§ 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) 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).
   (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
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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 payment for a CAP drug that the approved CAP vendor has not been contracted to furnish under the CAP.

(iv) Customer service/Grievance process.

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

(vi) Financial performance and solvency.

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

(viii) Internal financial controls.

(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.

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