

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.

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

§ 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.

(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) For other exigent circumstances defined by CMS.

(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

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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 14 calendar days of the date of drug administration;

(xi) Agrees to submit an appeal accompanied by all required documentation (such as medical records or a certification) necessary to support payment if the participating CAP physician's drug administration claim for a CAP drug is denied;

(xii) Agrees not to transport CAP drugs from one practice location (place of service) to another location;

(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).

(5) *Additional opt out provision.* In addition to the circumstances listed in paragraph (a)(2) of this section, if the approved CAP vendor refuses to ship to the participating CAP physician because the conditions of § 414.914(h) were met, the physician can withdraw from the CAP category for the remainder of

the year immediately upon notice to CMS and the approved CAP vendor.

(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:

(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]

§ 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:

(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 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.