

(g) *Certification by the review entity.* If a party meets the requirements for the EAJR, the review entity certifies in writing that—

(1) The material facts involved in the claim are not in dispute;

(2) Except as indicated in paragraph (g)(3) of this section, the Secretary's interpretation of the law is not in dispute;

(3) The sole issue(s) in dispute is the constitutionality of a statutory provision, or the validity of a provision of a regulation, CMS Ruling, or national coverage determination;

(4) But for the provision challenged, the requestor would receive a favorable decision on the ultimate issue (such as whether a claim should be paid); and

(5) The certification by the review entity is the Secretary's final action for purposes of seeking expedited judicial review.

(h) *Effect of certification by the review entity.* If an EAJR request results in a certification described in paragraph (g) of this section—

(1) The party that requested the EAJR is considered to have waived any right to completion of the remaining steps of the administrative appeals process regarding the matter certified.

(2) The requestor has 60 calendar days, beginning on the date of the review entity's certification within which to bring a civil action in Federal district court.

(3) The requestor must satisfy the requirements for venue under section 1869(b)(2)(C)(iii) of the Act, as well as the requirements for filing a civil action in a Federal district court under § 405.1136(a) and § 405.1136(c) through § 405.1136(f).

(i) *Rejection of EAJR.* (1) If a request for EAJR does not meet all the conditions set out in paragraphs (b), (c) and (d) of this section, or if the review entity does not certify a request for EAJR, the review entity advises in writing all parties that the request has been denied, and forwards the request to OMHA or the Council, which will treat it as a request for hearing or for Council review, as appropriate.

(2) Whenever a review entity forwards a rejected EAJR request to OMHA or the Council, the appeal is considered timely filed, and if an adju-

dication time frame applies to the appeal, the adjudication time frame begins on the day the request is received by OMHA or the Council from the review entity.

(j) *Interest on any amounts in controversy.* (1) If a provider or supplier is granted judicial review in accordance with this section, the amount in controversy, if any, is subject to annual interest beginning on the first day of the first month beginning after the 60 calendar day period as determined in accordance with paragraphs (f)(4) or (h)(2) of this section, as applicable.

(2) The interest is awarded by the reviewing court and payable to a prevailing party.

(3) The rate of interest is equal to the rate of interest applicable to obligations issued for purchase by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this subpart is commenced.

(4) No interest awarded in accordance with this paragraph shall be income or cost for purposes of determining reimbursement due to providers or suppliers under Medicare.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65334, Dec. 9, 2009; 82 FR 5108, Jan. 17, 2017]

ALJ HEARINGS

§ 405.1000 Hearing before an ALJ and decision by an ALJ or attorney adjudicator: General rule.

(a) If a party is dissatisfied with a QIC's reconsideration, or if the adjudication period specified in § 405.970 for the QIC to complete its reconsideration has elapsed, the party may request a hearing before an ALJ.

(b) A hearing before an ALJ may be conducted in-person, by video-teleconference (VTC), or by telephone. At the hearing, the parties may submit evidence (subject to the restrictions in § 405.1018 and § 405.1028), examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, CMS or its contractor may participate in the proceedings under § 405.1010, or join the hearing before an ALJ as a party under § 405.1012.

(d) The ALJ or attorney adjudicator conducts a de novo review and issues a decision based on the administrative record, including, for an ALJ, any hearing record.

(e) If all parties who are due a notice of hearing in accordance with § 405.1020(c) waive their right to appear at the hearing in person or by telephone or video-teleconference, the ALJ or an attorney adjudicator may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

(f) The ALJ may require the parties to participate in a hearing if it is necessary to decide the case. If the ALJ determines that it is necessary to obtain testimony from a non-party, he or she may hold a hearing to obtain that testimony, even if all of the parties who are entitled to a notice of hearing in accordance with § 405.1020(c) have waived the right to appear. In that event, however, the ALJ will give the parties the opportunity to appear when the testimony is given, but may hold the hearing even if none of the parties decide to appear.

(g) An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a fully favorable finding for the appellant, and no other party to the appeal is liable for the claims at issue, unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012.

(h) If more than one party timely files a request for hearing on the same claim before a decision is made on the first timely filed request, the requests are consolidated into one proceeding and record, and one decision, dismissal, or remand is issued.

[82 FR 5109, Jan. 17, 2017]

§ 405.1002 Right to an ALJ hearing.

(a) A party to a QIC reconsideration has a right to a hearing before an ALJ if—

(1) The party files a written request for an ALJ hearing within 60 calendar days after receipt of the notice of the QIC's reconsideration.

(2) The party meets the amount in controversy requirements of § 405.1006.

(3) For purposes of this section, the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the reconsideration, unless there is evidence to the contrary.

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the office specified in the QIC's reconsideration.

(b) A party who files a timely appeal before a QIC and whose appeal continues to be pending before a QIC at the end of the period described in § 405.970 has a right to a hearing before an ALJ if—

(1) The party files a written request with the QIC to escalate the appeal for a hearing before an ALJ after the period described in § 405.970(a) and (b) has expired and the party files the request in accordance with § 405.970(d);

(2) The QIC does not issue a decision or dismissal order within 5 calendar days of receiving the request for escalation in accordance with § 405.970(e)(2); and

(3) The party has an amount remaining in controversy specified in § 405.1006.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65335, Dec. 9, 2009; 82 FR 5109, Jan. 17, 2017]

§ 405.1004 Right to a review of QIC notice of dismissal.

(a) A party to a QIC's dismissal of a request for reconsideration has a right to have the dismissal reviewed by an ALJ or attorney adjudicator if—

(1) The party files a written request for review within 60 calendar days after receipt of the notice of the QIC's dismissal.

(2) The party meets the amount in controversy requirements of § 405.1006.

(3) For purposes of this section, the date of receipt of the QIC's dismissal is presumed to be 5 calendar days after the date of the dismissal notice, unless there is evidence to the contrary.

(4) For purposes of meeting the 60 calendar day filing deadline, the request is considered as filed on the date it is received by the office specified in the QIC's dismissal.

(b) If the ALJ or attorney adjudicator determines that the QIC's dismissal was in error, he or she vacates

§ 405.1006

42 CFR Ch. IV (10–1–24 Edition)

the dismissal and remands the case to the QIC for a reconsideration in accordance with § 405.1056.

(c) If the ALJ or attorney adjudicator affirms the QIC's dismissal of a reconsideration request, he or she issues a notice of decision affirming the QIC dismissal in accordance with § 405.1046(b).

(d) The ALJ or attorney adjudicator may dismiss the request for review of a QIC's dismissal in accordance with § 405.1052(b).

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37703, June 30, 2005; 74 FR 65335, Dec. 9, 2009; 82 FR 5109, Jan. 17, 2017]

§ 405.1006 Amount in controversy required for an ALJ hearing and judicial review.

(a) *Definitions.* For the purposes of aggregating claims to meet the amount in controversy requirement for an ALJ hearing or judicial review:

(1) “Common issues of law and fact” means the claims sought to be aggregated are denied, or payment is reduced, for similar reasons and arise from a similar fact pattern material to the reason the claims are denied or payment is reduced.

(2) “Delivery of similar or related services” means like or coordinated services or items provided to one or more beneficiaries.

(b) *ALJ review.* To be entitled to a hearing before an ALJ, the party must meet the amount in controversy requirements of this section.

(1) For ALJ hearing requests, the required amount remaining in controversy must be \$100 increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) as measured from July 2003 to the July preceding the current year involved.

(2) If the figure in paragraph (b)(1) of this section is not a multiple of \$10, then it is rounded to the nearest multiple of \$10. The Secretary will publish changes to the amount in controversy requirement in the FEDERAL REGISTER when necessary.

(c) *Judicial review.* To be entitled to judicial review, a party must meet the amount in controversy requirements of

this subpart at the time it requests judicial review.

(1) For review requests, the required amount remaining in controversy must be \$1,000 or more, adjusted as specified in paragraphs (b)(1) and (b)(2) of this section.

(2) [Reserved]

(d) *Calculating the amount remaining in controversy—*(1) *In general.* The amount remaining in controversy is computed as the actual amount charged the individual for the items and services in the disputed claim, reduced by—

(i) Any Medicare payments already made or awarded for the items or services; and

(ii) Any deductible and/or coinsurance amounts that may be collected for the items or services.

(2) *Limitation on liability.* Notwithstanding paragraph (d)(1) of this section, when payment is made for items or services under section 1879 of the Act or § 411.400 of this chapter, or the liability of the beneficiary for those services is limited under § 411.402 of this chapter, the amount in controversy is computed as the amount the beneficiary would have been charged for the items or services in question if those expenses were not paid under § 411.400 of this chapter or if that liability was not limited under § 411.402 of this chapter, reduced by any deductible and/or coinsurance amounts that may be collected for the items or services.

(3) *Item or service terminations.* When a matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services, the amount in controversy is calculated in accordance with paragraph (d)(1) of this section, except that the amount charged to the individual and any deductible and coinsurance that may be collected for the items or services are calculated using the amount the beneficiary would have been charged if the beneficiary had received the items or services the beneficiary asserts should have been covered based on the beneficiary's current condition, and Medicare payment were not made for the items or services.

(4) *Overpayments.* Notwithstanding paragraph (d)(1) of this section, when an appeal involves an identified overpayment, the amount in controversy is the amount of the overpayment specified in the demand letter, or the amount of the revised overpayment if the amount originally demanded changes as a result of a subsequent determination or appeal, for the items or services in the disputed claim. When an appeal involves an estimated overpayment amount determined through the use of statistical sampling and extrapolation, the amount in controversy is the total amount of the estimated overpayment determined through extrapolation, as specified in the demand letter, or as subsequently revised.

(5) *Coinsurance and deductible challenges.* Notwithstanding paragraph (d)(1) of this section, for appeals filed by beneficiaries challenging only the computation of a coinsurance amount or the amount of a remaining deductible, the amount in controversy is the difference between the amount of the coinsurance or remaining deductible, as determined by the contractor, and the amount of the coinsurance or remaining deductible the beneficiary believes is correct.

(6) *Fee schedule or contractor price challenges.* Notwithstanding paragraph (d)(1) of this section, for appeals of claims where the allowable amount has been paid in full and the appellant is challenging only the validity of the allowable amount, as reflected on the published fee schedule or in the published contractor-priced amount applicable to the items or services in the disputed claim, the amount in controversy is the difference between the amount the appellant argues should have been the allowable amount for the items or services in the disputed claim in the applicable jurisdiction and place of service, and the published allowable amount for the items or services.

