

TO: Healthcare Clients

FROM: Alston & Bird LLP

DATE: January 24, 2017

RE: **Summary of Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures; Final Rule**

On January 13, 2017, the Centers for Medicare & Medicaid Services (“CMS” or “the agency”) published a final rule that revises the procedures that the Department of Health and Human Services (“HHS”) is to follow at the Administrative Law Judge (“ALJ”) level for appeals of payment and coverage determinations for items and services furnished to Medicare beneficiaries, enrollees in Medicare Advantage and other Medicare competitive health plans, and enrollees in Medicare prescription drug plans, as well as appeals of Medicare beneficiary enrollment and entitlement determinations, and certain Medicare premium appeals. The rule also revises procedures that HHS is to follow at the CMS and Medicare Appeals Council (“Council”) levels of appeal for certain matters affecting the ALJ level.¹ CMS received 68 comments on its proposed rule. Much of the rule is being finalized as proposed.

The effective date of the final rule is March 20, 2017. However, at this time, the disposition of the rule is uncertain. On January 20, 2017, President Donald Trump’s Chief of Staff Reince Priebus issued a memorandum to the heads of executive departments and agencies regarding a “regulatory freeze pending review.” The memorandum directs agencies how to proceed with respect to regulations like this one, which has been published in the Federal Register but which has not taken effect yet. For such rules, as permitted by applicable law, agencies are to postpone the effective date for 60 days from the date of the memorandum (which, in this case, is one day later than the original effective date of the final rule). The memorandum states: “Following the delay on effective date: (a) for those regulations that raise no substantial questions of law or policy, no further action needs to be taken; and (b) for those regulations that raise substantial questions of law or policy, agencies should notify the OMB director and take further appropriate action in consultation with the OMB director.” The memo does not define “substantial questions of law or policy.”

Following is a summary of the final rule.

I. Background

There are multiple administrative appeal processes for Medicare fee-for-service (“FFS”) claims, entitlement and certain premium initial determinations; Medicare Advantage (“MA”) and other competitive health plan organization determinations; and Part D plan sponsor coverage determinations and certain premium determinations. The first and second levels of administrative appeals are administered by Medicare Administrative Contractors (“MACs”), Part D plan sponsors, MA organizations and plans, or by the Social Security Administration (“SSA”). Appeals can be handled by ALJs at the Office of Medicare

¹ 82 Fed. Reg. 4974 (Jan. 17, 2017).

Hearings and Appeals (“OMHA”) if the amount in controversy and other requirements are met after the first and second levels of appeal.

In recent years, the Medicare appeals process has experienced what CMS calls “an unprecedented and sustained increase in the number of appeals.” The number of requests for an ALJ hearing or review increased 1,222 percent from FY 2009 through FY 2014. CMS attributes this growth to the increase in the size of the Medicare beneficiary population, enhanced monitoring of payment accuracy in the Medicare program, growth in appeals from State Medicaid agencies for those dually-eligible for Medicare and Medicaid, and implementation of the Recovery Audit Contractor (“RAC”) program. This rule is one approach the agency is taking to address the appeals backlog.

II. General Provisions of the Final Rule

A. Precedential Final Decisions of the Secretary

CMS is finalizing its proposal to introduce precedential authority into the Medicare claim and entitlement appeals process and grant authority to the Chair of the Departmental Appeals Board (“DAB”) to designate a final decision of the Secretary issued by the Council as precedential. CMS believes that this would provide a consistent body of final decisions upon which stakeholders could determine whether to seek appeals. Precedential decisions will be published in the Federal Register and posted on a publicly-accessible HHS website, with necessary precautions taken to remove personally identifiable information that cannot be disclosed without the individual’s consent. Decisions of the Council will bind all lower-level decision-makers from the date that the decisions are posted on the HHS website.

Precedential decisions will be binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration (“SSA”) to the extent that SSA components adjudicate matters under the jurisdiction of CMS, in the same manner as CMS Rulings under current regulations.

In response to commenters’ suggestions about the criteria that Chair of the DAB should use to determine whether a decision is precedential, CMS determined to add the following language to § 401.109²: “In determining which decisions should be designated as precedential, the DAB chair may take into consideration decisions that address, resolve, or clarify recurring legal issues, rules, or policies, or that may have broad application or impact, or involve issues of public interest.” The Council’s legal analysis and interpretation of an authority or provision that is binding or owed substantial deference will be binding in future determinations and appeals in which the same authority or provision is applied and is still in effect. In addition, precedential decisions designated by the Chair of the DAB would be binding on the qualified independent contractor (“QIC”).

B. Attorney Adjudicators

The agency is finalizing its proposal, without modification, to allow attorney adjudicators to issue decisions when a decision can be issued without an ALJ conducting a hearing under the regulations, dismissals when an appellant withdraws his or her request for an ALJ hearing, and remands for information that can only be provided by CMS or its contractors or at the direction of the Council, as well as to conduct

² All regulations referenced in this summary are included in Title 42 of the Code of Federal Regulations.

reviews of QIC and IRE dismissals. CMS also is finalizing its proposal to revise the rules so that decisions and dismissals issued by attorney adjudicators may be reopened and/or appealed in the same manner as equivalent decisions and dismissals issued by ALJs. CMS believes that allowing attorney adjudicators to issue decisions, dismissals, and remands and to conduct reviews of QIC and IRE dismissals will expand the pool of OMHA adjudicators and allow ALJs to focus on cases going to a hearing, while still providing appellants with quality reviews and decisions, dismissals, and remands. The rights associated with an appeal adjudicated by an ALJ will extend to any appeal adjudicated by an attorney adjudicator, including any applicable adjudication time frame, escalation option, and/or right of appeal to the Council.

III. Specific Provisions of the Proposed Rule

A. Provisions of Part 405, Subpart I and Part 423, Subparts M and U

1. General Provisions, Reconsiderations, Reopenings, and Expedited Access to Judicial Review

a. Part 423, Subpart M General Provisions (§ 423.562)

CMS is finalizing its proposal to revise the rule to insert “or attorney adjudicator” or “or attorney adjudicator’s” after each instance of “ALJ” or “ALJ’s,” respectively. It also is removing “hearing” before “decision” in regulations, to reflect that an attorney adjudicator issues decisions without conducting a hearing, and an ALJ may issue a decision without conducting a hearing.

b. Part 423, Subpart U Title and Scope (§ 423.1968)

The current heading of part 423, subpart U references ALJ hearings but does not reference decisions. CMS is revising the heading by replacing “ALJ Hearings” with “ALJ hearings and ALJ and attorney adjudicator decisions.” CMS also is expanding the scope of subpart U to include actions by attorney adjudicators.

c. Medicare Initial Determinations, Redeterminations and Appeals General Description (§ 405.904)

Current § 405.904 provides a general overview of the entitlement and claim appeals process to which part 405, subpart I applies. To provide for the possibility that a decision may be issued without conducting a hearing by an ALJ or an attorney adjudicator, CMS is adding language to provide that if the beneficiary is dissatisfied with the decision of an ALJ or attorney adjudicator when no hearing is conducted, the beneficiary may request that the Council review the case in order to provide a comprehensive overview of the entitlement and claim appeals process, with information on the potential for and right to appeal decisions by ALJs when no hearing is conducted, and the right to appeal decisions by attorney adjudicators, if the attorney adjudicator proposals are made final.

d. Parties to the Initial Determinations, Redeterminations, Reconsiderations, Proceedings on a Request for Hearing, and Council Review (§ 405.906)

Current § 405.906 discusses parties to the appeals process and addresses parties to the redetermination, reconsideration, hearing and MAC. CMS is replacing the phrases “hearing and MAC” and “hearing, and MAC review,” with “proceedings on a request for hearing, and Council review.”

e. Medicaid State Agencies (§ 405.908)

CMS is replacing “ALJ” with “OMHA” to provide that the State agency has party status regardless of the adjudicator assigned to the State agency’s request for an ALJ hearing or request for review of a QIC dismissal at the OMHA level of review, as attorney adjudicators may issue decisions on requests for hearing and adjudicate requests for reviews of QIC dismissals.

f. Appointed Representatives (§ 405.910)

To assist adjudicators in sharing and disseminating confidential information only with appropriate individuals, CMS is finalizing its proposal to add a requirement to include the Medicare national provider identifier (“NPI”) of the provider or supplier that furnished the item or service when the provider or supplier is the party appointing a representative. The requirement to identify the beneficiary’s Medicare health insurance claim number (“HICN”) when the beneficiary is the party appointing a representative will be retained.

To address the effect of a defective appointment on the adjudication of an appeal to which an adjudication time frame applies, CMS will extend an applicable adjudication time frame to the date that the defect in the appointment was cured or the party notifies the adjudicator that he or she will proceed with the appeal without a representative. CMS also is replacing “ALJ level” with “OMHA level” so there is no confusion that proceedings at the OMHA level are considered proceedings before the Secretary for purposes of appointed representative fees, regardless of whether the case is assigned to an ALJ or attorney adjudicator. CMS is inserting “or attorney adjudicator” after “ALJ” where applicable.

