

§ 414.423 Appeals process for breach of a DMEPOS competitive bidding program contract actions.

This section implements an appeals process for suppliers that CMS has determined are in breach of their Medicare DMEPOS Competitive Bidding Program contract and where CMS has issued a notice of breach of contract indicating its intent to take action(s) pursuant to § 414.422(g)(2).

(a) *Breach of contract.* CMS may take one or more of the actions specified in § 414.422(g)(2) as a result of a supplier's breach of their DMEPOS Competitive Bidding Program contract.

(b) *Notice of breach of contract—(1) CMS notification.* If CMS determines a supplier to be in breach of its contract, it will notify the supplier of the breach of contract in a notice of breach of contract.

(2) *Content of the notice of breach of contract.* The CMS notice of breach of contract will include the following:

(i) The details of the breach of contract.

(ii) The action(s) that CMS is taking as a result of the breach of the contract pursuant to § 414.422(g)(2), and the duration of or timeframe(s) associated with the action(s), if applicable.

(iii) The right to request a hearing by a CBIC hearing officer and, depending on the nature of the breach, the supplier may also be allowed to submit a corrective action plan (CAP) in lieu of requesting a hearing by a CBIC hearing officer, as specified in paragraph (c)(1)(i) of this section.

(iv) The address to which the written request for a hearing must be submitted.

(v) The address to which the CAP must be submitted, if applicable.

(vi) The effective date of the action(s) that CMS is taking is the date specified by CMS in the notice of breach of contract, or 45 days from the date of the notice of breach of contract unless:

(A) A timely hearing request has been filed; or

(B) A CAP has been submitted within 30 days of the date of the notice of breach of contract where CMS allows a supplier to submit a CAP.

(c) *Corrective action plan (CAP)—(1) Option for a CAP.* (i) CMS has the op-

tion to allow a supplier to submit a written CAP to remedy the deficiencies identified in the notice at its sole discretion, including where CMS determines that the delay in the effective date of the breach of contract action(s) caused by allowing a CAP will not cause harm to beneficiaries. CMS will not allow a CAP if the supplier has been excluded from any Federal program, debarred by a Federal agency, or convicted of a healthcare-related crime, or for any other reason determined by CMS.

(ii) If a supplier chooses not to submit a CAP, if CMS determines that a supplier's CAP is insufficient, or if CMS does not allow the supplier the option to submit a CAP, the supplier may request a hearing on the breach of contract action(s).

(2) *Submission of a CAP.* (i) If allowed by CMS, a CAP must be submitted within 30 days from the date on the notice of breach of contract. If the supplier decides not to submit a CAP the supplier may, within 30 days of the date on the notice, request a hearing by a CBIC hearing officer.

(ii) Suppliers will have the opportunity to submit a CAP when they are first notified that they have been determined to be in breach of contract. If the CAP is not acceptable to CMS or is not properly implemented, suppliers will receive a subsequent notice of breach of contract. The subsequent notice of breach of contract may, at CMS' discretion, allow the supplier to submit another written CAP pursuant to paragraph (c)(1)(i) of this section.

(d) *The purpose of the CAP.* The purpose of the CAP is:

(1) For the supplier to remedy all of the deficiencies that were identified in the notice of breach of contract.

(2) To identify the timeframes by which the supplier will implement each of the components of the CAP.

(e) *Review of the CAP.* (1) The CBIC will review the CAP. Suppliers may only revise their CAP one time during the review process based on the deficiencies identified by the CBIC. The CBIC will submit a recommendation to CMS for each applicable breach of contract action concerning whether the CAP includes the steps necessary to remedy the contract deficiencies as

identified in the notice of breach of contract.

(2) If CMS accepts the CAP, including the supplier's designated timeframe for its completion, the supplier must provide a follow-up report within 5 days after the supplier has fully implemented the CAP that verifies that all of the deficiencies identified in the CAP have been corrected in accordance with the timeframes accepted by CMS.

(3) If the supplier does not implement a CAP that was accepted by CMS, or if CMS does not accept the CAP submitted by the supplier, then the supplier will receive a subsequent notice of breach of contract, as specified in paragraph (b) of this section.

(f) *Right to request a hearing by the CBIC Hearing Officer.* (1) A supplier who receives a notice of breach of contract (whether an initial notice of breach of contract or a subsequent notice of breach of contract under § 414.422(e)(3)) has the right to request a hearing before a CBIC hearing officer who was not involved with the original breach of contract determination.

