

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 updated 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.*

* * *

(f) * * *

(2) * * *

(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) * * *

(iv) In the case of additions requested under paragraph (f)(2)(v) of this section, address and document the need for such an expansion based on demand for the product(s).

* * *

(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.

■ 23. Section 414.908 is amended by revising paragraph (a)(3)(xii) to read as follows:

§ 414.908 Competitive acquisition program.

(a) * * *

(3) * * *

(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.

* * *

■ 24. Section 414.914 is amended by revising paragraph (f)(12) to read as follows:

§ 414.914 Terms of contract.

* * *

(f) * * *

(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;

* * *

■ 25. Section 414.916 is amended by—

■ A. Redesignating paragraph (b)(4) as (b)(5).

■ B. Adding new paragraph (b)(4).

The addition reads as follows:

§ 414.916 Dispute resolution for vendors and beneficiaries.

* * *

(b) * * *

(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.

* * *

■ 26. Section 414.917 is amended by revising paragraph (b)(4) to read as follows:

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

* * *

(b) * * *

(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.

* * *

■ 27. Section 414.930 is amended by—

■ A. Revising paragraph (a).

■ B. Redesignating paragraph (b)(1)(v) as paragraph (b)(1)(vi).

■ C. Adding new paragraph (b)(1)(v).

The revision and addition 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) *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) * * *

(1) * * *

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

* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 28. The authority citation for part 415 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart D—Physician Services in Teaching Settings

■ 29. Section 415.178 is revised to read as follows:

§ 415.178 Anesthesia services.

(a) General rule. (1) For services furnished prior to January 1, 2010, an unreduced physician fee schedule payment may be made if a physician is involved in a single anesthesia procedure involving an anesthesia resident. In the case of anesthesia services, the teaching physician must be present during all critical portions of the procedure and immediately available to furnish services during the entire service or procedure. The teaching physician cannot receive an unreduced fee if he or she performs services involving other patients during the period the anesthesia resident is furnishing services in a single case. Additional rules for payment of anesthesia services involving residents are specified in § 414.46(c)(1)(iii) of this chapter.

(2) For services furnished on or after January 1, 2010, payment made under § 414.46(e) of this chapter if the teaching anesthesiologist (or different teaching anesthesiologists in the same anesthesia group practice) is present during all critical or key portions of the anesthesia service or procedure involved; and the teaching anesthesiologist (or another anesthesiologist with whom the teaching anesthesiologist has entered into an arrangement) is immediately available to furnish anesthesia services during the entire procedure.

(b) Documentation. Documentation must indicate the teaching physician's presence during all critical or key portions of the anesthesia procedure and the immediate availability of another teaching anesthesiologist.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 30. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

Subpart B—Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities

■ 31. Section 485.70 is amended by revising paragraph (j) to read as follows:

§ 485.70 Personnel qualifications.

* * * * *

(j) A respiratory therapist must complete one the following criteria:

(1) Criterion 1. All of the following must be completed:

(i) Be licensed by the State in which practicing, if applicable.

(ii) Have successfully completed a nationally-accredited educational program for respiratory therapists.

(iii)(A) Be eligible to take the registry examination administered by the National Board for Respiratory Care for respiratory therapists; or

(B) Have passed the registry examination administered by the National Board for Respiratory Care for respiratory therapists.

(2) Criterion 2: All of the following must be completed:

(i) Be licensed by the State in which practicing, if applicable.

(ii) Have equivalent training and experience as determined by the National Board for Respiratory Care.

* * * * *

PART 498—APPEALS PROCEDURES FOR DETERMINATIONS THAT AFFECT PARTICIPATION IN THE MEDICARE PROGRAM AND FOR DETERMINATIONS THAT AFFECT THE PARTICIPATION OF ICFs/MR AND CERTAIN NFs IN THE MEDICAID PROGRAM

■ 32. The authority citation for part 498 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart A—General Provisions

■ 33. Section 498.2 is amended by adding paragraph (13) to the definition of "supplier" to read as follows:

§ 498.2 Definitions.

* * * * *

Supplier * * *

(13) A site approved by CMS to furnish intensive cardiac rehabilitation services.

Authority: Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program.

Dated: October 26, 2009.

Charlene Frizzera,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 29, 2009.

Kathleen Sebelius,

Secretary.

Note: These addenda will not appear in the Code of Federal Regulations.

Addendum A: Explanation and Use of Addendum B

The addenda on the following pages provide various data pertaining to the Medicare fee schedule for physicians' services furnished in 2010. Addendum