

which the drug has been approved by the Food and Drug Administration.”

Pub. L. 109-91, § 103(a)(1), inserted before period at end “, as such sections were in effect on December 8, 2003”.

#### EFFECTIVE DATE OF 2010 AMENDMENT

Pub. L. 111-148, title III, § 3301(c)(2), Mar. 23, 2010, 124 Stat. 468, provided that: “The amendments made by this subsection [amending this section] shall apply to costs incurred on or after July 1, 2010.”

Pub. L. 111-148, title III, § 3314(b), Mar. 23, 2010, 124 Stat. 479, provided that: “The amendments made by subsection (a) [amending this section] shall apply to costs incurred on or after January 1, 2011.”

#### EFFECTIVE DATE OF 2008 AMENDMENT

Pub. L. 110-275, title I, § 175(b), July 15, 2008, 122 Stat. 2581, provided that: “The amendments made by subsection (a) [amending this section] shall apply to prescriptions dispensed on or after January 1, 2013.”

Pub. L. 110-275, title I, § 182(a)(2), July 15, 2008, 122 Stat. 2583, provided that: “The amendments made by this subsection [amending this section] shall apply to plan years beginning on or after January 1, 2009.”

#### EFFECTIVE DATE OF 2005 AMENDMENT

Pub. L. 109-91, title I, § 103(c), Oct. 20, 2005, 119 Stat. 2092, provided that: “The amendment made by subsection (a)(1) [amending this section] shall take effect as if included in the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) and the amendment made by subsection (a)(2) [amending this section] shall apply to coverage for drugs dispensed on or after January 1, 2007.”

#### CONSTRUCTION OF 2010 AMENDMENT

Pub. L. 111-152, title I, § 1101(a)(2), Mar. 30, 2010, 124 Stat. 1037, provided that: “Section 3315 of the Patient Protection and Affordable Care Act [section 3315 of Pub. L. 111-148, amending this section] (including the amendments made by such section) is repealed, and any provision of law amended or repealed by such sections [sic] is hereby restored or revived as if such section had not been enacted into law.”

#### CONSTRUCTION

Pub. L. 109-91, title I, § 103(b), Oct. 20, 2005, 119 Stat. 2092, provided that: “Nothing in this section [amending this section and enacting provisions set out as a note under this section] shall be construed as preventing a prescription drug plan or an MA-PD plan from providing coverage of drugs for the treatment of sexual or erectile dysfunction as supplemental prescription drug coverage under section 1860D-2(a)(2)(A)(ii) of the Social Security Act (42 U.S.C. 1395w-102(a)(2)(A)(ii)).”

#### PAYMENT FOR ADMINISTRATION OF PART D VACCINES IN 2007

Pub. L. 109-432, div. B, title II, § 202(a), Dec. 20, 2006, 120 Stat. 2986, provided that: “Notwithstanding any other provision of law, in the case of a vaccine that is a covered part D drug under section 1860D-2(e) of the Social Security Act (42 U.S.C. 1395w-102(e)) and that is administered during 2007, the administration of such vaccine shall be paid under part B of title XVIII of such Act [42 U.S.C. 1395j et seq.] as if it were the administration of a vaccine described in section 1861(s)(10)(B) of such Act (42 U.S.C. 1395w(s)(10)(B)) [probably should be 1395x(s)(10)(B)].”

### § 1395w-103. Access to a choice of qualified prescription drug coverage

#### (a) Assuring access to a choice of coverage

##### (1) Choice of at least two plans in each area

The Secretary shall ensure that each part D eligible individual has available, consistent

with paragraph (2), a choice of enrollment in at least 2 qualifying plans (as defined in paragraph (3)) in the area in which the individual resides, at least one of which is a prescription drug plan. In any such case in which such plans are not available, the part D eligible individual shall be given the opportunity to enroll in a fallback prescription drug plan.

#### (2) Requirement for different plan sponsors

The requirement in paragraph (1) is not satisfied with respect to an area if only one entity offers all the qualifying plans in the area.

#### (3) Qualifying plan defined

For purposes of this section, the term “qualifying plan” means—

(A) a prescription drug plan; or

(B) an MA-PD plan described in section 1395w-21(a)(2)(A)(i) of this title that provides—

(i) basic prescription drug coverage; or

(ii) qualified prescription drug coverage that provides supplemental prescription drug coverage so long as there is no MA monthly supplemental beneficiary premium applied under the plan, due to the application of a credit against such premium of a rebate under section 1395w-24(b)(1)(C) of this title.

#### (b) Flexibility in risk assumed and application of fallback plan

In order to ensure access pursuant to subsection (a) of this section in an area—

(1) the Secretary may approve limited risk plans under section 1395w-111(f) of this title for the area; and

(2) only if such access is still not provided in the area after applying paragraph (1), the Secretary shall provide for the offering of a fallback prescription drug plan for that area under section 1395w-111(g) of this title.

(Aug. 14, 1935, ch. 531, title XVIII, § 1860D-3, as added Pub. L. 108-173, title I, § 101(a)(2), Dec. 8, 2003, 117 Stat. 2081.)

### § 1395w-104. Beneficiary protections for qualified prescription drug coverage

#### (a) Dissemination of information

##### (1) General information

##### (A) Application of MA information

A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1395w-22(c)(1) of this title relating to such plan, insofar as the Secretary determines appropriate with respect to benefits provided under this part, and including the information described in subparagraph (B).

##### (B) Drug specific information

The information described in this subparagraph is information concerning the following:

(i) Access to specific covered part D drugs, including access through pharmacy networks.