(e) *Aggregating claims to meet the amount in controversy—*(1) *Aggregating claims in appeals of QIC reconsiderations for an ALJ hearing.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

(i) The claims were previously reconsidered by a QIC;

(ii) The appellant(s) requests aggregation of claims appealed in the same request for ALJ hearing, or in multiple requests for an ALJ hearing filed with the same request for aggregation, and the request is filed within 60 calendar days after receipt of all of the reconsiderations being appealed; and

(iii) The claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

(2) *Aggregating claims that are escalated from the QIC level for an ALJ hearing.* Either an individual appellant or multiple appellants may aggregate two or more claims to meet the amount in controversy for an ALJ hearing if—

(i) The claims were pending before the QIC in conjunction with the same request for reconsideration;

(ii) The appellant(s) requests aggregation of the claims for an ALJ hearing in the same request for escalation; and

(iii) The claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve common issues of law and fact. Part A and Part B claims may be combined to meet the amount in controversy requirements.

(f) *Content of request for aggregation.* When an appellant(s) seeks to aggregate claims in a request for an ALJ hearing, the appellant(s) must—

§ 405.1008

(1) Specify all of the claims the appellant(s) seeks to aggregate; and

(2) State why the appellant(s) believes that the claims involve common issues of law and fact or delivery of similar or related services.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65335, Dec. 9, 2009; 82 FR 5109, Jan. 17, 2017; 84 FR 19870, May 7, 2019]

§ 405.1008 Parties to the proceedings on a request for an ALJ hearing.

The party who filed the request for hearing and all other parties to the reconsideration are parties to the proceedings on a request for an ALJ hearing. In addition, a representative of CMS or its contractor may be a party under the circumstances described in § 405.1012.

[82 FR 5110, Jan. 17, 2017]

§ 405.1010 When CMS or its contractors may participate in the proceedings on a request for an ALJ hearing.

(a) *When CMS or a contractor can participate.* (1) CMS or its contractors may elect to participate in the proceedings on a request for an ALJ hearing upon filing a notice of intent to participate in accordance with paragraph (b) of this section.

(2) An ALJ may request, but may not require, CMS and/or one or more of its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any. The ALJ cannot draw any adverse inferences if CMS or the contractor decides not to participate in any proceedings before the ALJ, including the hearing.

(b) *How an election is made—* (1) *No notice of hearing.* If CMS or a contractor elects to participate before receipt of a notice of hearing, or when a notice of hearing is not required, it must send written notice of its intent to participate to—

(i) The assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the request for hearing is not yet assigned to an ALJ or attorney adjudicator; and

(ii) The parties who were sent a copy of the notice of reconsideration or, for escalated requests for reconsideration, any party that filed a request for reconsideration or was found liable for

the services at issue subsequent to the initial determination.

(2) *Notice of hearing.* If CMS or a contractor elects to participate after receipt of a notice of hearing, it must send written notice of its intent to participate to the ALJ and the parties who were sent a copy of the notice of hearing.

(3) *Timing of election.* CMS or a contractor must send its notice of intent to participate—

(i) If no hearing is scheduled, no later than 30 calendar days after notification that a request for hearing was filed; or

(ii) If a hearing is scheduled, no later than 10 calendar days after receipt of the notice of hearing by the QIC or another contractor designated by CMS to receive the notice of hearing.

(c) *Roles and responsibilities of CMS or a contractor as a participant.* (1) Subject to paragraphs (d)(1) through (3) of this section, participation may include filing position papers and/or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of a party to the hearing.

(2) When CMS or its contractor participates in an ALJ hearing, CMS or its contractor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the parties, except as provided in paragraph (d)(3) of this section. However, the parties may provide testimony to rebut factual or policy statements made by a participant and the ALJ may question the participant about its testimony.

(3) CMS or contractor position papers and written testimony are subject to the following:

(i) Unless the ALJ or attorney adjudicator grants additional time to submit the position paper or written testimony, a position paper or written testimony must be submitted within 14 calendar days of an election to participate if no hearing has been scheduled, or no later than 5 calendar days prior to the hearing if a hearing is scheduled.

(ii) A copy of any position paper or written testimony it submits to OMHA must be sent within the same time frame specified in paragraph (c)(3)(i) of this section to—

(A) The parties that are required to be sent a copy of the notice of intent to participate in accordance with paragraph (b)(1) of this section, if the position paper or written testimony is being submitted before receipt of a notice of hearing for the appeal; or

(B) The parties who were sent a copy of the notice of hearing, if the position paper or written testimony is being submitted after receipt of a notice of hearing for the appeal.

(iii) If CMS or a contractor fails to send a copy of its position paper or written testimony to the parties or fails to submit its position paper or written testimony within the time frames described in this paragraph, the position paper or written testimony will not be considered in deciding the appeal.

(d) *Limitation on participating in a hearing.* (1) If CMS or a contractor has been made a party to a hearing in accordance with § 405.1012, no entity that elected to be a participant in the proceedings in accordance with this section (or that elected to be a party to the hearing but was made a participant in accordance with § 405.1012(d)(1)) may participate in the oral hearing, but such entity may file a position paper and/or written testimony to clarify factual or policy issues in the case.

(2) If CMS or a contractor did not elect to be a party to a hearing in accordance with § 405.1012 and more than one entity elected to be a participant in the proceedings in accordance with this section, only the first entity to file a response to the notice of hearing as provided under § 405.1020(c) may participate in the oral hearing. Entities that filed a subsequent response to the notice of hearing may not participate in the oral hearing, but may file a position paper and/or written testimony to clarify factual or policy issues in the case.

(3) If CMS or a contractor is precluded from participating in the oral hearing under paragraph (d)(1) or (2) of this section, the ALJ may grant leave to the precluded entity to participate in the oral hearing if the ALJ determines that the entity's participation is necessary for a full examination of the matters at issue. If the ALJ does not grant leave to the precluded entity to

participate in the oral hearing, the precluded entity may still be called as a witness by CMS or a contractor that is a party to the hearing in accordance with § 405.1012.

(e) *Invalid election.* (1) An ALJ or attorney adjudicator may determine that a CMS or contractor election is invalid under this section if the election was not timely filed or the election was not sent to the correct parties.

(2) If an election is determined to be invalid, a written notice must be sent to the entity that submitted the election and the parties who are entitled to receive notice of the election in accordance with this section.

(i) If no hearing is scheduled or the election was submitted after the hearing occurred, the written notice of invalid election must be sent no later than the date the notice of decision, dismissal, or remand is mailed.

(ii) If a hearing is scheduled, the written notice of invalid election must be sent prior to the hearing. If the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the election, and the written notice must be sent as soon as possible after the oral notice is provided.

[82 FR 5110, Jan. 17, 2017, as amended at 84 FR 19870, May 7, 2019]

§ 405.1012 When CMS or its contractors may be a party to a hearing.

(a) *When CMS or a contractor can elect to be a party to a hearing.* (1) Unless the request for hearing is filed by an unrepresented beneficiary, and unless otherwise provided in this section, CMS or one of its contractors may elect to be a party to the hearing upon filing a notice of intent to be a party to the hearing in accordance with paragraph (b) of this section no later than 10 calendar days after receipt of the notice of hearing by the QIC or another contractor designated by CMS to receive the notice of hearing.

(2) Unless the request for hearing is filed by an unrepresented beneficiary, an ALJ may request, but may not require, CMS and/or one or more of its contractors to be a party to the hearing. The ALJ cannot draw any adverse

inferences if CMS or the contractor decides not to be a party to the hearing.

(b) *How an election is made.* If CMS or a contractor elects to be a party to the hearing, it must send written notice to the ALJ and the parties who were sent a copy of the notice of hearing of its intent to be a party to the hearing.

(c) *Roles and responsibilities of CMS or a contractor as a party.* (1) As a party, CMS or a contractor may file position papers, submit evidence, provide testimony to clarify factual or policy issues, call witnesses or cross-examine the witnesses of other parties.

(2) CMS or contractor position papers, written testimony, and evidentiary submissions are subject to the following:

(i) Any position paper, written testimony, and/or evidence must be submitted no later than 5 calendar days prior to the hearing unless the ALJ grants additional time to submit the position paper, written testimony, and/or evidence.

(ii) A copy of any position paper, written testimony, and/or evidence it submits to OMHA must be sent within the same time frame specified in paragraph (c)(2)(i) of this section to the parties who were sent a copy of the notice of hearing.

(iii) If CMS or a contractor fails to send a copy of its position paper, written testimony, and/or evidence to the parties or fails to submit its position paper, written testimony, and/or evidence within the time frames described in this section, the position paper, written testimony, and/or evidence will not be considered in deciding the appeal.

(d) *Limitation on participating in a hearing.* (1) If CMS and one or more contractors, or multiple contractors, file an election to be a party to the hearing, the first entity to file its election after the notice of hearing is issued is made a party to the hearing and the other entities are made participants in the proceedings under § 405.1010, subject to § 405.1010(d)(1) and (3), unless the ALJ grants leave to an entity to also be a party to the hearing in accordance with paragraph (d)(2) of this section.

(2) If CMS or a contractor filed an election to be a party in accordance

with this section but is precluded from being made a party under paragraph (d)(1) of this section, the ALJ may grant leave to be a party to the hearing if the ALJ determines that the entity's participation as a party is necessary for a full examination of the matters at issue.

(e) *Invalid election.* (1) An ALJ may determine that a CMS or contractor election is invalid under this section if the request for hearing was filed by an unrepresented beneficiary, the election was not timely, the election was not sent to the correct parties, or CMS or a contractor had already filed an election to be a party to the hearing and the ALJ did not determine that the entity's participation as a party is necessary for a full examination of the matters at issue.

(2) If an election is determined to be invalid, a written notice must be sent to the entity that submitted the election and the parties who were sent the notice of hearing.

(i) If the election was submitted after the hearing occurred, the written notice of invalid election must be sent no later than the date the decision, dismissal, or remand notice is mailed.

(ii) If the election was submitted before the hearing occurs, the written notice of invalid election must be sent prior to the hearing. If the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity that submitted the election, and the written notice to the entity and the parties who were sent the notice of hearing must be sent as soon as possible after the oral notice is provided.

[82 FR 5111, Jan. 17, 2017, as amended at 84 FR 19870, May 7, 2019]

§ 405.1014 Request for an ALJ hearing or a review of a QIC dismissal.

(a) *Content of the request.* (1) The request for an ALJ hearing or a review of a QIC dismissal must be made in writing. The request must include all of the following—

(i) The name, address, and Medicare health number of the beneficiary whose

claim is being appealed, and the beneficiary's telephone number if the beneficiary is the appealing party and not represented.

