

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.

*Emergency situation* means, for the purposes of the CAP, an unforeseen occurrence or situation determined by the participating CAP physician, in his or her clinical judgment, to require prompt action or attention for purposes of permitting the participating CAP physician to use a drug from his or her own stock, if the other requirements of § 414.906(e) are met.

*Local carrier* means an entity assigned by CMS to process and pay claims for administration of drugs and biologicals under the CAP.

*Low volume dose* means, with respect to determination of whether an increased applicable percentage is warranted, an FDA-labeled dose of a drug for which the volume removed from the vial or container containing the labeled dose does not exceed 0.4 mL.

*Manufacturer's average sales price* means the price calculated and reported by a manufacturer under part 414, subpart J of this chapter.

*Multiple source drug* means a drug described by section 1847A(c)(6)(C) of the Act.

*New refund quarter* means a calendar quarter that is included in a report described in § 414.940(a) that is sent in the first year following the year in which the calendar quarter occurs.

*Pacific Territories* means, for purposes of the CAP, American Samoa, Guam, or the Northern Mariana Islands.

*Participating CAP physician* means a physician electing to participate in the CAP, as described in this subpart. The participating CAP physician must complete and sign the participating CAP physician election agreement. Physicians who do not participate in Medicare but who elect to participate in the CAP must agree to accept assignment for CAP drug administration claims.

*Participating CAP physician election agreement* means the agreement that the physician signs to notify CMS of the physician's election to participate in the CAP and to agree to the terms and conditions of CAP participation as set forth in this subpart.

*Prescription order* means a written order submitted by the participating CAP physician to the approved CAP vendor that meets the requirements of this subpart.

*Qualifying biosimilar biological product* means a biosimilar biological product (as described in section 1847A(b)(1)(C) of the Act) with an average sales price (as described in section 1847A(b)(8)(A)(i) of the Act) less than the average sales price of the reference biological for a calendar quarter during the applicable 5-year period.

*Reference biological product* means the biological product licensed under such section 351 of the PHSA that is referred to in the application of the biosimilar biological product as defined at section 1847A(c)(6)(I) of the Act.

*Refundable single-dose container or single-use package drug* means a single source drug or biological or a biosimilar biological product for which payment is made under this part and that is furnished from a single-dose container or single-use package based on FDA-approved labeling or product information. The term “refundable single-dose container or single-use package drug” excludes—

(1) A drug that is a therapeutic radiopharmaceutical, a diagnostic radiopharmaceutical, or an imaging agent as identified in the drug's FDA-approved labeling.

(2) A drug for which the FDA-approved labeling for any National Drug Code assigned to a billing and payment code of such drug requires filtration during the drug preparation process, prior to dilution and administration and that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process.

(3) A drug approved or licensed by the FDA on or after November 15, 2021, until the last day of the sixth full quarter for which the drug has been marketed (as reported to CMS) for the first National Drug Code assigned to the billing and payment code of such drug.

*Routine delivery* means delivery of a drug within 2 business days 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, routine delivery of drug means delivery of a CAP drug within 7 business days in appropriate shipping and

packaging. In each case, this timeframe will 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.

*Single source drug* means a drug described by section 1847A(c)(6)(D) of the Act.

*Timely delivery* means delivery of a CAP drug within the defined routine and emergency delivery timeframes. Compliance with timely delivery standards is also a factor for evaluation of potential and approved CAP vendors.

*Unit* is defined as in part 414, subpart J of this chapter.

*Updated refund quarter* means a calendar quarter that is included in a report described in §414.940(a) that is sent in the second year following the year in which the calendar quarter occurs.

*Wholesale acquisition cost (WAC)* means the price described by section 1847A(c)(6)(B) of the Act.

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#### **§414.904 Average sales price as the basis for payment.**

(a) *Method of payment.* Payment for a drug furnished on or after January 1, 2005 is based on the lesser of—

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

(2) 106 percent of the average sales price, subject to the applicable limitations specified in paragraph (d) of this section or subject to the exceptions described in paragraph (e) of this section.

(3) For purposes of this paragraph—

(i) CMS calculates an average sales price payment limit based on the amount of product included in a vial or other container as reflected on the FDA-approved label.

(ii) Additional product contained in the vial or other container does not represent a cost to providers and is not incorporated into the ASP payment limit.

(iii) No payment is made for amounts of product in excess of that reflected on the FDA-approved label.

(b) *Multiple source drugs*—(1) *Average sales prices.* The average sales price for all drug products included within the same multiple source drug billing and payment code is the volume-weighted average of the manufacturers' average sales prices for those drug products.

(2) *Calculation of the average sales price.* (i) For dates of service before April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to the drug products) of the manufacturer's average sales price and the total number of units sold; and

(B) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug products.

(ii) For dates of service on or after April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to such drug products) of the manufacturer's average sales price, determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code and the total number of units sold; and

(B) Dividing the sum determined under clause (A) by the sum of the products (for each National Drug Code assigned to such drug products) of the total number of units sold and the total number of billing units for the National Drug Code for the billing and payment code.

(iii) For purposes of this subsection and subsection (c), the term billing unit means the identifiable quantity associated with a billing and payment code, as established by CMS.

(c) *Single source drugs*—(1) *Average sales price.* The average sales price is the volume-weighted average of the manufacturers' average sales prices for all National Drug Codes assigned to the drug or biological product.

(2) *Calculation of the average sales price.* (i) For dates of service before April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to the drug product) of the manufacturer's average sales price and the total number of units sold; and

(B) Dividing that sum by the sum of the total number of units sold for all NDCs assigned to the drug product.

(ii) For dates of service on or after April 1, 2008, the average sales price is determined by—

(A) Computing the sum of the products (for each National Drug Code assigned to such drug products) of the manufacturer's average sales price, determined by the Secretary without dividing such price by the total number of billing units for the National Drug Code for the billing and payment code and the total number of units sold; and

(B) Dividing the sum determined under clause (A) by the sum of the products (for each National Drug Code assigned to such drug products) of the total number of units sold and the total number of billing units for the National Drug Code for the billing and payment code.

(d) *Limitations on the average sales price*—(1) *Wholesale acquisition cost for a single source drug.* The payment limit for a single source drug product is the lesser of 106 percent of the average sales price for the product or 106 percent of the wholesale acquisition cost for the product.

(2) *Payment limit for a drug furnished to an end-stage renal disease patient.* (i) Effective for drugs and biologicals furnished in 2005, the payment for such drugs and biologicals, including erythropoietin, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility and not paid on a cost basis is acquisition cost as determined by the Inspector General report as required by section 623(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 inflated by the percentage increase in the Producer Price Index.

(ii) Except as provided in paragraph (a) of this section, the payment for drugs and biologicals, furnished to an end-stage renal disease patient that is separately billed by an end-stage renal disease facility, is based on 106 percent of the average sales price.

(iii) Effective for drugs and biologicals furnished in CY 2006 and subsequent calendar years, the payment for such drugs and biologicals furnished in connection with renal dialysis services and separately billed by freestanding and hospital-based renal dialysis facilities not paid on a cost basis is the amount determined under section 1847A of the Act.

(3) *Widely available market price and average manufacturer price.* If the Inspector General finds that the average sales price exceeds the widely available market price or the average manufacturer price by the applicable threshold percentage specified in paragraph (d)(3)(iii) or (iv) of this section, the Inspector General is responsible for informing the Secretary (at such times as specified by the Secretary) and the payment amount for the drug or biological will be substituted subject to the following adjustments:

(i) The payment amount substitution will be applied at the next average sales price payment amount calculation period after the Inspector General informs the Secretary (at such times specified by the Secretary) about billing codes for which the average sales price has exceeded the average manufacturer price by the applicable threshold percentage, and will remain in effect for 1 quarter after publication.

(ii) Payment at 103 percent of the average manufacturer price for a billing code will be applied at such times when all of the following criteria are met:

(A) The threshold for making price substitutions, as defined in paragraph (d)(3)(iii) of this section is met.

(B) 103 percent of the average manufacturer price is less than the 106 percent of the average sales price for the quarter in which the substitution would be applied.

(C) Beginning in 2013, the drug and dosage form described by the HCPCS code is not identified by the FDA to be in short supply at the time that ASP calculations are finalized.

(iii) The applicable percentage threshold for average manufacturer price comparisons is 5 percent and is reached when—

(A) The average sales price for the billing code has exceeded the average manufacturer price for the billing code

by 5 percent or more in 2 consecutive quarters, or 3 of the previous 4 quarters immediately preceding the quarter to which the price substitution would be applied; and

(B) The average manufacturer price for the billing code is calculated using the same set of National Drug Codes used for the average sales price for the billing code.

(iv) The applicable percentage threshold for widely available market price comparisons is 5 percent.

