

(1) Prior to an individual's initial enrollment period for Part D, as described under § 423.38(a);

(2) Prior to the effective date of enrollment in the prescription drug coverage and upon any change that affects whether the coverage is creditable prescription drug coverage;

(3) Prior to the commencement of the Annual Coordinated Election Period as defined in § 423.38(b); and

(4) Upon request by the individual.

(g) *When an individual is not adequately informed of coverage.* If an individual establishes to CMS that he or she was not adequately informed that his or her prescription drug coverage was not creditable prescription drug coverage, the individual may apply to CMS to have the coverage treated as creditable prescription drug coverage for purposes of applying the late penalty described in § 423.46.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20505, Apr. 15, 2008; 77 FR 22168, Apr. 12, 2012]

### Subpart C—Benefits and Beneficiary Protections

#### § 423.100 Definitions.

As used in this part, unless otherwise specified—

*Actual cost* means the negotiated price for a covered Part D drug when the drug is purchased at a network pharmacy, and the usual and customary price when a beneficiary purchases the drug at an out-of-network pharmacy consistent with § 423.124(a).

*Affected enrollee* means a Part D enrollee who is currently taking a covered Part D drug that is either being removed from a Part D plan's formulary, or whose preferred or tiered cost-sharing status is changing.

*Alternative prescription drug coverage* means coverage of Part D drugs, other than standard prescription drug coverage that meets the requirements of § 423.104(e). The term alternative prescription drug coverage must be either—

(1) *Basic alternative coverage* (alternative coverage that is actuarially equivalent to defined standard coverage, as determined through processes and methods established under § 423.265(d)(2)); or

(2) *Enhanced alternative coverage* (alternative coverage that meets the requirements of § 423.104(f)(1)).

*Applicable beneficiary* means an individual who, on the date of dispensing a covered Part D drug—

(1) Is enrolled in a prescription drug plan or an MA-PD plan;

(2) Is not enrolled in a qualified retiree prescription drug plan;

(3) Is not entitled to an income-related subsidy under section 1860D-14(a) of the Act;

(4) Has reached or exceeded the initial coverage limit under section 1860D-2(b)(3) of the Act during the year;

(5) Has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1860D-2(b)(4)(B) of the Act; and

(6) Has a claim that—

(i) Is within the coverage gap;

(ii) Straddles the initial coverage period and the coverage gap;

(iii) Straddles the coverage gap and the annual out-of-pocket threshold; or

(iv) Spans the coverage gap from the initial coverage period and exceeds the annual out-of-pocket threshold.

*Applicable drug* means a Part D drug that is—

(1)(i) Approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA); or

(ii) In the case of a biological product, licensed under section 351 of the Public Health Service Act (other than a product licensed under subsection (k) of such section 351); and

(2)(i) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in;

(ii) If the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in; or

(iii) Is provided to a particular applicable beneficiary through an exception

or appeal for that particular applicable beneficiary.

*Basic prescription drug coverage* means coverage of Part D drugs that is either standard prescription drug coverage or basic alternative coverage.

*Bioequivalent* has the meaning given such term in section 505(j)(8) of the Food, Drug, and Cosmetic Act.

*Contracted pharmacy network* means licensed pharmacies, including retail, mail-order, and institutional pharmacies under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to Part D enrollees.

*Coverage gap* means the period in prescription drug coverage that occurs between the initial coverage limit and the out-of-pocket threshold. For purposes of applying the initial coverage limit, Part D sponsors must apply their plan specific initial coverage limit under basic alternative, enhanced alternative or actuarially equivalent Part D benefit designs.

*Covered Part D drug* means a Part D drug that is included in a Part D plan's formulary, or treated as being included in a Part D plan's formulary as a result of a coverage determination or appeal under §§ 423.566, 423.580, and 423.600, 423.610, 423.620, and 423.630, and obtained at a network pharmacy or an out-of-network pharmacy in accordance with § 423.124.