(ii) The name, address, and telephone number, of the appellant, when the appellant is not the beneficiary.

(iii) The name, address, and telephone number, of the designated representative, if any.

(iv) The Medicare appeal number or document control number, if any, assigned to the QIC reconsideration or dismissal notice being appealed.

(v) The dates of service of the claim(s) being appealed, if applicable.

(vi) The reasons the appellant disagrees with the QIC's reconsideration or other determination being appealed.

(2) The appellant must submit a statement of any additional evidence to be submitted and the date it will be submitted.

(3) Special rule for appealing statistical sample and/or extrapolation. If the appellant disagrees with how a statistical sample and/or extrapolation was conducted, the appellant must—

(i) Include the information in paragraphs (a)(1) and (2) of this section for each sample claim that the appellant wishes to appeal;

(ii) File the request for hearing for all sampled claims that the appellant wishes to appeal within 60 calendar days of the date the party receives the last reconsideration for the sample claims, if they were not all addressed in a single reconsideration; and

(iii) Assert the reasons the appellant disagrees with how the statistical sample and/or extrapolation was conducted in the request for hearing.

(b) *Complete request required.* (1) A request must contain the information in paragraph (a)(1) of this section to the extent the information is applicable, to be considered complete. If a request is not complete, the appellant will be provided with an opportunity to complete the request, and if an adjudication time frame applies, it does not begin until the request is complete. If the appellant fails to provide the information necessary to complete the request within the time frame provided, the appellant's request for hearing or review will be dismissed.

(2) If supporting materials submitted with a request clearly provide information required for a complete request, the materials will be considered in determining whether the request is complete.

(c) *When and where to file.* The request for an ALJ hearing or request for review of a QIC dismissal must be filed—

(1) Within 60 calendar days from the date the party receives notice of the QIC's reconsideration or dismissal, except as provided in paragraph (a)(3)(ii) of this section for appeals of extrapolations;

(2) With the office specified in the QIC's reconsideration or dismissal. If the request for hearing is timely filed with an office other than the office specified in the QIC's reconsideration, the request is not treated as untimely, and any applicable time frame specified in § 405.1016 for deciding the appeal begins on the date the office specified in the QIC's reconsideration or dismissal receives the request for hearing. If the request for hearing is filed with an office, other than the office specified in the QIC's reconsideration or dismissal, OMHA must notify the appellant of the date the request was received in the correct office and the commencement of any applicable adjudication time frame.

(d) *Copy requirement.* (1) The appellant must send a copy of the request for hearing or request for review of a QIC dismissal to the other parties who were sent a copy of the QIC's reconsideration or dismissal. If additional materials submitted with the request are necessary to provide the information required for a complete request in accordance with paragraph (b) of this section, copies of the materials must be sent to the parties as well (subject to authorities that apply to disclosing the personal information of other parties). If additional evidence is submitted with the request for hearing, the appellant may send a copy of the evidence, or briefly describe the evidence pertinent to the party and offer to provide copies of the evidence to the party at the party's request (subject to authorities that apply to disclosing the evidence).

(2) Evidence that a copy of the request for hearing or request for review of a QIC dismissal, or a copy of submitted evidence or a summary thereof, was sent in accordance with paragraph (d)(1) of this section includes—

(i) Certification on the standard form for requesting an ALJ hearing or requesting a review of a QIC dismissal that a copy of the request is being sent to the other parties;

(ii) An indication, such as a copy or “cc” line, on a request for hearing or request for review of a QIC dismissal that a copy of the request and any applicable attachments or enclosures are being sent to the other parties, including the name and address of the recipient;

(iii) An affidavit or certificate of service that identifies the name and address of the recipient, and what was sent to the recipient; or

(iv) A mailing or shipping receipt that identifies the name and address of the recipient, and what was sent to the recipient.

(3) If the appellant, other than an unrepresented beneficiary, fails to send a copy of the request for hearing or request for review of a QIC dismissal, any additional materials, or a copy of submitted evidence or a summary thereof, as described in paragraph (d)(1) of this section, the appellant will be provided with an additional opportunity to send the request, materials, and/or evidence or summary thereof, and if an adjudication time frame applies, it begins upon receipt of evidence that the request, materials, and/or evidence or summary thereof were sent. If the appellant, other than an unrepresented beneficiary, again fails to provide evidence that the request, materials, and/or evidence or summary thereof were sent within the additional time frame provided to send the request, materials, and/or evidence or summary thereof, the appellant’s request for hearing or request for review of a QIC dismissal will be dismissed.

(e) *Extension of time to request a hearing or review.* (1) If the request for hearing or review of a QIC dismissal is not filed within 60 calendar days of receipt of the QIC’s reconsideration or dismissal, an appellant may request an

extension for good cause (See § 405.942(b)(2) and (3)).

(2) Any request for an extension of time must be in writing, give the reasons why the request for a hearing or review was not filed within the stated time period, and must be filed with the request for hearing or request for review of a QIC dismissal, or upon notice that the request may be dismissed because it was not timely filed, with the office specified in the notice of reconsideration or dismissal.

(3) An ALJ or attorney adjudicator may find there is good cause for missing the deadline to file a request for an ALJ hearing or request for review of a QIC dismissal, or there is no good cause for missing the deadline to file a request for a review of a QIC dismissal, but only an ALJ may find there is no good cause for missing the deadline to file a request for an ALJ hearing. If good cause is found for missing the deadline, the time period for filing the request for hearing or request for review of a QIC dismissal will be extended. To determine whether good cause for late filing exists, the ALJ or attorney adjudicator uses the standards set forth in § 405.942(b)(2) and (3).

(4) If a request for hearing is not timely filed, any applicable adjudication period in § 405.1016 begins the date the ALJ or attorney adjudicator grants the request to extend the filing deadline.

(5) A determination granting a request to extend the filing deadline is not subject to further review.

[82 FR 5112, Jan. 17, 2017, as amended at 84 FR 19870, May 7, 2019]

§ 405.1016 Time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration.

(a) *Adjudication period for appeals of QIC reconsiderations.* When a request for an ALJ hearing is filed after a QIC has issued a reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the QIC’s notice of reconsideration, unless

the 90 calendar day period has been extended as provided in this subpart.

(b) *When the adjudication period begins.* (1) Unless otherwise specified in this subpart, the adjudication period specified in paragraph (a) of this section begins on the date that a timely filed request for hearing is received by the office specified in the QIC's reconsideration, or, if it is not timely filed, the date that the ALJ or attorney adjudicator grants any extension to the filing deadline.

(2) If the Council remands a case and the case was subject to an adjudication time frame under paragraph (a) or (c) of this section, the remanded appeal will be subject to the adjudication time frame of paragraph (a) of this section beginning on the date that OMHA receives the Council remand.

(c) *Adjudication period for escalated requests for QIC reconsiderations.* When an appeal is escalated to OMHA because the QIC has not issued a reconsideration determination within the period specified in §405.970, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 180 calendar day period beginning on the date that the request for escalation is received by OMHA in accordance with §405.970, unless the 180 calendar day period is extended as provided in this subpart.

(d) *Waivers and extensions of adjudication period.* (1) At any time during the adjudication process, the appellant may waive the adjudication period specified in paragraphs (a) and (c) of this section. The waiver may be for a specific period of time agreed upon by the ALJ or attorney adjudicator and the appellant.

(2) The adjudication periods specified in paragraphs (a) and (c) of this section are extended as otherwise specified in this subpart, and for the following events—

(i) The duration of a stay of action on adjudicating the claims or matters at issue ordered by a court or tribunal of competent jurisdiction; or

(ii) The duration of a stay of proceedings granted by an ALJ or attorney adjudicator on a motion by an appellant, provided no other party also

filed a request for hearing on the same claim at issue.

(e) *Effect of exceeding adjudication period.* If an ALJ or attorney adjudicator fails to issue a decision, dismissal order, or remand to the QIC within an adjudication period specified in this section, subject to paragraphs (b) and (d) of this section, the party that filed the request for hearing may escalate the appeal in accordance with paragraph (f) of this section. If the party that filed the request for hearing does not elect to escalate the appeal, the appeal remains pending with OMHA for a decision, dismissal order, or remand.

(f) *Requesting escalation.*—(1) *When and how to request escalation.* An appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending with OMHA at the end of the applicable adjudication period under paragraph (a) or (c) of this section, subject to paragraphs (b) and (d) of this section, may exercise the option of escalating the appeal to the Council by filing a written request with OMHA to escalate the appeal to the Council and sending a copy of the request to escalate to the other parties who were sent a copy of the QIC reconsideration.

(2) *Escalation.* If the request for escalation meets the requirements of paragraph (f)(1) of this section and an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the later of 5 calendar days of receiving the request for escalation, or 5 calendar days from the end of the applicable adjudication period set forth in paragraph (a) or (c) of this section, subject to paragraphs (b) and (d) of this section, OMHA will take the following actions—

(i) Send a notice to the appellant stating that an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the adjudication period set forth in paragraph (a) or (c) of this section, the QIC reconsideration will be the decision that is subject to Council review consistent with §405.1102(a), and the appeal will be escalated to the Council for a review in accordance with §405.1108; and

(ii) Forward the case file to the Council.

§ 405.1018

(3) *Invalid escalation request.* If an ALJ or attorney adjudicator determines the request for escalation does not meet the requirements of paragraph (f)(1) of this section, OMHA will send a notice to the appellant explaining why the request is invalid within 5 calendar days of receiving the request for escalation.

[82 FR 5113, Jan. 17, 2017]

§ 405.1018 Submitting evidence.

(a) *When evidence may be submitted.* Except as provided in this section, parties must submit all written or other evidence they wish to have considered with the request for hearing, by the date specified in the request for hearing in accordance with § 405.1014(a)(2), or if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing.

(b) *Effect on adjudication period.* If a party submits written or other evidence later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period specified in § 405.1016 is extended by the number of calendar days in the period between 10 calendar days after receipt of the notice of hearing and the day the evidence is received.

(c) *New evidence.* (1) Any evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier that is not submitted prior to the issuance of the QIC's reconsideration determination must be accompanied by a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker (see § 405.1028).

(2) If a statement explaining why the evidence was not previously submitted to the QIC or a prior decision-maker is not included with the evidence, the evidence will not be considered.

(d) *When this section does not apply.* (1) The requirements in paragraphs (a) and (b) of this section do not apply to oral testimony given at a hearing, or to evidence submitted by an unrepresented beneficiary.