(4) *Payment adjustment for certain drugs for which there is a self-administered version*—(i) *In general.* Except as provided in paragraphs (d)(4)(ii) and (iii) of this section, if the Inspector General identifies a drug or biological product in a study described in section 1847A(g)(1) of the Act, the Secretary must apply the payment limit for the applicable billing and payment code as specified in paragraph (d)(4)(iv) of this section, beginning with the first day of the second quarter after such study is publicly available. The methodology described in this paragraph will be recalculated each quarter thereafter, except when conditions described in paragraph (d)(4)(ii) are met.

(ii) *Exception.* The adjustment described in paragraph (d)(4)(i) of this section does not apply to the payment limit for a billing and payment code for a quarter if, at the time that ASP calculations are finalized for such quarter, the drug in the dosage form described by the billing and payment code is included by the FDA on the drug shortage list in effect under section 506E of the Federal Food, Drug, and Cosmetic Act.

(iii) *Special rule for certain billing and payment codes.* Effective July 1, 2021, for a billing and payment code described under section 1847A(g)(3) of the Act, the payment limit for the applicable billing and payment code must be determined as described in paragraph (d)(4)(iv) of this section, and the exception specified at paragraph (d)(4)(ii) of this section does not apply.

(iv) *Lesser-of methodology.* For purposes of this section, the payment limit is the lesser of:

(A) The payment limit determined under section 1847A of the Act for such billing and payment code if each Na-

tional Drug Code for such product so identified under section 1847A(g)(1) of the Act were excluded from such determination; and

(B) The payment limit otherwise determined under section 1847A of the Act for such billing and payment code without application of section 1847A(g) of the Act.

(v) *NDC changes.* For an Inspector General-identified National Drug Code, as described under section 1847A(g)(1) or (3) of the Act, for which the manufacturer has redesignated the National Drug Code (without changes to the dosage form), the application of the lesser-of methodology described in this paragraph must use manufacturer-reported ASP data associated with the redesignated National Drug Code in the same manner as the one originally identified by the Inspector General.

(e) *Exceptions to the average sales price*—(1) *Vaccines.* The payment limits for hepatitis B vaccine furnished to individuals at high or intermediate risk of contracting hepatitis B (as defined in §410.63(a) of this subchapter), pneumococcal vaccine, influenza vaccine, and COVID-19 vaccine are calculated using 95 percent of the average wholesale price.

(2) *Infusion drugs furnished through a covered item of durable medical equipment.* The payment limit for an infusion drug furnished before January 1, 2017, through a covered item of durable medical equipment is calculated using 95 percent of the average wholesale price in effect on October 1, 2003.

(3) *Blood and blood products.* In the case of blood and blood products (other than blood clotting factors), the payment limits are determined in the same manner as the payment limits were determined on October 1, 2003.

(4) *Payment amount in a case where the average sales price during the first quarter of sales is unavailable.* During an initial period (not to exceed a full calendar quarter) in which data on the prices for sales of the drug are not sufficiently available from the manufacturer to compute an average sales price:

(i) *In general.* Except as provided in paragraph (e)(4)(ii) of this section,

(A) For dates of service before January 1, 2019, the payment amount for the

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drug is based on the wholesale acquisition cost or the Medicare Part B drug payment methodology in effect on November 1, 2003.

(B) For dates of service on or after January 1, 2019, the payment amount for the drug is an amount not to exceed 103 percent of the wholesale acquisition cost or based on the Medicare Part B drug payment methodologies in effect on November 1, 2003.

(ii) *Limitation on payment amount for biosimilar biological products during initial period.* For dates of service on or after July 1, 2024, the payment amount for a biosimilar biological product (as defined in § 414.902) during the initial period is the lesser of the following:

(A) The payment amount for the biosimilar biological product as determined under clause (e)(4)(i)(B) of this section or

(B) 106 percent of the amount determined under section 1847A(b)(1)(B) of the Act for the reference biological product (as defined in § 414.902).

(5) *Treatment of certain drugs.* Beginning with April 1, 2008, the payment amount for—

(i) Each single source drug or biological described in section 1842(o)(1)(G) that is treated as a multiple source drug because of the application of section 1847A(c)(6)(C)(ii) is the lower of—

(A) The payment amount that would be determined for such drug or biological applying section 1847A(c)(6)(C)(ii); or

(B) The payment amount that would have been determined for such drug or biological if section 1847A(c)(6)(C)(ii) were not applied.

(ii) A multiple source drug described in section 1842(o)(1)(G) (excluding a drug or biological that is treated as a multiple source drug because of the application of section 1847A(c)(6)(C)(ii)) is the lower of—

(A) The payment amount that would be determined for such drug or biological taking into account the application of section 1847A(c)(6)(C)(ii); or

(B) The payment amount that would have been determined for such drug or biological if section 1847A(c)(6)(C)(ii) were not applied.

(f) Except as otherwise specified (see paragraph (e)(2) of this section) for in-

fusion drugs, the payment limits are updated quarterly.

(g) The payment limit is computed without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

(h) The payment amount is subject to applicable deductible and coinsurance.

(i) If manufacturer ASP data is not available prior to the publication deadline for quarterly payment limits and the unavailability of manufacturer ASP data significantly changes the quarterly payment limit for the billing code when compared to the prior quarter's billing code payment limit, the payment limit is calculated by carrying over the most recent available manufacturer ASP price from a previous quarter for an NDC in the billing code, adjusted by the weighted average of the change in the manufacturer ASPs for the NDCs that were reported for both the most recently available previous quarter and the current quarter.

(j) *Biosimilar biological products—(1) In general.* Except as provided in paragraph (j)(2), effective January 1, 2016, the payment amount for a biosimilar biological product (as defined in § 414.902), for all NDCs assigned to such product, is the sum of the average sales price of all NDCs assigned to the biosimilar biological products included within the same billing and payment code as determined under section 1847A(b)(6) of the Act, and 6 percent of the amount determined under section 1847A(b)(4) of the Act for the reference biological product (as defined in § 414.902).

(2) *Temporary increase in Medicare Part B payment for qualifying biosimilar biological products.* In the case of a qualifying biosimilar biological product (as defined in § 414.902) that is furnished during the applicable 5-year period (as defined in § 414.902) for such product, the payment amount for such product with respect to such period is the sum determined under as determined under section 1847A(b)(6) of the Act and 8 percent of the amount determined under section 1847A(b)(4) of the

Act for the reference biological product (as defined in § 414.902).

[69 FR 66424, Nov. 15, 2004, as amended at 70 FR 70332, Nov. 21, 2005; 71 FR 69788, Dec. 1, 2006; 72 FR 66402, Nov. 27, 2007; 73 FR 69937, Nov. 19, 2008; 73 FR 80304, Dec. 31, 2008; 74 FR 62012, Nov. 25, 2009; 75 FR 73626, Nov. 29, 2010; 76 FR 73473, Nov. 28, 2011; 77 FR 69368, Nov. 16, 2012; 80 FR 71382, Nov. 16, 2015; 82 FR 53363, Nov. 15, 2017; 83 FR 60074, Nov. 23, 2018; 85 FR 71197, Nov. 6, 2020; 86 FR 65669, Nov. 19, 2021; 87 FR 70226, Nov. 18, 2022; 88 FR 79532, Nov. 16, 2023]

**§ 414.906 Competitive acquisition program as the basis for payment.**

(a) *Program payment.* Beginning in 2006, as an alternative to payment under § 414.904, payment for a CAP drug may be made through the CAP if the following occurs:

(1) The CAP drug is supplied under the CAP by an approved CAP vendor as specified in § 414.908(b).

(2) The claim for the prescribed drug is submitted by the approved CAP vendor that supplied the drug, and payment is made only to that vendor.

(3) The approved CAP vendor collects applicable deductible and coinsurance with respect to the drug furnished under the CAP only after the drug is administered to the beneficiary.

(4) The approved CAP vendor delivers CAP drugs directly to the participating CAP physician in unopened vials or other original containers as supplied by the manufacturer or from a distributor that has acquired the products directly from the manufacturer and includes language with the shipping material stating that the drug was acquired in a manner consistent with all statutory requirements. If the approved CAP vendor opts to split shipments, the participating CAP physician must be notified in writing which can be included with the initial shipment, and each incremental shipment must arrive at least 2 business days before the anticipated date of administration.

(5) The approved CAP vendor bills Medicare only for the amount of the drug administered to the patient, and the beneficiary's coinsurance will be calculated from the quantity of drug that is administered.

(b) *Exceptions to competitive acquisition.* Specific CAP drugs, including a

category of these drugs, may be excluded from the CAP if the application of competitive bidding to these drugs—

(1) Is not likely to result in significant savings; or

(2) Is likely to have an adverse impact on access to those drugs.