*Daily cost-sharing rate* means, as applicable, the established—

(1) Monthly copayment under the enrollee's Part D plan, divided by 30 or 31 and rounded to the nearest lower dollar amount, if any, or to another amount, but in no event to an amount that would require the enrollee to pay more for a month's supply of the prescription than would otherwise be the case; or

(2) Coinsurance percentage under the enrollee's Part D plan.

*Dispensing fees* means costs that—

(1) Are incurred at the point of sale and pay for costs in excess of the ingredient cost of a covered Part D drug each time a covered Part D drug is dispensed;

(2) Include only pharmacy costs associated with ensuring that possession of the appropriate covered Part D drug is transferred to a Part D enrollee. Pharmacy

costs include, but are not limited to, any reasonable costs associated with a pharmacist's time in checking the computer for information about an individual's coverage, performing quality assurance activities consistent with § 423.153(c)(2), measurement or mixing of the covered Part D drug, filling the container, physically providing the completed prescription to the Part D enrollee, delivery, special packaging, and salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and acquiring and maintaining technology and equipment necessary to operate the pharmacy. Dispensing fees should take into consideration the number of dispensing events in a billing cycle, the incremental costs associated with the type of dispensing methodology, and with respect to Part D drugs dispensed in LTC facilities, the techniques to minimize the dispensing of unused drugs. Dispensing fees may also take into account costs associated with data collection on unused Part D drugs and restocking fees associated with return for credit and reuse in long-term care pharmacies, when return for credit and reuse is permitted under the State in law and is allowed under the contract between the Part D sponsor and the pharmacy.

(3) Do not include administrative costs incurred by the Part D plan in the operation of the Part D benefit, including systems costs for interfacing with pharmacies.

*Government-funded health program* means any program established, maintained, or funded, in whole or in part, by the Government of the United States, by the government of any State or political subdivision of a State, or by any agency or instrumentality of any of the foregoing, which uses public funds, in whole or in part, to provide to, or pay on behalf of, an individual the cost of Part D drugs, including any of the following:

(1) An approved State child health plan under title XXI of the Act providing benefits for child health assistance that meets the requirements of section 2103 of the Act;

(2) The Medicaid program under title XIX of the Act or a waiver under section 1115 of the Act;

(3) The veterans' health care program under Chapter 17 of title 38 of the United States Code;

(4) The Indian Health Service program under the Indian Health Care Improvement Act under Chapter 18 of title 25 of the United States Code; and

(5) Any other government-funded program whose principal activity is the direct provision of health care to persons.

*Group health plan*, for purposes of applying the definition of incurred costs in § 423.100, has the meaning given such term in 29 U.S.C. 1167(1), but specifically excludes a personal health savings vehicle, as used in this subpart.

*Incurred costs* means costs incurred by a Part D enrollee for—

(1)(i) Covered Part D drugs that are not paid for under the Part D plan as a result of application of any annual deductible or other cost-sharing rules for covered Part D drugs prior to the Part D enrollee satisfying the out-of-pocket threshold under § 423.104(d)(5)(iii), including any price differential for which the Part D enrollee is responsible under § 423.124(b); or

(ii) Nominal cost-sharing paid by or on behalf of an enrollee, which is associated with drugs that would otherwise be covered Part D drugs, as defined in § 423.100, but are instead paid for, with the exception of said nominal cost-sharing, by a patient assistance program providing assistance outside the Part D benefit, provided that documentation of such nominal cost-sharing has been submitted to the Part D plan consistent with the plan processes and instructions for the submission of such information; and

(2) That are paid for—

(i) By the Part D enrollee or on behalf of the Part D enrollee by another person, and the Part D enrollee (or person paying on behalf of the Part D enrollee) is not reimbursed through insurance or otherwise, a group health plan, or other third party payment arrangement, or the person paying on behalf of the Part D enrollee is not paying under insurance or otherwise, a group health plan, or third party payment arrangement;

(ii) Under State Pharmaceutical Assistance Program (as defined in § 423.464); by the Indian Health Service,

an Indian tribe or tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act) or under an AIDS Drug Assistance Program (as defined in part B of title XXVI of the Public Health Service); or by a manufacturer as payment for an applicable discount (as defined in § 423.2305) or under the Medicare Coverage Gap Discount Program (as defined in § 423.2305); or

(iii) Under § 423.782 of this part.

