection (s)(2)(K), certified nurse-midwife services, qualified psychologist services, and services of a certified registered nurse anesthetist; and

(5) the services of a private-duty nurse or other private-duty attendant.

Paragraph (4) shall not apply to services provided in a hospital by—

(6) an intern or a resident-in-training under a teaching program approved by the Council on Medical Education of the American Medical Association or, in the case of an osteopathic hospital, approved by the Committee on Hospitals of the Bureau of Professional