DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 401, 405, 422, 423, and 478

[HHS–2015–49]

RIN 0991–AC02

Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the procedures that the Department of Health and Human Services would follow at the Administrative Law Judge 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. In addition, this proposed rule would revise procedures that the Department of Health and Human Services would follow at the Centers for Medicare & Medicaid Services (CMS) and the Medicare Appeals Council (Council) levels of appeal for certain matters affecting the Administrative Law Judge level.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. eastern standard time (e.s.t.) on August 29, 2016.

ADDRESSES: In commenting, refer to ''HHS–2015–49'' at the top of your comments. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. We will not accept comments submitted after the comment period.

You may submit comments in one of two ways (to ensure that we do not receive duplicate copies, please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this proposed rule at *www.regulations.gov*. For new users, you can find instructions on how to find a proposed rule and submit comments under the ''Help'' tab at *www.regulations.gov*.

If you are submitting comments electronically, we strongly encourage you to submit any comments or attachments in Microsoft Word format. If you must submit a comment in Portable Document Format (PDF), we strongly encourage you to convert the PDF to print-to-PDF format or to use some other commonly used searchable text format. Please do not submit the PDF in a scanned or read-only format. Using a print-to-PDF format allows us to electronically search and copy certain portions of your submissions.

2. *U.S. Mail or commercial delivery.* You may send written comments to the following address ONLY: Office of Medicare Hearings and Appeals, Department of Health and Human Services, Attention: HHS–2015–49, 5201 Leesburg Pike, Suite 1300, Falls Church, VA 22041.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

Privacy Note: Because comments will be made available for public viewing in their entirety on the Federal eRulemaking portal, commenters should exercise caution and only include in their comments information that they wish to make publicly available.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Rita Wurm, (410) 786–1139 (for issues related to CMS appeals policies and reopening policies).

Jason Green, (571) 777–2723 (for issues related to Administrative Law Judge appeals policies).

Debbie Nobleman, (202) 565–0139 (for issues related to Council appeals policies).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We will post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 4 weeks after publication of a document, at the headquarters of the Office of Medicare Hearings and Appeals, 1700 North Moore Street, Suite 1650, Arlington, Virginia 22209, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, phone (703) 235–0635.

Abbreviations

Because we refer to a number of terms by abbreviation or a shortened form in this proposed rule, we are listing these abbreviations and shortened forms, and their corresponding terms in alphabetical order below:

Act—Social Security Act
ALJ—Administrative Law Judge
APA—Administrative Procedures Act
BIPA—Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Pub. L. 106–554)
CMS—Centers for Medicare & Medicaid Services
Council—Medicare Appeals Council
DAB—Departmental Appeals Board
HHS—U.S. Department of Health and Human Services
IRE—Independent Review Entity
IRMAA—Income Related Monthly Adjustment Amount
MA—Medicare Advantage
MAO—Medicare Advantage Organization
MMA—Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173)
OIG—HHS Office of Inspector General
OMHA—Office of Medicare Hearings and Appeals
QIC—Qualified Independent Contractor
QIO—Quality Improvement Organization
SSA—Social Security Administration

Section 1557 of the Affordable Care Act

Independent of the standards proposed in this rule, the Department commits to complying with section 1557 of the Affordable Care Act, Public Law 111–148, 124 Stat. 470 (42 U.S.C. 18116), which prohibits discrimination on the basis of race, color, national origin, sex, age, or disability in certain health programs and activities. HHS issued a proposed rule to implement section 1557, *Nondiscrimination in Health Programs and Activities,* on September 8, 2015. 80 FR 54172. The proposed rule would apply, in part, to health programs and activities administered by the Department.

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I. Background

In accordance with provisions of sections 1155, 1852, 1860D–4, 1869, and 1876 of the Act, and their implementing regulations, there are multiple administrative appeal processes for Medicare fee-for-service (Part A and Part B) claim, entitlement and certain premium initial determinations; Medicare Advantage (Part C) and other competitive health plan organization determinations; and Part D plan sponsor coverage determinations and certain premium determinations. The first, and in many instances a second, level of administrative appeal are administered

by Medicare contractors, Part D plan sponsors, Medicare Advantage organizations or Medicare plans, or by the SSA. For example, under section 1869 of the Act, the Medicare claims appeal process involves redeterminations conducted by the Medicare Administrative Contractors (which are independent of the staff that made the initial determination) followed by reconsiderations conducted by QICs. However, all of the appeals discussed in this proposed regulation could be appealed to the ALJs at OMHA if the amount in controversy requirement and other requirements are met after these first and/or second levels of appeal.

OMHA, a staff division within the Office of the Secretary of HHS, administers the nationwide ALJ hearing program for Medicare claim, organization and coverage determination, and entitlement and certain premium appeals. If the amount in controversy and other filing requirements are met, a hearing before an ALJ is available following a QIO reconsidered determination under section 1155 of the Act; an SSA or QIC reconsideration, or a request for QIC reconsideration for which a decision is not issued timely and a party requests escalation of the matter under section 1869(b)(1)(A) and (d) of the Act (Part A and Part B appeals); an IRE reconsideration or QIO reconsidered determination under sections 1876(c)(5)(B) or 1852(g)(5) of the Act (Part C and other managed health plan appeals); or an IRE reconsideration under section 1860D–4(h) of the Act (Part D appeals). In addition, under current regulations a review by an ALJ is available following a dismissal of a request for reconsideration, if the amount in controversy and other filing requirements are met.

OMHA provides Medicare beneficiaries and the providers and suppliers that furnish items or services to Medicare beneficiaries, as well as applicable plans, MAOs, and Medicaid State agencies with a fair and impartial forum to address disagreements regarding: Medicare coverage and payment determinations made by Medicare contractors, MAOs, or Part D plan sponsors; and determinations related to Medicare beneficiary eligibility and entitlement, Part B late enrollment penalties, and IRMAAs, which apply to Medicare Part B and Part D premiums, made by SSA. Further review of OMHA ALJ decisions, except decisions affirming a dismissal of a request for reconsideration, is available from the Medicare Appeals Council (Council) within the DAB, a staff division within the Office of the Secretary of HHS. Judicial review is then available for Council decisions in Federal courts, if the amount in controversy and other requirements are met.

OMHA ALJs began adjudicating appeals in July 2005, based on section 931 of the MMA, which required the transfer of responsibility for the ALJ hearing level of the Medicare claim and entitlement appeals process from SSA to HHS. New rules at 42 CFR part 405, subpart I and subpart J were also established to implement statutory changes to the Medicare fee-for-service (Part A and Part B) appeals process made by BIPA in 2000 and the MMA in 2003. Among other things, these new rules addressed appeals of reconsiderations made by QICs, which were created by BIPA for the Part A and Part B programs. These rules also apply to appeals of SSA reconsiderations. The statutory changes made by BIPA included a 90-day adjudication time frame for ALJs to adjudicate appeals of QIC reconsiderations beginning on the date that a request for an ALJ hearing is timely filed. The new part 405, subpart I rules were initially proposed in the November 15, 2002 **Federal Register** (67 FR 69312) (2002 Proposed Rule) to implement BIPA, and were subsequently implemented in an interim final rule with comment period, which also set forth new provisions to implement the MMA, in the March 8, 2005 **Federal Register** (70 FR 11420) (2005 Interim Final Rule). Correcting amendments to the 2005 Interim Final Rule were published in the June 30, 2005 **Federal Register** (70 FR 37700) (2005 Correcting Amendment I) and in the August 26, 2005 **Federal Register** (70 FR 50214) (2005 Correcting Amendment II), and the final rule was published in the December 9, 2009 **Federal Register** (74 FR 65296) (2009 Final Rule). Subsequent revisions to part 405, subpart I to implement the Strengthening Medicare and Repaying Taxpayers Act of 2012 (SMART Act, Pub. L. 112–242) were published in the February 27, 2015 **Federal Register** (80 FR 10611) (SMART Act Final Rule).

In addition to the part 405, subpart I rules, OMHA applies the rules at 42 CFR part 478, subpart B to individuals' appeals of QIO reconsidered determinations; part 422, subpart M to appeals of IRE reconsiderations or QIO reconsidered determinations under the Medicare Advantage (Part C) and other competitive health plan programs; and part 423, subpart U to appeals of IRE reconsiderations under the Medicare prescription drug (Part D) program.

In recent years, the Medicare appeals process has experienced an unprecedented and sustained increase in the number of appeals. At OMHA, for example, the number of requests for an ALJ hearing or review increased 1,222 percent, from fiscal year (FY) 2009 through FY 2014. The increasing number of requests has strained OMHA's available resources and resulted in delays for appellants to obtain hearings and decisions.

Despite significant gains in OMHA ALJ productivity (in FY 2014, each OMHA ALJ issued, on average, a record 1,048 decisions and an additional 456 dismissals), and CMS and OMHA initiatives to address the increasing number of appeals, the number of requests for an ALJ hearing and requests for reviews of QIC and IRE dismissals continue to exceed OMHA's capacity to adjudicate the requests. As of April 30, 2016, OMHA had over 750,000 pending appeals, while OMHA's adjudication capacity was 77,000 appeals per year, with an additional adjudication capacity of 15,000 appeals per year expected by the end of Fiscal Year 2016.

HHS has a three-prong approach to addressing the increasing number of appeals and the current backlog of claims waiting to be adjudicated at OMHA: (1) Request new resources to invest at all levels of appeal to increase adjudication capacity and implement new strategies to alleviate the current backlog; (2) take administrative actions to reduce the number of pending appeals and implement new strategies to alleviate the current backlog ; and (3) propose legislative reforms that provide additional funding and new authorities to address the volume of appeals. In this notice of proposed rulemaking, HHS is pursuing the three-prong approach by proposing rules that would expand the pool of available OMHA adjudicators and improve the efficiency of the appeals process by streamlining the processes so less time is spent by adjudicators and parties on repetitive issues and procedural matters.

II. General Provisions of the Proposed Regulations

A. Precedential Final Decisions of the Secretary

Council decisions are binding on the parties to that particular appeal and are the final decisions of the Secretary from which judicial review may be sought under section 205(g) of the Act, in accordance with current §§ 405.1130, 422.612(b), 423.2130, and 478.46(b). As explained in the 2009 Final Rule (74 FR 65307 through 65308), ''binding'' indicates the parties are obligated to

abide by the adjudicator's action or decision unless further recourse is available and a party exercises that right. ''Final'' indicates that no further administrative review of the decision is available and judicial review may be immediately sought.

In 1999, the OIG issued a report entitled ''Medicare Administrative Appeals—ALJ Hearing Process'' (OEI–04–97–00160) (Sept. 1999) (*http://oig.hhs.gov/oei/reports/oei-04-97-00160.pdf*). In that report, the OIG noted that the DAB respondents voiced strong interest in having precedent setting authority in the Medicare administrative appeals process ''to clean-up inconsistencies in the appeals process.'' The OIG recommended that such a case precedent system be established.

Pursuant to section 931(a) of the MMA, HHS and SSA developed a plan for the transition of the ALJ hearing function for some types of Medicare appeals from SSA to HHS, and addressed the feasibility of precedential authority of DAB decisions. See *Report to Congress: Plan for the Transfer of Responsibility for Medicare Appeals* (Mar. 2004) (*https://www.ssa.gov/legislation/medicare/medicare_appeal_transfer.pdf*). HHS determined that at that time, it was not feasible or appropriate to confer precedential authority on Council decisions, but indicated that it would reevaluate the merits of granting precedential authority to some or all Council decisions after the BIPA and MMA changes to the appeals process were fully implemented.

BIPA and MMA changes to the appeals process have now been fully implemented and we believe it is appropriate to propose that select Council decisions be made precedential to increase consistency in decisions at all levels of appeal for appellants. Proposed § 401.109 would introduce precedential authority to the Medicare claim and entitlement appeals process under part 405, subpart I; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B. Proposed § 401.109(a) would grant authority to the Chair of the DAB to designate a final decision of the Secretary issued by the Council as precedential. We believe this would provide appellants with a consistent body of final decisions of the Secretary upon which they could determine whether to seek appeals. It would also assist appeal adjudicators at all levels of appeal by providing clear direction on repetitive legal and policy questions, and in limited circumstances, factual questions. In the limited circumstances in which a precedential decision would apply to a factual question, the decision would be binding where the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the Council issued the precedential final decision.

It is appropriate for the DAB Chair to have the role of designating select Council decisions as precedential. The DAB Chair leads the DAB, which was established in 1973. The DAB has wide jurisdiction over disputes arising under many HHS programs and components, and has issued precedential decisions for many years within several of its areas of jurisdiction. (Examples of DAB jurisdiction may be found at 45 CFR part 16, 42 CFR part 498, 42 CFR part 426, and on the DAB's Web site at *www.hhs.gov/dab*.) The Council has been housed within the DAB as an organization since 1995 and is itself also under the leadership of the DAB Chair. Thus, the DAB Chair brings both expertise in the Medicare claims appeals over which the Council has jurisdiction and experience from the DAB's precedential cases to carrying out the role of designating Council decisions to be precedential. Moreover, having the designation performed by the DAB Chair respects the continued independence of the Council as an adjudicative body by allowing the DAB to determine the effect of its own decisions. Limiting binding precedential effect to selected decisions provides the necessary discretion to designate as precedential those Council decisions in which a significant legal or factual issue was fully developed on the record and thoroughly analyzed. Designation might not be appropriate where an issue was mentioned in the decision as relevant but was not outcome determinative, and therefore may not have been as fully developed as is necessary for precedential decisions or where the issues addressed are not likely to have broad application beyond the particular case.

To help ensure appellants and other stakeholders are aware of Council decisions that are designated as precedential, we are proposing that § 401.109(b) would require notice of precedential decisions to be published in the **Federal Register**, and the decisions themselves would be made available to the public, with necessary precautions taken to remove personally identifiable information that cannot be disclosed without the individual's consent. Designated precedents would be posted on an accessible Web site maintained by HHS. Decisions of the Council would bind all lower-level decision-makers from the date that the decisions are posted on the HHS Web site.

Proposed § 401.109(c) would make these precedential decisions binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on SSA to the extent that SSA components adjudicate matters under the jurisdiction of CMS, in the same manner as CMS Rulings under current § 401.108. That means the precedential decision would be binding on CMS and its contractors in making initial determinations, redeterminations, and reconsiderations, under part 405 subpart I, or equivalent determinations under parts 422 subpart M, 423 subparts M and U, and 478 subpart B; OMHA ALJs and, as proposed in II.B below, attorney adjudicators; the Council in its future decisions; and SSA to the extent that it adjudicates matters under the jurisdiction of CMS. Individual determinations and decisions by CMS contractors, OMHA ALJs, and the Council currently are not precedential and have no binding effect on future initial determinations (and equivalent determinations) or claims appeals. We are not proposing to change the non-precedential status and non-binding effect on future initial determinations (and equivalent determinations) or claim appeals of any determinations or decisions except as to Council decisions designated as precedential by the DAB Chair.

Proposed § 401.109(d) would specify the scope of the precedential effect of a Council decision designated by the DAB Chair. The Council's legal analysis and interpretation of an authority or provision that is binding (see, for example §§ 405.1060 and 405.1063) or owed substantial deference (see, for example § 405.1062) would be binding in future determinations and appeals in which the same authority or provision is applied and is still in effect. However, if CMS revises the authority or provision that is the subject of a precedential decision, the Council's legal analysis and interpretation would not be binding on claims or other disputes to which the revised authority or provision applies. For example, if a Council decision designated as precedential by the DAB Chair interprets a CMS manual instruction, that interpretation would be binding on pending and future appeals and initial determinations to which that manual instruction applies. However, CMS would be free to follow its normal internal process to revise the manual instruction at issue. Once the revised instruction is issued through the CMS process, the revised instruction would

apply to making initial determinations on all claims thereafter. This would help ensure that CMS continues to have the ultimate authority to administer the Medicare program and promulgate regulations, and issue sub-regulatory guidance and policies on Medicare coverage and payment.

If the decision is designated as precedential by the DAB Chair, proposed § 401.109(d) would also make the Council's findings of fact binding in future determinations and appeals that involve the same parties and evidence. For example, if a precedential Council decision made findings of fact related to the issue of whether an item qualified as durable medical equipment and the same issue was in dispute in another appeal filed by the same party, and that party submitted the same evidence to support its assertion, the findings of fact in the precedential Council decision would be binding. However, we note that many claim appeals turn on evidence of a beneficiary's condition or care at the time discrete items or services are furnished, and therefore proposed § 401.109 is unlikely to apply to findings of fact in these appeals.

In addition, consistent with proposed § 401.109, we are proposing at § 405.968(b)(1) to add precedential decisions designated by the Chair of the Departmental Appeals Board as an authority that is binding on the QIC. We are also proposing at §§ 405.1063 and 423.2063, which currently cover the applicability of laws, regulations, and CMS Rulings, to add new paragraph (c) to the sections to provide that precedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 are binding on all CMS components, all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS. Finally, we are proposing to add precedential decisions to the titles of §§ 405.1063 and 423.2063 to reflect the additional topic covered by proposed paragraph (c).

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Precedential final decisions of the Secretary'' at the beginning of your comment.

B. Attorney Adjudicators

Sections 1155, 1852(g)(5), 1860D–4(h), 1869(b)(1)(A), and 1876(c)(5)(B) provide a right to a hearing to the same extent as provided in section 205(b) by the HHS Secretary for certain appealable decisions by Medicare contractors or SSA, when the amount in controversy and other filing requirements are met. Hearings under these statutory provisions are conducted by OMHA ALJs with delegated authority from the HHS Secretary, in accordance with these sections and the APA.

Under current §§ 405.1038 and 423.2038, OMHA ALJs are also responsible for a portion of the appeals workload that does not require a hearing because a request for an ALJ hearing may also be addressed without conducting a hearing. For example, under §§ 405.1038 and 4423.2038, if the evidence in the hearing record supports a finding in favor of the appellant(s) on every issue, or if all parties agree in writing that they do not wish to appear before the ALJ at a hearing, the ALJ may issue a decision on the record without holding a hearing. Under current §§ 405.1052(a)(1) and 423.2052(a)(1), OMHA ALJs must also address a large number of requests to withdraw requests for ALJ hearings, which appellants often file pursuant to litigation settlements, law enforcement actions, and administrative agreements in which they agree to withdraw appeals and not seek further appeals of resolved claims. In addition, pursuant to §§ 405.1004 and 423.2004, OMHA ALJs review whether a QIC or IRE dismissal was in error. Under these sections, the ALJ reviews the dismissal, but no hearing is required. In FY 2015, OMHA ALJs addressed approximately 370 requests to review whether a QIC or IRE dismissal was in error. Also adding to the ALJs' workload are remands to Medicare contractors for information that can only be provided by CMS or its contractors under current §§ 405.1034(a) and 423.2034(a), and for further case development or information at the direction of the Council. Staff may identify the basis for these remands before an appeal is assigned to an ALJ and a remand order is prepared, but an ALJ must review the appeal and issue the remand order, taking the ALJ's time and attention away from hearings and making decision on the merits of appeals.

Under section 1869(d) of the Act, an ALJ must conduct and conclude a hearing on a decision of a QIC under subsection (c). Subsection (c) of section 1869 of the Act involves the conduct of reconsiderations by QICs. We believe that the statute does not require the action to be taken by an ALJ in cases where there is no QIC reconsideration (for example, where the QIC has issued a dismissal), or in cases of a remand or a withdrawal of a request for an ALJ hearing, and therefore the findings of fact and conclusions of law need not be rendered. ALJ hearings are ideally suited to obtain testimony and other evidence, and hear arguments related to the merits of a claim or other determination on appeal. ALJs are highly qualified to conduct those hearings and make findings of fact and conclusions of law to render a decision in the more complex records presented with a mix of documentary and testimonial evidence. However, well-trained attorneys can perform a review of the administrative record and more efficiently draft the appropriate order for certain actions, such as issuing dismissals based on an appellant's withdrawal of a request for an ALJ hearing, remanding appeals for information or at the direction of the Council, and conducting reviews of QIC and IRE dismissals.

In addition, current §§ 405.1038 and 423.2038 provide mechanisms for deciding cases without an oral hearing, based on the written record. Cases may be decided without an oral hearing when the record supports a finding in favor of the appellant(s) on every issue; all of the parties have waived the oral hearing in writing; or the appellant lives outside of the United States and did not inform the ALJ that he or she wishes to appear, and there are no other parties who wish to appear. In these circumstances, the need for an experienced adjudicator knowledgeable in Medicare coverage and payment law continues, and well-trained attorneys can review the record, identify the issues, and make the necessary findings of fact and conclusions of law when the regulations do not require a hearing to issue a decision in the appealed matter.

To enable OMHA to manage requests for an ALJ hearing and requests for reviews of QIC and IRE dismissals in a more timely manner and increase service to appellants, while preserving access to a hearing before an ALJ in accordance with the statutes, we are proposing to revise rules throughout part 405, subparts I and J; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B, to provide authority that would 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 reviews of QIC and IRE dismissals. We also are proposing 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. Allowing attorney adjudicators to issue decisions, dismissals, and remands as described above, and to conduct reviews of QIC and IRE dismissals would 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. In addition, the rights associated with an appeal adjudicated by an ALJ would 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.

In addition, we note that even if an attorney adjudicator was assigned to adjudicate a request for an ALJ hearing, that hearing request still could be reassigned to an ALJ for an oral hearing if the attorney adjudicator determined that a hearing could be necessary to render a decision. For example, if the parties waived their rights to an oral hearing in writing, allowing a decision to be issued without conducting an oral hearing in accordance with current §§ 405.1038(b)(1) or 423.2038(b)(1), but the attorney adjudicator believed testimony by the appellant or another party would be necessary to decide the appeal, the attorney adjudicator would refer the appeal to an ALJ to determine whether conducting an oral hearing would be necessary to decide the appeal regardless of the waivers, pursuant to current §§ 405.1036(b)(3) or 423.2036(b)(3). We also note that parties to a decision that is issued without an ALJ conducting an oral hearing pursuant to current §§ 405.1038(a) or 423.2038(a) (that is, the decision is favorable to the appellant on every issue and therefore may be issued based on the record alone) continue to have a right to a hearing and a right to examine the evidence on which the decision is based and may pursue that right by requesting a review of the decision by the Council, which can remand the case for an ALJ to conduct a hearing and issue a new decision.

To implement this proposal, we are proposing to revise provisions throughout part 405 subpart I, part 422 subpart M, part 423 subparts M and U, and part 478 subpart U, as detailed in proposed revisions to specific sections, in section III of this proposed rule, below. In addition, we are proposing to define an attorney adjudicator in § 405.902, which provides definitions that apply to part 405 subpart I. We are proposing to define an ''attorney adjudicator'' in § 405.902 as a licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance. In addition, we are proposing to indicate in § 405.902 that the attorney adjudicator is authorized to take the actions provided for in subpart I on requests for ALJ hearing and requests for reviews of QIC dismissals. These proposals would provide the public with an understanding of the attorney adjudicator's qualifications and scope of authority, and we also note that attorney adjudicators would receive the same training as OMHA ALJs.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Attorney Adjudicators'' at the beginning of your comment.

C. Application of 405 Rules to Other Parts

Current § 422.562(d) states that unless subpart M regarding grievances, organization determinations and appeals under the Medicare Advantage program provides otherwise, the regulations found in part 405 apply under subpart M to the extent appropriate. In addition, current § 422.608, which is a section within subpart M, provides that the regulations under part 405 regarding Council review apply to the subpart to the extent that they are appropriate.

Similar to current § 422.562(d), § 478.40(c) indicates that the part 405 regulations apply to hearings and appeals under subpart B of part 478 regarding QIO reconsiderations and appeals, unless they are inconsistent with specific provisions in subpart B. Thus, the part 405 rules are used, to the extent appropriate, for administrative review and hearing procedures in the absence of specific provisions related to administrative reviews and hearing procedures in part 422, subpart M; and part 478, subpart B, respectively. These general references to part 405 are often helpful in filling in gaps in procedural rules when there is no rule on point in the respective part. However, there has been confusion on the application of part 405 rules when a part 405 rule implements a specific statutory provision that is not in the authorizing statute for the referring subpart and HHS has not adopted a similar policy for the referring subpart in its discretion to administer the Medicare Advantage, QIO, and cost plan appeals programs. For example, certain procedures and provisions of section 1869 of the Act (governing certain determinations and appeals under Medicare Part A and Part B) that are implemented in part 405, subpart I are different than or not addressed in sections 1155 (providing for reconsiderations and appeals of QIO determinations), 1852(g) (providing for appeals of MA organization determinations), and 1876 (providing for appeals of organization determinations made by section 1876 health maintenance organizations (HMOs) and competitive medical plans (CMPs). Section 1869 of the Act provides for, among other things, redeterminations of certain initial determinations, QIC reconsiderations following redeterminations or expedited determinations; ALJ hearings and decisions following a QIC reconsideration; DAB review following ALJ decisions; specific time frames in which to conduct the respective adjudications; and, at certain appeal levels, the option to escalate appeals to the next level of appeal if the adjudication time frames are not met. In addition, section 1869(b)(3) of the Act does not permit providers and suppliers to introduce evidence in an appeal brought under section 1869 of the Act after the QIC reconsideration, unless there is good cause that precluded the introduction of the evidence at or before the QIC reconsideration.

In contrast, sections 1852(g)(5) of the Act and 1876(c)(5)(B) of the Act incorporate some, but not all, of the provisions of section 1869 of the Act, and add certain requirements, such as making the MAO, HMO, or CMP a party to an ALJ hearing. For example, sections 1852(g)(5) and 1876(c)(5)(B) of the Act specifically incorporate section 1869(b)(1)(E)(iii) of the Act to align the amount in controversy requirements for an ALJ hearing and judicial review among the three sections. However, sections 1852(g) and 1876(c)(5)(B) do not incorporate adjudication time frames and escalation provisions, or the limitation on new evidence provision of section 1869(b)(3) of the Act.

Additionally, section 1155 of the Act provides for an individual's right to appeal certain QIO reconsidered determinations made under section 1154 of the Act directly to an ALJ for hearing. However, section 1155 of the Act does not reference section 1869 of the Act or otherwise establish an adjudication time frame, and provides for a different amount in controversy requirement for an ALJ hearing.

Despite these statutory distinctions, HHS has established similar procedures by regulation to the extent practicable, when not addressed by statute. For example, section 1860D–4(h) of the Act, which addresses appeals of coverage

determinations under Medicare Part D, incorporates paragraphs (4) and (5) of section 1852(g) of the Act. As discussed above, section 1852(g) does not incorporate adjudication time frames from section 1869 of the Act or otherwise establish such time frames. However, through rulemaking for Part D coverage determination appeals, HHS has adopted a 90-day adjudication time frame for standard requests for an ALJ hearing and requests for Council review of an ALJ decision, as well as a 10-day adjudication time frame when the criteria for an expedited hearing or review are met.

To clarify the application of the part 405 rules, we are proposing revisions to parts 422 and 478. Proposed §§ 422.562(d) and 422.608 would provide that the part 405 rules do not apply when the part 405 rule implements a statutory provision that is not also applicable to section 1852 of the Act. Similarly, proposed § 478.40(c) would provide that the part 405 rules do not apply when the part 405 rule implements a statutory provision that is not also applicable to section 1155 of the Act. In addition, proposed § 478.40(c) removes language that equates an initial determination and reconsidered determination made by a QIO to contractor initial determinations and reconsidered determinations under part 405 because that language has caused confusion with provisions that are specific to part 405 and QIC reconsiderations, and it is not necessary to apply the remaining part 405, subpart I procedural rules in part 478, subpart B proceedings. In addition to clarifying the application of part 405 rules to other parts, these revisions would help ensure that statutory provisions that are specific to certain Medicare appeals are not applied to other appeals without HHS first determining, through rulemaking, whether it would be appropriate to apply a provision and how best to tailor aligning policies for those other appeals.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Application of part 405 rules to other parts'' at the beginning of your comment.

D. OMHA References

When the 2005 Interim Final Rule was published in March 2005, implementing the part 405, subpart I rules, OMHA was not yet in operation. Further, processes and procedures were being established under the part 405 subpart I rules, with new CMS contractors and the newly transitioned ALJ hearing function. Since that time, OMHA and CMS and its contractors have developed operating arrangements to help ensure appeals flow between CMS contractors and OMHA, and that appeal instructions for appellants provide clear direction on how and where to file requests for hearings and reviews. However, many of the current rules for the ALJ hearing program that OMHA administers reflect the transition that was occurring at the time of the 2005 Interim Final Rule, and OMHA is not mentioned in the regulation text.

To provide clarity to the public on the role of OMHA in administering the ALJ hearing program, and to clearly identify where requests and other filings should be directed, we are proposing to define OMHA in § 405.902 as the Office of Medicare Hearings and Appeals within the U.S. Department of Health and Human Services, which administers the ALJ hearing process in accordance with section 1869(b)(1) of the Act. We are also proposing to amend rules throughout part 405, subparts I and J; part 422, subpart M; part 423, subparts M and U; and part 478, subpart B to reference OMHA or an OMHA office, in place of current references to an unspecified entity, ALJs, and ALJ hearing offices, when a reference to OMHA or an OMHA office provides a clearer explanation of a topic. To implement this proposal, we are proposing to revise provisions throughout part 405 subparts I and J, part 422 subpart M, part 423 subparts M and U, and part 478 subpart U, as detailed in proposed revisions to specific sections, in section III of this proposed rule, below.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''OMHA references'' at the beginning of your comment.

E. Medicare Appeals Council References

The Council is currently referred to as the ''MAC'' throughout current part 405, subpart I; part 422, subpart M; and part 423, subparts M and U. This reference has caused confusion in recent years with the transition from Fiscal Intermediaries and Carriers, to Medicare administrative contractors—for which the acronym ''MAC'' is also commonly used—to process claims and make initial determinations and redeterminations in the Medicare Part A and Part B programs. In addition, current §§ 422.618 and 422.619 reference the Medicare Appeals Council but use ''Board'' as the shortened reference, and part 478, subpart B, references the DAB as the reviewing entity for appeals of ALJ decisions and dismissals but the Council is the entity that conducts reviews of ALJ decisions and dismissals, and issues final decisions of the Secretary for Medicare appeals under part 478, subpart B.

To address potential confusion with references to Medicare administrative contractors and align references to the Council as the reviewing entity for appeals of ALJ decisions and dismissals throughout part 405, subpart I; part 422, subpart M; and part 423, subparts M and U, we are proposing to amend the following rules to replace ''MAC'' or ''Board'' with ''Council'': §§ 405.902, 405.904, 405.906, 405.908, 405.910, 405.926, 405.980, 405.982, 405.984, 405.990, 405.1026, 405.1036, 405.1037, 405.1042, 405.1046, 405.1048, 405.1050, 405.1052, 405.1054, 405.1060, 405.1063, 405.1062, 405.1100, 405.1102, 405.1104 (as re-designated and revised as proposed § 405.1016(e)–(f)), 405.1106, 405.1108, 405.1110, 405.1112, 405.1114, 405.1116, 405.1118, 405.1120, 405.1122, 405.1124, 405.1126, 405.1128, 405.1130, 405.1132, 405.1134, 405.1136, 405.1138, 405.1140, 422.561, 422.562, 422.608, 422.612, 422.616, 422.618, 422.619, 422.622, 422.626, 423.560, 423.562, 423.1968, 423.1974, 423.1976, 423.1978, 423.1980, 423.1982, 423.1984, 423.1990, 423.2026, 423.2036, 423.2042, 423.2046, 423.2048, 423.2050, 423.2052, 423.2054, 423.2062, 423.2063, 423.2100, 423.2102, 423.2106, 423.2108, 423.2110, 423.2112, 423.2114, 423.2116, 423.2118, 423.2120, 423.2122, 423.2124, 423.2126, 423.2128, 423.2130, 423.2134, 423.2136, 423.2138, and 423.2140.

In addition, to align references to the Council as the reviewing entity for appeals of ALJ decisions and dismissals in part 478, subpart B, we are proposing to amend §§ 478.46 and 478.48 to replace ''Departmental Appeals Board'' and ''DAB,'' with ''Medicare Appeals Council'' and ''Council''.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Medicare Appeals Council references'' at the beginning of your comment.

III. Specific Provisions of the Proposed Rule

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

1. Overview

Part 405, subpart I and part 423, subpart U contain detailed procedures for requesting and adjudicating a request for an ALJ hearing, and a request for a review of a QIC or IRE dismissal. Part 423, subpart U provisions were proposed in the March 17, 2008 **Federal**

Register (73 FR 14342) and made final in the December 9, 2009 **Federal Register** (74 FR 65340), and generally follow the part 405, subpart I procedures. In this proposed rule, we generally discuss proposals related to part 405, subpart I, and then whether any aligning revisions to part 423, subpart U, are proposed, unless a provision is specific to Part 405 and there is no corresponding part 423 provision.

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

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

Current § 423.562(b)(4) lists the appeal rights of a Part D plan enrollee, if the enrollee is dissatisfied with any part of a coverage determination. Specifically, paragraph (b)(4)(v) describes the right to request Council review of the ALJ's hearing decision if the ALJ affirms the IRE's adverse coverage determination in whole or in part, and paragraph (b)(4)(vi) describes the right to judicial review of the hearing decision if the Council affirms the ALJ's adverse coverage determination in whole or in part, and the amount in controversy requirements are met. We are proposing to revise paragraph (b)(4)(v) to insert ''or attorney adjudicator'' after each instance of ''the ALJ.'' This proposal is necessary to implement the proposal to allow attorneys to adjudicate requests for an ALJ hearing when no hearing is conducted as proposed in section II.B above, by stating the right to request Council review of an attorney adjudicator decision that affirms the IRE's adverse coverage determination. We also are proposing to remove ''hearing'' before ''decision'' in paragraph (b)(4)(v) to reflect that an attorney adjudicator issues decisions without conducting a hearing, and an ALJ may issue a decision without conducting a hearing.

In paragraph (b)(4)(vi), we are proposing to remove ''ALJ's'' and insert ''ALJ's or attorney adjudicator's'' in its place to implement the proposal to allow attorneys to adjudicate requests for an ALJ hearing when no hearing is conducted as proposed in section II.B above, by including an attorney adjudicator's decision as a decision that may be affirmed by the Council. We also are proposing to remove ''hearing'' before ''decision'' in paragraph (b)(4)(vi) because while the Council may conduct a hearing, Council decisions are generally issued without conducting a hearing, and the decision of the Council is subject to judicial review.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Part 423, subpart M general provisions'' at the beginning of your comment.

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. We are proposing to revise the heading by replacing ''ALJ Hearings'' with ''ALJ hearings and ALJ and attorney adjudicator decisions'' to reflect that subpart U covers decisions by ALJs and attorney adjudicators, as proposed in section II.B above.

Current § 423.1968 explains the scope of the requirements in subpart U. We are proposing at § 423.1968 to expand the scope of subpart U to include actions by attorney adjudicators, as proposed in section II.B above. Specifically, we are proposing at § 423.1968(a) to add that subpart U sets forth requirements relating to attorney adjudicators with respect to reopenings; at § 423.1968(b) to add that subpart U sets forth requirements relating to ALJ decisions and decisions of attorney adjudicators if no hearing is conducted; and at § 423.1968(d) to add that subpart U sets forth the requirements relating to Part D enrollees' rights with respect to ALJ hearings and ALJ or attorney adjudicator reviews. These changes would be necessary to accurately describe the scope of the revised provisions of subpart U to implement the attorney adjudicator proposal discussed in section II.B above.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Part 423, subpart U title and scope'' at the beginning of your comment.

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

Section 405.904(a) provides a general overview of the entitlement and claim appeals process to which part 405, subpart I applies. Current paragraphs (a)(1) and (a)(2) provide that if a beneficiary obtains a hearing before an ALJ and is dissatisfied with the decision of the ALJ, the beneficiary may request that the Council review the case. To provide for the possibility that a decision may be issued without conducting a hearing by an ALJ, as permitted under current rules, or an attorney adjudicator, as proposed in II.B above, we are proposing to add language in paragraphs (a)(1) and (a)(2) 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. This proposal would 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.

We are inviting public comments on this proposal. If you choose to comment on the proposal in this section, please include the caption ''Medicare initial determinations, redeterminations and appeals general description'' at the beginning of your comment.

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 subsection (b) currently addresses parties to the redetermination, reconsideration, hearing and MAC. We are proposing in the paragraph heading and introductory text to subsection (b) to replace the phrases ''hearing and MAC'' and ''hearing, and MAC review,'' respectively, with ''proceedings on a request for hearing, and Council review'' because, absent an assignment of appeal rights, the parties are parties to all of the proceedings on a request for hearing, including the hearing if one is conducted, and they are parties to the Council's review.

We are inviting public comments on this proposal. If you choose to comment on the proposal in this section, please include the caption ''Parties to the initial determinations, redeterminations, reconsiderations, hearings, and reviews'' at the beginning of your comment.

e. Medicaid State Agencies (§ 405.908)

Current § 405.908 discusses the role of Medicaid State agencies in the appeals process and states that if a State agency files a request for redetermination, it may retain party status at the QIC, ALJ, MAC and judicial review levels. We are proposing to replace ''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, as proposed in section II.B above.

We are inviting public comments on this proposal. If you choose to comment on the proposal in this section, please include the caption ''Medicaid State agencies'' at the beginning of your comment.

f. Appointed Representatives (§ 405.910)

The 2002 Proposed Rule (67 FR 69318 through 69319) explained that the § 405.910 requirements for a valid appointment of a representative are necessary to help ensure that adjudicators are sharing and disseminating confidential information with the appropriate individuals. The 2005 Interim Final Rule (70 FR 11428 through 11431) adopted a general requirement to include a beneficiary's health insurance claim number (HICN) for a valid appointment of a representative in § 405.910(c)(5). The SMART Act Final Rule (80 FR 10614, 10617) revised § 405.910(c)(5) to explicitly limit the requirement to include a beneficiary's HICN to instances in which the beneficiary is the party appointing a representative. However, the Medicare manual provision for completing a valid appointment of representative (Medicare Claims Processing Manual (Internet-Only Manual 100–4), chapter 29, § 270.1.2) details the requirements for an appointment of representation to contain a unique identifier of the party being represented. Specifically, if the party being represented is the beneficiary, the Medicare number must be provided, and if the party being represented is a provider or supplier, the National Provider Identifier (NPI) number should be provided. Additionally, the official form for executing a valid appointment of representative (form CMS–1696, available at *https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS1696.pdf*) provides a blank space for the party to include a Medicare or NPI number. To assist adjudicators in sharing and disseminating confidential information only with appropriate individuals, we are proposing to revise § 405.910(c)(5) to add a requirement to include the Medicare NPI of the provider or supplier that furnished the item or service when the provider or supplier is the party appointing a representative. We are retaining the requirement to identify the beneficiary's Medicare HICN when the beneficiary is the party appointing a representative.

Current § 405.910 also addresses defective appointments, and delegations and revocations of appointments. However, there has been confusion on the effects on the adjudication of an appeal when a defective appointment must be addressed, or when an adjudicator is not timely informed of a delegation or revocation of an appointment. To address the effect of a defective appointment on the adjudication of an appeal to which an adjudication time frame applies, we are proposing to add § 405.910(d)(3), which would extend an applicable adjudication time frame from the later of (1) the date that a defective appointment of representative was filed or (2) the date the current appeal request was filed by the prospective appointed representative, 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. We are proposing this revision because, in accordance with current § 405.910(d)(1) and (d)(2), a prospective appointed representative lacks the authority to act on behalf of a party and is not entitled to obtain or receive any information related to the appeal. Thus, contact with the party may be necessary to obtain missing information from the appointment, which may delay adjudicating the appeal until the appointment is cured or the party decides to proceed with the appeal without a representative. However, we are proposing that if the request was filed by a prospective appointed representative, the request would be considered filed for the purpose of determining timeliness of the request, even if the individual is not the appointed representative after the appointment is cured, or the party decides to proceed with the appeal without a representative.

We are also proposing at § 405.910(f)(1) to replace ''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.

Current § 405.910(i)(2) and (i)(3) provide that if an appeal involves an appointed representative, an ALJ sends notices of actions or appeal decisions, and requests for information or evidence regarding a claim that is appealed to the appointed representative. We are proposing to insert ''or attorney adjudicator'' after ''ALJ'' in § 405.910(i)(2) and (i)(3). This proposal would provide that attorney adjudicators (as proposed in section II.B above), like an ALJ under the current provisions, would send notices of actions or appeal decisions, and requests for information or evidence regarding a claim that is appealed to the appointed representative.

A representative and/or the represented party is responsible for keeping the adjudicator of a pending appeal current on the status of the representative. In practice, sometimes adjudicators are not informed of a delegation or revocation of an appointment of representative that has been filed for an appeal, which results in confusion and potentially duplicative or unnecessary proceedings. We are proposing to revise § 405.910(l)(2) (which, as described later, we are proposing to re-designate as (l)(1)(ii)) to add that a delegation 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. This proposed revision would emphasize the importance of keeping adjudicators current on the status of the representative and also state the effects of failing to do so. Proposed § 405.910(l)(2) also serves to assist adjudicators in sharing and disseminating confidential information only with appropriate individuals, and to provide adjudicators with appropriate contact information for scheduling purposes. To accommodate proposed paragraph (l)(2), current paragraph (l), except for the title of the paragraph, would be re-designated as paragraph (l)(1), and the current subparagraphs would also be re-designated accordingly. In addition, we are proposing to add a missing ''by'' in current paragraph (l)(1)(ii) (re-designated as (l)(1)(i)) of § 405.910 to indicate that a designee accepts to be obligated ''by'' and comply with the requirements of representation. We are also proposing to revise language in current paragraph (l)(2) (re-designated as (1)(l)(ii)) of § 405.910 to clarify that ''this signed statement'' refers to the ''written statement signed by the party,'' and the written statement signed by the party is not required when the appointed representative and designee are attorneys in the same law firm or organization and the notice of intent to delegate under paragraph (l)(1)(i) indicates that fact. To further emphasize the importance of keeping adjudicators current on the status of the representative and clarify the effects of failing to do so, we are also proposing

to add § 405.910(l)(3) and (m)(4) that a party's or representative's failure to notify the adjudicator that an appointment of representative has been delegated or revoked, respectively, is not good cause for missing a deadline or not appearing at a hearing.

We are not proposing any changes for part 423, subpart U because it does not have a corresponding provision for representative appointments.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Appointed representatives'' at the beginning of your comment.

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

Current § 405.926(l) provides that an ALJ's decision to reopen or not to reopen a decision is not an initial determination, and in accordance with the introductory language of § 405.926, is therefore not appealable under subpart I. In section III.A.2.l below, we are proposing to revise the reopening rules to provide that attorney adjudicators would have the authority to reopen their decisions to the same extent that ALJs may reopen their decisions under the current provisions. We are proposing to insert ''or attorney adjudicator's'' after ''ALJ's'' in § 405.926(l) to provide that the attorney adjudicator's decision to reopen a decision also is an action that is not an initial determination and therefore not an appealable action under subpart I.

Current § 405.926(m) provides that a determination that CMS or its contractors may participate in or act as parties in an ALJ hearing is not an initial determination, and in accordance with the introductory language of § 405.926, is therefore not appealable under subpart I. As explained in section III.A.3.f below, we are proposing to revise § 405.1010, which currently discusses when CMS or a contractor may participate in an ALJ hearing. As explained in the proposal to revise § 405.1010, 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. To align with our proposed revision to § 405.1010, we are proposing to revise § 405.926(m) to indicate that CMS or its contractors may participate in the full scope of the proceedings on a request for an ALJ hearing, including the hearing, by replacing ''participate in or act as parties in an ALJ hearing,'' with ''participate in the proceedings on a request for an ALJ hearing or act as parties in an ALJ hearing.''

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Actions that are not initial determinations'' at the beginning of your comment.

h. Notice of a Redetermination (§ 405.956)

Current § 405.956(b)(8) requires that the notice of a redetermination include a statement that evidence not submitted to the QIC is not considered at an ALJ hearing or further appeal, unless the appellant demonstrates good cause as to why that evidence was not provided previously. We are proposing to remove ''an ALJ hearing'' and add ''the OMHA level'' in its place so that the notice of a redetermination is clear that, absent good cause and subject to the exception in § 405.956(d) 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, as defined in Section II.B above.

We are inviting public comments on this proposal. If you choose to comment on the proposal in this section, please include the caption ''Notice of a redetermination'' at the beginning of your comment.

i. Time Frame 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)

As discussed in the 2005 Interim Final Rule (70 FR 11444 through 11445) and the 2009 Final Rule (74 FR 65311 through 65312), HHS adopted a policy of providing for one level of administrative review of a dismissal of a request for appeal. As a result, an adjudicator's decision or dismissal when reviewing a dismissal action issued at the previous level is binding and not subject to further review. The policy balances a party's need for review and the need for administrative finality. The policy is embodied in the rules relating to reviews of dismissals at the next adjudicative level in current §§ 405.972(e), 405.974(b)(3), 405.1004(c), 405.1102(c), 405.1108(b), and 405.1116.

At the QIC level of appeal, a review of a contractor redetermination and a review of a contractor's dismissal of a request for a redetermination are both characterized as a ''reconsideration.'' While the outcome of a QIC's reconsideration of a contractor dismissal is differentiated and further reviews are not permitted in accordance with current § 405.974(b)(3), an ambiguity exists with regard to the time frame for completing this type of reconsideration and escalation options when that time frame is not met. Current § 405.970 establishes the time frame for making a reconsideration without further qualification. However, section 1869(b)(1)(D)(i) of the Act establishes that a right to a reconsideration of an initial determination (which includes a redetermination under section 1869(a)(3)(D) of the Act) exists if a timely request for a reconsideration is filed within 180 days following receipt of a contractor's redetermination, which is discussed in current § 405.962. In contrast, current § 405.974(b)(1) requires that a request for a QIC reconsideration of a contractor's dismissal of a request for redetermination must be filed within 60 calendar days after receiving the contractor's notice of dismissal. Section 1869 of the Act does not address dismissals. Rather, section 1869(c)(3)(C)(i) and (c)(3)(C)(ii) of the Act only provide for a time frame to complete a reconsideration of an initial determination, and an option to escalate a case if that time frame is not met.

The effect of the ambiguity in current § 405.970 is the potential escalation of a request for a QIC reconsideration of a contractor's dismissal when the reconsideration is not completed within 60 calendar days of a timely filed request for a reconsideration of the dismissal, and a potential hearing being required in accordance with current § 405.1002(b). The potential effect of this ambiguity is contrary to the policy of limiting reviews of dismissals to the next adjudicative level of administrative appeal, as well as the statutory construct for providing ALJ hearings after QIC reconsiderations of redeterminations, or escalations of requests for reconsiderations following a redetermination. We also note that in the parallel context of an ALJ review of a QIC's dismissal of a request for reconsideration, current §§ 405.1002 and 405.1004 establish a clear distinction between a request for hearing following a QIC reconsideration and a request for a review of a QIC dismissal, and current §§ 405.1016 and 405.1104 address the adjudication time frames for ALJ decisions, and the option to escalate an appeal to the Council when a time frame is not met, only in the context of a request for hearing, in accordance with section 1869(d)(1) and (d)(3)(A) of the Act.

