

§ 414.701

(v) A statement of the reasons why the ground ambulance organization does not agree with CMS' determination and any supporting documentation.

(f) *Public availability of data.* Beginning in 2024, and at least once every 2 years thereafter, CMS will post on its website data that it collected under this section, including but not limited to summary statistics and ground ambulance organization characteristics.

(g) *Limitations on review.* There is no administrative or judicial review under section 1869 or section 1878 of the Act, or otherwise of the data required for submission under paragraph (b) of this section or the selection of ground ambulance organizations under paragraph (c) of this section.

[84 FR 63193, Nov. 15, 2019, as amended at 86 FR 65669, Nov. 19, 2021; 87 FR 70226, Nov. 18, 2022]

Subpart I—Payment for Drugs and Biologicals

SOURCE: 69 FR 1116, Jan. 7, 2004, unless otherwise noted.

§ 414.701 Purpose.

This subpart implements section 1842(o) of the Act by specifying the methodology for determining the payment allowance limit for drugs and biologicals covered under Part B of Title XVIII of the Act (hereafter in this subpart referred to as the “program”) that are not paid on a cost or prospective payment system basis. Examples of drugs that are subject to the rules contained in this subpart are: Drugs furnished incident to a physician's service; durable medical equipment (DME) drugs; separately billable drugs at independent dialysis facilities not under the ESRD composite rate; statutorily covered drugs, for example, influenza, pneumococcal, hepatitis, and COVID-19 vaccines, antigens, hemophilia blood clotting factor, immunosuppressive drugs and certain oral anticancer drugs.

[85 FR 71197, Nov. 6, 2020]

42 CFR Ch. IV (10–1–23 Edition)

§ 414.704 Definitions.

As used in this subpart, the following definition applies. *Drug* refers to both drugs and biologicals.

§ 414.707 Basis of payment.

(a) *Method of payment.* (1) Payment for a drug in calendar year 2004 is based on the lesser of—

(i) The actual charge on the claim for program benefits; or

(ii) 85 percent of the average wholesale price determined as of April 1, 2003, subject to the exceptions as specified in paragraphs (a)(2) through (a)(8) of this section.

(2) The payment limits for the following drugs are calculated using 95 percent of the average wholesale price:

(i) Blood clotting factors.

(ii) A drug or biological furnished during 2004 that was not available for Medicare payment as of April 1, 2003.

(iii) Pneumococcal, influenza, and COVID-19 vaccines as well as hepatitis B vaccine that is furnished to individuals at high or intermediate risk of contracting hepatitis B (as defined in § 410.63(a) of this subchapter).

(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

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