(2) A supplier that wishes to appeal the breach of contract action(s) specified in the notice of breach of contract must submit a written request to the CBIC. The request for a hearing must be submitted to the CBIC within 30 days from the date of the notice of breach of contract.

(3) A request for hearing must be in writing and submitted by an authorized official of the supplier.

(4) The appeals process for the Medicare DMEPOS Competitive Bidding Program is not to be used in place of other existing appeals processes that apply to other parts of Medicare.

(5) If the supplier is given the opportunity to submit a CAP and a CAP is not submitted and the supplier fails to timely request a hearing, the breach of contract action(s) will take effect 45 days from the date of the notice of breach of contract.

(g) *The CBIC Hearing Officer schedules and conducts the hearing.* (1) Within 30 days from the receipt of the supplier's timely request for a hearing the hearing officer will contact the parties to schedule the hearing.

(2) The hearing may be held in person or by telephone at the parties' request.

(3) The scheduling notice to the parties must indicate the time and place for the hearing and must be sent to the parties at least 30 days before the date of the hearing.

(4) The hearing officer may, on his or her own motion, or at the request of a party, change the time and place for the hearing, but must give the parties to the hearing 30 days' notice of the change.

(5) The hearing officer's scheduling notice must provide the parties to the hearing the following information:

(i) A description of the hearing procedure.

(ii) The specific issues to be resolved.

(iii) The supplier has the burden to prove it is not in violation of the contract or that the breach of contract action(s) is not appropriate.

(iv) The opportunity for parties to the hearing to submit additional evidence to support their positions, if requested by the hearing officer.

(v) A notification that all evidence submitted, both from the supplier and CMS, will be provided in preparation for the hearing to all affected parties at least 15 days prior to the scheduled date of the hearing.

(h) *Burden of proof and evidence submission.* (1) The burden of proof is on the Competitive Bidding Program contract supplier to demonstrate to the hearing officer with convincing evidence that it has not breached its contract or that the breach of contract action(s) is not appropriate.

(2) The supplier's evidence must be submitted with its request for a hearing.

(3) If the supplier fails to submit the evidence at the time of its submission, the Medicare DMEPOS supplier is precluded from introducing new evidence later during the hearing process, unless permitted by the hearing officer.

(4) CMS also has the opportunity to submit evidence to the hearing officer within 10 days of receiving the scheduling notice.

(5) The hearing officer will share all evidence submitted by the supplier and/or CMS, with all parties to the hearing at least 15 days prior to the scheduled date of the hearing.

(i) *Role of the hearing officer.* The hearing officer will conduct a thorough

and independent review of the evidence including the information and documentation submitted for the hearing and other information that the hearing officer considers pertinent for the hearing. The role of the hearing officer includes, at a minimum, the following:

(1) Conduct the hearing and decide the order in which the evidence and the arguments of the parties are presented;

(2) Determine the rules on admissibility of the evidence;

(3) Examine the witnesses, in addition to the examinations conducted by CMS and the contract supplier;

(4) The CBIC may assist CMS in the appeals process including being present at the hearing, testifying as a witness, or performing other, related ministerial duties;

(5) Determine the rules for requesting documents and other evidence from other parties;

(6) Ensure a complete record of the hearing is made available to all parties to the hearing;

(7) Prepare a file of the record of the hearing which includes all evidence submitted as well as any relevant documents identified by the hearing officer and considered as part of the hearing; and

(8) Comply with all applicable provisions of Title 18 and related provisions of the Act, the applicable regulations issued by the Secretary, and manual instructions issued by CMS.

(j) *Hearing officer recommendation.* (1) The hearing officer will issue a written recommendation(s) to CMS within 30 days of the close of the hearing unless an extension has been granted by CMS because the hearing officer has demonstrated that an extension is needed due to the complexity of the matter or heavy workload. In situations where there is more than one breach of contract action presented at the hearing, the hearing officer will issue separate recommendations for each breach of contract action.

(2) The recommendation(s) will explain the basis and the rationale for the hearing officer's recommendation(s).

(3) The hearing officer must include the record of the hearing, along with all evidence and documents produced

during the hearing along with its recommendation(s).

(k) *CMS' final determination.* (1) CMS' review of the hearing officer's recommendation(s) will not allow the supplier to submit new information.

(2) After reviewing the hearing officer's recommendation(s), CMS' decision(s) will be made within 30 days from the date of receipt of the hearing officer's recommendation(s). In situations where there is more than one breach of contract action presented at the hearing, and the hearing officer issues multiple recommendations, CMS will render separate decisions for each breach of contract action.