*Insurance* means a health plan that provides, or pays the cost of Part D drugs, including, but not limited to, any of the following:

(1) Health insurance coverage (as defined in 42 U.S.C. 300gg-91(b)(1));

(2) A Medicare Advantage plan (as described under section 1851(a)(2) of the Act); and

(3) A PACE organization (as defined under sections 1894(a)(3) and 1934(a)(13) of the Act)

but specifically excluding a personal health savings vehicle.

*I/T/U pharmacy* means a pharmacy operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization, all of which are defined in section 4 of the Indian Health Care Improvement Act, 25 U.S.C. 1603.

*Long-term care facility* means a skilled nursing facility as defined in section 1819(a) of the Act, or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act.

*Long-term care pharmacy* means a pharmacy owned by or under contract with a long-term care facility to provide prescription drugs to the facility's residents.

*Long-term care network pharmacy* means a long-term care pharmacy that is a network pharmacy.

*Negotiated prices* means prices for covered Part D drugs that—

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as the amount such network entity will receive, in total, for a particular drug;

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(2) Are reduced by those discounts, direct or indirect subsidies, rebates, other price concessions, and direct or indirect remuneration that the Part D sponsor has elected to pass through to Part D enrollees at the point of sale; and

(3) Includes any dispensing fees.

*Network pharmacy* means a licensed pharmacy that is under contract with a Part D sponsor to provide covered Part D drugs at negotiated prices to its Part D plan enrollees.

*Non-preferred pharmacy* means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at higher cost-sharing levels than apply at a preferred pharmacy.

*Or otherwise* means through a government-funded health program.

*Out-of-network pharmacy* means a licensed pharmacy that is not under contract with a Part D sponsor to provide negotiated prices to Part D plan enrollees.

*Part D drug* means—

(1) Unless excluded under paragraph (2) of this definition, any of the following if used for a medically accepted indication (as defined in section 1860D–2(e)(4) of the Act)—

(i) A drug that may be dispensed only upon a prescription and that is described in sections 1927(k)(2)(A)(i) through (iii) of the Act.

(ii) A biological product described in sections 1927(k)(2)(B)(i) through (iii) of the Act.

(iii) Insulin described in section 1927(k)(2)(C) of the Act.

(iv) Medical supplies associated with the injection of insulin, including syringes, needles, alcohol swabs, and gauze.

(v) A vaccine licensed under section 351 of the Public Health Service Act and for vaccine administration on or after January 1, 2008, its administration.

(vi) Supplies that are directly associated with delivering insulin into the body, such as an inhalation chamber used to deliver the insulin through inhalation.

(vii) A combination product approved and regulated by the FDA as a drug, vaccine, or biologic described in para-

graphs (1)(i), (ii), (iii), or (v) of this definition.

(2) Does not include any of the following:

(i) Drugs for which payment as so prescribed and dispensed or administered to an individual is available for that individual under Part A or Part B (even though a deductible may apply, or even though the individual is eligible for coverage under Part A or Part B but has declined to enroll in Part A or Part B).

(ii) Drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under Medicaid under sections 1927(d)(2) or (d)(3) of the Act, except for smoking cessation agents.

(iii) Medical foods, defined as a food that is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation, and that are not regulated as drugs under section 505 of the Federal Food, Drug, and Cosmetic Act.

*Person* means a natural person, corporation, mutual company, unincorporated association, partnership, joint venture, limited liability company, trust, estate, foundation, not-for-profit corporation, unincorporated organization, government or governmental subdivision or agency.