A representative and/or the represented party is responsible for keeping the adjudicator of a pending appeal current on the status of the representative. CMS is adding that a delegation to a representative is not effective until the adjudicator receives a copy of the party’s written acceptance of the delegation, unless the representative and designee are attorneys in the same law firm or organization, in which case the written notice to the party of the delegation may be submitted if the acceptance is not obtained from the party.

g. Actions That Are Not Initial Determinations (§ 405.926)

CMS is revising the reopening rules to provide that attorney adjudicators have the authority to reopen their decisions to the same extent that ALJs may reopen their decisions under the current provisions. CMS or a contractor may elect to participate in the proceedings on a request for an ALJ hearing for which no hearing is conducted, in addition to participating in an ALJ hearing as a non-party participant.

h. Notice of Redetermination (§ 405.956)

CMS is removing “an ALJ hearing” and adding “the OMHA level” in its place so that the notice of a redetermination is clear that, absent good cause and subject to the exception for beneficiaries not represented by a provider or supplier, evidence that was not submitted to the QIC is not considered by an ALJ or an attorney adjudicator.

i. Timeframe for Making a Reconsideration Following a Contractor Redetermination, Withdrawal or Dismissal of a Request for Reconsideration, and Reconsideration (§§ 405.970, 405.972, and 405.974)

CMS is amending several titles to provide that the provisions apply only to a request for a reconsideration following a contractor redetermination and not to a request for QIC review of a contractor's dismissal of a request for redetermination. The agency is replacing "the ALJ hearing office" with "OMHA" because the QIC sends case files for escalated cases to a centralized location, not to individual field offices. To provide additional clarity on the procedures for reviews of dismissal actions, CMS also is replacing the references to a "reconsideration" of a contractor's dismissal of a request for redetermination with the word "review" so that the QIC's action is referred to as a review of a contractor's dismissal of a request for redetermination.

j. Notice of Reconsideration (§ 405.976)

The current rule requires that the QIC notice of reconsideration contain a statement of whether the amount in controversy needed for an ALJ hearing is met when the reconsideration is partially or fully unfavorable. CMS is revising the methodology for calculating the amount in controversy required for an ALJ hearing to better align the amount in controversy with the actual amount in dispute (see Sec. III.A.2.d, below).

k. Effect of a Reconsideration (§ 405.978)

CMS is inserting "or attorney adjudicator" after the first use of "ALJ" to indicate that a QIC reconsideration is binding on all parties unless, among other things, an ALJ or attorney adjudicator decision is issued in accordance with a request for an ALJ hearing.

l. Reopenings (§§ 405.980, 405.982, 405.984, 423.1978, 423.1980, 423.1982, and 423.1984)

An ALJ may issue a decision on a request for hearing without conducting a hearing in specified circumstances. An attorney adjudicator will be able to issue decisions on requests for an ALJ hearing in specified circumstances, issue dismissals when a party withdraws a request for hearing, and issue decisions on requests to review QIC or IRE dismissals.

CMS is specifying that the Council may reopen "an ALJ or attorney adjudicator" decision consistent with the current policy that the Council may reopen an ALJ decision, and to differentiate from provisions that provide for the Council to reopen its review decision. The agency also is inserting "Council" before "review" to clarify that a party to a Council review may request that the Council reopen its decision.

m. Expedited Access to Judicial Review (§§ 405.990 and 423.1990)

These sections set forth the procedures governing expedited access to judicial review ("EAJR"). To simplify the process for requesting parties, and to help ensure the timely processing of EAJR requests, CMS will direct EAJR requests to the DAB, which administers the EAJR process. Specifically, the requestor or enrollee may file a written EAJR request with the DAB with the request for ALJ hearing or Council review if a request for ALJ hearing or Council review is not pending, or file a written EAJR request with the DAB if an appeal is already pending for an ALJ hearing or otherwise before OMHA or the Council. The review entity will forward a rejected EAJR request to OMHA or the Council instead of an ALJ hearing office or the Council, to align with the revised EAJR filing process in which a request for ALJ hearing is submitted to the DAB with an EAJR request. If an adjudication time frame applies to an appeal, the

adjudication time frame begins on the day the request for hearing is received by OMHA or the request for review is received by the Council from the EAJR review entity.

2. ALJ hearings

a. Hearing Before an ALJ and Decision by an ALJ or Attorney Adjudicator: General Rule (§§ 405.1000 and 423.2000)

CMS or a contractor may elect to participate in a hearing, and CMS, the Independent Review Entity (“IRE”), or Part D plan sponsor may request to participate in a hearing. CMS is finalizing that these entities may elect (for § 405.1010) or request (for § 423.2010) to participate in the proceedings on a request for hearing, including participation before a hearing is scheduled. CMS or its contractor may join the hearing before an ALJ as a party under § 405.1012.

Some current rules provide that a decision is based on the hearing record,³ and others reference a hearing record in describing when a decision can be issued based on the record without a hearing.⁴ CMS is revising the rules so that a decision is based on the administrative record, including, for an ALJ, any hearing record.

The rules discuss two circumstances in which a decision on a request for hearing can be issued by an ALJ without conducting a hearing, either where the parties waive the hearing or where the record supports a fully favorable finding. CMS is modifying the circumstances in which a decision on a request for hearing can be issued without conducting a hearing: no hearing will be required when waivers are obtained by the parties entitled to a notice of hearing, or when the record supports a fully favorable finding for the appellant and there is no other party or no other party is entitled to a notice of hearing.

QICs are required to consolidate requests for a reconsideration filed by different parties on the same claim before a reconsideration is made on the first timely filed request. CMS will require that when more than one party files a timely 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.

b. Right to an ALJ Hearing (§§ 405.1002 and 423.2002)

The current rules provide that a request for a hearing is considered filed on the date it is received by the entity specified in the QIC’s or IRE’s reconsideration. CMS is finalizing its proposal to replace “entity” with “office” to avoid confusion that the request may be filed with OMHA as an entity, and therefore any OMHA office, rather than the specific OMHA office identified in the QIC’s or IRE’s reconsideration. The agency is adding language to clarify that if a request for hearing is filed timely with an office other than the office specified in the QIC’s reconsideration, the request is not treated as untimely. When a party files a request with the QIC to escalate the appeal, it is escalated to “the ALJ level.” CMS is replacing “to the ALJ level” with “for a hearing before an ALJ.”

³ §§ 405.1000(d) and 423.2000(d).

⁴ §§ 405.1000(g) and 423.2000(g).

c. Right to Review of QIC or IRE Notice of Dismissal (§§ 405.1004 and 423.2004)

If an ALJ determines that the QIC's or IRE's dismissal was in error, he or she vacates the dismissal and remands the case to a QIC or IRE. CMS is finalizing its proposal to revise the remand provisions and add new rules to govern when remands may be issued, whether and to what extent remands may be reviewed, providing notice of a remand, and the effect of a remand.

An ALJ's decision regarding a QIC's or IRE's dismissal of a reconsideration request is binding and not subject to further review, and the dismissal of a request for ALJ review of a QIC's or IRE's dismissal of a reconsideration request is binding and not subject to further review, unless vacated by the Council. CMS is distinguishing the two situations by proposing a separate paragraph for each outcome.

d. Amount in Controversy Required for an ALJ Hearing (§§ 405.1006, 405.976(b)(7), 423.1970, 422.600(b), 478.44(a))

The Social Security Act ("Act") states that a party is entitled to a hearing before the Secretary and judicial review, subject to the amount in controversy and other requirements. To align the title of § 405.1006 with the Act, CMS is finalizing its proposal that the amount in controversy is required "for" an ALJ hearing and judicial review rather than "to request" an ALJ hearing and judicial review.

In an effort to align the amount in controversy with a better approximation of the amount at issue in an appeal, CMS proposed to revise the basis used to calculate the amount in controversy. CMS proposed that for items and services with a published Medicare fee schedule or published contractor-priced amount, the basis for the amount in controversy would be the allowable amount, which would be the amount reflected on the fee schedule or in the contractor-priced amount for those items or services in the applicable jurisdiction and place of service. It had proposed this in part because, it estimated, it could remove appeals related to over 2,600 low-value Part B claims per year from the ALJ hearing process, after accounting for the likelihood that appellants would aggregate claims to meet the minimum amount in controversy threshold. However, commenters were concerned that the proposal would prevent physicians, beneficiaries, and other appellants from appealing low-dollar claims and it would create confusion among appellants, ALJs, and attorney adjudicators. CMS will continue to use the methodology currently set forth in § 405.1006(d)(1), which is "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 and services."

CMS is finalizing its proposal for determining the amount in controversy when a provider or supplier terminates the provision of a Medicare-covered item or service, or when the beneficiary does not elect to continue receiving the item or service. Also, when a claim appeal involves an overpayment determination, the amount in controversy will be the amount of the overpayment specified in the demand letter. When a matter involves an estimated overpayment amount determined through the use of sampling and extrapolation, the estimated overpayment as extrapolated to the entire statistical sampling universe is the amount in controversy.

e. Parties to an ALJ Hearing (§§ 405.1008 and 423.2008)

The current rules identify the parties "to the ALJ hearing." CMS is replacing "parties to an ALJ hearing" with "parties to the proceedings on a request for an ALJ hearing."

f. CMS and CMS Contractors as Participants or Parties in the Adjudication Process (§§ 405.1010, 405.1012, and 423.2010)

i. When CMS or its Contractors May Participate in the Proceedings on a Request for an ALJ Hearing (§ 405.1010)

Per the final rule, 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; and the ALJ cannot draw any adverse inferences if CMS or the contractor decides not to participate in the proceedings. If CMS or a contractor elects to participate before receipt of a notice of hearing or when a notice of hearing is not required, CMS or the contractor must send written notice of its intent to participate to the parties who were sent a copy of the notice of reconsideration, and to the assigned ALJ or attorney adjudicator, or if the appeal is not yet assigned, to a designee of the Chief ALJ. If CMS or a contractor elects to participate after receiving a notice of hearing, CMS or the contractor is to send written notice of its intent to participate to the ALJ and the parties who were sent a copy of the notice of hearing.

