

§ 414.800

42 CFR Ch. IV (10–1–24 Edition)

Drug	Percentage used to calculate 2004 payment limit
DOLASETRON MESYLATE	80
FILGRASTIM	81
HYLAN G-F 20	82
MYCOPHENOLATE MOFETIL	86
GRANISETRON HCL	80
ONDANSETRON	87
VINORELBINE TARTATE	81
SARGRAMOSTIM	80
TOPOTECAN	84
IPRATROPIUM BROMIDE	80
ALBUTEROL SULFATE	80
IMMUNE GLOBULIN	80
LEUCOVORIN CALCIUM	80
DOXORUBICIN HCL	80
DEXAMETHOSONE SODIUM PHOSPHATE ...	86
HEPARIN SODIUM LOCK-FLUSH	80
CROMOLYN SODIUM	80
ACETYLCYSTEINE	80

(5) The payment limits for imiglucerase and alglucerase are calculated using 94 percent of the average wholesale price determined as of April 1, 2003.

(6) Exception. The payment limit for a drug otherwise subject to paragraph (a)(1)(ii) or paragraph (a)(4) of this section may be calculated using the percentage of the average wholesale price as the Secretary deems appropriate based on data and information submitted by the drug manufacturer.

(i) The manufacturer must submit data after October 15, 2003 and before January 1, 2004.

(ii) The percentage only applies for drugs furnished on or after April 1, 2004.

(7) In the case of blood and blood products (other than blood clotting factors), the payment limits shall be determined in the same manner as such payment limit was determined on October 1, 2003.

(b) *Mandatory assignment.* Effective with services furnished on or after February 1, 2001, payment for any drug covered under Part B of Medicare may be made on an assignment-related basis only. All billers must accept the program allowed charge as payment in full and may not bill nor collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts, if applicable. Violations of this requirement may subject the supplier to sanctions, as provided by the statute (See § 402 of this chapter).

(c) *Mandatory reporting of anemia quality indicators.* The following provisions are effective January 1, 2008:

(1) Each request for payment for anti-anemia drugs furnished to treat anemia resulting from the treatment of cancer must report the beneficiary's most recent hemoglobin or hematocrit level;

(2) Each request for payment for use of erythropoiesis stimulating agents must report the beneficiary's most recent hemoglobin or hematocrit level.

[69 FR 1116, Jan. 7, 2004, as amended at 72 FR 66402, Nov. 27, 2007; 85 FR 71197, Nov. 6, 2020; 87 FR 70226, Nov. 18, 2022]

Subpart J—Submission of Manufacturer's Average Sales Price Data

SOURCE: 69 FR 17938, Apr. 6, 2004, unless otherwise noted.

§ 414.800 Purpose.

This subpart implements section 1847A of the Act by specifying the requirements for submission of a manufacturer's average sales price data for certain drugs and biologicals covered under Part B of Title XVIII of the Act that are paid under sections 1842(o)(1)(D), 1847A, and 1881(b)(13)(A)(ii) of the Act.

§ 414.802 Definitions.

As used in this subpart, unless the context indicates otherwise—

Bona fide service fees means fees paid by a manufacturer to an entity, that represent fair market value for a bona fide, itemized service actually performed on behalf of the manufacturer that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement, and that are not passed on in whole or in part to a client or customer of an entity, whether or not the entity takes title to the drug.

Drug means a drug or a biological, and for purposes of applying section 1847A(f) of the Act, includes an item, service, supply, or product that is payable under Medicare Part B as a drug or biological.

Manufacturer means any entity that is engaged in the following (This term

does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law):

(1) 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.

(2) The packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Unit means the product represented by the 11-digit National Drug Code, unless otherwise specified by CMS to account for situations where labeling indicates that the amount of drug product represented by a National Drug Code varies. The method of counting units excludes units of CAP drugs (as defined in §414.902 of this part) sold to an approved CAP vendor (as defined in §414.902 of this part) for use under the CAP (as defined in §414.902 of this part).

[69 FR 17938, Apr. 6, 2004, as amended at 71 FR 48143, Aug. 18, 2006; 71 FR 69787, Dec. 1, 2006; 74 FR 62012, Nov. 25, 2009; 76 FR 73473, Nov. 28, 2011; 86 FR 65669, Nov. 19, 2021]

§414.804 Basis of payment.