(2) The requirements in paragraph (c) of this section do not apply to oral testimony given at a hearing, or to evidence submitted by an unrepresented beneficiary, CMS or any of its contractors, a Medicaid State agency, an ap-

42 CFR Ch. IV (10–1–24 Edition)

plicable plan, or a beneficiary represented by someone other than a provider or supplier.

[82 FR 5113, Jan. 17, 2017]

§ 405.1020 Time and place for a hearing before an ALJ.

(a) *General.* The ALJ sets the time and place for the hearing, and may change the time and place, if necessary.

(b) *Determining how appearances are made—*(1) *Appearances by unrepresented beneficiaries.* The ALJ will direct that the appearance of an unrepresented beneficiary who filed a request for hearing be conducted by video-teleconferencing (VTC) if the ALJ finds that VTC technology is available to conduct the appearance, unless the ALJ find good cause for an in-person appearance.

(i) The ALJ may also offer to conduct a hearing by telephone if the request for hearing or administrative record suggests that a telephone hearing may be more convenient for the unrepresented beneficiary.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, may find good cause that an in-person hearing should be conducted if—

(A) VTC or telephone technology is not available; or

(B) Special or extraordinary circumstances exist.

(2) *Appearances by individuals other than unrepresented beneficiaries.* The ALJ will direct that the appearance of an individual, other than an unrepresented beneficiary who filed a request for hearing, be conducted by telephone, unless the ALJ finds good cause for an appearance by other means.

(i) The ALJ may find good cause for an appearance by VTC if he or she determines that VTC is necessary to examine the facts or issues involved in the appeal.

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, also may find good cause that an in-person hearing should be conducted if—

(A) VTC and telephone technology are not available; or

(B) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) A notice of hearing is sent to all parties that filed

an appeal or participated in the reconsideration; any party who was found liable for the services at issue subsequent to the initial determination or may be found liable based on a review of the record; the QIC that issued the reconsideration or from which the request for reconsideration was escalated, or another contractor designated to receive the notice of hearing by CMS; and CMS or a contractor that elected to participate in the proceedings in accordance with § 405.1010(b) or that the ALJ believes would be beneficial to the hearing, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require all parties to the ALJ hearing to reply to the notice by:

(i) Acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing, or whether they object to the proposed time and/or place of the hearing;

(ii) If the party or representative is an entity or organization, specifying who from the entity or organization plans to attend the hearing, if anyone, and in what capacity, in addition to the individual who filed the request for hearing; and

(iii) Listing the witnesses who will be providing testimony at the hearing.

(3) The notice of hearing will require CMS or a contractor that wishes to attend the hearing as a participant to reply to the notice by:

(i) Acknowledging whether it plans to attend the hearing at the time and place proposed in the notice of hearing; and

(ii) Specifying who from the entity plans to attend the hearing.

(d) *A party's right to waive a hearing.* A party may also waive the right to a hearing and request a decision based on the written evidence in the record in accordance with § 405.1038(b). As provided in § 405.1000, an ALJ may require the parties to attend a hearing if it is necessary to decide the case. If an ALJ determines that it is necessary to obtain testimony from a non-party, he or she may still hold a hearing to obtain that testimony, even if all of the parties have waived the right to appear. In those cases, the ALJ will give the parties the opportunity to appear when

the testimony is given but may hold the hearing even if none of the parties decide to appear.

(e) *A party's objection to time and place of hearing.* (1) If a party objects to the time and place of the hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing.

(2) The party must state the reason for the objection and state the time and place he or she wants the hearing to be held.

(3) The request must be in writing, except that a party may orally request that a hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing. The ALJ must document all oral requests for a rescheduled hearing in writing and maintain the documentation in the administrative record.

(4) The ALJ may change the time or place of the hearing if the party has good cause.

(5) If the party's objection to the place of the hearing includes a request for an in-person or VTC hearing, the objection and request are considered in paragraph (i) of this section.

(f) *Good cause for changing the time or place.* The ALJ can find good cause for changing the time or place of the scheduled hearing and reschedule the hearing if the information available to the ALJ supports the party's contention that—

(1) The party or his or her representative is unable to attend or to travel to the scheduled hearing because of a serious physical or mental condition, incapacitating injury, or death in the family; or

(2) Severe weather conditions make it impossible to travel to the hearing; or

(3) Good cause exists as set forth in paragraph (g) of this section.

(g) *Good cause in other circumstances.* (1) In determining whether good cause exists in circumstances other than those set forth in paragraph (f) of this section, the ALJ considers the party's reason for requesting the change, the facts supporting the request, and the impact of the proposed change on the efficient administration of the hearing process.

(2) Factors evaluated to determine the impact of the change include, but are not limited to, the effect on processing other scheduled hearings, potential delays in rescheduling the hearing, and whether any prior changes were granted the party.

(3) Examples of other circumstances a party might give for requesting a change in the time or place of the hearing include, but are not limited to, the following:

(i) The party has attempted to obtain a representative but needs additional time.

(ii) The party's representative was appointed within 10 calendar days of the scheduled hearing and needs additional time to prepare for the hearing.

(iii) The party's representative has a prior commitment to be in court or at another administrative hearing on the date scheduled for the hearing.

(iv) A witness who will testify to facts material to a party's case is unavailable to attend the scheduled hearing and the evidence cannot be otherwise obtained.

(v) Transportation is not readily available for a party to travel to the hearing.

(vi) The party is unrepresented, and is unable to respond to the notice of hearing because of any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) that he or she has.

(vii) The party or representative has a prior commitment that cannot be changed without significant expense.

(viii) The party or representative asserts that he or she did not receive the notice of hearing and is unable to appear at the scheduled time and place.

(h) *Effect of rescheduling hearing.* If a hearing is postponed at the request of the appellant for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the adjudication period specified in § 405.1016.

(i) *A party's request for an in-person or VTC hearing.* (1) If an unrepresented beneficiary who filed the request for hearing objects to a VTC hearing or to the ALJ's offer to conduct a hearing by telephone, or if a party other than an

unrepresented beneficiary who filed the request for hearing objects to a telephone or VTC hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a VTC or an in-person hearing.

(2) The party must state the reason for the objection and state the time and/or place he or she wants an in-person or VTC hearing to be held.

(3) The request must be in writing.

(4) When a party's request for an in-person or VTC hearing as specified under paragraph (i)(1) of this section is granted and an adjudication time frame applies in accordance with § 405.1016, the ALJ issues a decision, dismissal, or remand to the QIC within the adjudication time frame specified in § 405.1016 (including any applicable extensions provided in this subpart) unless the party requesting the hearing agrees to waive such adjudication time frame in writing.

(5) The ALJ may grant the request, with the concurrence of the Chief ALJ or designee if the request was for an in-person hearing, upon a finding of good cause and will reschedule the hearing for a time and place when the party may appear in person or by VTC before the ALJ. Good cause is not required for a request for VTC hearing made by an unrepresented beneficiary who filed the request for hearing and objects to an ALJ's offer to conduct a hearing by telephone.

(j) *Amended notice of hearing.* If the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to all of the parties who were sent a copy of the notice of hearing and CMS or its contractors that elected to be a participant or party to the hearing in accordance with § 405.1022(a).

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 74 FR 65335, Dec. 9, 2009; 82 FR 5114, Jan. 17, 2017; 84 FR 19870, May 7, 2019]

§ 405.1022 Notice of a hearing before an ALJ.

(a) *Issuing the notice.* After the ALJ sets the time and place of the hearing, notice of the hearing will be mailed or otherwise transmitted in accordance with OMHA procedures to the parties

and other potential participants, as provided in § 405.1020(c) at their last known address, or given by personal service, except to a party or potential participant who indicates in writing that it does not wish to receive this notice. The notice is mailed, transmitted, or served at least 20 calendar days before the hearing unless the recipient agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days before the hearing.

(b) *Notice information.* (1) The notice of hearing contains—

(i) A statement that the issues before the ALJ include all of the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor, for the claims specified in the request for hearing; and

(ii) A statement of any specific new issues the ALJ will consider in accordance with § 405.1032.

(2) The notice will inform the parties that they may designate a person to represent them during the proceedings.

(3) The notice must include an explanation of the procedures for requesting a change in the time or place of the hearing, a reminder that the ALJ may dismiss the hearing request if the appellant fails to appear at the scheduled hearing without good cause, and other information about the scheduling and conduct of the hearing.

(4) The appellant will also be told if his or her appearance or that of any other party or witness is scheduled by VTC, telephone, or in person. If the ALJ has scheduled the appellant or other party to appear at the hearing by VTC, the notice of hearing will advise that the scheduled place for the hearing is a VTC site and explain what it means to appear at the hearing by VTC.

(5) The notice advises the appellant or other parties that if they object to appearing by VTC or telephone, and wish instead to have their hearing at a time and place where they may appear in person before the ALJ, they must follow the procedures set forth at § 405.1020(i) for notifying the ALJ of their objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the appellant, any other party to the reconsideration to whom the notice of hearing was sent, or their representative does not acknowledge receipt of the notice of hearing, OMHA attempts to contact the party for an explanation.

(2) If the party states that he or she did not receive the notice of hearing, a copy of the notice is sent to him or her by certified mail or other means requested by the party and in accordance with OMHA procedures.

(3) The party may request that the ALJ reschedule the hearing in accordance with § 405.1020(e).

[82 FR 5115, Jan. 17, 2017]

§ 405.1024 Objections to the issues.

(a) If a party objects to the issues described in the notice of hearing, he or she must notify the ALJ in writing at the earliest possible opportunity before the time set for the hearing, and no later than 5 calendar days before the hearing.

(b) The party must state the reasons for his or her objections and send a copy of the objections to all other parties who were sent a copy of the notice of hearing, and CMS or a contractor that elected to be a party to the hearing.

(c) The ALJ makes a decision on the objections either in writing, at a pre-hearing conference, or at the hearing.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65335, Dec. 9, 2009; 82 FR 5115, Jan. 17, 2017]

§ 405.1026 Disqualification of the ALJ or attorney adjudicator.

(a) An ALJ or attorney adjudicator cannot adjudicate an appeal if he or she is prejudiced or partial to any party or has any interest in the matter pending for decision.

(b) If a party objects to the ALJ or attorney adjudicator assigned to adjudicate the appeal, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing if a hearing is scheduled, or the ALJ or attorney adjudicator at any time before a decision, dismissal order, or remand order is issued if no hearing is scheduled. The ALJ or attorney adjudicator

considers the party's objections and decides whether to proceed with the appeal or withdraw.

