

513.2 Definitions.

For the purpose of this part the following definitions are applicable unless otherwise stated:

Add-on percentage means the percentage above 100 percent.

Alternative add-on payment means the payment described in § 513.220.

Applicable ASP means the payment amount determined in accordance with section 1847A of the Act for a quarter minus the applicable add-on percentage.

ASP stands for average sales price.

ASP calendar quarter means the period that is two calendar quarters prior to the calendar quarter to which the MFN Drug Payment Amount will apply.

CCN stands for CMS Certification Number.

Country-level price means the unadjusted country-level price for an MFN Model drug at the HCPCS code level as calculated in accordance with § 513.210(b)(2).

CPI-U stands for Consumer Price Index for All Urban Consumers based on all items in U.S. city average and not seasonally adjusted.

Days means calendar days.

DME stands for Durable Medical Equipment.

FDA stands for Food and Drug Administration.

GDP stands for gross domestic product.

GDP-adjusted country-level price means the country-level price adjusted by the GDP adjuster as calculated in accordance with § 513.210(b)(4).

GDP adjuster means the country-specific adjuster as calculated in accordance with § 513.210(b)(3).

HCPCS stands for Healthcare Common Procedure Coding System.

HCPCS code level means the specified drug and amount described in the HCPCS code long descriptor.

MAC stands for Medicare Administrative Contractor.

Manufacturer's average sales price has the same meaning as under 42 CFR Subpart J.

MFN stands for most favored nation.

MFN beneficiary means an individual who is furnished an MFN Model drug by an MFN participant and who, on the date of service, is enrolled in Medicare Part B, has Medicare as his or her primary payer, and is not covered under Medicare Advantage or any other group health plan, including a United Mine Workers of America health plan.

MFN Drug Payment Amount means the portion of the total allowed payment amount for an MFN Model drug determined in accordance with § 513.210.

MFN Model drug means a separately payable Medicare Part B drug or biological described by a HCPCS code included on the MFN Model Drug HCPCS Codes List.

MFN Model Drug HCPCS Codes List means the list of drugs included in the MFN Model for a given calendar quarter of a performance year established under § 513.130.

MFN participant means a Medicare participating provider or supplier, identified by its CCN or TIN, that is required to participate in the MFN Model in accordance with § 513.100(b).

MFN Model Payment means the total payment to an MFN participant for an MFN Model drug in accordance with subpart C of this part, inclusive of the MFN Drug Payment Amount and the Alternative Add-on Payment.

MFN Price means the lowest GDP-adjusted country-level price of the countries specified in § 513.140(b) for an MFN Model drug.

Model performance period means the 7-year period of time beginning on January 1, 2021, through December 31, 2027.

NOC stands for not otherwise classified.

OIG stands for the Department of Health and Human Services Office of Inspector General.

Outpatient prospective payment system (OPPS) means the payment system for designated hospital outpatient items and services and certain Medicare Part B services furnished to hospital inpatients when Part A payment cannot be made as defined by section 1833(t) of the Act.

Performance year means each 12-month period beginning on January 1 and ending on December 31 during the performance period for the MFN Model specified in § 513.1(c).

Provider means a “provider of services” as defined under section 1861(u) of the Act and codified at § 400.202 of this chapter.

Supplier means a supplier as defined in section 1861(d) of the Act and codified at § 400.202 of this chapter.

TIN stands for taxpayer identification number.

WAC means wholesale acquisition cost as defined at section 1847A(c)(6)(B) of the Act.

