

§ 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.

(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 incon-

sistent 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