To address this unintended outcome of current § 405.970, we are proposing to amend the title of § 405.970 and

paragraphs (a), (b)(1), (b)(2), (b)(3), (c), (e)(1), and (e)(2)(i) to provide that the provisions would only apply 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. These proposed revisions would further our policy on reviews of dismissals and help appellants better understand what may be escalated to OMHA for an ALJ hearing. We are also proposing to replace ''the ALJ hearing office'' in current paragraph (e)(2)(ii) with ''OMHA'' because the QIC sends case files for escalated cases to a centralized location, not to individual field offices. We did not propose any parallel changes for part 423 because subpart U does not address IRE reconsiderations and subpart M does not have a provision with the same ambiguity.

To provide additional clarity to the procedures for reviews of dismissal actions we are also proposing to amend the text in §§ 405.972(b)(3), (e) and 405.974(b)(3), and the introductory text of § 405.974(b) to replace 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. We are also proposing to revise the section heading of § 405.972 to read ''Withdrawal or dismissal of a request for reconsideration or review of a contractor's dismissal of a request for redetermination'' and the section heading of § 405.974 to read, ''Reconsideration and review of a contractor's dismissal of a request for redetermination.'' These proposed revisions are consistent with the description of a reconsideration in section 1869(c)(3)(B)(i) of the Act and § 405.968(a). A QIC's review of a contractor dismissal action is limited to the appropriateness of the dismissal action and does not consist of a review of the initial determination and redetermination, which is the meaning attributed to a reconsideration. In reviewing a contractor dismissal action, the QIC either affirms or vacates the dismissal of the request for redetermination. If a dismissal action is vacated, the appeal is remanded back to the MAC to conduct a redetermination on the merits (§ 405.974).

Current § 405.972(e) provides that a QIC's dismissal of a request for reconsideration is binding unless it is modified or reversed by an ALJ under § 405.1004. As discussed in section II.B above, we are proposing that an attorney adjudicator may conduct a review of a QIC's dismissal of a request for reconsideration and in section III.A.3.c below, we are proposing to revise § 405.1004 to provide the effect of an attorney adjudicator's action taken in reviewing the QIC dismissal is equivalent to the effect of an ALJ's action taken in reviewing the QIC dismissal. To align with our proposed revision to § 405.1004, we are proposing to insert ''or attorney adjudicator'' after ''an ALJ'' in § 405.972(e) to indicate that a QIC's dismissal of a request for reconsideration is binding unless it is modified or reversed by an ALJ or attorney adjudicator under § 405.1004.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Time frame for making a reconsideration following a contractor redetermination, withdrawal or dismissal of a request for reconsideration, and reconsideration'' at the beginning of your comment.

j. Notice of Reconsideration (§ 405.976)

Section 1869(b)(3) of the Act states that a provider or supplier may not introduce evidence in any appeal that was not presented at the reconsideration conducted by a QIC unless there is good cause as to why the evidence was not provided prior to the issuance of the QIC's reconsideration. Under this authority, current § 405.976(b)(5)(ii) provides that a notice of reconsideration must include a summary of the rationale for the reconsideration that specifies that all evidence that is not submitted prior to the issuance of the reconsideration will not be considered at the ALJ level, or made part of the administrative record, unless the appellant demonstrates good cause as to why the evidence was not provided prior to the issuance of the QIC's reconsideration; however, it does not apply to a beneficiary unless the beneficiary is represented by a provider or supplier or to state Medicaid agencies. The statement that the evidence will not be made part of the administrative record is inconsistent with our practice of making a complete record of the administrative proceedings for further reviews, including documents submitted by parties that were not considered in making the decision. Current § 405.1028(c) states that if good cause does not exist, the ALJ must exclude the evidence from the proceedings and may not consider it in reaching a decision. However, it does not instruct the ALJ to remove the evidence from the administrative record, and to do so would preclude an effective review of the good cause determination. In addition, we noted in the 2005 Interim Final Rule (70 FR 11464) that under current § 405.1042(a)(2), excluded evidence is part of the record because it states that in the record, the ALJ must also discuss any evidence excluded under § 405.1028 and include a justification for excluding the evidence. To help ensure that the evidence is preserved in the administrative record, we are proposing to delete ''or made part of the administrative record'' from the paragraph in § 405.976(b)(5)(ii).

Current § 405.976(b)(7) 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. As further discussed in section III.A.3.d below, we are proposing revisions to § 405.976(b)(7) along with revisions to the methodology for calculating the amount in controversy required for an ALJ hearing under § 405.1006(d) to better align the amount in controversy with the actual amount in dispute. Please refer to section III.A.3.d for a discussion of these proposals.

We are not proposing any changes to part 423 because subpart U does not address IRE reconsiderations and subpart M does not contain similar provisions.

We are inviting public comments on this proposal. If you choose to comment on the proposal in this section, please include the caption ''Notice of reconsideration'' at the beginning of your comment.

k. Effect of a Reconsideration (§ 405.978)

Current § 405.978 discusses the effect of a QIC reconsideration, and states that a reconsideration is binding on all parties unless, among other things, an ALJ decision is issued in accordance to a request for an ALJ hearing made in accordance with § 405.1014. As discussed in section II.B above, we are proposing that an attorney adjudicator may issue a decision on a request for an ALJ hearing when a hearing is not conducted, and in section III.A.3.v below, we are proposing to revise § 405.1048 to provide the effect of an attorney adjudicator's decision is equivalent to the effect of an ALJ's decision. To align with our proposals to provide that an attorney adjudicator may issue a decision on a request for an ALJ hearing when a hearing is not conducted and the effect of that decision is equivalent to the effect of an ALJ's decision, we are proposing to insert ''or attorney adjudicator'' after the first use of ''ALJ'' in § 405.978(a) 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 to a request for an ALJ hearing made in accordance with § 405.1014.

We are inviting public comments on this proposal. If you choose to comment on the proposal in this section, please include the caption ''Effect of a reconsideration'' at the beginning of your comment.

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

Sections 405.980 and 423.1980 set forth the rules governing reopening and revision of initial determinations, redeterminations, reconsiderations, decisions, and reviews; §§ 405.982 and 423.1982 set forth the rules governing notice of a revised determination or decision; and §§ 405.984 and 423.1984 set forth the rules on the effect of a revised determination or decision. Pursuant to current §§ 405.1038 and 423.2038, an ALJ may issue a decision on a request for hearing without conducting a hearing in specified circumstances. As proposed in section II.B above, an attorney adjudicator also would 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.

We are proposing to insert ''or attorney adjudicator'' or ''attorney adjudicator's,'' after ''ALJ'' or ''ALJ's'' in §§ 405.980(a)(1)(iii), (a)(4), (a)(5), (d) introductory text, (d)(2), (e)(2); 405.982(a), (b); 405.984(d); 423.1980(a)(1)(iii), (a)(4), (d) introductory text, (d)(2), (e)(2); 423.1982(a), (a)(1), (a)(2), (b), (b)(1), and (b)(2); 423.1984(d); 423.1978(a); 423.1980(a)(2). These proposals would provide that decisions issued by attorney adjudicators, as proposed in section II.B above, may be reopened in the same manner as decisions issued by an ALJ (that is, when there is good cause in accordance with §§ 405.986 or 423.1986, or the decision was procured by fraud or similar fault), and with the same limitations, requirements, and effects as reopening an ALJ decision. We believe it is necessary for an attorney adjudicator or the Council to have the authority to reopen the attorney adjudicator's decision on the same bases as an ALJ or the Council may reopen the ALJ's decision under the current rules; to address instances in which there is good cause to reopen the attorney adjudicator's decision (in accordance with §§ 405.986 or 423.1986) or the attorney adjudicator's decision was procured by fraud or similar fault; and the action should be subject to the same limitations and requirements, and have the same effects as an ALJ's action under the provisions.

We are also proposing to replace ''hearing decision,'' ''hearing decisions,'' or ''hearings,'' with ''decision'' or ''decisions'' in the titles of current §§ 405.980 and 423.1980; §§ 405.980(a)(1)(iii), (d) introductory text, (d)(2), (e) introductory text, and (e)(2); 423.1980(a)(1)(iii), (d) introductory text, (d)(2), (e) introductory text, and (e)(2); to replace ''hearing'' with ''ALJ or attorney adjudicator decision'' in §§ 405.980(a)(1)(iv), (a)(4), (e)(2); 423.1980(a)(1)(iv), (a)(2), and (e)(2); and to replace ''ALJ hearing decisions'' and ''hearing decision,'' with ''ALJ or attorney adjudicator decisions'' and ''ALJ or attorney adjudicator decision'', respectively, in §§ 405.984(d) and 423.1984(d). These proposals would avoid any confusion that reopening under these provisions is limited to decisions for which an oral hearing was conducted, whether the decision is issued by an ALJ without conducting a hearing, as permitted under current rules or by an attorney adjudicator without conducting a hearing, as proposed in section II.B above.

In addition, we are proposing to add in §§ 405.980(a)(1)(iii), (d)(2), (e)(2), and 423.1980(a)(1)(iii), (d)(2), (e)(2) that an ALJ, or attorney adjudicator as proposed in section II.B above, revises ''his or her'' decision and may reopen ''his or her'' decision, which reflects our current policy that the deciding ALJ may reopen his or her decision, and avoids any potential confusion that an ALJ or attorney adjudicator may reopen the decision of another ALJ or attorney adjudicator. We are also proposing to insert ''its'' before ''review'' in §§ 405.980(a)(1)(iv) and 423.1980(a)(1)(iv) to indicate that the Council's review decision may only be reopened by the Council, to differentiate it from an ALJ or attorney adjudicator decision that the Council may also reopen. In addition, we are proposing to specify in §§ 405.980(d)(2) and (e)(2), and 423.1980(d)(2) and (e)(2) 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 the provisions from §§ 405.980(d)(3) and (e)(3), and 423.1980(d)(3) and (e)(3), which provide for the Council to reopen its review decision. We also propose in § 405.980(e)(3) to insert ''Council'' before ''review'' to clarify that a party to a Council review may request that the Council reopen its decision.

Finally, we are proposing at § 405.984(c) to replace ''in accordance with § 405.1000 through § 405.1064'' with ''in accordance with § 405.1000 through § 405.1063'' to account for the proposed removal of § 405.1064 discussed below.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Reopenings'' at the beginning of your comment.

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

Sections 405.990 and 423.1990 set forth the procedures governing expedited access to judicial review (EAJR). Current §§ 405.990(d) and 423.1990(d) allow a requesting party to file an EAJR request with an ALJ or the Council, which is then responsible for forwarding the request to the EAJR review entity within 5 calendar days of receipt. In accordance with current §§ 405.990(f) and 423.1990(e), a request for EAJR must be acted upon by the EAJR review entity within 60 calendar days after the date that the review entity receives a request and accompanying documents and materials. In practice, this process has resulted in confusion and delays for requesting parties when EAJR requests are sent directly to an ALJ or the Council. To simplify the process for requesting parties and to help ensure the timely processing of EAJR requests, we are proposing to revise §§ 405.990(d)(1) and 423.1990(d)(1) to direct EAJR requests to the DAB, which administers the EAJR process. Specifically, we are proposing at §§ 405.990(d)(1)(i) and (ii), and 423.1990(d)(1)(i) and (ii) that 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. We are also proposing to revise §§ 405.990(i)(1) and (2) and 423.1990(h)(1) and (2) so that the review entity would 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; this would also help ensure OMHA can process the request for an ALJ hearing as quickly as possible in the event an EAJR request is rejected.

Current §§ 405.990(i)(2) and 423.1990(h)(2) provide that a 90 calendar day time frame will apply to an appeal when a rejected EAJR request is received by the hearing office or the Council. Current § 405.990(b)(1)(ii) states that an EAJR request may be filed when a request for a QIC reconsideration has been escalated for an ALJ hearing, and in accordance with current § 405.1016(c), a 180 calendar day time frame will apply in that circumstance. In addition, current §§ 405.1036(d) and 423.2036(d) allow an appellant or enrollee to waive the adjudication period for an ALJ to issue a decision specified in §§ 405.1016 and 405.2016, respectively, at any time during the hearing process. To address the possibility that a time frame other than 90 calendar days applies to an appeal, or no adjudication time frame applies to an appeal, we are proposing to revise §§ 405.990(i)(2) and 423.1990(h)(2) to remove the reference to 90 calendar days and provide that 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.

In addition, proposed § 405.990(i)(1) would remove the redundant ''request'' after ''EAJR request'' in current paragraph (i)(1), which was a drafting error; and proposed § 423.1990(b)(1)(i) would remove ''final'' before referring to a decision, dismissal, or remand order of the ALJ or attorney adjudicator, as proposed in section II.B above, because as we explained in the 2009 Final Rule (74 FR 65307 through 65308), final decisions of the Secretary are those for which judicial review may be immediately sought under section 205(g) of the Act and the use of ''final'' in current § 423.1990(b)(1)(i) may cause confusion with such a final decision.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Expedited access to judicial review'' at the beginning of your comment.

3. ALJ Hearings

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

Current §§ 405.1000 and 423.2000 provide a general overview and rules for hearings before an ALJ and decisions on requests for hearings. We are proposing to revise §§ 405.1000(d), (e), (g); and 423.2000(d), (e), (g) to include decisions by attorney adjudicators, as proposed in section II.B above. We are also proposing to retitle the sections to reflect that the provisions of the section extend to decisions by both ALJ and attorney adjudicators. We are proposing to change the language in §§ 405.1000(a), (b), (c), and (d); and 423.2000(a) and (b) to state that a hearing may only be conducted by an ALJ. These proposals would provide readers with an accurate overview of how a request for an ALJ hearing would be adjudicated, including the potential that a decision could be issued without conducting a hearing by an ALJ or an attorney adjudicator as proposed in section II.B above, while informing readers that if a hearing is conducted, an ALJ will conduct the hearing.

Current § 405.1000(c) provides that CMS or a contractor may elect to participate in a hearing, and § 423.2000(c) provides that CMS, the IRE or Part D plan sponsor may request to participate in a hearing. As discussed in section III.A.3.f below, we are proposing to revise §§ 405.1010 and 423.2010 so 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. We are proposing to revise §§ 405.1000(c) and 423.2000(c) so that the sections would reference §§ 405.1010 and 423.2010, respectively, with regard to participating in the proceedings. By referencing §§ 405.1010 and 423.2010, the proposed revisions would direct readers to those sections addressing the full scope of potential participation by CMS or its contractors, or a Part D plan sponsor, on a request for an ALJ hearing, including participating in the proceedings on a request for an ALJ hearing, which as discussed in proposed §§ 405.1010 and 423.2010, may include any proceedings before an oral hearing is scheduled. We are also proposing in § 405.1000(c) to state that CMS or its contractor may join the hearing before an ALJ as a party under § 405.1012, which would direct readers to the appropriate section addressing the full scope of CMS or its contractor acting as a party. (Because CMS, the IRE, and the Part D plan sponsor may not be a party to a hearing under part 423, subpart U, there is no corollary to § 405.1012 in that subpart and therefore a similar revision is not proposed for § 423.2000(c).)

Current §§ 405.1000(d) and 423.2000(d) provide that a decision is based on the hearing record, and current §§ 405.1000(g) and 423.2000(g) reference a hearing record in describing when a decision can be issued based on the record, without a hearing. However, current §§ 405.1042 and 423.2042 identify the record as the administrative record. The references to a hearing record in current paragraphs (d) and (g) may cause confusion when no hearing is conducted. To make the terminology consistent throughout the rules, account for decisions that are issued without a hearing being conducted, and minimize confusion, we are proposing to revise §§ 405.1000(d) and 423.2000(d) so that a decision is based on the administrative record, including, for an ALJ, any hearing record, and §§ 405.1000(g) and 423.2000(g) to provide that a decision is based on the administrative record.

Current § 405.1000(e) and (g) 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. Related to current § 405.1000(e), current § 405.1000(f) discusses the ALJ's authority to conduct a hearing even if the parties waive the hearing. As discussed in section III.A.3.r below, we are proposing to revise § 405.1038 to modify the circumstances in which a decision on a request for hearing can be issued without conducting a hearing. As discussed in the proposed revisions to § 405.1038, we would require that waivers be obtained by the parties entitled to a notice of hearing in accordance with § 405.1020(c), or to require that 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 in accordance with § 405.1020(c). Proposed § 405.1000(e), (f), and (g) would be revised for consistency with the § 405.1038 proposals and to accurately summarize when a decision on a request for hearing can be issued without conducting a hearing in accordance with proposed § 405.1038. We are not proposing similar changes in § 423.2000(e), (f), and (g) because we are not proposing changes to when a decision on a request for hearing can be issued without conducting a hearing in § 423.2038.

Current § 405.964(c) requires a QIC 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. While current § 405.1044 permits an ALJ to consolidate requests for hearing if one or more of the issues to be considered at the hearing are the same issues that are involved in another request for hearing pending before the same ALJ, the provision is discretionary and dependent on the requests being

assigned to the same ALJ. To mitigate the potential of requests for hearing on the same claim filed by different parties being separately adjudicated, we are proposing to add § 405.1000(h) to 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. We note that if a decision was issued on the first timely request before an additional request is timely filed or good cause is found to extend the period to file the additional request for hearing, a reopening of the decision may be considered by the deciding adjudicator in accordance with § 405.980. For example, if a request is submitted with new and material evidence that was not available at the time of the decision and may result in a different conclusion, the reopening provisions at § 405.980 would apply. Because only the enrollee is a party in a part 423, subpart U proceeding on a request for an ALJ hearing, no corresponding changes are proposed for § 423.2000.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Hearing before an ALJ and decision by an ALJ or attorney adjudicator general rule'' at the beginning of your comment.

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

Current §§ 405.1002 and 423.2002 discuss a right to an ALJ hearing. Current §§ 405.1002(a) and 423.2002(a) provide that a party to a QIC reconsideration or the enrollee who receives an IRE reconsideration, respectively, may ''request'' a hearing before an ALJ if the party or enrollee files a timely request and meets the amount in controversy requirement. However, a party or enrollee is entitled to a hearing only when those requirements are met. See sections 1860D–4(h) and 1869(b)(1)(A) of the Act. Therefore, we are proposing to revise §§ 405.1002(a) and 423.2002(a) introductory text to state that the party to a QIC reconsideration or the enrollee who receives an IRE reconsideration has a right to a hearing rather than may request a hearing. These proposed changes would align the provisions with the statute and clarify that the party or enrollee has a right to a hearing before an ALJ when the criteria are met.

Current §§ 405.1002(a)(4) and 423.2002(e) provide that the request is considered filed on the date it is received by the entity specified in the QIC's or IRE's reconsideration. There has been confusion when a request is sent to an OMHA office that is not specified in the reconsideration, and this error causes delays in processing the request. We are proposing to revise §§ 405.1002(a)(4) and 423.2002(e) 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. This would help ensure appellants are aware that a request for hearing must be filed with the office indicated in the notice of reconsideration to avoid delays. For example, when the notice of reconsideration indicates that a request for hearing must be filed with the OMHA central docketing office, an appellant will cause a delay if the request is sent to the QIC or IRE, or an OMHA field office. We also note that as explained in the 2009 Final Rule (74 FR 65319 through 65320), pursuant to current § 405.1014(b)(2), if a request for hearing is timely filed with an entity other than the entity specified in the notice of reconsideration, the request is not treated as untimely or otherwise rejected. This would remain true for requests that are timely filed with an office other than the office specified in the notice of reconsideration, pursuant to proposed § 405.1014(c)(2), which incorporates the requirement from current § 405.1014(b)(2). This would also apply in part 423, subpart U adjudications because the same language appears in current § 423.2014(c)(2) and is incorporated in proposed § 423.2014(d)(2).

Current § 405.1002(b)(1) provides that when a party files a request with the QIC to escalate the appeal, it is escalated to ''the ALJ level.'' We are proposing to revise § 405.1002(b)(1) to replace ''to the ALJ level'' with ''for a hearing before an ALJ'' so that when a request for a QIC reconsideration is escalated, it is escalated ''for a hearing before an ALJ.'' This would help ensure that the right to a hearing is clear when an appeal is escalated from the QIC. There is no corresponding provision in part 423, subpart U.

Current § 423.2002(c) provides that the ALJ must document all oral requests for expedited hearings. However, an ALJ is not assigned to an appeal until after the request for hearing is received and processed. Thus, we are proposing to revise § 423.2002(c) to state that ''OMHA'' must document all oral requests for expedited hearings. There is no corresponding provision in part 405, subpart I.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Right to an ALJ hearing'' at the beginning of your comment.

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

Current §§ 405.1004 and 423.2004 discuss the right to an ALJ review of a QIC notice of dismissal or IRE notice of dismissal, respectively. As proposed in section II.B above, attorney adjudicators or ALJs would conduct reviews of QIC or IRE dismissals. Accordingly, we are proposing to remove references to an ALJ in the titles of proposed §§ 405.1004 and 423.2004, though ALJs would continue to have the authority to conduct reviews of QIC or IRE dismissals if a request for a review of a QIC or IRE dismissal is assigned to an ALJ. We also propose to insert ''or attorney adjudicator'' after ALJ in §§ 405.1004(a) introductory language, (b), (c); and 423.2004(a) introductory language, (b), and (c), to provide that an attorney adjudicator could review a QIC or IRE dismissal, as proposed in section II.B above. We also are proposing to replace the reference to ''entity'' in current §§ 405.1004(a)(4) and 423.2004(a)(4), with ''office,'' for the same reasons discussed above in III.A.3.b, for amending parallel language in §§ 405.1002 and 423.2002.

Current §§ 405.1004(b) and 423.2004(b) provide that 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. As discussed in III.A.3.p below, we are proposing to revise the remand provisions and add new §§ 405.1056 and 405.1058, 423.2056, and 423.2058 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. We are also proposing to revise §§ 405.1004(b) and 423.2004(b) to add references to proposed §§ 405.1056 and 423.2056, respectively, to explain that the remand would be in accordance with proposed §§ 405.1056 and 423.2056, which as discussed in section III.A.3.p below, would address issuing remands and notices thereof, including for remands of QIC or IRE dismissals.

Current §§ 405.1004(c) and 423.2004(c) state that 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 that 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 under § 405.1108(h) or § 423.2108(b), respectively. In our experience, these sections as currently drafted have been a source of confusion for adjudicators and appellants. The two sentences convey different actions that can result from a request for review of a QIC or IRE dismissal—a decision regarding whether the QIC's or IRE's dismissal was correct, or a dismissal of the appellant's request for an ALJ review of the QIC's or IRE's dismissal. We are proposing to separate and further distinguish the two situations to avoid the current confusion that results from two of the three possible outcomes that may result from a request to review a QIC or IRE dismissal (the third being a remand of the dismissal, addressed in paragraph (b) in the respective sections) being in the same paragraph by proposing a separate paragraph for each outcome currently addressed in paragraph (c).

We are proposing to revise §§ 405.1004(c) and 423.2004(c) to include the possible outcome in the first sentence of current §§ 405.1004(c) and 423.2004(c) of a decision affirming the QIC's or IRE's dismissal. We also are proposing to move language in current §§ 405.1004(c) and 423.2004(c) stating that the decision of an ALJ on a request for review of a QIC dismissal is binding and not subject to further review, to proposed §§ 405.1048(b) and 423.2048(b), which as discussed in section III.A.3.v below, would address the effects of decisions on requests to review a QIC or IRE dismissal. In addition, we are proposing in §§ 405.1004(c) and 423.2004(c), respectively, to state that a decision affirming a QIC or IRE dismissal would be issued in accordance with proposed §§ 405.1046(b) and 423.2046(b), which as discussed in section III.A.3.v below, would address issuing decisions on requests for review of a QIC or IRE dismissal and notices thereof.

The 2009 Final Rule (74 FR 65311 through 65312) also explained that if a request for ALJ review of a QIC dismissal was invalid and thus subject to dismissal, the dismissal of the request to review a QIC dismissal was binding and not subject to further review (however, a party could request that the dismissal be vacated by the Council pursuant to § 405.1108(b)). We are proposing to add §§ 405.1004(d) and 423.2004(d) to state that the ALJ or attorney adjudicator may dismiss a request for review of a QIC's or an IRE's dismissal in accordance with proposed §§ 405.1052(b) or 423.2052(b), respectively, which as discussed in section III.A.3.x below, would address dismissals of requests for review of a QIC or IRE dismissal and notices thereof. We also are proposing to move language in current §§ 405.1004(c) and 423.2004(c) stating that the dismissal is binding and not subject to further review unless the dismissal is vacated, to proposed §§ 405.1054(b) and 423.2054(b), which would address the effects of a dismissal of a request for review of a QIC's or an IRE's dismissal and as discussed in section III.A.3.x below, would provide authority for an ALJ or attorney adjudicator to vacate a dismissal and therefore replace the current reference to the Council.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Right to a review of QIC or IRE notice of dismissal'' at the beginning of your comment.

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

Current § 405.1006 sets forth the requirements for meeting the amount in controversy for an ALJ hearing. The title of current § 405.1006 states that the amount in controversy is required to ''request'' an ALJ hearing and judicial review. However, as discussed in III.A.3.b above, section 1869(b)(1)(A) of the 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 statutory provision, we are proposing that the amount in controversy is required ''for'' an ALJ hearing and judicial review rather than ''to request'' an ALJ hearing and judicial review. Put another way, a party may request an ALJ hearing or judicial review, albeit unsuccessfully, without satisfying the amount in controversy requirement.

Section 1869(b)(1)(E) of the Act establishes the minimum amounts in controversy for a hearing by the Secretary and for judicial review, but does not establish how to calculate the amounts in controversy. Current § 405.1006(d) states that the amount remaining in controversy is calculated based on the actual amount charged to the individual (a beneficiary) for the items or services in question (commonly referred to as billed charges), reduced by any Medicare payments already made or awarded for the items or services, and any deductible and coinsurance amounts applicable to the particular case. In an effort to align the amount in controversy with a better approximation of the amount at issue in an appeal, we are proposing to revise the basis (that is, the starting point before any deductions for any payments already made by Medicare or any coinsurance or deductible that may be collected) used to calculate the amount in controversy. For appeals of claims submitted by providers of services, physicians, and other suppliers that are priced based on a published Medicare fee schedule or published contractor priced amount (as discussed below), rather than using the actual amount charged to the individual as the basis for the amount in controversy, we are proposing to use the Medicare allowable amount for the items and/or services being appealed, subject to the exceptions discussed below. An allowable amount is the maximum amount of the billed charge deemed payable for the item or service. For the purposes of the amount in controversy under § 405.1006, we are proposing at § 405.1006(d)(2)(i)(A) that for items and services with a published Medicare fee schedule or published contractor-priced amount, the basis for the amount in controversy is 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.

For a vast majority of items and services furnished and billed by physicians and other suppliers, allowable amounts are determined based on Medicare fee schedules. Fee schedules are updated and published on an annual basis by CMS through rulemaking, and CMS and its contractors have tools and resources available to inform physicians and other suppliers of allowable amounts based on these fee schedules, including the Physician Fee Schedule Look-up Tool available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PFSlookup/* and spreadsheets for other fee schedules that can be accessed on the CMS Web site through the fee schedule main page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/FeeScheduleGenInfo/index.html.* Allowable amounts for many contractor priced items and services are also included in these tools and resources. Allowable amounts are included on the Medicare remittance advice for paid items and services, but not for items and services that are denied. However, where the allowable amount for an item or service is determined based on a published fee schedule or contractor priced amount, we anticipate that appellants, other than beneficiaries who

are not represented by a provider, supplier, or Medicaid State agency, would be able to use the existing CMS and contractor tools and resources to determine allowable amounts for denied services when filing a request for hearing, and those amounts could be verified by OMHA in determining whether the claims included in the request meet the amount in controversy requirement. As discussed below, where the appellant is a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, CMS would require the QIC to specify in the notice of reconsideration, for partially or fully unfavorable reconsideration decisions, whether the amount remaining in controversy is estimated to meet or not meet the amount required for an ALJ hearing under proposed § 405.1006(d).

Due to the pricing methodology for many items and services furnished by providers of services, such as hospitals, hospices, home health agencies, and skilled nursing facilities, at the present time an allowable amount is not easily discerned or verified with existing CMS and contractor pricing tools (for example, there is no pricing tool available for hospital outpatient services paid under the outpatient prospective payment system (OPPS)) for pre-payment claim denials (where items or services on the claim are denied, in full or in part, before claim payment has been made). Similarly, items and services furnished by providers or suppliers that are always non-covered, as well as unlisted procedures, may not have published allowable amounts based on a fee schedule or a published contractor-priced amount. Therefore, we are proposing at § 405.1006(d)(2)(i)(B) to continue using the provider's or supplier's billed charges as the basis for calculating the amount in controversy for appeals of claims that are not priced according to a CMS-published fee schedule and do not have a published contractor-priced amount (except as discussed below). We note that the method for calculating the amount in controversy in this scenario would be the same as under current § 405.1006(d), and we believe that all appellants have access to this information through claims billing histories, remittance advices, or the column titled ''Amount Provider [or Supplier] Charged'' on the Medicare Summary Notice. However, we are soliciting comment on whether existing tools and resources are available that would enable providers, suppliers, and Medicaid State agencies to submit an allowable amount in their request for hearing (as proposed in Section III.A.3.g.i below) for items and services not subject to published fee schedules or published contractor priced amounts, and whether those amounts could also be verified by OMHA. We are also soliciting comment on how such tools and resources could be used in appeals filed by beneficiaries.

Current § 405.1006(d)(1) introductory text uses ''the actual amount charged the individual for the items and services in question'' as the basis (starting point) for calculating the amount in controversy, before any reductions described in paragraphs (d)(1)(i) and (ii) (for any Medicare payments already made or awarded and any deductible and coinsurance applicable in the particular case) occur. For the reasons discussed above, we are proposing to revise paragraph (d)(1) introductory text to state that in situations other than those described in § 405.1006(d)(3) through (7) (discussed below), the amount in controversy is computed as ''the basis for the amount in controversy for the items and services in the disputed claim as defined in paragraph (d)(2)'', less applicable reductions described in paragraphs (d)(1)(i) and (ii), and are proposing to revise paragraph (d)(2) to specify the amount that would be used as the basis for the amount in controversy on a situational basis. We are also proposing at § 405.1006(d)(3) through (7) five exceptions to the general calculation methodology specified in proposed paragraphs (d)(1) and (2).

There has also been confusion in calculating the amount in controversy when an appealed reconsideration involves multiple claims. Section 1869 of the Act and part 405, subpart I provide for an appeals process in which each claim decision is appealed and separately adjudicated. However, in some instances, claims are considered together based on an appellant's request. To address confusion with calculating the amount in controversy when reconsiderations involve multiple claims and to help ensure § 405.1006 clearly conveys that the amount in controversy requirement must be met for each appealed claim unless the claim can be aggregated as discussed below, proposed § 405.1006(d)(1) would clarify that the amount in controversy is based on the items or services in the disputed ''claim.''

We are proposing to maintain the current reduction to the calculation of the amount in controversy in § 405.1006(d)(1)(i), which states that the basis for the amount in controversy is reduced by any Medicare payments already made or awarded for the items or services. In addition, current § 405.1006(d)(1)(ii) provides that the basis for the amount in controversy is further reduced by ''[a]ny deductible and coinsurance amounts applicable in the particular case.'' We are proposing to revise § 405.1006(d)(1)(ii) to read, ''Any deductible and/or coinsurance amounts that may be collected for the items or services.'' We believe revising this provision is appropriate to better align the amount at issue in the appeal and the amount in controversy so that in situations where a provider or supplier is prohibited from collecting applicable coinsurance and/or deductible, or must refund any such amounts already collected, the basis for the amount in controversy is not reduced by that amount (for example, if a provider or supplier is held liable for denied services under the limitation on liability provision in section 1879 of the Act, any amounts collected for the denied service, including coinsurance and/or deductible must be refunded).

As discussed above, we are proposing at § 405.1006(d)(2)(i) that, for situations other than those described in § 405.1006(d)(2)(ii) and (iii), the basis for calculating the amount in controversy under § 405.1006(d)(1) would be the Medicare allowable amount, which is 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 if there is a published Medicare fee schedule or published contractor-priced amount for the items or services in the disputed claim; or if there is no published Medicare fee schedule or contractor-priced amount for the items or services in the disputed claim, the basis for the amount in controversy would be the provider or supplier's billed charges submitted on the claim for the items and services. We believe providers, suppliers, and Medicaid State agencies would be able to utilize existing CMS and CMS contractor tools and resources to determine the allowable amount for items and services with published fee schedule or published contractor-priced amounts, and for items or services without a published fee schedule or published contractor priced amount, the calculation methodology for the amount in controversy would be the same as the calculation methodology specified in current § 405.1006(d). However, there may be instances where a beneficiary would appeal a claim for items and services for which the allowable amount would be the basis for the amount in controversy under proposed § 405.1006(d)(2)(i)(A) (for example, a claim for items or services with a published fee schedule or published

contractor-priced amount that does not involve an overpayment and for which the beneficiary has not been determined to be financially responsible). We believe most beneficiaries are not familiar with published fee schedule or contractor-priced amounts and may be unable to determine the amount in controversy in these circumstances with the resources currently available to them. However, as discussed below, we are proposing at § 405.976(b)(7) that the QIC include in the notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration is partially or fully unfavorable to the appellant. For appeals filed by beneficiaries, often the amount at issue is aligned not with the Medicare allowable amount, but rather with the billed charges of the provider or supplier. For example, where a beneficiary is held financially responsible for a denied claim under the limitation on liability provisions in section 1879 of the Act because he or she received an Advance Beneficiary Notice of Noncoverage (ABN), the beneficiary is responsible for the billed charges on the claim. Or, for a claim not submitted on an assignment-related basis that is denied, the beneficiary may be responsible for the billed charges, or the billed charges subject to the limiting charge in section 1848(g) of the Act. Medicare notifies the beneficiary of the amount he or she may be billed for denied services on the Medicare Summary Notice in a column titled, ''Maximum You May Be Billed.'' For appeals filed by a provider, supplier, or Medicaid State agency for denied items or services for which the beneficiary was determined to be financially responsible, we believe providers, suppliers, and Medicaid State agencies would have sufficient access to the provider or supplier's billing information and Medicare claims processing data to determine the amount charged to the beneficiary. Accordingly, we are proposing at § 405.1006(d)(2)(ii) that for any items or services for which a beneficiary has been determined to be financially responsible, the basis for the amount in controversy is the actual amount charged to the beneficiary (or the maximum amount the beneficiary may be charged if no bill has been received) for the items or services in the disputed claim. As discussed above, this amount would be set forth on the Medicare Summary Notice in the column titled ''Maximum You May Be Billed.''

We are also proposing at § 405.1006(d)(2)(iii) that if a beneficiary received or may be entitled to a refund of the amount the beneficiary previously paid to the provider or supplier for the items or services in the disputed claim under applicable statutory or regulatory authorities, the basis for the amount in controversy would be the actual amount originally charged to the beneficiary for the items or services in the disputed claim, as we believe that the amount originally charged to the beneficiary is more reflective of the actual amount at issue for the beneficiary and for the provider or supplier in this situation. We believe appellants would have access to and would use the same information for determining the basis for the amount in controversy under paragraph § 405.1006(d)(2)(iii) as they would under § 405.1006(d)(2)(ii).

As discussed above, we are proposing at § 405.1006(d)(3) through (7) five exceptions to the general methodology used to calculate the amount in controversy specified in § 405.1006(d)(1). Current § 405.1006(d)(2) provides that, notwithstanding current § 405.1006(d)(1), when payment is made for items or services under section 1879 of the Act or § 411.400, or the liability of the beneficiary for those services is limited under § 411.402, the amount in controversy is computed as the amount that the beneficiary would have been charged for the items or services in question if those expenses were not paid under § 411.400 or if that liability was not limited under § 411.402, reduced by any deductible and coinsurance amounts applicable in the particular case. We are proposing to re-designate current § 405.1006(d)(2) as § 405.1006(d)(3) and to revise the paragraph to state that when payment is made for items or services under section 1879 of the Act or § 411.400, or the liability of the beneficiary for those services is limited under § 411.402, the amount in controversy would be calculated in accordance with § 405.1006(d)(1) and (2)(i), except there is no deduction under paragraph (d)(1)(i) for expenses that are paid under § 411.400 or as a result of liability that is limited under § 411.402. For example, when a claim for items or service is denied under section 1862(a)(1)(A) of the Act because the items or services were not reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member, Medicare payment may nonetheless be made under the limitation on liability provisions of § 1879 of the Act if neither the provider/supplier nor the beneficiary knew, or could reasonably have been expected to know, that payment would not be made. In instances such as these, we are proposing that the amount in controversy would be calculated as if the items or services in the disputed claim were denied and no payment had been made under section 1879 of the Act. We believe this exception is appropriate because appellants may still wish to appeal findings of non-coverage related to items and services for which liability of the party was limited or payment was made under section 1879 of the Act or § 411.400 or for which the beneficiary was indemnified under § 411.402, but if these payments or indemnifications were deducted from the basis for the amount in controversy, the amount in controversy could be zero. As this exception relates only to whether deductions are made under § 405.1006(d)(1)(i) for any Medicare payments already made or awarded for the items or service, and the amount in controversy would otherwise be calculated in accordance with proposed § 405.1006(d)(1) and (d)(2)(i), we believe appellants would have access to and would use the same information for determining the amount in controversy under § 405.1006(d)(3) as they would under § 405.1006(d)(1) and (d)(2)(i).

Current § 405.1006 does not address calculating the amount in controversy for matters involving a provider or supplier termination of a Medicare-covered item or service when the beneficiary did not elect to continue receiving the item or service (for example, § 405.1206(g)(2) provides that if a beneficiary is dissatisfied with a QIO's determination on his or her discharge and is no longer an inpatient in a hospital, the determination is subject to the general claims appeal process). In this circumstance, items and services have not been furnished, and therefore, a claim has not been submitted. Yet the beneficiary may elect not to continue receiving items or services while appealing the provider or supplier termination due to potential financial responsibility for the items or services. While an amount in controversy cannot be assessed for a period of time during which no items or services were furnished, a beneficiary may assert a continuing need for the items or services based on his or her condition at the time an appeal is heard. To address this circumstance, we are proposing new § 405.1006(d)(4), which would provide that when a matter involves a provider or supplier

termination of Medicare-covered items or services and the beneficiary did not elect to continue receiving the items or services that are disputed by a beneficiary, the amount in controversy is calculated as discussed above regarding proposed (d)(1) and (d)(2)(ii) (which addresses situations where the beneficiary is determined to be financially responsible), except that the basis for the amount in controversy and any deductible and coinsurance that may be collected for the items or services are calculated using the amount the beneficiary would have been charged if the beneficiary had received the items or services that the beneficiary asserts should be covered by Medicare based on the beneficiary's current condition at the time an appeal is heard, and Medicare payment was not made. This proposal would allow the beneficiary to pursue coverage for an item or service and potentially meet the amount in controversy requirement in instances in which he or she would not otherwise be able to pursue a hearing before an ALJ because no items or services have been rendered and therefore no amount in controversy exists because there is no disputed claim. In these instances, the beneficiary has been notified of a preliminary decision by a provider or supplier that Medicare will not cover continued provision of the items or services in dispute. Therefore, we believe using the amount the beneficiary would be charged if the beneficiary elected to continue receiving the items or services that the beneficiary asserts should be covered and if Medicare payment were not made for these items or services (in other words, the amount the beneficiary would be charged if the beneficiary were financially responsible for these items or services) is most reflective of the actual amount in dispute. Most beneficiary appeals of provider or supplier terminations of Medicare-covered items or services involve the termination of Part A services and, therefore, we expect it would be rare that the amount in controversy would be less than that required for an ALJ hearing. However, we expect that beneficiaries wishing to determine if the amount in controversy required for an ALJ hearing was met could obtain from the provider or supplier the amount the beneficiary would be charged if the beneficiary elected to continue receiving the items or services and Medicare payment were not made. In addition, as discussed below, we are proposing at § 405.976(b)(7) that the QIC would include in its notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

We considered using Medicare payable amounts for denied items and services as the basis for the amount in controversy calculation specified in proposed § 405.1006(d)(1), as that would be a more precise estimate of the amount at issue in the appeal than either the Medicare allowable amount or the billed charges. Payable amounts would take into account payment rules related to the items and services furnished that may increase or decrease allowable amounts (for example, multiple surgery reductions, incentive payments, and competitive bidding payments). However, CMS systems do not currently calculate payable amounts for denied services, and undertaking major system changes would delay implementation and has been determined not to be cost effective. While payable amounts may be a better representation of the amount at issue in the appeal, we believe the Medicare allowable amount and the other amount in controversy calculations provided in proposed § 405.1006(d) are appropriate and reliable estimates that align well with the amount at issue for claims for which a payable amount has not been calculated.

However, for post-payment denials, or overpayments, a payable amount has been determined and would be the most reliable indicator of the amount actually at issue in the appeal. Therefore, we are proposing new § 405.1006(d)(5) to state that, notwithstanding the calculation methodology in proposed paragraphs (d)(1) and (2), when a claim appeal involves an overpayment determination, the amount in controversy would be the amount of the overpayment specified in the demand letter. In a post-payment denial, the amount of the overpayment identified in the demand letter is readily available to appellants, and is the most accurate reflection of the amount actually at issue in the appeal. In addition, current § 405.1006 does not address appeals that involve an estimated overpayment amount determined through the use of sampling and extrapolation. In this circumstance, the claims sampled to determine the estimated overpayment may not individually meet the amount in controversy requirement, but the estimated overpayment determined through the use of extrapolation may meet the amount in controversy requirement. To address this circumstance, we are also proposing in new § 405.1006(d)(5) that 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. This proposal would provide appellants the opportunity to appeal claims that may not individually meet the amount in controversy requirement if such claims were part of the sample used in making an overpayment determination that does meet the amount in controversy requirement. Because the overpayment determination reflects the amount for which the appellant is financially responsible, we believe it would be appropriate to allow appellants to appeal individual claims in the sample that was used to determine the overpayment. Whether an appeal involves an individual overpayment or an estimated overpayment determined through the use of sampling and extrapolation, we believe appellants against whom an overpayment was assessed would need only to consult the demand letter they received in order to determine the amount in controversy. However, we expect there may be circumstances where a beneficiary wishes to appeal an overpayment that was assessed against a provider or supplier, and in these situations the beneficiary may not have a copy of the demand letter that was received by the provider or supplier. For this reason, and as discussed below, we are proposing at § 405.976(b)(7) that the QIC would include in its notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable. We are also proposing new § 405.1006(d)(6), which would provide that when a beneficiary files an appeal challenging only the computation of a coinsurance amount, or the amount of a remaining deductible applicable to the items or services in the disputed claim, the amount in controversy is the difference between the amount of the coinsurance or remaining deductible, as determined by the contractor, and the amount of the coinsurance or remaining deductible the beneficiary believes is correct. We believe this provision is appropriate in these instances because,

without this provision, the amount in controversy determined under the general calculation methodology in § 405.1006(d)(1) would be zero for a paid claim. In addition, we believe that the calculation proposed at § 405.1006(d)(6) would appropriately reflect the amount at issue for the beneficiary in these appeals where the computation of a coinsurance amount, or the amount of a remaining applicable deductible is challenged. We believe beneficiaries would have access to the coinsurance and/or deductible amounts determined by the contractor for the paid claim on the beneficiary's Medicare Summary Notice, in the column titled ''Maximum You May Be Billed,'' and would need only to subtract the amount of coinsurance and/or deductible the beneficiary believes he or she should have been charged in order to arrive at the amount in controversy. We expect it would be extremely rare for a non-beneficiary appellant to file an appeal challenging the computation of a coinsurance amount or the amount of a remaining deductible.

In addition, we are proposing new § 405.1006(d)(7), which would provide that for appeals of claims where the allowable amount has been paid in full and the appellant is challenging only the validity of the allowable amount, as reflected in the published Medicare fee schedule or in the published contractor priced amount applicable to the items or services in the disputed claim, the amount in controversy is the difference between the amount the appellant argues should have been the allowable amount for the items or services in the disputed claim in the applicable jurisdiction and place of service, and the published allowable amount for the items or services. We believe this provision is appropriate in these instances because, without this provision, the amount in controversy determined under the general calculation methodology in § 405.1006(d)(1) would be zero for such paid claims. In addition, we believe that the calculation proposed at § 405.1006(d)(7) would appropriately reflect the amount at issue for the appellant in these appeals. We believe that, generally, these types of appeals are filed by providers and suppliers who are already familiar with the allowable amount for the items or services in the disputed claim based on information obtained from published fee schedules or contractor-priced amounts. Further, we believe that a fee schedule or contractor price challenge filed by a beneficiary on a paid claim would be a very rare occurrence. However, as discussed below, in the event a beneficiary would want to file such an appeal, the beneficiary could obtain an estimate of the amount in controversy from the QIC reconsideration. As discussed further below, we are proposing at § 405.976(b)(7) that the QIC would include in its notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

In the event that a reconsideration, or a redetermination if the appeal was escalated from the QIC without a reconsideration, involves multiple claims and some or all do not meet the amount in controversy requirement, section 1869 of the Act states that, in determining the amount in controversy, the Secretary, under regulations, shall allow two or more appeals to be aggregated if the appeals involve the delivery of similar or related services to the same individual by one or more providers or suppliers, or common issues of law and fact arising from services furnished to two or more individuals by one or more providers or suppliers. Under this authority, § 405.1006(e) provides for aggregating claims to meet the amount in controversy requirement.

The title of current § 405.1006(e)(1) for aggregating claims when appealing a QIC reconsideration is phrased differently than the corresponding title for aggregating claims when escalating a request for a QIC reconsideration in current § 405.1006(e)(2), which may cause confusion. We are proposing to revise the title to § 405.1006(e)(1) to ''Aggregating claims in appeals of QIC reconsiderations for an ALJ hearing'' so it clearly applies to aggregating claims in appeals of QIC reconsiderations, and is parallel to the phrasing used in the title of § 405.1006(e)(2). The proposed titles of § 405.1006(e)(1) and (e)(2), and proposed § 405.1006(e)(2)(ii) would also replace ''to the ALJ level'' with ''for an ALJ hearing'' to again highlight that the appeal of a QIC reconsideration or escalation of a request for a QIC reconsideration is for an ALJ hearing.