(c) *Computation of payment amount.* Except as specified in paragraph (c)(2) of this section, payment for CAP drugs is based on bids submitted as a result of the bidding process as described in § 414.910 of this subpart.

(1) *Single payment amount.* (i) A single payment amount for each CAP drug in the competitive acquisition area is determined on the basis of the bids submitted and accepted and updated from the bidding period to the beginning of the payment year.

(ii) The single payment amount is then updated quarterly based on the approved CAP vendor's reasonable net acquisition costs for that category as determined by CMS, and limited by the weighted payment amount established under section 1847A of the Act across all drugs for which a composite bid is required in the category.

(iii) The payment amount for each other drug for which the approved CAP vendor submits a bid in accordance with § 414.910 of this subpart and each other drug that is approved by CMS for the approved CAP vendor to furnish under the CAP is also updated quarterly based on the approved CAP vendor's reasonable net acquisition costs for each HCPCS code and limited by the payment amount established under section 1847A of the Act.

(2) *Updates to payment amount.* (i) The first update is effective on the first day of claims processing for the first quarter of an approved CAP vendor's contract. The first quarterly contract update is based on the reasonable net acquisition cost (RNAC) data reported to CMS or its designee for any purchases of drug before the beginning of CAP claims processing for the contract period and reported to CMS no later than 30 days before the beginning of CAP claims processing.

(ii) For subsequent quarters, each approved CAP vendor must report to CMS or its designee RNAC data for a quarter of CAP drug purchases within 30 days of the close of that quarter.

(iii) For all quarters, only RNAC data from approved CAP vendors that are supplying CAP drugs under their CAP contract at the time updates are being calculated must be used to calculate updated CAP payment amounts.

(iv) CMS excludes such RNAC data submitted by an approved CAP vendor if, during the time calculations are being done, CMS knows that the approved CAP vendor will not be under contract for the applicable quarterly update.

(v) The payment amount weights must be calculated based on the more recent of the following:

(A) Contract bidding weights.

(B) CAP claims data.

(vi) The payment limit must be determined using the most recent payment limits available to CMS under section 1847A of the Act.

(vii) The following payment amount update calculation must be applied for the group of all drugs for which a composite bid is required.

(A) The most recent previous composite payment amount for the group is updated by—

(1) Calculating the percent change in reasonable net acquisition costs for each approved CAP vendor;

(2) Calculating the median of all participating approved CAP vendors' adjusted CAP payment amounts; and

(3) Limiting the payment as described in paragraph (c)(1) of this section.

(B) The median percent change, subject to the limit described in paragraph (c)(1) of this section, must be the update percentage for that quarter.

(C) The single update percentage must be applied to the payment amount for each drug in the group of drugs for which a composite bid is required in the category.

(viii) The following payment amount update calculation must be applied for each of the following items: Each HCPCS code not included in the composite bid list; Each HCPCS code added to the drug list during the contract period; and each drug that has not yet been assigned a HCPCS code, but for which a HCPCS code will be established.

(A) The most recent previous payment amount for each drug must be up-

dated by calculating the percent change in reasonable net acquisition costs for each approved CAP vendor, then calculating the median of all participating approved CAP vendors' adjusted CAP payment amounts.

(B) The median percent change calculated for each drug, subject to the limit described in paragraph (c)(1) of this section, must be applied to the payment amount for each drug.

(3) *Alternative payment amount.* The alternative payment amount established under section 1847A of the Act may be used to establish payment for a CAP drug if—

(i) The drug is properly assigned to a category established under the CAP; and

(ii) It is a drug for which a HCPCS code must be established.

(d) *Adjustments.* There is an established process for adjustments to payments to account for drugs that were billed, but which were not administered.

(e) *Resupply of participating CAP physician drug inventory.* A participating CAP physician may acquire drugs under the CAP to resupply his or her private inventory if all of the following requirements are met:

(1) The drugs were required immediately.

(2) The participating CAP physician could not have anticipated the need for the drugs.

(3) The approved CAP vendor could not have delivered the drugs in a timely manner. For purposes of this section, timely manner means delivery within the emergency delivery time-frame, as defined in § 414.902.

(4) The participating CAP physician administered the drugs in an emergency situation, as defined in § 414.902.

(f) *Substitution or addition of drugs on an approved CAP vendor's CAP drug list—*(1) *Short-term substitution of a CAP drug.* On an occasional basis (for a period of time less than 2 weeks), an approved CAP vendor may agree to furnish a substitute NDC within a HCPCS code on the approved CAP vendor's CAP drug list if the approved CAP vendor—

(i) Is willing to accept the payment amount that was established for the HCPCS code under this section; and



(ii) Obtains the participating CAP physician's prior approval.

(2) *Long-term substitution or addition of a CAP drug.* An approved CAP vendor may submit a request, as specified in paragraph (f)(3) of this section, for approval to substitute an NDC supplied by the approved CAP vendor for another NDC within the same HCPCS code or to add an NDC to the approved CAP vendor's drug list, if at least one of the following criteria is met:

(i) Proposed substitution of an NDC for a period of 2 weeks or longer.

(ii) Proposed addition of one or more NDCs within a HCPCS code included in the CAP drug category specified by CMS or on the approved CAP vendor's approved CAP drug list.

(iii) Proposed addition of—

(A) One or more newly issued HCPCS codes; or

(B) One of the following single indication orphan drug J codes or their updates: J0205, J0256, J9300, J1785, J2355, J3240, J7513, J9010, J9015, J9017, J9160, J9216.

(iv) Beginning January 1, 2007, the proposed addition of a drug(s) that has not yet been assigned a HCPCS code, but for which a HCPCS code must be established.

(v) On or after January 1, 2010, the proposed addition of drugs with similar therapeutic uses to drugs already supplied under the CAP by the approved CAP vendor(s).

(3) *Requesting the addition or substitution of CAP drug.* An approved CAP vendor that meets the one of the criteria specified in paragraph (f)(2) must submit a written request to CMS or its designee. The request must—

(i) Specify the NDC(s) and the respective HCPCS code that is to be added or substituted.

(ii) Address the rationale for the substitution or addition of the NDC(s) or the addition of the HCPCS code(s) as applicable; and

(iii) Address the impact of the substitution of the NDC(s) or the addition of the NDC(s) or HCPCS code(s), or both on—

(A) Patient and drug safety;

(B) Drug waste; and

(C) The potential for cost savings.

(iv) In the case of additions requested under paragraph (f)(2)(v) of this sec-

tion, address and document the need for such an expansion based on demand for the product(s).

(4) *Approval of a request(s).* CMS or its designee notifies the approved CAP vendor of its decision.

(i) Except as specified in paragraph (f)(4)(ii) of this section, an approved request is effective at the beginning of the next calendar quarter.

(ii) Approved substitutions for request based on a drug shortage or other exigent circumstance may become effective immediately provided that—

(A) CMS approves the immediate substitution; and

(B) The approved CAP vendor's notifies its CAP participating physicians of the substitution immediately following CMS approval.

(5) *Payment for an approved drug change(s).* The payment for—

(i) Substituted or added CAP drugs that are within a HCPCS code for which payment is computed under paragraph (c)(1) of this section is the single payment for that HCPCS code, as determined and updated in accordance with paragraph (c)(1) of this section; or

(ii) Added CAP drugs that are not within a HCPCS code for which payment is computed under paragraph (c)(1) of this section is specified under paragraph (c)(2) of this section.

(g) *Deletion of drugs on an approved CAP vendor's CAP drug list.* Deletion of drugs on an approved CAP vendor's CAP drug list due to unavailability requires a written request and approval as described in paragraphs (f)(3)(i) through (iii) and (f)(4) of this section.

[70 FR 39094, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005; 71 FR 9460, Feb. 24, 2006; 74 FR 62012, Nov. 25, 2009]

#### §414.908 Competitive acquisition program.

(a) Participating CAP *physician selection of an approved CAP vendor.* (1) CMS provides the participating CAP physician with a process for the selection of an approved CAP vendor on an annual basis, with exceptions as specified in §414.908(a)(2). Participating CAP physicians will also receive information about the CAP in the enrollment process for Medicare participation set forth in section 1842(h) of the Act.

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(2) A participating CAP physician may select an approved CAP vendor outside the annual selection process or opt out of the CAP for the remainder of the annual selection period when—

(i) The selected approved CAP vendor ceases participation in the CAP;

(ii) The physician leaves a group practice participating in CAP;

(iii) The participating CAP physician relocates to another competitive acquisition area; or

(iv) The approved CAP vendor refuses to ship to the participating CAP physician because the conditions of § 414.914(i) have been met (if this subparagraph (a)(2)(iv) applies, the physician can withdraw from the CAP category for the remainder of the year immediately upon notice to CMS and the approved CAP vendor); or

(v) Other exigent circumstances defined by CMS are present, including—

(A) If, up to and including 60 days after the effective date of the physician's CAP election agreement, the participating CAP physician submits a written request to the designated carrier to terminate the CAP election agreement because CAP participation imposes a burden on the physician's practice. The written request must document the burden. The designated carrier will process the participating CAP physician's request and CMS will approve or deny the request under the dispute resolution process as specified under § 414.917 of this subpart.