(a) *Calculation of manufacturer's average sales price.* (1) The manufacturer's average sales price for a quarter for a drug represented by a particular 11-digit National Drug Code must be calculated as the manufacturer's sales to all purchasers in the United States for that particular 11-digit National Drug Code (after excluding sales as specified in paragraph (a)(4) of this section and then deducting price concessions as specified in paragraphs (a)(2) and (a)(3) of this section) divided by the total number of units sold by the manufacturer in that quarter (after excluding units associated with sales as specified in paragraph (a)(4) of this section).

(2) *Price concessions.* (i) In calculating the manufacturer's average sales price, a manufacturer must deduct price concessions. Price concessions include the following types of transactions and items:

- (A) Volume discounts.
- (B) Prompt pay discounts.
- (C) Cash discounts.

(D) Free goods that are contingent on any purchase requirement.

(E) Chargebacks and rebates (other than rebates under the Medicaid program).

(ii) For the purposes of paragraph (a)(2)(i), bona fide services fees are not considered price concessions.

(3) To the extent that data on price concessions, as described in paragraph (a)(2) of this section, are available on a lagged basis, the manufacturer must estimate this amount in accordance with the methodology described in this paragraph.

(i)(A) For each National Drug Code with at least 12 months of sales (including products for which the manufacturer has redesignated the National Drug Code for the specific product and package size and has 12 months of sales across the prior and current National Drug Codes), after adjusting for exempted sales, the manufacturer calculates a percentage equal to the sum of the price concessions for the most recent 12-month period available associated with sales subject to the average sales price reporting requirement divided by the total in dollars for the sales subject to the average sales price reporting requirement for the same 12-month period.

(B) For each National Drug Code with less than 12 months of sales, the calculation described in paragraph (i)(A) of this section is performed for the time period equaling the total number of months of sales.

(ii) The manufacturer multiplies the applicable percentage described in paragraph (a)(3)(i)(A) or (a)(3)(i)(B) of this section by the total in dollars for the sales subject to the average sales price reporting requirement (after adjusting for exempted sales) for the quarter being submitted. (The manufacturer must carry a sufficient number of decimal places in the calculation of the price concessions percentage in order to round accurately the net total sales amount for the quarter to the nearest whole dollar.) The result of this multiplication is then subtracted from the total in dollars for the sales subject to the average sales price reporting requirement (after adjusting for exempted sales) for the quarter being submitted.

(iii) The manufacturer uses the result of the calculation described in paragraph (a)(3)(ii) of this section as the numerator and the number of units sold in the quarter (after adjusting for exempted sales) as the denominator to calculate the manufacturer's average sales price for the National Drug Code for the quarter being submitted.

(iv) *Example.* After adjusting for exempted sales, the total lagged price concessions (discounts, rebates, etc.) over the most recent 12-month period available associated with sales for National Drug Code 12345–6789–01 subject to the ASP reporting requirement equal \$200,000, and the total in dollars for the sales subject to the average sales price reporting requirement for the same period equals \$600,000. The lagged price concessions percentage for this period equals $200,000/600,000 = 0.33333$. The total in dollars for the sales subject to the average sales price reporting requirement for the quarter being reported, equals \$50,000 for 10,000 units sold. The manufacturer's average sales price calculation for this National Drug Code for this quarter is: $\$50,000 - (0.33333 \times \$50,000) = \$33,334$ (net total sales amount); $\$33,334/10,000 = \3.33 (average sales price).

(4) *Exempted sales.* (i) In calculating the manufacturer's average sales price, a manufacturer must exclude sales that are exempt from inclusion in the determination of the best price under section 1927(c)(1)(C)(i) of the Act and sales that are merely nominal in amount as applied for purposes of section 1927(c)(1)(C)(ii)(III) of the Act, as limited by section 1927(c)(1)(D) of the Act.

(ii) In determining nominal sales exempted under section 1927(c)(1)(C)(ii)(III) of the Act, the manufacturer calculates the average manufacturer price as defined in section 1927(k) of the Act and then identifies sales that are eligible to be considered a nominal sale under section 1927(c)(1)(D) of the Act and are at less than 10 percent of the average manufacturer price. To identify nominal sales, the manufacturer must use the average manufacturer price for the calendar quarter that is the same calendar quarter as the average sales price reporting period.

(5) The manufacturer's average sales price must be calculated by the manufacturer every calendar quarter and submitted to CMS within 30 days of the close of the quarter. The first quarter submission must be submitted by April 30, 2004. Subsequent reports are due not later than 30 days after the last day of each calendar quarter.

(6) The manufacturer's average sales price must be calculated based on the amount of product in a vial or other container as conspicuously reflected on the FDA approved label as defined by section 201(k) of the Food, Drug, and Cosmetic Act.