When CMS or a contractor has been made a party to the hearing, CMS or a contractor that elected to be a participant or was made a participant 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 (oral testimony and attendance at the hearing would not be permitted). The ALJ will have the discretion to allow additional participation in the oral hearing when the ALJ determines an entity's participation is necessary for a full examination of the matters at issue. The final rule includes criteria for when an election may be deemed invalid and provides standards for notifying the entity and the parties when an election is deemed invalid.

ii. When CMS, the IRE, or Part D Plan Sponsors May Participate in the Proceedings on a Request for an ALJ Hearing (§ 423.2010)

With respect to Medicare Part D claims, CMS, the IRE, and the Part D plan sponsor will have an opportunity to participate in the proceedings on a request for an ALJ hearing at two distinct points in the adjudication process, but the current policy of requiring the entity to request to participate is maintained. CMS is adding new provisions to establish criteria for when a request to participate may be deemed invalid and to provide standards for notifying the entity and the enrollee when a request to participate is deemed invalid.

iii. When CMS or its Contractors May be Party to a Hearing (§ 405.1012)

The current rule does not limit the number entities that may elect to be a party to the hearing. Going forward, CMS will allow either CMS or one of its contractors to elect to be a party to the hearing (unless the request for hearing is filed by an unrepresented beneficiary, which precludes CMS and its contractors from electing to be a party to the hearing). An ALJ may request but not require CMS and/or one or more of its contractors to be a party to the hearing. An ALJ cannot draw any adverse inferences if CMS or a contractor decides not to enter as a party.

CMS or the contractor will be required to send written notice of its intent to be a party to the hearing to the ALJ and the parties identified in the notice of hearing, which includes the appellant. As a party to the hearing, 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. The final rule sets forth

parameters for submitting position papers, written testimony, and evidence and requires that copies of position papers, written testimony, and evidence be sent to the parties that were sent a copy of the notice of hearing, within the same timeframes as apply to submission to OMHA.

CMS is finalizing its proposal to limit the number of entities that participate in a hearing unless an ALJ determines that an entity's participation is necessary for a full examination of the matters at issue. Notwithstanding this limitation, an ALJ could grant leave for additional entities to be parties to the hearing if the ALJ determines that an entity's participation as a party is necessary for full examination of the matters at issue. (If an ALJ does not grant leave to the precluded entity to participate in the oral hearing, the precluded entity still may be called as a witness by CMS or a contractor that is a party to a hearing.) An ALJ may not request that CMS and/or one or more of its contractors be a party to the hearing if the request for hearing was filed by an unrepresented beneficiary. Also, an ALJ or attorney adjudicator may determine an election is invalid if the election was not timely or the election was not sent to the correct parties.

g. Request for an ALJ Hearing or Review of a QIC or IRE Dismissal (§§ 405.1014, 423.1972 and 423.2014)

i. Requirements for a Request for Hearing or Review of a QIC or IRE Dismissal

CMS is finalizing its proposal to reorganize requirements for requests for hearing or review of a QIC or IRE dismissal. It is not finalizing its proposal to require that such a request include a statement of whether the filing party is aware that it or the claim is the subject of an investigation or proceeding by the Office of Inspector General or another law enforcement agency. It also is declining to finalize its proposal to require that providers, suppliers, Medicaid agencies, applicable plans, and beneficiaries represented by a provider, supplier, or Medicaid agency include in a request for hearing the amount in controversy applicable to the disputed claim.

ii. Requests for Hearing Involving Statistical Sampling and Extrapolations

CMS is finalizing its addition of a new rule to address appeals in which an appellant raises issues regarding a statistical sampling methodology and/or an extrapolation that was used in making an overpayment determination. As finalized, the rule states that if an appellant is challenging the statistical sampling methodology and/or extrapolation, the appellant's request for hearing must include certain information for each sample claim that the appellant wishes to appeal and assert the reasons the appellant disagrees with the statistical sampling methodology and/or extrapolation in the request for hearing.

iii. Opportunity to Cure Defective Filings (§ 405.1014(b))

CMS is specifying the procedure for curing defective filings of requests or for hearings.

iv. Where and When to File a Request for Hearing or Review of a QIC or IRE Dismissal

CMS is finalizing its proposal addressing when and where to file a request for hearing or review. It is incorporating into one section the parameters for a request for a review of a QIC dismissal and a request for a review of an IRE dismissal, and the current 60 calendar day period to file a request for hearing after a party receives a QIC or an IRE reconsideration also applies after a party receives a QIC or IRE dismissal. CMS is adding an exception for requests for hearing on sample claims that are part of a statistical sample

and/or extrapolation that the appellant also wishes to challenge; these would be filed together, which may be more than 60 calendar days after the appellant receives the first QIC reconsideration of one of the sample claims. In addition, CMS is replacing the statement that a request must be “submitted,” and instead stating that a request must be “filed.” CMS is replacing references to sending requests to the “entity” specified in the QIC’s or IRE’s reconsideration with sending requests to the “office” specified in the QIC’s or IRE’s reconsideration or dismissal, respectively, so they are properly routed. The adjudication time frame is affected only if there is an applicable adjudication time frame for the appeal.

v. *Sending Copies of a Request for Hearing and Other Evidence to Other Parties to the Appeal*

CMS is amending the current copy requirement by requiring an appellant to send a copy of a request for an ALJ hearing or review of a QIC dismissal only to the other parties who were sent a copy of the QIC’s reconsideration or dismissal. This change makes the standard consistent with requests for Council review.

If additional materials submitted with a request for hearing or a request for review of a QIC dismissal are necessary to provide the information required for a complete request, 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).

CMS is establishing standards that an appellant is to follow to satisfy the materials submission requirement. Evidence that a copy of the request for hearing or review, or a copy of submitted evidence or a summary thereof, was sent includes: (1) certifications that a copy of the request for hearing or request for review of a QIC dismissal is being sent to the other parties on the standard form for requesting a hearing or review of a QIC dismissal; (2) an indication, such as a copy or “cc” line on a request for hearing or review, 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 recipients; (3) an affidavit or certificate of service that identifies the name and address of the recipient and what was sent to the recipient; or (4) a mailing or shipping receipt that identifies the name and address of the recipient and what was sent to the recipient.

If an appellant 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 the submitted evidence or a summary thereof, the appellant will have an opportunity to cure the defects by sending the request, materials, and/or evidence or summary thereof. If an adjudication time frame applies, it will not begin until receipt of evidence that the request, materials, and/or evidence or summary thereof were sent. If an appellant does not provide evidence within the timeframe provided to demonstrate that the request, materials, and/or evidence or summary thereof were sent to other parties, the appellant’s request for hearing or review will be dismissed. However, CMS is adding language to formalize its existing policy of providing leniency to an unrepresented beneficiary who does not provide evidence that the materials were sent to other beneficiaries within the applicable timeframe.

- vi. *Extending Time to File a Request for Hearing or Review of a QIC or IRE Dismissal (§§ 405.1014 and 423.2014)*

CMS is finalizing its proposal that the provisions for extensions of time to file a request for hearing would extend to requests for reviews of QIC and IRE dismissals.

- h. *Time Frames for Deciding an Appeal of a QIC or IRE Reconsideration or an Escalated Request for a QIC Reconsideration, and Request for Council Review When an ALJ Does Not Issue a Decision Timely (§§ 405.1016, 405.1104 and 423.2016)*

- i. *Time Frames for Deciding an Appeal of a QIC or an Escalated Request for a QIC Reconsideration (§ 405.1016)*

CMS has set forth timeframes for a decision, dismissal order, or remand by an ALJ or attorney adjudicator; when the adjudication period begins; the adjudication period for escalated requests for QIC reconsiderations; waivers and extensions of adjudication periods; and information about the effect of exceeding an adjudication period.

- ii. *Incorporation of the Provisions of § 405.1104 (Request for Council Review When an ALJ Does Not Issue a Decision Timely) into § 405.1016(f)*

CMS is finalizing the provisions of this section as proposed. If an ALJ or an attorney adjudicator assigned to a request for hearing does not issue a decision, dismissal order, or remand to the QIC within an adjudication period specified in the section, the party that filed the request for hearing may escalate the appeal when the adjudication period expires. However, if the adjudication period expires and the party that filed the request for hearing does not exercise the option to escalate the appeal, the appeal remains pending with OMHA for a decision, dismissal order, or remand. The appeal remains pending with OMHA to be inclusive of situations in which the appeal is assigned to an ALJ or attorney adjudicator, or not yet assigned.

The current rule describes how to request an escalation. CMS is removing the current requirement to request Council review in the course of requesting an escalation and to describe when and how to request escalation. CMS is replacing “ALJ” with “OMHA” where applicable to be inclusive of attorney adjudicators. CMS also is finalizing its proposal that a written request to escalate an appeal to the Council is to be filed with OMHA to allow OMHA to provide a central filing option for escalation requests and that the request for escalation is to be sent to other parties who were sent a copy of the QIC reconsideration. The appellant is to send a copy of the escalation request to the other parties who were sent a copy of the QIC reconsideration so appellants will be aware of the requirement and which parties must be sent a copy of the escalation request.

CMS is revising the escalation process. If an escalation request meets the requirements in the paragraph above, and an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand within the later of five calendar days of receiving the request for escalation or five calendar days from the end of the applicable adjudication period, OMHA will send a notice to the appellant to that effect. The notice will state that the QIC reconsideration will be the decision that is subject to Council review and that the appeal will be escalated to the Council. OMHA then will forward the case file, which will include the file received from the QIC and the request for escalation and all other materials filed with OMHA, to the Council.

