

§ 423.642

the extent a fallback prescription drug plan contract is terminated by CMS.

§ 423.642 Notice of contract determination.

(a) When CMS makes a contract determination under § 423.641, it gives the PDP sponsor written notice.

(b) The notice specifies the—

(1) Reasons for the determination; and

(2) The Part D sponsor's right to request a hearing.

(c) *CMS-initiated terminations*—(1) *General rule.* Except as provided in (c)(2) of this section, CMS mails notice to the Part D plan sponsor 45 calendar days before the anticipated effective date of the termination.

(2) *Exception.* If a contract is terminated in accordance with § 423.509(b)(2)(i) of this part, CMS notifies the Part D plan sponsor of the date that it will terminate the Part D plan sponsor's contract.

(d) When CMS determines that it will not authorize a contract renewal, CMS mails the notice to the Part D sponsor by August 1 of the current contract year.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68733, Dec. 5, 2007; 75 FR 19823, Apr. 15, 2010; 79 FR 29965, May 23, 2014]

§ 423.643 Effect of contract determination.

The contract determination is final and binding unless a timely request for a hearing is filed under 423.651.

[72 FR 68733, Dec. 5, 2007]

§ 423.650 Right to a hearing, burden of proof, standard of proof, and standards of review.

(a) *Right to a hearing.* The following parties are entitled to a hearing:

(1) A contract applicant that has been determined to be unqualified to enter into a contract with CMS under Part D of Title XVIII of the Act in accordance with § 423.502 and § 423.503 of this part.

(2) A Part D sponsor whose contract has been terminated in accordance with § 423.509 of this part.

(3) A Part D sponsor whose contract has not been renewed in accordance with § 423.507 of this part.

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(4) A Part D sponsor who has had an intermediate sanction imposed in accordance with § 423.752(a) through (b).

(b) *Burden of proof, standard of proof, and standard of review at hearing.* (1) During a hearing to review a contract determination as described at § 423.641(a) of this subpart, the applicant has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.502 and § 423.503 of this part.

(2) During a hearing to review a contract determination as described at § 423.641(b) of this part, the Part D plan sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.507 of this part.

(3) During a hearing to review a contract determination as described at § 423.641(c) of this subpart, the Part D plan sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.509 of this part.

(4) During a hearing to review the imposition of an intermediate sanction as described at § 423.750 of this part, the Part D sponsor has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 423.752 of this part.

(c) *Timing of favorable decision.* Notice of any decision favorable to the Part D sponsor appealing a determination that it is not qualified to enter into a contract with CMS must be issued by September 1 for the contract in question to be effective on January 1 of the following year.

[75 FR 19824, Apr. 15, 2010, as amended at 80 FR 7965, Feb. 12, 2015]

§ 423.651 Request for hearing.

(a) *Method and place for filing a request.* (1) A request for a hearing must be made in writing and filed by an authorized official of the contract applicant or Part D plan sponsor that was the party to the determination under the appeal.

(2) The request for the hearing must be filed in accordance with the requirements specified in the notice.

(b) *Time for filing a request.* A request for a hearing must be filed within 15 calendar days after the receipt of the notice of the contract determination or intermediate sanction.

(c) *Parties to a hearing.* The parties to a hearing must be—

(1) The parties described in § 423.650;

(2) At the discretion of the hearing officer, any interested parties who make a showing that their rights may be prejudiced by the decision to be rendered at the hearing; and

(3) CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 72 FR 68734, Dec. 5, 2007; 75 FR 19824, Apr. 15, 2010]

§ 423.652 Postponement of effective date of a contract determination when a request for a hearing is filed timely.

(a) *Hearing.* When a request for a hearing is timely filed, CMS will postpone the proposed effective date of the contract determination listed at 423.641 until a hearing decision is reached and affirmed by the Administrator following review pursuant to 423.666 in instances where a Part D sponsor or CMS requests Administrator review and the Administrator accepts the matter for review.

(b) *Exceptions:* (1) If a final decision is not reached on CMS' determination for an initial contract by September 1, CMS will not enter into a contract with the applicant for the following year.

(2) A contract terminated in accordance with § 423.509(b)(2)(i) of this part will be terminated on the date specified by CMS and will not be postponed if a hearing is requested.

[72 FR 68734, Dec. 5, 2007, as amended at 75 FR 19824, Apr. 15, 2010; 83 FR 16753, Apr. 16, 2018]

§ 423.653 Designation of hearing officer.

CMS designates a hearing officer to conduct the hearing. The hearing officer need not be an ALJ.

§ 423.654 Disqualification of hearing officer.

(a) A hearing officer may not conduct a hearing in a case in which he or she is prejudiced or partial to any party or

has any interest in the matter pending for decision.

(b) A party to the hearing who objects to the designated hearing officer must notify that officer in writing at the earliest opportunity.

(c) The hearing officer must consider the objections, and may, at his or her discretion, either proceed with the hearing or withdraw.

(1) If the hearing officer withdraws, CMS designates another hearing officer to conduct the hearing.

(2) If the hearing officer does not withdraw, the objecting party may, after the hearing, present objections and request that the officer's decision be revised or a new hearing be held before another hearing officer. The objections must be submitted in writing to CMS.

§ 423.655 Time and place of hearing.

(a) The hearing officer—

(1) Fixes a time and place for the hearing, which is not to exceed 30 calendar days after the receipt of request for the hearing;

(2) Sends written notice to the parties that informs the parties of the general and specific issues to be resolved, the burden of proof, and information about the hearing procedure.

(b)(1) The hearing officer may, on his or her own motion, change the time and place of the hearing.

(2) The hearing officer may adjourn or postpone the hearing.

(c)(1) The Part D plan sponsor or CMS may request an extension by filing a written request no later than 10 calendar days prior to the scheduled hearing.

(2) When either the Part D plan sponsor or CMS requests an extension the hearing officer will provide a one-time 15-calendar day extension.

(3) Additional extensions may be granted at the discretion of the hearing officer.

[75 FR 19824, Apr. 15, 2010]

§ 423.656 Appointment of representatives.

A party may appoint as its representative at the hearing anyone not disqualified or suspended from acting as a representative before the Secretary or otherwise prohibited by law.