

**§ 414.800**

**42 CFR Ch. IV (10–1–06 Edition)**

hepatitis B (as determined by the Secretary).

(iv) A drug or biological furnished during 2004 in connection with the furnishing of renal dialysis services if separately billed by renal dialysis facilities.

(3) The payment limits for infusion drugs furnished through a covered item of durable medical equipment are calculated using 95 percent of the average wholesale price in effect on October 1, 2003.

(4) The payments limits for drugs contained in the following table are calculated based on the percentages of the average wholesale price determined as of April 1, 2003 that are specified in the table.

Drug	Percentage used to calculate 2004 payment limit
EPOETIN ALFA .....	87
LEUPROLIDE ACETATE .....	81
GOSERELIN ACETATE .....	80
RITUXIMAB .....	81
PACLITAXEL .....	81
DOCETAXEL .....	80
CARBOPLATIN .....	81
IRINOTECAN .....	80
GEMCITABINE HCL .....	80
PAMIDRONATE DISODIUM .....	85
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 sec-

tion 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).

**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—

*Drug* means both drugs and biologicals.

*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. During the first 3 years of the CAP (as defined in § 414.902), the method of counting units excludes units of CAP drugs (as defined in § 414.902) sold to an approved CAP vendor (as defined in § 414.902) for use under the CAP (as defined in § 414.902).

[70 FR 69 FR 17938, Apr. 6, 2004, as amended at 71 FR 48143, Aug. 18, 2006]

**§ 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 or biological 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 deducting the types of items and transactions listed in paragraph (a)(2) of this section and excluding sales referenced in paragraph (a)(4) of this section) divided by the total number of units sold by the manufacturer in that quarter (after excluding units associated with sales referenced in paragraph (a)(4) of this section).

(2) In calculating the manufacturer's average sales price, a manufacturer must deduct the following types of transactions and items:

- (i) Volume discounts.
- (ii) Prompt pay discounts.
- (iii) Cash discounts.
- (iv) Free goods that are contingent on any purchase requirement.
- (v) Chargebacks and rebates (other than rebates under the Medicaid drug rebate program).

(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 paragraphs (a)(3)(i) through (a)(3)(iv) of this section.

(i) For each such National Drug Code, 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.

(ii) The manufacturer then multiplies the percentage described in paragraph (a)(3)(i) of this section by the total in dollars for the sales subject to the average sales price reporting requirement 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 for the quarter being submitted.

(iii) The manufacturer then 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 as the denominator to calculate the manufacturer's average sales price for the National Drug Code in the quarter being submitted.

(iv) *Example.* The total lagged price concessions (discounts, rebates, etc.) over the most recent 12-month period available associated with direct sales for National Drug Code 12345-6789-01 subject to the ASP reporting requirement equal \$200,000. 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  $200,000/600,000 = .33333$ . The total in dollars for the direct sales subject to the average sales price reporting requirement for the quarter being reported equals \$50,000 for 10,000 units sold. Assuming no non-