*Personal health savings vehicle* means a vehicle through which individuals can set aside their own funds to pay for health care expenses, including covered Part D drugs, on a tax-free basis including any of the following—

(1) A Health Savings Account (as defined under section 220 of the Internal Revenue Code);

(2) A Flexible Spending Account (as defined in section 106(c)(2) of the Internal Revenue Code) offered in conjunction with a cafeteria plan under section 125 of the Internal Revenue Code; and

(3) An Archer Medical Savings Account (as defined under section 223 of the Internal Revenue Code);

but specifically excluding a Health Reimbursement Arrangement (as described under Internal Revenue Ruling

2002-41 and Internal Revenue Notice 2002-45)

*Plan allowance* means the amount Part D plans that offer coverage other than defined standard coverage may use to determine their payment and Part D enrollees' cost-sharing for covered Part D drugs purchased at an out-of-network pharmacy or in a physician's office in accordance with the requirements of § 423.124(b).

*Preferred drug* means a covered Part D drug on a Part D plan's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug in the plan's formulary.

*Preferred pharmacy* means a network pharmacy that offers covered Part D drugs at negotiated prices to Part D enrollees at lower levels of cost-sharing than apply at a non-preferred pharmacy under its pharmacy network contract with a Part D plan.

*Qualified prescription drug coverage* means any standard prescription drug coverage or alternative prescription drug coverage

*Retail pharmacy* means any licensed pharmacy that is not a mail order pharmacy from which Part D enrollees could purchase a covered Part D drug without being required to receive medical services from a provider or institution affiliated with that pharmacy.

*Required prescription drug coverage* means coverage of Part D drugs under an MA-PD plan that consists of either—

(1) Basic prescription drug coverage; or

(2) Enhanced alternative coverage, provided there is no MA monthly supplemental beneficiary premium (as defined under section 1854(b)(2)(C) of the Act) applied under the plan due to the application of a credit against the premium of a rebate under § 422.266(b) of this chapter.

*Rural* means a five-digit ZIP code in which the population density is less than 1,000 individuals per square mile.

*Standard prescription drug coverage* means coverage of Part D drugs that meets the requirements of § 423.104(d). The term standard prescription drug coverage must be either—

(1) *Defined standard coverage* (standard prescription drug coverage that

provides for cost-sharing as described in § 423.104(d)(2)(i)(A) and (d)(5)(i)); or

(2) *Actuarially equivalent standard coverage* (standard prescription drug coverage that provides for cost-sharing as described in § 423.104(d)(2)(i)(B) or cost-sharing as described in § 423.104(d)(5)(ii), or both).

*Suburban* means a five-digit ZIP code in which the population density is between 1,000 and 3,000 individuals per square mile.

*Supplemental benefits* means benefits that meet the requirements of § 423.104(f)(1)(ii).

*Therapeutically equivalent* refers to drugs that are rated as therapeutic equivalents under the Food and Drug Administration's most recent publication of "Approved Drug Products with Therapeutic Equivalence Evaluations."

*Third party payment arrangement* means any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

*Urban* means a five-digit ZIP code in which the population density is greater than 3,000 individuals per square mile.

*Usual and customary (U&C) price* means the price that an out-of-network pharmacy or a physician's office charges a customer who does not have any form of prescription drug coverage for a covered Part D drug.

*Valid prescription* means a prescription that complies with all applicable State law requirements constituting a valid prescription.