(B) If, more than 60 days after the effective date of the physician's CAP election agreement, the participating CAP physician submits a written request to the designated carrier to terminate the CAP election agreement because, based on a change in circumstances of which the participating CAP physician was not previously aware, CAP participation imposes a burden on the physician's practice. The written request must document the burden. The designated carrier will process the participating CAP physician's request and CMS will approve or deny the request under the dispute resolution process as specified under § 414.917 of this subpart.

(3) The physician participating in the CAP—

(i) Elects to use an approved CAP vendor for the drug category and area as set forth in § 414.908(b);

(ii) Completes and signs the CAP election agreement;

(iii) Submits a written prescription order to the approved CAP vendor with complete patient information for patients new to the approved CAP vendor or when information changes. Abbreviated information may be sent on all subsequent orders for a patient for which the approved CAP vendor has previously received complete information and that has no changes to the original information. Prescription orders may be initiated by telephone, with a follow-up written order provided within 8 hours for routine deliveries and immediately for emergency deliveries;

(iv) Does not receive payment for the CAP drug;

(v) Except where applicable State pharmacy law prohibits it, provides the following information to the approved CAP vendor to facilitate collection of applicable deductible and coinsurance as described in § 414.906(a)(3):

(A) Date of order.

(B) Beneficiary name, address, and phone number.

(C) Physician identifying information:

Name, practice location/shipping address, group practice information (if applicable), PIN, and UPIN.

(D) Drug name.

(E) Strength.

(F) Quantity ordered.

(G) Dose.

(H) Frequency/instructions.

(I) Anticipated date of administration.

(J) Beneficiary Medicare information/Health insurance (HIC) number.

(K) Supplementary insurance information (if applicable).

(L) Medicaid information (if applicable).

(M) Additional patient information: date of birth, allergies, height/weight, ICD-9-CM (if necessary).

(vi) Agrees to accept the particular National Drug Codes (NDCs) supplied by the approved CAP vendor for the duration of the participating CAP physician's enrollment with the approved CAP vendor, subject to paragraphs

(a)(3)(vii) and (a)(3)(xiv) of this section. By electing to participate with an approved CAP vendor, the participating CAP physician also agrees to accept the changes to the approved CAP vendor's CAP drug list that have been approved in accordance with §414.906(f).

(vii) Agrees to place routine orders for CAP drugs at the HCPCs level, except when medical necessity requires a particular formulation on the approved CAP vendor's CAP drug list. Medical necessity must be documented. When the conditions of this paragraph are met, the participating CAP physician may submit a prescription order to the approved CAP vendor that specifies the NDC.

(viii) Notifies the approved CAP vendor when a drug is not administered or a smaller amount was administered than was originally ordered. The participating CAP physician and the approved CAP vendor agree on how to handle the unused CAP drug. If it is agreed that the participating CAP physician will maintain the CAP drug in his inventory for administration at a later date, the participating CAP physician submits a new prescription order at that time. This prescription order specifies that the CAP drug is being obtained from the participating CAP physician's CAP inventory and shipment should not occur;

(ix) Maintains a separate electronic or paper inventory for each CAP drug obtained;

(x) Agrees to file the Medicare claim within 30 calendar days of the date of drug administration.

(xi) Agrees to submit documentation such as medical records or certification, as necessary, to support payment for a CAP drug;

(xii) Agrees not to transport CAP drugs from one practice location or place of service to another location except in accordance with a written agreement between the participating CAP physician and the approved CAP vendor that requires that drugs are not subjected to conditions that will jeopardize their integrity, stability, and/or sterility while being transported.

(xiii) Agrees to provide the CMS-developed CAP fact sheet to beneficiaries; and

(xiv) May receive payment under the ASP system when medical necessity requires a certain brand or formulation of a drug that the approved CAP vendor has not been contracted to furnish under the CAP.

(4) Physician group practices. If a physician group practice using a group billing number(s) elects to participate in the CAP, all physicians in the group are considered to be participating CAP physicians when using the group's billing number(s).

(b) *Program requirements.* (1) CMS selects approved CAP vendors through a competition among entities based on the following:

(i) Submission of the bid prices using the OMB-approved Vendor Application and Bid Form for CAP drugs within the category and competitive acquisition area that—

(A) Places the vendor among the qualified bidders with the lowest five composite bids; and

(B) Does not exceed the weighted payment amount established under section 1847A of the Act across all drugs in that category.

(ii) Ability to ensure product integrity.

(iii) Customer service/Grievance process.

(iv) At least 3 years experience in furnishing Part B injectable drugs.

(v) Financial performance and solvency.

(vi) Record of integrity and the implementation of internal integrity measures.

(vii) Internal financial controls.

(viii) Acquisition of all CAP drugs directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer.

(ix) Maintenance of appropriate licensure to supply CAP drugs in States in which they are supplying CAP drugs.

(x) Cost-sharing assistance as described in §414.914(g).

(xi) Other factors as determined by CMS.

(2) Approved CAP vendors must also meet the contract requirements under §414.914.

(c) *Additional considerations.* CMS may refuse to award a contract or terminate an approved CAP vendor contract based upon the following:

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(1) Suspension or revocation by the Federal or State government of the entity's license for distribution of drugs, including controlled substances.

(2) Exclusion of the entity under section 1128 of the Act from participation in Medicare or other Federal health care programs. These considerations are in addition to CMS' ability to terminate the approved CAP vendor for cause as specified in § 414.914(a).

(3) Past violations or misconduct related to the pricing, marketing, distribution, or handling of drugs provided incident to a physician's service.

(d) *Multiple source drugs.* In the case of multiple source drugs, there must be a competition among entities for the acquisition of at least one CAP drug within each billing and payment code within each category for each competitive acquisition area.

(e) *Multiple contracts for a category and area.* The number of bidding qualified entities that are awarded a contract for a given category and area may be limited to no fewer than two.

[70 FR 39094, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005; 72 FR 66402, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

### § 414.910 Bidding process.

(a) Entities may bid to furnish CAP drugs in all competitive acquisition areas of the United States, or one or more specific competitive acquisition areas.

(b) The amount of the bid for any CAP drug for a specific competitive acquisition area must be uniform for all portions of that competitive acquisition area.

(c) A submitted bid price must include the following:

(1) All costs related to the delivery of the drug to the participating CAP physician.

(2) The costs of dispensing (including shipping) of the drug and management fees. The costs related to the administration of the drug or wastage, spillage, or spoilage may not be included.

[70 FR 39095, July 6, 2005]

### § 414.912 Conflicts of interest.

(a) Approved CAP vendors and applicants that bid to participate in the CAP are subject to the following:

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(1) The conflict of interest standards and requirements of the Federal Acquisition Regulation (FAR) organizational conflict of interest guidance, found under FAR subpart 9.5.

(2) Those requirements and standards contained in each individual contract awarded to perform functions under section 1847B of the Act.

(b) *Post-award conflicts of interest.* Approved CAP vendors must have a code of conduct that establishes policies and procedures for recognizing and resolving conflicts of interest between the approved CAP vendor and any entity, including the Federal Government, with whom it does business. The code of conduct which is submitted as part of the application must—

(1) State the need for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for conflicts of interest; and

(2) State the approved CAP vendor's expectations for management, employees, contractors, and agents to comply with the approved CAP vendor's code of conduct, and policies and procedures for detecting, preventing, and resolving conflicts of interest.

[70 FR 39094, July 6, 2005]

### § 414.914 Terms of contract.

(a) The contract between CMS and the approved CAP vendor will be for a term of 3 years, unless terminated or suspended earlier as provided in this section or provided in § 414.917. The contract may be terminated—

(1) By CMS for default if the approved CAP vendor violates any term of the contract; or

(2) In the absence of a contract violation, by either CMS or the approved CAP vendor, if the terminating party notifies the other party by June 30 for an effective date of termination of December 31 of that year.

(b) The contract will provide for a code of conduct for the approved CAP vendor that includes standards relating to conflicts of interest standards as set forth at § 414.912.

(c) The approved CAP vendor will have and implement a compliance plan that contains policies and procedures that control program fraud, waste, and

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abuse, and consists of the following minimum elements:

(1) Written policies, procedures, and standards of conduct articulating the organization's commitment to comply with all applicable Federal and State laws, regulations, and guidance, including, but not limited to, the Prescription Drug Marketing Act (PDMA), the physician self-referral ("Stark") prohibition, the Anti-Kickback statute and the False Claims Act.