If an ALJ or attorney adjudicator determines an escalation request does not meet the requirements, OMHA will send a notice to the appellant within five calendar days of receiving the request for escalation, explaining why the request is invalid. If an ALJ or attorney adjudicator were to determine the request for escalation was invalid for a reason that could be corrected (for example, if the request was premature), the appellant can file a new escalation request when the adjudication period expires.

iii. Time Frames for Deciding an Appeal of an IRE Reconsideration (§ 423.2016)

CMS is retitling several paragraphs to refer to standard appeals and expedited appeals because the time frames apply to issuing a decision, dismissal, or remand, and are not limited to appeals in which a hearing is conducted. CMS is adopting adjudication timeframes for appeals that are remanded by the Council. CMS will require that if the standards for an expedited appeal continue to be met after the appeal is remanded from the Council, the 10-day expedited time frame will apply to an appeal remanded by the Council. CMS is revising the expedited appeal request process to permit an ALJ or attorney adjudicator to review a request for an expedited hearing but not require the same ALJ or attorney adjudicator to adjudicate the expedited appeal, to provide OMHA with greater flexibility to review and assign requests for expedited hearings and help ensure the 10-day adjudication process is completed as quickly as the enrollee's health requires.

i. Submitting Evidence (§§ 405.1018 and 423.2018)

The current rule states that, except as otherwise provided, parties must submit all written evidence they wish to have considered at the hearing with the request for hearing (or within 10 calendar days of receiving the notice of hearing). CMS will provide for the submission of other evidence, in addition to written evidence, that the parties wish to have considered. 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, or if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing.

If evidence is submitted later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period 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. For expedited appeals, the adjudication time frame is affected if the evidence is submitted later than two calendar days after receipt of the notice of expedited hearing because two calendar days is the equivalent time frame to submit evidence. If the provider or supplier, or beneficiary represented by a provider or supplier, fails to include the statement explaining why the evidence was not previously submitted, the evidence would not be considered (this requirement does not apply to oral testimony or to unrepresented beneficiaries).

j. Time and Place for a Hearing Before an ALJ (§§ 405.1020 and 423.2020)

CMS is finalizing the provisions of this section as proposed, with one modification. A telephone hearing is the default hearing method, unless the appellant is an unrepresented beneficiary. CMS is providing two standards for determining how appearances are made, depending on whether appearances are by unrepresented beneficiaries or by individuals other than unrepresented beneficiaries. The ALJ will direct that the appearance of an unrepresented beneficiary who filed a request for hearing will be conducted by video teleconferencing ("VTC") if the ALJ finds that VTC technology is available to conduct the appearance, unless the ALJ finds good cause for an in-person appearance. The ALJ will be allowed to offer to conduct a telephone hearing if the request for hearing or administrative record suggests that a telephone hearing may be more convenient to the unrepresented beneficiary.

For appearances by an individual other than an unrepresented beneficiary who files a request for hearing, the ALJ will direct that those individuals appear by telephone, unless the ALJ finds good cause for an appearance by other means. Further, 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 or may find good cause that an in-person hearing should be conducted if VTC and telephone technology are not available, or special or extraordinary circumstances exist.

A party that may be found liable based on a review of the record must be sent a notice of hearing. The notice of hearing also is to be sent to CMS or a contractor that elected to participate in the hearings, or that the ALJ believes would be beneficial to the hearing (this is a change that was not proposed and that is new to the final rule). The rule requires all parties to the ALJ hearing to reply to the notice by acknowledging whether they plan to attend the hearing at the time and place proposed in the hearing, or whether they object to the proposed time and/or place of the hearing. CMS is adopting corresponding revisions for an enrollee's or his or her representative's reply to the notice of hearing.

CMS is removing the provision for CMS or a contractor that wishes to participate in the hearing to reply to the notice of hearing in the same manner as a party because a non-party may not object to the proposed time and place of the hearing, or present witnesses. Instead, CMS will require CMS or a contractor that wishes to attend the hearing as a participant to reply to the notice of hearing by acknowledging whether it plans to attend the hearing at the time and place proposed in the notice of hearing and specifying who from the entity plans to attend the hearing.

A party may waive the right to a hearing and request a decision based on the written evidence in the record, but an ALJ may require the parties to attend a hearing if it is necessary to decide the case. CMS is adopting corresponding revisions for an enrollee to waive his or her right to a hearing and request a decision based on the written evidence in the record, but an ALJ can require the enrollee to attend a hearing if it is necessary to decide the case.

A request for a hearing must be in writing, except that a party may request orally that a hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing, and the ALJ must document the oral request in the administrative record. CMS is adopting a corresponding provision for an enrollee to request a rescheduled standard hearing orally, and to modify the documentation requirement, which was limited to documenting oral requests made for expedited hearings, to include all oral objections.

The current rules provide a list of examples of circumstances a party might give for requesting a change in the time or place of the hearing. CMS is including the following two additional examples: (1) the party or representative has a prior commitment that cannot be changed without significant expense, in order to account for circumstances in which travel or other costly events may conflict with the time and place of a hearing, which the ALJ may determine warrants good cause for changing the time or place of the hearing; and (2) 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, which the ALJ may determine warrants good cause for changing the time or place of the hearing.

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 in-person hearing.

The current rules do not address what occurs when the ALJ changes the time or place of the hearing. CMS is adding a provision titled “Amended notice of hearing” to clarify that, 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.

k. Notice of a Hearing Before an ALJ and Objections to the Issues (§§ 405.1022, 405.1024, 423.2022, and 423.2024)

CMS is finalizing its proposal to provide that a notice of hearing is to be mailed or otherwise transmitted in accordance with OMHA procedures, or personally served, except to a party or other potential participant who indicates in writing that he or she does not wish to receive the notice. The notice must be mailed, transmitted, or served at least 20 calendar days (or three calendar days if expedited) before the hearing unless the recipient agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days (or three calendar days if expedited) before the hearing. A recipient’s waiver of the requirement to mail, transmit, or serve the notice at least 20 or three calendar days (as applicable) before the hearing will be effective only for the waiving recipient and does not affect the rights of other recipients.

CMS will require the notice of hearing to include a general statement putting the parties on notice 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. The notice of hearing also is to contain a statement of any specific new issues that the ALJ will consider to help ensure the parties and potential participants are provided with notice of any new issues of which the ALJ is aware at the time the notice of hearing is sent and can prepare for the hearing accordingly.

If a party cannot attend a hearing, the party may request that the ALJ reschedule the hearing in accordance with other rules. CMS is removing references to using e-mail and fax and adding that a notice may be sent by certified mail or other means requested by the party and in accordance with OMHA procedures.

The current rule sets forth the provision regarding objections by a party to the issues described in the notice of hearing, requiring a party to send a copy of its objection to the issues to all other parties to the appeal. CMS will require that the copy must be sent only to the 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.

l. Disqualification of the ALJ or Attorney Adjudicator (§§ 405.1026 and 423.2026)

CMS is finalizing its proposal to require that 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 any time before a decision, dismissal order, or remand order is issued if no hearing is scheduled. The current rule does not address the impact of a party objection and adjudicator’s withdrawal on an adjudication time frame. Going forward, CMS will require that if a party objects to the ALJ or attorney adjudicator, and the ALJ or attorney adjudicator subsequently withdraws from the appeal, any applicable adjudication time frame that applies shall be extended by 14 calendar days.

m. Review of Evidence Submitted by the Parties (§ 405.1028)

CMS is revising the title to reflect that the regulation would apply more broadly to the review of evidence submitted by the parties because a hearing may not be conducted and an attorney adjudicator would review evidence in deciding appeals. After a hearing is requested but before it is held by an ALJ (to reinforce that hearings are only conducted by ALJs), or before a decision is issued if no hearing is held, the ALJ or attorney adjudicator is to review any new evidence. In addition, CMS is removing the duplicative statement indicating the review is conducted on “any new evidence submitted with the request for hearing (or within 10 calendar days of receiving the notice of hearing) as specified in § 405.1018.”

The final rule specifies when an ALJ can find good cause for submitting evidence for the first time at the OMHA level and establishes four additional circumstances in which good cause for submitting new evidence may be found. CMS will permit an attorney adjudicator to find good cause, because attorney adjudicators will examine new evidence in deciding appeals on requests for an ALJ hearing. Good cause is found when the new evidence is, in the opinion of the ALJ, material to a new issue identified.

CMS is finalizing its proposal that good cause is found when the party was unable to obtain the evidence before the QIC issued its reconsideration and the party submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates that the party made reasonable attempts to obtain the evidence before the QIC issued its reconsideration. Good cause also may be found when the party asserts that the evidence was submitted to the QIC or another contractor and the party submits evidence that, in the opinion of the ALJ or attorney adjudicator, demonstrates that the new evidence indeed was submitted to the QIC or another contractor before the QIC issued the reconsideration.

