

IRA Glossary

Drug Price Negotiation Definitions

BIOSIMILAR BIOLOGICAL PRODUCT: a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another licensed biological product. 42 U.S. Code § Section 1320f(c) (incorporating 42 U.S. Code § 1847A(c)(6) by reference).

GROSS COVERED PRESCRIPTION DRUG COSTS (GCPDC): with respect to a part D eligible individual enrolled in a prescription drug plan or MA-PD plan during a coverage year, the costs incurred under the plan, including costs directly related to the dispensing of covered part D drugs and costs relating to the deductible, but excluding administrative costs. The determination of the costs is independent of whether they are paid by the individual or under the plan, regardless of whether the coverage under the plan exceeds basic prescription drug coverage. 42 U.S. Code § 1320f(c) (incorporating 42 U.S.C. 1395w-115(b)(3) by reference).

INITIAL PRICE APPLICABILITY YEAR (IPAY): a year, beginning with 2026, during which the Maximum Fair Price first applies. 42 U.S. Code § 1320f(b).

MANUFACTURER: any entity engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or engaged in packaging, repackaging, labeling, relabeling, or distribution of prescription drug products. This term excludes a wholesale distributor or a retail pharmacy. 42 U.S. Code § Section 1320f(c) (incorporating 42 U.S. Code § Section 1927(k)(5) by reference).

MAXIMUM FAIR PRICE (MFP): the price negotiated under the Medicare Price Negotiation Program. 42 U.S. Code § 1320f(c).

MAXIMUM FAIR PRICE ELIGIBLE INDIVIDUAL: (a) for a selected drug dispensed at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a prescription drug plan under part D of title XVIII or an MA-PD plan and where coverage is provided under such plan for the selected drug; and (b) for a selected drug furnished or administered by a hospital, physician, or other provider of services, an individual who is enrolled under part B of title XVIII or an MA plan under part C, if payment may be made under part B for the selected drug. 42 U.S. Code § 1320f(c).

NEGOTIATION PERIOD: with respect to an initial price applicability year with respect to a selected drug, the period beginning on the sooner of the date on which the manufacturer

and the Secretary enter into a negotiation agreement or February 28 following the selected drug publication date for the selected drug; and ending on November 1 of the year that begins 2 years prior to the initial price applicability year (e.g. February 28 through November 1, 2026 for IPAY 2028). 42 U.S. Code § 1320f(b).

PRICE APPLICABILITY PERIOD: the period beginning with the first initial price applicability year that a qualifying single source drug is a selected drug and ending with the last year during which the drug is a selected drug. 42 U.S. Code § 1320f(b).

REFERENCE PRODUCT: the single biological product against which a biological product is evaluated in an application for licensure of biological products as biosimilar or interchangeable is submitted. 42 U.S. Code § 1320f(c) (incorporating section 42 USC 262(i) by reference).

SELECTED DRUG PUBLICATION DATE: February 1 of the year that begins 2 years prior to each initial price applicability year. 42 U.S. Code § 1320f(b).

TOTAL EXPENDITURES: the total gross covered prescription drug costs under part D. The term ‘total expenditures’ excludes, for expenditures under part B, expenditures for a drug or biological product that are bundled or packaged into the payment for another service. 42 U.S. Code § 1320f(c).

UNIT (of a drug or biological product): the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished. 42 U.S. Code § 1320f(c).

Medicare Prescription Payment Plan Definitions

APPLICABLE BENEFICIARY: an individual who, on the date of dispensing a covered part D drug— (A) is enrolled in a prescription drug plan or an MA–PD plan; (B) is not enrolled in a qualified retiree prescription drug plan; (C) is not entitled to an income-related subsidy under section 1395w–114(a) of this title ; and (D) who— (i) has reached or exceeded the initial coverage limit under section 1395w–102(b)(3) of this title during the year; and (ii) has not incurred costs for covered part D drugs in the year equal to the annual out-of-pocket threshold specified in section 1395w–102(b)(4)(B) of this title. 42 U.S. Code § 1395w–114a(g)(1).

APPLICABLE DRUG: A covered part D drug or biological product that is not excluded under statutory provisions and is subject to the rebate requirements based on price increases that exceed inflation. 42 U.S. Code § 1395w–114c(g)(2).

COVERAGE YEAR: The 12-month period beginning on January 1 and ending on December 31. 42 U.S. Code § 1395w-114a(a)(3).

INSTALLMENT PAYMENT AMOUNT: The monthly amount an applicable beneficiary is required to pay under the Medicare Prescription Payment Plan, determined by dividing the individual's out-of-pocket costs for covered Part D drugs for the coverage year by 12, or by the number of months remaining in the year if elected after January. 42 U.S. Code § 1395w-114a(b)(2).

MEDICARE PRESCRIPTION PAYMENT PLAN: The program established under section 1860D-2 of the Social Security Act that permits applicable beneficiaries to elect to pay out-of-pocket costs for covered Part D drugs in monthly installments rather than at the point of sale. 42 U.S. Code § 1395w-114a(a)(1).

OUT-OF-POCKET MAXIMUM: The amounts that would otherwise be payable by an applicable beneficiary for covered part D drugs under the plan, including deductible, coinsurance, and copayment amounts, but excluding monthly plan premiums. 42 U.S. Code § 1395w-114a(a)(5).

INITIAL COVERAGE LIMIT: such limit as established under section 1395w-102(b)(3) of this title for a year before 2025, or, in the case of coverage that is not standard prescription drug coverage, the comparable limit (if any) established under the coverage for such year. 42 U.S. Code § 1395w-151(a)(6).

Inflation Rebates Definitions

APPLICABLE PERIOD: The 12-month period beginning October 1 and ending September 30. 42 U.S. Code § 1395w-114b(g)(7).

APPLICABLE PERIOD CPI-U: The consumer price index for all urban consumers (United States city average) for the applicable period. 42 U.S. Code § 1395w-114b(g)(5).

AVERAGE MANUFACTURER PRICE (AMP): With respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies that purchase drugs directly from the manufacturer. 42 U.S. Code § 1396r-8(k)(1).

BENCHMARK PERIOD CPI-U: the consumer price index for all urban consumers (United States city average) for January 2021. 42 U.S. Code § 1395w-114b(g)(4).

COVERED PART D DRUG: 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. 42 CFR § 428.20.

PART D REBATABLE DRUG: a drug or biological that is a covered part D drug, excluding a drug or biological if the average annual total cost per individual is less than an amount by the Secretary, subject to increases in the consumer price index for all urban consumers (United States city average). 42 U.S. Code § 1395w-114b(g)(1).

PAYMENT AMOUNT BENCHMARK PERIOD: the period beginning January 1, 2021, and ending in the month immediately prior to October 1, 2021. 42 U.S. Code § 1395w-114b(g)(3).