(2) The designation of a compliance officer and compliance committee accountable to senior management.

(3) Effective training and education of the compliance officer and organization employees, contractors, agents, and directors.

(4) Enforcement of standards through well publicized disciplinary guidelines.

(5) Procedures for effective internal monitoring and auditing.

(6) Procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives relating to the organization's contract as an approved CAP vendor.

(i) If the approved CAP vendor discovers evidence of misconduct related to payment or delivery of drugs or biologicals under the contract, it will conduct a timely and reasonable inquiry into that conduct.

(ii) The approved CAP vendor will conduct appropriate corrective actions including, but not limited to, repayment of overpayments and disciplinary actions against responsible individuals, in response to potential violations referenced at paragraph (c)(6)(i) of this section.

(7) Procedures to voluntarily self-report potential fraud or misconduct related to the CAP to the appropriate government agency.

(d) The contract must provide for disclosure of the approved CAP vendor's reasonable, net acquisition costs for a specified period of time, not to exceed quarterly.

(e) The contract must provide for appropriate adjustments as described in §414.906(c)(1).

(f) Under the terms of the contract, the approved CAP vendor must also—

(1) Have sufficient arrangements to acquire and deliver CAP drugs within

the category in the competitive acquisition area specified by the contract;

(2) Have arrangements in effect for shipment at least 5 weekdays each week of CAP drugs under the contract, including the ability to comply with the routine and emergency delivery timeframes defined in §414.902;

(3) Have procedures in place to address and resolve complaints of participating CAP physicians and individuals and inquiries regarding shipment of CAP drugs;

(4) Have a grievance and appeals process for dispute resolution;

(5) Respond within 2 business days to any inquiry, or sooner if the inquiry is related to drug quality;

(6) Staff a toll-free telephone line from 8:30 a.m. or earlier and until 5 p.m. or later for all time zones served in the continental United States by the CAP vendor on business days (Monday through Friday excluding Federal holidays) to provide customer assistance, and establish reasonable hours of operation for Hawaii, Alaska, Puerto Rico, and the other U.S. territories;

(7) Staff an emergency toll-free telephone line for weekend and evening access when the call center is closed, and determine what hours on Saturday and Sunday the call center is staffed and which hours a toll-free emergency line is activated; and

(8) Include assistance for the disabled, the hearing impaired, and Spanish-speaking inquirers in all customer service operations.

(9) Meet applicable licensure requirements in each State in which it supplies drugs under the CAP;

(10) Be enrolled in Medicare as a participating supplier;

(11) Comply with all applicable Federal and State laws, regulations and guidance related to the prevention of fraud and abuse;

(12) Supply CAP drugs upon receipt of a prescription order to all participating CAP physicians who have selected the approved CAP vendor, except when the conditions of paragraph (h) of this section or §414.916(b) of this subpart are met;

(13) Provide direct notification to participating CAP physicians enrolled with them of updates to the approved

CAP vendor's CAP drug list on a quarterly basis. Changes must be disseminated at least 30 days before the approved changes are due to take effect, unless immediate notification as described in § 414.906(f)(4) is required. The approved CAP vendor's entire CAP drug list must be disseminated at least once yearly; and approved CAP vendors must make a complete list that incorporates the most recent updates available to physicians on an ongoing basis. CMS posts on its web site the updated CAP drug lists for each approved CAP vendor.

(14) Ensure that subcontractors who are involved in providing services under the approved CAP contractor's CAP contract meet all requirements and comply with all laws and regulations relating to the services they provide under the CAP program. Notwithstanding any relationship the CAP vendor may have with any subcontractor, the approved CAP vendor maintains ultimate responsibility for adhering to and otherwise fully complying with all terms and conditions of its contract with CMS;

(15) Comply with product integrity and record keeping requirements including but not limited to drug acquisition, handling, storage, shipping, drug waste, and return processes; and

(16) Comply with such other terms and conditions as CMS may specify in the CAP contract consistent with section 1847B of the Act.

(g) Under the terms of the contract, the approved CAP vendor must provide assistance to beneficiaries experiencing financial difficulty in paying their cost-sharing amounts through any one or all of the following:

(1) Referral to a bona fide and independent charitable organization.

(2) Implementation of a reasonable payment plan.

(3) A full or partial waiver of the cost-sharing amount after determining in good faith that the individual is in financial need or the failure of reasonable collection efforts, provided that the waiver meets all of the requirements of section 1128A(i)(6)(A) of the Act and the corresponding regulations at paragraph (1) of the definition of "Remuneration" in § 1003.101 of this title. The availability of waivers may

not be advertised or be made as part of a solicitation. Approved CAP vendors must inform beneficiaries that they generally make available the categories of assistance described in paragraphs (g)(1), (g)(2), and (g)(3) of this section. In no event may the approved CAP vendor include or make any statements or representations that promise or guarantee that beneficiaries receive cost-sharing waivers.

(h) The approved CAP vendor must verify drug administration prior to collection of any applicable cost sharing amount.

(1) The approved CAP vendor documents, in writing, the following information necessary to verify drug administration:

(i) Beneficiary name.

(ii) Health insurance number.

(iii) Expected date of administration.

(iv) Actual date of administration.

(v) Identity of the participating CAP physician.

(vi) Prescription order number.

(vii) Identity of the individuals who supply and receive the information.

(viii) Dosage supplied.

(ix) Dosage administered.

(2) If the information is obtained verbally, the approved CAP vendor must also maintain the following information:

(i) The identities of individuals who exchanged the information.

(ii) The date and time that the information was obtained.

(3) The approved CAP vendor must provide this information to CMS or the beneficiary upon request.

(i) The approved CAP vendor must comply with the following procedures before it may refuse to make further shipments of CAP drugs to a participating CAP physician on behalf of a beneficiary:

(1) Subsequent to receipt of payment by Medicare, or the verification of drug administration by the participating CAP physician, the approved CAP vendor must bill any applicable supplemental insurance policies.

(2) An approved CAP vendor that has received payment from the designated carrier for CAP drugs that have not been administered must promptly refund payment for such drugs to the designated carrier and must refund any

coinsurance and deductible collected from the beneficiary and his or her supplemental insurer.

(3) At the time of billing the beneficiary, or the participating CAP physician's presentation of the bill on behalf of the approved CAP vendor, the approved CAP vendor must inform the beneficiary of any types of cost-sharing assistance that may be available consistent with the requirements of section 1128A(a)(5) of the Act and §414.914(g).

(4) If the beneficiary demonstrates a financial need, the approved CAP vendor must follow the conditions outlined in paragraph (g) of this section.

(5) For purposes of paragraph (i) of this section delivery means postmark date, or the date the coinsurance bill or notice was presented to the beneficiary by the participating CAP physician on behalf of the approved CAP vendor.

(i) Except as specified in paragraph (i)(5)(ii) of this section, if after 45 days from delivery of the approved CAP vendor's bill to the beneficiary, the beneficiary's cost-sharing obligation remains unpaid, the approved CAP vendor may refuse further shipments to the participating CAP physician for that beneficiary.

(ii) If the beneficiary has requested cost-sharing assistance within 45 days of receiving delivery of the approved CAP vendor's bill, provisions of paragraphs (i)(6), (i)(7), or (i)(8) of this section, apply.

(6) If the approved CAP vendor implements a reasonable payment plan, as specified in §414.914(g)(2), the approved CAP vendor must continue to ship CAP drugs for the beneficiary, as long as the beneficiary remains in compliance with the payment plan and makes an initial payment under the plan within 15 days after the delivery of the approved CAP vendor's written notice to the beneficiary offering the payment plan.

(7) If the approved CAP vendor has waived the cost-sharing obligations in accordance with section 1128A of the Act and §414.914(g)(3), the approved CAP vendor may not refuse to ship drugs for that beneficiary.

(8) If the approved CAP vendor refers the beneficiary to a bona fide and independent charity in accordance with

§414.914(g)(1), the approved CAP vendor may refuse to ship drugs if the past due balance is not paid 15 days after the date of delivery of the approved CAP vendor's written notice to the beneficiary containing the referral for cost-sharing assistance.

(9) The approved CAP vendor may refuse to make further shipments to that participating CAP physician on behalf of the beneficiary for the lesser of the end of the calendar year or until the beneficiary's balance is paid in full.

[70 FR 39096, July 6, 2005, as amended at 70 FR 70333, Nov. 21, 2005; 72 FR 66403, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

#### **§414.916 Dispute resolution for vendors and beneficiaries.**

(a) *General rule.* Cases of an approved CAP vendor's dissatisfaction with denied drug claims are resolved through a voluntary alternative dispute resolution process delivered by the designated carrier, and a reconsideration process provided by CMS.