Current § 405.1006(e)(1)(ii) provides that to aggregate claims, the request for ALJ hearing must list all of the claims to be aggregated. This has caused confusion because some appellants read current § 405.1006(e)(1)(ii) as allowing appeals of new claims to be aggregated with claims in previously filed appeals, provided the new request for hearing lists the claims involved in the previously filed appeals. However, current § 405.1006(e)(2)(i), which applies to aggregating claims that are escalated from the QIC for a hearing before an ALJ, requires that the claims were pending before the QIC in conjunction with the same request for reconsideration. We note that in the context of a request for hearing, aggregating new claims with claims from previously filed requests could delay the adjudication of the requests and is inconsistent with the current rule for aggregating claims that are escalated from the QIC. To address these issues and bring consistency to the aggregation provisions, we are proposing to revise § 405.1006(e)(1)(ii) to require the appellant(s) to request aggregation of the claims in the same request for ALJ hearing or in multiple requests for an ALJ hearing filed with the same request for aggregation. This would allow an individual or multiple appellants to file either one request for an ALJ hearing for multiple claims to be aggregated, or multiple requests for an ALJ hearing for the appealed claims when requesting aggregation, while requiring them to be filed together with the associated request for aggregation. We are also proposing in § 405.1006(e)(1)(iii) and (e)(2)(iii) that an ALJ or attorney adjudicator may determine that the claims that a single appellant seeks to aggregate involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate involve common issues of law and fact, but only an ALJ may determine the claims that a single appellant seeks to aggregate do not involve the delivery of similar or related services, or the claims that multiple appellants seek to aggregate do not involve common issues of law and fact. We are proposing this because an attorney adjudicator adjudicating requests for an ALJ hearing when no hearing is conducted, as proposed in section II.B above, would not be permitted under this proposed rule to dismiss a request for an ALJ hearing due to procedural issues such as an invalid aggregation request. Because only an ALJ would be permitted to dismiss a request for an ALJ hearing because there is no right to a hearing, which includes not meeting the amount in controversy requirement for a hearing, in accordance with proposed § 405.1052(a), an attorney adjudicator could not make a determination that the aggregation criteria were not met because that determination would result

in a dismissal of a request for an ALJ hearing.

Current § 405.976(b)(7) 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. We are proposing to revise § 405.976(b)(7) to require that the QIC notice of reconsideration include a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing only if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration is partially or fully unfavorable. In line with current practice, we are not proposing to require that the QIC indicate what it believes to be the exact amount in controversy, but rather only an estimate of whether it believes the amount in controversy is met, because we believe the ultimate responsibility for determining whether the amount in controversy required for an ALJ hearing is met lies with appellants, subject to verification by an ALJ or attorney adjudicator (though, as discussed in section II.B above, only an ALJ would be able to dismiss a request for hearing for failure to meet the amount in controversy required for an ALJ hearing). We believe that providers, suppliers, and Medicaid State agencies have the tools, resources, and payment information necessary to calculate the amount in controversy in accordance with § 405.1006(d), and are familiar with the allowable amounts for the places of service in which they operate. Furthermore, applicable plans against whom a Medicare Secondary Payer overpayment is assessed would have access to the overpayment amount specified in the demand letter, which would be used to determine the amount in controversy under proposed § 405.1006(d)(5). Thus, we do not believe it is necessary for the QICs to continue to provide this statement for providers, suppliers, applicable plans, Medicaid State agencies, or beneficiaries represented by providers, suppliers or Medicaid State agencies. Furthermore, as discussed in section III.A.3.g.i below, we are proposing that appellants, other than beneficiaries who are not represented by a provider, supplier, or Medicaid State agency, include the amount in controversy in their requests for hearing (unless the matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services). As providers, suppliers, Medicaid State agencies, applicable plans, and beneficiaries represented by a provider, supplier, or Medicaid State agency would be responsible for calculating the amount in controversy and including it on the request for hearing as proposed in section III.A.3.g.i, we do not believe a statement by the QIC that indicates only whether the amount in controversy was or was not met adds significant value to such appellants. Furthermore, we expect that the Medicare allowable amount under proposed § 405.1006(d)(2)(i)(A) would be the basis for the amount in controversy in the majority of Part B appeals filed by non-beneficiary appellants. While QICs have access to the amount charged to an individual based on billed charges, the allowable amounts for claims vary based on where these items and services were furnished, and the applicable fee schedules and contractor-priced amounts, and continuing to require the QICs to include a statement whether the amount in controversy needed for an ALJ hearing is met in all instances in which the decision is partially or fully unfavorable to the appellant would require substantially more work by the QIC, and could delay reconsiderations and increase costs to the government.

Although we are not proposing that beneficiaries who are not represented by a provider, supplier, or Medicaid State agency would need to include the amount in controversy on their requests for hearing (as discussed later in this preamble), we do believe there may be instances where a beneficiary would want to know if the amount in controversy meets the amount required for an ALJ hearing when deciding whether to file a request for hearing. We believe there may be instances where a beneficiary who is not represented by a provider, supplier, or Medicaid State agency may not currently have sufficient information to determine whether the amount in controversy required for an ALJ hearing is met under proposed § 405.1006. For example, under proposed § 405.1006(d)(2)(i)(A), for items and services with a published Medicare fee schedule or published contractor-priced amount (and for which the beneficiary was determined to be not financially responsible), the basis for the amount in controversy would generally be the allowable amount, which is 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. Beneficiaries not represented by a provider, supplier, or Medicaid State agency would not generally be expected to be familiar with fee schedule and contractor-priced amounts, and we believe they may have difficulty determining whether the amount in controversy required for an ALJ hearing is met in these cases. We also believe beneficiaries not represented by a provider, supplier, or Medicaid State agency might be unable to determine the amount of an overpayment assessed against a provider or supplier for items or services furnished to the beneficiary for purposes of calculating the amount in controversy under proposed § 405.1006(d)(5), as the beneficiary might not have access to the demand letter received by the provider or supplier, and may no longer have access to the Medicare Summary Notice reflecting the original payment amount. Accordingly, because there are situations where such beneficiaries may not have sufficient information to determine the amount in controversy, we are proposing to revise § 405.976(b)(7) to state that the QIC would include in its notice of reconsideration a statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if the request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency, and the reconsideration decision was partially or fully unfavorable.

Current § 423.1970 describes the amount in controversy requirement for part 423, subpart U proceedings. For the same reasons we are proposing to revise § 405.1006(e)(1)(ii), we are proposing in § 423.1970(c)(1)(ii) and (c)(2)(ii) to provide that a single enrollee's or multiple enrollees' request for aggregation, respectively, must be filed at the same time the request (or requests) for hearing for the appealed reconsiderations is filed. In addition, we are proposing to revise § 423.1970(c)(1)(ii) and § 423.1970(c)(2)(ii) to state that the request for aggregation and requests for hearing must be filed within 60 calendar days after receipt of the notice of reconsideration for each reconsideration being appealed, unless the deadline is extended in accordance with § 423.2014(d). This will help ensure there is no confusion that the timely filing requirement applies to each of the requests for hearing filed with the request for aggregation. Because we are proposing to directly reference the 60 calendar day filing requirement under

§ 423.1972(b) and the possible extension of the filing requirement under § 423.2014(d), we are also proposing to remove the current references in § 423.1970(c)(1)(ii) and (c)(2)(ii) to the filing requirement in § 423.1972(b). In addition, for the same reasons we are proposing to revise § 405.1006(e)(1)(iii) and (e)(2)(iii), we are proposing in § 423.1970(c)(1)(iii) and (c)(2)(iii) that an ALJ or attorney adjudicator may determine that the appeals that a single enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee, or the appeals that multiple enrollees seek to aggregate involve the same prescription drugs, but only an ALJ may determine appeals that a single enrollee seeks to aggregate do not involve the delivery of prescription drugs to a single enrollee, or the appeals that multiple enrollees seek to aggregate do not involve the same prescription drugs. We are proposing to replace ''prescription'' in current § 423.1970(c)(2)(iii) with ''prescription drugs'' in proposed § 423.1970(c)(2)(iii) for consistency with current and proposed § 423.1970(c)(1)(iii). Finally, we are also proposing to correct the spelling of ''prescription'' in current § 423.1970(c)(2)(iii).

Current § 422.600(b) provides that the amount in controversy for appeals of reconsidered determinations to an ALJ (under the Part C Medicare Advantage program), is computed in accordance with part 405. However, if the basis for the appeal is the MAO's refusal to provide services, current § 422.600(c) provides that the projected value of those services are used to compute the amount in controversy. We are not proposing to revise these provisions because we believe the proposed revisions to § 405.1006 described above encompass and have application to the scenarios appealed under part 422, subpart M. In particular, we note that as is the case under current § 405.1006, if an enrollee received items or services and is financially responsible for payment because the MAO has refused to cover the item or services, the amount in controversy would be calculated using the billed charges as the basis for the amount in controversy, as provided in proposed § 405.1006(d)(2)(ii). If the enrollee did not receive the items or services, the provisions of current § 422.600(c) would apply. We also note that current §§ 422.622(g)(2) and 422.626(g)(3) provides for an appeal to an ALJ, the Council, or federal court of an IRE's affirmation of a termination of provider services ''as provided for under [part 422, subpart M],'' thus triggering the amount in controversy rules in 422.600, which cross-reference part 405 (that is, the rules proposed here). Proposed § 405.1006 would address scenarios appealed under part 422, subpart M that are not clearly addressed in current § 405.1006, such as provider service terminations, which would be addressed in proposed § 405.1006(d)(4), and coinsurance and deductible challenges, which would be addressed in proposed § 405.1006(d)(6).

Current § 478.44(a) also references back to part 405 provisions for determining the amount in controversy when requesting an ALJ hearing after a QIO reconsidered determination. We have proposed revisions to § 478.44 in section III.D.3, below, to update part 405 references, but we are not proposing in § 478.44 to revise how the current or proposed part 405 provision would be applied in calculating the amount in controversy. Similar to the part 422, subpart M provisions discussed above, we believe the proposed revisions to § 405.1006 described above encompass and have application to the scenarios appealed under part 478, subpart B.

We are inviting public comments on these proposals. If you choose to comment on issues in this section, please include the caption ''Amount in controversy required for an ALJ hearing'' at the beginning of your comment.

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

Current §§ 405.1008 and 423.2008 discuss the parties to an ALJ hearing. Because current §§ 405.1002(a) and 423.2002(a) already address who may request a hearing before an ALJ after a QIC or IRE issues a reconsideration and current § 405.1002(b) addresses who may request escalation of a request for a QIC reconsideration, we are proposing to remove current §§ 405.1008(a) and 423.2008(a).

We are proposing to retain and revise the language as discussed below in current §§ 405.1008(b) and 423.2008(b), but remove the paragraph designation. Current §§ 405.1008(b) and 423.2008(b) identify the parties ''to the ALJ hearing,'' but this could be read to be limited to parties to an oral hearing, if a hearing is conducted. To address this potential confusion, we are proposing to revise §§ 405.1008 and 423.2008 to replace ''parties to an ALJ hearing'' with ''parties to the proceedings on a request for an ALJ hearing'' and ''party to the ALJ hearing'' with ''party to the proceedings on a request for an ALJ hearing.'' Likewise, we also are proposing to revise the titles to §§ 405.1008 and 423.2008 from ''Parties to an ALJ hearing'' to ''Parties to the proceedings on a request for an ALJ hearing.''

We are inviting public comments on these proposals. If you choose to comment the proposals in this section, please include the caption ''Parties to an ALJ hearing'' at the beginning of your comment.

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

Consistent with section 1869(c)(3)(J) of the Act, §§ 405.1010 and 405.1012 allow CMS and its contractors to elect to be a participant or a party to a Part A or Part B hearing before an ALJ. Current § 423.1010 allows CMS, a Part D plan sponsor, or an IRE to request to be a participant in the proceedings of a Part D hearing before an ALJ. Since current §§ 405.1010, 405.1012, and 423.2010 were added, CMS and its contractors, including the Part D IRE, and Part D plan sponsors, have assisted the ALJ hearing process by clarifying factual and policy issues, which provides ALJs with more information to resolve the issues on appeals. However, as we have gained experience with CMS and these entities as participants and parties to hearings, we have heard from ALJs and stakeholders that additional parameters are needed to help ensure hearings with the entities are as efficient as possible; expectations and roles are clear; and the entities have an opportunity to assist with appeals for which no hearing is conducted.

Therefore, we are proposing significant revisions to §§ 405.1010, 405.1012, and 423.2010 to achieve these objectives.

Proposed §§ 405.1010 (When CMS or its contractors may participate in the proceedings on a request for an ALJ hearing), 405.1012 (When CMS or its contractors may be a party to a hearing), and 423.2010 (When CMS, the IRE, or Part D plan sponsor may participate in the proceedings on a request for an ALJ hearing) would be reorganized and aligned for clarity, and revised to improve the participation process. The proposed revised sections would be similarly structured to address when an entity may elect or request to participate in the proceedings on a request for an ALJ hearing, or be a party to a hearing; how elections or requests are made; the roles and responsibilities of CMS and its contractors; limitations on hearing participation; and invalid elections or requests.

i. Section 405.1010: When CMS or Its Contractors May Participate in the Proceedings on a Request for an ALJ Hearing

Current § 405.1010(a) provides that an ALJ may request, but may not require, CMS and/or its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any, and CMS or its contractors may elect to participate in the hearing process. Under current § 405.1010(b), if that election is made, CMS or its contractor must advise the ALJ, the appellant, and all other parties identified in the notice of hearing of its intent to participate no later than 10 calendar days after receiving the notice of hearing. Section 405.1010(c) sets forth what participation includes and § 405.1010(d) states that participation does not include CMS or its contractor being called as a witness during the hearing. Section 405.1010(e) requires CMS or its contractors to submit any position papers within the time frame designated by the ALJ. Finally, § 405.1010(f) states that the ALJ cannot draw any adverse inferences if CMS or a contractor decides not to participate in any proceedings before an ALJ, including the hearing.

The reference to the period in which an election to participate must be filed beginning upon receipt of the notice of hearing in current § 405.1010(b) has caused confusion when CMS or its contractors attempt to enter proceedings before a hearing is scheduled, or when no notice of hearing is necessary because an appeal may be decided on the record. To help ensure that CMS and its contractors have the opportunity to enter the proceedings with minimal disruption to the adjudication process prior to a hearing being scheduled or when a hearing may not be conducted, we are proposing in § 405.1010(a)(1) to provide that CMS or its contractors may elect to participate in the proceedings on a request for an ALJ hearing upon filing a notice of intent to participate in accordance with paragraph (b), at either of, but not later than, two distinct points in the adjudication process described in paragraph (b)(3).

As provided in current § 405.1010(a) and (f), we are proposing at § 405.1010(a)(2) that an ALJ may request but may not require CMS and/or one or more of its contractors to participate in any proceedings before the ALJ, including the oral hearing, if any; and the ALJ cannot draw any adverse inferences if CMS or the contractor decides not to participate in the proceedings.

We are proposing in § 405.1010(b) to address how CMS or a contractor makes an election to participate in an appeal, before or after receipt of a notice of hearing or when a notice of hearing is not required. Under proposed § 405.1010(b)(1), we are proposing that if CMS or a contractor elects to participate before receipt of a notice of hearing (such as during the 30 calendar day period after being notified that a request for hearing was filed as proposed in § 405.1010(b)(3)(i)) 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, as proposed in section II.B above, or if the appeal is not yet assigned, to a designee of the Chief ALJ. Proposed § 405.1010(b)(1) would provide for sending the written notice of intent to participate to an ALJ or attorney adjudicator assigned to an appeal because, as we discuss in proposed in section II.B, an attorney adjudicator also would have the authority to issue decisions on a request for an ALJ hearing when no hearing is conducted, and in accordance with proposed § 405.1010, CMS or its contractors are permitted to participate in the proceedings on such a request. Proposed § 405.1010(b)(1) would also provide for sending the notice of intent to participate to a designee of the Chief ALJ if a request for an ALJ hearing is not yet assigned to an ALJ or attorney adjudicator because CMS or a contractor could file an election to be a participant in the proceedings before the assignment process is complete. Proposed § 405.1010(b)(1) would help ensure that the potential parties to a hearing, if a hearing is conducted, would receive notice of the intent to participate, and also help ensure that adjudicators who are assigned to an appeal after an election is made would be aware of the election. Because only an ALJ may conduct a hearing and the parties to whom a notice of hearing is sent may differ from the parties who were sent a copy on the notice of reconsideration, we are proposing at § 405.1010(b)(2) that if CMS or a contractor elects to participate after receiving a notice of hearing, CMS or the contractor would send written notice of its intent to participate to the ALJ and the parties who were sent a copy of the notice of hearing.

Under proposed § 405.1010(b)(3)(i), CMS or a contractor would have an initial opportunity to elect to be a participant in an appeal within 30 calendar days after notification that a request for hearing has been filed with OMHA, if no hearing is scheduled. CMS and its contractors have the capability to see that a QIC reconsideration had been appealed to OMHA in the case management system used by QICs. This system would provide constructive notice to the QICs when the system indicates an appeal has been filed with OMHA, which OMHA can monitor through the date that the reconsideration data is transferred to OMHA to adjudicate the request for an ALJ hearing. Under proposed § 405.1010(b)(3)(ii), a second opportunity to elect to be a participant in an appeal would become available if a hearing is scheduled; as in the current rule, CMS or a contractor would have 10 calendar days after receiving the notice of hearing to make the election.

We considered allowing CMS or a contractor to make an election at any time prior to a decision being issued if a hearing was not scheduled, or sending a notice that a decision would be issued without a hearing and establishing an election period after such notice. However, both of these options would disrupt and delay the adjudication process, as well as add administrative burdens on OMHA. We believe the 30 calendar day period after notification that a request for hearing was filed is sufficient time for CMS or a contractor to determine whether to elect to be a participant in the appeal while the record is reviewed for case development and to prepare for the hearing, or determine whether a decision may be appropriate based on the record in accordance with § 405.1038.

We are proposing to consolidate current § 405.1010(c) through (e) in proposed § 405.1010(c) to address the roles and responsibilities of CMS or a contractor as a participant. Proposed § 405.1010(c)(1) would incorporate current § 405.1010(c), which provides that participation may include filing position papers or providing testimony to clarify factual or policy issues, but it does not include calling witnesses or cross-examining a party's witnesses. However, we are proposing to revise § 405.1010(c) to state in § 405.1010(c)(1) that participation may include filing position papers ''and/or'' providing testimony to emphasize that either or both may be done, and to state that participation would be subject to proposed § 405.1010(d)(1) through (3) (discussed below). We are proposing to incorporate current § 405.1010(d) in proposed § 405.1010(c)(2) to provide that when CMS or a contractor participates in a hearing, they may not be called as witnesses and, thus, are not

subject to examination or cross-examination by parties to the hearing. However, to be clear about how a party and the ALJ may address statements made by CMS or a contractor during the hearing given that limitation, we also are proposing in § 405.1010(c)(2) that the parties may provide testimony to rebut factual or policy statements made by the participant, and the ALJ may question the participant about the testimony.

We are proposing to incorporate current § 405.1010(e) in proposed § 405.1010(c)(3) with certain revisions as discussed below. Current § 405.1010(e) states that CMS or its contractor must submit any position papers within the time frame designated by the ALJ. We are proposing in § 405.1010(c)(3) to include written testimony in the provision, establish deadlines for submission of position papers and written testimony that reflect the changes in participation elections in proposed 405.1010(b), and require that copies of position papers and written testimony be sent to the parties. Specifically, we are proposing in § 405.1010(c)(3)(i) that CMS or a contractor position paper or written testimony must be submitted within 14 calendar days of an election to participate if no hearing has been scheduled, or no later than 5 calendar days prior to the scheduled hearing unless additional time is granted by the ALJ. We are proposing to add ''written testimony'' to recognize that CMS or a contractor may submit written testimony as a participant, in addition to providing oral testimony at a hearing. We are proposing to require position papers and written testimony be submitted within 14 calendar days after an election if no hearing is scheduled to help ensure the position paper and/or written testimony are available when determinations are made to schedule a hearing or issue a decision based on the record in accordance with § 405.1038. We also are proposing to require that if a hearing is scheduled, position papers and written testimony be submitted no later than 5 calendar days prior to the hearing (unless the ALJ grants additional time) to help ensure the ALJ and the parties have an opportunity to review the materials prior to the hearing. Additionally, under proposed § 405.1010(c)(3)(ii), CMS or a contractor would need to send a copy of any position paper or written testimony submitted to OMHA to the parties who were sent a copy of the notice of reconsideration if the position paper or written testimony is submitted to OMHA before receipt of a notice of hearing, or to the parties who were sent a copy of the notice of hearing if the position paper or written testimony is submitted after receipt of a notice of hearing. Current § 405.1010 does not address the repercussions of a position paper not being submitted in accordance with the section. Therefore, we are proposing in § 405.1010(c)(3)(iii) that a position paper or written testimony would not be considered in deciding an appeal if CMS or a contractor fails to send a copy of its position paper or written testimony to the parties, or fails to submit its position paper or written testimony within the established time frames. This would help ensure CMS or contractor position papers and written testimony are submitted timely and shared with the parties.

Current §§ 405.1010 does not limit the number of entities that may elect to be participants, which currently includes participating in a hearing if a hearing is conducted, and current § 405.1012 does not limit the number of entities that may elect to be a party to a hearing. This has resulted in hearings for some appeals being difficult to schedule and taking longer to conduct due to multiple elections. To address these issues, we are proposing at § 405.1010(d)(1) that when CMS or a contractor has been made a party to the hearing under § 405.1012, CMS or a contractor that elected to be a participant under § 405.1010 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). Similarly, we are proposing at § 405.1010(d)(1) that CMS or a contractor that elected to be a party to the hearing, but was made a participant under § 405.1012(d)(1), as discussed below, would also be precluded from participating in the oral hearing, but would be permitted to file a position paper and/or oral testimony to clarify factual or policy issues in the case. We are proposing at § 405.1010(d)(2) that if CMS or a contractor did not elect to be a party to the hearing under § 405.1012, but more than one entity elected to be a participant under § 405.1010, only the first entity to file a response to the notice of hearing as provided under § 405.1020(c) may participate in the oral hearing, but additional entities that filed a subsequent response to the notice of hearing could file a position paper and/or written testimony to clarify factual or policy issues in the case (though they would not be permitted to attend the hearing or provide oral testimony). We are proposing that the first entity to file a response to the notice of hearing as provided under § 405.1020(c) may participate in the hearing for administrative efficiency. Under this approach, if multiple entities elected to participate in the proceedings prior to the issuance of a notice of hearing, in accordance with proposed § 405.1010(b)(1), any of these entities wishing to participate in the oral hearing would need to indicate this intention in the response to the notice of hearing. If more than one entity indicated its intention to attend and participate in the oral hearing, only the first entity to file its response would be permitted to do so. The remaining entities would be permitted only to file a position paper and/or written testimony (unless the ALJ grants leave to additional entities to attend the hearing, as discussed below). We considered an alternate proposal of the first entity that made an election to participate being given priority for participating in the hearing, but believe that would result in other participants being uncertain whether they will be participating in the hearing until as few as 5 days prior to the hearing. We also considered a process in which the ALJ would assess which participant that responded to the notice of hearing would be most helpful to the ALJ at the hearing, or in the alternative, permitting all participants to be at the hearing unless the ALJ determined a participant is not necessary for the hearing, but both of these approaches would add administrative burden to the ALJ and could result in participants and parties being uncertain of which participants will be at the hearing until shortly before the hearing. We welcome comments on the alternatives considered above, and other potential alternatives.

Notwithstanding the limitations on CMS and CMS contractor participation in proposed § 405.1010(d)(1) and (2), proposed § 405.1010(d)(3) would provide the ALJ with the necessary 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. For example, if an appeal involves LCDs from multiple MAC jurisdictions, the ALJ may determine that allowing additional MACs to participate in a hearing is necessary for a full examination of the matters at issue. Similarly, if an overpayment determined through the use of a statistical sample and extrapolation is at issue, the ALJ may determine that

allowing the contractor that conducted the sampling to participate in the hearing is necessary to address issues related to the sampling and extrapolation, in addition to another contractor that made an election to clarify the policy and factual issues related to the merits of claims in the sample.

Currently, there are no provisions in § 405.1010 to address the possibility of CMS or a contractor making an invalid election. We are proposing to revise § 405.1010(e) to add new provisions to establish criteria for when an election may be deemed invalid and provide standards for notifying the entity and the parties when an election is deemed invalid. Proposed § 405.1010(e)(1) would provide that an ALJ or attorney adjudicator may determine an election is invalid if the election was not timely filed or the election was not sent to the correct parties. This would help ensure that CMS and its contractors make timely elections and inform parties of elections. To provide notice to the entity and the parties that an election was deemed invalid, proposed § 405.1010(e)(2) would require a written notice of an invalid election be sent to the entity that submitted the election and the parties who are entitled to receive notice of the election. If no hearing is scheduled for the appeal or the election was submitted after the hearing occurred, proposed § 405.1010(e)(2)(i) would provide that the notice of an invalid election be sent no later than the date the decision, dismissal, or remand notice is mailed. If a hearing is scheduled for the appeal, proposed § 405.1010(e)(2)(ii) would provide that the written notice of an invalid election is sent prior to the hearing, and that if the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice must be provided to the entity, and the written notice must be sent as soon as possible after the oral notice is provided.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Section 405.1010: When CMS or its contractors may participate in the proceedings on a request for an ALJ hearing'' at the beginning of your comment.

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

Current § 423.2010 is similar to current § 405.1010, except that CMS, the IRE, or the Part D plan sponsor may only request to participate, and the time periods to request to participate are shorter than the time periods to elect to participate under § 405.1010, which provides the ALJ with time to consider the request to participate and make a determination on whether to allow participation by the entity. In addition, current § 423.2010 addresses participation in Part D expedited appeals. Like proposed § 405.1010(a), we are proposing at § 423.2010(a) to provide CMS, the IRE, and the Part D plan sponsor with 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. We are proposing at § 423.2010(b)(3)(i) and (ii) that, if no hearing is scheduled, CMS, the IRE and/or the Part D plan sponsor would have an initial opportunity to request to be a participant in an appeal within 30 calendar days after notification that a standard request for hearing was filed with OMHA, or within 2 calendar days after notification that a request for an expedited hearing was filed. The initial 30 calendar day period after notification that a standard request for hearing was filed with OMHA would be the same time frame provided under § 405.1010 for initial CMS and contractor elections, and we believe that 30 calendar day period after notification that a request for hearing was filed is sufficient time for CMS, the IRE, and the Part D plan sponsor to determine whether to request to be a participant in the proceedings and for the request to be considered and granted or denied as the case is reviewed to determine whether a decision may be appropriate based on the record in accordance with § 423.2038. We believe the 2 calendar day period after notification that an expedited request for hearing was filed is a reasonable period of time for CMS, the IRE, or the Part D plan sponsor to determine whether to request to be a participant in the proceedings given the 10-day adjudication time frame. We are proposing at § 423.2010(b)(3)(iii) and (iv) to provide a second opportunity to request to be a participant in an appeal if a hearing is scheduled. We are proposing at § 423.2010(b)(3)(iii) that if a non-expedited hearing is scheduled, CMS, the IRE, or the Part D plan sponsor would continue to have 5 calendar days after receiving the notice of hearing to make the request. We are proposing at § 423.2010(b)(3)(iv) that if an expedited hearing is scheduled, CMS, the IRE, or the Part D plan sponsor would continue to have 1 calendar day after receiving the notice of hearing to make the request. These time frames are carried over from current § 423.2010(b)(1) and (b)(3), and provide the ALJ with time to consider the request and notify the entity of his or her decision on the request to participate. As provided in current § 423.2010(a) and (g), we are proposing at § 423.2010(a)(2) to provide that an ALJ may request but may not require CMS, the IRE, or the Part D plan sponsor to participate in any proceedings before the ALJ, including the oral hearing, if any, and that the ALJ may not draw any adverse inferences if CMS, the IRE, or the Part D plan sponsor declines to be a participant to the proceedings.

The standards governing how an election is made in proposed § 405.1010(b) would be adopted in proposed § 423.2010(b) governing how a request to participate is made, except that an oral request to participate could be made for an expedited hearing, and OMHA would notify the enrollee of the request to participate in such cases.

Current § 423.2010(b)(2) and (b)(4) provide that an ALJ will notify an entity requesting to participate of the decision on the request within 5 calendar days for a request related to a non-expedited hearing, or 1 calendar day for a request related to an expedited hearing. These time frames would be incorporated in proposed § 423.2020(c). In addition, proposed § 423.2020(c)(1) would provide that if no hearing is scheduled, the notification is made at least 20 calendar days before the ALJ or attorney adjudicator (as proposed in section II.B above) issues a decision, dismissal, or remand. This would provide the participant with time to submit a position paper in accordance with proposed § 423.2010(d)(3)(i), as discussed below. Current § 423.2010(c) would also be incorporated into proposed § 423.2010(c), so that the provision clearly states that the assigned ALJ or attorney adjudicator (as proposed in section II.B above) has discretion to not allow CMS, the IRE, or the Part D plan sponsor to participate. Proposed § 423.2010(c) would provide that an attorney adjudicator as well as the ALJ may make a decision on a request to participate because a request to participate may be submitted for appeals that may be assigned to an attorney adjudicator and those appeals could also benefit from CMS, the IRE, or the Part D plan sponsor participation in the proceedings. We are not proposing to limit the number of participants in a hearing similar to proposed § 405.1010(d) because the ALJ has the discretion to deny a request to participate under § 423.1010 and may

therefore deny a request to participate if the ALJ determines that a hearing would have sufficient participant involvement or does not need participant involvement.

We are proposing at § 423.2010(d) to consolidate current § 423.2010(d) through (f), to address the roles and responsibilities of CMS, the IRE, or the Part D plan sponsor as a participant. Specifically, we are proposing at § 423.2010(d)(1) to generally incorporate current § 423.2010(d), which provides that participation may include filing position papers or providing testimony to clarify factual or policy issues, but it does not include calling witnesses or cross-examining a party's witnesses. However, we are proposing in § 423.2010(d)(1) that participation may include filing position papers ''and/or'' providing testimony to emphasize that either or both may be done, and to remove the limitation that testimony must be written because participation may include providing oral testimony during the hearing. We are proposing at § 423.2010(d)(2) to incorporate current § 423.2010(e), which provides that when participating in a hearing, CMS, the IRE, or the Part D plan sponsor may not be called as a witness during the hearing and, thus, are not subject to examination or cross-examination by the enrollee at the hearing. However, to be clear about how an enrollee and the ALJ may address statements made by CMS, the IRE, or the Part D plan sponsor during the hearing given that limitation, we also are proposing in § 423.2010(d)(2) that the enrollee may rebut factual or policy statements made by the participant, and the ALJ may question the participant about its testimony.

We are proposing at § 423.2010(d)(3) to incorporate current § 423.2010(f) with certain revisions as discussed below. Current § 423.2010(f) states that CMS, the IRE, and/or the Part D plan sponsor must submit any position papers within the time frame designated by the ALJ. We are proposing in § 423.2010(d)(3) to include written testimony in the provision, establish deadlines for submission of position papers and written testimony that reflect the changes in participation elections in proposed 423.2010(b), and require that copies of position papers and written testimony be sent to the enrollee. Specifically, we are proposing in § 423.2010(d)(3) that, unless the ALJ or attorney adjudicator grants additional time to submit a position paper or written testimony, a CMS, the IRE, or the Part D plan sponsor position paper or written testimony must be submitted within 14 calendar days for a standard appeal or 1 calendar day for an expedited appeal after receipt of the ALJ's or attorney adjudicator's decision on a request to participate if no hearing has been scheduled, or no later than 5 calendar days prior to a non-expedited hearing or 1 calendar day prior to an expedited hearing. We are proposing to add ''written testimony'' to recognize that CMS, the IRE, or the Part D plan sponsor or a contractor may submit written testimony as a participant, in addition to providing oral testimony at a hearing. We are proposing to require that position papers and written testimony be submitted within 14 calendar days for a standard appeal or 1 calendar day for an expedited appeal after receipt of the ALJ's or attorney adjudicator's decision on a request to participate if no hearing has been scheduled to help ensure the position paper and/or written testimony are available when determinations are made to schedule a hearing or issue a decision based on the record in accordance with § 405.1038. We also are proposing to require that if a hearing is scheduled, position papers and written testimony be submitted no later than 5 calendar days prior to a non-expedited hearing or 1 calendar day prior to an expedited hearing (unless the ALJ grants additional time) to help ensure the ALJ and the enrollee have an opportunity to review the materials prior to the hearing. Similar to proposed § 405.1010(c)(3)(iii), we also are proposing at § 423.2010(d)(3)(ii) that a copy of the position paper or written testimony must be sent to the enrollee, and at § 423.2010(d)(iii) that a position paper or written testimony would not be considered in deciding an appeal if CMS, the IRE, and/or the Part D plan sponsor fails to send a copy of the position paper or written testimony to the enrollee or fails to submit the position paper or written testimony within the established time frames. This would help ensure CMS, IRE, or Part D plan sponsor position papers and written testimony are submitted timely and shared with the enrollee.

Currently, there are no provisions in § 423.2010 to address the possibility of CMS, the IRE, and/or the Part D plan sponsor making an invalid request to participate. We are proposing to revise § 423.2010(e) to add new provisions to establish criteria for when a request to participate may be deemed invalid and provide standards for notifying the entity and the enrollee when a request to participate is deemed invalid. Proposed § 423.2010(e)(1) would provide that an ALJ or attorney adjudicator may determine a request to participate is invalid if the request to participate was not timely filed or the request to participate was not sent to the enrollee. This would help ensure that CMS, the IRE, and/or the Part D plan sponsor make timely requests to participate and inform the enrollee of requests. To provide notice to the entity and the enrollee that a request to participate was deemed invalid, proposed § 423.2010(e)(2) would require a written notice of an invalid request be sent to the entity that made the request and the enrollee. If no hearing is scheduled for the appeal or the request was made after the hearing occurred, proposed § 423.2010(e)(2)(i) would provide that the notice of an invalid request be sent no later than the date the decision, dismissal, or remand order is mailed. If a non-expedited hearing is scheduled for the appeal, proposed § 423.2010(e)(2)(ii) would provide that written notice of an invalid request is sent prior to the hearing, and that if the notice would be sent fewer than 5 calendar days before the hearing, oral notice must be provided to the entity, and the written notice must be sent as soon as possible after the oral notice is provided. If an expedited hearing is scheduled for the appeal, proposed § 423.2010(e)(2)(iii) would provide that oral notice of an invalid request must be provided to the entity, and the written notice must be sent as soon as possible after the oral notice is provided. We are proposing to require the oral notice for expedited hearings because the very short time frames involved in expedited hearing proceedings often do not allow for delivery of a written notice and the oral notice will help ensure the entity is made aware of the invalid request prior to the hearing.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Section 423.2010: When CMS, the IRE, or Part D plan sponsors may participate in the proceedings on a request for an ALJ hearing'' at the beginning of your comment.

iii. Section 405.1012: When CMS or Its Contractors May Be a Party to a Hearing

Current § 405.1012(a) states that CMS and/or its contractors may be a party to an ALJ hearing unless the request for hearing is filed by an unrepresented beneficiary. Current § 405.1012(b) states that CMS and/or the contractor(s) advises the ALJ, appellant, and all other parties identified in the notice of hearing that it intends to participate as a party no later than 10 calendar days after receiving the notice of hearing. Current § 405.1012(c) states that, when CMS or its contractors participate in a

hearing as a party, it may file position papers, provide testimony to clarify factual or policy issues, call witnesses or cross-examine the witnesses of other parties. CMS or its contractor(s) will submit any position papers within the time frame specified by the ALJ. CMS or its contractor(s), when acting as parties, may also submit additional evidence to the ALJ within the time frame designated by the ALJ. Finally, current § 405.1012(d) states that the ALJ may not require CMS or a contractor to enter a case as a party or draw any adverse inferences if CMS or a contractor decides not to enter as a party. As stated previously, we are proposing significant changes to § 405.1012.

Current § 405.1012 does not limit the number entities that may elect to be a party to the hearing. This has resulted in hearings for some appeals being difficult to schedule and taking longer to conduct due to multiple elections. To address these issues, we are proposing at § 405.1012(a)(1), except as provided in proposed paragraph (d) discussed below, to only 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). Current § 405.1012(b) states that CMS or a contractor advises the ALJ, appellant, and all other parties identified in the notice of hearing that it intends to participate as a party no later than 10 calendar days after receiving the notice of hearing. We are proposing at § 405.1012(a) to incorporate and revise a portion of current § 405.1012(b), to require that an election to be a party must be filed no later than 10 calendar days after the QIC receives the notice of hearing, because notices of hearing are sent to the QIC in accordance with § 405.1020(c) (the remaining portion of current § 405.1012(b) is incorporated with revisions into proposed § 405.1012(b), as discussed below).

Current § 405.1012 does not have a provision similar to current § 405.1010(a), which states that an ALJ may request that CMS and/or one or more of its contractors participate in the proceedings, but current § 405.1012(d) does provide that the ALJ may not require CMS or a contractor to enter a case as a party or draw any adverse inference if CMS or a contractor decided not to enter as a party. In practice, ALJs do at times request that CMS or a contractor elect to be a party to the hearing, in conjunction with a request for participation under current § 405.1010(a). To align the provisions and reflect ALJ practices, we are proposing at § 405.1012(a)(2) to state that an ALJ may request but not require CMS and/or one or more of its contractors to be a party to the hearing. We also are proposing in § 405.1012(a)(2) to incorporate current § 405.1012(d) to provide that that an ALJ cannot draw any adverse inferences if CMS or a contractor decides not to enter as a party.

We are proposing at § 405.1012(b) to address how CMS or a contractor elects to be a party to the hearing. We are proposing to follow the same process in current § 405.1012(b) so that under proposed § 405.1012(b), CMS or the contractor would 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.

We are proposing to set forth the roles and responsibilities of CMS or a contractor as a party in § 405.1012(c). Proposed § 405.1012(c)(1) would incorporate current § 405.1012(c) with some changes in wording, both of which provide that 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. We are proposing in § 405.1012(c)(2) to include written testimony, such as an affidavit or deposition, in the provision; establish deadlines for submission of position papers, written testimony, and evidence; and require that copies of position papers, written testimony, and evidence be sent to the parties that were sent a copy of the notice of hearing. Specifically, we are proposing in § 405.1012(c)(2)(i) and (c)(2)(ii) that any position papers, written testimony, and evidence must be submitted no later than 5 calendar days prior to the hearing, unless the ALJ grants additional time to submit the materials, and copies must be sent to the parties who were sent a copy of the notice of hearing. We are proposing to add ''written testimony'' to recognize that CMS or a contractor may submit written testimony, in addition to providing oral testimony at a hearing. We also are proposing to require that position papers, written testimony, and/or evidence be submitted no later than 5 calendar days prior to the hearing (unless the ALJ grants additional time), and that copies be submitted to the parties sent notice of the hearing, to help ensure the ALJ and the parties have an opportunity to review the materials prior to the hearing. Current § 405.1012 does not address the consequence of failure to submit a position paper or evidence in accordance with the section. We are proposing in § 405.1012(c)(2)(iii) that a position paper, written testimony, and/or evidence would not be considered in deciding an appeal if CMS or a contractor fails to send a copy of its position paper, written testimony, and/or evidence to the parties or fails to submit the position paper, written testimony, and/or evidence within the established time frames. This would help ensure CMS or contractor position papers and evidence are submitted timely and shared with the parties.

As discussed above, current § 405.1012 does not limit the number entities (that is, CMS and its contractors) that may elect to be a party to the hearing and, as also discussed above, we are proposing to revise § 405.1010 and 405.1012 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. We are proposing to revise § 405.1012(d)(1) to provide that if CMS and one or more contractors, or multiple contractors file elections to be a party to a hearing, the first entity to file its election after the notice of hearing is issued is made a party to the hearing and the other entities are made participants in the proceedings under § 405.1010, subject to § 405.1010(d)(1) and (3) (and as such may file position papers and provide written testimony to clarify factual or policy issues in the case, but may not participate in the oral hearing unless the ALJ grants leave to the entity to participate in the oral hearing in accordance with § 405.1010(d)(3)). Similar to proposed § 405.1010(d)(3), we are also proposing in § 405.1012(d)(2) that, notwithstanding the limitation in proposed § 405.1012(d)(1), an ALJ may 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.

We believe allowing the first entity to file an election after a notice of hearing is issued to be a party to the hearing is administratively efficient and provides an objective way to determine which entity is made a party based on the competing elections, while providing an opportunity to participate in the appeal by filing a position paper and/or written testimony under § 405.1010 for those that file later in time, or to be made a participant or party to the hearing by the ALJ under the ALJ's discretionary authority under proposed §§ 405.1010(d)(3) and 405.1012(d)(2). We considered an alternate proposal of the first entity that had elected

participant status under § 405.1010, if any, being given priority for being made a party to the hearing, but believe that would result in other entities making a party election being uncertain whether they will be made a party to the hearing until as few as 5 days prior to the hearing (assuming the notice of hearing is sent 20 days prior to the scheduled hearing, as required by § 405.1022(a), the QIC receives the notice of hearing 5 days later, and the entity or entities responding to the notice of hearing can make their election as late as 10 calendar days after the QIC's receipt of the notice, leaving only 5 days prior to the hearing). We also considered a process by which the ALJ would assess which entity making a party election would be most helpful to the ALJ at the hearing, or in the alternative, permitting all entities that filed a party election to be made a party to the hearing unless the ALJ determined an entity is not necessary for the hearing, but both of these approaches would add administrative burden to the ALJ and could result in CMS, contractors and parties being uncertain of which entities will be parties to the hearing until shortly before the hearing. We welcome comments on the alternatives considered above.

Finally, we are proposing to add new § 405.1012(e) to address the possibility of CMS or a contractor making an invalid election. Proposed § 405.1012(e)(1) would provide that an ALJ or attorney adjudicator may determine an election is invalid if the request for hearing was filed by an unrepresented beneficiary, the election was not timely, the election was not sent to the correct parties, or CMS or a contractor had already filed an election to be a party to the hearing and the ALJ did not determine that the entity's participation as a party is necessary for a full examination of the matters at issue. This would help ensure that CMS and its contractors make timely elections and inform parties of elections, and also provide a mechanism to address an election when the request for hearing was filed by an unrepresented beneficiary or when another entity has already filed an election to be a party to the hearing. To provide notice to the entity and the parties that an election was deemed invalid, proposed § 405.1012(e)(2) would require a written notice of an invalid election be sent to the entity that made the election and the parties who were sent the notice of hearing. If the election was submitted after the hearing occurred, proposed § 405.1012(e)(2)(i) would provide that the notice of an invalid election be sent no later than the date the decision, dismissal, or remand notice is mailed. If the election was submitted before the hearing occurs, proposed § 405.1012(e)(2)(ii) would provide that the written notice of invalid election is sent prior to the hearing, and that if the notice would be sent fewer than 5 calendar days before the hearing is scheduled to occur, oral notice would be provided to the entity that submitted the election, and the written notice to the entity and the parties who were sent the notice of hearing would be sent as soon as possible after the oral notice is provided.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Section 405.1012: When CMS or its contractors may be a party to a hearing'' at the beginning of your comment.

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

Current §§ 405.1014 and 423.2014 explain the requirements for requesting an ALJ hearing, including what must be contained in the request, when and where to file the request, the extension of time to request a hearing, and in § 405.1014 to whom a copy of the request for hearing must be sent. We are proposing to restructure the sections, clarify and provide additional instructions, and address other matters that have caused confusion for parties and adjudicators.

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

We are proposing to revise the title and provisions of §§ 405.1014 and 423.2014 to more clearly cover a request for a review of a QIC or IRE dismissal. While the current requirements for requesting an ALJ hearing are generally used for requesting a review of a QIC or IRE dismissal in form HHS–725, we believe that explicitly extending §§ 405.1014 and 423.2014 to cover requests for these types of review would provide clarity to parties and adjudicators on the requirements for requesting a review of a QIC or IRE dismissal. As such, we are proposing in the title to § 405.1014 and in subsection (a)(1) (current subsection (a)) to add ''or a review of a QIC dismissal'' after ''ALJ hearing,'' and in subsection (c) (current subsection (b)) to delete ''after a QIC reconsideration'' and add ''or request for review of a QIC dismissal'' after ''an ALJ hearing.'' Similarly, we are proposing in the title to § 423.2014 and in subsection (a)(1) (current subsection (a)) to add ''or a review of an IRE dismissal'' after ''ALJ hearing,'' and in subsection (d) (current subsection (c)) to add ''or request for review of an IRE dismissal'' after ''IRE reconsideration.''

We are proposing in § 405.1014(a)(1)(i) through (a)(1)(vi) to incorporate current § 405.1014(a)(1) through (a)(6) with revisions. In addition to the current requirements in subsection (a)(1), we are proposing in § 405.1014(a)(1)(i) to require the beneficiary's telephone number if the beneficiary is the filing party and is not represented. This would help ensure that OMHA is able to make timely contact with the beneficiary to clarify his or her filing, or other matters related to the adjudication of his or her appeal, including scheduling the hearing. We are proposing in § 405.1014(a)(1)(ii) to require the appellant's telephone number, along with the appellant's name and address as currently required in subsection (a)(2), when the appellant is not the beneficiary, and in § 405.1014(a)(1)(iii) to require a representative's telephone number, along with the representative's name and address which is currently included in subsection (a)(3), if a representative is involved. Like the beneficiary telephone number requirement, these requirements would help ensure that OMHA is able to make timely contact with a non-beneficiary appellant and any representative involved in the appeal to clarify the filing or other matters related to the adjudication of the appeal, including scheduling the hearing. Current subsection (a)(4) states that the request must include the document control number assigned to the appeal by the QIC, if any. We are proposing in § 405.1014(a)(1)(iv) to require the Medicare appeal number or document control number, if any, assigned to the QIC reconsideration or dismissal notice being appealed, to reduce confusion for appellants. We are proposing in § 405.1014(a)(1)(v) to add language to the current language in subsection (a)(5), so that instead of requiring the ''dates of service,'' we would require the ''dates of service for the claims being appealed, if applicable,'' because an appellant may appeal some but not all of the partially favorable or unfavorable claims in a QIC reconsideration and a small number of appeals do not involve a date of service (for example, entitlement appeals). We are proposing to incorporate the same language in current subsection (a)(6) into proposed subsection (a)(1)(vi).

We are proposing to add a new requirement to the content of the request in § 405.1014(a)(1)(vii) by

requiring a statement of whether the filing party is aware that it or the claim is the subject of an investigation or proceeding by the OIG or other law enforcement agencies. This information is necessary to assist OMHA staff in checking whether the provider or supplier was excluded from the program on the date of service at issue prior to scheduling a hearing or issuing a decision, as well as for the ALJ to determine whether to request the participation of CMS or any program integrity contractors that may have been involved in reviewing the claims below. However, we note that the information is only required if the filing party is aware of an investigation and proceeding, and the information would not be the basis for a credibility determination on evidence or testimony, as an investigation or allegations prior to findings of wrongdoing by a court of competent jurisdiction are not an appropriate foundation for credibility determinations in the context of part 405, subpart I administrative appeals.

