

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.