(7) Each report must be certified by one of the following:

(i) The manufacturer's Chief Executive Officer (CEO).

(ii) The manufacturer's Chief Financial Officer (CFO).

(iii) An individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or CFO.

(b) [Reserved]

[69 FR 17938, Apr. 6, 2004, as amended at 69 FR 55764, Sept. 16, 2004; 70 FR 70332, Nov. 21, 2005; 71 FR 69787, Dec. 1, 2006; 72 FR 18914, Apr. 16, 2007; 75 FR 73626, Nov. 29, 2010]

§ 414.806 Penalties associated with misrepresentation and the failure to submit timely and accurate ASP data.

(a) *Misrepresentation.* Section 1847A(d)(4)(A) of the Act specifies the penalties associated with misrepresentations in the reporting of the manufacturer's average sales price for a drug as defined at § 414.802.

(b) *Failure to provide timely information or the submission of false information.* (1) For a manufacturer that has entered into and has in effect a rebate agreement under section 1927 of the Act, section 1927(b)(3)(C) of the Act specifies the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

(2) For a manufacturer that has not entered into and does not have in effect a rebate agreement under section 1927 of the Act, sections 1847A(d)(4)(B) and (C) of the Act specify the penalties associated with a manufacturer's failure

to submit timely information or the submission of false information.

[86 FR 65669, Nov. 19, 2021]

Subpart K—Payment for Drugs and Biologicals Under Part B

SOURCE: 69 FR 66424, Nov. 15, 2004, unless otherwise noted.

§ 414.900 Basis and scope.

(a) This subpart implements sections 1842(o), 1847A, and 1847B of the Act and outlines two payment methodologies applicable to drugs and biologicals covered under Medicare Part B that are not paid on a cost or prospective payment system basis.

(b) Examples of drugs that are subject to the requirements specified in this subpart are:

- (1) Drugs furnished incident to a physician's service; durable medical equipment (DME) drugs.
- (2) Separately billable drugs at independent dialysis facilities not under the ESRD composite rate.
- (3) Statutorily covered drugs, for example—
 - (i) Influenza.
 - (ii) Pneumococcal, Hepatitis B, and COVID-19 vaccines.
 - (iii) Antigens.
 - (iv) Hemophilia blood clotting factor.
 - (v) Immunosuppressive drugs.
 - (vi) Certain oral anti-cancer drugs.

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 39093, July 6, 2005; 85 FR 71197, Nov. 6, 2020]

§ 414.902 Definitions.

As used in this subpart, unless the context indicates otherwise—

Applicable five-year period means:

- (1) For a qualifying biosimilar biological product for which payment has been made under section 1847A(b)(8) of the Act as of September 30, 2022, the 5-year period beginning on October 1, 2022; and
- (2) For a qualifying biosimilar biological product for which payment is first made under section 1847A(b)(8) of the Act during a calendar quarter during the period beginning October 1, 2022 and ending December 31, 2027, the 5-year period beginning on the first day

of such calendar quarter during which such payment is first made.

Approved CAP vendor means an entity that has been awarded a contract by CMS to participate in the competitive acquisition program under 1847B of the Act.

Bid means an offer to furnish a CAP drug within a category of CAP drugs in a competitive acquisition area for a particular price and time period.

Biosimilar biological product means 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 biological product licensed under section 351 of the Public Health Service Act (PHSA) as defined at section 1847A(c)(6)(H) of the Act.

CAP drug means a physician-administered drug or biological furnished on or after January 1, 2006 described in section 1842(o)(1)(C) of the Act and supplied by an approved CAP vendor under the CAP as provided in this subpart.

Competitive acquisition area means a geographic area established by the Secretary for purposes of implementing the CAP required by section 1847B of the Act.

Competitive acquisition program (CAP) means a program as defined under section 1847B of the Act.

Designated carrier means an entity assigned by CMS to process and pay claims for drugs and biologicals under the CAP.

Drug means both drugs and biologicals.

Emergency delivery means delivery of a CAP drug within one business day in appropriate shipping and packaging, in all areas of the United States and its territories, with the exception of the Pacific Territories. In the Pacific Territories, emergency delivery means delivery of a CAP drug within 5 business days in appropriate shipping and packaging. In each case, this timeframe shall be reduced if product stability requires it, meaning that the manufacturer's labeling instructions, drug compendia, or specialized drug stability references indicate that a shorter delivery timeframe is necessary to avoid adversely affecting the product's integrity, safety, or efficacy.