(c) If the ALJ or attorney adjudicator withdraws, another ALJ or attorney adjudicator will be assigned to adjudicate the appeal. If the ALJ or attorney adjudicator does not withdraw, the party may, after the ALJ or attorney adjudicator has issued an action in the case, present his or her objections to the Council in accordance with § 405.1100 through § 405.1130. The Council will then consider whether the decision or dismissal should be revised or if applicable, a new hearing held before another ALJ. If the case is escalated to the Council after a hearing is held but before the ALJ issues a decision, the Council considers the reasons the party objected to the ALJ during its review of the case and, if the Council deems it necessary, may remand the case to another ALJ for a hearing and decision.

(d) If the party objects to the ALJ or attorney adjudicator and the ALJ or attorney adjudicator subsequently withdraws from the appeal, any adjudication time frame that applies to the appeal in accordance with § 405.1016 is extended by 14 calendar days.

[82 FR 5115, Jan. 17, 2017]

§ 405.1028 Review of evidence submitted by parties.

(a) *New evidence*—(1) *Examination of any new evidence.* After a hearing is requested but before a hearing is held by an ALJ or a decision is issued if no hearing is held, the ALJ or attorney adjudicator will examine any new evidence submitted in accordance with § 405.1018, by a provider, supplier, or beneficiary represented by a provider or supplier to determine whether the provider, supplier, or beneficiary represented by a provider or supplier had good cause for submitting the evidence for the first time at the OMHA level.

(2) *Determining if good cause exists.* An ALJ or attorney adjudicator finds good cause when—

(i) The new evidence is, in the opinion of the ALJ or attorney adjudicator, material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration;

(ii) The new evidence is, in the opinion of the ALJ, material to a new issue identified in accordance with § 405.1032(b)(1);

(iii) The party was unable to obtain the evidence before the QIC issued its reconsideration and submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates the party made reasonable attempts to obtain the evidence before the QIC issued its reconsideration;

(iv) The party asserts that the evidence was submitted to the QIC or another contractor and submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates the new evidence was submitted to the QIC or another contractor before the QIC issued the reconsideration; or

(v) In circumstances not addressed in paragraphs (a)(2)(i) through (iv) of this section, the ALJ or attorney adjudicator determines that the party has demonstrated that it could not have obtained the evidence before the QIC issued its reconsideration.

(3) *If good cause does not exist.* If the ALJ or attorney adjudicator determines that there was not good cause for submitting the evidence for the first time at the OMHA level, the ALJ or attorney adjudicator must exclude the evidence from the proceeding and may not consider it in reaching a decision.

(4) *Notification to parties.* If a hearing is conducted, as soon as possible, but no later than the start of the hearing, the ALJ must notify all parties and participants who responded to the notice of hearing whether the evidence will be considered or is excluded from consideration.

(b) *Duplicative evidence.* The ALJ or attorney adjudicator may exclude from consideration any evidence submitted by a party at the OMHA level that is duplicative of evidence already in the record forwarded to OMHA.

[82 FR 5115, Jan. 17, 2017]

§ 405.1030 ALJ hearing procedures.

(a) *General rule.* A hearing is open to the parties and to other persons the ALJ considers necessary and proper.

(b) *At the hearing.* (1) At the hearing, the ALJ fully examines the issues,

questions the parties and other witnesses, and may accept evidence that is material to the issues consistent with §§ 405.1018 and 405.1028.

(2) The ALJ may limit testimony and/or argument at the hearing that are not relevant to an issue before the ALJ, that are repetitive of evidence or testimony already in the record, or that relate to an issue that has been sufficiently developed or on which the ALJ has already ruled. The ALJ may, but is not required to, provide the party or representative with an opportunity to submit additional written statements and affidavits on the matter, in lieu of testimony and/or argument at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(3) If the ALJ determines that a party or party's representative is uncooperative, disruptive to the hearing, or abusive during the course of the hearing after the ALJ has warned the party or representative to stop such behavior, the ALJ may excuse the party or representative from the hearing and continue with the hearing to provide the other parties and participants with an opportunity to offer testimony and/or argument. If a party or representative was excused from the hearing, the ALJ will provide the party or representative with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing, and the party or representative may request a recording of the hearing in accordance with § 405.1042 and respond in writing to any statements made by other parties or participants and/or testimony of the witnesses at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing. If the missing evidence is in the possession of the appellant, and the appellant is a provider, supplier, or a beneficiary represented by a provider or supplier, the ALJ must determine if the appellant had

good cause in accordance with § 405.1028 for not producing the evidence earlier.

(d) *Effect of new evidence on adjudication period.* If an appellant, other than an unrepresented beneficiary, submits evidence pursuant to paragraph (b) or (c) of this section, and an adjudication period applies to the appeal, the adjudication period specified in § 405.1016 is extended in accordance with § 405.1018(b).

(e) *Continued hearing.* (1) A hearing may be continued to a later date. Notice of the continued hearing must be sent in accordance with § 405.1022, except that a waiver of notice of the hearing may be made in writing or on the record, and the notice is sent to the parties and participants who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate.

(2) If the appellant requests the continuance and an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period is extended by the period between the initial hearing date and the continued hearing date.

(f) *Supplemental hearing.* (1) The ALJ may conduct a supplemental hearing at any time before he or she mails a notice of the decision in order to receive new and material evidence, obtain additional testimony, or address a procedural matter. The ALJ determines whether a supplemental hearing is necessary and if one is held, the scope of the hearing, including when evidence is presented and what issues are discussed. Notice of the supplemental hearing must be sent in accordance with § 405.1022, except that the notice is sent to the parties and participants who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate.

(2) If the appellant requests the supplemental hearing and an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period is extended by the period between the initial hearing date and the supplemental hearing date.

[82 FR 5116, Jan. 17, 2017]

§ 405.1032 Issues before an ALJ or attorney adjudicator.

(a) *General rule.* The issues before the ALJ or attorney adjudicator include all the issues for the claims or appealed matter specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. (For purposes of this provision, the term "party" does not include a representative of CMS or one of its contractors that may be participating in the hearing.)

(b) *New issues*—(1) *When a new issue may be considered.* A new issue may include issues resulting from the participation of CMS or its contractor at the OMHA level of adjudication and from any evidence and position papers submitted by CMS or its contractor for the first time to the ALJ. The ALJ or any party may raise a new issue relating to a claim or appealed matter specified in the request for hearing; however, the ALJ may only consider a new issue, including a favorable portion of a determination on a claim or appealed matter specified in the request for hearing, if its resolution could have a material impact on the claim or appealed matter and—

(i) There is new and material evidence that was not available or known at the time of the determination and that may result in a different conclusion; or

(ii) The evidence that was considered in making the determination clearly shows on its face that an obvious error was made at the time of the determination.

(2) *Notice of the new issue.* The ALJ may consider a new issue at the hearing if he or she notifies the parties that were or will be sent the notice of hearing about the new issue before the start of the hearing.

(3) *Opportunity to submit evidence.* If notice of the new issue is sent after the notice of hearing, the parties will have at least 10 calendar days after receiving notice of the new issue to submit evidence regarding the issue, and without affecting any applicable adjudication period. If a hearing is conducted before the time to submit evidence regarding the issue expires, the record

will remain open until the opportunity to submit evidence expires.

(c) *Adding claims to a pending appeal.* (1) Claims that were not specified in a request for hearing may only be added to a pending appeal if the claims were adjudicated in the same reconsideration that is appealed, and the period to request an ALJ hearing for that reconsideration has not expired, or an ALJ or attorney adjudicator extends the time to request an ALJ hearing on those claims in accordance with § 405.1014(e).

(2) Before a claim may be added to a pending appeal, the appellant must submit evidence that demonstrates the information that constitutes a complete request for hearing in accordance with § 405.1014(b) and other materials related to the claim that the appellant seeks to add to the pending appeal were sent to the other parties to the claim in accordance with § 405.1014(d).

(d) *Appeals involving statistical sampling and extrapolations*—(1) *Generally.* If the appellant does not assert the reasons the appellant disagrees with how a statistical sample and/or extrapolation was conducted in the request for hearing, in accordance with § 405.1014(a)(3)(iii), issues related to how the statistical sample and extrapolation were conducted shall not be considered or decided.

(2) *Consideration of sample claims.* If a party asserts a disagreement with how a statistical sample and/or extrapolation was conducted in the request for hearing, in accordance with § 405.1014(a)(3)(iii), paragraphs (a) through (c) of this section apply to the adjudication of the sample claims but, in deciding issues related to how a statistical sample and/or extrapolation was conducted the ALJ or attorney adjudicator must base his or her decision on a review of the entire sample to the extent appropriate to decide the issue.

[82 FR 5116, Jan. 17, 2017]

§ 405.1034 Requesting information from the QIC.

(a) If an ALJ or attorney adjudicator believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only

by CMS or its contractors, the information may be requested from the QIC that conducted the reconsideration or its successor.

(1) Official copies of redeterminations and reconsiderations that were conducted on the appealed claims, and official copies of dismissals of a request for redetermination or reconsideration, can be provided only by CMS or its contractors. Prior to issuing a request for information to the QIC, OMHA will confirm whether an electronic copy of the redetermination, reconsideration, or dismissal is available in the official system of record, and if so will accept the electronic copy as an official copy.

(2) “Can be provided only by CMS or its contractors” means the information is not publicly available, is not in the possession of, and cannot be requested and obtained by one of the parties. Information that is publicly available is information that is available to the general public via the Internet or in a printed publication. Information that is publicly available includes, but is not limited to, information available on a CMS or contractor Web site or information in an official CMS or DHHS publication (including, but not limited to, provisions of NCDs or LCDs, procedure code or modifier descriptions, fee schedule data, and contractor operating manual instructions).

(b) The ALJ or attorney adjudicator retains jurisdiction of the case, and the case remains pending at OMHA.

(c) The QIC has 15 calendar days after receiving the request for information to furnish the information or otherwise respond to the information request directly or through CMS or another contractor.

(d) If an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period is extended by the period between the date of the request for information and the date the QIC responds to the request or 20 calendar days after the date of the request, whichever occurs first.

[82 FR 5117, Jan. 17, 2017, as amended at 84 FR 19870, May 7, 2019]

§ 405.1036 Description of an ALJ hearing process.

(a) *The right to appear and present evidence.* (1) Any party to a hearing has

the right to appear before the ALJ to present evidence and to state his or her position. A party may appear by video-teleconferencing (VTC), telephone, or in person as determined under § 405.1020.