In other circumstances, the ALJ or attorney adjudicator may find good cause for new evidence when the ALJ or attorney adjudicator determines the party has demonstrated that it could not have obtained the evidence before the QIC issued its reconsideration. Notification about whether the evidence is to be considered or excluded applies only when a hearing is conducted, and notification of a determination regarding new evidence will be made only to parties and participants who responded to the notice of hearing, since all parties may not be sent a copy of the notice of hearing or attend the hearing. The ALJ is to notify all parties and participants whether the new evidence would be considered or is excluded from consideration (rather than only whether the evidence will be excluded from the hearing), and this determination is to be made no later than the start of the hearing, if a hearing is conducted. 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.

n. ALJ Hearing Procedures (§§ 405.1030 and 423.2030)

The Administrative Procedure Act (“APA”) provides an ALJ with the authority to regulate the course of a hearing, subject to the rules of the agency.⁵ In rare circumstances, OMHA ALJs have encountered a party or representative that makes it difficult or impossible for the ALJ to regulate the course of a hearing, or for other parties to present their side of the dispute. CMS is adding provisions to address these circumstances in a consistent manner that protects the interests of the parties and the integrity of the hearing process.

⁵ See 5 U.S.C. § 556(c)(5).

CMS is replacing the current language stating that an ALJ may accept “documents that are material to the issues” with “evidence that is material to the issues,” because not all evidence that may be submitted is documentary evidence (for example, photographs). CMS also is addressing circumstances in which a party or representative continues with testimony and argument that are not relevant to the issues before the ALJ or that address a matter for which the ALJ believes he or she has sufficient information or on which the ALJ has already ruled. In these circumstances, the ALJ may limit testimony and/or argument at the hearing, and may, at the ALJ’s discretion, 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, within a time frame designated by the ALJ. In the final rule, CMS has added that the ALJ shall have the authority to limit testimony and/or argument when it is repetitive of evidence or testimony already in the record or that relates to an issue that has been developed sufficiently or on which the ALJ already has ruled.

In the final rule, the agency also addresses circumstances in which a party or representative is uncooperative, disruptive, or abusive during the course of the hearing. In these circumstances, the ALJ will have the clear authority to excuse the party or representative from the hearing and continue with the hearing to provide the other parties and participants with the opportunity to offer testimony and/or argument.

Current § 405.1030(c) addresses evidence that the ALJ determines is missing at the hearing, and provides that if the 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 whether the appellant had good cause for not producing the evidence earlier. In the final rule, the agency is adding that the ALJ must determine whether the appellant had good cause for not producing the evidence. CMS is revising § 405.1030(d) to address the effect of an evidentiary submission on an adjudication period. Any applicable adjudication period is extended if an appellant other than an unrepresented beneficiary submits evidence.

A hearing may be continued to a later date and the notice of the continued hearing is to be sent, except that a waiver of the notice of hearing may be made in writing or on the record, and the notice of continued hearing will be sent to the parties and participants who attended the hearing, and any additional parties or potential parties or participants the ALJ determines are appropriate. In the event that the appellant requests a continuance and an adjudication period applies to the appeal, the adjudication period will be extended by the period between the initial hearing date and the continued hearing date.

On occasion, after a hearing is conducted, an ALJ find that additional testimony or evidence is necessary to decide the issues on appeal, or a procedural matter needs to be addressed. Current § 405.1030(f) allows an ALJ to reopen a hearing to receive new and material evidence; it is required that the evidence: (1) was not available or known at the time of the hearing; and (2) may result in a different conclusion. However, the current rule does not provide a mechanism to address procedural matters, or to obtain additional information through evidence or testimony that may have been available at the time of hearing and may result in a different outcome but the importance of which was not recognized until after a post-hearing review of the case. CMS is finalizing its proposal that a supplemental hearing may be conducted at the ALJ’s discretion at any time before the ALJ mails a notice of decision in order to receive new and material evidence, obtain additional testimony, or address a procedural matter. A notice of the supplemental hearing is to be sent to the participants and parties who attended the hearing, but the ALJ has the discretion to send the notice to additional parties, or potential parties or participants the ALJ determines are appropriate. In the event that the appellant requested the supplemental hearing and an adjudication period

applies to the appeal, the adjudication period will be extended by the period between the initial hearing date and the supplemental hearing date.

o. Issues Before an ALJ or Attorney Adjudicator (§§ 405.1032 and 423.2032)

The current rule states 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. The agency is finalizing its proposal in § 405.1032(a) that 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.

Per the final rule, the ALJ may consider the new issue, including a favorable portion of a determination on a claim or appealed matter specified in the request for hearing, only if its resolution could have a material impact on the claim or appealed matter, and: (1) there is new or material evidence that was not available or known at the time of the determination and which may result in a different conclusion; or (2) 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. Notice of the new issue must be provided before the start of the hearing, but the agency will limit the notice to the parties who were or will be sent the notice of hearing, rather than the current standard to notice "all of the parties." If notice of the new issue is sent after the notice of hearing, the parties will have at least 10 calendar days after receiving the notice of the new issue to submit evidence regarding the issue. The ALJ then will determine whether the new evidence is material to the new issue identified by the ALJ. If an adjudication time frame applies to the appeal, the adjudication period will not be affected by the submission of evidence. If the hearing is conducted before the expiration of the time to submit evidence regarding the issue, the record will remain open until the opportunity to submit evidence expires to provide the parties sufficient time to submit evidence regarding the issue.

Claims that were not specified in a request for hearing may be added to a pending appeal only if the claims is adjudicated in the same reconsideration that is appealed in the request for hearing, 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 to be added. CMS will require that before a claim may be added to a pending appeal, the appellant must submit evidence that demonstrates that the information that constitutes a complete request for hearing 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. When an appeal involves a statistical sample and an extrapolation and the appellant wishes to challenge how the statistical sample and/or extrapolation was conducted, as discussed previously, CMS will require the appellant to assert the reasons the appellant disagrees with how the statistical sampling and/or extrapolation was conducted in the request for hearing.

p. Requesting Information from the QIC or IRE, and Remanding an Appeal (§§ 405.1034, 405.1056, 405.1058, 423.2034, 423.2056, and 423.2058)

CMS is revising the sections that cover obtaining information that can be provided only by CMS or its contractors, or the Part D plan sponsor, and establishing new rules to address remands to a QIC, and new rules to address remands to an IRE. The agency will maintain the current standards for requesting information that is missing from the written record when that information can be provided only by CMS or

its contractors, but it will limit the action to a request for information directed to the QIC that conducted the reconsideration or its successor (if a QIC contract has been awarded to a new contractor). In the final rule, the agency is adding a provision that prior to requesting information from the QIC, OMHA will confirm whether an electronic copy of the redetermination or reconsideration is available in the official system of record, and if so will accept the electronic copy as an official copy. While CMS is retaining the definition of “can be provided only by CMS or its contractors,” the agency is specifying that official copies of redeterminations and reconsiderations that were conducted on the appealed claims can be provided only by CMS or its contractors, the ALJ or attorney adjudicator will retain jurisdiction of the case, and the case will remain pending at OMHA.

The QIC will have 15 calendar days after receiving the request for information to furnish the information or otherwise respond to the request for information, either directly or through CMS or another contractor. If an adjudication period applies to the appeal, the adjudication period will be 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 is less. The final rule provides for an accelerated response time frame for expedited appeals because of the urgency involved. For expedited appeals, CMS the IRE will have two calendar days after receiving a request for information to furnish the information or otherwise respond to the request, and the extension to the adjudication time frame will be up to three calendar days, to allow for time to transmit the request to the IRE and for the IRE to respond.

CMS has added a new section to describe when a request for hearing or request for review of a QIC dismissal may be remanded, and another to describe the effect of a remand. A remand is permitted if an ALJ or attorney adjudicator requests an official copy of a missing redetermination or reconsideration for an appealed claim, and the QIC or another contractor does not furnish the copy within the time frame required. A remand also is permitted when the QIC does not furnish a case file for an appealed reconsideration. In the situation where a record is reconstructed by the QIC, the reconstructed record will be returned to OMHA, the case no longer will be remanded and the reconsideration no longer will be vacated, and if an adjudication period applies to the case, the period will be extended by the time between the date of the remand and the date the case is returned to OMHA because OMHA was unable to adjudicate the appeal between when it was remanded and when it was returned to OMHA.

On occasion, an ALJ finds that a QIC issued a reconsideration that addresses coverage or payment issues related to the appealed claim when a redetermination was required and no redetermination was conducted, or the contractor dismissed the request for redetermination and the appellant appealed the contractor’s dismissal. In either circumstance, the reconsideration was issued in error because the appellant did not have a right to the reconsideration in accordance with the current rule, which provides a right to a reconsideration only when a redetermination is made by a contractor. CMS is addressing these circumstances so that, 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) or the request for redetermination was dismissed (and not vacated), the reconsideration will be remanded to the QIC that issued the reconsideration, or its successor, to re-adjudicate the request for reconsideration.

OMHA ALJs sometimes receive requests for remands from CMS or a party because the matter can be resolved by a CMS contractor if jurisdiction of the claim is returned to the QIC. CMS is providing a mechanism for these remands. 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 request a remand of the appeal jointly 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 is likely to resolve the matter in dispute. The ALJ or attorney adjudicator is allowed to determine whether to grant the request and issue the remand, based on his or her determination of whether remanding the case likely will resolve the matter in dispute. If an enrollee wants evidence of a change in his or her condition to be considered in the appeal, the appeal will be remanded to the IRE for consideration of the evidence on the change in condition.

CMS is providing a mechanism to request a review of a remand by allowing a party, or CMS or one of its contractors, to file a request to review a remand with the Chief ALJ or a designee within 30 calendar days of receiving a notice of remand. If the Chief ALJ or designee determines that the remand is not authorized, the remand order will be vacated. The determination on a request to review a remand order is binding and not subject to further review so adjudication of the appeal can proceed. A remand of a request for hearing or request for review is binding unless it is vacated by the Chief ALJ or a designee.

q. Description of the ALJ Hearing Process and Discovery (§§ 405.1036, 405.1037, and 423.2036)

The current rule states that a party may “send the ALJ” a written statement indicating that he or she does not wish to appear at the hearing. CMS is revising this provision to state that a party may “submit to OMHA” a written statement indicating that he or she does not wish to appear at the hearing. The statement could be submitted to OMHA or to the ALJ or attorney adjudicator, after the request is assigned, to provide more flexibility and to accommodate situations where an ALJ or attorney adjudicator has not been assigned a request for hearing.

