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(ii) Continue to investigate, consistent with §414.916(b)(2) of this chapter, and within 2 business days of receipt, do any of the following:

(A) Request a single, 2-business day extension. No later than the end of any 2-business day extension, the designated carrier must make findings and a recommendation as provided in subparagraph (B) or (C).

(B) Submit a recommendation and relevant findings to CMS that the requesting participating CAP physician not be permitted to terminate his or her participation in the CAP.

(C) Submit a recommendation and relevant findings to CMS that the requesting participating CAP physician not be permitted to terminate his or her participation in the CAP.

(ii) In the case of a request made under §414.908(a)(2)(v)(B), the designated carrier also shall include in its recommendation its finding with respect to whether the request is based on a change in circumstances of which the participating CAP physician was previously unaware.

(2) CMS will consider the carrier's findings and recommendation and may also make its own findings. As a result, CMS will—

(i) Approve or deny the request to terminate participation in the CAP within 2 business days of receipt of the recommendation.

(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 regula-

tion 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.

[70 FR 39098, July 6, 2005, as amended at 72 FR 66403, Nov. 27, 2007; 74 FR 62013, Nov. 25, 2009]

§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]

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

(vi) 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.

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(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.

[72 FR 66404, Nov. 27, 2007, as amended at 74 FR 62013, Nov. 25, 2009]

§ 414.940 Refund for certain discarded single-dose container or single-use package drugs.

(a) *Provision of information to manufacturers*—(1) *In general.* For each calendar quarter beginning on or after January 1, 2023, CMS reports to each manufacturer (as defined in § 414.802) of a refundable single-dose container or single-use package drug the following for the calendar quarter:

(i) Information on the total number of billing units of the billing and payment code of such drug, if any, that were discarded during such quarter, as determined by the JW modifier (or any successor modifier that includes the same data).

(ii) The refund amount that the manufacturer is liable for pursuant to paragraph (a)(3) of this section.

(iii) For purposes of this section, the term billing unit means the identifiable quantity associated with a billing and payment code, as established by CMS.

(2) *Exclusion of units of packaged drugs.* The total number of billing units of the billing and payment code of a refundable single-dose container or single-use package drug of a manufacturer furnished during a calendar quarter for

purposes of paragraph (a)(1) of this section, and the determination of the estimated total allowed charges for the drug in the quarter for purposes of paragraph (c)(2) of this section, shall not include such units that are packaged into the payment amount for an item or service and are not separately payable.

(3) *Reports.* Reports are sent once annually.

(b) *Manufacturer requirement.* For each calendar quarter beginning on or after January 1, 2023, the manufacturer of a refundable single-dose container or single-use package drug shall, for such drug, pay a refund that is equal to the amount determined in accordance with paragraph (c) of this section for such drug for such quarter.

(1) Refund amounts that the manufacturer is liable for pursuant to this paragraph are paid in 12-month intervals, in a manner specified by CMS.

(2) In the case that a disputed report results in a refund amount due, refund amounts that the manufacturer is liable for pursuant to this paragraph shall be paid no later than 30 days following the resolution of the dispute.

(3) Amounts paid as refunds pursuant to this paragraph shall be deposited into the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Act.

(c) *Refund amount.* The amount of the refund specified in this paragraph is, with respect to a refundable single-dose container or single-use package drug of a manufacturer assigned to a billing and payment code for a calendar quarter beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which—

(1) The product of:

(i) The total number of units of the billing and payment code for such drug that were discarded during such quarter; and

(ii) The amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such quarter.

(2) Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such drug for the quarter.