(2) A party may also make his or her appearance by means of a representative, who may make the appearance by VTC, telephone, or in person, as determined under § 405.1020.

(3) Witness testimony may be given and CMS participation may also be accomplished by VTC, telephone, or in person, as determined under § 405.1020.

(b) *Waiver of the right to appear.* (1) A party may submit to OMHA a written statement indicating that he or she does not wish to appear at the hearing.

(2) The appellant may subsequently withdraw his or her waiver at any time before the notice of the hearing decision is issued; however, by withdrawing the waiver the appellant agrees to an extension of the adjudication period as specified in § 405.1016 that may be necessary to schedule and hold the hearing.

(3) Other parties may withdraw their waiver up to the date of the scheduled hearing, if any. Even if all of the parties waive their right to appear at a hearing, the ALJ may require them to attend an oral hearing if he or she believes that a personal appearance and testimony by the appellant or any other party is necessary to decide the case.

(c) *Presenting written statements and oral arguments.* A party or a person designated to act as a party’s representative may appear before the ALJ to state the party’s case, to present a written summary of the case, or to enter written statements about the facts and law material to the case in the record. A copy of any written statements must be provided to the other parties to a hearing, if any, at the same time they are submitted to the ALJ.

(d) *Witnesses at a hearing.* Witnesses may appear at a hearing. They testify under oath or affirmation, unless the ALJ finds an important reason to excuse them from taking an oath or affirmation. The ALJ may ask the witnesses any questions relevant to the

issues and allows the parties or their designated representatives to do so.

(e) *What evidence is admissible at a hearing.* The ALJ may receive evidence at the hearing even though the evidence is not admissible in court under the rules of evidence used by the court.

(f) *Subpoenas.* (1) Except as provided in this section, when it is reasonably necessary for the full presentation of a case, an ALJ may, on his or her own initiative or at the request of a party, issue subpoenas for the appearance and testimony of witnesses and for a party to make books, records, correspondence, papers, or other documents that are material to an issue at the hearing available for inspection and copying. An ALJ may not issue a subpoena to CMS or its contractors, on his or her own initiative or at the request of a party, to compel an appearance, testimony, or the production of evidence.

(2) A party's written request for a subpoena must—

- (i) Give the names of the witnesses or documents to be produced;
- (ii) Describe the address or location of the witnesses or documents with sufficient detail to find them;
- (iii) State the important facts that the witness or document is expected to prove; and
- (iv) Indicate why these facts cannot be proven without issuing a subpoena.

(3) Parties to a hearing who wish to subpoena documents or witnesses must file a written request for the issuance of a subpoena with the requirements set forth in paragraph (f)(2) of this section with the ALJ no later than the end of the discovery period established by the ALJ under § 405.1037(c).

(4) Where a party has requested a subpoena, a subpoena will be issued only where a party—

- (i) Has sought discovery;
- (ii) Has filed a motion to compel;
- (iii) Has had that motion granted by the ALJ; and
- (iv) Nevertheless, has not received the requested discovery.

(5) Reviewability of subpoena rulings—

(i) *General rule.* An ALJ ruling on a subpoena request is not subject to immediate review by the Council. The ruling may be reviewed solely during the course of the Council's review spec-

ified in § 405.1016(e) and (f), § 405.1102, or § 405.1110, as applicable. *Exception.* To the extent a subpoena compels disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was made before an ALJ, the Council may review immediately the subpoena or that portion of the subpoena as applicable.

(ii) Where CMS objects to a subpoena ruling, the Council must take review and the subpoena ruling at issue is automatically stayed pending the Council's order.

(iii) Upon notice to the ALJ that a party or non-party, as applicable, intends to seek Council review of the subpoena, the ALJ must stay all proceedings affected by the subpoena.

(iv) The ALJ determines the length of the stay under the circumstances of a given case, but in no event is the stay less than 15 calendar days beginning after the day on which the ALJ received notice of the party or non-party's intent to seek Council review.

(v) If the Council grants a request for review of the subpoena, the subpoena or portion of the subpoena, as applicable, is stayed until the Council issues a written decision that affirms, reverses, or modifies the ALJ's action on the subpoena.

(vi) If the Council does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the ALJ's action stands.

(6) *Enforcement.* (i) If the ALJ determines, whether on his or her own motion or at the request of a party, that a party or non-party subject to a subpoena issued under this section has refused to comply with the subpoena, the ALJ may request the Secretary to seek enforcement of the subpoena in accordance with section 205(e) of the Act, 42 U.S.C. 405(e).

(ii) Any enforcement request by an ALJ must consist of a written notice to the Secretary describing in detail the ALJ's findings of noncompliance and his or her specific request for enforcement, and providing a copy of the subpoena and evidence of its receipt by certified mail by the party or nonparty subject to the subpoena.

(iii) The ALJ must promptly mail a copy of the notice and related documents to the party subject to the subpoena, and to any other party and affected non-party to the appeal.

[70 FR 11472, Mar. 8, 2005, as amended at 74 FR 65336, Dec. 9, 2009; 82 FR 5117, Jan. 17, 2017]

§ 405.1037 Discovery.

(a) *General rules.* (1) Discovery is permissible only when CMS or its contractor elects to be a party to an ALJ hearing, in accordance with § 405.1012.

(2) The ALJ may permit discovery of a matter that is relevant to the specific subject matter of the ALJ hearing, provided the matter is not privileged or otherwise protected from disclosure and the ALJ determines that the discovery request is not unreasonable, unduly burdensome or expensive, or otherwise inappropriate.

(3) Any discovery initiated by a party must comply with all requirements and limitations of this section, along with any further requirements or limitations ordered by the ALJ.

(b) *Limitations on discovery.* Any discovery before the ALJ is limited.

(1) A party may request of another party the reasonable production of documents for inspection and copying.

(2) A party may not take the deposition, upon oral or written examination, of another party unless the proposed deponent agrees to the deposition or the ALJ finds that the proposed deposition is necessary and appropriate in order to secure the deponent's testimony for an ALJ hearing.

(3) A party may not request admissions or send interrogatories or take any other form of discovery not permitted under this section.

(c) *Time limits.* (1) A party's discovery request is timely if the date of receipt of a request by another party is no later than the date specified by the ALJ.

(2) A party may not conduct discovery any later than the date specified by the ALJ.

(3) Before ruling on a request to extend the time for requesting discovery or for conducting discovery, the ALJ must give the other parties to the appeal a reasonable period to respond to the extension request.

(4) The ALJ may extend the time in which to request discovery or conduct discovery only if the requesting party establishes that it was not dilatory or otherwise at fault in not meeting the original discovery deadline.

(5) If the ALJ grants the extension request, it must impose a new discovery deadline and, if necessary, reschedule the hearing date so that all discoveries end no later than 45 calendar days before the hearing.

(d) *Motions to compel or for protective order.* (1) Each party is required to make a good faith effort to resolve or narrow any discovery dispute.

(2) A party may submit to the ALJ a motion to compel discovery that is permitted under this section or any ALJ order, and a party may submit a motion for a protective order regarding any discovery request to the ALJ.

(3) Any motion to compel or for protective order must include a self-sworn declaration describing the movant's efforts to resolve or narrow the discovery dispute. The declaration must also be included with any response to a motion to compel or for protective order.

(4) The ALJ must decide any motion in accordance with this section and any prior discovery ruling in the appeal.

(5) The ALJ must issue and mail to each party a discovery ruling that grants or denies the motion to compel or for protective order in whole or in part; if applicable, the discovery ruling must specifically identify any part of the disputed discovery request upheld and any part rejected, and impose any limits on discovery the ALJ finds necessary and appropriate.

(e) *Reviewability of discovery and disclosure rulings.*—(1) *General rule.* An ALJ discovery ruling, or an ALJ disclosure ruling such as one issued at a hearing is not subject to immediate review by the Council. The ruling may be reviewed solely during the course of the Council's review specified in § 405.1016(e) and (f), § 405.1100, § 405.1102, or § 405.1110, as applicable.

(2) *Exception.* To the extent a ruling authorizes discovery or disclosure of a matter for which an objection based on privilege, or other protection from disclosure such as case preparation, confidentiality, or undue burden, was

made before the ALJ, the Council may review that portion of the discovery or disclosure ruling immediately.

(i) Where CMS objects to a discovery ruling, the Council must take review and the discovery ruling at issue is automatically stayed pending the Council's order.

(ii) Upon notice to the ALJ that a party intends to seek Council review of the ruling, the ALJ must stay all proceedings affected by the ruling.

(iii) The ALJ determines the length of the stay under the circumstances of a given case, but in no event must the length of the stay be less than 15 calendar days beginning after the day on which the ALJ received notice of the party or non-party's intent to seek Council review.

(iv) Where CMS requests the Council to take review of a discovery ruling or where the Council grants a request, made by a party other than CMS, to review a discovery ruling, the ruling is stayed until the time the Council issues a written decision that affirms, reverses, modifies, or remands the ALJ's ruling.

(v) With respect to a request from a party, other than CMS, for review of a discovery ruling, if the Council does not grant review or take own motion review within the time allotted for the stay, the stay is lifted and the ruling stands.

(f) *Adjudication period.* If an adjudication period applies to the appeal in accordance with § 405.1016, and a party requests discovery from another party to the hearing, the adjudication period is extended for the duration of discovery, from the date a discovery request is granted until the date specified for ending discovery.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 74 FR 65336, Dec. 9, 2009; 82 FR 5117, Jan. 17, 2017]

§ 405.1038 Deciding a case without a hearing before an ALJ.

(a) *Decision fully favorable.* If the evidence in the administrative record supports a finding fully in favor of the appellant(s) on every issue and no other party to the appeal is liable for claims at issue, an ALJ or attorney adjudicator may issue a decision without giving the parties prior notice and with-

out an ALJ conducting a hearing, unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012. The notice of the decision informs the parties that they have the right to a hearing and a right to examine the evidence on which the decision is based.

(b) *Parties do not wish to appear.* (1) An ALJ or attorney adjudicator may decide a case on the record and without an ALJ conducting a hearing if—

(i) All the parties who would be sent a notice of hearing in accordance with § 405.1020(c) indicate in writing that they do not wish to appear before an ALJ at a hearing, including a hearing conducted by telephone or video-teleconferencing, if available; or

(ii) The appellant lives outside the United States and does not inform OMHA that he or she wants to appear at a hearing before an ALJ, and there are no other parties who would be sent a notice of hearing in accordance with § 405.1020(c) and who wish to appear.

(2) When a hearing is not held, the decision of the ALJ or attorney adjudicator must refer to the evidence in the record on which the decision was based.