As discussed in Section III.A.3.d above, we are proposing changes to 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. We are also proposing new § 405.1014(a)(1)(viii) to require that providers, suppliers, Medicaid State agencies, applicable plans, and beneficiaries represented by a provider, supplier, or Medicaid State agency include in their request for hearing the amount in controversy applicable to the disputed claim, as specified in § 405.1006(d), unless the matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services. As we discussed in section III.A.3.d., in instances where the Medicare allowable amount would serve as the basis for the amount in controversy (which we believe would be the majority of Part B appeals), we believe providers, suppliers, and Medicaid State agencies would be able to utilize existing CMS tools and resources to determine the allowable amount used as the basis for the amount in controversy under proposed § 405.1006(d)(2)(i)(A) and arrive at the amount in controversy after deducting any Medicare payments that have already been made or awarded and any deductible and/or coinsurance that may be collected for the items and services in the disputed claim. In addition, we believe that providers, suppliers, applicable plans, and Medicaid State agencies also would have access to the billing, payment and other necessary information to calculate the amount in controversy under other provisions of § 405.1006(d). For scenarios where the basis for the amount in controversy would be calculated in accordance with proposed § 405.1006(d)(2)(i)(B), (ii), (iii), or where the amount in controversy would be calculated in accordance with § 405.1006(d)(3), (5), (6), or (7), we discuss in section III.A.3.d above how appellants would determine the amount in controversy in order to include it on their request for hearing. However, because we believe there may be instances where a beneficiary who is not represented by a provider, supplier, or Medicaid State agency may not have the information necessary to determine the amount in controversy under § 405.1006(d) (as discussed above), we are not proposing to require beneficiaries who are not represented by a provider, supplier, or Medicaid State agency to include the amount in controversy in their requests for hearing. Furthermore, as noted above, we are not proposing that any appellant include the amount in controversy on requests for hearing where the amount in controversy would be calculated in accordance with § 405.1006(d)(4) (for a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services). We expect that, in this situation, a beneficiary could easily determine whether the minimum amount in controversy required for an ALJ hearing would be met through a conversation with the provider or supplier, or from the statement we are proposing the QIC include in its notice of reconsideration as discussed in section III.A.3.d above. However, we believe the exact amount in controversy could be difficult to determine because it may depend on unknown factors, such as the length of continued services that may be required, and so we are not requiring appellants to include this amount in the request for hearing.

Lastly, current § 405.1014(a)(7), which requires a statement of any additional evidence to be submitted and the date it will be submitted, would be separately designated in its entirety as proposed § 405.1014(a)(2) because the information in proposed § 405.1014(a)(1) must be present for a request for hearing to be processed and therefore would make the request subject to dismissal if the information is not provided, as discussed below. In contrast, the information in proposed § 405.1014(a)(2) is only necessary if evidence would be submitted and would not make the request subject to dismissal if not present in the request.

Similar to proposed § 405.1014(a), we are proposing at § 423.2014(a)(1)(i) through (a)(1)(vi) to incorporate current § 423.2014(a)(1) through (a)(6) with revisions. Current subsection (a)(3) states that the request must include the appeals case number assigned to the appeal by the IRE, if any. We are proposing in § 405.1014(a)(1)(iii) to revise the requirement to state that the request must include the Medicare appeal number, if any, assigned to the IRE reconsideration or dismissal being appealed, to reflect the terminology used by the IRE and thereby reduce confusion for enrollees. Current subsection (a)(6) states that the request must include the reasons the enrollee disagrees with the IRE's reconsideration. We are proposing to insert ''or dismissal'' after ''reconsideration'' to again reflect the terminology used by the IRE and thereby reduce confusion for enrollees. For the same reasons as we proposed for § 405.1014(a)(1)(vii), we are proposing at § 423.2014(a)(1)(vii) to require a statement of whether the enrollee is aware that he or she, or the prescription for the drug being appealed, is the subject of an investigation or proceeding by the OIG or other law enforcement agencies. In addition, we are proposing at § 423.2014(a)(2) to incorporate the current § 423.2014(a)(7) requirement to include a statement of any additional evidence to be submitted and the date it will be submitted, and at § 423.2014(a)(3) to incorporate the current § 423.2014(a)(8) requirement to include a statement that the enrollee is requesting an expedited hearing, if applicable.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Requirements for a request for hearing or review of a QIC or IRE dismissal'' at the beginning of your comment.

ii. Requests for Hearing Involving Statistical Sampling and Extrapolations

We are proposing to add new § 405.1014(a)(3) 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. OMHA has encountered significant issues when an appellant challenges aspects of a statistical sampling methodology and/or the results of extrapolations in separate

appeals for each sampled claim involved in the statistical sampling and/or extrapolation. Appeals often need to be reassigned to avoid multiple adjudicators addressing the challenges to the statistical sampling methodology and/or extrapolation, and any applicable adjudication time frames attach to the individual appeals. Under proposed § 405.1014(a)(3), if an appellant is challenging the statistical sampling methodology and/or extrapolation, the appellant's request for hearing must include the information in proposed § 405.1014(a)(1) and (a)(2) for each sample claim that the appellant wishes to appeal, be filed within 60 calendar days of the date that the party received the last reconsideration for the sample claims (if they were not all addressed in a single reconsideration), and assert the reasons the appellant disagrees with the statistical sampling methodology and/or extrapolation in the request for hearing. We believe it would be appropriate in this situation to allow the appellant's request for hearing to be filed within 60 calendar days of the date that the party received the last reconsideration for the sample claims (if they were not all addressed in a single reconsideration), because if the appellant also wishes to challenge the statistical sampling methodology and/or extrapolation, the appellant would wait to file a request for hearing until all of the QIC reconsiderations for the sample units are received, which could be more than 60 calendar days after the first received QIC reconsideration of one of the sample claims. We also state that the 60 calendar day period in proposed § 405.1014(a)(3)(ii) would begin on the date the party receives the last reconsideration of a sample claim, regardless of the outcome of the claim in the reconsideration or whether the sample claim is appealed in the request for hearing. We believe proposed § 405.1014(a)(3) would balance the party's rights to request a hearing on individual claims when only the sample claims are appealed, with the needs to holistically address issues related to statistical sampling methodologies and extrapolations when those determinations are also challenged. We are not proposing any corresponding changes to § 423.2014 because sampling and extrapolation are not currently used in Part D appeals.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Requests for hearing involving statistical sampling and extrapolations'' at the beginning of your comment.

iii. Opportunity To Cure Defective Filings

There has been considerable confusion on the implications of not providing the information required by current § 405.1014(a) in order to perfect a request for hearing, and significant time and resources have been spent on this procedural matter by parties, OMHA, and the Council. To provide clearer standards and reduce confusion, we are proposing in § 405.1014(b)(1) that a request for hearing or request for a review of a QIC dismissal must contain the information specified in proposed § 405.1014(a)(1) to the extent the information is applicable, to be complete, and § 405.1014(b)(1) would provide that any applicable adjudication time frame does not begin until the request is complete because the information is necessary to the adjudication of the appeal. We are proposing in § 405.1014(b)(1) to also provide an appellant with an opportunity to complete the request if the request is not complete. However, if the appellant fails to provide the information necessary to complete the request in the time frame provided, the request would not be complete and would be dismissed in accordance with proposed § 405.1052(a)(7) or (b)(4). We are also proposing at § 405.1014(b)(2) to allow for consideration of supporting materials submitted with a request when determining whether the request is complete, provided the necessary information is clearly identifiable in the materials, to provide that an appellant's request and supporting materials is considered in its totality. For example, if an appellant were to submit a request for hearing and included a copy of the QIC reconsideration, the Medicare appeal number on the QIC reconsideration would generally satisfy the subsection (a)(1)(iv) requirement because it clearly provides the information. However, if there are multiple claims in the QIC reconsideration, the same document possibly would not satisfy subsection (a)(1)(v) because the appellant is not required to appeal all partially favorable or unfavorable claims, and subsection (a)(1)(v) requires the appellant to indicate the dates of service for the claims that are being appealed. Similarly, including medical records only for the dates of service that the appellant wishes to appeal would generally not satisfy subsection (a)(1)(v) because it would be unclear whether the appellant intended to limit the appeal to only those dates of service for which medical records were included, or those were the only dates of service for which the appellant had medical records. We are proposing that the provisions of proposed § 405.1014(b) be adopted in proposed § 423.2014(c) for requesting an ALJ hearing or a review of an IRE dismissal in Part D appeals.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Opportunity to cure defective filings'' at the beginning of your comment.

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

We are proposing to incorporate portions of current § 405.1014(b) in proposed § 405.1014(c) and portions of current § 423.2014(c) in proposed § 423.2014(d) to address when and where to file a request for hearing or review. We are proposing in §§ 405.1014(c) introductory language and (c)(1), and 423.2014(d) introductory language and (d)(1), to incorporate a request for a review of a QIC dismissal and a request for a review of an IRE dismissal, respectively, and provide that 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, which is the time frame stated in §§ 405.1004 and 423.2004 to request a review of a QIC or IRE dismissal, respectively. We also are proposing in § 405.1014(c)(1) to add an exception for requests filed in accordance with proposed § 405.1014(a)(3)(ii), because as discussed above, we are proposing to require that requests for hearing on sample claims that are part of a statistical sample and/or extrapolation that the appellant also wishes to challenge 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, we are proposing to revise the statement that a request must be ''submitted'' in current § 423.2014(c)(1), with a request must be ''filed'' in § 423.2014(d)(1), for consistency with § 405.1014 and § 422.602, both of which use the term ''filed.'' We are also proposing in §§ 405.1014(c)(2) and 423.2014(d)(2) to replace references to sending requests to the ''entity'' specified in the QIC's or IRE's reconsideration in current §§ 405.1014(b)(2) and 423.2014(c)(2), with sending requests to the ''office'' specified in the QIC's or IRE's reconsideration or dismissal, respectively, so they are properly routed. As discussed in III.A.3.b. and III.A.3.c, above, regarding proposed

§§ 405.1002 and 405.1004, and 423.2002 and 423.2004, replacing ''entity'' with ''office'' in §§ 405.1014, 423.1972, and 423.2014 would help ensure appellants are aware that a request for hearing or request for a review of a QIC or IRE dismissal must be filed with the office indicated in the QIC's or IRE's reconsideration or dismissal and avoid delays. However, we again note that for the few requests for hearing that are misrouted by a party, a notice would be sent to the appellant when the request for hearing is received in the correct office and the date the timely request was received by the incorrect office would be used to determine the timeliness of the request, in accordance with proposed §§ 405.1014(c)(2) and 423.2014(d)(2)(i), which would incorporate the misrouted request provisions from current §§ 405.1014(b)(2) and 423.2014(c)(2)(i). We are also proposing in §§ 405.1014(c)(2) and 423.2014(d)(2)(i) that the adjudication time frame is only affected if there is an applicable adjudication time frame for the appeal.

Current § 423.1972(b) states that an enrollee must file a request for a hearing within 60 calendar days of the date of the notice of the IRE reconsideration determination. This requirement differs from § 423.2002(a)(1), which states that a request for hearing must be filed within 60 calendar days after receipt of the IRE's reconsideration (this is also the standard for filing Part A and Part B requests for hearing after receipt of QIC reconsiderations, at § 405.1002(a)(1). We are proposing to revise § 423.1972(b)(1) to state that a request for hearing must be filed within 60 calendar days after receipt of the IRE's reconsideration. We also are proposing to add new § 423.1972(b)(2), to incorporate current § 423.2002(d), which provides the date of receipt of the reconsideration is presumed to be 5 calendar days after the date of the written reconsideration unless there is evidence to the contrary (this is also a presumption for receipt of QIC reconsiderations in Part A and Part B appeals, at § 405.1002). These changes would align proposed § 423.1972(b) with current § 423.2002, and remove potential enrollee confusion on when a request for an ALJ hearing must be filed.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Where and when to file a request for hearing or review of a QIC or IRE dismissal'' at the beginning of your comment.

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

We are proposing to incorporate the portion of current § 405.1014(b)(2) that states that the appellant must also send a copy of the request for hearing to the other parties and failure to do so will toll the ALJ's 90 calendar day adjudication deadline until all parties to the QIC reconsideration receive notice of the requested ALJ hearing in proposed § 405.1014(d) with changes discussed below. Current § 405.1014(b)(2) has been another source of considerable confusion, and significant time and resources have been spent on this procedural matter by parties, OMHA, and the Council. Current § 405.1014(b)(2) requires an appellant to send a copy of the request for hearing to the other parties. Other parties consist of all of the parties specified in § 405.906(b) as parties to the reconsideration, including beneficiaries in overpayment cases that involve multiple beneficiaries who have no liability, in which case the QIC may elect to only send a notice of reconsideration to the appellant, in accordance with § 405.976(a)(2). We are proposing in § 405.1014(d)(1) to amend the current copy requirement by only requiring an appellant to send a copy of a request for an ALJ hearing or review of a QIC dismissal to the other parties who were sent a copy of the QIC's reconsideration or dismissal. This change would make the standard consistent with requests for Council review, a copy of which must be sent by the appellant to the other parties who received a copy of an ALJ's decision or dismissal, in accordance with current § 405.1106(a). This change would also extend the requirement to requests for review of a QIC dismissal to provide the other parties who received notice of the QIC's dismissal action with notice of the appellant's appeal of that action.

We are also proposing in § 405.1014(d)(1) to address whether copies of materials that an appellant submits with a request for hearing or request for review of a QIC dismissal must be sent to other parties. Currently some ALJs consider the materials to be part of the request and require an appellant to send copies of all materials submitted with a request, while other ALJs do not consider the materials to be part of the request. We are proposing in § 405.1014(d)(1) that if additional materials submitted with a request are necessary to provide the information required for a complete request in accordance with proposed § 405.1014(b), 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). For example, if a complete request includes a position paper or brief that explains the reasons the appellant disagrees with the QIC's reconsideration, in accordance with proposed § 405.1014(a)(1)(v), a copy of the position paper or brief would be sent to the other parties, subject to any authorities that apply to disclosing the personal information of other parties. However, additional evidence such as medical records, is generally not required for a complete request, and therefore copies would not have to be sent, but could instead be summarized and provided to the other parties at their request, again subject to any authorities that apply to disclosing the personal information of other parties. This approach would balance the objectives of ensuring that parties to a claim and an appeal of that claim remain informed of the proceedings that are occurring on the claim, with the burdens on appellants to keep their co-parties so informed. We also note that in sending a copy of the request for hearing and associated materials, appellants are free to include cover letters to explain the request, but we note that such letters on their own do not satisfy the copy requirement in its current or proposed form. No corresponding changes are proposed in § 423.2014 because the enrollee is the only party to the appeal.

Current § 405.1014 does not contain standards for what constitutes evidence that a copy of the request for hearing or review, or copy of the evidence or a summary thereof, was sent to the other parties, which has led to confusion and inconsistent practices. Therefore, we are proposing in § 405.1014(d)(2) to address this issue by establishing standards that an appellant would follow to satisfy the requirement. We are proposing in § 405.1014(d)(2) that 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. We believe these options would provide an appellant with flexibility to document the copy requirement was satisfied and bring consistency to the process.

Beyond stating that an adjudication time frame is tolled if a party does not satisfy the copy requirement, current § 405.1014 does not address the consequence of not satisfying the requirement, and adjudicators are faced with an appeal being indefinitely tolled because an appellant refuses to comply with the requirement. OMHA ALJs have addressed this issue by providing appellants with an opportunity to send the required copy of the request for hearing, and by informing the appellant that if the copy is not sent, its request will be dismissed. This allows OMHA ALJs to remove requests that do not satisfy the requirement from their active dockets so time and resources can be focused on appeals of those who comply with the rules. We are proposing in § 405.1014(d)(3) that, if the 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 would be provided with an opportunity to cure the defects by sending the request, materials, and/or evidence or summary thereof described in proposed subsection (d)(1). Further, proposed § 405.1014(d)(3) would provide that if an adjudication time frame applies, it does not begin until evidence that the request, materials, and/or evidence or summary thereof were sent is received. We are also proposing in § 405.1014(d)(3) that if an appellant does not provide evidence within the time frame 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 would be dismissed.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Sending copies of a request for hearing and other evidence to other parties to the appeal'' at the beginning of your comment.

vi. Extending Time To File a Request for Hearing or Review of a QIC or IRE Dismissal

We are proposing that the provisions of current §§ 405.1014(c) and 423.2014(d) for extensions of time to file a request for hearing would be incorporated in proposed §§ 405.1014(e) and 423.2014(e) with changes, and would extend to requests for reviews of QIC and IRE dismissals. On occasion, OMHA is asked whether a request for an extension should be filed without a request for hearing, for a determination on the request for extension before the request for hearing is filed. In those instances, we ask the filer to file both the request for hearing and request for extension at the same time because an independent adjudication of the extension request would be inefficient and any adjudication time frame begins on the date that the ALJ grants the extension request, in accordance with current §§ 405.1014(c)(4) and 423.2014(d)(4). We are proposing in §§ 405.1014(e)(2) and 423.2014(e)(3) to require a request for an extension be filed with the request for hearing or request for review of a QIC or IRE dismissal, with the office specified in the notice of reconsideration or dismissal. Proposed §§ 405.1014(e)(2) and 423.2014(e)(3) would also align the provision with proposed §§ 405.1014(c) and 423.2014(d) by specifying that a request for an extension must be filed with the ''office,'' rather than the ''entity,'' specified in the notice of reconsideration. We are proposing in § 405.1014(e)(3) and 423.2014(e)(4) that an ALJ or attorney adjudicator may find good cause to extend the deadline to file a request for an ALJ hearing or a request for a review of a QIC or IRE dismissal, or there is no good cause for missing the deadline to file a request for a review of a QIC or IRE dismissal, but only an ALJ may find there is no good cause for missing the deadline to file a request for an ALJ hearing. Because only an ALJ may dismiss a request for an ALJ hearing for an untimely filing in accordance with proposed §§ 405.1052 and 423.2052, an attorney adjudicator could not make a determination on a request for an extension that would result in a dismissal of a request for hearing. We are also proposing to incorporate current §§ 405.1014(c)(4) and 423.2014(d)(5) into proposed §§ 405.1014(e)(4) and 423.2014(e)(5), but indicate that the adjudication time frame begins on the date the ALJ or attorney adjudicator grants the request to extend the filing deadline only if there is an applicable adjudication period. Finally, we are proposing in §§ 405.1014(e)(5) and 423.2014(e)(6) to add a new provision to provide finality for the appellant with regard to a determination to grant an extension of the filing deadline. We are proposing that if an ALJ or attorney adjudicator were to make a determination to grant the extension, the determination is not subject to further review. However, we are not precluding review of a determination to deny an extension because such a denial would result in a dismissal for an untimely filing, and the dismissal and determination on the request for an extension would be subject to review by the Council.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Extending time to file a request for hearing or review of a QIC or IRE dismissal'' at the beginning of your comment.

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. Section 405.1016: Time frames for Deciding an Appeal of a QIC or an Escalated Request for a QIC Reconsideration

Current § 405.1016 addresses the adjudication time frames for requests for hearing filed after a QIC has issued its reconsideration, in accordance with section 1869(d)(1)(A) of the Act, and escalations of requests for a QIC reconsideration when the QIC does not issue its reconsideration within its adjudication time frame, which is permitted by section 1869(c)(3)(C)(ii) of the Act. We are proposing to revise the title of § 405.1016 from ''Time frames for deciding an appeal before an ALJ'' to ''Time frames for deciding an appeal of a QIC reconsideration or escalated request for a QIC reconsideration'' because the section specifically applies to appeals of QIC reconsiderations and escalated requests for QIC reconsiderations (as specified in current and proposed § 405.1016(a) and (c)). This revision would also allow for application of this section to requests for hearing adjudicated by attorney adjudicators, as proposed in Section II.B. above. We also are proposing to replace each instance of the term ''the ALJ'' with ''the ALJ or attorney adjudicator'' throughout proposed § 405.1016 to assist appellants in understanding that an adjudication time frame, and the option to escalate, also

would apply to a request for an ALJ hearing following a QIC reconsideration when the request has been assigned to an attorney adjudicator, as proposed in section II.B, above. We are not proposing to change the reference to ''a request for an ALJ hearing'' because, as explained above in section II.B, even if an appellant waives its right to hearing, the case would remain subject to a potential oral hearing before an ALJ, and we believe the request is therefore properly characterized as a request for an ALJ hearing.

We are proposing to add titles to proposed § 405.1016(a) to indicate that this paragraph discusses the adjudication period for appeals of QIC reconsiderations, and proposed § 405.1016(c) to indicate that this paragraph discusses the adjudication period for escalated requests for QIC reconsiderations. In addition, proposed § 405.1016(a) and (c) would remove ''must,'' in providing that when a request for an ALJ hearing is filed after a QIC has issued a reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the QIC, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the QIC's notice of reconsideration. While the statute envisions that appeals will be adjudicated within the statutory time frame, the statute also provides for instances in which the adjudication time frame is not met by allowing an appellant to escalate his or her appeal to the next level of appeal. We believe ''must'' should be reserved for absolute requirements, and in the context of adjudication time frames, the statute provides the option for an appellant to escalate an appeal if the adjudication time frame is not met.

We are proposing to add a title to proposed § 405.1016(b) to indicate that the paragraph discusses when an adjudication period begins. Current § 405.1016(b), which explains that the adjudication period for an appeal of a QIC reconsideration begins on the date that a timely filed request for hearing is received unless otherwise specified in the subpart, would be re-designated as proposed § 405.1016(b)(1). We are proposing in § 405.1016(b)(2) that if the Council remands a case and the case was subject to an adjudication time frame under paragraph (a) or (c), the remanded appeal would be subject to the adjudication time frame of § 405.1016(a) beginning on the date that OMHA receives the Council remand. Currently the regulations do not address whether an adjudication time frame applies to appeals that are remanded from the Council, and whether escalation is an option for these appeals. To provide appellants with an adjudication time frame for remanded appeals that were subject to an adjudication time frame when they were originally appealed to OMHA, proposed § 405.1016(b)(2) would apply the adjudication time frame under § 405.1016(a) to a remanded appeal that was subject to an adjudication time frame under paragraph (a) or (c). For example, if an ALJ decision reviewed by the Council involved a QIC reconsideration and was remanded by the Council, a 90 calendar day time frame would apply from the date that OMHA received the remand order. If the adjudication time frame is not met under proposed § 405.1016(b)(2), the appeal would be subject to escalation, in accordance with proposed § 405.1016(e).

In addition, we are proposing in § 405.1016(a) and (b) to align the paragraphs with proposed § 405.1014(c) by specifying that a request for hearing is received by the ''office,'' rather than the ''entity,'' specified in the QIC's notice of reconsideration.

We are proposing to add a title to proposed § 405.1016(d) to indicate that the paragraph discusses waivers and extensions of the adjudication period. We are proposing in § 405.1016(d)(1) to incorporate the adjudication period waiver provision in current § 405.1036(d), which states that, at any time during the hearing process, the appellant may waive the adjudication deadline specified in § 405.1016 for issuing a hearing decision, and that the waiver may be for a specific period of time agreed upon by the ALJ and the appellant. We are proposing to move the provision because we believe it is more appropriately addressed in § 405.1016, as it is directly related to the adjudication period. Proposed § 405.1016(d) would also revise the language in current § 405.1036(d) to reference an attorney adjudicator consistent with our proposals in Section II.B. above; to reference the ''adjudication'' process rather than the ''hearing process'' to account for appeals that may not involve a hearing, to consistently reference an adjudication ''period'' for internal consistency, and to replace the reference to § 405.1016 with internal paragraph references.

Current § 405.1016 does not address delays that result from stays ordered by U.S. Courts. In addition, we have had instances in which an appellant requests a stay of action on his or her appeals while related matters are addressed by another court or tribunal, or by investigators. To address these circumstances, we are proposing in § 405.1016(d)(2) that the adjudication periods specified in paragraphs (a) and (c) are extended as otherwise specified in this subpart, and for the duration of any stay of action on adjudicating the claims or matters at issue ordered by a court or tribunal of competent jurisdiction, or the duration of any stay of proceedings granted by an ALJ or attorney adjudicator on the motion of the appellant, provided no other party also filed a request for hearing on the same claim at issue.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Section 405.1016: Time frames for deciding an appeal of a QIC or an escalated request for a QIC reconsideration'' at the beginning of your comment.

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

Current § 405.1104 addresses how to request escalation from an ALJ to the Council, when an ALJ has not issued a decision, dismissal or remand on a QIC reconsideration within an applicable adjudication time frame, in accordance with section 1869(d)(3)(A) of the Act in paragraph (a); the procedures for escalating an appeal in paragraph (b); and the status of an appeal for which the adjudication time frame has expired but the appellant has not requested escalation in paragraph (c). We are proposing to remove and reserve § 405.1104 and incorporate the current § 405.1104 providing for escalating a request for an ALJ hearing to the Council into proposed § 405.1016(e) and (f) with revisions, as its current placement in the Council portion of part 405, subpart I has caused confusion. We also are proposing to insert ''or attorney adjudicator'' after ''ALJ'' in proposed § 405.1016(e) and (f) to assist appellants in understanding that the effect of exceeding the adjudication period and the option to escalate would apply to a request for an ALJ hearing following a QIC reconsideration when the request has been assigned to an attorney adjudicator, as discussed in section II.B, above.

Current § 405.1104(c) is titled ''No escalation'' and states that if the ALJ's adjudication period set forth in § 405.1016 expires, the case remains pending with the ALJ until a decision, dismissal order, or remand order is issued or the appellant requests

escalation to the Council. We are proposing in § 405.1016(e) to incorporate current § 405.1104(c) with changes. We are proposing to revise the paragraph title for proposed § 405.1016(e) to indicate that the paragraph discusses the effect of exceeding the adjudication period. Proposed § 405.1016(e) would provide that if an ALJ or an attorney adjudicator assigned to a request for hearing (as proposed in section II.B above) 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. We are proposing to indicate that 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.

Current § 405.1104(a) describes how to request an escalation and states that an appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending before the ALJ at the end of the applicable ALJ adjudication period may request Council review if the appellant files a written request with the ALJ to escalate the appeal to the Council after the adjudication period has expired, and the ALJ does not issue a decision, dismissal order, or remand order within the later of 5 calendar days of receiving the request for escalation or 5 calendar days from the end of the applicable adjudication period set forth in § 405.1016. We are proposing in § 405.1016(f)(1) to remove the requirement to request Council review in the course of requesting an escalation and to describe when and how to request escalation. Specifically, we are proposing to revise the current procedures at § 405.1104(a) and (a)(1), to provide that an appellant who files a timely request for a hearing with OMHA and whose appeal continues to be pending at the end of an applicable adjudication period may exercise the option to escalate the appeal to the Council by filing a written request with OMHA to escalate the appeal to the Council, which would simplify the process for appellants and adjudicators by only requiring appellants to file a single request for escalation with OMHA. We are proposing to replace the reference to an appeal that ''continues to be pending before the ALJ'' in current § 405.1104(a) with an appeal that ''continues to be pending with OMHA'' in proposed § 405.1016(f)(1) to be inclusive of situations in which the appeal is assigned to an ALJ or attorney adjudicator, or not yet assigned. We are also proposing that a written request to escalate an appeal to the Council would be filed with OMHA to allow OMHA to provide a central filing option for escalation requests. Current § 405.1106(b) requires that the appellant send a copy of the escalation request to the other parties and failing to do so tolls the Council's adjudication deadline set forth in § 405.1100 until the other parties to the hearing have received notice. As discussed in section III.A.5.c below, we are proposing to revise § 405.1106(b) to require that the request for escalation be sent to other parties who were sent a copy of the QIC reconsideration. Therefore, we are also proposing at § 405.1016(f)(1) that the appellant would send a copy of the escalation request to the other parties who were sent a copy of the QIC reconsideration so appellants would be aware of the requirement and which parties must be sent a copy of the escalation request.

Current § 405.1104(b) describes the escalation process and states if the ALJ is not able to issue a decision, dismissal order, or remand order within the time period set for in paragraph (a)(2) of the section (later of 5 calendar days of receiving the request for escalation or 5 calendar days from the end of the applicable adjudication period set forth in § 405.1016), he or she sends notice to the appellant acknowledging receipt of the request for escalation and confirming that the ALJ is not able to issue a decision, dismissal order, or remand order within the statutory time frame, or if the ALJ does not act on a request for escalation within the time period set forth in paragraph (a)(2) of the section or does not send the required notice to the appellant, the QIC decision becomes the decision that is subject to Council review consistent with § 405.1102(a). This process has caused confusion for both appellants and adjudicators because an initial escalation request must be filed with the ALJ, and if the ALJ is unable to issue a decision, dismissal or remand within 5 calendar days of receiving the escalation request or within 5 calendar days from the end of the applicable adjudication period, the appellant must file a request for Council review to move the appeal to the Council level, which some appellants do not file. This leaves it unclear to the ALJ and support staff whether to continue adjudicating the appeal after issuing a notice that the ALJ is unable to issue a decision, dismissal or remand within 5 calendar days of receiving the escalation request. We are proposing in § 405.1016(f)(2) to revise the escalation process. Specifically, we are proposing that if an escalation request meets the requirements of proposed § 405.1016(f)(1), and an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand within the later of 5 calendar days of receiving the request for escalation or 5 calendar days from the end of the applicable adjudication period, OMHA (to be inclusive of situations in which the appeal is assigned to an ALJ or attorney adjudicator, or not yet assigned) would send a notice to the appellant stating that an ALJ or attorney adjudicator is not able to issue a decision, dismissal order, or remand order within the adjudication period set forth in paragraph (a) or (c) of § 405.1016. We also are proposing that the notice would state that the QIC reconsideration would be the decision that is subject to Council review consistent with § 405.1102(a); and the appeal would be escalated to the Council in accordance with § 405.1108. OMHA would then forward the case file, which would include the file received from the QIC and the request for escalation and all other materials filed with OMHA, to the Council. We believe that this proposed process would help alleviate the current confusion, and would simplify the escalation process for appellants because appellants would not have to file a separate request for Council review after filing an escalation request with OMHA.

Currently, invalid escalation requests are not addressed in the regulations. We are proposing in § 405.1016(f)(3) to address invalid escalation requests. We are proposing that if an ALJ or attorney adjudicator determines an escalation request does not meet the requirements of proposed § 405.1016(f)(1), OMHA would send a notice to the appellant explaining why the request is invalid within 5 calendar days of receiving the request for escalation. For example, an escalation request would be deemed invalid if escalation is not available for the appeal, such as appeals of SSA reconsiderations; the escalation request is premature because the adjudication period has not expired; or the party that filed the escalation request did not file the request for hearing. 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 could file a new escalation request when the adjudication period expires.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Section 405.1016: Escalation of a request for an ALJ hearing'' at the beginning of your comment.

iii. Section 423.2016: Time frames for Deciding an Appeal of an IRE Reconsideration

Current § 423.2016 addresses the adjudication time frames for requests for hearing filed after an IRE has issued its reconsideration. The title of current § 423.2016 states, ''Timeframes for deciding an Appeal before an ALJ.'' We are proposing to revise the title of § 423.2016 to read ''Time frames for deciding an appeal of an IRE reconsideration'' in order to state that the section addresses adjudication time frames related to appeals of IRE reconsiderations and to accommodate the application of this section to attorney adjudicators, as proposed in Section II.B. above, and as discussed earlier. We also are proposing to insert ''or attorney adjudicator'' after ''ALJ'' throughout proposed § 423.2016 so that an adjudication time frame would apply to a request for an ALJ hearing following an IRE reconsideration when the request has been assigned to an attorney adjudicator, as discussed in section II.B, above.

Current § 423.2016(a) and (b) explain the adjudication time frames for standard and expedited appeals of IRE reconsiderations, respectively. However, the current paragraph titles refer to hearings and expedited hearings. We are proposing at § 423.2016(a) and (b) to retitle the 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. Similar to proposed § 405.1016, we are proposing at § 423.2016(a) and (b) to remove ''must'' in providing when an ALJ or attorney adjudicator issues a decision, dismissal order, or remand to the IRE, as appropriate, after the request for hearing is received by the office specified in the IRE's notice of reconsideration because there may be instances in which a decision, dismissal, or remand cannot be issued within the adjudication time frame, though we expect those instances to be rare because beneficiary and enrollee appeals are generally prioritized by OMHA. In addition, we are proposing in § 423.2016(a) and (b) to replace references to sending a request to the ''entity'' specified in the IRE's reconsideration, with the ''office'' specified in the IRE's reconsideration notice, to minimize confusion and delays in filing requests with OMHA. Similar to proposed § 405.1016(b)(2), we are proposing at § 423.2016(a)(3) and (b)(6) to adopt adjudication time frames for appeals that are remanded by the Council. Specifically, we are proposing in § 423.2016(a)(3) that if the Council remands a case and the case was subject to an adjudication time frame, the remanded appeal would be subject to the same adjudication time frame beginning on the date that OMHA receives the Council remand to provide enrollees with an adjudication time frame for remanded appeals. In § 423.2016(b)(6), we are proposing to 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 would apply to an appeal remanded by the Council. If the standards for an expedited appeal are no longer met, the adjudication time frame for standard appeals would apply because the criteria for an expedited hearing are no longer present. Finally, we are proposing at § 423.2016(b) to revise 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. For example, if an attorney adjudicator were to review a request for an expedited hearing and determine that the standards for an expedited hearing were met, but did not believe a decision could be issued without a hearing, the attorney adjudicator could provide the enrollee with notice that the appeal would be expedited and transfer the appeal to an ALJ for an expedited hearing and decision.

As described in section III.A.3.q below, we are proposing to move the provision for waiving the adjudication period from current § 423.2036(d) to proposed § 423.2016(c) because proposed § 423.2016 addresses adjudication time frames and we believe the section is a better place for discussing adjudication time frame waivers.

We are proposing that the provisions of proposed § 405.1016(d) be adopted in proposed § 423.2016(c) for adjudication period waivers and stays of the proceedings ordered by a court or granted by an ALJ or attorney adjudicator on motion by an enrollee.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Section 423.2016: Time frames for deciding an appeal of an IRE reconsideration'' at the beginning of your comment.

i. Submitting Evidence (§§ 405.1018 and 423.2018)

Current §§ 405.1018 and 423.2018 address submitting evidence before an ALJ hearing is conducted. We are proposing to retitle the sections from ''Submitting evidence before the ALJ hearing'' to ''Submitting evidence'' because evidence may be submitted and considered in appeals for which no hearing is conducted by an ALJ, and we believe an attorney adjudicator should be able to consider submitted evidence in deciding appeals as proposed in section II.B above. For the same reason, we are proposing in § 423.2018 to replace the references to ''hearings'' in the heading to paragraph (a) and in the introductory text to paragraphs (b) and (c), with ''appeals.'' We are also proposing to add headings to paragraphs that do not currently have headings, for clarity of the matters addressed in the paragraphs.

Current § 405.1018(a) states that, except as provided in this section, 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). We are proposing in § 405.1018(a) to provide for the submission of other evidence, in addition to written evidence, that the parties wish to have considered. Other evidence could be images or data submitted on electronic media. This revision would also be adopted in proposed § 405.1018(b) and § 423.2018(a), (b), and (c). We are also proposing in § 405.1018(a) to remove ''at the hearing'' so that parties would submit all written or other evidence they wish to have considered, and consideration of the evidence would not be limited to the hearing. We are proposing a corresponding change at proposed § 423.2018(a).

Current § 405.1018(a) states that evidence must be submitted with the request for hearing, or within 10 calendar days of receiving the notice of hearing. This provision has caused confusion as to when evidence is required to have been submitted

because current § 405.1014(a)(7) allows an appellant to state in the request for hearing that additional evidence will be submitted and the date it will be submitted. To reconcile the provisions, we are proposing in § 405.1018(a) to provide that parties must submit all written or other evidence they wish to have considered with the request for hearing, by the date specified in the request for hearing in accordance with proposed § 405.1014(a)(2), or if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing. We also are proposing that these revisions would be adopted in proposed § 423.2018(b) and (c).

Current § 405.1018(b) addresses how the submission of evidence impacts the adjudication period, and provides that if evidence is submitted later than 10 calendar days after receiving the notice of hearing, the period between when the evidence ''was required to have been submitted'' and the time it is received does not count towards an adjudication period. To simplify the provision, we are proposing at § 405.1018(b) that 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. This revision would also be adopted in proposed § 423.2018(b)(2) and (c)(2), except that in (c)(2), the adjudication time frame is affected if the evidence is submitted later than 2 calendar days after receipt of the notice of expedited hearing because 2 calendar days is the equivalent time frame to submit evidence for expedited appeals before the adjudication period is affected under current § 423.2018.

Current § 405.1018(c) addresses new evidence, and is part of the implementation of section 1869(b)(3) of the Act, which precludes a provider or supplier from introducing evidence after the QIC reconsideration unless there is good cause that prevented the evidence from being introduced at or before the QIC's reconsideration. These provisions, which provide for the early submission of evidence, allow adjudicators to obtain evidence necessary to reach the correct decision as early in the appeals process as possible. We are proposing to incorporate current § 405.1018(c), which requires a provider, supplier, or beneficiary represented by a provider or supplier that wishes to introduce new evidence to submit a statement explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker, in proposed § 405.1018(c)(1). However, current § 405.1018 does not address the consequences of not submitting the statement. The statute sets a bar to introducing new evidence, and the submitting party must establish good cause by explaining why the evidence was not previously submitted to the QIC, or a prior decision-maker. However, when a provider or supplier, or beneficiary represented by a provider or supplier, fails to include the required statement, OMHA ALJs and staff spend time seeking out the explanation and following up with parties to fulfill their obligation. Thus, we are proposing to revise § 405.1018(c)(2) to state that 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. Because only the enrollee is a party to a Part D appeal, there is no corresponding provision in proposed § 423.2016.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Submitting evidence'' at the beginning of your comment.

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

As the ALJ hearing function transitioned from SSA, where hearings could be held at over 140 hearing sites nation-wide, to OMHA with four field offices, OMHA became one of the first agencies to use video-teleconferencing (VTC) as the default mode of administrative hearings. The effective use of VTC mitigated OMHA's reduced geographic presence, and allowed OMHA to operate more efficiently and at lower cost to the American taxpayers. However, the preference of most appellants quickly turned to hearings conducted by telephone. In FY 2015, over 98% of hearings before OMHA ALJs were conducted by telephone. Telephone hearings provide parties and their representatives and witnesses with the opportunity to participate in the hearing process with minimal disruption to their day, and require less administrative burden at even lower cost to the American taxpayers than hearings conducted by VTC. OMHA ALJs also prefer telephone hearings in most instances, because they allow more hearings to be conducted without compromising the integrity of the hearing. However, when the ALJ conducting the hearing believes visual interaction is necessary for a hearing, he or she may conduct a VTC hearing, and when special circumstances are presented, ALJs may conduct in-person hearings.

Despite the shift in preferences for most appellants to telephone hearings, current § 405.1020 still makes VTC the default mode of hearing, with the option to offer a telephone hearing to appellants. In fact, some appellants have required the more expensive VTC hearing even when their representative is presenting only argument and no testimony is being offered. We believe this is inefficient and results in wasted time and resources that could be invested in adjudicating additional appeals, and unnecessarily increases the administrative burdens and costs on the government for conducting a hearing with little to no discernable benefit to the parties in adjudicating denials of items or services that have already been furnished. Based on these considerations, we are proposing that a telephone hearing be the default method, unless the appellant is an unrepresented beneficiary. We believe this balances the costs and administrative burdens with the interests of the parties, recognizing that unrepresented beneficiaries may have an increased need and desire to visually interact with the ALJ.

We are proposing in 405.1020(b) to provide two standards for determining how appearances are made, depending on whether appearances are by unrepresented beneficiaries or by individuals other than unrepresented beneficiaries. The provisions of current § 405.1020(b) would be incorporated into proposed § 405.1020(b)(1) and revised to be specific to an appearance by an unrepresented beneficiary who files a request for hearing. We are proposing in subsection (b)(1) that the ALJ would direct that the appearance of an unrepresented beneficiary who filed a request for hearing be conducted by 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. As in the current rule, we also are proposing in § 405.1020(b)(1) to allow the ALJ 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. The current standard for determining whether an in-person hearing should be conducted involves a finding that VTC technology is not available or special or extraordinary circumstances exist. Because, absent special or extraordinary circumstances, a hearing could still be conducted by telephone if VTC technology were unavailable, we are proposing that the standard for an in-

person hearing be revised to state that VTC or telephone technology is not available or special or extraordinary circumstances exist, and the determination would be characterized as finding good cause for an in-person hearing, to align with current § 405.1020(i)(5), which provides for granting a request for an in-person hearing on a finding of good cause. We also are proposing in §§ 405.1020(b)(1) and 405.1020(i)(5) to replace the reference to obtaining the concurrence of the ''Managing Field Office ALJ'' with the ''Chief ALJ or designee.'' The position of the Managing Field Office ALJ became what is now an Associate Chief ALJ, see 80 FR 2708, and using ''Chief ALJ or designee'' would provide OMHA with the flexibility to designate the appropriate individual regardless of future organizational changes. We are proposing to adopt these revisions in proposed §§ 423.2020(b)(1), for appearances by unrepresented enrollees and 423.2020(i)(5), for when an ALJ may grant a request for an in-person hearing. We are also proposing in § 405.1020(b)(1) to replace ''videoteleconferencing,'' with ''video-teleconferencing,'' for consistency with terminology used in §§ 405.1000, 405.1036, 423.2000, 423.2020 and 423.2036.

Proposed § 405.1020(b)(2) addresses appearances by an individual other than an unrepresented beneficiary who files a request for hearing. We are proposing in § 405.1020(b)(2) that the ALJ would direct that those individuals appear by telephone, unless the ALJ finds good cause for an appearance by other means. Further, we are proposing in § 405.1020(b)(2) that 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. Also, we are proposing that the ALJ, with the concurrence of the Chief ALJ or designee, 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. We are proposing to adopt these revisions in § 423.2020(b)(2) for appearances by represented enrollees, which is more specific than proposed § 405.1020(b)(2) because only enrollees are parties to appeals under part 423, subpart U, and the provisions of subsection (b)(2) would apply only to appearances by represented enrollees.

Current § 405.1020(c)(1) states that the ALJ sends a notice of hearing. This has caused confusion as to whether the ALJ must personally sign the notice, or whether it can be sent at the direction of the ALJ. We believe that the notice may be sent at the direction of the ALJ, and requiring an ALJ signature adds an unnecessary step in the process of issuing the notice. Therefore, we are proposing in § 405.1020(c)(1) that a notice of hearing be sent without further qualification, and to let other provisions indicate the direction that is necessary from the ALJ in order to send the notice, such as § 405.1022(c)(1), which provides that the ALJ sets the time and place of the hearing. We are proposing to adopt these provisions in § 423.2020(a)(1).

Current § 405.1020(c)(1) also requires that the notice of hearing be sent to the parties who filed an appeal or participated in the reconsideration, any party who was found liable for the services at issue subsequent to the initial determination, and the QIC that issued the reconsideration. However, there are instances in which a party who does not meet the criteria may face liability because the ALJ may consider a new issue based on a review of the record. To address this, we are proposing in § 405.1020(c)(1) to add that a party that may be found liable based on a review of the record must be sent a notice of hearing. In addition, current § 405.1020 does not address notices of hearing sent to CMS or a non-QIC contractor. Currently, ALJs may also send a notice of hearing to CMS or a contractor when the ALJ believes their input as a participant or party may be beneficial. We are proposing in § 405.1020(c)(1) that the notice of hearing also be sent to CMS or a contractor that the ALJ believes would be beneficial to the hearing. We are not proposing any corresponding revisions to current § 423.2020(c)(1) because only enrollees are parties to appeals under part 423, subpart U.

OMHA ALJs have expressed concern that parties and representatives who appear at a hearing with multiple individuals and witnesses who were not previously identified, complicate and slow the hearing process. While a party or representative has considerable leeway in determining who will attend the hearing or be called as a witness, prior notice of those individuals is necessary for the ALJs to schedule adequate hearing time, manage their dockets, and conduct the hearing. To address these concerns, we are proposing at § 405.1020(c)(2)(ii) to add a requirement to specify the individuals from the entity or organization who plan to attend the hearing if the party or representative is an entity or organization, and at subsection (c)(2)(iii) to add a requirement to list the witnesses who will be providing testimony at the hearing, in the response to the notice of hearing. We also are proposing to consolidate the provisions in current § 405.1020(c)(2)(i) and (c)(2)(ii) in proposed § 405.1020(c)(2)(i) to simplify the provisions related to the current requirements for replying to the notice of hearing. Thus, proposed subsection (c)(2)(i) would require 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. We are proposing at § 423.2020(c)(2) to adopt corresponding revisions for an enrollee's or his or her representative's reply to the notice of hearing.

We also are proposing in § 405.1020(c)(2) to remove 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, we are proposing in § 405.1020(c)(3) to 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. We are proposing at § 423.2020(c)(3) to adopt corresponding revisions for CMS', the IRE's, or the Part D plan sponsor' reply to the notice of hearing when the entity requests to attend the hearing as a participant.

In discussing a party's right to waive a hearing, current § 405.1020(d) states that a party may waive the right to a hearing and request that the ALJ issue a decision based on the written evidence in the record. In light of proposed § 405.1038(b), which would allow attorney adjudicators to issue decisions in appeals that do not require hearings on the record without an ALJ conducting a hearing in certain situations, we are proposing in § 405.1020(d) to state that a party also may waive the right to a hearing and request a decision based on the written evidence in the record in accordance with § 405.1038(b), but an ALJ may require the parties to attend a hearing if it is necessary to decide the case. We are proposing at § 423.2020(d) to adopt 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 in accordance with § 423.2038(b), but an ALJ could require the enrollee to attend a hearing if it is necessary to decide the case. These references would direct readers to

the section that provides the authority for a decision based on the written record, which would provide them with a complete explanation of when the authority may be used and notify them that an ALJ or attorney adjudicator may issue the decision.

In addressing the ALJ's authority to change the time or place of the hearing if the party has good cause to object, current § 405.1020(e) requires a party to make the request to change the time or place of the hearing in writing. However, on occasion, a party may need to request a change on the day prior to, or the day of a hearing due to an emergency, such as a sudden illness or injury, or inability to get to a site for the hearing. In this circumstance, we believe an oral request should be permitted. Therefore, we are proposing in § 405.1020(e)(3) that the request must be in writing, except that a party may orally request that a hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing, and the ALJ must document the oral request in the administrative record. We are proposing at § 423.2020(e)(3) to adopt a corresponding provision for an enrollee to orally request a rescheduled standard hearing, and to modify the documentation requirement, which is currently limited to documenting oral requests made for expedited hearings, to include all oral objections.

In addition, current §§ 405.1020(e)(4) and 423.2020(e)(4), which explain the ALJ may change the time or place of the hearing if the party has good cause, contain a parenthetical that references the procedures that an ALJ follows when a party does not respond to a notice of hearing and fails to appear at the time and place of the hearing. The parenthetical does not appear to address or assist in understanding the circumstances covered by current §§ 405.1020(e)(4) and 423.2020(e)(4), and we, therefore, are proposing to remove the parenthetical from the respective sections.

Current §§ 405.1020(g)(3) and 423.2020(g)(3) provide a list of examples of circumstances a party might give for requesting a change in the time or place of the hearing. We have heard from ALJs and stakeholders that it would be helpful to also include 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 determines 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. We are proposing in §§ 405.1020(g)(3)(vii) and (viii), and 423.1020(g)(3)(vii) and (viii) to add these two examples to address these circumstances. We believe these additional examples would provide greater flexibility in the appeals process and better accommodate the needs of appellants.

We are proposing in §§ 405.1020(h) and 423.2020(h) to revise the references to the adjudication ''deadline'' with references to the adjudication ''period,'' for consistency in terminology with the specified cross-references.

