

(4) Comply with any other requirements specified by CMS.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009; 77 FR 22171, Apr. 12, 2012; 83 FR 16752, Apr. 16, 2018; 84 FR 19872, May 7, 2019]

**§ 423.604 Effect of a reconsideration determination.**

A reconsideration determination is final and binding on the enrollee and the Part D plan sponsor, unless the enrollee files a request for a hearing under the provisions of § 423.2014.

[70 FR 4525, Jan. 28, 2005, as amended at 74 FR 65363, Dec. 9, 2009; 84 FR 19872, May 7, 2019]

**§§ 423.610–423.634 [Reserved]**

**§ 423.636 How a Part D plan sponsor must effectuate standard redeterminations, reconsiderations, or decisions.**

(a) *Reversals by the Part D plan sponsor—(1) Requests for benefits.* If, on redetermination of a request for benefit, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.

(2) *Requests for payment.* If, on redetermination of a request for payment, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize payment for the benefit within 14 calendar days from the date it receives the request for redetermination, and make payment no later than 30 calendar days after the date the plan sponsor receives the request for redetermination.

(3) *Review of an at-risk determination.* If, on redetermination of an at-risk determination made under a drug management program in accordance with § 423.153(f), the Part D plan sponsor reverses its at-risk determination, the Part D plan sponsor must implement the change to the at-risk determination as expeditiously as the enrollee's health condition requires, but no later than 7 calendar days from the date it receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor—(1) Requests for benefits.* If, on appeal of a request for benefit, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute within 72 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(2) *Requests for payment.* If, on appeal of a request for payment, the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize payment for the benefit within 72 hours, but make payment no later than 30 calendar days from the date it receives notice reversing the coverage determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(3) *Review of an at-risk determination.* If, on appeal of an at-risk determination made under a drug management program in accordance with § 423.153(f), the determination by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must implement the change to the at-risk determination within 72 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

[70 FR 4525, Jan. 28, 2005, as amended at 83 FR 16752, Apr. 16, 2018]

**§ 423.638 How a Part D plan sponsor must effectuate expedited redeterminations or reconsiderations.**

(a) *Reversals by the Part D plan sponsor—(1) Requests for benefits.* If, on an expedited redetermination of a request for benefits, the Part D plan sponsor reverses its coverage determination, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health

condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.

(2) *Review of an at-risk determination.* If, on an expedited redetermination of an at-risk determination made under a drug management program in accordance with § 423.153(f), the Part D plan sponsor reverses its at-risk determination, the Part D plan sponsor must implement the change to the at-risk determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after the date the Part D plan sponsor receives the request for redetermination.

(b) *Reversals other than by the Part D plan sponsor—*(1) *Requests for benefits.* If the expedited determination or expedited redetermination for benefits by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must authorize or provide the benefit under dispute as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

(2) *Review of an at-risk determination.* If the expedited redetermination of an at-risk determination made under a drug management program in accordance with § 423.153(f) by the Part D plan sponsor is reversed in whole or in part by the independent review entity, or at a higher level of appeal, the Part D plan sponsor must implement the change to the at-risk determination as expeditiously as the enrollee's health condition requires but no later than 24 hours from the date it receives notice reversing the determination. The Part D plan sponsor must inform the independent review entity that the Part D plan sponsor has effectuated the decision.

[83 FR 16753, Apr. 16, 2013]

## Subpart N—Medicare Contract Determinations and Appeals

### § 423.641 Contract determinations.

This subpart establishes the procedures for reviewing the following contract determinations:

(a) A determination that an entity is not qualified to enter into a contract with CMS under Part D of title XVIII of the Act.

(b) A determination not to authorize a renewal of a contract with a PDP sponsor in accordance with § 423.507(b).

(c) A determination to terminate a contract with a PDP sponsor in accordance with § 423.509.

(d) Fallback entities are governed under subpart Q of this part, and are not subject to this subpart, except to 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.