(c) *Stipulated decision.* If CMS or one of its contractors submits a written statement or makes an oral statement at a hearing indicating the item or service should be covered or payment may be made, and the written or oral statement agrees to the amount of payment the parties believe should be made if the amount of payment is an issue before the ALJ or attorney adjudicator, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the appellant or other liable parties on the basis of the statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision.

[82 FR 5117, Jan. 17, 2017]

§ 405.1040 Prehearing and posthearing conferences.

(a) The ALJ may decide on his or her own, or at the request of any party to the hearing, to hold a prehearing or posthearing conference to facilitate the hearing or the hearing decision.

(b) The ALJ informs the parties who will be or were sent a notice of hearing

in accordance with § 405.1020(c), and CMS or a contractor that has elected to be a participant in the proceedings or party to the hearing at the time the notice of conference is sent, of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless a party indicates in writing that it does not wish to receive a written notice of the conference.

(c) At the conference—

(1) The ALJ or an OMHA attorney designated by the ALJ conducts the conference, but only the ALJ conducting a conference may consider matters in addition to those stated in the conference notice if the parties consent to consideration of the additional matters in writing.

(2) An audio recording of the conference is made.

(d) The ALJ issues an order to all parties and participants who attended the conference stating all agreements and actions resulting from the conference. If a party does not object within 10 calendar days of receiving the order, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on all parties.

[82 FR 5118, Jan. 17, 2017]

§ 405.1042 The administrative record.

(a) *Creating the record.* (1) OMHA makes a complete record of the evidence and administrative proceedings on the appealed matter, including any prehearing and posthearing conferences, and hearing proceedings that were conducted.

(2) The record will include marked as exhibits, the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney adjudicator admits. The record will also include any evidence excluded or not considered by the ALJ or attorney adjudicator, including, but not limited to, new evidence submitted by a provider or supplier, or beneficiary represented by a

provider or supplier, for which no good cause was established, and duplicative evidence submitted by a party.

(3) A party may request and review a copy of the record prior to or at the hearing, or, if a hearing is not held, at any time before the notice of decision is issued.

(4) If a request for review is filed or the case is escalated to the Council, the complete record, including any prehearing and posthearing conference and hearing recordings, is forwarded to the Council.

(5) A typed transcription of the hearing is prepared if a party seeks judicial review of the case in a Federal district court within the stated time period and all other jurisdictional criteria are met, unless, upon the Secretary's motion prior to the filing of an answer, the court remands the case.

(b) *Requesting and receiving copies of the record.* (1) While an appeal is pending at OMHA, a party may request and receive a copy of all or part of the record from OMHA, including any index of the administrative record, documentary evidence, and a copy of the audio recording of the oral proceedings. The party may be asked to pay the costs of providing these items.

(2) If a party requests a copy of all or part of the record from OMHA or the ALJ or attorney adjudicator and an opportunity to comment on the record, any adjudication period that applies in accordance with § 405.1016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the party's response.

(3) If a party requests a copy of all or part of the record and the record, including any audio recordings, contains information pertaining to an individual that the requesting party is not entitled to receive, such as personally identifiable information or protected health information, such portions of the record will not be furnished unless the requesting party obtains consent from the individual.

[82 FR 5118, Jan. 17, 2017]

§ 405.1044 Consolidated proceedings.

(a) *Consolidated hearing.* (1) A consolidated hearing may be held if one or more of the issues to be considered at

the hearing are the same issues that are involved in one or more other appeals pending before the same ALJ.

(2) It is within the discretion of the ALJ to grant or deny an appellant's request for consolidation. In considering an appellant's request, the ALJ may consider factors such as whether the claims at issue may be more efficiently decided if the appeals are consolidated for hearing. In considering the appellant's request for consolidation, the ALJ must take into account any adjudication deadlines for each appeal and may require an appellant to waive the adjudication deadline associated with one or more appeals if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

(3) The ALJ may also propose on his or her own motion to consolidate two or more appeals in one hearing for administrative efficiency, but may not require an appellant to waive the adjudication deadline for any of the consolidated cases.

(4) Notice of a consolidated hearing must be included in the notice of hearing issued in accordance with §§ 405.1020 and 405.1022.

(b) *Consolidated or separate decision and record.* (1) If the ALJ decides to hold a consolidated hearing, he or she may make either—

(i) A consolidated decision and record; or

(ii) A separate decision and record on each appeal.

(2) If a separate decision and record on each appeal is made, the ALJ is responsible for making sure that any evidence that is common to all appeals and material to the common issue to be decided, and audio recordings of any conferences that were conducted and the consolidated hearing are included in each individual administrative record, as applicable.

(3) If a hearing will not be conducted for multiple appeals that are before the same ALJ or attorney adjudicator, and the appeals involve one or more of the same issues, the ALJ or attorney adjudicator may make a consolidated decision and record at the request of the appellant or on the ALJ's or attorney adjudicator's own motion.

(c) *Limitation on consolidated proceedings.* Consolidated proceedings may only be conducted for appeals filed by the same appellant, unless multiple appellants aggregated claims to meet the amount in controversy requirement in accordance with § 405.1006 and the beneficiaries whose claims are at issue have all authorized disclosure of their protected information to the other parties and any participants.

[82 FR 5118, Jan. 17, 2017]

§ 405.1046 Notice of an ALJ or attorney adjudicator decision.

(a) *Decisions on requests for hearing—*

(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses or remands the request for hearing, the ALJ or attorney adjudicator will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision. The decision must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions. OMHA mails or otherwise transmits a copy of the decision to all the parties at their last known address and the QIC that issued the reconsideration or from which the appeal was escalated. For overpayment cases involving multiple beneficiaries, where there is no beneficiary liability, the ALJ or attorney adjudicator may choose to send written notice only to the appellant. In the event a payment will be made to a provider or supplier in conjunction with the ALJ's or attorney adjudicator's decision, the contractor must also issue a revised electronic or paper remittance advice to that provider or supplier.

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by a beneficiary and must include—

(i) The specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination;

(ii) For any new evidence that was submitted for the first time at the OMHA level and subject to a good cause determination pursuant to

§ 405.1028, a discussion of the new evidence and the good cause determination that was made;

(iii) The procedures for obtaining additional information concerning the decision; and

(iv) Notification of the right to appeal the decision to the Council, including instructions on how to initiate an appeal under this section.

(3) *Limitation on decision.* When the amount of payment for an item or service is an issue before the ALJ or attorney adjudicator, the ALJ or attorney adjudicator may make a finding as to the amount of payment due. If the ALJ or attorney adjudicator makes a finding concerning payment when the amount of payment was not an issue before the ALJ or attorney adjudicator, the contractor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's or attorney adjudicator's decision is not binding on the contractor for purposes of determining the amount of payment due. The amount of payment determined by the contractor in effectuating the ALJ's or attorney adjudicator's decision is a new initial determination under § 405.924.

(b) *Decisions on requests for review of a QIC dismissal*—(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses the request for review of a QIC dismissal, or the QIC's dismissal is vacated and remanded, the ALJ or attorney adjudicator will issue a written decision affirming the QIC's dismissal. OMHA mails or otherwise transmits a copy of the decision to all the parties that received a copy of the QIC's dismissal.

(2) *Content of the notice.* The decision must be written in a manner calculated to be understood by a beneficiary and must include—

(i) The specific reasons for the determination, including a summary of the evidence considered and applicable authorities;

(ii) The procedures for obtaining additional information concerning the decision; and

(iii) Notification that the decision is binding and is not subject to further review, unless reopened and revised by the ALJ or attorney adjudicator.

(c) *Recommended decision.* An ALJ or attorney adjudicator issues a recommended decision if he or she is directed to do so in the Council's remand order. An ALJ or attorney adjudicator may not issue a recommended decision on his or her own motion. The ALJ or attorney adjudicator mails a copy of the recommended decision to all the parties at their last known address.

[82 FR 5119, Jan. 17, 2017, as amended at 84 FR 19871, May 7, 2019]

§ 405.1048 The effect of an ALJ's or attorney adjudicator's decision.

(a) The decision of the ALJ or attorney adjudicator on a request for hearing is binding on all parties unless—

(1) A party requests a review of the decision by the Council within the stated time period or the Council reviews the decision issued by an ALJ or attorney adjudicator under the procedures set forth in § 405.1110, and the Council issues a final decision or remand order or the appeal is escalated to Federal district court under the provisions at § 405.1132 and the Federal district court issues a decision.

(2) The decision is reopened and revised by an ALJ or attorney adjudicator or the Council under the procedures explained in § 405.980;

(3) The expedited access to judicial review process at § 405.990 is used;

(4) The ALJ's or attorney adjudicator's decision is a recommended decision directed to the Council and the Council issues a decision; or

(5) In a case remanded by a Federal district court, the Council assumes jurisdiction under the procedures in § 405.1138 and the Council issues a decision.

(b) The decision of the ALJ or attorney adjudicator on a request for review of a QIC dismissal is binding on all parties unless the decision is reopened and revised by the ALJ or attorney adjudicator under the procedures in § 405.980.

[82 FR 5119, Jan. 17, 2017]

§ 405.1050 Removal of a hearing request from OMHA to the Council.

If a request for hearing is pending before OMHA, the Council may assume responsibility for holding a hearing by

requesting that OMHA send the hearing request to it. If the Council holds a hearing, it conducts the hearing according to the rules for hearings before an ALJ. Notice is mailed to all parties at their last known address informing them that the Council has assumed responsibility for the case.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5118, Jan. 17, 2017]

§ 405.1052 Dismissal of a request for a hearing before an ALJ or request for review of a QIC dismissal.

(a) *Dismissal of request for hearing.* An ALJ dismisses a request for a hearing under any of the following conditions:

(1) Neither the party that requested the hearing nor the party's representative appears at the time and place set for the hearing, if—

(i) The party was notified before the time set for the hearing that the request for hearing might be dismissed for failure to appear, the record contains documentation that the party acknowledged the notice of hearing, and the party does not contact the ALJ within 10 calendar days after the hearing, or does contact the ALJ but the ALJ determines the party did not demonstrate good cause for not appearing; or

(ii) The record does not contain documentation that the party acknowledged the notice of hearing, the ALJ sends a notice to the party at the last known address asking why the party did not appear, and the party does not respond to the ALJ's notice within 10 calendar days after receiving the notice or does contact the ALJ but the ALJ determines the party did not demonstrate good cause for not appearing.

(iii) In determining whether good cause exists under paragraphs (a)(1)(i) and (ii) of this section, the ALJ considers any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language), that the party may have.