We are proposing revisions to § 405.1020(i) to align the provision with proposed § 405.1020(b). We are proposing in § 405.1020(i) that 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 party would be required to state the reason for the objection and the time and/or place that he or she wants an in-person or VTC hearing to be held, and the request must be in writing. We are proposing in § 405.1020(i)(4) to incorporate the current § 405.1020(i)(4) provision that requires the appeal to be adjudicated within the time frame specified in § 405.1016 if a request for an in-person or VTC hearing is granted unless the party waives the time frame in writing. However, we are proposing at § 405.1020(i)(4) to revise the language to more accurately state that the ALJ issues a ''decision, dismissal, or remand to the QIC,'' rather than just a ''decision,'' within the adjudication time frame specified in § 405.1016. We are proposing revisions to § 423.2020(i) to align the provision with proposed § 423.2020(b). We are proposing in § 423.2020(i) that if an unrepresented enrollee 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 represented enrollee who filed the request for hearing objects to a telephone or VTC hearing, the enrollee or representative 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 enrollee would be required to state the reason for the objection and the time and/or place that he or she wants an in-person or VTC hearing to be held. We are proposing in § 423.2020(i)(4) to incorporate the current § 423.2020(i)(4) provision with some modifications so that the appeal would be adjudicated within the time frame specified in § 423.2016 if a request for an in-person or VTC hearing is granted unless the party waives the time frame in writing. We are proposing at § 423.2020(i)(4) to revise the language to more accurately state that the ALJ issues a ''decision, dismissal, or remand to the IRE,'' rather than just a ''decision,'' within the adjudication time frame specified in § 405.1016 and to include requests for VTC hearings as well as requests for in-person hearings. In addition, we are proposing at §§ 405.1020(i)(5) and 423.2020(i)(5) to provide that upon a finding of good cause, a hearing would be rescheduled at a time and place when the party may appear in person or by VTC, to account for objections to VTC hearings as well as objections to telephone hearings or offers to conduct a hearing via telephone. We are also proposing to replace ''concurrence of the Managing Field Office ALJ'' with ''concurrence of the Chief ALJ or a designee'' because the position of Managing Field Office ALJ was replaced by the position of Associate Chief ALJ (80 FR 2708) and providing a more general reference would provide greater flexibility in the future as position titles change.

Current §§ 405.1020 and 423.2020 do not address what occurs when the ALJ changes the time or place of the hearing. We are proposing at § 405.1020(j) to add 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, in accordance with the procedures of § 405.1022(a), which addresses issuing a notice of hearing. We are proposing at § 423.2020(j) to add a provision 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 the enrollee and CMS, the IRE, and/or the Part D plan sponsor in accordance with the procedures of § 423.2022(a), which addresses issuing a notice of hearing. These would help ensure that if changes are made to the time or place of the hearing, a new

notice is issued or waivers are obtained in a consistent manner.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Time and place for a hearing before an ALJ'' at the beginning of your comment.

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

Current § 405.1022(a) provides that a notice of hearing will be mailed or personally served to the parties and other potential participants, but a notice is not sent to a party who indicates in writing that it does not wish to receive the notice. Current § 423.2022(a) provides that a notice of hearing will be mailed or otherwise transmitted, or personally served, unless the enrollee or other potential participant indicates in writing that he or she does not wish to receive the notice. However, currently § 405.1022(a) is limiting because it does not contemplate transmitting the notice by means other than mail or personal service even though technologies continue to develop and notice could be provided by secure email or a secure portal. Also, notices must be sent in accordance with any OMHA procedures that apply, such as procedures to protect personally identifiable information. In addition, the exception in current § 405.1022(a) does not contemplate a scenario in which a potential participant indicates that it does not wish to receive the notice, as is provided for in current § 423.2022(a). We are proposing in §§ 405.1022(a) and 423.2022(a) to address these issues and align the sections by providing that a notice of hearing would 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.

Current §§ 405.1022(a) and 423.2022(a) provide that a notice of hearing does not have to be sent to a party who indicates in writing that it does not wish to receive the notice and that the notice is mailed or served at least 20 calendar days (for Parts A and B and for non-expedited Part D hearings), or 3 calendar days (for expedited Part D hearings) before the hearing. The provisions do not address the situation where a party wishes to receive the notice, but agrees to the notice being mailed fewer than 20 calendar days (or 3 calendar days if expedited) before the hearing, which may be necessary to accommodate an appellant's request to conduct a hearing in fewer than 20 or 3 calendar days. We are proposing to revise §§ 405.1022(a) and 423.2022(a) to address this situation by providing the notice is mailed, transmitted, or served at least 20 calendar days (or 3 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 3 calendar days if expedited) before the hearing. However, we note that like a recipient's waiver of receiving a notice of hearing, a recipient's waiver of the requirement to mail, transmit, or serve the notice at least 20 or 3 calendar days (as applicable) before the hearing would only be effective for the waiving recipient and does not affect the rights of other recipients.

Current § 405.1022(b)(1) requires a notice of hearing to contain a statement of the specific issues to be decided and inform the parties that they may designate a person to represent them during the proceedings. These statements of issues take time to develop, and current § 405.1032, which addresses the issues before an ALJ, provides that the issues before the ALJ are all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor. Current § 405.1032 also permits an ALJ to consider a new issue at the hearing, if notice of the new issue is provided to all parties before the start of the hearing. To streamline the notice of hearing, rather than require the notice of hearing to contain a statement of the specific issues to be decided, we are proposing in § 405.1022(b)(1) to 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. This is consistent with the standard for determining the issues before the ALJ in proposed § 405.1032(a). However, we also are proposing in § 405.1022(b)(1) that the notice of hearing also would contain a statement of any specific new issues that the ALJ will consider in accordance with § 405.1032 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. For example, if in the request for hearing an appellant raises an issue with the methodology used to sample claims and extrapolate an overpayment, and that issue had not been brought out in the initial determination, redetermination, or reconsideration, the issue would be a new issue and the specific issue would be identified in the notice of hearing. To accommodate proposed § 405.1022(b)(1), we are proposing that the portion of current § 405.1022(b)(1) that requires the notice of hearing to inform the parties that they may designate a person to represent them during the proceedings would be re-designated as § 405.1022(b)(2), and current subsections (b)(2), (b)(3), and (b)(4) would be re-designated as subsections (b)(3), (b)(4), and (b)(5), respectively. We are proposing at § 423.2022(b) to adopt corresponding revisions for notice information in part 423, subpart U proceedings.

Current § 405.1022(c)(1) provides that if the appellant, any other party to the reconsideration to whom the notice of hearing was sent, or their representative does not acknowledge receipt of the notice of hearing, the ALJ hearing office attempts to contact the party for an explanation. We are proposing to replace ''ALJ hearing office'' with ''OMHA'' because OMHA is the responsible entity.

Current § 405.1022(c)(2) provides that if a party states that he or she did not receive the notice of hearing, an amended notice is sent to him or her. The reference to an amended notice has caused confusion, as the original notice does not need to be amended unless the hearing is rescheduled. We are proposing in § 405.1022(c)(2) to remove the reference to an ''amended'' notice of hearing and provide that a copy of the notice of hearing is sent to the party. However, if a party cannot attend the hearing, we are proposing in new § 405.1022(c)(3) that the party may request that the ALJ reschedule the hearing in accordance with proposed § 405.1020(e), which discusses a party's objection to the time and place of hearing. We are proposing at § 423.2022(c) to adopt corresponding revisions for providing a copy of the notice of hearing if the enrollee did not acknowledge it and states that he or she did not receive it in part 423, subpart U proceedings.

Current § 405.1022(c)(2) provides that if a party did not receive the notice of hearing, a copy of the notice may be sent by certified mail or email, if available. Current § 423.2022(c)(2) provides an additional option to send the copy by fax. However, use of email to send documents that contain a beneficiary's or enrollee's personally identifiable information is not currently permitted by OMHA policy, and faxes

must be sent in accordance with procedures to protect personally identifiable information. We are proposing in §§ 405.1022(c)(2) and 423.2022(c)(2) to remove the references to using email and fax, and to add that a notice may be sent by certified mail or other means requested by the party and in accordance with OMHA procedures. This would provide the flexibility to develop alternate means of transmitting the request and allow OMHA to help ensure necessary protections are in place to comply with HHS information security policies. Finally, the parenthetical in current §§ 405.1022(c)(2) and 423.2022(c)(2) is not applicable. We believe it was attempting to cross-reference the provision related to requesting a rescheduled hearing. Therefore, we are proposing in §§ 405.1022(c)(2) and 423.2022(c)(2) to remove the parenthetical. As discussed above, proposed §§ 405.1022(c)(3) and 423.2022(c)(3) would address the option for a party to request a rescheduled hearing and contain the correct cross-reference.

Current § 405.1024 sets forth the provision regarding objections by a party to the issues described in the notice of hearing. Current § 405.1024(b) requires a party to send a copy of its objection to the issues to all other parties to the appeal. We are proposing to revise § 405.1024(b) to provide that the copy is only sent 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, because we believe sending a copy of the objection to additional parties is unnecessary and causes confusion for parties who were not sent a copy of the notice of hearing. No corresponding change is proposed in § 423.2024 because only the enrollee is a party.

Current § 405.1024(c) states that an ALJ makes a decision on the objection to the issues either in writing or at the hearing. We are proposing to revise § 405.1024(c) to add the option for an ALJ to make a decision on the objections at a prehearing conference, which is conducted to facilitate the hearing, as well as at the hearing. We believe this added flexibility would allow ALJs to discuss the objections with the parties and make a decision on the record before the hearing at the prehearing conference. However, we note that the ALJ's decision on an objection to the issues at a prehearing conference pursuant to proposed § 405.1024(c) would not be subject to the objection process for a prehearing conference order under § 405.1040(d). A decision on an objection to the issues is not an agreement or action resulting from the prehearing conference, but rather the ALJ's decision on a procedural matter for which the ALJ has discretion, and we do not believe the parties should have a right of veto through the prehearing conference order objection process. We also are proposing at § 423.2024(c) to adopt a corresponding revision for a decision on an objection to the issues in part 423, subpart U proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Notice of a hearing before an ALJ and objections to the issue'' at the beginning of your comment.

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

Current § 405.1026 provides a process for a party to request that an ALJ disqualify himself or herself from an appeal, or for an ALJ to disqualify himself or herself from an appeal on the ALJ's own motion. We are proposing to revise § 405.1026 to replace the current references to conducting a hearing with references to adjudicating an appeal, to make it is clear that disqualification is not limited to ALJs or cases where a hearing is conducted to help ensure that an attorney adjudicator, as proposed in section II.B above, also cannot adjudicate an appeal if he or she is prejudiced or partial to any party, or has any interest in the matter pending for decision. Current § 405.1026(b) requires that, if a party objects to the ALJ who will conduct the hearing, the party must notify the ALJ within 10 calendar days of the date of the notice of hearing. The ALJ considers the party's objections and decides whether to proceed with the hearing or withdraw. However, the current rule does not address appeals for which no hearing is scheduled and/or no hearing will be conducted. Therefore, we are proposing to revise § 405.1026(b) 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. We also are proposing to revise § 405.1026(c) to state that an ALJ or attorney adjudicator is ''assigned'' to adjudicate an appeal, rather than ''appointed,'' for consistency in terminology, and to replace ''hearing decision'' with ''decision or dismissal'' because not all decisions are issued following a hearing and an appellant may have objected in an appeal that was dismissed, for which review may also be requested from the Council. In addition, we are proposing to add ''if applicable'' in discussing that the Council would consider whether a new hearing is held because not all appeals may have had or require a hearing. We are proposing at § 423.2026 to adopt corresponding revisions for disqualification of an ALJ or attorney adjudicator in part 423, subpart U proceedings.

Current § 405.1026 does not address the impact of a party objection and adjudicator's withdrawal on an adjudication time frame. The withdrawal of an adjudicator and re-assignment of an appeal will generally cause a delay in adjudicating the appeal. We are proposing in new § 405.1026(d) that if the party objects to the ALJ or attorney adjudicator, and the ALJ or attorney adjudicator subsequently withdrawals from the appeal, any applicable adjudication time frame that applies is extended by 14 calendar days. This would allow the appeal to be re-assigned and for the new adjudicator to review the appeal. We are proposing at § 423.2026(d) to adopt a corresponding provision for the effect of a disqualification of an adjudicator on an adjudication time frame in part 423, subpart U proceedings, but are proposing that if an expedited hearing is scheduled, the time frame is extended by 2 calendar days, to balance the need for the newly assigned adjudicator to review the appeal, and the enrollee's need to receive a decision as quickly as possible.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Disqualification of the ALJ or attorney adjudicator'' at the beginning of your comment.

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

Current § 405.1028 addresses the prehearing review of evidence submitted to the ALJ. We are proposing to revise the title of § 405.1028 to reflect that the regulation would more broadly apply 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 as proposed in section II.B above.

Proposed § 405.1028(a) would incorporate current § 405.1028(a) to address new evidence. Current § 405.1028(a) states that after a hearing is requested but before it is held, the ALJ will examine 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, by a provider, supplier, or beneficiary represented by a provider or supplier to determine whether there was good cause for submitting evidence for the first time at the ALJ level. However, this provision and the other provisions in current § 405.1028 do not address the review of new evidence when no hearing is conducted for an appeal. Therefore, we are proposing to revise § 405.1028(a) to add § 405.1028(a)(1), (2), (3), and (4), and are proposing in § 405.1028(a)(1) that after a hearing is requested but before it is held by an ALJ (to reinforce that hearings are only conducted by ALJs), or a decision is issued if no hearing is held, the ALJ or attorney adjudicator would review any new evidence. In addition, we are proposing in § 405.1028(a)(1) to remove 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,'' because § 405.1018 discusses when evidence may be submitted prior to a hearing and, as explained in III.A.3.i above, proposed § 405.1018 would revise the language that is duplicated in current § 405.1028. We believe that the better approach going forward is simply to reference § 405.1018 by indicating that the review is conducted on ''any new evidence submitted in accordance with § 405.1018.'' This would remind parties that evidence must be submitted in accordance with § 405.1018, while minimizing confusion on which section is authoritative with regard to when evidence may be submitted.

In a 2012 OIG report on the ALJ hearing process (OEI–02–10–00340), the OIG reported concerns regarding the acceptance of new evidence in light of the statutory limitation at section 1869(b)(3) of the Act on new evidence submitted by providers and suppliers. The OIG concluded that the current regulations regarding the acceptance of new evidence provide little guidance and only one example of good cause, and recommended revising the regulations to provide additional examples and factors for ALJs to consider when determining good cause.

Section 1869(b)(3) of the Act states that a provider or supplier may not introduce evidence in any appeal that was not presented at the QIC reconsideration unless there is good cause which precluded the introduction of such evidence at or before that reconsideration. This section presents a Medicare-specific limitation on submitting new evidence, and therefore limits the authority of an ALJ to accept new evidence under the broader APA provisions (see 5 U.S.C. 556(c)(3) (''Subject to published rules of the agency and within its power, employees presiding at hearings may– . . . receive relevant evidence . . . .'')). Section 1869(b)(3) of the Act also presents a clear intent by Congress to limit the submission of new evidence after the QIC reconsideration, which must be observed.

In light of the OIG conclusion and recommendation and to more effectively implement section 1869(b)(3) of the Act, we are proposing to incorporate current § 405.1028(b) in proposed § 405.1028(a)(2) on when an ALJ could find good cause for submitting evidence for the first time at the OMHA level, and to establish four additional circumstances in which good cause for submitting new evidence may be found. We are also proposing to permit an attorney adjudicator to find good cause because attorney adjudicators would be examining new evidence in deciding appeals on requests for an ALJ hearing as proposed in section II.B above, and we believe the same standard for considering evidence should apply.

We are proposing in § 405.1028(a)(2)(i) to adopt the example in current § 405.1028(b) and provide that good cause is found when the new evidence is, in the opinion of the ALJ or attorney adjudicator, material to an issue addressed in the QIC's reconsideration and that issue was not identified as a material issue prior to the QIC's reconsideration.

We are proposing in § 405.1028(a)(2)(ii) to provide that good cause is found when the new evidence is, in the opinion of the ALJ, material to a new issue identified in accordance with § 405.1032(b). This would provide parties with an opportunity to submit new evidence to address a new issue that was identified after the QIC's reconsideration. However, the authority is limited to ALJs because, as discussed in proposed § 405.1032, only an ALJ may raise a new issue on appeal.

We are proposing in § 405.1028(a)(2)(iii) to provide 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. For example, if specific medical records are necessary to support a provider's or supplier's claim for items or services furnished to a beneficiary, the provider or supplier must make reasonable attempts to obtain the medical records, such as requesting records from a beneficiary or the beneficiary's physician when it became clear the records are necessary to support the claim, and following up on the request. Obtaining medical records, in some cases from another health care professional, and submitting those records to support a claim for services furnished to a beneficiary is a basic requirement of the Medicare program (see sections 1815(a) and 1833(e) of the Act, and § 424.5(a)(6)), and we expect instances where records cannot be obtained in the months leading up to a reconsideration should be rare. If the provider or supplier was unable to obtain the records prior to the QIC issuing its reconsideration, good cause for submitting the evidence after the QIC's reconsideration could be found when the ALJ or attorney adjudicator determines that the provider or supplier submitted evidence that demonstrates the party made reasonable attempts to obtain the evidence before the QIC issued its reconsideration.

We are proposing at § 405.1028(a)(2)(iv) to provide that good cause is 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 was indeed submitted to the QIC or another contractor before the QIC issued the reconsideration. For example, if a provider or supplier submitted evidence to the QIC or another contractor and through administrative error, the evidence is not associated with the record that is forwarded to OMHA, good cause may be found when the ALJ or attorney adjudicator determines that the provider or supplier submitted evidence that demonstrates the new evidence was submitted to the QIC or another contractor before the QIC issued the reconsideration.

Finally, we are proposing at § 405.1028(a)(2)(v) to provide that in circumstances not addressed in proposed paragraphs (i) through (iv), 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. We expect proposed paragraphs (i) through (iv) to cover most circumstances in which a provider or supplier attempts to introduce new evidence after the QIC reconsideration, but we believe this additional provision is necessary to allow for a good cause finding in any

other circumstance that meets the requirements of section 1869(b)(3) of the Act. Paragraph (v) helps ensure that OMHA fulfills the statutory requirement by requiring that the ALJ or attorney adjudicator make a determination on whether the party could have obtained the evidence before the QIC issued its reconsideration.

To accommodate the new structure of proposed § 405.1028, we are proposing that current paragraphs (c) and (d) be re-designated as paragraphs (a)(3) and (a)(4), respectively. In addition, we are proposing at § 405.1028(a)(4) that notification about whether the evidence would be considered or excluded applies only when a hearing is conducted, and notification of a determination regarding new evidence would 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. We note that if a hearing is not conducted, whether the evidence was considered or excluded would be discussed in the decision, pursuant to proposed § 405.1046(a)(1), as discussed in section III.A.3.v below. We also are proposing at § 405.1028(a)(4) that the ALJ would 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 that this determination would be made no later than the start of the hearing, if a hearing is conducted. If evidence is excluded, it is excluded from consideration, not just the hearing, and evidence may be excluded from consideration even when no hearing is conducted. We believe that this would provide greater clarity to parties and participants regarding the ALJ's determination with respect to new evidence, and the effect of the exclusion of such evidence on the proceedings.

Current § 405.1028 does not address duplicative evidence. However, duplicative evidence is a significant challenge for OMHA because appellants often submit copies of medical records and other submissions that were filed at prior levels of appeal and are in the record forwarded to OMHA. While we recognize that appellants want to ensure the evidence is in the record and considered, we are also mindful that the APA provides that as a matter of policy, an agency shall provide for the exclusion of unduly repetitious evidence (see 5 U.S.C. 556(d)).

We are proposing in § 405.1028(b) that 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. In addition to establishing a general policy for the exclusion of unduly repetitious evidence, this would reduce confusion as to which of the multiple copies of records to review, and would reduce administrative burden.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Review of evidence submitted by the parties'' at the beginning of your comment.

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

The APA provides an ALJ with the authority to regulate the course of a hearing, subject to the rules of the agency (see 5 U.S.C. 556(c)(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. This may occur when a party or representative continues to present testimony or argument on a matter that is not relevant to the issues before the ALJ, or on a matter for which the ALJ believes he or she has sufficient information or on which the ALJ has already ruled. This may also occur when a party or representative is uncooperative, disruptive, or abusive during the course of the hearing. Sections 405.1030 and 423.2030 sets forth the rules that govern ALJ hearing procedures. We are proposing to revise §§ 405.1030(b) and 423.2030(b) to add provisions to address these circumstances in a consistent manner that protects the interests of the parties and the integrity of the hearing process. To accommodate these proposals, we are proposing to re-designate paragraph (b) in both §§ 405.1030 and 423.2030 as paragraph (b)(1), and to be consistent with proposed §§ 405.1018 and 423.2018, would replace 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).

We are proposing in § 405.1030(b)(2) to address 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. Proposed § 405.1030(b)(2) would allow the ALJ to effectively regulate the course of the hearing by providing the ALJ with the clear authority to limit testimony and/or argument during the hearing, while providing an avenue for the ALJ to allow the testimony and/or argument to be entered into the record. We are proposing at § 423.2030(b)(2) to adopt a corresponding revision for limiting testimony and argument at a hearing, and at the ALJ's discretion, provide an opportunity to submit additional written statements and affidavits in part 423, subpart U proceedings.

We are proposing at § 405.1030(b)(3) to address circumstances in which a party or representative is uncooperative, disruptive, or abusive during the course of the hearing. In these circumstances, we are proposing that the ALJ would 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. However, in this circumstance, the ALJ would be required to provide the excused party or representative with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing. Further, the party also would be allowed to request a copy of the audio recording of the hearing in accordance with § 405.1042 and respond in writing to any statements made by other parties or participants and/or testimony of the witnesses at the hearing, within a time frame designated by the ALJ. These proposals would allow the ALJ to effectively regulate the course of the hearing and balance the excused party's right to present his or her case, present rebuttal evidence, and cross-examine the witnesses of other parties with allowing the party to submit written statements and affidavits. We are proposing at § 423.2030(b)(3) to adopt a corresponding revision for excusing an enrollee or representative who is uncooperative, disruptive, or abusive during the hearing in part 423, subpart U proceedings.

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. We are proposing to revise § 405.1030(c) to add that the ALJ must determine whether the appellant had good cause in accordance with § 405.1028 for not producing the evidence. Section 1869(b)(3) of the Act applies to limit submission of all new evidence after the QIC reconsideration by a provider or supplier absent good cause, and the proposed addition would create consistent application of the standards for determining whether there is good cause to admit new evidence, regardless of when the evidence is submitted after the QIC reconsideration. We are not proposing any corresponding changes to current § 423.2030(c) because the limitation on new evidence does not apply in part 423, subpart U proceedings.

Current § 405.1030(d) and (e) discuss what happens if an ALJ determines there was or was not good cause for not producing the new evidence earlier. Current § 405.1030(d) provides that if the ALJ determines that good cause exists, the ALJ considers the evidence in deciding the case, and the adjudication period is tolled from the date of the hearing to the date that the evidence is submitted. Current § 405.1030(e) provides that if the ALJ determines that good cause does not exist, the evidence is excluded, with no impact on an applicable adjudication period. Current § 405.1030(d) and (e) have caused confusion in light of § 405.1018, which indicates that the adjudication period will be affected if evidence is submitted later than 10 calendar days after receipt of the notice of hearing, unless the evidence is submitted by an unrepresented beneficiary. It has also potentially created an incentive for appellants to disregard § 405.1018 because current § 405.1030(b) appears to allow evidence to be submitted at the hearing without affecting the adjudication time frame; and § 405.1030(c) allows the ALJ to stop a hearing temporarily if there is material evidence missing, with the effect of tolling the adjudication time frame from the date of the hearing to the date the evidence is submitted, if the evidence is in the possession of an appellant who is a provider or supplier or beneficiary represented by a provider or supplier, and the ALJ finds good cause to admit the evidence. In addition, OMHA ALJs have expressed concern that current § 405.1030(e) does not affect the adjudication period when an equal amount of time is spent reviewing evidence and making a good cause determination, regardless of whether good cause is found.

Therefore, we are proposing to revise § 405.1030(d) to address the effect of an evidentiary submission on an adjudication period. We are proposing in § 405.1030(d) that any applicable adjudication period is extended in accordance with proposed § 405.1018(b) if an appellant other than an unrepresented beneficiary submits evidence pursuant to proposed § 405.1030(b), which generally allows for submission of evidence at the hearing, or proposed § 405.1030(c), which specifically addresses evidence that the ALJ determines is missing at the hearing. Under proposed § 405.1018(b), any adjudication period that applies to the appeal would be extended by the number of days starting 10 calendar days after receipt of the notice of hearing, and ending when the evidence is submitted, whether it is at the hearing pursuant to proposed § 405.1030(b)(1), or at a later time pursuant to proposed § 405.1030(c). Proposed § 405.1030(d) would provide appellants with an incentive to submit evidence they wish to have considered early in the adjudication process, allow the ALJ to consider the evidence and effectively prepare for the hearing, and minimize any delays in the adjudication process resulting from the late introduction of evidence during the hearing process. Proposed § 405.1030(d) would also remove the potential incentive to disregard § 405.1018, and reconcile any inconsistency in the effect of a late evidentiary submission on an applicable adjudication period by incorporating the § 405.1018 provisions by reference rather than establishing a different standard for evidence submitted during the course of or after a hearing. We are proposing at § 423.2030(d) to adopt a corresponding provision for the effect on an adjudication time frame when new evidence is submitted by a represented enrollee in a standard appeal, or an unrepresented or represented enrollee in an expedited appeal, in accordance with current § 423.2018(b) or (c), as applicable.

Continuing a hearing is referenced in current § 405.1030(c), but is not otherwise addressed in part 405, subpart I. We are proposing in § 405.1030(e)(1) that a hearing may be continued to a later date and that the notice of the continued hearing would be sent in accordance with the proposed § 405.1022, except that a waiver of the notice of hearing may be made in writing or on the record, and the notice of continued hearing would 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. The notice requirement would help ensure that the general hearing notice requirements are met for a continued hearing, but allow a waiver of the notice of hearing to be made in writing or on the record. We believe the added option of waiving the notice of hearing on the record in the context of a continued hearing would facilitate scheduling the continued hearing when all parties and participants who are in attendance at the hearing agree to the continued hearing date, or alternatively agree on the record to the notice being mailed, transmitted, or served fewer than 20 calendar days before the hearing. In addition, proposed § 405.1030(e)(1) would only require that a notice of the continued hearing be sent to the participants and parties who attended the hearing, but would provide the ALJ with the discretion to also send the notice to additional parties, or potential parties or participants. We believe that a notice of the continued hearing to a party, or potential party or participant, who did not attend the hearing is not necessary unless the ALJ determines otherwise based on the circumstances of the case. In the event that the appellant requested the continuance and an adjudication period applies to the appeal, we are proposing in § 405.1030(e)(2) to provide that the adjudication period would be extended by the period between the initial hearing date and the continued hearing date. We believe an appellant's request for a continuance of the hearing is similar to an appellant's request to reschedule a hearing, and if the request is granted, the adjudication period for the appellant's request for hearing should be adjusted accordingly. We are proposing at § 423.2030(e) to adopt corresponding provisions for continued hearings in part 423, subpart U proceedings.

On occasion, after a hearing is conducted, ALJs 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 pursuant to § 405.986, which requires that the evidence (1) was not available or known at the time of the hearing, and (2) may result in a different conclusion. However, current § 405.1030(f) 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. We are proposing in § 405.1030(f)(1) to remove the ''reopen'' label and provide for a ''supplemental'' hearing rather than reopening the hearing to distinguish it from reopening a decision and the standards for reopening a decision. We are also proposing 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. The ALJ would determine whether a supplemental hearing is necessary, and if one is held, the scope of the supplemental hearing, including when evidence is presented and what issues are discussed. In addition, we are proposing at § 405.1030(f)(1) that a notice of the supplemental hearing be sent in accordance with § 405.1022 to the participants and parties who attended the hearing, but would provide the ALJ with the discretion to also send the notice to additional parties, or potential parties or participants the ALJ determines are appropriate. Similar to the proposed notice of a continued hearing explained above, we believe that a notice of the supplemental hearing to a party, or potential party or participant, who did not attend the hearing is not necessary unless the ALJ determines otherwise based on the circumstances of the case. In the event that the appellant requested the supplemental hearing and an adjudication period applies to the appeal, we are proposing at § 405.1030(f)(2) to provide that the adjudication period would be extended by the period between the initial hearing date and the supplemental hearing date. We believe an appellant's request for a supplemental hearing is similar to an appellant's request for a continuance or to reschedule a hearing, and if the request is granted, the adjudication period for the appellant's request for hearing should be adjusted accordingly. We are proposing at § 423.2030(f) to adopt corresponding provisions for supplemental hearings in part 423, subpart U proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''ALJ hearing procedures'' at the beginning of your comment.

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

Current §§ 405.1032 and 423.2032 address the issues that are before the ALJ. We are proposing to revise the title of the section to indicate that the proposed provision also would apply to issues before an attorney adjudicator, as proposed in section II.B above, if an attorney adjudicator is assigned to an appeal.

Current § 405.1032(a) 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. However, when a request for hearing involves a reconsideration of multiple claims and the appellant does not identify one or more of the claims that were not decided entirely in the party's favor at initial determination, redetermination, or reconsideration, it is unclear whether the ALJ should review all of the claims that were not decided entirely in the party's favor at initial determination, redetermination, or reconsideration, or just those claims specified by the appellant in the request for hearing. An appellant is required to identify the dates of service for the claims that it wishes to appeal in its request for hearing under § 405.1014, and some appellants have indicated that they do not specify a denied claim in a request for hearing when they agree that the record does not support coverage of the claim. To address the ambiguity, and in the interest of efficiency and consistency with § 405.1014, we are proposing in § 405.1032(a) that the issues before the ALJ or attorney adjudicator include all the issues for the claims or appealed matter (for example, for appeals that do not involve a claim for items or services furnished to a beneficiary, such as Medicare Secondary Payer appeals and terminations of coverage) 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. We are proposing at § 423.2032(a) to adopt a corresponding revision for issues in part 423, subpart U proceedings, except the term claims is not used because part 423, subpart U appeals do not involve claims.

Current § 405.1032(a) also notes that if evidence presented before the hearing causes the ALJ to question a favorable portion of the determination, the ALJ notifies the parties before the hearing and may consider it an issue at the hearing. As explained in the 2005 Interim Final Rule (70 FR 11462), this provision relates to the favorable portion of an appealed claim, and that the favorable issue is a new issue that must meet the requirements of current paragraph (b). However, in practice, this provision has been read to allow consideration of separate claims that were decided in a party's favor at lower appeal levels in multiple-claim appeals, and at times read independently from paragraph (b). To address this confusion, we are proposing to move this language in § 405.1032(a) to proposed § 405.1032(b), with the revisions discussed below. We are proposing at § 423.2032(a) and (b) to adopt corresponding revisions for new issues in part 423, subpart U proceedings.

Current § 405.1032(b) allows new issues to be considered at the hearing if: (1) the ALJ notifies the parties about the new issue before the start of the hearing; (2) the resolution of the new issue could have a material impact on the claim or claims that are the subject of the request for hearing; and (3) its resolution is permissible under the rules governing reopening of determinations and decisions. We are proposing at § 405.1032(b) to incorporate these provisions, with the revisions discussed below, as well as the language regarding consideration of favorable issues moved from current § 405.1032(a), in a revised structure.

We are proposing in § 405.1032(b)(1) to address when a new issue may be considered. Specifically, we are proposing that the ALJ may only consider the new issue, including a favorable portion of a determination on a claim or appealed matter specified in the request for hearing, if its resolution could have a material impact on the claim or appealed matter, and (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. This would consolidate the current provisions to better convey when a new issue may be considered, clarify that a new issue relates to a claim or appealed matter specified in the request for hearing, and provide the applicable standards from the reopening rules referenced in current § 405.1032(b)(1)(ii). We are proposing in § 405.1032(b)(1) to continue to provide that the new issue may be raised by the ALJ or any party and may include issues resulting from the participation of CMS, but correct the language so that it also references participation of CMS

contractors. We are proposing at § 423.2032(b)(1) to adopt corresponding revisions for when new issues may be considered in part 423, subpart U proceedings.

We are proposing at § 405.1032(b)(2) to continue to provide that notice of the new issue must be provided before the start of the hearing, but would 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.'' Because notice of the new issue may be made in the notice of hearing or after the notice of hearing, and parties generally have 10 calendar days after receipt of the notice of hearing to submit evidence, we are proposing at § 405.1032(b)(3) to also provide that if notice of the new issue is sent after the notice of hearing, the parties would have at least 10 calendar days after receiving the notice of the new issue to submit evidence regarding the issue. As provided in proposed § 405.1028(a)(2)(ii), the ALJ would then 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 would not be affected by the submission of evidence. Further, we are proposing at § 405.1032(b)(3) that if the hearing is conducted before the time to submit evidence regarding the issue expires, the record would remain open until the opportunity to submit evidence expires to provide the parties sufficient time to submit evidence regarding the issue. We are proposing at § 423.2032(b)(2) and (b)(3) to adopt corresponding provisions for providing notice of new issues to enrollees and an opportunity to submit evidence, and to add that an enrollee will have 2 calendar days after receiving notice of the new issue in an expedited appeal to submit evidence, which corresponds to the length of time permitted under proposed § 423.2018(c) to submit evidence after receiving a notice of expedited hearing.

Current § 405.1032(c) states that an ALJ cannot add any claim, including one that is related to an issue that is appropriately before an ALJ, to a pending appeal unless the claim has been adjudicated at the lower appeal levels and all parties are notified of the new issues before the start of the hearing. However, in practice, we are unaware that this provision is used, and to the extent it may be used, we believe it would be disruptive to the adjudication process, result in filing requirements not being observed, and risk adjudication of the same claim by multiple adjudicators. Therefore, we are proposing to maintain the topic of adding claims to a pending appeal, but replace the language of current § 405.1032(c), as explained below.

A reconsideration may be appealed for an ALJ hearing regardless of the number of claims involved in the reconsideration. However, we recognize that a party may not specify all of the claims from a reconsideration that he or she wishes to appeal in the party's request for hearing. We are proposing in § 405.1032(c)(1) to address this circumstance by providing that claims that were not specified in a request for hearing may only be added to a pending appeal if the claims were adjudicated in the same reconsideration that is appealed 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 in accordance with proposed § 405.1014(e). We believe that this would result in less disruption to the adjudication process, greater adherence to filing requirements, and reduce the risk of adjudication of the same claim by multiple adjudicators. To help ensure that the copy requirement of proposed § 405.1014(d) is observed, we are proposing at § 405.1032(c)(2) to 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 in accordance with § 405.1014(b) and other materials related to the claim that the appellant seeks to add to the pending appeal were sent to the other parties to the claim in accordance with § 405.1014(d). We are proposing at § 423.2032(c) to adopt a provision corresponding to proposed § 405.1032(c)(1), but we are not proposing to adopt a provision corresponding to § 405.1032(c)(2) because there is no § 423.2014 requirement for an enrollee to send a copy of his or her request to others.

Current § 405.1032 does not address issues related to an appeal that involves a disagreement with how a statistical sample and/or extrapolation was conducted. 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, we are proposing at § 405.1014(a)(3)(iii) to 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. We are proposing at § 405.1032(d)(1) to reinforce this requirement by excluding issues related to how the statistical sample and/or extrapolation were conducted if the appellant does not comply with § 405.1014(a)(3)(iii). In addition to reinforcing the proposed requirement at § 405.1014(a)(3)(iii), we believe that excluding the issue is appropriate because an appellant should reasonably be aware of whether it disagrees with how the statistical sampling and/or extrapolation was conducted at the time it files a request for hearing, and raising the issue later in the adjudication process or at the hearing can cause significant delays in adjudicating an appeal because the ALJ may need to conduct additional fact finding, find it necessary to request participation of CMS or one of its contractors, and/or call expert witnesses to help address the issue.

Related to the issues that an ALJ must consider, the 2005 Interim Final Rule (70 FR 11466) explained that current § 405.1064 was added to set forth a general rule regarding ALJ decisions that are based on statistical samples because a decision that is based on only a portion of a statistical sample does not accurately reflect the entire record. As discussed in the 2009 Final Rule (74 FR 65328), current § 405.1064 explains that when an appeal from the QIC involves an overpayment, and the QIC used a statistical sample in reaching its reconsideration, the ALJ must base his or her decision on a review of all claims in the sample. However, while a review of the claims selected for the sample is necessary to review issues related to a contested sample and extrapolation, for example to determine whether the sample claims were appropriately selected for a representative sample of the universe, current § 405.1064 has been read more broadly to also require adjudication of each sample claim, regardless of whether the sample claim was adjudicated favorably at lower appeal levels. We do not believe adjudicating sample claims that were decided favorably at lower levels of appeal, or sample claims that are not appealed by a party, is necessary to adjudicate broader issues with how sampling and extrapolation was conducted, and the broader reading of current § 405.1064 results in unnecessary adjudications of claims that were not appealed.

To clarify what is at issue and what must be considered in appeals involving statistical sampling and extrapolations, we are proposing to remove current § 405.1064, and address the matter in § 405.1032(d)(2). We are proposing in § 405.1032(d)(2) that if a party asserts a disagreement with how the statistical sampling methodology and

extrapolation were conducted in the request for hearing, in accordance with proposed § 405.1014(a)(3)(iii), § 405.1032(a) through (c) would apply to the adjudication of the sample claims. The result of applying proposed § 405.1032(a) and (b) would be that only the sample units that were specified in the request for hearing are individually adjudicated, subject to a new issue being identified for an appealed claim. However, proposed § 405.1032(c) would permit adding sample claims to a pending appeal if they were adjudicated in the appealed reconsideration and the time to request a hearing on the reconsideration has not expired, or the ALJ or attorney adjudicator extends the time to request an ALJ hearing on those claims in accordance with § 405.1014(e). To incorporate the principle embodied in current § 405.1064, we are proposing in § 405.1032(d)(2) that in deciding issues related to how a statistical sample and/or extrapolation was conducted, the ALJ or attorney adjudicator would base his or her decision on a review of the entire sample to the extent appropriate to decide the issue. We believe this more clearly conveys the intent of the rule and recognizes that an individual adjudication of each claim in the sample is not always necessary to decide an issue related to how a statistical sample and/or extrapolation was conducted, such as whether there is documentation so that the sampling frame can be re-created, as required by the Medicare Program Integrity Manual (Internet-Only Manual 100–08) (see chapter 8, § 8.4.4.4.1). We are not proposing any corresponding changes in § 423.2030 because statistical sampling and extrapolation are not currently used for matters that are subject to part 423, subpart U proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Issues before an ALJ or attorney adjudicator'' at the beginning of your comment.

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)

Current §§ 405.1034 and 423.2034 describe when an ALJ may request information from, or remand a case to a QIC or IRE. When the ALJ believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors, including an IRE, or the Part D plan sponsor, current §§ 405.1034(a) and 423.2034(a) allow an ALJ to remand the case to the QIC or IRE that issued the reconsideration, or retain jurisdiction of the case and request that the entity forward the missing information to the appropriate hearing office. The 2005 Interim Final Rule (70 FR 11465) explained that in the rare instance in which the file lacks necessary technical information that can only be provided by CMS or its contractors, it was believed that the most effective way of completing the record is to return the case, via remand, to the contractor; however, the ALJ also had the option of asking the entity to forward the missing information to the ALJ hearing office. In practice, stakeholders have expressed frustration and concern with the remand provisions because in accordance with the definition of a remand in § 405.902, a remand vacates the lower level appeal decision and therefore may require a QIC or IRE to issue a new reconsideration, for which the appellant must submit a new request for hearing, which causes additional delay in reaching finality on the disputed claims. In addition, current §§ 405.1034 and 423.2034 do not address providing notice of a remand or the effects of a remand.

To address stakeholders' concerns with the current remand provisions, and areas not addressed in current §§ 405.1034 and 423.2034, we are proposing to revise the sections to cover obtaining information that can be provided only by CMS or its contractors, or the Part D plan sponsor, and establishing new §§ 405.1056 and 405.1058 to address remands to a QIC, and new §§ 423.2056 and 423.2058 to address remands to an IRE.

We are proposing in § 405.1034(a) to 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 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 addition, we are revising § 405.1034(a) to include attorney adjudicators because attorney adjudicators would be authorized to adjudicate appeals, as proposed in section II.B. Also, while we are proposing to retain the definition of ''can be provided only by CMS or its contractors'' in § 405.1034(a)(2), we are proposing at § 405.1034(a)(1) to specify that official copies of redeterminations and reconsiderations that were conducted on the appealed claims can be provided only by CMS or its contractors. The redetermination and reconsideration are important documents that establish the issues on appeal, and while the parties often have copies of them, we believe the record should include official copies from the contractors. In addition, we are proposing at § 405.1034(b) to specify that the ALJ or attorney adjudicator would retain jurisdiction of the case, and the case would remain pending at OMHA. We are proposing at § 423.2034(a) and (b) to adopt corresponding provisions for when information may be requested from an IRE and that jurisdiction is retained at OMHA in part 423, subpart U proceedings.

We are proposing in § 405.1034(c) that the QIC would 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. This proposal would provide the ALJ or attorney adjudicator, the QIC, and the parties with a benchmark for obtaining the information and determining when adjudication of the case can resume. We are proposing in § 405.1034(d) that, if an adjudication period applies to the appeal in accordance with § 405.1016, the adjudication period would 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. We recognize that other provisions that extend an applicable adjudication period generally involve an appellant's action or omission that delays adjudicating an appeal within an applicable time frame, but we believe that an extension is also warranted to fully develop the record when the written record is missing information that is essential to resolving the issues on appeal, and that 20 calendar days (5 calendar days for the request to be received by the QIC and 15 calendar days for the QIC to respond) is a relatively modest delay in order to obtain missing information that is essential to resolving the appeal. We are proposing at § 423.2034(c) and (d) to adopt corresponding provisions for the IRE to furnish the information or otherwise respond to the request for information, either directly or through CMS or the Part D plan sponsor, and the effect on any applicable adjudication time frame in part 423, subpart U proceedings. In addition, we are proposing at § 423.2034(c) and (d) to provide for an accelerated response time frame for expedited appeals because of the urgency involved. For expedited appeals, we are proposing that the IRE

would have 2 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 would be up to 3 calendar days, to allow for time to transmit the request to the IRE and for the IRE to respond.

We are proposing to add new § 405.1056 to describe when a request for hearing or request for review of a QIC dismissal may be remanded, and new § 405.1058 to describe the effect of a remand. We are proposing in § 405.1056(a)(1) to permit a remand if an ALJ or attorney adjudicator requests an official copy of a missing redetermination or reconsideration for an appealed claim in accordance with proposed § 405.1034, and the QIC or another contractor does not furnish the copy within the time frame specified in § 405.1034. We also are proposing in § 405.1056(a)(2) to permit a remand when the QIC does not furnish a case file for an appealed reconsideration. The remand under both provisions would direct the QIC or other contractor (such as a Medicare Administrative Contractor that made the redetermination) to reconstruct the record or initiate a new appeal adjudication. We expect this type of remand to be very rare, but we believe it is necessary to help ensure a complete administrative record of the administrative adjudication of a claim. To address the possibility that the QIC or another contractor is able to reconstruct the record for a remanded case, we are proposing in § 405.1056(a)(3) to provide that in the situation where a record is reconstructed by the QIC, the reconstructed record would be returned to OMHA, the case would no longer be remanded and the reconsideration would no longer be vacated, and if an adjudication period applies to the case, the period would 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. This would help ensure that appellants are not required to re-start the ALJ hearing or dismissal review process in the event that the QIC or another contractor is able to reconstruct the record. We are proposing at § 423.2056(a) to adopt corresponding provisions for remanding cases in which there is a missing appeal determination or the IRE is unable to furnish the case file in part 423, subpart U proceedings.

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 current § 405.960, which only provides a right to a reconsideration when a redetermination is made by a contractor. We do not believe that an administrative error made by the QIC conveys rights that are not afforded under the rules. We are proposing in § 405.1056(b) to address 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 would be remanded to the QIC that issued the reconsideration, or its successor, to re-adjudicate the request for reconsideration. We again expect this type of remand to be rare, but believe it is necessary to correct administrative errors in the adjudication process. We are proposing at § 423.2056(b) to adopt a corresponding provision for when an IRE issues a reconsideration that addresses drug coverage when no redetermination was conducted or a request for redetermination was dismissed and is appealed to OMHA under part 423, subpart U.

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. Current § 405.1034 does not address this type of request. We are proposing at § 405.1056(c)(1) to provide a mechanism for these remands. Specifically, we are proposing that at any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the appellant and CMS or one of its contractors, may jointly request a remand of the appeal to the entity that conducted the reconsideration. We are proposing that the request include the reasons why the appeal should be remanded and indicate whether remanding the case would likely resolve the matter in dispute. Proposed § 405.1056(c)(2) would allow the ALJ or attorney adjudicator to determine whether to grant the request and issue the remand, based on his or her determination of whether remanding the case would likely resolve the matter in dispute. We believe this added flexibility would allow appellants and CMS and its contractors to expedite resolution of a disputed claim when there is agreement to do so. We are proposing at § 423.2056(c) to adopt corresponding provisions for requested remands in part 423, subpart U proceedings.

Current § 405.1034(b) provides that if, consistent with current § 405.1004(b), the ALJ determines that a QIC's dismissal of a request for reconsideration was in error, the case will be remanded to the QIC. We are proposing at § 405.1056(d) to incorporate this provision and proposed § 423.2056(d) would adopt a corresponding provision to incorporate current § 423.2034(b)(1) for remanding cases in which an IRE's dismissal of a request for reconsideration was in error, in part 423, subpart U proceedings. In addition, we are proposing at § 423.2056(e) to incorporate current § 423.2034(b)(2), which provides that if an enrollee wants evidence of a change in his or her condition to be considered in the appeal, the appeal would be remanded to the IRE for consideration of the evidence on the change in condition.

Current § 405.1034(c) provides that the ALJ remands an appeal to the QIC that made the reconsideration if the appellant is entitled to relief pursuant to 42 CFR 426.460(b)(1), 426.488(b), or 426.560(b)(1), and provides that unless the appellant is entitled to such relief, the ALJ applies the LCD or NCD in place on the date the item or service was provided. We are proposing to incorporate these provisions at § 405.1056(e). We did not propose any corresponding provision for § 423.2056 because there is not a similar current provision for part 423, subpart U proceedings.

As noted above, current § 405.1034 does not address providing a notice of remand. We are proposing at § 405.1056(f) to provide that OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to all of the parties who were sent a copy of the request at their last known address, and CMS or a contractor that elected to be a participant to the proceedings or a party to the hearing. The notice would state that, as discussed below, there is a right to request that the Chief ALJ or a designee review the remand. We believe this would help ensure that the parties and CMS and its contractors receive notice that the remand order has been issued. We are proposing at § 423.2056(f) to adopt a corresponding provision for a notice of remand in part

423, subpart U proceedings, except that only the enrollee receives notice because only the enrollee is a party, and CMS, the IRE, and the Part D plan sponsor only receive notice if they requested to participate and the request was granted.