(b) *Dispute resolution.* (1) When an approved CAP vendor is not paid on claims submitted to the designated carrier, the vendor may appeal to the designated carrier to counsel the responsible participating CAP physician on his or her agreement to file a clean claim and pursue an administrative appeal in accordance with subpart H of part 405 of this chapter. If problems persist, the approved CAP vendor may ask the designated carrier to—

(i) Review the participating CAP physician's performance; and

(ii) Potentially recommend to CMS that CMS suspend the participating CAP physician's CAP election agreement.

(2) The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the participating CAP physician has been filing his or her CAP drug administration claims in accordance with the requirements for physician participation in the CAP as set forth in §414.908(a)(3). The recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and gather relevant additional information from the participating CAP physician before deciding whether to suspend the participating CAP physician's CAP election agreement. A suspension commencing before October 1 will conclude on December 31 of the same year. A suspension commencing on or after October 1 will conclude on December 31 of the next year.

(4) Upon notification from CMS of a participating CAP physician's suspension from the program, the approved CAP vendor must cease delivery of CAP drugs to the suspended participating CAP physician until the suspension has been lifted.

(5) The participating CAP physician may appeal that suspension by requesting a reconsideration of CMS' decision. The reconsideration will address whether the participating CAP physician's denied claims and appeals were the result of the participating CAP physician's failure to participate in accordance with the requirements of §414.908(a)(3).

(c) *Reconsideration*—(1) *Right to a reconsideration*. A participating CAP physician dissatisfied with a determination that his or her CAP election agreement has been suspended by CMS or a determination under §414.917(d) denying the participating CAP physician's request to terminate participation in the CAP under §414.908(a)(v) is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration*. CMS reconsiders any determination to suspend a participating CAP physician's election agreement if the participating CAP physician files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration*. A participating CAP physician who is dissatisfied with a CMS decision to suspend his or her CAP election agreement may request a reconsideration of the decision by filing a request with CMS. The request must be filed within 30 days of receipt of the CMS decision letter notifying the participating CAP physician of CMS' decision to suspend his or her CAP election

agreement. From the date of receipt of the decision letter until the day the reconsideration determination is final, the ASP payment methodology under section 1847A of the Act applies to the physician.

(4) *Content of request*. The request for reconsideration must specify—

(i) The findings or issues with which the participating CAP physician disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the participating CAP physician's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from approved CAP vendors, local carriers, or beneficiaries.

(5) *Withdrawal of request for reconsideration*. A participating CAP physician may withdraw his or her request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing*. In response to a request for reconsideration, CMS may, at its discretion, provide the participating CAP physician the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the participating CAP physician the opportunity to present, by telephone or in person, evidence to rebut CMS' decision to suspend or terminate a participating CAP physician's CAP election agreement.

(7) *Informal hearing procedures*. (i) CMS provides written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the participating CAP physician requesting the reconsideration, including—

(1) Authorized representatives;

(2) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts);



(3) Representatives from the local carrier;

(4) Representatives from the approved CAP vendor; and

(5) Legal counsel.

(B) The hearing is conducted by the hearing officer who receives relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified in paragraph (c)(7)(ii)(A) of this section; and

(E) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer presents the findings and recommendations to the participating CAP physician who requested the reconsideration. If the hearing officer decides to conduct an in-person or telephone hearing, the hearing officer will send a hearing notice to the participating CAP physician within 10 days of receipt of the hearing request, and the findings and recommendations are due to the participating CAP physician within 30 days of the hearing's conclusion.

(ii) The written report of the hearing officer includes separate numbered findings of fact and the legal conclusions of the hearing officer.

(9) *Final reconsideration determination.*

(i) The hearing officer's decision is final unless the director of the CMS Center for Medicare Management or his or her designee chooses to review that decision within 30 days. If the decision is favorable to the participating CAP physician, then the participating CAP physician may resume his or her participation in CAP. The hearing officer and the CMS official may review decisions that are favorable or unfavorable to the participating CAP physician.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official issues a final reconsideration determination to the participating CAP physician on the basis of the hearing officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final. If the final decision is unfavorable to the participating CAP physician, then the participating CAP physician's CAP election agreement is terminated.

(d) The approved CAP vendor may not charge the beneficiary for the full drug coinsurance amount if the designated contractor did not pay the approved CAP vendor in full, unless a properly executed advance beneficiary notice is in place. When a beneficiary receives an inappropriate coinsurance bill, the beneficiary may participate in the approved CAP vendor's grievance process to request correction of the approved CAP vendor's file. If the beneficiary is dissatisfied with the result of the approved CAP vendor's grievance process, the beneficiary may request intervention from the designated carrier. This is in addition to, rather than in place of, any other beneficiary appeal rights. The designated carrier will first investigate the facts and then facilitate correction to the appropriate claim record and beneficiary file.

[70 FR 39097, July 6, 2005, as amended at 72 FR 66403, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

**§414.917 Dispute resolution and process for suspension or termination of approved CAP contract and termination of physician participation under exigent circumstances.**

(a) *General rule.* If a participating CAP physician finds an approved CAP vendor's service, or the quality of a CAP drug supplied by the approved CAP vendor to be unsatisfactory, then the physician may address the issue first through the approved CAP vendor's grievance process, and second through an alternative dispute resolution process administered by the designated carrier and CMS. If CMS suspends an approved CAP vendor's CAP contract for noncompliance or terminates the CAP contract in accordance

with § 414.914(a), the approved CAP vendor may request a reconsideration in accordance with paragraph (c) of this section.

(b) *Dispute resolution.* (1) When a participating CAP physician is dissatisfied with an approved CAP vendor's service or the quality of a CAP drug supplied by the approved CAP vendor, then the participating CAP physician may use the approved CAP vendor's grievance process. If the service or quality issues are not resolved through the grievance process to the physician's satisfaction, then the participating CAP physician may ask the designated carrier to—

(i) Review the approved CAP vendor's performance; and

(ii) Potentially recommend termination of the approved CAP vendor's CAP contract.

(2) *Responsibility of the designated carrier.* The designated carrier—

(i) Gathers information from the local carrier, the participating CAP physician, the beneficiary, and the approved CAP vendor; and

(ii) Makes a recommendation to CMS on whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract. This recommendation will include numbered findings of fact.

(3) CMS will review the recommendation of the designated carrier and, gather relevant additional information from the approved CAP vendor, the participating CAP physician, the local carrier, and the beneficiary before deciding whether to terminate the approved CAP vendor's CAP contract.

(4) The approved CAP vendor may appeal that termination by requesting a reconsideration. A determination must be made as to whether the approved CAP vendor has been meeting the service and quality obligations of its CAP contract. The approved CAP vendor's contract will remain suspended during the reconsideration process.

(c) *Reconsideration.*—(1) *Right to reconsideration.* An approved CAP vendor dissatisfied with a determination that its CAP contract has been suspended or terminated by CMS is entitled to a reconsideration as provided in this subpart.

(2) *Eligibility for reconsideration.* CMS will reconsider any determination to

suspend or terminate an approved CAP vendor's contract if the approved CAP vendor files a written request for reconsideration in accordance with paragraphs (c)(3) and (c)(4) of this section.

(3) *Manner and timing of request for reconsideration.* An approved CAP vendor that is dissatisfied with a CMS decision to suspend or terminate its CAP contract may request a reconsideration of the decision by filing a request with CMS. The request must be filed within 30 days of receipt of the CMS decision letter notifying the approved CAP vendor of the suspension or termination of its CAP contract.

(4) *Content of request.* The request for reconsideration must specify—

(i) The findings or issues with which the approved CAP vendor disagrees;

(ii) The reasons for the disagreement;

(iii) A recital of the facts and law supporting the approved CAP vendor's position;

(iv) Any supporting documentation; and

(v) Any supporting statements from participating CAP physicians, the local carrier, or beneficiaries.

(5) *Withdrawal of request for reconsideration.* An approved CAP vendor may withdraw its request for reconsideration at any time before the issuance of a reconsideration determination.

(6) *Discretionary informal hearing.* In response to a request for reconsideration, CMS may, at its discretion, provide the approved CAP vendor the opportunity for an informal hearing that—

(i) Is conducted by a hearing officer appointed by the Director of the CMS Center for Medicare Management or his or her designee; and

(ii) Provides the approved CAP vendor the opportunity to present, by telephone or in person, evidence to rebut CMS' decision to suspend or terminate the approved CAP vendor's CAP contract.

(7) *Informal hearing procedures.* (i) CMS will provide written notice of the time and place of the informal hearing at least 10 days before the scheduled date.

(ii) The informal reconsideration hearing will be conducted in accordance with the following procedures:

(A) The hearing is open to CMS and the approved CAP vendor requesting the reconsideration, including—

- (1) Authorized representatives;
- (2) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts);
- (3) Representatives from the local carriers and the designated carrier;
- (4) The participating CAP physician who requested the suspension, if any; and
- (5) Legal counsel.