(2) The person or entity requesting a hearing has no right to it under § 405.1002.

(3) The party did not request a hearing within the stated time period and the ALJ has not found good cause for

extending the deadline, as provided in § 405.1014(e).

(4) The beneficiary whose claim is being appealed died while the request for hearing is pending and all of the following criteria apply:

(i) The request for hearing was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the ALJ considers if the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation on liability provisions based on the denial of the services at issue.

(ii) No other individuals or entities that have a financial interest in the case wish to pursue an appeal under § 405.1002.

(iii) No other individual or entity filed a valid and timely request for an ALJ hearing in accordance to § 405.1014.

(5) The ALJ dismisses a hearing request entirely or refuses to consider any one or more of the issues because a QIC, an ALJ or attorney adjudicator, or the Council has made a previous determination or decision under this subpart about the appellant's rights on the same facts and on the same issue(s) or claim(s), and this previous determination or decision has become binding by either administrative or judicial action.

(6) The appellant abandons the request for hearing. An ALJ may conclude that an appellant has abandoned a request for hearing when OMHA attempts to schedule a hearing and is unable to contact the appellant after making reasonable efforts to do so.

(7) The appellant's request is not complete in accordance with § 405.1014(a)(1) or the appellant, other than an unrepresented beneficiary, did not send a copy of its request to the other parties in accordance with § 405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send a copy of the request to the other parties.

(b) *Dismissal of request for review of a QIC dismissal.* An ALJ or attorney adjudicator dismisses a request for review

of a QIC dismissal under any of the following conditions:

(1) The person or entity requesting a review of a dismissal has no right to it under § 405.1004.

(2) The party did not request a review within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in § 405.1014(e).

(3) The beneficiary whose claim is being appealed died while the request for review is pending and all of the following criteria apply:

(i) The request for review was filed by the beneficiary or the beneficiary's representative, and the beneficiary's surviving spouse or estate has no remaining financial interest in the case. In deciding this issue, the ALJ or attorney adjudicator considers if the surviving spouse or estate remains liable for the services that were denied or a Medicare contractor held the beneficiary liable for subsequent similar services under the limitation on liability provisions based on the denial of the services at issue.

(ii) No other individuals or entities that have a financial interest in the case wish to pursue an appeal under § 405.1004.

(iii) No other individual or entity filed a valid and timely request for a review of the QIC dismissal in accordance to § 405.1014.

(4) The appellant's request is not complete in accordance with § 405.1014(a)(1) or the appellant, other than an unrepresented beneficiary, did not send a copy of its request to the other parties in accordance with § 405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send a copy of the request to the other parties.

(c) *Withdrawal of request.* At any time before notice of the decision, dismissal, or remand is mailed, if only one party requested the hearing or review of the QIC dismissal and that party asks to withdraw the request, an ALJ or attorney adjudicator may dismiss the request for hearing or request for review of a QIC dismissal. This request for withdrawal may be submitted in writing, or a request to withdraw a request for hearing may be made orally at a hearing before the ALJ. The request

for withdrawal must include a clear statement that the appellant is withdrawing the request for hearing or review of the QIC dismissal and does not intend to further proceed with the appeal. If an attorney or other legal professional on behalf of a beneficiary or other appellant files the request for withdrawal, the ALJ or attorney adjudicator may presume that the representative has advised the appellant of the consequences of the withdrawal and dismissal.

(d) *Notice of dismissal.* OMHA mails or otherwise transmits a written notice of the dismissal of the hearing or review request to the appellant, all parties who were sent a copy of the request for hearing or review at their last known address, and to CMS or a CMS contractor that is a party to the proceedings on a request for hearing. The notice states that there is a right to request that the ALJ or attorney adjudicator vacate the dismissal action. The appeal will proceed with respect to any other parties who filed a valid request for hearing or review regarding the same claim or disputed matter.

(e) *Vacating a dismissal.* If good and sufficient cause is established, the ALJ or attorney adjudicator may vacate his or her dismissal of a request for hearing or review within 180 calendar days of the date of the notice of dismissal.

[82 FR 5119, Jan. 17, 2017, as amended at 84 FR 19871, May 7, 2019]

§ 405.1054 Effect of dismissal of a request for a hearing or request for review of QIC dismissal.

(a) The dismissal of a request for a hearing is binding, unless it is vacated by the Council under § 405.1108(b), or vacated by the ALJ or attorney adjudicator under § 405.1052(e).

(b) The dismissal of a request for review of a QIC dismissal of a request for reconsideration is binding and not subject to further review unless it is vacated by the ALJ or attorney adjudicator under § 405.1052(e).

[82 FR 5120, Jan. 17, 2017]

§ 405.1056 Remands of requests for hearing and requests for review.

(a) *Missing appeal determination or case record.* (1) If an ALJ or attorney adjudicator requests an official copy of

a missing redetermination or reconsideration for an appealed claim in accordance with § 405.1034, and the QIC or another contractor does not furnish the copy within the time frame specified in § 405.1034, the ALJ or attorney adjudicator may issue a remand directing the QIC or other contractor to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(2) If the QIC does not furnish the case file for an appealed reconsideration, an ALJ or attorney adjudicator may issue a remand directing the QIC to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(3) If the QIC or another contractor is able to reconstruct the record for a remanded case and returns the case to OMHA, the case is no longer remanded and the reconsideration is no longer vacated, and any adjudication period that applies to the appeal in accordance with § 405.1016 is extended by the period between the date of the remand and the date that case is returned to OMHA.

(b) *No redetermination.* If an ALJ or attorney adjudicator finds that the QIC issued a reconsideration that addressed coverage or payment issues related to the appealed claim and no redetermination of the claim was made (if a redetermination was required under this subpart) or the request for redetermination was dismissed, the reconsideration will be remanded to the QIC, or its successor to re-adjudicate the request for reconsideration.

(c) *Requested remand—(1) Request contents and timing.* At any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the appellant and CMS or one of its contractors may jointly request a remand of the appeal to the entity that conducted the reconsideration. The request must include the reasons why the appeal should be remanded and indicate whether remanding the case will likely resolve the matter in dispute.

(2) *Granting the request.* An ALJ or attorney adjudicator may grant the request and issue a remand if he or she determines that remanding the case will likely resolve the matter in dispute.

(d) *Remanding a QIC's dismissal of a request for reconsideration.* (1) Consistent with § 405.1004(b), an ALJ or attorney adjudicator will remand a case to the appropriate QIC if the ALJ or attorney adjudicator determines that a QIC's dismissal of a request for reconsideration was in error.

(2) If an official copy of the notice of dismissal or case file cannot be obtained from the QIC, an ALJ or attorney adjudicator may also remand a request for review of a dismissal in accordance with the procedures in paragraph (a) of this section.

(e) *Relationship to local and national coverage determination appeals process.*

(1) An ALJ or attorney adjudicator remands an appeal to the QIC that made the reconsideration if the appellant is entitled to relief pursuant to § 426.460(b)(1), § 426.488(b), or § 426.560(b)(1) of this chapter.

(2) Unless the appellant is entitled to relief pursuant to § 426.460(b)(1), § 426.488(b), or § 426.560(b)(1) of this chapter, the ALJ or attorney adjudicator applies the LCD or NCD in place on the date the item or service was provided.

(f) *Notice of remand.* OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to the appellant, all of the parties who were sent a copy of the request at their last known address, and CMS or a contractor that elected to be a participant in the proceedings or party to the hearing. The notice states that there is a right to request that the Chief ALJ or a designee review the remand, unless the remand was issued under paragraph (d)(1) of this section.

(g) *Review of remand.* Upon a request by a party or CMS or one of its contractors filed within 30 calendar days of receiving a notice of remand, the Chief ALJ or designee will review the remand, and if the remand is not authorized by this section, vacate the remand order. The determination on a request to review a remand order is binding and not subject to further review. The review of remand procedures provided for in this paragraph are not

Centers for Medicare & Medicaid Services, HHS

§ 405.1063

available for and do not apply to remands that are issued under paragraph (d)(1) of this section.

[82 FR 5121, Jan. 17, 2017, as amended at 84 FR 19871, May 7, 2019]

§ 405.1058 Effect of a remand.

A remand of a request for hearing or request for review is binding unless vacated by the Chief ALJ or a designee in accordance with § 405.1056(g).

[82 FR 5121, Jan. 17, 2017]

APPLICABILITY OF MEDICARE COVERAGE POLICIES

§ 405.1060 Applicability of national coverage determinations (NCDs).

(a) *General rule.* (1) An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare.

(2) An NCD does not include a determination of what code, if any, is assigned to a particular item or service covered under Medicare or a determination of the amount of payment made for a particular item or service.

(3) NCDs are made under section 1862(a)(1) of the Act as well as under other applicable provisions of the Act.

(4) An NCD is binding on fiscal intermediaries, carriers, QIOs, QICs, ALJs and attorney adjudicators, and the Council.

(b) *Review by an ALJ or attorney adjudicator.* (1) An ALJ or attorney adjudicator may not disregard, set aside, or otherwise review an NCD.

(2) An ALJ or attorney adjudicator may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim.

(c) *Review by the Council.* (1) The Council may not disregard, set aside, or otherwise review an NCD for purposes of a section 1869 claim appeal, except that the DAB may review NCDs as provided under part 426 of this title.

(2) The Council may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether

the NCD was applied correctly to the claim.

[70 FR 11472, Mar. 8, 2005, as amended at 70 FR 37704, June 30, 2005; 82 FR 5121, Jan. 17, 2017]

§ 405.1062 Applicability of local coverage determinations and other policies not binding on the ALJ or attorney adjudicator and Council.

(a) ALJs and attorney adjudicators and the Council are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case.

(b) If an ALJ or attorney adjudicator or Council declines to follow a policy in a particular case, the ALJ or attorney adjudicator or Council decision must explain the reasons why the policy was not followed. An ALJ or attorney adjudicator or Council decision to disregard such policy applies only to the specific claim being considered and does not have precedential effect.

(c) An ALJ or attorney adjudicator or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. An ALJ or the DAB may review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 of this title.

[70 FR 11472, Mar. 8, 2005, as amended at 82 FR 5121, Jan. 17, 2017]

§ 405.1063 Applicability of laws, regulations, CMS Rulings, and precedential decisions.

(a) All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act and applicable implementing regulations, are binding on ALJs and attorney adjudicators, and the Council.

(b) CMS Rulings are published under the authority of the Administrator, CMS. Consistent with § 401.108 of this chapter, rulings are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security