Stakeholders have recounted instances in which they believe a remand was not authorized by the regulations, but were unable to take any action to correct the perceived error because a remand is not an appealable action and current § 405.1034 does not provide a review mechanism. We do not believe that remands should be made appealable actions, but recognize that stakeholders need a mechanism to address remands that they believe are not authorized by the regulation. We are proposing in § 405.1056(g) to provide 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 by § 405.1056, the remand order would be vacated. We are also proposing that 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. We are proposing at § 423.2056(g) to adopt a corresponding provision for reviewing a remand in part 423, subpart U proceedings.

Current § 405.1034 does not discuss the effect of a remand. We are proposing at § 405.1058, similar to current §§ 405.1048 and 405.1054 which describe the effects of a decision and dismissal, respectively, that a remand of a request for hearing or request for review is binding unless it is vacated by the Chief ALJ or a designee in accordance with proposed § 405.1056(g). We believe the provision would add clarity for the parties and other stakeholders on the effect of a remand order. We are proposing at § 423.2058 to adopt a corresponding provision for the effect of a remand in part 423, subpart U proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Requesting information from the QIC or IRE, and remanding an appeal'' at the beginning of your comment.

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

Current §§ 405.1036 and 423.2036 describe the ALJ hearing process, including the right to appear and present evidence, waiving the right to appear at the hearing, presenting written statements and oral arguments, waiver of the adjudication period, what evidence is admissible at the hearing, subpoenas, and witnesses at a hearing. Current § 405.1037 describes the discovery process in part 405, subpart I proceedings, which is permitted when CMS or a contractor elects to be a party to the ALJ hearing; there is no corresponding provision for part 423, subpart U proceedings because CMS, the IRE, and the Part D plan sponsor may not be made parties to the hearing.

Current § 405.1036(b)(1) states that a party may ''send the ALJ'' a written statement indicating that he or she does not wish to appear at the hearing. We are proposing at § 405.1036(b)(1) to revise 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. While the written statement could still be sent to an ALJ who is assigned to a request for hearing, we are proposing that the statement could be submitted to OMHA (for example, the statement could be submitted with the request for hearing), or to the ALJ or attorney adjudicator, as proposed in section II.B above, 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. We are proposing at § 423.2036(b)(1) to adopt a corresponding revision for submitting a waiver of the right to appear in part 423, subpart U proceedings. In addition, we are proposing at § 423.2036(b)(1)(ii) to revise the current requirement for the ''ALJ hearing office'' to document oral requests to require ''OMHA'' to document oral requests, to help ensure that applicability of the requirement is clear regardless of whether the oral request is received by an adjudicator in an OMHA field office after the appeal is assigned to an ALJ or attorney adjudicator, or the oral request is received in the OMHA central office before the appeal is assigned to an ALJ or attorney adjudicator.

As discussed in section III.A.3.h above, we are proposing to move the provision for waiving the adjudication period from current § 405.1036(d) to proposed § 405.1016(d) because proposed § 405.1016 addresses adjudication time frames and we believe the section is a better place for discussing adjudication time frame waivers. To accommodate moving current § 405.1036(d) to proposed § 405.1016(d), we are proposing to re-designate current § 405.1036(g), which describes witnesses at the hearing, as proposed § 405.1036(d) because it more logically follows the discussion of presenting witnesses and oral arguments in current § 405.1036(c). For the same reasons, we are proposing to move the provisions at § 423.2036(d) to proposed § 423.2016(c), and proposing at § 423.2036(d) to re-designate current § 423.2036(g) as proposed § 423.2036(d) to describe witnesses at a hearing in part 423, subpart U proceedings.

Current § 405.1036(f) discusses subpoenas. Current § 405.1036(f)(5)(i) states that an ALJ ruling on a subpoena request is not subject to immediate review by the Council and may be reviewed solely during the course of the Council's review specified in § 405.1102 (for requests for Council review when an ALJ issues a decision or dismissal), § 405.1104 (for requests for escalation to the Council), or § 405.1110 (for referrals for own motion review by the Council). As discussed in section III.A.3.h.ii above, we are proposing to remove section § 405.1104 and relocate provisions dealing with escalation to the Council to § 405.1016. Because the process for requesting escalation to the Council is now described in proposed § 405.1016(e) and (f), we are proposing at § 405.1036(f)(5)(i) to replace the reference to § 405.1104 with a reference to § 405.1016(e) and (f). Current § 405.1036(f)(5)(ii) discusses CMS objections to a ''discovery ruling'' in the context of a paragraph on reviewability of subpoena rulings and current § 405.1037(e)(2)(i) separately addresses CMS objections to a discovery ruling. We are proposing to revise § 405.1036(f)(5)(ii) to replace the current reference to a ''discovery ruling'' with ''subpoena ruling'' so it is consistent with the topic covered by § 405.1036(f). No corresponding revisions are necessary in § 423.2036(f) because there is no reference to a ''discovery ruling.''

Current § 405.1037(a)(1) 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 CMS or one of its contractors can elect to be a participant in the proceedings, including the hearing, in accordance with current and proposed § 405.1010, or elect to be a party to the hearing in accordance with current and proposed § 405.1012. We are proposing to revise § 405.1037(a)(1) to state that discovery is permissible only when CMS or its contractor elects to be a party to an ALJ hearing, in accordance with proposed § 405.1012. As noted above, there are no provisions for discovery in part 423, subpart U proceedings because CMS, the IRE, or

the Part D plan sponsor are not permitted to be a party to the hearing.

Current § 405.1037(e)(1) states that an ALJ discovery ruling or disclosure ruling is not subject to immediate review by the Council and may be reviewed solely during the course of the Council's review specified in § 405.1100 (for Council review in general), § 405.1102 (for requests for Council review when an ALJ issues a decision or dismissal), § 405.1104 (for requests for escalation to the Council), or § 405.1110 (for referrals for own motion review by the Council). For the reasons discussed above with regard to similar proposed changes in § 405.1036, we are proposing at § 405.1037(e)(1) to replace the reference to § 405.1104 with a reference to § 405.1016(e) and (f).

Current § 405.1037(f) describes the effect of discovery on an adjudication time frame, and provides that the time frame is tolled until the discovery dispute is resolved. However, it does not clearly state when the effect on an adjudication time frame begins, and ''discovery dispute'' is not used elsewhere in the section. In addition, current § 405.1037(f) does not contemplate that an adjudication time frame may not apply (for example, when the adjudication time frame is waived in accordance with proposed § 405.1016(d)). Therefore, we are proposing to revise § 405.1037(f) to state that if an adjudication period applies to the appeal in accordance with § 405.1016, and a party requests discovery from another party to the hearing, the adjudication period is extended for the duration of discovery, from the date a discovery request is granted until the date specified for ending discovery. We believe this revision would provide a clearer standard for how an adjudication period is affected by discovery proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Description of the ALJ hearing process and discovery'' at the beginning of your comment.

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

Current § 405.1038(a) provides authority to issue a ''wholly favorable'' decision without a hearing before an ALJ and without giving the parties prior notice when the evidence in the hearing record supports a finding in favor of the appellant(s) on every issue. We are proposing in § 405.1038 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, as proposed in section II.B above, 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 in accordance with § 405.1012. Proposed § 405.1038(a) would replace ''wholly favorable'' with ''fully favorable'' in the subsection heading to align with language in § 405.1000(g), which addresses a fully favorable decision being made on the record, and the nomenclature used in OMHA's day to day operations. Proposed § 405.1038(a) would also replace ''hearing record'' with ''administrative record'' for consistency with other references to the record, and replace ''hearing decision'' with ''decision,'' for consistency with other references to a decision. We are proposing at § 423.2038(a) to adopt corresponding revisions to align with language in § 423.2000(g) and to make references to the record and decisions consistent in part 423, subpart U proceedings.

Proposed § 405.1038(a) would 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 could not be issued pursuant to proposed § 405.1038(a) if another party to the appeal is liable for the claims at issue. Second, a decision could not be issued pursuant to proposed § 405.1038(a) if CMS or a contractor elected to be a party to the hearing in accordance with § 405.1012. We recognize that this may limit decisions that may be issued pursuant to § 405.1038(a); however, we believe only a small number of appeals would be affected, and the new limitations would mitigate the impact of such a decision on the other parties to the appeal and the likelihood of an appeal to, and remand from, the Council. No corresponding changes are proposed in § 423.2038(a) because only the enrollee is a party in part 423, subpart U proceedings.

Current § 405.1038(b)(1) 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. We are proposing to retain this structure in proposed § 405.1038(b) but are proposing some changes. Current § 405.1038(b)(1)(i) requires all parties to indicate in writing that they do not wish to appear before the ALJ at a hearing, and as indicated above, current § 405.1038(b)(1)(ii) is contingent on no other parties wishing to appeal. However, the requirement to obtain a writing from all parties or determine the wishes of the non-appellant parties has limited the utility of the provisions. While all parties have a right to appear at the hearing, a notice of hearing is not sent to parties who did not participate in the reconsideration and were not found liable for the items or services at issue after the initial determination, in accordance with current § 405.1020(c). We are proposing at § 405.1038(b)(1)(i) and (b)(1)(ii) to modify the requirements so writings only need to be obtained 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. In addition, proposed § 405.1038(b)(1) would reinforce that only an ALJ conducts a hearing by indicating an ALJ or attorney adjudicator may decide a case on the record without an ALJ conducting a hearing. Proposed § 405.1038(b)(1)(ii) also would indicate that an appellant who lives outside of the United States would inform ''OMHA'' rather than ''the ALJ'' that he or she wants to appear at a hearing before an ALJ, so an appellant could make that indication before an appeal is assigned to an ALJ or attorney adjudicator. We are proposing at § 423.2038(b)(1) and (b)(1)(ii) to adopt corresponding revisions to reinforce that only an ALJ conducts a hearing and an enrollee who lives outside of the United States would inform OMHA that he or she wishes to appear at a hearing before an ALJ, but the other changes in proposed § 405.1038(b) are not made to § 423.2038(b) because only the enrollee is a party in part 423, subpart U proceedings. We are also proposing in § 405.1038(b)(1)(i) to replace ''videoteleconferencing,'' and in § 423.2038(b)(1)(i) to replace ''video teleconferencing,'' with ''video-teleconferencing,'' for consistency with terminology used in §§ 405.1000, 405.1036, 423.2000, 423.2020, and 423.2036.

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. However, there are no current provisions that address this circumstance and it is one that is ideal for a summary decision in favor of the parties based on the statement by CMS or its contractor, in lieu of a full decision that includes findings of fact, conclusions of law, and other decision requirements. We are proposing to add § 405.1038(c) to provide a 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. We are proposing at § 423.2038(c) to adopt a corresponding authority for stipulated decisions in part 423, subpart U proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Deciding a case without a hearing before an ALJ'' at the beginning of your comment.

s. Prehearing and Posthearing Conferences (§§ 405.1040 and 423.2040)

Current § 405.1040 discusses prehearing and posthearing conferences and permits the ALJ to hold these conferences to facilitate the hearing or hearing decision. Current § 405.1040(b) requires an ALJ to inform ''the parties'' of the time, place, and purpose of the prehearing or posthearing conference, unless a party indicates in writing that it does not wish to receive a written notice of the conference. In accordance with current § 405.1020(c), the notice of hearing is not sent to a party who did not participate in the reconsideration and was not found liable for the services at issue after the initial determination. Therefore, we are proposing to modify § 405.1040(b) to state that the ALJ would inform parties who would be or were sent a notice of hearing in accordance with § 405.1020(c). In addition, current § 405.1040(b) does not provide for conference notice to be sent to CMS or a contractor that elected to be a participant in the proceedings or a party to the hearing at the time the conference notice is sent, which has caused confusion when CMS or a contractor has made an election before or after a conference. Therefore, we are proposing at § 405.1040(b) that a conference notice be sent to CMS or a contractor that has elected to be a participant in the proceedings or a party to the hearing at the time the conference notice is sent. We believe these changes would help ensure the appropriate parties and participants are provided with notice of, and have an opportunity to attend, a conference. We are proposing at § 423.2040(b) and (c) to adopt corresponding revisions for prehearing conference notices in non-expedited and expedited hearings respectively to state that a conference notice is sent to CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant in the hearing, but we are not proposing to make other changes in proposed § 405.1040(b) to § 423.2040 because only the enrollee is a party in part 423, subpart U proceedings. In addition, because an oral request not to receive a notice of the conference is permitted for expedited hearings, we are proposing at § 423.2040(d) to revise the requirement for an ''ALJ hearing office'' to document such an oral request to provide more generally that oral requests must be documented, which is generally done by the ALJ's support staff, rather than other office staff. In addition, we are proposing at § 423.2040(d) that documentation of an oral request not to receive written notice of the conference must be added to the administrative record for consistency in how the record is referenced.

Current § 405.1040(c) states that, at the conference, the ALJ may consider matters in addition to those stated in the notice of hearing, if the parties consent in writing. However, OMHA ALJs have indicated that providing them with the discretion to delegate conducting a conference to an attorney would add efficiency to the process. OMHA attorneys are licensed attorneys who support ALJs in evaluating appeals and preparing appeals for hearing, as well as drafting decisions, and are well versed in Medicare coverage and payment policy, as well as administrative procedure. Therefore, we are proposing at § 405.1040(c)(1) that, at the conference, the ALJ or an OMHA attorney designated by the ALJ may conduct the conference, but only the ALJ conducting a conference may consider matters in addition to those stated in the conference notice if the parties consent to consideration of the additional matters in writing. This revision would allow an OMHA attorney designated by the ALJ assigned to an appeal to conduct a conference, but would only allow an ALJ conducting the conference to consider matters in addition to those stated in the conference notice. We believe allowing ALJs to delegate the task of conducting a conference (consistent with the conference notice stating the purpose of the conference, in accordance with § 405.1040(b)) would provide ALJs with the flexibility to use OMHA attorneys and provide ALJs with more time to devote to hearings and decisions. We also believe using attorneys to conduct conferences is appropriate because conferences are informal proceedings to facilitate a hearing or decision, and do not involve taking testimony or receiving evidence, both of which occur at the hearing. We also note that the results of the conference embodied in a conference order are subject to review and approval by the ALJ, and ultimately subject to an objection by the parties, under the provisions of current § 405.1040, which are carried over in proposed § 405.1040. We are proposing at § 423.2040(e)(1) to adopt corresponding revisions for allowing an ALJ to delegate conducting a conference to an OMHA attorney, in part 423, subpart U proceedings.

Current § 405.1040(c) references the notice of hearing in discussing the matters that are considered at a conference. However, a notice of hearing may not have been issued at the time a prehearing conference is scheduled, and the matters being addressed in the appeal may have evolved since a notice of hearing was issued by the time a posthearing conference is scheduled, resulting in confusion on the permissible scope of the matters discussed at a conference. Therefore, § 405.1040(c)(1) would state that the matters that are considered at a conference are those stated in the conference notice (that is, the purpose of the conference, as discussed in current § 405.1040(b)).

Current § 405.1040(c) states that a record of the conference is made. However, that requirement has been read and applied differently by adjudicators. We are proposing at § 405.1040(c)(2) to require that an audio recording of the conference 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. We are proposing at § 423.2040(e)(1) and (e)(2) to adopt corresponding revisions to reference a conference notice and clarify that an audio recording of the conference is made in part 423, subpart U proceedings.

Current § 405.1040(d) requires the ALJ to issue an order stating all agreements and actions resulting from the conference. If the parties do not object, the agreements and actions become part of the hearing record and are binding on

all parties. It does not state to whom a conference order is issued, and again broadly references parties in indicating who may object to the order. In addition, current § 405.1040(d) does not establish a time period within which an objection must be made before the order becomes part of the record and binding on the parties. Therefore, we are proposing to revise § 405.1040(d) to state that the ALJ issues an order to all parties and participants who attended the conference stating all agreements and actions resulting from the conference. If a party does not object within 10 calendar days of receiving the order, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on all parties. Proposed § 405.1040(d) would provide that 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 as in current § 405.1040(d), only a party could object to the order. Proposed § 405.1040(d) would also establish that 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 would also provide the ALJ with the discretion to grant additional time. In addition, proposed § 405.1040(d) would replace ''hearing record'' with ''administrative record'' for consistency with other references to the record. Further, proposed § 405.1040(d) would continue to only allow the ALJ to issue a conference order, because we believe the ALJ should review and approve the actions and agreements resulting from the conference, and only an ALJ should issue an order that would be binding on the parties, if no objection is made. We are proposing at § 423.2040(f) to adopt corresponding revisions to clarify to whom a conference order is sent and the time frame to object to the order, and to specify that agreements and actions resulting from the conference become part of the ''administrative record'' (rather than ''hearing record'') in part 423, subpart U proceedings. However, we are proposing to add that an enrollee must object to a conference order within 1 calendar day of receiving the order for expedited hearings because of the abbreviated time frame under which an expedited hearing and decision must be completed.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Prehearing and posthearing conferences'' at the beginning of your comment.

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

The administrative record is HHS's record of the administrative proceedings, and is initially 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 §§ 405.1042 and 423.2042 vary widely. Given the importance of the administrative record, we are proposing to revise §§ 405.1042 and 423.2042 to provide for more consistency and to clarify its contents and other administrative matters.

Current § 405.1042(a)(1) provides that the ALJ makes a complete record of the evidence, including the hearing proceedings, if any. However, this provision has been limiting and causes confusion in developing procedures to ensure the completeness of the record and in bringing consistency to how the record is structured because individual adjudicators organize the record differently. We are proposing to revise § 405.1042(a)(1) to require OMHA to make a complete record of the evidence and administrative proceedings on the appealed matter, including any prehearing and posthearing conferences, and hearing proceedings that were conducted. Proposed § 405.1042(a)(1) would vest OMHA, rather than the ALJ, with the responsibility of making a complete record of the evidence and administrative proceedings in the appealed matter, including any prehearing and posthearing conferences and hearing proceedings. This would provide OMHA with more discretion to develop polices and uniform procedures for constructing the administrative record, while preserving the role of the ALJ or attorney adjudicator, as proposed in section II.B above, to identify the evidence that was used in making the determinations below and the evidence that was used in making his or her decision. We are proposing at § 423.2042(a)(1) to also adopt corresponding revisions to indicate OMHA makes a complete record of the evidence and administrative proceedings in the appealed matter in part 423, subpart U proceedings.

Current § 405.1042(a)(2) discusses which documents in the record are marked as exhibits, and 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. It further states that in the record, the ALJ also must discuss any evidence excluded under § 405.1028 and include a justification for excluding the evidence. We are proposing to revise § 405.1042(a)(2) to state that the record would include marked as exhibits, the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney admits. We are proposing that attorney adjudicators could mark exhibits because as proposed in section II.B, attorney adjudicators would be adjudicating requests for hearing and requests for review of a QIC dismissal, and should indicate the portions of the record that he or she considered in making the decision in the same manner as an ALJ. Proposed § 405.1042(a)(2) would continue to require certain evidence to be marked as exhibits, but would clarify what would be marked, replacing ''the documents used in making the decision under review,'' with ''the appealed determinations, and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision.'' We believe this would clarify that the exhibited portion of the record includes, at minimum, the appealed determinations, documents and other evidence used in making the appealed determinations, and documents and other evidence used in making the ALJ's or attorney adjudicator's decision. The illustrative list of documents that may be marked as exhibits pursuant to the rule in current § 405.1042(a)(2) would be incorporated in proposed § 405.1042(a)(2) without change. We also are proposing to clarify at § 405.1042(a)(2) that the record would 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. However, such excluded evidence would not be marked as an exhibit because the evidence was not considered in making the ALJ's or attorney adjudicator's decision. We are proposing at § 423.2042(a)(2) to adopt corresponding revisions to clarify what would be exhibited in part 423, subpart U proceedings, except the reference to new evidence submitted by a provider or supplier, or beneficiary represented by a provider or supplier, for which no good cause was established as an example of evidence excluded or not considered by the ALJ or attorney adjudicator, because there is no such limitation on new evidence in part 423, subpart U proceedings.

As stated previously, current § 405.1042(a)(2) includes requirements to discuss any evidence excluded under current § 405.1028 and include a justification for excluding the evidence. We are proposing in § 405.1042(a)(2) to remove these requirements. We believe the requirement to justify excluding the evidence is not necessary and is in tension with the requirement for a provider or supplier, or beneficiary represented by a provider or supplier, to establish good cause for submitting new evidence before it may be considered. Section 1869(b)(3) of the Act establishes a general prohibition on new evidence that must be overcome, and proposed § 405.1028 would implement the statute by requiring the party to explain why the evidence was not submitted prior to the QIC reconsideration, and the ALJ or attorney adjudicator to make a finding of good cause to admit the evidence. In place of the current § 405.1042(a)(2) requirement, as we discuss later, we are proposing at § 405.1046(a)(2)(ii) to 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 would be discussed in the decision. We believe the decision is the appropriate place to discuss the new evidence and document the good cause determination, and the discussion should focus on the good cause determination required by proposed § 405.1028, regardless of whether good cause was found. We are not proposing any corresponding changes to § 423.2042 because there is no provision equivalent to the current § 405.1042(a)(2) requirement to discuss any excluded evidence.

Current § 405.1042(a)(3) 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. However, this is rarely done in practice. More often, a party requests a copy of the record prior to the hearing, in accordance with current § 405.1042(b). We are proposing to revise § 405.1042(a)(3) 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. This revision would allow a party to request and review a copy of the record ''prior to or at the hearing'' to more accurately reflect the practices of parties. In addition, proposed § 405.1042(a)(3) would remove 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, as proposed in section II.B, may issue the decision. We are proposing at § 423.2042(a)(3) to adopt corresponding revisions for part 423, subpart U proceedings.

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. We are proposing at § 405.1042(a)(4) to add that the record includes recordings of prehearing and posthearing conferences in addition to the hearing recordings, to reinforce that recordings of conferences are part of the complete record. We are proposing at § 423.2042(a)(4) to adopt corresponding revisions for part 423, subpart U proceedings.

Current § 405.1042(b)(1) describes how a party may request and receive copies of the record from the ALJ. However, after a case is adjudicated, OMHA releases custody of the record and forwards it to a CMS contractor or SSA, and the record may go on to the Council for another administrative proceeding. This results in confusion for parties when they request a copy of the record and OMHA is unable to provide it. We are proposing at § 405.1042(b)(1) that a party may request and receive a copy of the record from OMHA while an appeal is pending at OMHA. We also are proposing at § 405.1042(b)(1) to replace 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. We also are proposing to change the parallel reference to ''the exhibits list'' in § 405.1118 to ''any index of the administrative record.'' In addition, proposed § 405.1042(b)(1) would replace the reference to a ''tape'' of the oral proceeding with an ''audio recording'' of the oral proceeding because tapes are no longer used and a more general reference would accommodate future changes in recording formats. We also are proposing to replace a parallel reference at § 405.1118 to a copy of the ''tape'' of the oral proceedings with a copy of the ''audio recording'' of the oral proceedings. We are proposing at §§ 423.2042(b)(1) and 423.2118 to adopt corresponding revisions for part 423, subpart U proceedings, but note that current § 423.2118 refers to a ''CD'' of the oral proceedings.

Current § 405.1042(b)(2) provides that 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. We are proposing to revise § 405.1042(b)(2) to state, if a party requests a copy of all or part of the record from OMHA or the ALJ or attorney adjudicator and an opportunity to comment on the record, any adjudication period that applies in accordance with § 405.1016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the party's response. This proposed revision would clarify that a party may request a ''copy of'' all or part of the record, and would add that the request may be made to OMHA, or the ALJ or attorney adjudicator, because a party may request a copy of the record before it is assigned to an ALJ or attorney adjudicator. In addition, proposed § 405.1042(b)(2) would revise the discussion of the effect of requesting an opportunity to comment on the record on an adjudication period to remove the specific reference to a 90 calendar day adjudication period, because in accordance with proposed § 405.1016, an adjudication period may be 90 or 180 calendar days, or alternatively may be waived by the appellant and therefore not apply. We are proposing at § 423.2042(b)(2) to adopt corresponding revisions for part 423, subpart U proceedings.

Current § 405.1042 does not address the circumstance in which a party

requests a copy of the record but is not entitled to receive some of the documents in the record. For example, when an appeal involves multiple beneficiaries and one beneficiary requests a copy of the record, the records related to other beneficiaries may not be released to the requesting beneficiary unless he or she obtains consent from the other beneficiaries to release the records that pertain to them. Proposed § 405.1042(b)(3) would address the possibility that a party requesting a copy of the record is not entitled to receive the entire record. Specifically, we are proposing in § 405.1042(b)(3) that if a party requests a copy of all or part of the record and the record, including any audio recordings, contains information pertaining to an individual that the requesting party is not entitled to receive (for example, personally identifiable information or protected health information), those portions of the record would not be furnished unless the requesting party obtains consent from the individual. For example, if a beneficiary requests a copy of the record for an appeal involving multiple beneficiaries, the portions of the record pertaining to the other beneficiaries would not be furnished to the requesting beneficiary unless he or she obtains consent from the other beneficiaries. We believe proposed § 405.1042(b)(3) would help ensure that parties are aware that they may not be entitled to receive all portions of the record. We are proposing at § 423.2042(b)(3) to adopt corresponding revisions for part 423, subpart U proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''The administrative record'' at the beginning of your comment.

u. Consolidated Proceedings (§§ 405.1044 and 423.2044)

Current §§ 405.1044 and 423.2044 explain that a consolidated hearing may be held at the request of an appellant or on the ALJ's own motion, if one or more of the issues to be considered at the hearing are the same issues that are involved in another request for hearing or hearings pending before the same ALJ, and CMS is notified of an ALJ's intention to conduct a consolidated hearing. If a consolidated hearing is conducted, current §§ 405.1044 and 423.2044 further provide that the ALJ may make a consolidated decision and record for the claims involved in the consolidated hearing, or may make a separate decision and record for each claim involved in the consolidated hearing. This authority is useful in allowing an ALJ and the appellant to conduct a single proceeding on multiple appealed claims or other determinations that are before the ALJ, reducing time and expense for the appellant and the government to resolve the appealed matter. However, the current provisions have caused confusion, and have been limiting in circumstances in which no hearing is conducted.

Current § 405.1044 uses the terms ''requests for hearing,'' ''cases,'' and ''claims'' interchangeably, which has resulted in confusion because an appeal, or ''case,'' before an ALJ may involve multiple requests for hearing, if an appellant's requests were combined into one appeal for administrative efficiency prior to being assigned to the ALJ. In addition, a request for hearing may involve one or more claims. We are proposing in § 405.1044 to use the term ''appeal'' to specify that appeals may be consolidated for hearing, and a single decision and record may be made for consolidated appeals. We are proposing to use ''appeal'' because an appeal is assigned a unique ALJ appeal number, for which a unique decision and record is made. We also are proposing to move current § 405.1044(b) to new subsection (a)(2), and to also replace the term ''combined'' with ''consolidated'' for consistent use in terminology. Further, we are proposing at § 423.2044 to adopt corresponding revisions to use consistent terminology in part 423, subpart U proceedings.

Current § 405.1044(a) through (d) 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. Proposed § 405.1044(a) would incorporate current § 405.1044(a) through (c) to combine the provisions related to a consolidated hearing. In addition, proposed § 405.1044(a)(4) would replace the current requirement to notify CMS that a consolidated hearing will be conducted in current § 405.1044(d) with a requirement to include notice of the consolidated hearing in the notice of hearing issued in accordance with §§ 405.1020 and 405.1022. This would help ensure notice is provided to the parties and CMS, as well as its contractors, in a consistent manner, and reduce administrative burden on ALJs and their staff by combining that notice into the existing notice of hearing. We are proposing at § 423.2044(a) to adopt corresponding revisions for part 423, subpart U proceedings.

Current § 405.1044(e) 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. However, there has been confusion on whether separate records may be maintained and a consolidated decision can be issued, as well as what must be included with the records when separate records are maintained. Proposed § 405.1044(b) would incorporate some of current § 405.1044(e) and add provisions for making a consolidated record and decision. We are proposing at § 405.1044(b)(1) that 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 proposed revision would maintain the current option to make a consolidated record and decision, or maintain separate records and issue separate decisions, but restructures the provision to highlight that these are two mutually exclusive options. This proposal is important because issuing a consolidated decision without also consolidating the record, or issuing separate decisions when a record has been consolidated, complicates effectuating a decision and further reviews of the appeal(s). We are proposing in § 405.1044(b)(2) that, 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. Proposed § 405.1044(b)(2) would address the confusion that sometimes results in a copy of the audio recording of a consolidated hearing not being included in the administrative records of each constituent appeal when separate records are maintained, by clarifying that if a separate decision and record is made, audio recordings of any conferences that were conducted and the consolidated hearing are included in each individual record. This proposal is important because the record for each individual appeal must be complete. We are proposing at § 423.2044(b)(1) and (b)(2) to adopt corresponding revisions for part 423, subpart U proceedings.

Current § 405.1044 does not contemplate a consolidated record and decision unless a consolidated hearing was conducted, which is limiting when multiple appeals for an appellant can be consolidated in a decision issued on the record without a hearing. We are proposing to add § 405.1044(b)(3), which would provide that, if a hearing would not be conducted for multiple appeals that are before the same ALJ or attorney adjudicator as proposed in section II.B, 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. This would provide authority for an ALJ or attorney adjudicator to make a consolidated decision and record on the same basis that a consolidated hearing may be conducted. We believe this authority would add efficiency to the adjudication process when multiple appeals pending before the same adjudicator can be decided without conducting a hearing. We are proposing at § 423.2044(b)(3) to adopt a corresponding provision for part 423, subpart U proceedings.

Current § 405.1044 also does not clearly address consolidating hearings for multiple appellants, including situations in which a beneficiary files a request for hearing on the same claim appealed by a provider or supplier, and the provider or supplier has other pending appeals that could be consolidated pursuant to current § 405.1044. The general practice is that a consolidated hearing is conducted for the appeals of a single appellant. This is supported by the reference to ''an'' appellant in current § 405.1044(b), and helps ensure the hearing and record is limited to protected information that the appellant is authorized to receive. Therefore, we are proposing to add § 405.1044(c) to provide that consolidated proceedings may only be conducted for appeals filed by the same appellant, unless multiple appellants aggregated claims to meet the amount in controversy requirement in accordance with § 405.1006, and the beneficiaries whose claims are at issue have all authorized disclosure of their protected information to the other parties and any participants. This would help ensure that beneficiary information is protected from disclosure to parties who are not authorized to receive it, including when a beneficiary requests a hearing for the same claim that has been appealed by a provider or supplier, and appeals of other beneficiaries' claims filed by the provider or supplier are also pending before the same ALJ or attorney adjudicator. We are proposing at § 423.2044(c) to adopt a corresponding provision for part 423, subpart U proceedings.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Consolidated proceedings'' at the beginning of your comment.

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

Current §§ 405.1046 and 423.2046 describe the requirements for a decision and 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, and recommended decisions. Current §§ 405.1048 and 423.2048 describe the effects of an ALJ's decision. However, the current sections only apply 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. We are proposing to consolidate the provisions of each section that apply to a decision on a request for hearing under proposed §§ 405.1046(a), 405.1048(a), 423.2046(a) and 423.2048(a), with further revisions discussed below, and introduce new §§ 405.1046(b), 405.1048(b), 423.2046(b) and 423.2048(b) to address a decision on a request for review of a QIC or IRE dismissal, as well as to revise the titles and provisions of the sections to expand their coverage to include decisions by attorney adjudicators, as proposed in II.B above. We also are proposing to remove current § 405.1046(d), which addresses the timing of a decision on a request for hearing because it is redundant with § 405.1016 and could lead to confusion if a different adjudication period applies, such as a 180-calendar day period for an escalated request for QIC reconsideration, or if no adjudication period applies, such as when the period is waived by the appellant. Similarly, we are proposing to remove current §§ 423.2046(a)(1) and (d) because the adjudication time frames discussed in the provisions are redundant with provisions in proposed § 423.2016. In addition, we are proposing to re-designate current §§ 405.1046(e) and 423.2046(e), as proposed §§ 405.1046(c) and 423.2046(c) respectively, to reflect the revised structure of proposed §§ 405.1046 and 423.2046.

Current § 405.1046 states that an ALJ will issue a decision unless a request for hearing is dismissed. We are proposing to revise § 405.1046(a) to state that an ALJ or attorney adjudicator would 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. There has been confusion regarding the content requirements of the decision itself, as well as whether the findings or conclusions in a QIC reconsideration or the arguments of the parties may be referenced or adopted in the decision by reference. We believe that while the issues that are addressed in a decision are guided by the reconsideration, as well as the initial determination and redetermination, and a party may present arguments in a framework that reflects recommended findings and conclusions, the concept of a de novo review requires an ALJ or attorney adjudicator to make independent findings and conclusions. To address this confusion, we are proposing in § 405.1046(a) to 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, though the ALJ or attorney adjudicator may ultimately make the same findings and conclusions. As discussed in and for the reasons stated in section III.A.3.t above, proposed § 405.1046(a)(2)(ii) would also require that if new evidence was 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 would be discussed in the decision. We are proposing at § 423.2046(a) to adopt corresponding revisions for decisions on requests for hearing under part 423, subpart U, except the proposals related to discussing new evidence and good cause determinations related to new evidence because there are no current requirements to establish good cause for submitting new evidence in part 423, subpart U proceedings.

Current § 405.1046(a) requires that a decision be mailed. As OMHA transitions to a fully electronic case processing and adjudication environment, new options for transmitting a decision to the parties and CMS contractors may become available, such as through secure portals for parties or through inter-system transfers for CMS contractors. We are proposing in § 405.1046(a) to revise the requirement that a decision be mailed to

state that OMHA ''mails or otherwise transmits a copy of the decision,'' to allow for additional options to transmit the decision as technologies develop. We are proposing to revise § 423.2046(a) to adopt a corresponding revision for sending a decision under part 423, subpart U.

Current § 405.1046(a) also requires that a copy of the decision be sent to the QIC that issued the reconsideration. However, if the decision is issued pursuant to escalation of a request for a reconsideration, no reconsideration was issued. To address this circumstance, we are proposing in § 405.1046(a) that the decision would be issued to the QIC that issued the reconsideration or from which the appeal was escalated. In addition, we are proposing in § 405.1046(a) to replace ''reconsideration determination'' with ''reconsideration'' for consistency in referencing the QIC's action. Current § 405.1046(a) also requires that a copy of the decision be sent to the contractor that made the initial determination. However, this requirement adds to the administrative burden on OMHA and we believe is unnecessary in light of the requirement that a copy of the decision be sent to the QIC and the original decision is forwarded as part of the administrative record to another CMS contractor to effectuate the decision. Thus, we are proposing in § 405.1046(a) to remove the requirement to send a copy of the decision to the contractor that issued the initial determination. In addition, we are proposing in § 423.2046(a) to replace ''reconsideration determination'' with ''reconsideration'' for consistency in referencing the IRE's action in part 423, subpart U proceedings, but we are not proposing to incorporate other changes proposed for § 405.1046(a) in proposed § 423.2046(a) because: (1) escalation is not available in part 423, subpart U proceedings; and (2) the Part D plan sponsor, which makes the initial coverage determination, has an interest in receiving and reviewing ALJ and attorney adjudicator decisions related to an enrollee's appeal of drug coverage.

As discussed above, we are proposing to revise § 405.1046(b) to explain the process for making a decision on a request for review of a QIC dismissal. In accordance with proposed § 405.1004, we are proposing in § 405.1046(b)(1) that 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 issues a written decision affirming the QIC's dismissal. We are proposing in § 405.1046(b)(1) that OMHA would mail or otherwise transmit a copy of the decision to all the parties that received a copy of the QIC's dismissal because we believe that the QIC would appropriately identify the parties who have an interest in the dismissal, and that notice of the decision on a request for review of a QIC dismissal to any additional parties is unnecessary. We also believe that notice to the QIC is not necessary when its dismissal is affirmed because it has no further obligation to take action on the request for reconsideration that it dismissed. We are proposing in § 405.1046(b)(2)(i) that the decision affirming a QIC dismissal must describe the specific reasons for the determination, including a summary of the evidence considered and applicable authorities, but are not proposing to require a summary of clinical or scientific evidence because such evidence is not used in making a decision on a request for a review of a QIC dismissal. In addition, we are proposing that § 405.1046(b)(2)(ii) and (iii) would explain that the notice of decision would describe the procedures for obtaining additional information concerning the decision, and would 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. We are proposing to revise § 423.2046(b) to adopt corresponding provisions for a decision on requests for review of an IRE dismissal under part 423, subpart U, except that the notice of decision will only be sent to the enrollee because only the enrollee is a party.

We are proposing to revise the title of current § 405.1048 to read ''The effect of an ALJ's or attorney adjudicator's decision'' and to replace the current introductory statement in § 405.1048(a) that ''The decision of the ALJ is binding on all parties to the hearing'' with ''The decision of the ALJ or attorney adjudicator is binding on all parties'' to make the subsection applicable to decisions by attorney adjudicators and because the parties are parties to the decision regardless of whether a hearing was conducted. We also are proposing in § 405.1048(b) that 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 explained in § 405.980. We are proposing to revise § 423.2048 to adopt corresponding provisions for the effects of ALJ and attorney adjudicator decisions under part 423, subpart U.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Notice of decision and effect of an ALJ's or attorney adjudicator's decision'' at the beginning of your comment.

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

Current §§ 405.1050 and 423.2050 explain the process for the Council to assume responsibility for holding a hearing if a request for hearing is pending before an ALJ. We are proposing to replace ''an ALJ'' with ''OMHA'' in the section title, and to replace ''pending before an ALJ'' with ''pending before OMHA,'' and ''the ALJ send'' with ''OMHA send'' in the section text. In accordance with section II.B above, these proposed revisions would provide that a request for hearing may be removed to the Council regardless of whether the request is pending before an ALJ or an attorney adjudicator. We are not proposing to replace the last instance of ''ALJ'' in the section text because it refers specifically to hearings conducted by an ALJ.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Removal of a hearing request from an ALJ to the Council'' at the beginning of your comment.

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)

Current §§ 405.1052 and 423.2052 describe the circumstances in which a request for hearing may be dismissed and the requirements for a notice of dismissal, and current §§ 405.1054 and 423.2054 describe the effect of a dismissal of a request for hearing. However, both current sections apply to a dismissal of a request for hearing, leaving ambiguities when issuing a dismissal of a request for review of a QIC or IRE dismissal. We are proposing to maintain the provisions of each section that apply to a dismissal of a request for hearing in proposed §§ 405.1052(a), 405.1054(a), 423.2052(a) and 423.2054(a), with further revisions discussed below, and to introduce new §§ 405.1052(b), 405.1054(b), 423.2052(b) and 423.2054(b) to address a dismissal of a request for review of a QIC or IRE dismissal. However, we are proposing to re-designate and revise §§ 405.1052(a)(1) and 423.2052(a)(1), as discussed below, and re-designate the remaining paragraphs in §§ 405.1052(a) and 423.2052(a) accordingly. We are also

proposing to remove the introductory language to current §§ 405.1052 and 423.2052 because it is unnecessary to state that a dismissal of a request for hearing is in accordance with the provisions of the section, as the provisions are themselves binding authority and state in full when a request for hearing may be dismissed. In addition, we are proposing to revise the titles of the sections to expand their coverage to include dismissals of requests to review a QIC or IRE dismissal. Furthermore, we are proposing to re-designate and revise current §§ 405.1052(b) and 423.2052(b), which describe notices of dismissal, as proposed §§ 405.1052(d) and 423.2052(d) respectively, to reflect the revised structure of proposed §§ 405.1052 and 423.2052. We also are proposing to remove current § 423.2052(a)(8) and (c) because current § 423.2052(a)(8) restates current § 423.1972(c)(1), which already provides that a request for hearing will be dismissed if the request itself shows that the amount in controversy is not met, and current § 423.2052(c) restates current § 423.1972(c)(2), which already provides that if after a hearing is initiated, the ALJ finds that the amount in controversy is not met, the ALJ discontinues the hearing and does not rule on the substantive issues raised in the appeal. We note that a dismissal would be warranted in these circumstances pursuant to current § 423.2052(a)(3), which is carried over as proposed § 423.2052(a)(2) because the enrollee does not have a right to a hearing if the amount in controversy is not met.

We are proposing to re-designate and revise current §§ 405.1052(a)(1) and 423.2052(a)(1) as proposed §§ 405.1052(c) and 423.2052(c) to separately address dismissals based on a party's withdrawal. We are proposing in §§ 405.1052(c) and 423.2052(c) to include withdrawals of requests to review a QIC dismissal because we also propose to add provisions to address other dismissals of those requests at §§ 405.1052(b) and 423.2052(b). We also are proposing that 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 as proposed in section II.B above, both ALJs and attorney adjudicators would be able to adjudicate requests to review a QIC dismissal. In addition, we are proposing that an ALJ or attorney adjudicator may dismiss a request for hearing based on a party's withdrawal of his or her request. As discussed in section II.B above, we believe that well-trained attorneys can efficiently perform a review of these requests and issue dismissals. We believe using attorney adjudicators to the maximum extent possible would help OMHA be more responsive to appellants and allow ALJs to focus on conducting hearings and issuing decisions. We also are proposing to revise the language in current §§ 405.1052(a)(1) and 423.2052(a)(1) (as redesignated in proposed §§ 405.1052(c) and 423.2052(c)) to (1) replace ''notice of the hearing decision'' with ''notice of the decision, dismissal or remand'' to reflect that a decision may be issued without a hearing, and to reflect other possible outcomes of the proceeding (dismissal and remand), and (2) to clarify that a request to withdraw a request for hearing may be made orally at a hearing before the ALJ because only an ALJ may conduct a hearing.

Current § 405.1052(a)(2) 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. The current alternatives have caused confusion for appellants in understanding whether they are required to submit a statement explaining a failure to appear. Further, current provisions do not require evidence in the record to document an appellant was aware of the time and place of the hearing, and this has resulted in remands from the Council. We are proposing to simplify 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. We are proposing at § 405.1052(a)(1)(i) to set forth the first alternative which would provide 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. We are proposing at § 405.1052(a)(1)(ii) to set forth the second alternative which would provide 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. In either circumstance, we are maintaining in proposed § 405.1052(a)(1) the current standard that in determining whether good cause exists, the ALJ considers any physical, mental, educational, or linguistic limitations that the party may have identified. We believe proposed § 405.1052(a)(1) would help ensure that appellants have consistent notice of a possible dismissal for failure to appear and an opportunity to provide a statement explaining why they did not appear before a dismissal is issued. We are proposing to revise § 423.2052(a)(1) to adopt corresponding revisions for dismissing a request for hearing under part 423, subpart U.

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 (OMHA Case Processing Manual, division 2, chapter 3, section II–3–6 D and E). A dismissal is appropriate because as an administrative matter, the proceedings on the request do not begin until the information necessary to adjudicate the request is provided and the appellant sends a copy of the request to the other parties. Additionally, a request cannot remain pending indefinitely once an appellant has demonstrated that he or she is unwilling to provide the necessary information or to send a copy of the request to the other parties. Therefore, we are proposing at § 405.1052(a)(7) to explain that a request for hearing may be dismissed if the request is not complete in accordance with proposed § 405.1014(a)(1) or the appellant did not send copies of its request to the other parties in accordance with proposed § 405.1014(d), after the appellant is provided with an opportunity to complete the request and/or send copies of the request to the other parties. We believe adding this provision would emphasize the importance of following the requirements for filing a request for hearing, and clarify the outcome if the requirements are not met and the appellant does not cure identified defects after being provided with an opportunity to do so. We are proposing at § 423.2052(a)(7) to adopt a corresponding provision for dismissing a request for hearing under part 423, subpart U.

As discussed above, we are proposing to add § 405.1052(b) to explain when a request for review of a QIC dismissal would be dismissed. Under proposed § 405.1052(b), a request for review could be dismissed in the following circumstances: (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; and (4) the appellant's request for review is not complete in accordance with proposed § 405.1014(a)(1) or the appellant does not send a copy of the request to the other parties in accordance with proposed § 405.1014(d), after being provided with an opportunity to complete the request and/or send a copy of the request to the other parties. We believe these provisions would encompass the reasons for dismissing a request for a review of a QIC dismissal, and are necessarily differentiated from dismissing a request for hearing because, as explained in section III.A.3.c above, we do not believe there is a right to a hearing for requests for a review of a QIC dismissal. We are proposing at § 423.2052(b) to adopt corresponding provisions for dismissing requests for a review of an IRE dismissal under part 423, subpart U proceedings.

As discussed above, current § 405.1052(b) describes the requirements for providing notice of the dismissal and we are proposing to re-designate the paragraph as proposed § 405.1052(d). For the same reasons discussed in section III.A.3.v above for allowing a notice of a decision to be provided by means other than mail, we are proposing in § 405.1052(d) that OMHA may mail or ''otherwise transmit'' notice of a dismissal. We are proposing to revise § 423.2052(d) to adopt a corresponding revision for notices of dismissal under part 423, subpart U.

Current § 405.1052(b) requires notice of the dismissal to be sent to all parties at their last known address. However, we believe that requirement is overly inclusive and causes confusion by requiring notice of a dismissal to be sent to parties who have not received a copy of the request for hearing or request for review that is being dismissed. Thus, we are proposing to revise § 405.1052(d) to state that the notice of dismissal is 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. In addition, we are proposing at § 405.1052(d) that if a party's request for hearing or request for review is dismissed, the appeal would proceed with respect to any other parties who also filed a valid request for hearing or review regarding the same claim or disputed matter. This would address the rare circumstance in which more than one party submits a request, but the request of one party is dismissed. In that circumstance, the appeal proceeds on the request that was not dismissed, and the party whose request was dismissed remains a party to the proceedings but does not have any rights associated with a party that filed a request, such as the right to escalate a request for hearing. We are not proposing a corresponding revision to § 423.2052(c) because only the enrollee is a party to an appeal under part 423, subpart U.

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. As explained in the 2005 Interim Final Rule (70 FR 11465), the authority for an ALJ to vacate his or her own dismissal was not regarded as an effective remedy because the record was no longer in the ALJ hearing office, and the resolution was complicated when appellants simultaneously asked the ALJ to vacate the dismissal order and asked the Council to review the dismissal. However, in practice, the lack of the authority for an ALJ to vacate his or her own dismissal has constrained ALJs' ability to correct erroneous dismissals that can be easily remedied by the ALJ, and has caused unnecessary work for the Council. We are proposing to add § 405.1052(e) to provide the authority for an ALJ or an attorney adjudicator, as proposed in section II.B above, to vacate his or her own dismissal within 6 months of the date of the notice of dismissal, in the same manner as a QIC can vacate its own dismissal. We believe that this authority would reduce unnecessary appeals to the Council and provide a more timely resolution of dismissals for appellants, whether the dismissal was issued by an ALJ or attorney adjudicator. We also note that the coordination for obtaining the administrative record and addressing instances in which an appellant also requests a review of the dismissal by the Council can be addressed through operational coordination among CMS, OMHA, and the DAB. We are proposing in § 423.2052(e) to adopt a corresponding provision for vacating a dismissal under part 423, subpart U.