The current rule provides that discovery is permissible only when CMS or its contractors elects to participate in an ALJ hearing as a party. While the intent is generally clear, the use of “participate” is potentially confusing, given that CMS or one of its contractors can elect to be a participant in the proceedings, including the hearing, or elect to be a party to the hearing. The final rule clarifies that discovery is permissible only when CMS or its contractor elects to be a party to an ALJ hearing. If an adjudication period applies to the appeal, 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.

r. Deciding a Case Without a Hearing Before an ALJ (§§ 405.1038 and 423.2038)

The agency is finalizing its proposal that if the evidence in the administrative record supports a finding 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 without an ALJ conducting a hearing, unless CMS or a contractor has elected to be a party to the hearing.

The final rule also add two new limitations on issuing a decision without a hearing before an ALJ when the evidence in the administrative record supports a finding in favor of the appellant(s) on every issue. First, a decision cannot be issued pursuant to § 405.1038(a) if another party to the appeal is liable for the claims at issue. Second, a decision cannot be issued pursuant to § 405.1038(a) if CMS or a contractor elected to be a party to the hearing.

The current rule permits the ALJ to decide a case on the record and not conduct a hearing if: (1) all the parties indicate in writing that they do not wish to appear before the ALJ at a hearing, including a

hearing conducted by telephone or video-teleconferencing, if available; or (2) an appellant lives outside of the United States and does not inform the ALJ that he or she wants to appear, and there are no other parties who wish to appear. CMS is modifying the requirements so writings need to be obtained only from, or wishes assessed from, parties who would be sent a notice of hearing, if a hearing were to be conducted. Using the notice of hearing standard protects the interests of potentially liable parties, while making the provisions a more effective option for the efficient adjudication of appeals.

On occasion, CMS or one of its contractors indicates that it believes an item or service should be covered or payment made on an appealed claim, either before or at a hearing. CMS is providing new authority for a stipulated decision, when 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 paid. In this situation, 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. The final rule includes a new requirement that when the amount of payment is an issue before an ALJ or attorney adjudicator, the written statement upon which a stipulated decision is based must include the amount of payment the parties believe should be made.

s. Prehearing and Post-hearing Conferences (§§ 405.1040 and 423.2040)

The final rule requires that an audio recording of prehearing and post-hearing conferences be made to establish a consistent standard and because the audio recording is the most administratively efficient way to make a record of the conference. The ALJ is to issue 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. The order is issued to the parties and participants who attended the conference to help ensure the appropriate parties and participants receive the order, but only a party could object to the order. An objection must be made within 10 calendar days of receiving the order to establish a consistent minimum standard for making objection to a conference order, but the rule also provides the ALJ with the discretion to grant additional time. An enrollee must object to a conference order within one calendar day of receiving the order for expedited hearings.

t. The Administrative Record (§§ 405.1042 and 423.2042)

The administrative record is HHS's record of the administrative proceedings and initially is established by OMHA ALJs and built from the records of CMS contractors that adjudicated the claim, or from records maintained by SSA in certain circumstances. After adjudication by OMHA, the Council may include more documents in the administrative record, if a request for Council review is filed or a referral to the Council is made. If a party then seeks judicial review, the administrative record is certified and presented to the Court as the official agency record of the administrative proceedings. The record is returned to the custody of CMS contractors or SSA after any administrative and judicial review is complete. Current practices in creating the administrative record in accordance with current rules vary widely. Given the importance of the administrative record, CMS is finalizing proposed revisions to §§ 405.1042 and 423.2042 to provide for more consistency and to clarify its contents and other administrative matters.

CMS will require OMHA to make a complete record of the evidence and administrative proceedings on the appealed matter and hearing proceedings. This is to provide OMHA with more

discretion to develop policies and uniform procedures for constructing the administrative record, while preserving the role of the ALJ or attorney adjudicator to identify the evidence that was used in making the determinations below and the evidence that was used in making his or her decision.

Current § 405.1042(a)(2) discusses which documents in the record are marked as exhibits, and it provides a non-exhaustive list of documents that are marked to indicate that they were considered in making the decisions under review or the ALJ's decision. Per the final rule, the record would include what is 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 admits. CMS is clarifying that the record will 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. All evidence presented should be included in the record, even if excluded from consideration, in order to help ensure a complete record of the evidence.

CMS is removing requirements to discuss any evidence excluded under current § 405.1028 and include a justification for excluding the evidence. In place of the current requirement, CMS will require that if new evidence is submitted for the first time at the OMHA level and subject to a good cause determination pursuant to proposed § 405.1028, the new evidence and good cause determination will be discussed in the decision.

The current rule provides that a party may review the record "at the hearing," or if a hearing is not held, at any time before the ALJ's notice of decision is issued. More often, a party requests a copy of the record prior to the hearing. The agency is revising the rule to state that a party may request and review 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. It is removing the reference to an "ALJ's" decision in explaining that if a hearing is not held, a party may request and review the record at any time before the notice of decision is issued, because in that circumstance an ALJ or attorney adjudicator may issue the decision.

Current § 405.1042(a)(4) provides for the complete record, including any recording of the hearing, to be forwarded to the Council when a request for review is filed or the case is escalated to the Council. However, in noting that the record includes recordings, only a recording of the hearing is mentioned. CMS is adding that the record includes recordings of prehearing and post-hearing conferences in addition to the hearing recordings to reinforce that recordings of conferences are part of the complete record.

A party may request and receive a copy of the record from OMHA while an appeal is pending at OMHA. CMS is replacing the reference to an "exhibit list" with a reference to "any index of the administrative record" to provide greater flexibility in developing a consistent structure for the administrative record. CMS also is changing the parallel reference to "the exhibits list" to "any index of the administrative record."

If a party requests all or part of the record from an ALJ and an opportunity to comment on the record, the time beginning with the ALJ's receipt of the request through the expiration of the time granted for the party's response does not count toward the 90 calendar day adjudication period. CMS is finalizing its proposal that 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 is extended

by the time beginning with the receipt of the request through the expiration of the time granted for the party's response.

The final rule addresses the possibility that a party requesting a copy of the record is not entitled to receive the entire record. CMS is proposing that if a party requests a copy of all or part of the record and the record contains information pertaining to an individual that the requesting party is not entitled to receive, those portions of the record would not be furnished unless the requesting party obtains consent from the individual.

u. Consolidated Proceedings (§§ 405.1044 and 423.2044)

The current rule describes when a consolidated hearing may be conducted, the effect on an adjudication period that applies to the appeal, and providing notice of the consolidated hearing to CMS. The final rule combines the provisions related to a consolidated hearing.

The current rule explains that when a consolidated hearing is conducted, the ALJ may consolidate the record and issue a consolidated decision, or the ALJ may maintain separate records and issue separate decisions on each claim. It also states that the ALJ ensures that any evidence that is common to all claims and material to the common issue to be decided is included in the consolidated record or each individual record, as applicable. The final rule adds provisions for making a consolidated record and decision. If the ALJ decides to hold a consolidated hearing, he or she may make either a consolidated decision and record, or a separate decision and record on each appeal. This would maintain the current choice but restructures the provision to highlight that these are two mutually exclusive options. 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.

The current rule does not contemplate a consolidated record and decision unless a consolidated hearing was conducted, which limits when multiple appeals for an appellant can be consolidated in a decision issued on the record without a hearing. The final rule states that if a hearing is not 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. In addition, a consolidated proceeding may be conducted only for appeals filed by the same appellant, unless multiple appellants aggregated claims to meet the amount in controversy requirement, and the beneficiaries whose claims are at issue have all authorized disclosure of their protected information to the other parties and any participants.

v. Notice of Decision and Effect of an ALJ's or Attorney Adjudicator's Decision (§§ 405.1046, 405.1048, 423.2046, and 423.2048)

The current rules describe the requirements for a decision and for providing notice of the decision, the content of the notice, the limitation on a decision that addresses the amount of payment for an item or a service, the timing of the decision, recommended decisions, and effects of a decision. However, the current sections apply only to a decision on a request for hearing, leaving ambiguities when issuing a decision on a request for review of a QIC or IRE dismissal. CMS is consolidating the provisions of each section that apply to a decision on a request for hearing and introducing new provisions to address a decision on a request for review of a QIC or IRE dismissal, as well as revising the titles and provisions of the sections to expand their coverage to include decisions by attorney adjudicators.

Current § 405.1046 states that an ALJ will issue a decision unless a request for hearing is dismissed. The final rule states that an ALJ or attorney adjudicator will issue a decision unless the request for hearing is dismissed or remanded in order to accommodate those situations where the ALJ or attorney adjudicator remands a case to the QIC. CMS will require that the decision include independent findings and conclusions to clarify that the ALJ or attorney adjudicator must make independent findings and conclusions, and may not merely incorporate the findings and conclusions offered by others, although the ALJ or attorney adjudicator ultimately may make the same findings and conclusions. The final rule also requires that if new evidence is submitted for the first time at the OMHA level and subject to a good cause determination, the new evidence and good cause determination is to be discussed in the decision.