(3) A notice of CMS' decision will be sent to the supplier and the hearing officer. The notice will indicate:

(i) If any breach of contract action(s) included in the notice of breach of contract, specified in paragraph (b)(1) of this section, still apply and will be effectuated, and

(ii) The effective date for any breach of contract action specified in paragraph (k)(3)(i) of this section.

(4) This decision(s) is final and binding.

(l) *Effect of breach of contract action(s)*—(1) *Effect of contract suspension.*

(i) All locations included in the contract cannot furnish competitive bid items to beneficiaries within a CBA and the supplier cannot be reimbursed by Medicare for these items for the duration of the contract suspension.

(ii) The supplier must notify all beneficiaries who are receiving rented competitive bid items or competitive bid items on a recurring basis of the suspension of their contract.

(A) The notice to the beneficiary from the supplier must be provided within 15 days of receipt of the final notice.

(B) The notice to the beneficiary must inform the beneficiary that they must select a new contract supplier to furnish these items in order for Medicare to pay for these items.

(2) *Effect of contract termination.* (i) All locations included in the contract can no longer furnish competitive bid items to beneficiaries within a CBA and the supplier cannot be reimbursed by Medicare for these items after the effective date of the termination.

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(ii) The supplier must notify all beneficiaries, who are receiving rented competitive bid items or competitive bid items received on a recurring basis, of the termination of their contract.

(A) The notice to the beneficiary from the supplier must be provided within 15 days of receipt of the final notice of termination.

(B) The notice to the beneficiary must inform the beneficiary that they are going to have to select a new contract supplier to furnish these items in order for Medicare to pay for these items.

(3) *Effect of preclusion.* A supplier who is precluded will not be allowed to participate in a specific round of the Competitive Bidding Program, which will be identified in the original notice of breach of contract, as specified in paragraph (b)(1) of this section.

(4) *Effect of other remedies allowed by law.* If CMS decides to impose other remedies under § 414.422(g)(2)(iv), the details of the remedies will be included in the notice of breach of contract, as specified in paragraph (b)(2) of this section.

[81 FR 77967, Nov. 4, 2016, as amended at 83 FR 57073, Nov. 14, 2018; 84 FR 60809, Nov. 8, 2019]

§ 414.424 Administrative or judicial review.

(a) There is no administrative or judicial review under this subpart of the following:

(1) Establishment of payment amounts.

(2) Awarding of contracts.

(3) Designation of CBAs.

(4) Phase-in of the competitive bidding programs.

(5) Selection of items for competitive bidding.

(6) Bidding structure and number of contract suppliers selected for a competitive bidding program.

(b) A denied claim is not appealable if the denial is based on a determination by CMS that a competitively bid item was furnished in a CBA in a manner not authorized by this subpart.

[72 FR 18085, Apr. 10, 2007]

§ 414.425 Claims for damages.

(a) *Eligibility for filing a claim for damages as a result of the termination of sup-*

plier contracts by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). (1) Any aggrieved supplier, including a member of a network that was awarded a contract for the Round 1 Durable Medical Prosthetics, Orthotics, and Supplies Competitive Bidding Program (DMEPOS CBP) that believes it has been damaged by the termination of its competitive bid contract, may file a claim under this section.

(2) A subcontractor of a contract supplier is not eligible to submit a claim under this section.

(b) *Timeframe for filing a claim.* (1) A completed claim, including all documentation, must be filed within 90 days of January 1, 2010 (the effective date of these damages provisions), unless that day is a Federal holiday or Sunday in which case it will fall to the next business day.

(2) The date of filing is the actual date of receipt by the CBIC of a completed claim that includes all the information required by this rule.

(c) *Information that must be included in a claim.* (1) Supplier's name, name of authorized official, U.S. Post Office mailing address, phone number, email address and bidding number, and National Supplier Clearinghouse Number;

(2) A copy of the signed contract entered into with CMS for the Round 1 DMEPOS Competitive Bidding Program;

(3) A detailed explanation of the damages incurred by this supplier as a direct result of the termination of the Round 1 competitive bid contract by MIPPA. The explanation must include all of the following:

(i) Documentation of the supplier's damages through receipts.

(ii) Records that substantiate the supplier's damages and demonstrate that the damages are directly related to performance of the Round 1 contract and are consistent with information the supplier provided as part of their bid.

(4) The supplier must explain how it would be damaged if not reimbursed.

(5) The claim must document steps the supplier took to mitigate any damages they may have incurred due to the