10.2 - Definition of Terms

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Unless otherwise stated in this chapter, the following definitions apply:

Actual cost: 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 42 CFR 423.124(a).

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.

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

Catastrophic coverage: The Part D benefit phase above the annual out-of-pocket threshold described at 42 CFR 423.104(d)(5)(iii) (and in section 20.3.1).

Contracted pharmacy network: 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.*

Employer/Union- Only Group Waiver Plan: For the purpose of this section, Medicare-approved prescription drug plans that qualify for waivers or modifications to their plan offerings consistent with Pub. 100-16, Medicare Managed Care Manual, Chapter 9, Section 10 and Pub. 100-18, Medicare Prescription Drug Benefit Manual, Chapter 12, Section 10.

Generic drug: A drug for which an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 USC 355(j)) is approved.

Government-funded health program: 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 42 CFR 423.100, has the meaning given such term in 29 U.S.C. 1167(1), but specifically excludes a personal health savings vehicle.

Insurance: 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 (MA) 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). This definition specifically excludes a personal health savings vehicle.

I/T/U pharmacy: 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 (LTC) facility: 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: 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: A long-term care pharmacy that is a network pharmacy.

Multiple source drug: A drug defined in section 1927(k)(7)(A)(i) of the Social Security Act.

Network pharmacy: 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: 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.

Non-applicable drugs: Covered Part D drugs that are not applicable drugs as defined in this section. This includes generic drugs.

Or otherwise: Through a government-funded health program.

Out-of-network (OON) pharmacy: A licensed pharmacy that is not under contract with a Part D sponsor to provide negotiated prices to Part D plan enrollees.

Parent organization: An organization that holds at least the majority of the voting stock in a legal entity that holds a Medicare Prescription Drug Plan (PDP) sponsor contract or a Medicare Advantage (MA) Organization contract.

Part D drug: A drug described in chapter 6, section 10, of this manual.

Person: 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: 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). This definition specifically excludes a Health Reimbursement Arrangement (as described under Internal Revenue Ruling 2002-41 and Internal Revenue Notice 2002-45).

Plan allowance: 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 42 CFR 423.124(b).

Plan Benefit Package (PBP): A set of benefits for a defined MA or PDP service area. The PBP is submitted by PDP sponsors and MA organizations to CMS for benefit analysis, marketing and beneficiary communication purposes.

Preferred drug: A covered Part D drug on a Part D sponsor's formulary for which beneficiary cost-sharing is lower than for a non-preferred drug on the sponsor's formulary.

Preferred multiple source drug: A drug that is both a preferred drug and a multiple source drug, meaning that one version of that drug is placed on the sponsor's formulary with lower cost sharing than for a non-preferred drug.

Preferred pharmacy: 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 sponsor.

Retail pharmacy: 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.

Rural: A five-digit ZIP Code in which the population density is less than 1,000 individuals per square mile.

Suburban: A five-digit ZIP Code in which the population density is between 1,000 and 3,000 individuals per square mile.

Supplemental drugs: Drugs that would be covered Part D drugs but for the fact that they are specifically excluded as Part D drugs under 42 CFR 423.100, and as described in section 20.1 of chapter 6. However, because such drugs must have otherwise qualified as covered Part D drugs

(as defined in section 10.2 of chapter 6) in order to be covered as a supplemental benefit, and because only prescription drugs are included in the definition of a Part D drug, over-the-counter drugs cannot be supplemental drugs, as discussed in section 10.10 of chapter 6. Supplemental drugs may be included as a supplemental benefit under enhanced alternative coverage, as described in section 20.4.2 of this chapter.

Therapeutically equivalent: 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: Any contractual or similar arrangement under which a person has a legal obligation to pay for covered Part D drugs.

Urban: 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: 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.