The current rule requires that a decision must be mailed. In the final rule, this has been changed to OMHA “mails or otherwise transmits a copy of the decision,” to allow for additional options to transmit the decision as technologies develop. The current rule also requires that a copy of the decision be sent to the QIC that issued the reconsideration. CMS is finalizing its proposal that the decision is to be issued to the QIC that issued the reconsideration or from which the appeal was escalated. CMS is removing the requirement to send a copy of the decision to the contractor that issued the initial determination.

Unless the ALJ or attorney adjudicator dismisses the request for review of a QIC’s dismissal or the QIC’s dismissal is vacated and remanded, the ALJ or attorney adjudicator is to issue a written decision affirming the QIC’s dismissal. OMHA will transmit a copy of the decision to all the parties that received a copy of the QIC’s dismissal. The decision affirming a QIC dismissal must describe the specific reasons for the determination, including a summary of the evidence considered and applicable authorities. In addition, the notice of decision is to describe the procedures for obtaining additional information concerning the decision and provide notification that the decision is binding and not subject to further review unless the decision is reopened and revised by the ALJ or attorney adjudicator. 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.

w. Removal of a Hearing Request From an ALJ to the Council (§§ 405.1050 and 423.2050)

The current rules explain the process for the Council to assume responsibility for holding a hearing if a request for hearing is pending before an ALJ. In the final rule, the agency replaces “an ALJ” with “OMHA” in the section title and replaces “pending before an ALJ” with “pending before OMHA,” and “the ALJ send” with “OMHA send” in the section text.

x. Dismissal of a Request for Hearing or Request for Review and Effect of a Dismissal of a Request for Hearing or Request for Review (§§ 405.1052, 405.1054, 423.2052 and 423.2054)

The final rule maintains the provisions of each section that apply to a dismissal of a request for hearing and introduces new sections to address a dismissal of a request for review of a QIC or IRE dismissal. CMS is revising the titles of the sections to expand their coverage to include dismissals of requests to review a QIC or IRE dismissal.

CMS is including withdrawals of requests to review a QIC dismissal because CMS also is adding provisions to address other dismissals of those requests. An ALJ or attorney adjudicator may dismiss a request for review of a QIC dismissal based on a party’s withdrawal of his or her request, because both

ALJs and attorney adjudicators will be able to adjudicate requests to review a QIC dismissal. An ALJ or attorney adjudicator may dismiss a request for hearing based on a party's withdrawal of his or her request.

The current rule describes three possible alternatives for dismissing a request for hearing when the party that requested the hearing, or the party's representative, does not appear at the time and place set for the hearing. CMS is simplifying the provision to provide two alternatives and to require that contact has been made with an appellant and documented or an opportunity to provide an explanation for failing to appear has been provided before a request for hearing is dismissed for failing to appear at the hearing. The first alternative provides that a request for hearing may be dismissed if the party that filed the request was notified before the time set for 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 does not provide good cause for not appearing. The second alternative provides that a request for hearing may be dismissed if the record does not contain documentation that the party acknowledged the notice of hearing, but the ALJ sends a notice to the party at his or her 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 respond, but does not provide good cause for not appearing.

Current OMHA policy provides that a request for hearing that does not meet the requirements of current § 405.1014 may be dismissed by an ALJ after an opportunity is provided to the appellant to cure an identified defect.⁶ In the final rule, CMS explains that a request for hearing may be dismissed if the request is not complete or the appellant did not send copies of its request to the other parties after the appellant is provided with an opportunity to complete the request and/or send copies of the request to the other parties. (The final rule clarifies that a request filed by an unrepresented beneficiary will not be subject to dismissal if the appellant fails to send a copy of the request to the other parties, in accordance with § 405.1014(d).)

A request for review of a QIC dismissal will be dismissed when: (1) the person or entity requesting the review has no right to the review of the QIC dismissal under proposed § 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; (3) a beneficiary or beneficiary's representative filed the request for review, and the beneficiary passed away while the request for review is pending and all of the following criteria apply: (i) a surviving spouse or estate has no remaining financial interest in the case, (ii) no other individuals or entities have a financial interests in the case and wish to pursue an appeal, and (iii) no other individual or entity filed a valid and timely request for a review of the QIC dismissal; or (4) the appellant's request for review is not complete or the appellant does not send a copy of the request to the other parties after being provided with an opportunity to complete the request and/or send a copy of the request to the other parties.

The current rule requires notice of the dismissal to be sent to all parties at their last known address. Going forward, the notice of dismissal will be sent to the parties who received a copy of the request for hearing or request for review because only those parties are on notice that a request was pending. If a party's request for hearing or request for review is dismissed, the appeal will proceed with respect to any other parties who also filed a valid request for hearing or review regarding the same claim or disputed matter. Current § 405.1052 does not include authority for an ALJ to vacate his or her own dismissal and instead requires an appellant to request the Council review an ALJ's dismissal. CMS is providing authority for an

⁶ OMHA Case Processing Manual, Division 2, Chapter 3, Sections II-3-6 D and E.

ALJ or an attorney adjudicator to vacate his or her own dismissal within six months of the date of the notice of dismissal, in the same manner as a QIC can vacate its own dismissal.

The dismissal of a request for hearing is binding unless it is vacated by the ALJ or attorney adjudicator in addition to the current provision that allows the dismissal to be vacated by the Council. 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.

3. *Applicability of Medicare Coverage Policies (§§ 405.1060, 405.1062, 405.1063, 423.2062, 423.2063)*

CMS is finalizing all language in this section of the proposed rule that it changed to create consistency with its proposal to allow the use of attorney adjudicators.

4. *Council Review and Judicial Review*

a. Council Review: General (§§ 405.1100, 423.1974 and 423.2100)

Per the final rule, the appellant may request that a case be escalated to the Council for a decision even if the ALJ or attorney adjudicator has not issued a decision, dismissal, or remand in his or her case. When the Council reviews an ALJ's or attorney adjudicator's decision, it undertakes a *de novo* review and may remand a case to an ALJ or attorney adjudicator, so that the same standard for review is applied to ALJ and attorney adjudicator decisions. The Council may remand an attorney adjudicator's decision to the attorney adjudicator so that, like an ALJ, the attorney adjudicator can take the appropriate action ordered by the Council (however, if the Council orders that a hearing must be conducted, the case will be transferred to an ALJ upon remand to the attorney adjudicator because only an ALJ may conduct a hearing).

The current rules provide that the Council issues a final decision, dismissal order, or remand no later than the period of time specified in the respective paragraph, beginning on the date that the request for review is received by the entity specified in the ALJ's written notice of decision. The final rule states that the period of time begins on the date that the request for review is received by the entity specified in the ALJ's or attorney adjudicator's written notice of decision because an attorney adjudicator also may issue a decision.

The current rule states in part that when deciding an appeal that was escalated from the ALJ level to the Council, the Council will issue a final decision or dismissal order or remand order within 180 calendar days of receipt of the appellant's request for escalation. The final rule states that if the Council remands an escalated appeal, the remand is to the OMHA Chief ALJ because the rare and unique circumstances in which an escalated appeal is remanded by the Council require immediate attention that the OMHA Chief ALJ is positioned to provide to minimize delay for the appellant and to minimize confusion if the case was not assigned to an ALJ or attorney adjudicator when it was escalated.

b. Request for Council Review When the ALJ Issues Decision or Dismissal (§§ 405.1102 and 423.2102)

The current rules discuss requests for Council review when an ALJ issues a decision or dismissal. Per the final rule, a party or enrollee to a decision or dismissal issued by an ALJ or attorney adjudicator

may request Council review if the party or enrollee files a written request for a Council review within 60 calendar days after receipt of the ALJ's or attorney adjudicator's decision or dismissal.

The current rules provide that a party or enrollee does not have a right to seek Council review of an ALJ's remand to a QIC or IRE, or an ALJ's affirmation of a QIC's or IRE's dismissal of a request for reconsideration. Going forward, an attorney adjudicator could adjudicate requests for a review of a QIC or IRE dismissal. In addition, the final rule establishes the authority for an ALJ or attorney adjudicator to vacate his or her own dismissal, and in accordance with the policy that a review of a dismissal is reviewable only at the next level of appeal, a party does not have the right to seek Council review of an ALJ's or attorney adjudicator's dismissal of a request for review of a QIC dismissal. The agency adds that a party does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to a QIC or IRE, affirmation of a QIC's or IRE's dismissal of a request for reconsideration, or dismissal of a request for review of a QIC or IRE dismissal.

c. Where a Request for Review or Escalation may be Filed (§§ 405.1106 and 423.2106)

If an appellant files a request to escalate an appeal to the Council level because the ALJ or attorney adjudicator has not completed his or her action on the request for hearing within an applicable adjudication period, the request for escalation must be filed with OMHA and the appellant also must send a copy of the request for escalation to the other parties who were sent a copy of the QIC reconsideration. The final rule refers to "an applicable adjudication period" to align the terminology and because an adjudication period may not apply to a specific case. Failing to copy the other parties will toll the Council's adjudication deadline until all parties who were sent a copy of the QIC reconsideration receive notice of the request for escalation, rather than notice of the request for Council review as is required currently.

d. Council Actions when Request for Review or Escalation is Filed (§§ 405.1108 and 423.2108)

CMS is replacing "ALJ level" with "OMHA level" to provide that the Council's actions with respect to a request for escalation are the same regardless of whether the case was pending before an ALJ or attorney adjudicator, or unassigned at the time of escalation. CMS also is finalizing its proposal to replace "remand to an ALJ for further proceedings, including a hearing" with "remand to OMHA for further proceedings, including a hearing."

e. Council Reviews on its Own Motion (§ 405.1110 and 423.2110)

CMS is modifying language to create consistency with the proposal for the use of attorney adjudicators.

f. Content of Request for Review (§§ 405.1112 and 423.2112)

CMS is modifying language to create consistency with the proposal for the use of attorney adjudicators.

