

(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.

■ 36. Section 414.930 is added to subpart K to read as follows:

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

(a) *Definition.* For 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 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. A compendium is indexed by drug or biological.

(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 desirable 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) 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.

■ 37. Subpart M is added to read as follows:

Subpart M—Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) Services

§ 414.1100 Basis and Scope.

This subpart implements sections 1834(k)(1) and (k)(3) of the Act by

specifying the payment methodology for comprehensive outpatient rehabilitation facility services covered under Part B of Title XVIII of the Act that are described at section 1861(cc)(1) of the Act.

§ 414.1105 Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) Services.

(a) *Payment under the physician fee schedule.* Except as otherwise specified under paragraphs (b), (c), (d), and (e) of this section payment for CORF services, as defined under § 410.100 of this chapter, is paid the lesser of 80 percent of the following:

(1) The actual charge for the item or service; or

(2) The nonfacility amount determined under the physician fee schedule established under section 1848(b) of the Act for the item or service.

(b) *Payment for physician services.* No separate payment for physician services that are CORF services under § 410.100(a) of this chapter will be made.

(c) *Payment for supplies and durable medical equipment, prosthetic and orthotic devices, and drugs and biologicals.* Supplies and durable medical equipment that are CORF services under § 410.100(l) of this chapter, prosthetic device services that are CORF services under § 410.100(f), orthotic devices that are CORF services under § 410.100(g) of this chapter and drugs and biologicals that are CORF services under § 410.100(k) of this chapter are paid the lesser of 80 percent of the following:

(1) The actual charge for the service provided that payment for such item is not included in the payment amount for other CORF services paid under paragraphs (a) or (d); or

(2) The amount determined under the DMEPOS fee schedule established under part 414 subparts D and F for the item or the single payment amount established under the DMEPOS competitive bidding program provided that payment for such item is not included in the payment amount for other CORF services paid under paragraphs (a) or (d).

(d) *Payment for drugs and biologicals.* Drugs and biologicals that are CORF services under § 410.100(j) of this chapter, are paid the lesser of 80 percent of the following:

(1) The actual charge for the service provided that payment for such item is not included in the payment amount for other CORF services paid under paragraphs (a) or (c); or

(2) The amount determined using the same methodology for drugs (as defined