(B) The hearing will be conducted by the hearing officer, who will receive relevant testimony;

(C) Testimony and other evidence may be accepted by the hearing officer even though it would be inadmissible under the rules of evidence applied in Federal courts;

(D) Either party may call witnesses from among those individuals specified in the paragraph (c)(7)(ii)(A) of this section; and

(E) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(8) *Hearing officer's findings.* (i) Within 30 days of the hearing officer's receipt of the hearing request, the hearing officer will present the findings and recommendations to the approved CAP vendor that requested the reconsideration. If the hearing officer conducts a hearing in person or by phone, the hearing officer will send a hearing notice to the approved CAP vendor within 10 days of receipt of the hearing request, and the findings and recommendations are due to the approved CAP vendor within 30 days from of the hearing's conclusion.

(ii) The written report of the hearing officer will include separate numbered findings of fact and the legal conclusions of the hearing officer.

(9) *Final reconsideration determination.*

(i) The hearing officer's decision is final unless the Director of the CMS Center for Medicare Management or his or her designee (CMS official) chooses to review that decision within 30 days. If the decision is favorable to the approved CAP vendor, then the approved CAP vendor may resume participation in CAP. The hearing officer

and the CMS official may review decisions that are favorable or unfavorable to the approved CAP vendor.

(ii) The CMS official may accept, reject, or modify the hearing officer's findings.

(iii) If the CMS official reviews the hearing officer's decision, the CMS official will issue a final reconsideration determination to the approved CAP vendor on the basis of the hearing officer's findings and recommendations and other relevant information.

(iv) The reconsideration determination of the CMS official is final.

(d) *CAP participating physicians' exigent circumstances provision.* The following process must be completed for participating CAP physicians' requests to terminate their participation in the program under exigent circumstances provisions described in §414.908(a)(2)(v):

(1) The designated carrier must—

(i) Determine whether a request to terminate CAP participation was related to approved CAP vendor service, and if so, forward the issue to the approved CAP vendor's grievance process within 1 business day of the receipt of the request; or

(ii) Continue to investigate, consistent with §414.916(b)(2) of this chapter, and within 2 business days of receipt, do any of the following:

(A) Request a single, 2-business day extension. No later than the end of any 2-business day extension, the designated carrier must make findings and a recommendation as provided in subparagraph (B) or (C).

(B) Submit a recommendation and relevant findings to CMS that the requesting participating CAP physician be permitted to terminate his or her participation in the CAP.

(C) Submit a recommendation and relevant findings to CMS that the requesting participating CAP physician not be permitted to terminate his or her participation in the CAP.

(ii) In the case of a request made under §414.908(a)(2)(v)(B), the designated carrier also shall include in its recommendation its finding with respect to whether the request is based on a change in circumstances of which the participating CAP physician was previously unaware.

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(2) CMS will consider the carrier's findings and recommendation and may also make its own findings. As a result, CMS will—

(i) Approve or deny the request to terminate participation in the CAP within 2 business days of receipt of the recommendation.

(ii) Communicate the decision to the appropriate Medicare contractors and the participating CAP physician.

(3) A denial of the participating CAP physician's request to terminate participation in the CAP must include written notification of the right to request reconsideration under § 414.916(c).

(4) Upon termination of participation in the CAP a physician must—

(i) Continue to submit claims for drugs supplied and administered under the CAP prior to the effective date of the physician's termination from the CAP consistent with § 414.908(a) until all such claims are timely submitted.

(ii) Return any unused CAP drugs that had not been administered to the beneficiary prior to the effective date of the physician's termination from the CAP to the approved CAP vendor consistent with applicable law and regulation and any agreement with the approved CAP vendor.

(iii) Cooperate in any post-payment review activities on claims submitted under the CAP, as required under section 1847B(a)(3) of the Act.

(5) An approved CAP vendor that has billed and been paid for CAP drugs that have not been administered must refund any payments made by CMS or the beneficiary and his or her supplemental insurer in accordance with § 414.914(h)(3)(i)(2) of this chapter.

[70 FR 39098, July 6, 2005, as amended at 72 FR 66403, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

#### § 414.918 Assignment.

Payment for a CAP drug may be made only on an assignment-related basis.

[70 FR 39099, July 6, 2005]

#### § 414.920 Judicial review.

The following areas under the CAP are not subject to administrative or judicial review:

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(a) The establishment of payment amounts.

(b) The awarding of vendor contracts.

(c) The establishment of competitive acquisition areas.

(d) The selection of CAP drugs.

(e) The bidding structure.

(f) The number of vendors selected.

[70 FR 39099, July 6, 2005]

#### § 414.930 Compendia for determination of medically-accepted indications for off-label uses of drugs and biologicals in an anti-cancer chemotherapeutic regimen.

(a) *Definitions.* For the purposes of this section:

*Compendium* means a comprehensive listing of FDA-approved drugs and biologicals or a comprehensive listing of a specific subset of drugs and biologicals in a specialty compendium, for example a compendium of anti-cancer treatment. A compendium—

(i) Includes a summary of the pharmacologic characteristics of each drug or biological and may include information on dosage, as well as recommended or endorsed uses in specific diseases.

(ii) Is indexed by drug or biological.

(iii) Has a publicly transparent process for evaluating therapies and for identifying potential conflicts of interests.

*Publicly transparent process for evaluating therapies* means that the process provides that the following information from an internal or external request for inclusion of a therapy in a compendium are available to the public for a period of not less than 5 years, which includes availability on the compendium's Web site for a period of not less than 3 years, coincident with the compendium's publication of the related recommendation:

(i) The internal or external request for listing of a therapy recommendation including criteria used to evaluate the request.

(ii) A listing of all the evidentiary materials reviewed or considered by the compendium pursuant to the request.

(iii) A listing of all individuals who have substantively participated in the review or disposition of the request.

(iv) Minutes and voting records of meetings for the review and disposition of the request.

*Publicly transparent process for identifying potential conflicts of interests* means that process provides that the following information is identified and made timely available in response to a public request for a period of not less than 5 years, coincident with the compendium's publication of the related recommendation:

(i) Direct or indirect financial relationships that exist between individuals or the spouse or minor child of individuals who have substantively participated in the development or disposition of compendia recommendations and the manufacturer or seller of the drug or biological being reviewed by the compendium. This may include, for example, compensation arrangements such as salary, grant, contract, or collaboration agreements between individuals or the spouse or minor child of individuals who have substantively participated in the review and disposition of the request and the manufacturer or seller of the drug or biological being reviewed by the compendium.

(ii) Ownership or investment interests between individuals or the spouse or minor child of individuals who have substantively participated in the development or disposition of compendia recommendations and the manufacturer or seller of the drug or biological being reviewed by the compendium.

(b) *Process for listing compendia for determining medically-accepted uses of drugs and biologicals in anti-cancer treatment.* (1) The CMS process—

(i) Receives formal written requests for changes to the list of compendia during a 30 day window beginning January 15 each year.

(ii) Publishes a listing of the timely, complete requests by March 15th and solicits public comment on the requests for 30 days. The listing identifies the requestor and the requested action.

(iii) Considers a compendium's attainment of the MedCAC (Medicare Evidence Development and Coverage Advisory Committee, previously known as the MCAC—Medicare Coverage Advisory Committee) recommended desir-

able characteristics of compendia (including explicit listing and recommendations) in reviewing requests. CMS may consider additional reasonable factors.

(iv) Considers a compendium's grading of evidence used in making recommendations regarding off-label uses and the process by which the compendium grades the evidence.

(v) Considers whether the publication that is the subject of the request meets the definition of a compendium in this section.

(vi) Publishes its decision no later than 90 days after the close of the public comment period.

(2) *Exception.* In addition to the annual process outlined in paragraph (b)(1) of this section, CMS may internally generate a request for changes to the list of compendia at any time.

(c) *Written request for review.* (1) CMS will review a complete, written request that is submitted in writing, electronically or via hard copy (no duplicate submissions) and includes the following:

(i) The full name and contact information of the requestor.

(ii) The full identification of the compendium that is the subject of the request, including name, publisher, edition if applicable, date of publication, and any other information needed for the accurate and precise identification of the specific compendium.

(iii) A complete written copy of the compendium that is the subject of the request.

(iv) The specific action that is requested of CMS.

(v) Materials that the requestor must submit for CMS review in support of the requested action.

(vi) A single compendium as its subject.

(d) CMS may at its discretion combine and consider multiple requests that refer to the same compendium.

(e) For the purposes of this section, publication by CMS may be accomplished by posting on the CMS Web site.