The current rule states that the written request for review must include the hearing office in which the appellant's request for hearing is pending if a party is requesting escalation from an ALJ to the Council. In light of the revisions to the escalation process, CMS is removing this requirement from § 405.1112(a)

because proposed § 405.1016 would provide that a request for escalation is filed with OMHA. If the request for escalation meets the requirements of § 405.1016(f)(1) and a decision, dismissal, or remand cannot be issued within five calendar days after OMHA receives the request, the appeal will be forwarded to the Council.

g. Dismissal of Request for Review (§§ 405.1114 and 423.2114)

CMS is modifying language to create consistency with the proposal for the use of attorney adjudicators.

h. Effect of Dismissal of Request for Council Review or Request for Hearing (§§ 405.1116 and 423.2116)

CMS is modifying language to create consistency with the proposal for the use of attorney adjudicators.

i. Obtaining Evidence from the Council (§§ 405.1118 and 423.2118)

Current §§ 405.1118 and 423.2118 provide that a party or an enrollee, respectively, may request and receive a copy of all or part of the record of the ALJ hearing. CMS is replacing “ALJ hearing” with “ALJ’s or attorney adjudicator’s action” and is replacing the reference to an “exhibits list” with a reference to “any index of the administrative record” to provide greater flexibility in developing a consistent structure for the administrative record. CMS also is replacing the reference to a “tape” of the oral proceeding with an “audio recording” of the oral proceeding.

j. What Evidence may be Submitted to the Council (§§ 405.1122 and 423.2122)

CMS is modifying language to create consistency with the proposal for the use of attorney adjudicators.

k. Case Remanded by the Council (§§ 405.1126 and 423.2126)

The current rule explains the Council’s remand authority. CMS is modifying language to create consistency with the proposal for the use of attorney adjudicators. The final rule also provides that an ALJ or attorney adjudicator is to take any action that is ordered by the Council and may take any additional action that is not inconsistent with the Council’s remand order.

l. Action of the Council (§§ 405.1128 and 423.2128)

CMS is modifying language to create consistency with the proposal for the use of attorney adjudicators.

m. Request for Escalation to Federal Court (§ 405.1132)

CMS is modifying language to create consistency with the proposal for the use of attorney adjudicators.

n. Judicial Review (§§ 405.1136, 423.1976, and 423.2136)

CMS is modifying language to create consistency with the proposal for the use of attorney adjudicators.

o. Case Remanded by a Federal Court (§§ 405.1138 and 423.2138)

CMS is modifying language to create consistency with the proposal for the use of attorney adjudicators.

p. Council Review of ALJ Decision in a Case Remanded by a Federal District Court (§§ 405.1140 and 423.2140)

CMS is modifying language to create consistency with the proposal for the use of attorney adjudicators.

B. Part 405, Subpart J Expedited Reconsiderations (§ 405.1204)

In accordance with section 1869(b)(1)(F) of the Act, the current rule provides for expedited QIC reconsiderations of certain QIO determinations related to provider-initiated terminations of Medicare-covered services and beneficiary discharges from a provider's facility. The agency is clarifying that a QIC reconsideration can be appealed to, or a request for a QIC reconsideration can be escalated to, OMHA for an ALJ hearing in accordance with part 405, subpart I.

The current rule states that the beneficiary has a right to escalate a request for a QIC reconsideration if the amount remaining in controversy after the QIO determination is \$100 or more. The final rule provides that there is a right to escalate a request for a QIC reconsideration if the amount remaining in controversy after the QIO determination meets the requirements for an ALJ hearing.

C. Part 422, Subpart M

1. General Provisions (§ 422.562)

The current rule states that if an enrollee receives immediate QIO review of a determination of non-coverage of inpatient hospital care, the QIO review decision is subject only to the appeal procedures set forth in parts 476 and 478 of title 42, chapter IV. CMS is deleting § 422.562(c)(1) to remove the outdated reference.

2. Notice of Reconsidered Determination by the Independent Entity (§ 422.594)

Current § 422.594(b)(2) requires the notice of the reconsideration determination by an IRE to inform the parties of their right to an ALJ hearing if the amount in controversy is \$100 or more, if the determination is adverse (does not completely reverse the MAO's adverse organization determination). CMS is amending this requirement so that the notice informs the parties of their right to an ALJ hearing if the amount in controversy meets the requirements of the part 405 computation of the amount in controversy.

3. *Request for an ALJ Hearing (§ 422.602)*

The current rule provides that a party must file a request for an ALJ hearing within 60 days of the date of the notice of the IRE's reconsidered determination. CMS aligns the part 422 timeframe for filing a request for an ALJ hearing with provisions for similar appeals under Medicare Part A and Part B, and Part D. A request for an ALJ hearing will be required to be filed within 60 calendar days of receiving the notice of a reconsidered determination, except when the time frame is extended by an ALJ or, as proposed, attorney adjudicator, as provided in part 405. To provide consistency for when a notice of a reconsidered determination is presumed to have been received, the date of receipt of the reconsideration is presumed to be five calendar days after the date of the notice of the reconsidered determination, unless there is evidence to the contrary, which is the same presumption that is applied to similar appeals under Medicare Part A and Part B at § 405.1002, and Part D at § 423.2002.

4. *Council Review (§ 422.608)*

Current § 422.608 provides that any party to the hearing, including the MAO, who is dissatisfied with the ALJ hearing decision may request that the Council review the ALJ's decision or dismissal. Henceforth, any party to the ALJ's or attorney adjudicator's decision or dismissal, including the MAO, who is dissatisfied with the decision or dismissal, may request that the Council review the decision or dismissal.

5. *Judicial Review (§ 422.612)*

CMS is modifying language to create consistency with the proposal for the use of attorney adjudicators.

6. *Reopening and Revising Determinations and Decisions (§ 422.616)*

CMS is modifying language to create consistency with the proposal for the use of attorney adjudicators.

7. *How an MA Organization must Effectuate Standard Reconsideration Determinations and Decisions, and Expedited Reconsidered Determinations (§§ 422.618 and 422.619)*

CMS is modifying language to create consistency with the proposal for the use of attorney adjudicators.

8. *Requesting Immediate QIO Review of the Decision to Discharge from the Inpatient Hospital and Fast-Track Appeals of Service Terminations to IREs (§§ 422.622 and 422.626)*

CMS is amending relevant references to provide that the appeal is made to OMHA for an ALJ hearing.

D. Part 478, Subpart B

1. *Applicability and Beneficiary's Right to a Hearing (§§ 478.14 and 478.40)*

The final rule replaces outdated references in §§ 478.14 and 478.40.

2. *Submitting a Request for a Hearing (§ 478.42)*

The current rule has outdated references to SSA offices that no longer are involved in the Medicare claim appeals process. In addition, current § 478.42(a) permits beneficiaries to file requests for an ALJ hearing with other entities, which could cause significant delays in obtaining a hearing before an OMHA ALJ. The final rule directs beneficiaries to file a request for an ALJ hearing with the OMHA office identified in the QIO's notice of reconsidered determination.

The final rule provides that the request for hearing must be filed within 60 "calendar" days of receiving notice of the QIO reconsidered determination and that the notice is presumed to be received five "calendar" days after the date of the notice. This is to align this provision with others that address requesting a hearing. The final rule amends the standard to demonstrate that notice of QIO reconsidered determination was not received within five calendar days by requiring "evidence" rather than the current "reasonable showing," and it also would revise when a request is considered filed, from the date it is postmarked to the date it is received by OMHA.

3. *Determining the Amount in Controversy (§ 478.44)*

The current rule explains that if an ALJ determines the amount in controversy is less than \$200, the ALJ, without holding a hearing, notifies the parties to the hearing, and if a request for hearing is dismissed because the amount in controversy is not met, a notice will be sent to the parties to the hearing. However, when a request for hearing is dismissed because the amount in controversy is not met, no hearing is conducted and the parties are parties to the proceedings regardless of whether a hearing was conducted. The final rule replaces "parties to the hearing" with "parties" so it is understood that they are parties regardless of whether a hearing is conducted. An attorney adjudicator may determine the amount in controversy and may determine the amount in controversy is less than \$200 and notify the parties to submit additional evidence to prove that the amount in controversy is at least \$200. An ALJ is to dismiss a request if at the end of the 15-day period to submit additional evidence to prove that the amount in controversy is at least \$200, the ALJ determines that the amount in controversy is less than \$200.

4. *Medicare Appeals Council and Judicial Review (§ 478.46)*

CMS is replacing "hearing decision" with "decision," and "ALJ" with "ALJ or attorney adjudicator" because hearings are not always conducted and a decision generally can be appealed regardless of whether a hearing was conducted, and attorney adjudicators may issue decisions or dismissals for which Council review may be requested.

5. *Reopening and Revision of a Reconsidered Determination or a Decision (§ 478.48)*

CMS is revising the title of § 478.48 to replace "hearing decision" with "decision," and to replace "ALJ" with "ALJ or attorney adjudicator" so the provision is understood to apply to decisions by ALJs, regardless of whether a hearing was conducted, or attorney adjudicators, as well as review decisions, which are conducted by the Medicare Appeals Council at the Departmental Appeals Board.

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We hope this summary is helpful to you. Please let us know if you have any questions.