

“(A) section 1871(a)(3) of the Social Security Act (42 U.S.C. 1395hh(a)(3)), as added by section 902(a)(1), shall not apply;

“(B) chapter 35 of title 44, United States Code, shall not apply; and

“(C) sections 553(d) and 801(a)(3)(A) of title 5, United States Code, shall not apply.

“(2) Section 1857(c)(5) of the Social Security Act (42 U.S.C. 1395w-27(c)(5)) shall apply with respect to section 1860D-31 of such Act, as added by section 101(a), in the same manner as it applies to part C of title XVIII of such Act [42 U.S.C. 1395w-21 et seq.].

“(3) The administration of such program shall be made without regard to chapter 35 of title 44, United States Code.

“(4)(A) There shall be no judicial review of a determination not to endorse, or enter into a contract, with a prescription drug card sponsor under section 1860D-31 of the Social Security Act.

“(B) In the case of any order issued to enjoin any provision of section 1860D-31 of the Social Security Act (or of [sic] any provision of this section [amending sections 1395r, 1395t, and 1396r-8 of this title and sections 6103 and 7213 of Title 26, Internal Revenue Code]), such order shall not affect any other provision of such section (or of this section) and all such provisions shall be treated as severable.”

SUBPART 5—DEFINITIONS AND MISCELLANEOUS PROVISIONS

**§ 1395w-151. Definitions; treatment of references to provisions in part C**

**(a) Definitions**

For purposes of this part:

**(1) Basic prescription drug coverage**

The term “basic prescription drug coverage” is defined in section 1395w-102(a)(3) of this title.

**(2) Covered part D drug**

The term “covered part D drug” is defined in section 1395w-102(e) of this title.

**(3) Creditable prescription drug coverage**

The term “creditable prescription drug coverage” has the meaning given such term in section 1395w-113(b)(4) of this title.

**(4) Part D eligible individual**

The term “part D eligible individual” has the meaning given such term in section 1395w-101(a)(3)(A) of this title.<sup>1</sup>

**(5) Fallback prescription drug plan**

The term “fallback prescription drug plan” has the meaning given such term in section 1395w-111(g)(4) of this title.

**(6) Initial coverage limit**

The term “initial coverage limit” means such limit as established under section 1395w-102(b)(3) of this title, or, in the case of coverage that is not standard prescription drug coverage, the comparable limit (if any) established under the coverage.

**(7) Insurance risk**

The term “insurance risk” means, with respect to a participating pharmacy, risk of the type commonly assumed only by insurers licensed by a State and does not include payment variations designed to reflect perform-

ance-based measures of activities within the control of the pharmacy, such as formulary compliance and generic drug substitution.

**(8) MA plan**

The term “MA plan” has the meaning given such term in section 1395w-101(a)(3)(B) of this title.<sup>1</sup>

**(9) MA-PD plan**

The term “MA-PD plan” has the meaning given such term in section 1395w-101(a)(3)(C) of this title.<sup>1</sup>

**(10) Medicare Prescription Drug Account**

The term “Medicare Prescription Drug Account” means the Account created under section 1395w-116(a) of this title.

**(11) PDP approved bid**

The term “PDP approved bid” has the meaning given such term in section 1395w-113(a)(6) of this title.

**(12) PDP region**

The term “PDP region” means such a region as provided under section 1395w-111(a)(2) of this title.

**(13) PDP sponsor**

The term “PDP sponsor” means a non-governmental entity that is certified under this part as meeting the requirements and standards of this part for such a sponsor.

**(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;

<sup>1</sup> See References in Text note below.

(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, and<sup>1</sup> 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.

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