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42 U.S. Code § 1395w-102

Prescription drug benefits

(a) Requirements

(1) In general

For purposes of this part and part C, the term "qualified prescription drug coverage" means either of the following:

(A) Standard prescription drug coverage with access to negotiated prices

Standard prescription drug coverage (as defined in subsection (b)) and access to negotiated prices under subsection (d).

(B) Alternative prescription drug coverage with at least actuarially equivalent benefits and access to negotiated prices

Coverage of covered part D drugs which meets the alternative prescription drug coverage requirements of subsection (c) and access to negotiated prices under subsection (d), but only if the benefit design of such coverage is approved by the Secretary, as provided under subsection (c).

(2) Permitting supplemental prescription drug coverage

(A) In general

Subject to subparagraph (B), qualified prescription drug coverage may include supplemental prescription drug coverage consisting of either or both of the following:

(i) Certain reductions in cost-sharing

(I) In general

A reduction in the annual deductible, a reduction in the coinsurance percentage or, for a year preceding 2025, an increase in the initial coverage limit with respect to covered part D drugs, or any combination thereof, insofar as such a reduction or increase increases the actuarial value of benefits above the actuarial value of basic prescription drug coverage.

(II) Construction

Nothing in this paragraph shall be construed as affecting the application of subsection (c)(3).

(ii) Optional drugs

Coverage of any product that would be a covered part D drug but for the application of subsection (e)(2)(A).

(B) Requirement

A PDP sponsor may not offer a prescription drug plan that provides supplemental prescription drug coverage pursuant to subparagraph (A) in an area unless the sponsor also offers a prescription drug plan in the area that only provides basic prescription drug coverage.

(3) Basic prescription drug coverage

For purposes of this part and part C, the term "basic prescription drug coverage" means either of the following:

(A) Coverage that meets the requirements of paragraph (1)(A).

(B) Coverage that meets the requirements of paragraph (1)(B) but does not have any supplemental prescription drug coverage described in paragraph (2)(A).

(4) Application of secondary payor provisions

The provisions of section 1395w–22(a)(4) of this title shall apply under this part in the same manner as they apply under part C.

(5) Construction

Nothing in this subsection shall be construed as changing the computation of incurred costs under subsection (b)(4).

(b) Standard prescription drug coverage

For purposes of this part and part C, the term "standard prescription drug coverage" means coverage of covered part D drugs that meets the following requirements:

(1) Deductible

(A) In general

Subject to paragraphs (8) and (9), the coverage has an annual deductible—

(i) for 2006, that is equal to $250; or

(ii) for a subsequent year, that is equal to the amount specified under this paragraph for the previous year increased by the percentage specified in paragraph (6) for the year involved.

(B) Rounding

Any amount determined under subparagraph (A)(ii) that is not a multiple of $5 shall be rounded to the nearest multiple of $5.

(2) Benefit structure

(A) 25 percent coinsurance

Subject to subparagraphs (C), (D), and (E) and paragraphs (8) and (9), the coverage has coinsurance (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3) for a year preceding 2025 and for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2025 and each subsequent year) that is—

(i) equal to 25 percent; or

(ii) actuarially equivalent (using processes and methods established under section 1395w–111(c) of this title) to an average expected payment of 25 percent of such costs.

(B) Use of tiers

Nothing in this part shall be construed as preventing a PDP sponsor or an MA organization from applying tiered copayments under a plan, so long as such tiered copayments are consistent with subparagraphs (A)(ii), (C), and (D).

(C) Coverage for generic drugs in coverage gap

(i) In general

Except as provided in paragraphs (4), (8), and (9), for a year preceding 2025, the coverage for an applicable beneficiary (as defined in section 1395w–114a(g)(1) of this title) has coinsurance (for costs

above the initial coverage limit under paragraph (3) and below the out-of-pocket threshold) for covered part D drugs that are not applicable drugs under section 1395w–114a(g)(2) of this title that is—

(I) equal to the generic-gap coinsurance percentage (specified in clause (ii)) for the year; or

(II) actuarially equivalent (using processes and methods established under section 1395w–111(c) of this title) to an average expected payment of such percentage of such costs for covered part D drugs that are not applicable drugs under section 1395w–114a(g)(2) of this title.

(ii) Generic-gap coinsurance percentage

The generic-gap coinsurance percentage specified in this clause for—

(I) 2011 is 93 percent;

(II) 2012 and each succeeding year before 2020 is the generic-gap coinsurance percentage under this clause for the previous year decreased by 7 percentage points; and

(III) 2020 through 2024 is 25 percent.

