

the request for the integrated reconsideration (or no later than upon expiration of an extension described in § 422.633(f)); or

(B) For a Part B drug, 7 calendar days after the date the applicable integrated plan receives the request for the integrated reconsideration.

(2) For a Medicaid benefit, if a State fair hearing officer reverses an applicable integrated plan's integrated reconsideration decision to deny, limit, or delay services that were not furnished while the appeal was pending, the applicable integrated plan must authorize or provide the disputed services promptly and as expeditiously as the enrollee's health condition requires but no later than 72 hours from the date it receives notice reversing the determination.

(3) Reversals by the Part C independent review entity, an administrative law judge or attorney adjudicator at the Office of Medicare Hearings and Appeals, or the Medicare Appeals Council must be effectuated under same timelines applicable to other MA plans as specified in §§ 422.618 and 422.619.

(e) *Services furnished while the appeal is pending.* If the applicable integrated plan or the State fair hearing officer reverses a decision to deny, limit, or delay Medicaid-covered benefits, and the enrollee received the disputed services while the integrated reconsideration was pending, the applicable integrated plan or the State must pay for those services, in accordance with State policy and regulations. If the applicable integrated plan reverses a decision to deny, limit, or delay Medicare-covered benefits, and the enrollee received the disputed services while the integrated reconsideration was pending, the applicable integrated plan must pay for those services.

[63 FR 35107, June 26, 1998, as amended at 87 FR 27898, May 9, 2022]

Subpart N—Medicare Contract Determinations and Appeals

SOURCE: 63 FR 35113, June 26, 1998, unless otherwise noted.

§ 422.641 Contract determinations.

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

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

(b) A determination not to authorize a renewal of a contract with an MA organization in accordance with § 422.506(b).

(c) A determination to terminate a contract with an MA organization in accordance with § 422.510(a).

(d) A determination that an entity is not qualified to offer a Specialized MA Plan for Special Needs Individuals as defined in §§ 422.2 and 422.4(a)(1)(iv).

[63 FR 35113, June 26, 1998, as amended at 77 FR 22168, Apr. 12, 2012; 80 FR 7962, Feb. 12, 2015]

§ 422.644 Notice of contract determination.

(a) When CMS makes a contract determination under § 422.641, it gives the MA organization written notice.

(b) The notice specifies—

(1) Reasons for the determination; and

(2) The MA organization's right to request a hearing.

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

(2) *Exception.* If a contract is terminated in accordance with § 422.510(b)(2)(i) of this part, CMS notifies the MA organization of the date that it will terminate the MA organization's contract.

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

[63 FR 35113, June 26, 1998, as amended at 72 FR 68724, Dec. 5, 2007; 75 FR 19813, Apr. 15, 2010; 80 FR 7962, Feb. 12, 2015]

§ 422.646

§ 422.646 Effect of contract determination.

The contract determination is final and binding unless a timely request for a hearing is filed under 422.662.

[72 FR 68724, Dec. 5, 2007]

§ 422.660 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 C of Title XVIII of the Act in accordance with §§ 422.501 and 422.502.

(2) An MA organization whose contract has been terminated in accordance with § 422.510.

(3) An MA organization whose contract has not been renewed in accordance with § 422.506.

(4) An MA organization who has had an intermediate sanction imposed in accordance with § 422.752(a) through (b) of this part.

(5) An applicant that has been determined to be unqualified to offer a Specialized MA Plan for Special Needs Individuals.

(b) *Burden of proof, standard of proof, and standards of review at a hearing.* (1) During a hearing to review a contract determination as described at § 422.641(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 §§ 422.501 and 422.502 of this part.

(2) During a hearing to review a contract determination as described at § 422.641(b) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.506 of this part.

(3) During a hearing to review a contract determination as described at § 422.641(c) of this subpart, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.510 of this part.

(4) During a hearing to review the imposition of an intermediate sanction

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as described at § 422.750, the MA organization has the burden of proving by a preponderance of the evidence that CMS' determination was inconsistent with the requirements of § 422.752(a) and (b).

(5) During a hearing to review a determination as described at § 422.641(d) 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 §§ 422.2; 422.4(a)(1)(iv); 422.101(f); 422.107, if applicable; and 422.152(g) of this part.

(c) *Timing of favorable decisions.* Notice of any decision favorable to the MA organization 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 19813, Apr. 15, 2010, as amended at 77 FR 22168, Apr. 12, 2012; 80 FR 7962, Feb. 12, 2015]

§ 422.662 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 MA organization 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 § 422.660;

(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.