To align the effects of a dismissal with proposed § 405.1052(e), we are proposing to add § 405.1054(a) to state that the dismissal of a request for hearing is binding unless it is vacated by the ALJ or attorney adjudicator under § 405.1052(e), in addition to the current provision that allows the dismissal to be vacated by the Council under § 405.1108(b). To explain the effect of a dismissal of a request for review of a QIC dismissal, consistent with § 405.1004, we are proposing in § 405.1054(b) to provide that the dismissal of a request for review of a QIC dismissal of a request for reconsideration is binding and not subject to further review unless it is vacated by the ALJ or attorney adjudicator under § 405.1052(e). We are proposing in § 423.2054 to adopt corresponding revisions for the effect of dismissals of request for hearing and requests for review of an IRE dismissal under part 423, subpart U.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Dismissal of a request for hearing or request for review and effect of a dismissal of a request for hearing or request for review'' at the beginning of your comment.

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

Current § 405.1060 addresses the applicability of national coverage determinations (NCDs) to claim appeals brought under part 405, subpart I and provides that an ALJ and the Council may not disregard, set aside, or otherwise review an NCD, but may review the facts of a particular case to determine whether an NCD applies to a specific claim for benefits and, if so, whether the NCD was applied correctly to the claim. Current § 405.1062 addresses the applicability of local coverage determinations (LCDs) and other policies, and specifies that ALJs and the Council are not bound by LCDs, local medical review policies (LMRPs), or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are

applicable to a particular case, and if an ALJ or the Council declines to follow a policy in a particular case, the ALJ or the Council must explain the reasons why the policy was not followed. Similarly, current § 423.2062 states that ALJs and the Council are not bound by CMS program guidance but will give substantial deference to these policies if they are applicable to a particular case, and if an ALJ or the Council declines to follow a policy in a particular case, the ALJ or the Council must explain the reasons why the policy was not followed. Current §§ 405.1062 and 423.2062 also provide that an ALJ or Council decision to disregard a policy applies only to the specific claim being considered and does not have precedential effect. Further, § 405.1062 states that an ALJ or the Council may not set aside or review the validity of an LMRP or LCD for purposes of a claim appeal. Current §§ 405.1063 and 423.2063 address the applicability of laws, regulations, and CMS Rulings, and provide that all laws and regulations pertaining to the Medicare program (and for § 405.1063 the Medicaid program as well), including but not limited to Titles XI, XVIII, and XIX of the Act and applicable implementing regulations, are binding on ALJs and the Council, and consistent with § 401.108, CMS Rulings are binding on all HHS components that adjudicate matters under the jurisdiction of CMS.

We are proposing to revise §§ 405.1060, 405.1062, 405.1063, 423.2062, and 405.2063 to replace ''ALJ'' or ''ALJs'' with ''ALJ or attorney adjudicator'' or ''ALJs or attorney adjudicators'' except in the second sentence of § 405.1062(c). As proposed in section II.B above, an attorney adjudicator would issue certain decisions and dismissals and therefore would apply the authorities addressed by these sections. Requiring the attorney adjudicators to apply the authorities in the same manner as an ALJ would provide consistency in the adjudication process, regardless of who is assigned to adjudicate a request for an ALJ hearing or request for review of a QIC or IRE dismissal. We are not proposing to revise the second sentence in current § 405.1062(c) because attorney adjudicators would not review or set aside an LCD (or any part of an LMRP that constitutes an LCD) in accordance with part 426 (part 426 appeals are currently heard by ALJs in the Civil Remedies Division of the DAB).

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Applicability of Medicare Coverage Policies'' at the beginning of your comment.

5. Council Review and Judicial Review

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

Current § 405.1100 discusses the Council review process. Current § 405.1100(a) states that the appellant or any other party to the hearing may request that the Council review an ALJ's decision or dismissal. We are proposing to revise § 405.1100(a) to replace ''the hearing'' with ''an ALJ's or attorney adjudicator's decision or dismissal,'' and ''an ALJ's decision or dismissal,'' with ''the ALJ's or attorney adjudicator's decision or dismissal'' because the parties are parties to the proceedings and the resulting decision or dismissal regardless of whether a hearing is conducted, and as proposed in section II.B above, an attorney adjudicator would be able to issue certain decisions or dismissals for which Council review maybe requested.

Current § 423.1974 states that an enrollee who is dissatisfied with an ALJ hearing decision may request that the Council review the ALJ's decision or dismissal as provided in § 423.2102, and current § 423.2100(a) states that consistent with § 423.1974, the enrollee may request that the Council review an ALJ's decision or dismissal. We are proposing to revise § 423.1974 to replace ''ALJ hearing decision'' with ''an ALJ's or attorney adjudicator's decision or dismissal,'' and to revise §§ 423.1974 and 423.2100(a) to replace ''ALJ's decision or dismissal'' with ''an ALJ's or attorney adjudicator's decision or dismissal'' because the parties are parties to the proceedings and resulting decision or dismissal regardless of whether a hearing is conducted, and as proposed in section II.B above, an attorney adjudicator may issue a decision or dismissal for which Council review maybe requested.

Current § 405.1100(b) provides that under the circumstances set forth in §§ 405.1104 and 405.1108, an appellant may request escalation of a case to the Council for a decision even if the ALJ has not issued a decision or dismissal in his or her case. We are proposing to revise § 405.1100(b) to provide that under circumstances set forth in §§ 405.1016 and 405.1108, 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. These revisions would reference § 405.1016, which, as discussed in section III.A.3.h above, would replace the current § 405.1104 provisions for escalating a case from the OMHA level to the Council. They would also provide that in addition to potentially issuing a decision or dismissal, an ALJ or attorney adjudicator, as proposed in section II.B above, may issue a remand—this would present a complete list of the actions that an ALJ or attorney adjudicator could take on an appeal.

Current §§ 405.1100(c) and 423.2100(b) and (c) state in part that when the Council reviews an ALJ's decision, it undertakes a de novo review, and the Council issues a final decision or dismissal order or remands a case to the ALJ. We are proposing to revise §§ 405.1100(c) and 423.2100(b) and (c) to state that 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. We are also proposing to revise §§ 405.1100(c) and 423.2100(c) to state that 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 were to order that a hearing must be conducted, the case would be transferred to an ALJ upon remand to the attorney adjudicator because only an ALJ may conduct a hearing).

Current § 423.2100(c) and (d) 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. We are proposing to revise § 423.2100(c) and (d) to state 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 may also issue a decision, as proposed in section II.B above. We are also proposing to revise § 423.2100(c) to correct a typographical error by inserting ''day'' into the current ''90 calendar period,'' so it is clear to enrollees that the period of time being referenced is the 90 calendar day period.

Current § 405.1100(d) 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. A remand from the Council

after an appeal is escalated to it is exceedingly rare and done in circumstances in which the Council must remand to an ALJ so that the ALJ may obtain information under current § 405.1034 that is missing from the written record and essential to resolving the issues on appeal, and that information can only be provided by CMS or its contractors, because the Council does not have independent authority to obtain the information from CMS or its contractors. In addition, an appeal may have not yet have been assigned to an ALJ, or could be assigned to an attorney adjudicator as proposed in section II.B above, when the appeal was escalated by the appellant. We are proposing to revise § 405.1100(d) to state 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.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Medicare Appeals Council review: general'' at the beginning of your comment.

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

Current §§ 405.1102 and 423.2102 discuss requests for Council review when an ALJ issues a decision or dismissal. Current §§ 405.1102(a)(1) and 423.2102(a)(1) provide that a party or enrollee, respectively, to ''the ALJ hearing'' may request a 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 decision or dismissal, which is in accordance with the criteria specified in current §§ 405.1102 and 423.2102. However, a party or enrollee is a party to the proceedings and resulting decision or dismissal, and may appeal the decision or dismissal regardless of whether a hearing was conducted in the appeal, and as proposed in section II.B above, an attorney adjudicator may issue a decision or dismissal for which Council review may be requested. To help ensure there is no confusion that a party or enrollee may seek Council review even if a hearing before an ALJ is not conducted or if an attorney adjudicator issues the decision or dismissal, we are proposing to revise §§ 405.1102(a)(1) and 423.2102(a)(1) to state 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.

Current §§ 405.1102(c) and 423.2102(c) provide that a party or enrollee, respectively, 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. However, under current §§ 405.1004(c) and 423.2004(c), a party or enrollee, respectively, may currently seek Council review of a dismissal of a request for review of a QIC or IRE dismissal because, as discussed in section III.A.3.x above, an ALJ does not currently have the authority to vacate his or her own dismissal. As proposed in section II.B above, an attorney adjudicator could adjudicate requests for a review of a QIC or IRE dismissal. In addition, proposed §§ 405.1052(e) and 423.2052(e) would establish 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 only reviewable at the next level of appeal, as discussed in section III.A.3.c above, proposed §§ 405.1102(c) and 423.2102(c) would be revised to indicate that 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. Therefore, we are proposing at §§ 405.1102(c) and 423.2102(c) to add 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.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Request for Council review when ALJ issues decision or dismissal'' at the beginning of your comment.

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

Current §§ 405.1106(a) and 423.2106 provide that when a request for a Council review is filed after an ALJ has issued a decision or dismissal, the request for review must be filed with the entity specified in the notice of the ALJ's action, and under § 405.1106, the appellant must also send a copy of the request for review to the other parties to the ALJ decision or dismissal who received a copy of the hearing decision or notice of dismissal. The sections also explain that if the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's action, the Council's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's action, and upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's action, the Council sends written notice to the appellant of the date of receipt of the request and commencement of the adjudication time frame. In addition, current § 405.1106(b) discusses that if an appellant files a request to escalate an appeal to the Council because the ALJ has not completed his or her action on the request for hearing within the adjudication deadline under § 405.1016, the request for escalation must be filed with both the ALJ and the Council, and the appellant must also send a copy of the request for escalation to the other parties and failure to copy the other parties tolls the Council's adjudication deadline set forth in § 405.1100 until all parties to the hearing receive notice of the request for Council review.

We are proposing in §§ 405.1106 and 423.2106 to replace all instances of ''ALJ'' with ''ALJ or attorney adjudicator,'' ''ALJ's action'' with ''ALJ's or attorney adjudicator's action,'' to provide that the sections apply to decisions and dismissals issued by an attorney adjudicator as well, as proposed in section II.B, and therefore appellants would have the same right to seek Council review of the attorney adjudicator's decision or dismissal, and the Council would have the authority to take the same actions in reviewing an attorney adjudicator's decision or dismissal. We are also proposing to replace ''a copy of the hearing decision under § 405.1046(a) or a copy of the notice of dismissal under § 405.1052(b)'' in § 405.1106(a) with ''notice of the decision or dismissal,'' because §§ 405.1046 and 405.1052 provide for notice of a decision or dismissal, respectively, to be sent, and a decision or dismissal may be issued by an ALJ or attorney adjudicator without conducting a hearing. In addition, in describing the consequences of failing to send a copy of the request for review to the other parties, we are proposing to replace ''until all parties to the hearing'' in

§ 405.1106(a) to ''until all parties to the ALJ or attorney adjudicator decision or dismissal,'' to align the language with the preceding sentences.

We are proposing to revise § 405.1106(b) to align the paragraph with the revised escalation process proposed at § 405.1016 (see section III.A.3.h.i above). Specifically, we are proposing to revise § 405.1106(b) to state that 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 under § 405.1016, the request for escalation must be filed with OMHA and the appellant must also send a copy of the request for escalation to the other parties who were sent a copy of the QIC reconsideration. This proposed revision would align this section with the revised process in proposed § 405.1016 by specifying that the request for escalation is filed with OMHA and removing the requirement for an appellant to also file the request with the Council. In addition, proposed § 405.1106(b) would specify that the request for escalation must be sent to the other parties who were sent a copy of the QIC reconsideration, which would align with the parties to whom the appellant is required to send a copy of its request for hearing. Proposed § 405.1106(b) would also refer to ''an applicable adjudication period'' under § 405.1016, to align the terminology and because an adjudication period may not apply to a specific case (for example, if the appellant waived an applicable adjudication time frame). Finally, proposed § 405.1106(b) would provide that failing to copy the other parties would 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 currently required, because the revised escalation process proposed at § 405.1016 would remove the requirement to file a request for Council review when escalation is requested from the OMHA to the Council level.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Where a request for review or escalation may be filed'' at the beginning of your comment.

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

Current §§ 405.1108 and 423.2108 describe the actions the Council may take upon receipt of a request for review or, for § 405.1108, a request for escalation. We are proposing at § 405.1108(d) introductory text to replace ''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. We are also proposing at § 405.1108(d)(3) to replace ''remand to an ALJ for further proceedings, including a hearing'' with ''remand to OMHA for further proceedings, including a hearing'' because we believe the Council could remand an escalated case to an ALJ or attorney adjudicator for further proceedings, but if the Council ordered that a hearing be conducted, the case would need to be remanded to an ALJ. We are not proposing any corresponding changes to § 423.2108 because escalation is not available for Part D coverage appeals.

We are also proposing in §§ 405.1108(b) and 423.2108(b), to provide that the dismissal for which Council review may be requested is a dismissal of a request for a hearing, because as discussed in section III.A.3.x above, proposed §§ 405.1054(b) and 423.2054(b) would provide that a dismissal of a request for a review of a QIC or IRE dismissal of a request for reconsideration is binding and not subject to further review. Finally, we are proposing to replace all remaining references in §§ 405.1108 and 423.2108 to ''ALJ'' with ''ALJ or attorney adjudicator'' and ''ALJ's'' with ''ALJ's or attorney adjudicator's'' to further provide that the Council's actions with respect to a request for review or escalation are the same for cases that were decided by or pending before an ALJ or an attorney adjudicator.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Council actions when request for review or escalation is filed'' at the beginning of your comment.

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

Current §§ 405.1110 and 423.2110 discuss Council reviews on its own motion. Current §§ 405.1110(a) and 423.2110(a) state the general rule that the Council may decide on its own motion to review a decision or dismissal issued by an ALJ, and CMS or its contractor, including the IRE, may refer a case to the Council within 60 calendar days after the date of the ALJ's decision or dismissal (for § 405.1110(a)) or after the ALJ's written decision or dismissal is issued (for § 423.2110(a)). Current §§ 405.1110(b) and 423.2110(b) provide the standards for CMS or its contractors to refer ALJ decisions and dismissals to the Council for potential review under the Council's authority to review ALJ decisions and dismissals on the Council's own motion, and require that a copy of a referral to the Council be sent to the ALJ whose decision or dismissal was referred, among others. Current §§ 405.1110(c) and 423.2110(c) explain the standards of review used by the Council in reviewing the ALJ's action. Current §§ 405.1110(d) and 423.2110(d) explain the actions the Council may take, including remanding the case to the ALJ for further proceedings, and state that if the Council does not act on a referral within 90 calendar days after receipt of the referral (unless the 90 calendar day period has been extended as provided in the respective subpart), the ALJ's decision or dismissal is binding (§ 405.1110(d) further specifies that the decision or dismissal is binding on the parties to the decision).

We are proposing at §§ 405.1110 and 423.2110 to replace each instance of ''at the ALJ level'' with ''at the OMHA level'' and ''ALJ proceedings'' with ''OMHA proceedings''. We believe the standards for referral to the Council by CMS or its contractor would be the same regardless of whether the case was decided by an ALJ or an attorney adjudicator, and that ''at the OMHA level'' and ''OMHA proceedings'' would reduce confusion in situations where the case was decided by an attorney adjudicator. We are proposing at § 405.1110(b)(2) to replace the references to current § 405.1052(b) with references to § 405.1052(d) to reflect the structure of proposed § 405.1052, and are also proposing to revise §§ 405.1110(b)(2) and 423.2110(b)(2)(ii) to state that CMS (in § 405.1110(b)(2)) or CMS or the IRE (in § 423.2110(b)(2)(ii)) sends a copy of its referral to the OMHA Chief ALJ. The current requirement to send a copy of the referral to the ALJ is helpful in allowing OMHA ALJs to review the positions that CMS is advocating before the Council, but at times has caused confusion as to whether the ALJ should respond to the referral (there is no current provision that allows the Council to consider a statement in response to the referral). In

addition, the proposed revision would allow OMHA to collect information on referrals, assess whether training or policy clarifications for OMHA adjudicators are necessary, and disseminate the referral to the appropriate ALJ or attorney adjudicator for his or her information. We are also proposing at § 405.1110(b)(2) to replace ''all other parties to the ALJ's decision'' with ''all other parties to the ALJ's or attorney adjudicator's action'' and at § 405.1110(d) to replace ''ALJ decision'' with ''ALJ or attorney adjudicator action'' to encompass both decisions and dismissals issued by an ALJ or an attorney adjudicator, as proposed in section II.B above. We believe that parties to an ALJ's dismissal or an attorney adjudicator's decision or dismissal have the same right to receive a copy of another party's written exceptions to an agency referral as the parties to an ALJ's decision, and that an ALJ's or attorney adjudicator's decision or dismissal is binding on the parties to the action. We are proposing to replace each remaining instance in §§ 405.1110 and 423.2110 of ''ALJ'' with ''ALJ or attorney adjudicator,'' ''ALJ's decision or dismissal'' with ''ALJ's or attorney adjudicator's decision or dismissal,'' ''ALJ's decision'' with ''ALJ's or attorney adjudicator's decision or dismissal,'' and ''ALJ's action'' with ''ALJ's or attorney adjudicator's action.'' These proposed revisions would provide that the sections apply to decisions and dismissals issued by an attorney adjudicator, as proposed in section II.B, and therefore CMS and its contractors would have the same right to refer attorney adjudicator decisions and dismissals to the Council, and the Council would have the authority to take the same actions and have the same obligations in deciding whether to review an attorney adjudicator's decision or dismissal on its own motion.

Finally, we are proposing at § 423.2110(b)(1) to replace ''material to the outcome of the claim'' with ''material to the outcome of the appeal'' because unlike Part A and Part B, no ''claim'' is submitted for drug coverage under Part D.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Council reviews on its own motion'' at the beginning of your comment.

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

Current §§ 405.1112 and 423.2112 discuss the content of a request for Council review. Current § 405.1112(a) requires a request for Council review to contain the date of the ALJ's decision or dismissal order, if any, among other information. Current § 423.2112(a)(1) states that the request for Council review must be filed with the entity specified in the notice of the ALJ's action. Current §§ 405.1112(b) and 423.2112(b) state that the request for review must identify the parts of the ALJ action with which the party or enrollee, respectively, requesting review disagrees and explain why he or she disagrees with the ALJ's decision, dismissal, or other determination being appealed. Current § 405.1112(b) provides an example that if the party requesting review believes that the ALJ's action is inconsistent with a statute, regulation, CMS Ruling, or other authority, the request for review should explain why the appellant believes the action is inconsistent with that authority. Current §§ 405.1112(c) and 423.2112(c) state that the Council will limit its review of an ALJ's action to those exceptions raised by the party or enrollee, respectively, in the request for review, unless the appellant is an unrepresented beneficiary or the enrollee is unrepresented. We are proposing at §§ 405.1112 and 423.2112 to replace ''ALJ's decision or dismissal'' with ''ALJ's or attorney adjudicator's decision or dismissal,'' ''ALJ action'' with ''ALJ or attorney adjudicator's action,'' ''ALJ's action'' with ''ALJ's or attorney adjudicator's action.'' These proposed revisions would provide that the sections apply to decisions and dismissals issued by an attorney adjudicator, as proposed in section II.B, and therefore information on the attorney adjudicator's decision and dismissal must be included in the request for Council review, and the scope of the Council's review would be the same as for an ALJ's decision or dismissal.

Current § 405.1112(a) states that a request for Council review must be filed with the Council or appropriate ALJ hearing office. However, this provision may cause confusion when read with current § 405.1106(a), which states that a request for review must be filed with the entity specified in the notice of the ALJ's action. In practice, OMHA notices of decision and dismissal provide comprehensive appeal instructions directing requests for Council review to be filed directly with the Council, and provide address and other contact information for the Council. Therefore, we are proposing to revise § 405.1112(a) to state that the request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action, which would to align § 405.1112(a) with current § 405.1106(a), and reaffirm that a request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action.

Current § 405.1112(a) also 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 proposed revisions to the escalation process discussed in section III.A.3.h.i above, we are proposing to remove this requirement from § 405.1112(a) because proposed § 405.1016 would provide that a request for escalation is filed with OMHA. In accordance with proposed § 405.1016, if the request for escalation meets the requirements of § 405.1016(f)(1) and a decision, dismissal, or remand cannot be issued within 5 calendar days after OMHA receives the request, the appeal would be forwarded to the Council.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Content of request for review'' at the beginning of your comment.

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

We are proposing at § 405.1114(c)(3) to replace ''ALJ hearing'' with ''ALJ's or attorney adjudicator's action.'' This proposed revision would provide that the paragraph applies to decisions and dismissals issued by an attorney adjudicator, as proposed in section II.B, and therefore a valid and timely request for Council review filed by another party to an attorney adjudicator's decision or dismissal would preclude dismissal of a request for Council review under § 405.1114(c). We are not proposing any corresponding changes to § 423.1114 because there is no provision equivalent to current § 405.1114(c)(3).

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Dismissal of request for review'' at the beginning of your comment.

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

Current §§ 405.1116 and 423.2116 describe the effect of a dismissal by the Council of a request for Council review or a request for hearing. We are proposing to replace ''ALJ'' with ''ALJ or attorney adjudicator'' to provide that the denial of a request for Council review of a dismissal issued by an attorney

adjudicator is binding and not subject to judicial review in the same manner as the denial of a request for Council review of a dismissal issued by an ALJ. We believe the Council's denial of a request to review an attorney adjudicator's dismissal would be subject to the same general rules described in sections III.A.3.c and III.A.3.x above pertaining to reviews of dismissals at the next adjudicative level, and that further review of the attorney adjudicator's dismissal in Federal district court would be unavailable.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Effect of dismissal of request for Council review or request for hearing'' at the beginning of your comment.

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. We are proposing to replace ''ALJ hearing'' with ''ALJ's or attorney adjudicator's action.'' This proposed revision would provide that a party to an attorney adjudicator action, or to an ALJ decision that was issued without a hearing, may request and receive a copy of all or part of the record to the same extent as a party to an ALJ hearing. We are also proposing to replace 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. In addition, we are proposing at § 405.1118 to replace the reference to a ''tape'' of the oral proceeding with an ''audio recording'' of the oral proceeding because tapes are no longer used and a more general reference would accommodate future changes in recording formats. We are proposing a parallel revision to § 423.2118 to replace the reference to a ''CD'' of the oral proceeding with an ''audio recording'' of the oral proceeding.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Obtaining evidence from the Council'' at the beginning of your comment.

j. What Evidence May Be Submitted to the Council (§§ 405.1122 and 423.2122)

Current §§ 405.1122 and 423.2122 describe the evidence that may be submitted to and considered by the Council, the process the Council follows in issuing subpoenas, the reviewability of Council subpoena rulings, and the process for seeking enforcement of subpoenas. Current § 405.1122(a)(1) provides that the Council will limit its review of the evidence to the evidence contained in the record of the proceedings before the ALJ, unless the hearing decision decides a new issue that the parties were not afforded an opportunity to address at the ALJ level. We are proposing at § 405.1122(a) introductory text and (a)(1) to replace each instance of ''ALJ's decision'' with ''ALJ's or attorney adjudicator's decision,'' ''before the ALJ'' with ''before the ALJ or attorney adjudicator,'' and ''the ALJ level'' with ''the OMHA level.'' We believe the standard for review of evidence at the Council level would be the same regardless of whether the case was decided by an ALJ or attorney adjudicator, as proposed in section II.B above, at the OMHA level. We are also proposing corresponding revisions to § 423.2122(a) introductory text and (a)(1). Also, to help ensure it is clear that the exception for evidence related to new issues raised at the OMHA level is not limited to proceedings in which a hearing before an ALJ was conducted, we are proposing at §§ 405.1122(a)(1) and § 423.2122(a)(1) to replace ''hearing decision'' with ''ALJ's or attorney adjudicator's decision.'' Current § 405.1122(a)(2) provides that if the Council determines that additional evidence is needed to resolve the issues in the case, and the hearing record indicates that the previous decision-makers have not attempted to obtain the evidence, the Council may remand the case to an ALJ to obtain the evidence and issue a new decision. For the reasons described above, we are proposing at § 405.1122(a)(2) to replace ''ALJ'' with ''ALJ or attorney adjudicator'' and ''hearing record'' with ''administrative record,'' along with corresponding revisions to § 423.2122(a)(2). Current § 405.1122(b)(1) describes the evidence that may be considered by the Council when a case is escalated from the ALJ level. For the reasons described above, we are proposing to replace ''ALJ level'' with ''OMHA level.'' We are not proposing any corresponding changes to § 423.2122 because escalation is not available for Part D coverage appeals. Finally, we are proposing to replace all remaining instances of ''ALJ'' in § 405.1122(b)(1), (b)(2), (c)(2), (c)(3) introductory text, (c)(3)(i), and (c)(3)(ii) with ''ALJ or attorney adjudicator,'' as we believe the Council's authority to consider evidence entered in the record by an attorney adjudicator and to remand a case to an attorney adjudicator for consideration of new evidence would be the same as the Council's current authority to consider evidence entered in the record by an ALJ and remand a case to an ALJ. We are not proposing any corresponding changes to § 423.2122 because there are no remaining references to ''ALJ.''

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''What evidence may be submitted to the Council'' at the beginning of your comment.

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

Current §§ 405.1126(a) and (b) explain the Council's remand authority. We are proposing to replace each instance of ''ALJ'' with ''ALJ or attorney adjudicator'' to provide that the Council may remand a case in which additional evidence is needed or additional action is required by the ALJ or attorney adjudicator, as proposed in section II.B above. Proposed § 405.1126(b) would also provide that an ALJ or attorney adjudicator would 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. We believe it is necessary for the Council to have the same authority to remand an attorney adjudicator's decision to the attorney adjudicator as the Council currently has to remand an ALJ's decision to the ALJ, and that the attorney adjudicator's actions with respect to the remanded case should be subject to the same requirements as an ALJ's actions under the current provisions. We are also proposing corresponding revisions to § 423.2126(a)(1) and (a)(2). Current §§ 405.1126(c) and (d) describe the procedures that apply when the Council receives a recommended decision from the ALJ, including the right of the parties to file briefs or other written statements with the Council. Because we are proposing in § 405.1126(a) for the Council to have the same authority to order an attorney adjudicator to issue a recommended decision on remand as the Council currently has to order an ALJ to issue a recommended decision, we are also proposing at § 405.1126(c) and (d) to replace ''ALJ'' with ''ALJ or attorney adjudicator'' to provide that the provisions apply to attorney adjudicators to the same extent as the provisions apply to ALJs, along with corresponding revisions to § 423.2126(a)(3) and (a)(4). Finally, current § 405.1126(e)(2) provides that if

the Council determines more evidence is required after receiving a recommended decision, the Council may again remand the case to an ALJ for further development and another decision or recommended decision. Because we believe the Council should have the same authority to remand a case to an attorney adjudicator following receipt of a recommended decision, we are proposing at § 405.1126(e)(2) to replace ''ALJ'' with ''ALJ or attorney adjudicator,'' along with a corresponding revision to § 423.2126(a)(5)(ii), and to insert ''if applicable'' after rehearing because a rehearing may not be applicable in every circumstance (for example, where an attorney adjudicator issued a recommended decision and the Council does not remand with instructions to transfer the appeal to an ALJ for a hearing).

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Case remanded by the Council'' at the beginning of your comment.

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

Current §§ 405.1128 and 423.2128 explain the actions the Council may take after reviewing the administrative record and any additional evidence (subject to the limitations on Council consideration of additional evidence). We are proposing at §§ 405.1128(a) and 423.2128(a) to replace ''ALJ'' with ''ALJ or attorney adjudicator,'' which would provide that the Council may make a decision or remand a case to an ALJ or to an attorney adjudicator (as proposed in section II.B above). We believe the Council should have the same authority to remand a case to an attorney adjudicator as the Council currently has to remand a case to an ALJ. Also, to help ensure there is no confusion that Council actions are not limited to proceedings in which a hearing before an ALJ was conducted, we are proposing at §§ 405.1128(b) and 423.2128(b) to replace ''the ALJ hearing decision'' with ''the ALJ's or attorney adjudicator's decision.''

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Action of the Council'' at the beginning of your comment.

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

Current § 405.1132 explains the process for an appellant to seek escalation of an appeal (other than an appeal of an ALJ dismissal) from the Council to Federal district court if the Council does not issue a decision or dismissal or remand the case to an ALJ within the adjudication time frame specified in § 405.1100, or as extended as provided in subpart I. We are proposing at § 405.1132 to replace each instance of ''ALJ'' with ''ALJ or attorney adjudicator.'' These revisions would provide that the appellant may request that escalation of a case, other than a dismissal issued by an ALJ or attorney adjudicator, as proposed in section II.B above to Federal district court if the Council is unable to issue a decision or dismissal or remand the case to an ALJ or attorney adjudicator within an applicable adjudication time frame, and that appellants may file an action in Federal district court if the Council is not able to issue a decision, dismissal, or remand to the ALJ or attorney adjudicator within 5 calendar days of receipt of the request for escalation or 5 calendar days from the end of the applicable adjudication time period. We are not proposing any corresponding changes to part 423, subpart U, as there is no equivalent provision because there are no escalation rights for Part D coverage appeals.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Request for escalation to Federal court'' at the beginning of your comment.

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

Current §§ 405.1136, 423.1976, and 423.2136 set forth the right to file a request for judicial review in Federal district court of a Council decision (or of an ALJ's decision if the Council declines review as provided in § 423.1976(a)(1)). Current § 405.1136 also provides that judicial review in Federal district court may be requested if the Council is unable to issue a decision, dismissal, or remand within the applicable time frame following an appellant's request for escalation. In addition, current §§ 405.1136 and 423.2136 specify the requirements and procedures for filing a request for judicial review, the Federal district court in which such actions must be filed, and describe the standard of review. We are proposing at §§ 405.1136, 423.1976, and 423.2136 to replace each instance of ''ALJ'' with ''ALJ or attorney adjudicator,'' and ''ALJ's'' with ''ALJ's or attorney adjudicator's'' to help ensure that there is no confusion that appellants may file a request for judicial review in Federal district court of actions made by an attorney adjudicator, as proposed in section II.B above (or by the Council following an action by an attorney adjudicator), to the same extent that judicial review is available for ALJ actions (or Council actions following an action by an ALJ).

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Judicial review'' at the beginning of your comment.

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

Current §§ 405.1138 and 423.2138 set forth the actions the Council may take when a Federal district court remands a case to the Secretary for further consideration. We are proposing at §§ 405.1138 and 423.2138, and 405.1140 and 423.2140 to replace ''ALJ'' with ''ALJ or attorney adjudicator'' to provide that when a case is remanded by a Federal district court for further consideration by the Secretary, the Council may remand the case to an ALJ or attorney adjudicator (as proposed in section II.B above), to issue a decision, take other action, or return the case to the Council with a recommended decision.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Case remanded by a Federal court'' at the beginning of your comment.

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

Current §§ 405.1140 and 423.2140 set forth the procedures that apply when a case is remanded to the Secretary for further consideration, and the Council subsequently remands the case to an ALJ, including the procedures for the Council to assume jurisdiction following the decision of the ALJ on its own initiative or upon receipt of written exceptions from a party or the enrollee. We are proposing to replace each instance of ''ALJ'' throughout §§ 405.1140 and 423.2140 with ''ALJ or attorney adjudicator'' and to replace the reference to ''ALJ's'' at §§ 405.1140(d) and 423.2140(d) with ''ALJ's or attorney adjudicator's.'' These revisions would provide that the Council may remand these cases to the ALJ or attorney adjudicator, as proposed in section II.B above, following remand from a Federal district court, and that the decision of the ALJ or attorney adjudicator becomes the final decision of the Secretary after remand unless the Council assumes

jurisdiction. These revisions would further apply the rules set forth in this section to cases reviewed by an attorney adjudicator as well as an ALJ. As described above in relation to the Council's general remand authority under §§ 405.1126 and 423.2126, we believe it is necessary for the Council to have the same authority to remand an attorney adjudicator's decision to the attorney adjudicator as the Council currently has to remand an ALJ's decision to the ALJ, and that would include cases that are remanded by a Federal district court to the Secretary for further consideration.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Council review of ALJ decision in a case remanded by a Federal district court'' at the beginning of your comment.

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

In accordance with section 1869(b)(1)(F) of the Act, current § 405.1204 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. Current § 405.1204(c)(4)(iii) explains that the QIC's initial notification may be done by telephone followed by a written notice that includes information about the beneficiary's right to appeal the QIC's reconsideration decision to an ALJ, and current § 405.1204(c)(5) provides that if the QIC does not issue a decision within 72 hours of receipt of the request for a reconsideration, the case can be escalated to the ''ALJ hearing level.'' For consistency with part 405, subpart I, and to explain the rules that apply to an ALJ hearing, we are proposing at § 405.1204(c)(4)(iii) and (c)(5) to amend these references to convey 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. We believe these revisions would explain where a request for an ALJ hearing is directed from a subpart J proceeding, and the rules that would be applied to the request for an ALJ hearing following the QIC's reconsideration or escalation of the request for a QIC reconsideration.

Current § 405.1204(c)(5) 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. However, this is inconsistent with the amount in controversy specified in section 1869(b)(1)(E) of the Act. We are proposing to revise § 405.1204(c)(5) to provide 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 under § 405.1006. We believe that this is more consistent with section 1869(b)(1)(E) of the Act, which provides that a hearing by the Secretary shall not be available to an individual if the amount in controversy is less than $100, as adjusted annually after 2004, which is implemented in § 405.1006, and would bring consistency to the amounts in controversy required for an escalation under subpart J and subpart I.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Part 405, subpart J expedited reconsiderations'' at the beginning of your comment.

C. Part 422, Subpart M

1. General Provisions (§ 422.562)

Current § 422.562(c)(1)(ii) 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. However, we believe this provision is an outdated reference that has been superseded by current § 422.622, which provides for requesting immediate QIO review of the decision to discharge an enrollee from an inpatient hospital setting and appeals of that review as described under part 422, subpart M. The regulatory provisions at § 422.622 describe the processes for QIO review of the decision to discharge an MA enrollee from the inpatient hospital setting. Section 422.622 also explains the availability of other appeals processes if the enrollee does not meet the deadline for an immediate QIO review of the discharge decision. These part 422, subpart M provisions govern the review processes for MA enrollees disputing discharge from an inpatient hospital setting. As noted above, we believe the references to the procedures in parts 476 and 478 at § 422.562(c)(1)(ii) are obsolete. Therefore, we are proposing to delete § 422.562(c)(1) to remove the outdated reference in current § 422.562(c)(1)(ii) and consolidate current (c)(1) and (c)(1)(i) into proposed (c)(1). We also note that changes to § 422.562(d) are proposed and discussed in section II.C, above.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''General provisions'' at the beginning of your comment.

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). We are proposing at § 422.594(b)(2) to amend 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 § 422.600, which in turn refers to the part 405 computation of the amount in controversy. We believe this would increase accuracy in conveying when a party has a right to an ALJ hearing, and would be more consistent with section 1852(g)(5) of the Act, which provides that a hearing by the Secretary shall not be available to an individual if the amount in controversy is less than $100, as adjusted annually in accordance with section 1869(b)(1)(E)(iii) of the Act, which is implemented in part 405 at § 405.1006. We discuss proposed changes to § 405.1006 in section III.A.3.d above.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Notice of reconsidered determination by the independent entity'' at the beginning of your comment.

3. Request for an ALJ Hearing (§ 422.602)

Current § 422.602(b) 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. However, in similar appeals brought under Medicare Part A and Part B at § 405.1002, and Part D at § 423.2002, a request for an ALJ hearing must be filed within 60 calendar days of receipt of a notice of reconsideration. We are proposing at § 422.602(b)(1) to align the part 422 time frame for filing a request for an ALJ hearing with provisions for similar appeals under Medicare Part A and Part B, and Part D. As proposed, a request for an ALJ hearing would 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, we are proposing at § 422.602(b)(2) that the date of receipt of the reconsideration is presumed to be 5 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.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Request for an ALJ hearing'' at the beginning of your comment.

4. Medicare Appeals Council (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. We believe that the reference to a hearing, hearing decision, then decision or dismissal may cause confusion regarding a party's right to request Council review. We are proposing at § 422.608 that any party to the ALJ's or, as proposed in section II.B above, 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. We believe this would resolve any potential confusion regarding a party's right to request Council review of a decision when a hearing was not conducted, and a dismissal of a request for hearing, and provide that the section applies to decisions and dismissals issued by an attorney adjudicator, as proposed in section II.B. Therefore, proposed § 422.608 would provide that a request for Council review may be filed by a party if he or she is dissatisfied with an ALJ's or attorney adjudicator's decision or dismissal.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Medicare Appeals Council (Council) review'' at the beginning of your comment. We discuss other proposed changes to § 422.608 in section II.D above.

5. Judicial Review (§ 422.612)

Current § 422.612 provides the circumstances under which a party may request judicial review of an ALJ or Council decision, and directs appellants to the procedures in part 405 for filing a request for judicial review. We are proposing at § 422.612(a) to replace each instance of ''ALJ's'' with ''ALJ's or attorney adjudicator's''. Thus, as provided in § 422.612(a), appellants would be able to file a request for judicial review in Federal district court of actions made by an attorney adjudicator, as proposed in section II.B above (or by the Council following an action by an attorney adjudicator), to the same extent that judicial review is available under § 412.622(a) for ALJ actions (or Council actions following an action by an ALJ).

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Judicial review'' at the beginning of your comment.

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

Current § 422.616(a) provides that the determination or decision of an MA organization, independent entity, ALJ, or the Council that is otherwise final and binding may be reopened and revised by the entity that made the determination or decision, subject to the rules in part 405. We are proposing at § 422.616(a) to replace ''ALJ'' with ''ALJ or attorney adjudicator.'' As described in section III.A.2.l above with respect to §§ 405.980, 405.982, 405.984, 423.1980, 423.1982, and 423.1984, we believe it is necessary for an attorney adjudicator to have the authority to reopen the attorney adjudicator's decision on the same bases as an ALJ may reopen the ALJ's decision under the current rules, and the action should be subject to the same limitations and requirements, and have the same effects as an ALJ's action under these provisions.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Reopening and revising determinations and decisions'' at the beginning of your comment.

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

Current § 422.618(c)(1) and (c)(2) provide instructions for effectuation of decisions issued by an ALJ, or at a higher level of appeal, that reverse an IRE's decision on a standard reconsidered determination or decision. We are proposing to replace ''ALJ'' with ''ALJ or attorney adjudicator'' at § 422.618(c)(1) and to make corresponding changes to § 422.619(c)(1) for decisions that reverse an IRE's decision on an expedited reconsidered determination or decision. We believe the process for effectuating the decision of an attorney adjudicator, as proposed in section II.B above, should be the same as the process for effectuating the decision of an ALJ.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''How an MA organization must effectuate standard reconsideration determinations and decisions, and expedited reconsidered determinations'' at the beginning of your comment.

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

In accordance with section 1852(g)(3) and (g)(4) of the Act, current §§ 422.622 and 422.626 provide for reviews of QIO determinations and expedited IRE reconsiderations of certain QIO determinations related to terminations of covered provider services furnished by home health agencies (HHAs), skilled nursing facilities (SNFs), and comprehensive outpatient rehabilitation facilities (CORFs) to a Medicare Advantage enrollee, and Medicare Advantage enrollee discharges from an inpatient hospital. Current § 422.622(g) provides that if an enrollee is still an inpatient in the hospital after a QIO determination reviewing a provider discharge from a hospital, the enrollee may request an IRE reconsideration of the QIO determination in accordance with § 422.626(g); and if an enrollee is no longer an inpatient in the hospital, the enrollee may appeal the QIO determination to an ALJ. Current § 422.626(g)(3) provides that if the IRE reaffirms its decision to terminate covered provider services furnished by a HHA, SNF, or CORF in whole or in part, the enrollee may appeal the IRE's reconsidered determination to an ALJ. We are proposing at §§ 422.622(g)(2) and 422.626(g)(3) to amend these references to provide that the appeal is made to OMHA for an ALJ hearing. We believe these revisions would clarify where a request for an ALJ hearing is directed.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Requesting immediate QIO review of the decision to discharge from the

inpatient hospital and fast-track appeals of service terminations to independent review entities (IREs)'' at the beginning of your comment.

D. Part 478, Subpart B

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

Current § 478.14(c)(2) explains that for the purposes of part 478 reconsideration and appeals, limitation of liability determinations on excluded coverage of certain services are made under section 1879 of the Act, and initial determinations under section 1879 of the Act and further appeals are governed by the reconsideration and appeal procedures in part 405, subpart G for determinations under Medicare Part A, and part 405, subpart H for determinations under Medicare Part B. In addition, current § 478.40 states that an ALJ hearing may be obtained from the SSA Office of Hearings and Appeals, and the provisions of subpart G of 42 CFR part 405 apply unless they are inconsistent with the specific provisions of subpart B of 42 CFR part 478. These references are outdated. Since §§ 478.14 and 478.40 were last updated in 1999, section 931 of the MMA transferred responsibility for the ALJ hearing function from SSA to HHS, and HHS established OMHA in 2005, to administer the ALJ hearing function, including ALJ hearings conducted under titles XI and XVIII of the Social Security Act (see 70 FR 36386). In addition, BIPA and the MMA established new appeal procedures that were implemented in 2005, at 42 CFR part 405, subpart I (70 FR 11420), and the portions of subparts G and H that previously applied to part 478, subpart B appeals were removed in 2012 (77 FR 29002). Proposed §§ 478.14 and 478.40 would replace the current outdated references to part 405, subparts G and H, with references to part 405, subpart I. Proposed § 478.40 would also update the reference to the entity with responsibility for the ALJ hearing function by replacing the SSA Office of Hearings and Appeals with OMHA.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Applicability and beneficiary's right to a hearing'' at the beginning of your comment.

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

Similar to current § 478.40, as discussed above, current § 478.42(a) has outdated references to SSA offices that are no longer 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. Proposed § 478.42(a) would direct beneficiaries to file a request for an ALJ hearing with the OMHA office identified in the QIO's notice of reconsidered determination. This revision would be clearer for beneficiaries, who are provided with appeal instructions by the QIOs, and reduce delays in obtaining a hearing by an OMHA ALJ.

Current § 478.42(b) requires that a request for hearing is filed within 60 calendar days of receipt of the notice of the QIO reconsidered determination and the date of receipt is assumed to be 5 days after the date on the notice unless there is a reasonable showing to the contrary. Current § 478.42(b) also provides that a request is considered filed on the date it is postmarked. To align part 478, subpart B with procedures for requesting an ALJ hearing under part 405, subpart I; part 422, subpart M; and part 423, subpart U, proposed § 478.42(b) would provide 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 5 ''calendar'' days after the date of the notice. In addition, to further align the part 478, subpart B procedures for requesting an ALJ hearing with the other parts, proposed § 478.42(c) would amend the standard to demonstrate that notice of QIO reconsidered determination was not received within 5 calendar days by requiring ''evidence'' rather than the current ''reasonable showing,'' and would also revise when a request is considered filed, from the date it is postmarked to the date it is received by OMHA. These changes would create parity with requests for hearing filed by beneficiaries and enrollees for similar services but under other parts of title 42, chapter IV.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Submitting a request for a hearing'' at the beginning of your comment.

3. Determining the Amount in Controversy (§ 478.44)

Current § 478.44(a) explains how the amount in controversy for an ALJ hearing is determined in part 478, subpart B hearings. Current § 478.44(a) has outdated references to §§ 405.740 and 405.817 from part 405, subparts G and H respectively, for calculating the amount in controversy for an individual appellant or multiple appellants. In 2012, subpart G was removed and subpart H was significantly revised and no longer applies to Medicare claim appeals (77 FR 29002). To update these reference to the current part 405 rules, proposed § 478.44(a) would replace the outdated cross-references for calculating the amount in controversy with § 405.1006(d) and (e), which describe the calculation for determining the amount in controversy and the standards for aggregating claims by an individual appellant or multiple appellants. We discuss proposed changes to § 405.1006 in section III.A.3.d above.

Current § 478.44(b) and (c) explain 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. To prevent potential confusion, proposed § 478.44(b) and (c) would replace ''parties to the hearing'' with ''parties'' so it is understood that they are parties regardless of whether a hearing is conducted. Because an attorney adjudicator would have to determine whether appeals assigned to him or her, as proposed in section II.B above, meet the amount in controversy requirement, we also propose at § 478.44(a) and (b) that an attorney adjudicator may determine that 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. However, because we are not proposing that an attorney adjudicator can dismiss a request for an ALJ hearing because the amount in controversy is not met, proposed § 478.44(c) provides that an ALJ would 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.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Determining the amount in controversy'' at the beginning of your comment.

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

Current § 478.46(a) states that the Council will review an ALJ's hearing decision or dismissal under the same circumstances as those set forth at 20 CFR 404.970, which is now an outdated reference to SSA Appeals Council procedures for Council review. We are proposing at § 478.46(a) to replace the outdated reference to 20 CFR 404.970 with references to current §§ 405.1102 (''Request for Council review when ALJ or attorney adjudicator issued a decision or dismissal'') and 405.1110 (''Council reviews on its own motion''). In addition, we are proposing in § 478.46(a) and (b) to replace ''hearing decision'' with ''decision,'' and ''ALJ'' with ''ALJ or attorney adjudicator'' because hearings are not always conducted and a decision can generally be appealed regardless of whether a hearing was conducted, and attorney adjudicators may issue decisions or dismissals for which Council review may be requested, as proposed in section II.B above.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Medicare Appeals Council and judicial review'' at the beginning of your comment.

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

The title of current § 478.48 references reopenings and revisions of reconsidered determinations and hearing decisions, and current § 478.48 has an outdated reference to subpart G of 42 CFR part 405 for the procedures for reopening a decision by an ALJ or the Departmental Appeals Board.

We are proposing to revise the title of § 478.48 to replace ''hearing decision'' with ''decision,'' and in proposed paragraphs (b) and (c) 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, as proposed in section II.B above, attorney adjudicators, as well as review decisions, which are conducted by the Medicare Appeals Council at the Departmental Appeals Board. We also propose at § 478.48(b) to replace the outdated reference to § 405.750(b), which was part of the now removed part 405, subpart G (77 FR 29016 through 29018), with § 405.980, which is the current part 405, subpart I reopening provision.

We are inviting public comments on these proposals. If you choose to comment on the proposals in this section, please include the caption ''Reopening and revision of a reconsidered determination or a decision'' at the beginning of your comment.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The PRA exempts most of the information collection activities referenced in this proposed rule. In particular, the implementing regulations of the PRA at 5 CFR 1320.4 exclude collection activities during the conduct of a civil action to which the United States or any official or agency thereof is a party. Civil actions include administrative actions such as redeterminations, reconsiderations, and/or appeals. Specifically, these actions are taken after the initial determination or a denial of payment, or MAO organization determination or Part D plan sponsor coverage determination. However, one requirement contained in this proposed rule is subject to the PRA because the burden is imposed prior to an administrative action or denial of payment. This requirement is discussed below.

