§ 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.

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.

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.