[63 FR 35113, June 26, 1998, as amended at 65 FR 40332, June 29, 2000; 72 FR 68724, Dec. 5, 2007; 75 FR 19813, Apr. 15, 2010]

§ 422.664 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 422.641 until a hearing decision is reached and affirmed by the Administrator following review according to 422.692 in instances where an MA organization 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 § 422.510(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 68724, Dec. 5, 2007, as amended at 75 FR 19813, Apr. 15, 2010; 83 FR 16734, Apr. 16, 2018]

§ 422.666 Designation of hearing officer.

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

§ 422.668 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 be-

fore another hearing officer. The objections must be submitted in writing to CMS.

§ 422.670 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 the request for the hearing; and

(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 MA organization 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 MA organization 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 19813, Apr. 15, 2010]

§ 422.672 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.

§ 422.674 Authority of representatives.

(a) A representative appointed and qualified in accordance with § 422.672 may, 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 had been sent to the party.

§ 422.676

§ 422.676 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 MA organization bears the burden of going forward and must first present evidence and argument before CMS presents its evidence and argument.

[63 FR 35113, June 26, 1998, as amended at 75 FR 19813, Apr. 15, 2010]

§ 422.678 Evidence.

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

§ 422.680 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.

§ 422.682 Witness lists and documents.

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

[75 FR 19813, Apr. 15, 2010]

§ 422.684 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 68725, Dec. 5, 2007]

§ 422.686 Record of hearing.

(a) A complete record of the proceedings at the hearing is made and

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transcribed and made available to all parties upon request.

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

§ 422.688 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.

§ 422.690 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 § 422.692, or reopened and revised in accordance with § 422.696.

§ 422.692 Review by the Administrator.

(a) *Request for review by Administrator.* CMS or an MA organization 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 § 422.690(b). Both the MA organization 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 decision 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 MA organization or CMS, whether the determination should be upheld, reversed, or modified.

(e) *Decision by the Administrator.* The Administrator issues a written decision, and furnishes the decision to the MA organization requesting review.

[63 FR 35113, June 26, 1998, as amended at 72 FR 68725, Dec. 5, 2007; 75 FR 19813, Apr. 15, 2010]

§ 422.694 Effect of Administrator's decision.

A decision by the Administrator under section 422.692 is final and binding unless it is reopened and revised in accordance with § 422.696.

§ 422.696 Reopening of a contract determination or decision of a hearing officer or the Administrator.

(a) *Contract determination.* CMS may reopen and revise an initial determination upon its own motion.

(b) *Decision of hearing officer.* A decision of a hearing officer that is unfavorable to any party and is otherwise final may be reopened and revised by the hearing officer upon the officer's own motion within one year of the notice of the hearing decision. Another hearing officer designated by CMS may reopen and revise the decision if the hearing officer who issued the decision is unavailable.

(c) *Decision of Administrator.* A decision by the Administrator that is otherwise final may be reopened and revised by the Administrator upon the Administrator's own motion within one year of the notice of the Administrator's decision.

(d) *Notices.* (1) The notice of reopening and of any revisions following the reopening is mailed to the parties.

(2) The notice of revision specifies the reasons for revisions.

[63 FR 35113, June 26, 1998, as amended at 72 FR 68725, Dec. 5, 2007; 75 FR 19814, Apr. 15, 2010]

Subpart O—Intermediate Sanctions

SOURCE: 63 FR 35115, June 26, 1998, unless otherwise noted.

§ 422.750 Types of intermediate sanctions and civil money penalties.

(a) The following intermediate sanctions may be imposed and will continue in effect until CMS is satisfied that the deficiencies that are the basis for the sanction determination have been corrected and are not likely to recur:

(1) Suspension of the MA organization's enrollment of Medicare beneficiaries.

(2) Suspension of payment to the MA organization for Medicare beneficiaries enrolled after the date CMS notifies the organization of the intermediate sanction.

(3) Suspension of communication activities to Medicare beneficiaries by an MA organization, as defined by CMS.

(b) CMS may impose civil money penalties as specified in 422.760.

[72 FR 68725, Dec. 5, 2007, as amended at 75 FR 19814, Apr. 15, 2010; 83 FR 16734, Apr. 16, 2018]

§ 422.752 Basis for imposing intermediate sanctions and civil money penalties.

(a) *All intermediate sanctions.* For the violations listed in this paragraph, CMS may impose one or more of the sanctions specified in § 422.750(a) of this subpart on any MA organization with a contract. The MA organization may also be subject to other remedies authorized under law.

(1) Fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has the substantial likelihood of adversely affecting) the individual.

(2) Imposes on MA enrollees premiums in excess of the monthly basic