

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-

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lagged price concessions apply, 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) In calculating the manufacturer's average sales price, a manufacturer must exclude sales that are exempt from the Medicaid best price calculation under sections 1927(c)(1)(C)(i) and 1927(c)(1)(C)(ii)(III) of the Act.

(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) 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.

[69 FR 17938, Apr. 6, 2004, as amended at 69 FR 55764, Sept. 16, 2004; 70 FR 70332, Nov. 21, 2005]

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

Section 1847A(d)(4) specifies the penalties associated with misrepresentations associated with ASP data. If the Secretary determines that a manufacturer has made a misrepresentation in the reporting of ASP data, a civil money penalty in an amount of up to \$10,000 may be applied for each price misrepresentation and for each day in which the price misrepresentation was applied. Section 1927(b)(3)(C) of the Act, as amended by section 303(i)(4) of the MMA, specifies the penalties associated with a manufacturer's failure to submit timely information or the submission of false information.

## 42 CFR Ch. IV (10-1-06 Edition)

### 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 and Hepatitis B 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]

#### § 414.902 Definitions.

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

*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.

*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.