(D) Coverage for applicable drugs in coverage gap

(i) In general

Except as provided in paragraphs (4), (8), and (9), for a year preceding 2025, the coverage for an applicable beneficiary (as defined in section 1395w–114a(g)(1) of this title) has coinsurance (for costs above the initial coverage limit under paragraph (3) and below the out-of-pocket threshold) for the negotiated price (as defined in section 1395w–114a(g)(6) of this title) of covered part D drugs that are applicable drugs under section 1395w–114a(g)(2) of this title that is—

(I) equal to the difference between—

(aa) the applicable gap percentage (specified in clause (ii) for the year); and

(bb) the discount percentage specified in section 1395w–114a(g)(4)(A) of this title for such applicable drugs (or, in the case of each of years 2019 through 2024, 50 percent); or

(II) actuarially equivalent (using processes and methods established under section 1395w–111(c) of this title) to an average expected payment of such percentage of such costs, for covered part D drugs that are applicable drugs under section 1395w–114a(g)(2) of this title.

(ii) Applicable gap percentage

The applicable gap percentage specified in this clause for—

(I) 2013 and 2014 is 97.5 percent;

(II) 2015 and 2016 is 95 percent;

(III) 2017 is 90 percent;

(IV) 2018 is 85 percent; and

(V) each of years 2019 through 2024 is 75 percent.

(E) Maximum monthly cap on cost-sharing payments

(i) In general

For plan years beginning on or after January 1, 2025, each PDP sponsor offering a prescription drug plan and each MA organization offering an MA–PD plan shall provide to any enrollee of such plan, including an enrollee who is a subsidy eligible individual (as defined in paragraph (3) of section 1395w–114(a) of this title), the option to elect with respect to a plan year to pay cost-sharing under the plan in monthly amounts that are capped in accordance with this subparagraph.

(ii) Determination of maximum monthly cap

For each month in the plan year for which an enrollee in a prescription drug plan or an MA–PD plan has made an election pursuant to clause (i), the PDP sponsor or MA organization shall determine a maximum monthly cap (as defined in clause (iv)) for such enrollee.

(iii) Beneficiary monthly payments

With respect to an enrollee who has made an election pursuant to clause (i), for each month described in clause (ii), the PDP sponsor or MA organization shall bill such enrollee an amount (not to exceed the maximum monthly cap) for the out-of-pocket costs of such enrollee in such month.

(iv) Maximum monthly cap defined

In this subparagraph, the term "maximum monthly cap" means, with respect to an enrollee—

(I) for the first month for which the enrollee has made an election pursuant to clause (i), an amount determined by calculating—

(aa) the annual out-of-pocket threshold specified in paragraph (4)(B) minus the incurred costs of the enrollee as described in paragraph (4)(C); divided by

(bb) the number of months remaining in the plan year; and

(II) for a subsequent month, an amount determined by calculating—

(aa) the sum of any remaining out-of-pocket costs owed by the enrollee from a previous month that have not yet been billed to the enrollee and any additional out-of-pocket costs incurred by the enrollee; divided by

(bb) the number of months remaining in the plan year.

(v) Additional requirements

The following requirements shall apply with respect to the option to make an election pursuant to clause (i) under this subparagraph:

(I) Secretarial responsibilities

The Secretary shall provide information to part D eligible individuals on the option to make such election through educational materials, including through the notices provided under section 1395b–2(a) of this title.

(II) Timing of election

An enrollee in a prescription drug plan or an MA–PD plan may make such an election—

(aa) prior to the beginning of the plan year; or

(bb) in any month during the plan year.

(III) PDP sponsor and MA organization responsibilities

Each PDP sponsor offering a prescription drug plan or MA organization offering an MA–PD plan—

(aa) may not limit the option for an enrollee to make such an election to certain covered part D drugs;

(bb) shall, prior to the plan year, notify prospective enrollees of the option to make such an election in promotional materials;

(cc) shall include information on such option in enrollee educational materials;

(dd) shall have in place a mechanism to notify a pharmacy during the plan year when an enrollee incurs out-of-pocket costs with respect to covered part D drugs that make it likely the enrollee may benefit from making such an election;

(ee) shall provide that a pharmacy, after receiving a notification described in item (dd) with respect to an enrollee, informs the enrollee of such notification;

(ff) shall ensure that such an election by an enrollee has no effect on the amount paid to pharmacies (or the timing of such payments) with respect to covered part D drugs dispensed to the enrollee; and

(gg) shall have in place a financial reconciliation process to correct inaccuracies in payments made by an enrollee under this subparagraph with respect to covered part D drugs during the plan year.

(IV) Failure to pay amount billed

If an enrollee fails to pay the amount billed for a month as required under this subparagraph—

(aa) the election of the enrollee pursuant to clause (i) shall be terminated and the enrollee shall pay the cost-sharing otherwise applicable for any covered part D drugs subsequently dispensed to the enrollee up to the annual out-of-pocket threshold specified in paragraph (4)(B); and

(bb) the PDP sponsor or MA organization may preclude the enrollee from making an election pursuant to clause (i) in a subsequent plan year.

(V) Clarification regarding past due amounts

Nothing in this subparagraph shall be construed as prohibiting a PDP sponsor or an MA organization from billing an enrollee for an amount owed under this subparagraph.

(VI) Treatment of unsettled balances

Any unsettled balances with respect to amounts owed under this subparagraph shall be treated as plan losses and the Secretary shall not be liable for any such balances outside of those assumed as losses estimated in plan bids.