[70 FR 4525, Jan. 28, 2005, as amended at 73 FR 20506, Apr. 15, 2008; 74 FR 1543, Jan. 12, 2009; 76 FR 21571, Apr. 15, 2011; 77 FR 22169, Apr. 12, 2012; 77 FR 32407, June 1, 2012; 79 FR 29962, May 23, 2014]

EFFECTIVE DATE NOTE: At 79 FR 29962, May 23, 2014, in § 423.100, the definition of "Negotiated prices" was revised, effective Jan. 1, 2016. For the convenience of the user, the revised text is set forth as follows:

#### § 423.100 Definitions

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*Negotiated prices* means prices for covered Part D drugs that meet all of the following:

(1) The Part D sponsor (or other intermediary contracting organization) and the network dispensing pharmacy or other network dispensing provider have negotiated as

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the amount such network entity will receive, in total, for a particular drug.

(2) Are inclusive of all price concessions from network pharmacies except those contingent price concessions that cannot reasonably be determined at the point-of-sale; and

(3) Include any dispensing fees; but

(4) Excludes additional contingent amounts, such as incentive fees, if these amounts increase prices and cannot reasonably be determined at the point-of-sale.

(5) Must not be rebated back to the Part D sponsor (or other intermediary contracting organization) in full or in part.

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§ 423.104 Requirements related to qualified prescription drug coverage.

(a) General. Subject to the conditions and limitations set forth in this subpart, a Part D sponsor must provide enrollees with coverage of the benefits described in paragraph (c) of this section. The benefits may be provided directly by the Part D sponsor or through arrangements with other entities. CMS reviews and approves these benefits consistent with § 423.272, and using written policy guidelines and requirements in this part and other CMS instructions.

(b) Availability of prescription drug plan. A PDP sponsor offering a prescription drug plan must offer the plan—

(1) To all Part D eligible beneficiaries residing in the plan’s service area; and

(2) At a uniform premium, with uniform benefits and level of cost-sharing throughout the plan’s service area.

(c) Types of benefits. The coverage provided by a Part D plan must be qualified prescription drug coverage.

(d) Standard prescription drug coverage. Standard prescription drug coverage includes access to negotiated prices as described under paragraph (g)(1) of this section, provides coverage of Part D drugs, and must meet the following requirements

(1) Deductible. An annual deductible equal to—

(i) For 2006. \$250; or

(ii) For years subsequent to 2006. The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in

paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of \$5.

(2) Cost-sharing under the initial coverage limit. (i) Subject to paragraph (d)(4) of this section, coinsurance for actual costs for covered Part D drugs covered under the Part D plan above the annual deductible specified in paragraph (d)(1) of this section, and up to the initial coverage limit under paragraph (d)(3) of this section, that is—

(A) Equal to 25 percent of actual cost; or

(B) Actuarially equivalent to an average expected coinsurance of no more than 25 percent of actual cost, as determined through processes and methods established under § 423.265(c) and (d).

(ii) Tiered copayments. A Part D plan providing actuarially equivalent standard coverage may apply tiered copayments, provided that any tiered copayments are consistent with paragraphs (d)(2)(i)(B) and (d)(4) of this section and are approved as described in § 423.272(b)(2).

(3) Initial coverage limit. Except as provided in paragraphs (d)(4) and (d)(5) of this section, the initial coverage limit is equal to—

(i) For 2006. \$2,250.

(ii) For years subsequent to 2006. The amount specified in this paragraph for the previous year, increased by the annual percentage increase specified in paragraph (d)(5)(iv) of this section, and rounded to the nearest multiple of \$10.

(4) Cost-sharing in the coverage gap for applicable beneficiaries. (i) Coinsurance in the coverage gap (as defined in § 423.100) for costs for covered Part D drugs that are not applicable drugs (as defined in § 423.100) under the Medicare coverage gap discount program that is—

(A) Equal to the generic gap coinsurance percentage described in paragraph (d)(4)(iii) of this section; or

(B) Actuarially equivalent to an average expected coinsurance for covered Part D drugs that are not applicable drugs under the Medicare coverage gap discount program, as determined through processes and methods established under § 423.265 (c) and (d).

(ii) Coinsurance in the coverage gap for the actual cost minus the dispensing fee and any vaccine administration fee for covered Part D drugs