[72 FR 66404, Nov. 27, 2007, as amended at 74 FR 62013, Nov. 25, 2009]

**§ 414.940 Refund for certain discarded single-dose container or single-use package drugs.**

(a) *Provision of information to manufacturers*—(1) *In general.* For each calendar quarter beginning on or after January 1, 2023, CMS reports to each manufacturer (as defined in § 414.802) of a refundable single-dose container or single-use package drug the following for the calendar quarter:

(i) Information on the total number of billing units of the billing and payment code of such drug, if any, that were discarded during such quarter, as determined by the JW modifier (or any successor modifier that includes the same data).

(ii) The refund amount that the manufacturer is liable for pursuant to paragraph (a)(3) of this section.

(iii) Reports will include information in paragraphs (a)(1)(i) and (ii) of this section for new refund quarters and updated refund quarters (as defined at § 414.902).

(iv) For purposes of this section, the term billing unit means the identifiable quantity associated with a billing and payment code, as established by CMS.

(2) *Exclusion of units of packaged drugs.* The total number of billing units of the billing and payment code of a refundable single-dose container or single-use package drug of a manufacturer furnished during a calendar quarter for purposes of paragraph (a)(1) of this section, and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (c)(2) of this section, shall not include such units that are packaged into the payment amount for an item or service and are not separately payable.

(3) *Report Timing.* Reports are sent once annually.

(b) *Manufacturer requirement.* For each calendar quarter beginning on or after January 1, 2023, the manufacturer of a refundable single-dose container or single-use package drug shall, for such drug, pay a refund that is equal to the amount determined in accordance with paragraph (c) of this section for such drug for such quarter.

(1) Refund amounts for which the manufacturer is liable, pursuant to

this paragraph, must be paid by December 31 of the year in which the report described in paragraph (a) of this section is sent, except that refund amounts for which the manufacturer is liable, pursuant to this paragraph, for amounts in the initial report for calendar quarters in 2023 must be paid no later than February 28, 2025.

(2) In the case that a disputed report results in a refund amount due, refund amounts that the manufacturer is liable for pursuant to this paragraph shall be paid no later than the dates specified in paragraph (b)(1) of this section or 30 days following the resolution of the dispute, whichever is later.

(3) Amounts paid as refunds pursuant to this paragraph shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act.

(c) *Refund amount.* The amount of the refund specified in this paragraph is with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code (except as provided in paragraph (c)(4) of this section) for:

(1) A new refund quarter (as defined at § 414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

(i) The product of the total number of units of the billing and payment code for such drug that were discarded during such new refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such new refund quarter;

(ii) Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such drug for the new refund quarter.

(2) The refund amount owed by a manufacturer for an updated refund quarter (as defined at § 414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

(i) The product of the total number of units of the billing and payment code for such drug that were discarded during such updated refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter.

(ii) Exceeds the difference of:

(A) An amount equal to the applicable percentage of the estimated total allowed charges for such a drug during the updated refund quarter; and

(B) The refund amount already paid for such refundable drug for such quarter.

(3) Negative refund amount for an updated refund quarter. If the refund amount described in paragraph (c)(2) of this section is negative, the amount will be netted from refunds owed for other updated and new refund quarters included in the same report as such updated refund quarter.

(4) Exception when there are multiple manufacturers. If there is more than one manufacturer of a refundable single-dose container or single-use package drug for a quarter, the refund amount for which a manufacturer is liable is an amount equal to the estimated amount (if any) by which—

(i) The product of the amount calculated in paragraph (c)(1) of this section and the percentage of billing unit sales (of the applicable billing and payment code attributed to the National Drug Code; exceeds:

(ii) The product of the amount in paragraph (c)(2) of this section and percentage of billing unit sales of the applicable billing and payment code attributed to the National Drug Code.

(iii) The number of billing unit sales for each NDC is the reported number of NDCs sold (as submitted in the ASP report to CMS each quarter) multiplied by the billing units per package for such NDC.

(d) *Applicable percentage.* For purposes of paragraph (c) of this section, and except as provided in paragraph (e) of this section, the applicable percentage is:

(1) 10 percent, unless specified otherwise in this section.

(2) 35 percent for a drug that is constituted with a hydrogel and has variable dosing based on patient-specific characteristics.

(3) 90 percent for a drug with a low volume dose (as defined at §414.902) contained within 0.1 mL or less.

(4) 45 percent for a drug with a low volume dose (as defined in §414.902) contained within 0.11 mL up to 0.4 mL.

(5) 26 percent for a drug designated an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition (or diseases or conditions) and approved by the FDA only for one or more indications within such designated rare disease or condition (or diseases or conditions) and is furnished to fewer than 100 unique beneficiaries per calendar year. A drug is furnished to fewer than 100 unique beneficiaries per calendar year when one of the following two conditions is met:

(i) The number of unique beneficiaries to whom the drug is furnished is less than 100 during the calendar year in which the refund quarter occurs; or

(ii) Either:

(A) In the case of a drug for which 3 or more years of data is available, the average of unique beneficiaries per year to whom the drug is furnished during the calendar year in which the refund quarter occurs and the 2 previous calendar years is less than 100; or

(B) In the case of a drug for which at least 2 but less than 3 years of data is available, the average of unique beneficiaries per year to whom the drug is furnished during the calendar year in which the refund quarter occurs and the previous calendar year is less than 100.

(e) *Application process for increased applicable percentage.* Manufacturers may submit an application to CMS requesting consideration of an increased applicable percentage for purposes of paragraph (c) of this section because of the drug's unique circumstances. The process for submitting such an application is as follows:

(1) *Application.* An application must include:

(i) A written request that a drug be considered for an increased applicable percentage based on its unique circumstances;

(ii) FDA-approved labeling for the drug, or, if the drug is not approved by the February 1 application deadline described in paragraph (e)(2) of this section, documentation of FDA acceptance of the application for review;

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(iii) Justification for the consideration of an increased applicable percentage based on such unique circumstances; and

(iv) Justification for the requested applicable percentage.

(2) *Application timeline.* An application must be submitted in a form and manner specified by CMS by February 1 of the calendar year prior to the year the increased applicable percentage would apply. An application for a drug that is not FDA-approved by February 1 must have FDA approval by August 1 and the manufacturer must notify and submit the FDA-approved label to CMS by September 1 of the calendar year prior to the year the increased applicable percentage would apply.

(3) *Application processing.* Following a review of timely applications, CMS will summarize its analyses of applications and propose appropriate increases in rulemaking. If adopted, the increased applicable percentage will be the applicable percentage for purposes of paragraph (c) of this section beginning as of the following January 1.

(f) *Dispute resolution.* Each manufacturer has an opportunity to dispute information in the report described in paragraph (a) of this section by submitting an error report as described in this paragraph.

(1) *Error report information.* To assert that there have been one or more errors in the report, a manufacturer must submit a dispute with each asserted error and provide the following information—

(i) Manufacturer name and address;

(ii) The name, telephone number, and email address of one or more employees or representatives of the manufacturer.

(iii) For a mathematical calculation error, the specific calculation element(s) that the manufacturer disputes and its proposed corrected calculation;

(iv) For any other asserted error, an explanation of the nature of the error, how the error affects the refund calculation, an explanation of why the manufacturer believes that an error occurred, the proposed correction to the error, and an explanation of why CMS should use the proposed corrected data.

(2) *Form, manner, and timing of submission.* Each manufacturer asserting an

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error must submit its error report(s), in the form and manner specified by CMS, within 30-days after the issuance of the report.

(g) *Enforcement—(1) Manufacturer audits.* Each manufacturer of a refundable single-dose container or single-use package drug that is required to provide a refund under this section shall be subject to periodic audit with respect to such drug and such refunds.

(2) *Civil money penalty.* The Secretary shall impose a civil money penalty on a manufacturer of a refundable single-dose container or single-use package drug who has failed to comply with the requirement under paragraph (b) of this section for such drug for a calendar quarter in an amount equal to the sum of—

(i) The amount that the manufacturer would have paid under such paragraph with respect to such drug for such quarter; and

(ii) 25 percent of such amount.

[87 FR 70226, Nov. 18, 2022, as amended at 88 FR 15920, Mar. 15, 2023; 88 FR 79532, Nov. 16, 2023]

### Subpart L—Supplying and Dispensing Fees

#### § 414.1000 Purpose.

This subpart implements section 1842(o)(2) and section 1842(o)(6) of the Act, as added by section 303(e)(2) of the MMA, by specifying a supplying fee for drugs and biologicals covered under Part B of Title XVIII of the Act that are described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

[69 FR 66425, Nov. 15, 2004]

#### § 414.1001 Basis of payment.

(a) *Supplying fees.* Beginning in CY 2006—

(1) A supplying fee of \$24 is paid to a pharmacy for the first prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act, that the pharmacy provided to a beneficiary during a 30-day period.

(2) A supplying fee of \$16 is paid to a pharmacy for each prescription following the first prescription (as specified in paragraph (a)(1) of this section)