(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

#### **§ 423.653**

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.

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(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.

#### **§ 423.657 Authority of representatives.**

(a) A representative appointed and qualified in accordance with § 423.656, on behalf of the represented party—

(1) Gives or accepts any notice or request pertinent to the proceedings set forth in this subpart;

(2) Presents evidence and allegations as to facts and law in any proceedings affecting that party; and

(3) Obtains information to the same extent as the party.

(b) A notice or request sent to the representative has the same force and effect as if it is sent to the party.

#### **§ 423.658 Conduct of hearing.**

(a) The hearing is open to the parties and to the public.

(b) The hearing officer inquires fully into all the matters at issue and receives in evidence the testimony of witnesses and any documents that are relevant and material.

(c) The hearing officer provides the parties an opportunity to enter any objection to the inclusion of any document.

(d) The Part D sponsor bears the burden of going forward and must first present evidence and argument before

CMS presents its evidence and argument.

[70 FR 4525, Jan. 28, 2005, as amended at 75 FR 19824, Apr. 15, 2010]

**§ 423.659 Evidence.**

The hearing officer rules on the admissibility of evidence and may admit evidence that is inadmissible under rules applicable to court procedures.

**§ 423.660 Witnesses.**

(a) The hearing officer may examine the witnesses.

(b) The parties or their representatives are permitted to examine their witnesses and cross-examine witnesses of other parties.

**§ 423.661 Witnesses lists and documents.**

Witness lists and documents must be identified and exchanged at least 5 calendar days prior to the scheduled hearing.

[75 FR 19824, Apr. 15, 2010]

**§ 423.662 Prehearing and summary judgment.**

(a) *Prehearing.* The hearing officer may schedule a prehearing conference if he or she believes that a conference would more clearly define the issues.

(b) *Summary judgment.* Either party to the hearing, may ask the hearing officer to rule on a motion for summary judgment.

[72 FR 68734, Dec. 5, 2007]

**§ 423.663 Record of hearing.**

(a) A complete record of the proceedings at the hearing is made and transcribed and made available to all parties upon request.

(b) The record may not be closed until a hearing decision is issued.

**§ 423.664 Authority of hearing officer.**

In exercising his or her authority, the hearing officer must comply with the provisions of title XVIII and related provisions of the Act, the regulations issued by the Secretary, and general instructions issued by CMS in implementing the Act.

**§ 423.665 Notice and effect of hearing decision.**

(a) As soon as practical after the close of the hearing, the hearing officer issues a written decision that—

(1) Is based upon the evidence of record; and

(2) Contains separately numbered findings of fact and conclusions of law.

(b) The hearing officer provides a copy of the hearing decision to each party.

(c) The hearing decision is final and binding unless it is reversed or modified by the Administrator following review under § 423.666, or reopened and revised in accordance with § 423.668.

**§ 423.666 Review by the Administrator.**

(a) *Request for review by Administrator.* CMS or a Part D plan sponsor that has received a hearing decision may request a review by the Administrator within 15 calendar days after receipt of the hearing decision as provided under § 423.665(b) of this subpart. Both the Part D plan sponsor and CMS may provide written arguments to the Administrator for review.

(b) *Decision to review the hearing decision.* After receiving a request for review, the Administrator has the discretion to elect to review the hearing determination in accordance with paragraph (d) of this section or to decline to review the hearing decision.

(c) *Notification of Administrator determination.* The Administrator notifies both parties of his or her determination regarding review of the hearing decision within 30 calendar days after receipt of request for review. If the Administrator declines to review the hearing decision or the Administrator does not make a determination regarding review within 30 calendar days, the decision of the hearing officer is final.

(d) *Review by the Administrator.* If the Administrator elects to review the hearing decision regarding a contract determination, the Administrator shall review the hearing officer's decision and determine, based upon this decision, the hearing record, and any written arguments submitted by the Part D sponsor or CMS, whether the determination should be upheld, reversed, or modified.