

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 2022 AMENDMENT

Pub. L. 117-169, title I, §11401(d), Aug. 16, 2022, 136 Stat. 1898, provided that: “Nothing in this section [amending this section and sections 1395w-114 and 1395w-115 of this title and enacting provisions set out as a note below] shall be construed as limiting coverage under part D of title XVIII of the Social Security Act [42 U.S.C. 1395w-101 et seq.] for vaccines that are not recommended by the Advisory Committee on Immunization Practices.”

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 L. 111-148, amending this section] (including the amendments made by such section) is repealed, and any provision of law amended or repealed by such sections [sic] is hereby restored or revived as if such section had not been enacted into law.”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)(i) of the Social Security Act (42 U.S.C. 1395w-102(a)(2)(A)(i)).”

IMPLEMENTATION OF PUB. L. 117-169 FOR CERTAIN YEARS

Pub. L. 117-169, title I, §11201(f), Aug. 16, 2022, 136 Stat. 1892, provided that: “The Secretary shall implement this section [enacting sections 1395w-114c and 1395w-114d of this title and amending this section and sections 1395w-24, 1395w-104, 1395w-111, 1395w-113, 1395w-114, 1395w-114a, 1395w-115, 1395w-116, 1395w-131, 1395w-132, 1395w-151, 1395w-153, and 1396r-8 of this title], including the amendments made by this section, for 2024, 2025, and 2026 by program instruction or other forms of program guidance.”

Pub. L. 117-169, title I, §11202(c), Aug. 16, 2022, 136 Stat. 1895, provided that: “The Secretary shall implement this section [amending this section], including the amendments made by this section, for 2025 by program instruction or other forms of program guidance.”

Pub. L. 117-169, title I, §11401(e), Aug. 16, 2022, 136 Stat. 1898, provided that: “The Secretary shall implement this section [amending this section and sections 1395w-114 and 1395w-115 of this title and enacting provisions set out as a note above], including the amendments made by this section, for 2023, 2024, and 2025, by program instruction or other forms of program guidance.”

Pub. L. 117-169, title I, §11406(d), Aug. 16, 2022, 136 Stat. 1904, provided that: “The Secretary shall implement this section [amending this section and sections 1395w-114 and 1395w-115 of this title] for plan years 2023, 2024, and 2025 by program instruction or other forms of program guidance.”

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) 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, subject to subparagraph (C), 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.

(ii) How any formulary (including any tiered formulary structure) used by the sponsor functions, including a description of how a part D eligible individual may obtain information on the formulary consistent with paragraph (3).

(iii) Beneficiary cost-sharing requirements and how a part D eligible individual may obtain information on such requirements, including tiered or other copayment level applicable to each drug (or class of drugs), consistent with paragraph (3).

(iv) The medication therapy management program required under subsection (c).

(v) The drug management program for at-risk beneficiaries under subsection (c)(5).

(vi) For plan year 2021 and each subsequent plan year, subject to subparagraph (C), with respect to the treatment of pain—

(I) the risks associated with prolonged opioid use; and

(II) coverage of nonpharmacological therapies, devices, and nonopioid medications—

(aa) in the case of an MA-PD plan under part C, under such plan; and

(bb) in the case of a prescription drug plan, under such plan and under parts A and B.

(C) Targeted provision of information

A PDP sponsor of a prescription drug plan may, in lieu of disclosing the information described in subparagraph (B)(vi) to each enrollee under the plan, disclose such information through mail or electronic communications to a subset of enrollees under the plan, such as enrollees who have been prescribed an opioid in the previous 2-year period.

(2) Disclosure upon request of general coverage, utilization, and grievance information

Upon request of a part D eligible individual who is eligible to enroll in a prescription drug plan, the PDP sponsor offering such plan shall provide information similar (as determined by the Secretary) to the information described in subparagraphs (A), (B), and (C) of section 1395w-22(c)(2) of this title to such individual.

(3) Provision of specific information

(A) Response to beneficiary questions

Each PDP sponsor offering a prescription drug plan shall have a mechanism for providing specific information on a timely basis to enrollees upon request. Such mechanism shall include access to information through the use of a toll-free telephone number and, upon request, the provision of such information in writing.

(B) Availability of information on changes in formulary through the Internet

A PDP sponsor offering a prescription drug plan shall make available on a timely basis through an Internet website information on specific changes in the formulary under the plan (including changes to tiered or preferred status of covered part D drugs).

(4) Claims information

A PDP sponsor offering a prescription drug plan must furnish to each enrollee in a form easily understandable to such enrollees—

(A) an explanation of benefits (in accordance with section 1395b-7(a) of this title or in a comparable manner); and

(B) when prescription drug benefits are provided under this part, a notice of the benefits in relation to—

(i) for a year preceding 2025, the initial coverage limit for the current year; and

(ii) the annual out-of-pocket threshold for the current year.

Notices under subparagraph (B) need not be provided more often than as specified by the Secretary and notices under subparagraph (B)(ii) shall take into account the application of section 1395w-102(b)(4)(C) of this title to the extent practicable, as specified by the Secretary.

(b) Access to covered part D drugs

(1) Assuring pharmacy access

(A) Participation of any willing pharmacy

A prescription drug plan shall permit the participation of any pharmacy that meets the terms and conditions under the plan.

(B) Discounts allowed for network pharmacies

For covered part D drugs dispensed through in-network pharmacies, a prescription drug plan may, notwithstanding subparagraph (A), reduce coinsurance or copayments for part D eligible individuals enrolled in the plan below the level otherwise required. In no case shall such a reduction result in an increase in payments made by the Secretary under section 1395w-115 of this title to a plan.