

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]

**§414.917 Dispute resolution and process for suspension or termination of approved CAP contract.**

(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.

(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.

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

[70 FR 39098, July 6, 2005]

### § 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:

(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]

## 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) 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 phar-

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macy provided to a beneficiary during a 30-day period.

(3) A separate supplying fee is paid to a pharmacy for each prescription of drugs and biologicals described in sections 1861(s)(2)(J), 1861(s)(2)(Q), and 1861(s)(2)(T) of the Act.

(b) *Supplying fees following transplant.* Beginning CY 2006—(1) A supplying fee of \$50 is paid to pharmacy for the initial supplied prescription of drugs and biologicals described in section 1861(s)(2)(J) of the Act, that the pharmacy provided to a patient during the first 30-day period following a transplant.

(2) A supplying fee of \$16 is paid to a pharmacy for each prescription following an initial prescription after a transplant (as specified in paragraph (b)(1) of this section) of drugs and biologicals describe in section 1861(s)(2)(J) of the Act, that the pharmacy provided to a beneficiary during a 30-day period.

(c) *30-day dispensing fees.* Beginning CY 2006—(1) A dispensing fee of \$57 is paid to a supplier to the extent that the prescription is for the initial dispensed 30-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 30-day supply.

(2) Except for supplied inhalation drugs that meet criteria described in paragraph (c)(1) of this section, a dispensing fee of \$33 is paid for each dispensed 30-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 30-day supply.

(d) *90-day dispensing fee.* Beginning CY 2006, a dispensing fee of \$66 is paid to a supplier for each dispensed 90-day supply of inhalation drugs furnished through durable medical equipment covered under section 1861(n) of the Act, regardless of the number of partial shipments of that 90-day supply.

[70 FR 70334, Nov. 21, 2005]