In summary, we are proposing at § 405.910 that when a provider or supplier is the party appointing a representative, the appointment of representation would include the Medicare National Provider Identifier (NPI) of the provider or supplier that furnished the item of service. Although this is a new regulatory requirement, the current Medicare Claims Processing Manual already states that the NPI should be included when a provider or supplier appoints a representative. The standardized form for appointing a representative, Form CMS–1696, currently provides a space for the information in question. Importantly, this form is currently approved under OMB control number 0938–0950 and expires June 30, 2018.

The burden associated with this requirement is the time and effort of an individual or entity who is a provider or supplier to prepare an appointment of representation containing the NPI. As stated earlier, this requirement and the related burden are subject to the PRA; however, because we believe that this information is already routinely being collected, we estimate there would be no additional burden for completing an appointment of representative in accordance with proposed 405.910.

If you wish to view the standardized form and the supporting documentation, you can download a copy from the CMS Web site at *https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-list.html*.

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements described above.

We are inviting public comment on the burden associated with these information collection requirements.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We have determined that the effect of this proposed rule does not reach this economic threshold and thus is not considered a major rule. As detailed above, this proposed rule would only make minimal changes to the existing Medicare appeals procedures for claims for benefits under or entitlement to the original Medicare programs, and coverage of items, services, and drugs under the Medicare Advantage and voluntary Medicare prescription drug programs. Thus, this proposed rule would have negligible financial impact on beneficiaries and enrollees, providers or suppliers, Medicare contractors, MAOs, and Part D plan sponsors, but would derive benefits to the program and appellants.

HHS recognizes that the current appeals backlog is a matter of great significance, and it has made it a priority to adopt measures that are designed to reduce the backlog and improve the overall Medicare appeals process moving forward. To that end, HHS has initiated a series of measures, including this proposed regulation, that are aimed at both reducing the backlog and creating a more efficient Medicare appeals system.

We believe the changes proposed in this regulation will help address the Medicare appeals backlog and create efficiencies at the ALJ level of appeal by allowing OMHA to reassign a portion of workload to non-ALJ adjudicators, reduce appeals of low-value claims, and reduce procedural ambiguities that result in unproductive efforts at OMHA and unnecessary appeals to the Medicare Appeals Council. In addition, the other proposed changes, including precedential decisions and generally limiting CMS and CMS contractor participation or party status at the OMHA level unless the ALJ determines participation by additional entities is necessary for a full examination of the matters at issue (as provided in proposed §§ 405.1010(d) and 405.1012(d)), will collectively make the ALJ hearing process more efficient through streamlined and standardized procedures and more consistent decisions, and reduce appeals to the Medicare Appeals Council.

In particular, we are able to estimate the impact from two of the proposed modifications: proposals to expand the pool of adjudicators and the modifications to calculating the amount in controversy (AIC) required for an ALJ hearing. Based on FY 2015, and an assumption that future years are similar to FY 2015, we estimate that the proposals to expand the pool of adjudicators at OMHA could redirect approximately 23,650 appeals per year to attorney adjudicators to process these appeals at a lower cost than would be required if only ALJs were used to address the same workload. If the number of requests for hearing, waivers of oral hearing, requests for review of a contractor dismissal, or appellant withdrawals of requests for hearing vary from FY 2015 in future years then the number of appeals potentially addressed by attorney adjudicators would likely also vary. Additionally, based on FY 2015 requests for an ALJ hearing, we estimate that revising the calculation methodology for the AIC required for an ALJ hearing could remove appeals related to over 2,600 Part B low-value claims per year from the ALJ hearing process, after accounting for the likelihood of appellants aggregating claims to meet the AIC. We also note that appeals filed by Medicare beneficiaries, and Medicare Advantage and Part D prescription drug plan enrollees would be minimally impacted because they often appeal claim or coverage denials for which they are financially responsible, and for which we would use the existing AIC calculation methodology. We note that this analysis is limited by the use of only one fiscal year's worth of data, and that there is uncertainty in this estimate as the number of appeals that would fall under the revised AIC calculation may vary from year to year.

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) (RFA) requires agencies to prepare an initial regulatory flexibility analysis to describe the impact of the proposed rule on small entities, unless the head of the agency can certify that the rule would not have a significant economic impact on a substantial number of small entities. The RFA generally defines a ''small entity'' as: (1) A proprietary firm meeting the size standards of the Small Business Administration (SBA); (2) a not-for-profit organization that is not dominant in its field; or (3) a small government jurisdiction with a population of less than 50,000. States and individuals are not included in the definition of ''small entity.'' HHS uses as its measure of significant economic impact on a substantial number of small entities a change in revenues of more than 3 to 5 percent.

For purposes of the RFA, most providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any one year. In addition, a number of MAOs and Part D plan sponsors (insurers) are small entities due to their nonprofit status; however, few if any meet the SBA size standard for a small insurance firm by having revenues of $38.5 million or less in any one year. Individuals and States are not included in the definition of a small entity. We have determined and we certify that this proposed rule would not have a significant economic impact on a substantial number of small entities because as noted above, this proposed rule if finalized would make only minimal changes to the existing appeals procedures. Therefore, we are not preparing an analysis for the RFA.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis (RIA) if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. For proposed rules, this analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We have determined that this proposed rule would not have a significant effect on the operations of a substantial number of small rural hospitals. As noted above, this proposed rule if finalized would make only minimal changes to the existing appeals procedures and thus, would not have a significant impact on small entities or the operations of a substantial number of small rural hospitals. Therefore, we are not preparing an analysis for section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that would include any Federal mandate that may result in expenditure in any one year by State, local, or Tribal governments, in the aggregate, or by the private sector, of $100 million in 1995 dollars, updated annually for inflation. Currently, that threshold is approximately $146 million. This proposed rule would not impose spending costs on State, local, or tribal governments in the aggregate, or on the private sector in the amount of $146 million in any one year, because as

noted above, this proposed rule if finalized would make only minimal changes to the existing appeals procedures.

VII. Federal Analysis

Executive Order 13132 on Federalism establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This proposed rule would not impose substantial direct requirement costs on State or local governments, preempt State law, or otherwise implicate federalism.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 401

Claims, Freedom of information, Health facilities, Medicare, Privacy.

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 478

Administrative practice and procedure, Health care, Health professions, Peer Review Organizations (PRO), Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 42 CFR chapter IV as set forth below:

PART 401—GENERAL ADMINISTRATIVE REQUIREMENTS

■ 1. The authority citation for part 401 continues to read as follows:

Authority: Secs. 1102, 1871, and 1874(e) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395w–5).

■ 2. Section 401.109 is added to read as follows:

§ 401.109 Precedential Final Decisions of the Secretary.

(a) The Chair of the Department of Health and Human Services Departmental Appeals Board may designate a final decision of the Secretary issued by the Medicare Appeals Council in accordance with part 405, subpart I; part 422, subpart M; part 423, subpart U; or part 478, subpart B, of this chapter as precedential.

(b) Precedential decisions are made available to the public, with personally identifiable information of the beneficiary removed, and have precedential effect from the date they are made available to the public. Notice of precedential decisions is published in the **Federal Register**.

(c) Medicare Appeals Council decisions designated in accordance with paragraph (a) of this section have precedential effect and are binding on all CMS components, on all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

(d) Precedential effect, as used in this section, means that the Medicare Appeals Council's—

(1) Legal analysis and interpretation of a Medicare authority or provision is binding and must be followed in future determinations and appeals in which the same authority or provision applies and is still in effect; and

(2) Factual findings are binding and must be applied to future determinations and appeals involving the same parties if the relevant facts are the same and evidence is presented that the underlying factual circumstances have not changed since the issuance of the precedential final decision.

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 3. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 4. Section 405.902 is amended by adding the definitions of ''Attorney Adjudicator'', ''Council'', and ''OMHA'' in alphabetical order and removing the definition of ''MAC'' to read as follows:

§ 405.902 Definitions.

* * * * *

Attorney Adjudicator means a licensed attorney employed by OMHA with knowledge of Medicare coverage and payment laws and guidance, and authorized to take the actions provided for in this subpart on requests for ALJ hearing and requests for reviews of QIC dismissals.

* * * * *

Council stands for the Medicare Appeals Council within the Departmental Appeals Board of the U.S. Department of Health and Human Services.

* * * * *

OMHA stands for the Office of Medicare Hearings and Appeals within the U.S. Department of Health and Human Services, which administers the ALJ hearing process in accordance with section 1869(b)(1) of the Act.

* * * * *

■ 5. Section 405.904 is amended by revising paragraphs (a)(1) and (2) to read as follows:

§ 405.904 Medicare initial determinations, redeterminations and appeals: General description.

(a) * * *

(1) *Entitlement appeals.* The SSA makes an initial determination on an application for Medicare benefits and/or entitlement of an individual to receive Medicare benefits. A beneficiary who is dissatisfied with the initial determination may request, and SSA will perform, a reconsideration in accordance with 20 CFR part 404, subpart J if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request a hearing before an Administrative Law Judge (ALJ) under this subpart (42 CFR part 405, subpart I). If the beneficiary obtains a hearing before an ALJ and is dissatisfied with the decision of the ALJ, or if the beneficiary requests a hearing and no hearing is conducted, and the beneficiary is dissatisfied with the decision of an ALJ or an attorney adjudicator, he or she may request the Medicare Appeals Council (Council) to review the case. Following the action of the Council, the beneficiary may be entitled to file suit in Federal district court.

(2) *Claim appeals.* The Medicare contractor makes an initial determination when a claim for Medicare benefits under Part A or Part B is submitted. A beneficiary who is dissatisfied with the initial determination may request that the contractor perform a redetermination of the claim if the requirements for obtaining a redetermination are met. Following the contractor's redetermination, the beneficiary may request, and the Qualified Independent Contractor (QIC) will perform, a reconsideration of the claim if the requirements for obtaining a reconsideration are met. Following the reconsideration, the beneficiary may request a hearing before an ALJ. If the beneficiary obtains a hearing before the ALJ and is dissatisfied with the decision of the ALJ, or if the beneficiary requests a hearing and no hearing is conducted, and the beneficiary is dissatisfied with the decision of an ALJ or attorney adjudicator, he or she may request the Council to review the case. If the Council reviews the case and issues a decision, and the beneficiary is dissatisfied with the decision, the beneficiary may file suit in Federal district court if the amount remaining in controversy and the other requirements for judicial review are met.

* * * * *

§ 405.906 [Amended]

■ 6. Section 405.906(b) introductory text is amended by—

■ a. Removing from the paragraph heading the phrase ''hearing and MAC'' and adding ''proceedings on a request for hearing, and Council review'' in its place.

■ b. Removing the phrase ''hearing, and MAC review'' and adding ''proceedings on a request for hearing, and Council review'' in its place.

§ 405.908 [Amended]

■ 7. Section 405.908 is amended by—

■ a. Removing the term ''ALJ'' and adding ''OMHA'' in its place.

■ b. Removing the term ''MAC'' and adding ''Council'' in its place.

■ 8. Section 405.910 is amended by—

■ a. Revising paragraph (c)(5).

■ b. Adding paragraph (d)(3).

■ c. Revising paragraphs (f)(1), (i)(2), and (3).

■ d. Revising paragraph (l).

■ e. Adding paragraph (m)(4).

The additions and revisions read as follows:

§ 405.910 Appointed representatives.

* * * * *

(c) * * *

(5) Identify the beneficiary's Medicare health insurance claim number when the beneficiary is the party appointing a representative, or identify the Medicare National Provider Identifier number of the provider or supplier that furnished the item or service when the provider or supplier is the party appointing a representative;

* * * * *

(d) * * *

(3) If an adjudication time frame applies, the time from the later of the date that a defective appointment of representative was filed or the current appeal request was filed by the prospective appointed representative, to the date when the defect was cured or the party notifies the adjudicator that he or she will proceed with the appeal without a representative does not count towards the adjudication time frame.

* * * * *

(f) * * *

(1) *General rule.* An appointed representative for a beneficiary who wishes to charge a fee for services rendered in connection with an appeal before the Secretary must obtain approval of the fee from the Secretary. Services rendered below the OMHA level are not considered proceedings before the Secretary.

* * * * *

(i) * * *

(2) *Appeals.* When a contractor, QIC, ALJ or attorney adjudicator, or the Council takes an action or issues a redetermination, reconsideration, or appeal decision, in connection with an initial determination, it sends notice of the action to the appointed representative.

(3) The contractor, QIC, ALJ or attorney adjudicator, or Council sends any requests for information or evidence regarding a claim that is appealed to the appointed representative. The contractor sends any requests for information or evidence regarding an initial determination to the party.

* * * * *

(l) *Delegation of appointment by appointed representative.* (1) An appointed representative may not designate another individual to act as the appointed representative of the party unless—

(i) The appointed representative provides written notice to the party of the appointed representative's intent to delegate to another individual, which contains the name of the designee and the designee's acceptance to be obligated by and comply with the requirements of representation under this subpart; and

(ii) The party accepts the designation as evidenced by a written statement signed by the party. The written statement signed by the party is not required when the appointed representative and designee are attorneys in the same law firm or organization and the notice described in paragraph (l)(1)(i) of this section so indicates.

(2) A delegation is not effective until the adjudicator receives a copy of the acceptance described in paragraph (l)(1)(ii) of this section, unless the appointed representative and designee are attorneys in the same law firm or organization, in which case the notice described in paragraph (l)(1)(i) of this section may be submitted even though the acceptance described in paragraph (l)(1)(ii) of this section is not required.

(3) A party's or representative's failure to notify the adjudicator that an appointment of representative has been delegated is not good cause for missing a deadline or not appearing at a hearing.

(m) * * *

(4) A party's or representative's failure to notify the adjudicator that an appointment of representative has been revoked is not good cause for missing a deadline or not appearing at a hearing.

■ 9. Section 405.926 is amended by revising paragraphs (l) and (m) to read as follows:

§ 405.926 Actions that are not initial determinations.

* * * * *

(l) A contractor's, QIC's, ALJ's or attorney adjudicator's, or Council's determination or decision to reopen or not to reopen an initial determination, redetermination, reconsideration, decision, or review decision.

(m) Determinations that CMS or its contractors may participate in the proceedings on a request for an ALJ hearing or act as parties in an ALJ hearing or Council review.

* * * * *

§ 405.956 [Amended]

■ 10. Section 405.956(b)(8) is amended by removing the phrase ''an ALJ hearing'' and adding ''the OMHA level'' in its place.

■ 11. Section 405.968 is amended by revising paragraph (b)(1) to read as follows:

§ 405.968 Conduct of a reconsideration.

* * * * *

(b) * * *

(1) National coverage determinations (NCDs), CMS Rulings, Council decisions designated by the Chair of the Departmental Appeals Board as having precedential effect under § 401.109 of this chapter, and applicable laws and regulations are binding on the QIC.

* * * * *

■ 12. Section 405.970 is amended by revising the section heading and paragraphs (a) introductory text, (b), (c) introductory text, (e)(1), (e)(2)(i) and (ii) to read as follows:

§ 405.970 Timeframe for making a reconsideration following a contractor redetermination.

(a) *General rule.* Within 60 calendar days of the date the QIC receives a timely filed request for reconsideration following a contractor redetermination or any additional time provided by paragraph (b) of this section, the QIC mails, or otherwise transmits to the parties at their last known addresses, written notice of—

* * * * *

(b) *Exceptions.* (1) If a QIC grants an appellant's request for an extension of the 180 calendar day filing deadline made in accordance with § 405.962(b), the QIC's 60 calendar day decision-making timeframe begins on the date the QIC receives the late filed request for reconsideration following a contractor redetermination, or when the request for an extension that meets the requirements of § 405.962(b) is granted, whichever is later.

(2) If a QIC receives timely requests for reconsideration following a contractor redetermination from multiple parties, consistent with § 405.964(c), the QIC must issue a reconsideration, notice that it cannot complete its review, or dismissal within 60 calendar days for each submission of the latest filed request.

(3) Each time a party submits additional evidence after the request for reconsideration following a contractor redetermination is filed, the QIC's 60 calendar day decisionmaking timeframe is extended by up to 14 calendar days for each submission, consistent with § 405.966(b).

(c) *Responsibilities of the QIC.* Within 60 calendar days of receiving a request for a reconsideration following a contractor redetermination, or any additional time provided for under paragraph (b) of this section, a QIC must take one of the following actions:

* * * * *

(e) * * *

(1) If the appellant fails to notify the QIC, or notifies the QIC that the appellant does not choose to escalate the case, the QIC completes its reconsideration following a contractor redetermination and notifies the appellant of its action consistent with § 405.972 or § 405.976.

(2) * * *

(i) Complete its reconsideration following a contractor redetermination and notify all parties of its decision consistent with § 405.972 or § 405.976.

(ii) Acknowledge the escalation notice in writing and forward the case file to OMHA.

■ 13. Section 405.972 is amended by—

■ a. Revising the section heading.

■ b. Amending paragraph (b)(3) by removing the phrase ''reconsideration of a contractor's dismissal'' and adding ''review of a contractor's dismissal'' in its place.

■ c. Amending paragraph (e) by adding the phrase ''or attorney adjudicator'' after the phrase ''modified or reversed by an ALJ'' and removing the phrase ''reconsideration of a contractor's dismissal'' and adding ''review of a contractor's dismissal'' in its place.

The revision reads as follows:

§ 405.972 Withdrawal or dismissal of a request for reconsideration or review of a contractor's dismissal of a request for redetermination.

* * * * *

■ 14. Section 405.974 is amended by—

■ a. Revising the section heading.

■ b. Amending the heading to paragraph (b) by removing the phrase ''Reconsideration of contractor's'' and adding ''Review of a contractor's'' in its place.

■ c. Amending paragraph (b)(3) by removing the word ''reconsideration'' and adding ''review'' in its place.

The revision reads as follows:

§ 405.974 Reconsideration and review of a contractor's dismissal of a request for redetermination.

* * * * *

■ 15. Section 405.976 is amended by—

■ a. Amending paragraph (b)(5)(ii) by removing the phrase ''at an ALJ level, or made part of the administrative record'' and adding ''at the OMHA level'' in its place.

■ b. Revising paragraph (b)(7) to read as follows:

§ 405.976 Notice of a reconsideration.

* * * * *

(b) * * *

(7) A statement of whether the amount in controversy is estimated to meet or not meet the amount required for an ALJ hearing, if—

(i) The request for reconsideration was filed by a beneficiary who is not represented by a provider, supplier, or Medicaid State agency; and

(ii) The reconsideration decision is partially or fully unfavorable.

* * * * *

§ 405.978 [Amended]

■ 16. Section 405.978(a) is amended by removing the phrase ''An ALJ decision'' and adding ''An ALJ or attorney adjudicator decision'' in its place.

■ 17. Section 405.980 is amended by revising the section heading and paragraphs (a)(1)(iii) and (iv), (a)(4) and (5), (d) paragraph heading, (d)(2) and (3), (e) paragraph heading, and (e)(2) and (3) to read as follows:

§ 405.980 Reopening of initial determinations, redeterminations, reconsiderations, decisions, and reviews.

(a) * * *

(1) * * *

(iii) An ALJ or attorney adjudicator to revise his or her decision; or

(iv) The Council to revise the ALJ or attorney adjudicator decision, or its review decision.

* * * * *

(4) When a party has filed a valid request for an appeal of an initial determination, redetermination, reconsideration, ALJ or attorney adjudicator decision, or Council review, no adjudicator has jurisdiction to reopen an issue on a claim that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the contractor, QIC, ALJ or attorney adjudicator, or Council may reopen as set forth in this section.

(5) The contractor's, QIC's, ALJ's or attorney adjudicator's, or Council's decision on whether to reopen is binding and not subject to appeal.

* * * * *

(d) *Time frame and requirements for reopening reconsiderations, decisions and reviews initiated by a QIC, ALJ or attorney adjudicator, or the Council.*

* * * * *

(2) An ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision on its own motion within 180 calendar days from the date of the decision for good cause in accordance with § 405.986. If the decision was procured by fraud or similar fault, then the ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision, at any time.

(3) The Council may reopen its review decision on its own motion within 180 calendar days from the date of the review decision for good cause in accordance with § 405.986. If the Council's decision was procured by fraud or similar fault, then the Council may reopen at any time.

(e) *Time frames and requirements for reopening reconsiderations, decisions, and reviews requested by a party.*

* * * * *

(2) A party to an ALJ or attorney adjudicator decision may request that an ALJ or attorney adjudicator reopen his or her decision, or the Council reopen an ALJ or attorney adjudicator decision, within 180 calendar days from the date of the decision for good cause in accordance with § 405.986.

(3) A party to a Council review may request that the Council reopen its decision within 180 calendar days from the date of the review decision for good cause in accordance with § 405.986.

§ 405.982 [Amended]

■ 18. Section 405.982(a) and (b) are amended by removing the phrase ''ALJ, or the MAC'' and adding the phrase ''ALJ or attorney adjudicator, or the Council'' in its place.

■ 19. Section 405.984 is amended by—

■ a. Amending paragraph (c) by removing the phrase ''in accordance with § 405.1000 through § 405.1064'' and adding ''in accordance with § 405.1000 through § 405.1063'' in its place.

■ b. Revising paragraphs (d) and (e) to read as follows:

§ 405.984 Effect of a revised determination or decision.

* * * * *

(d) *ALJ or attorney adjudicator decisions.* The revision of an ALJ or attorney adjudicator decision is binding upon all parties unless a party files a written request for a Council review that is accepted and processed in accordance with § 405.1100 through § 405.1130.

(e) *Council review.* The revision of a Council review is binding upon all parties unless a party files a civil action in which a Federal district court accepts jurisdiction and issues a decision.

* * * * *

■ 20. Section 405.990 is amended by—

■ a. Amending paragraph (a)(2) by removing the phrase ''Medicare Appeals Council (MAC)'' and adding the term ''Council'' in its place.

■ b. Amending paragraphs (b)(1) introductory text, (b)(1)(i)(B), (b)(4), and (d)(2)(ii) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ c. Amending paragraph (b)(1)(i)(A) by removing the phrase ''the ALJ has'' and adding ''the ALJ or attorney adjudicator has'' in its place.

■ d. Amending paragraph (b)(1)(ii) by removing the phrase ''to the ALJ level'' and adding ''to OMHA for an ALJ hearing'' in its place.

■ e. Amending paragraphs (c)(3), (4), and (5) by removing the term ''ALJ hearing decision'' and adding ''ALJ or attorney adjudicator decision'' in its place.

■ h. Revising paragraph (d)(1).

■ i. Amending paragraph (d)(2)(i) by removing the term ''ALJ's'' and adding ''ALJ's or attorney adjudicator's'' in its place.

■ j. Amending paragraph (d)(2)(ii) by removing the term ''MAC's'' and adding ''Council's'' in its place.

■ k. Revising paragraphs (i)(1) and (2).

The revisions read as follows:

§ 405.990 Expedited access to judicial review.

* * * * *

(d) * * *

(1) *Method and place for filing request.* The requestor may—

(i) If a request for ALJ hearing or Council review is not pending, file a written EAJR request with the HHS Departmental Appeals Board with his or her request for an ALJ hearing or Council review; or

(ii) If an appeal is already pending for an ALJ hearing or otherwise before OMHA, or the Council, file a written EAJR request with the HHS Departmental Appeals Board.

* * * * *

(i) * * *

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

(2) Whenever a review entity forwards a rejected EAJR request to OMHA or the Council, the appeal is considered timely filed, and if an adjudication time frame applies to the appeal, the adjudication time frame begins on the day the request is received by OMHA or the Council from the review entity.

* * * * *

■ 21. Section 405.1000 is revised to read as follows:

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

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

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

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

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

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

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

(g) An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a fully favorable finding for the appellant, and there is no other party or no other party is entitled to a notice of hearing in accordance with § 405.1020(c).

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

§ 405.1002 [Amended]

■ 22. Section 405.1002 is amended by—

■ a. Amending paragraph (a) introductory text by removing the phrase ''may request'' and adding ''has a right to'' in its place

■ b. Amending paragraph (a)(4) by removing the word ''entity'' and adding ''office'' in its place.

■ c. Amending paragraph (b)(1) by removing the phrase ''to the ALJ level'' and adding ''for a hearing before an ALJ'' in its place.

■ 23. Section 405.1004 is amended by—

■ a. Revising the section heading and paragraphs (a) introductory text, (a)(1) and (4), (b), and (c).

■ b. Adding paragraph (d).

The revisions and addition read as follows:

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

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

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

* * * * *

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

(b) If the ALJ or attorney adjudicator determines that the QIC's dismissal was in error, he or she vacates the dismissal and remands the case to the QIC for a reconsideration in accordance with § 405.1056.

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

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

■ 24. Section 405.1006 is amended by—

■ a. Revising the section heading and paragraphs (d)(1) introductory text, (d)(1)(ii), and (d)(2).

■ b. Adding paragraphs (d)(3) through (7).

■ c. Revising paragraphs (e)(1) introductory text, (e)(1)(ii) and (iii), (e)(2) introductory text, and (e)(2)(ii) and (iii).

The revisions and additions read as follows:

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

* * * * *

(d) * * *

(1) *In general.* In situations other than those described in paragraphs (d)(3) through (7) of this section, the amount remaining in controversy is computed as the basis for the amount in controversy for the items and services in the disputed claim, as defined in paragraph (d)(2) of this section, reduced by—

* * * * *

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

(2) *Basis for the amount in controversy.* For purposes of calculating the amount in controversy under paragraph (d)(1) of this section, the basis for the amount in controversy is defined as follows:

(i) *General rule.* For situations other than those described in paragraphs (d)(2)(ii) and (iii) of this section, the basis for the amount in controversy is determined as follows:

(A) For items and services with a published Medicare fee schedule or published contractor-priced amount, the basis for the amount in controversy is the allowable amount, which is 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.

(B) For items and services with no published Medicare fee schedule or published contractor-priced amount, the basis for the amount in controversy is the billed charges submitted on the claim for those items or services.

(ii) *Beneficiary financial responsibility.* For items and services for which a beneficiary has been determined to be financially responsible, the basis for the amount in controversy is the actual amount charged to the beneficiary (or the maximum amount the beneficiary may be charged if no bill has been received) for the items and services in the disputed claim.

(iii) *Refunds of amounts previously collected.* If a beneficiary received or may be entitled to a refund of the amount the beneficiary previously paid to the provider or supplier for the items or services in the disputed claim under applicable statutory or regulatory authority, the basis for the amount in controversy is the actual amount originally charged to the beneficiary for those items or services.

(3) *Limitation on liability.* When payment is made for items or services under section 1879 of the Act or § 411.400 of this chapter, or the liability of the beneficiary for those services is limited under § 411.402 of this chapter, the amount in controversy is calculated in accordance with paragraphs (d)(1) and (d)(2)(i) of this section, except there is no deduction under paragraph (d)(1)(i) for expenses that are paid under § 411.400 of this chapter or as a result of liability that is limited under § 411.402 of this chapter.

(4) *Item or service terminations.* When a matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services, the amount in controversy is calculated in accordance with paragraphs (d)(1) and (d)(2)(ii) of this section, except that the basis for the amount in controversy and any deductible and coinsurance that may be collected for the items or services are calculated using the amount the beneficiary would have been charged if the beneficiary had received the items or services the beneficiary asserts should have been covered based on the beneficiary's current condition, and Medicare payment were not made for the items or services.

(5) *Overpayments.* Notwithstanding paragraphs (d)(1) and (2) of this section, when an appeal involves an identified overpayment, the amount in controversy is the amount of the overpayment specified in the demand letter for the items or services in the disputed claim. When an appeal involves an estimated overpayment amount determined through the use of statistical sampling and extrapolation, the amount in controversy is the total amount of the estimated overpayment determined through extrapolation, as specified in the demand letter.

(6) *Coinsurance and deductible challenges.* Notwithstanding paragraphs (d)(1) and (2) of this section, for appeals filed by beneficiaries challenging only the computation of a coinsurance amount or the amount of a remaining deductible, the amount in controversy is the difference between the amount of the coinsurance or remaining deductible, as determined by the contractor, and the amount of the coinsurance or remaining deductible the beneficiary believes is correct.

(7) *Fee schedule or contractor price challenges.* Notwithstanding paragraphs (d)(1) and (2) of this section, for appeals of claims where the allowable amount has been paid in full and the appellant is challenging only the validity of the allowable amount, as reflected on the published fee schedule or in the published contractor-priced amount applicable to the items or services in the disputed claim, the amount in controversy is the difference between the amount the appellant argues should have been the allowable amount for the items or services in the disputed claim in the applicable jurisdiction and place of service, and the published allowable amount for the items or services.

(e) * * *

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

* * * * *

(ii) The appellant(s) requests aggregation of claims appealed in the same request for ALJ hearing, or in multiple requests for an ALJ hearing filed with the same request for aggregation, and the request is filed

within 60 calendar days after receipt of all of the reconsiderations being appealed; and

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

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

* * * * *

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

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

* * * * *

■ 25. Section 405.1008 is revised to read as follows:

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

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

■ 26. Section 405.1010 is revised to read as follows:

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

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

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

(b) *How an election is made.* (1) *No notice of hearing.* If CMS or a contractor elects to participate before receipt of a notice of hearing, or when a notice of hearing is not required, it must send written notice of its intent to participate to the assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the request for hearing is not yet assigned to an ALJ or attorney adjudicator, and the parties who were sent a copy of the notice of reconsideration.

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

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

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

(ii) If a hearing is scheduled, no later than 10 calendar days after receiving the notice of hearing.

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

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

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

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

(ii) A copy of any position paper or written testimony it submits to OMHA must be sent to—

(A) The parties who were sent a copy of the notice of reconsideration, if the position paper or written testimony is being submitted before receipt of a notice of hearing for the appeal; or

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

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

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

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

(3) If CMS or a contractor is precluded from participating in the oral hearing under paragraph (d)(1) or (2) of this section, the ALJ may grant leave to the precluded entity to participate in the oral hearing if the ALJ determines that the entity's participation is necessary for a full examination of the matters at issue.

(e) *Invalid election.* (1) An ALJ or attorney adjudicator may determine that a CMS or contractor election is invalid under this section if the election was

not timely filed or the election was not sent to the correct parties.

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

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

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

■ 27. Section 405.1012 is revised to read as follows:

* * * * *

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

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

(2) An ALJ may request, but may not require, CMS and/or one or more of its contractors to be a party to the hearing. The ALJ cannot draw any adverse inferences if CMS or the contractor decides not to be a party to the hearing.

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

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

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

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

(ii) A copy of any position paper, written testimony, and/or evidence it submits to OMHA must be sent to the parties who were sent a copy of the notice of hearing.

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

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

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

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

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

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

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

■ 28. Section 405.1014 is revised to read as follows:

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

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

(i) The name, address, and Medicare health insurance claim number of the beneficiary whose claim is being appealed, and the beneficiary's telephone number if the beneficiary is the appealing party and not represented.

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

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

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

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

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

(vii) A statement of whether the filing party is aware that it or the claim is the subject of an investigation or proceeding by the HHS Office of Inspector General or other law enforcement agencies.

(viii) For requests filed by providers, suppliers, Medicaid State agencies, applicable plans, or a beneficiary who is represented by a provider, supplier or Medicaid State agency, the amount in controversy applicable to the disputed claim determined in accordance with § 405.1006, unless the matter involves a provider or supplier termination of Medicare-covered items or services that is disputed by a beneficiary, and the beneficiary did not elect to continue receiving the items or services.

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

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

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

(ii) File the request for hearing for all sampled claims that the appellant

wishes to appeal within 60 calendar days of the date the party receives the last reconsideration for the sample claims, if they were not all addressed in a single reconsideration; and

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

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

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

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

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

(2) With the office specified in the QIC's reconsideration or dismissal. If the request for hearing is timely filed with an office other than the office specified in the QIC's reconsideration, any applicable time frame specified in § 405.1016 for deciding the appeal begins on the date the office specified in the QIC's reconsideration or dismissal receives the request for hearing. If the request for hearing is filed with an office, other than the entity office specified in the QIC's reconsideration or dismissal, OMHA must notify the appellant of the date the request was received in the correct office and the commencement of any applicable adjudication time frame.

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

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

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

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

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

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

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

(e) *Extension of time to request a hearing or review.* (1) If the request for hearing or review of a QIC dismissal is not filed within 60 calendar days of receipt of the QIC's reconsideration or dismissal, an appellant may request an extension for good cause (See § 405.942(b)(2) and (3)).

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

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

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

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

■ 29. Section 405.1016 is revised to read as follows:

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

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

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

(2) If the Council remands a case and the case was subject to an adjudication time frame under paragraph (a) or (c) of this section, the remanded appeal will

be subject to the adjudication time frame of paragraph (a) of this section beginning on the date that OMHA receives the Council remand.

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

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

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

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

(ii) The duration of a stay of proceedings granted by an ALJ or attorney adjudicator on a motion by an appellant, provided no other party also filed a request for hearing on the same claim at issue.

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

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

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

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

(ii) Forward the case file to the Council.

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

■ 30. Section 405.1018 is revised to read as follows:

§ 405.1018 Submitting evidence.

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

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

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

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

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

■ 31. Section 405.1020 is amended by—

■ a. Revising paragraphs (b), (c), (d), and (e)(3) and (4).

■ b. Adding paragraphs (g)(3)(vii) and (viii).

■ c. Revising paragraphs (h), (i) paragraph heading, and (i)(1), (2), (4), and (5).

■ d. Adding paragraph (j).

The revisions and additions read as follows:

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

* * * * *

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

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

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

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

(B) Special or extraordinary circumstances exist.

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

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

(ii) The ALJ, with the concurrence of the Chief ALJ or designee, also may find

good cause that an in-person hearing should be conducted if—

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

(B) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) A notice of hearing is sent to all parties that filed an appeal or participated in the reconsideration, any party who was found liable for the services at issue subsequent to the initial determination or may be found liable based on a review of the record, the QIC that issued the reconsideration, and CMS or a contractor that the ALJ believes would be beneficial to the hearing, advising them of the proposed time and place of the hearing.

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

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

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

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

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

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

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

(d) *A party's right to waive a hearing.* A party may also waive the right to a hearing and request a decision based on the written evidence in the record in accordance with § 405.1038(b). As provided in § 405.1000, an ALJ may require the parties to attend a hearing if it is necessary to decide the case. If an ALJ determines that it is necessary to obtain testimony from a non-party, he or she may still hold a hearing to obtain that testimony, even if all of the parties have waived the right to appear. In those cases, the ALJ will give the parties the opportunity to appear when the testimony is given but may hold the hearing even if none of the parties decide to appear.

(e) * * *

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

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

* * * * *

(g) * * *

(3) * * *

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

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

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

(i) *A party's request for an in-person or VTC hearing.* (1) If an unrepresented beneficiary who filed the request for hearing objects to a VTC hearing or to the ALJ's offer to conduct a hearing by telephone, or if a party other than an unrepresented beneficiary who filed the request for hearing objects to a telephone or VTC hearing, the party must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a VTC or an in-person hearing.

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

* * * * *

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

(5) The ALJ may grant the request, with the concurrence of the Chief ALJ or designee, upon a finding of good cause and will reschedule the hearing for a time and place when the party may appear in person or by VTC before the ALJ.

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

■ 32. Section 405.1022 is revised to read as follows:

§ 405.1022 Notice of a hearing before an ALJ.

(a) *Issuing the notice.* After the ALJ sets the time and place of the hearing, notice of the hearing will be mailed or otherwise transmitted in accordance with OMHA procedures to the parties and other potential participants, as provided in § 405.1020(c) at their last known address, or given by personal service, except to a party or potential participant who indicates in writing that it does not wish to receive this notice. The notice is mailed, transmitted, or served at least 20 calendar days before the hearing unless the recipient agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days before the hearing.

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

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

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

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

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

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

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

their objections and for requesting an in-person hearing.

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

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

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

■ 33. Section 405.1024 is amended by revising paragraphs (b) and (c) to read as follows:

§ 405.1024 Objections to the issues.

* * * * *

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

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

■ 34. Section 405.1026 is revised to read as follows:

§ 405.1026 Disqualification of the ALJ or attorney adjudicator.

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

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

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

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

■ 35. Section 405.1028 is revised to read as follows:

§ 405.1028 Review of evidence submitted by parties.

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

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

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

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

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

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

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

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

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

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

■ 36. Section 405.1030 is revised to read as follows:

§ 405.1030 ALJ hearing procedures.

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

(b) *At the hearing.* (1) At the hearing, the ALJ fully examines the issues, questions the parties and other witnesses, and may accept evidence that is material to the issues consistent with §§ 405.1018 and 405.1028.

(2) The ALJ may limit testimony and/or argument at the hearing that are not relevant to an issue before the ALJ, or that address an issue before the ALJ for which the ALJ determines he or she has sufficient information or on which the ALJ has already ruled. The ALJ may, but is not required to, provide the party or representative with an opportunity to submit additional written statements and affidavits on the matter, in lieu of testimony and/or argument at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(3) If the ALJ determines that a party or party's representative is uncooperative, disruptive to the hearing, or abusive during the course of the hearing, the ALJ may excuse the party or representative from the hearing and continue with the hearing to provide the other parties and participants with an opportunity to offer testimony and/or argument. If a party or representative was excused from the hearing, the ALJ will provide the party or representative with an opportunity to submit written statements and affidavits

in lieu of testimony and/or argument at the hearing, and the party or representative may request a recording of the hearing in accordance with § 405.1042 and respond in writing to any statements made by other parties or participants and/or testimony of the witnesses at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing. If the missing evidence is in the possession of the appellant, and the appellant is a provider, supplier, or a beneficiary represented by a provider or supplier, the ALJ must determine if the appellant had good cause in accordance with § 405.1028 for not producing the evidence earlier.

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

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

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

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

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

■ 37. Section 405.1032 is revised to read as follows:

§ 405.1032 Issues before an ALJ or attorney adjudicator.

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

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

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

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

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

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

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

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

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

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

■ 38. Section 405.1034 is revised to read as follows:

§ 405.1034 Requesting information from the QIC.

(a) If an ALJ or attorney adjudicator believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS or its contractors, the information may be requested from the QIC that conducted the reconsideration or its successor.

(1) Official copies of redeterminations and reconsiderations that were conducted on the appealed claims can be provided only by CMS or its contractors.

(2) ''Can be provided only by CMS or its contractors'' means the information

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

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

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

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

§ 405.1036 [Amended]

■ 39. Section 405.1036 is amended by—

■ a. Amending paragraph (b)(1) by removing the phrase ''send the ALJ'' and adding ''submit to OMHA'' in its place.

■ b. Removing paragraph (d).

■ c. Redesignating paragraph (g) as new paragraph (d).

■ d. Amending paragraphs (f)(5)(i), (ii), (iii), (iv), (v), and (vi) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ e. Amending paragraphs (f)(5)(i) and (ii) by removing the term ''MAC's'' and adding ''Council's'' in its place.

■ f. Amending paragraph (f)(5)(i) by removing the phrase ''specified in § 405.1102, § 405.1104, or § 405.1110'' and adding ''specified in § 405.1016(e) and (f), § 405.1102, or § 405.1110'' in its place.

■ g. Amending paragraph (f)(5)(ii) by removing the phrase ''discovery ruling'' each time it appears and adding ''subpoena ruling'' in its place.

■ 40. Section 405.1037 is amended by—

■ a. Revising paragraph (a)(1).

■ b. Amending paragraph (e)(1) by removing the phrase ''specified in § 405.1100, § 405.1102, § 405.1104, or § 405.1110'' and adding ''specified in § 405.1016(e) and (f), § 405.1100, § 405.1102, or § 405.1110'' in its place.

■ c. Amending paragraphs (e)(1), (e)(2) introductory text, (e)(2)(i), (ii), (iii), (iv), and (v) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ d. Amending paragraphs (e)(1) and (e)(2)(i) by removing the term ''MAC's'' and adding ''Council's'' in its place.

■ e. Revising paragraph (f).

The revisions read as follows:

§ 405.1037 Discovery.

(a) * * *

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

* * * * *

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

■ 41. Section 405.1038 is revised to read as follows:

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

(a) *Decision fully favorable.* If the evidence in the administrative record supports a finding fully in favor of the appellant(s) on every issue and no other party to the appeal is liable for claims at issue, an ALJ or attorney adjudicator may issue a decision without giving the parties prior notice and without an ALJ conducting a hearing, unless CMS or a contractor has elected to be a party to the hearing in accordance with § 405.1012. The notice of the decision informs the parties that they have the right to a hearing and a right to examine the evidence on which the decision is based.

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

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

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

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

(c) *Stipulated decision.* If CMS or one of its contractors submits a written statement or makes an oral statement at a hearing indicating the item or service should be covered or payment may be made, 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.

■ 42. Section 405.1040 is revised to read as follows:

§ 405.1040 Prehearing and posthearing conferences.

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

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

(c) At the conference—

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

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

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

■ 43. Section 405.1042 is revised to read as follows:

§ 405.1042 The administrative record.

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

(2) The record will include marked as exhibits, the appealed determinations,

and documents and other evidence used in making the appealed determinations and the ALJ's or attorney adjudicator's decision, including, but not limited to, claims, medical records, written statements, certificates, reports, affidavits, and any other evidence the ALJ or attorney adjudicator admits. The record will also include any evidence excluded or not considered by the ALJ or attorney adjudicator, including, but not limited to, new evidence submitted by a provider or supplier, or beneficiary represented by a provider or supplier, for which no good cause was established, and duplicative evidence submitted by a party.

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

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

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

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

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

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

■ 44. Section 405.1044 is revised to read as follows:

§ 405.1044 Consolidated proceedings.

(a) *Consolidated hearing.* (1) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in one or more other appeals pending before the same ALJ.

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

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

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

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

(i) A consolidated decision and record; or

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

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

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

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

■ 45. Section 405.1046 is revised to read as follows:

§ 405.1046 Notice of an ALJ or attorney adjudicator decision.

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

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

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

(ii) For any new evidence that was submitted for the first time at the OMHA level and subject to a good cause determination pursuant to § 405.1028, a discussion of the new evidence and the good cause determination that was made.

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

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

(3) *Limitation on decision.* When the amount of payment for an item or service is an issue before the ALJ or attorney adjudicator, the ALJ or attorney adjudicator may make a finding as to the amount of payment due. If the ALJ or attorney adjudicator makes a finding concerning payment when the amount of payment was not an issue before the

ALJ or attorney adjudicator, the contractor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's or attorney adjudicator's decision is not binding on the contractor for purposes of determining the amount of payment due. The amount of payment determined by the contractor in effectuating the ALJ's or attorney adjudicator's decision is a new initial determination under § 405.924.

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

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

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

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

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

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

■ 46. Section 405.1048 is revised to read as follows:

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

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

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

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

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

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

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

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

§ 405.1050 [Amended]

■ 47. Section 405.1050 is amended by—

■ a. Amending the section heading by removing the phrase ''an ALJ'' and adding ''OMHA'' in its place.

■ b. Amending the text of the section by removing the phrase ''pending before an ALJ'' and adding ''pending before OMHA'' in its place, and by removing the term ''the ALJ'' and adding ''OMHA'' in its place.

■ c. Amending the section heading and the text of the section by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ 48. Section 405.1052 is revised to read as follows:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(7) The appellant's request is not complete in accordance with

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

(b) *Dismissal of request for review of a QIC dismissal.* An ALJ or attorney adjudicator dismisses a request for review of a QIC dismissal under any of the following conditions:

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

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

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

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

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

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

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

(c) *Withdrawal of request.* At any time before notice of the decision, dismissal, or remand is mailed, if only one party requested the hearing or review of the QIC dismissal and that party asks to withdraw the request, an ALJ or attorney adjudicator may dismiss the request for hearing or request for review of a QIC dismissal. This request for withdrawal may be submitted in writing, or a request to withdraw a request for hearing may be made orally at a hearing before the ALJ. The request for withdrawal must include a clear statement that the appellant is withdrawing the request for hearing or review of the QIC dismissal and does not intend to further proceed with the appeal. If an attorney or other legal professional on behalf of a beneficiary or other appellant files the request for withdrawal, the ALJ or attorney adjudicator may presume that the representative has advised the appellant of the consequences of the withdrawal and dismissal.

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

(e) *Vacating a dismissal.* If good and sufficient cause is established, the ALJ or attorney adjudicator may vacate his or her dismissal of a request for hearing or review within 6 months of the date of the notice of dismissal.

■ 49. Section 405.1054 is revised to read as follows:

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

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

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

■ 50. Section 405.1056 is added before the undesignated center heading ''Applicability of Medicare Coverage Policies'' to read as follows:

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

(a) *Missing appeal determination or case record.* (1) If an ALJ or attorney adjudicator requests an official copy of a missing redetermination or reconsideration for an appealed claim in accordance with § 405.1034, and the QIC or another contractor does not furnish the copy within the time frame specified in § 405.1034, the ALJ or attorney adjudicator may issue a remand directing the QIC or other contractor to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

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

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

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

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

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

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

(e) *Relationship to local and national coverage determination appeals process.* (1) An ALJ or attorney adjudicator remands an appeal to the QIC that made the reconsideration if the appellant is entitled to relief pursuant to §§ 426.460(b)(1), 426.488(b), or 426.560(b)(1) of this chapter.

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

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

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

■ 51. Section 405.1058 is added before the undesignated center heading ''Applicability of Medicare Coverage Policies'' to read as follows:

§ 405.1058 Effect of a remand.

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

§ 405.1060 [Amended]

■ 52. Section 405.1060 is amended by—

■ a. Amending paragraph (a)(4) by removing the term ''ALJs'' and adding ''ALJs and attorney adjudicators'' in its place.

■ b. Amending paragraphs (a)(4), (c) paragraph heading, (c)(1), and (c)(2) by removing the term ''MAC'' and adding ''Council'' in its place.

■ c. Amending paragraphs (b) paragraph heading, (b)(1), and (b)(2) by removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.

§ 405.1062 [Amended]

■ 53. Section 405.1062 is amended by—

■ a. Amending the section heading and paragraphs (a) and (b) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ b. Amending the section heading and paragraph (b) by removing the term ''ALJ'' each time it appears and adding ''ALJ or attorney adjudicator'' in its place.

■ c. Amending paragraph (a) by removing the term ''ALJs'' and adding ''ALJs and attorney adjudicators'' in its place.

■ d. Amending paragraph (c) by removing the phrase ''An ALJ or MAC'' and adding ''An ALJ or attorney adjudicator or the Council'' in its place.

■ 54. Section 405.1063 is revised to read as follows:

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

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

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

(c) Precedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter, are binding on all CMS components, all HHS components that adjudicate matters under the jurisdiction of CMS, and on the Social Security Administration to the extent that components of the Social Security Administration adjudicate matters under the jurisdiction of CMS.

§ 405.1064 [Removed]

■ 55. Section 405.1064 is removed.

■ 56. Section 405.1100 is revised to read as follows:

§ 405.1100 Medicare Appeals Council review: General.

(a) The appellant or any other party to an ALJ's or attorney adjudicator's decision or dismissal may request that the Council review the ALJ's or attorney adjudicator's decision or dismissal.

(b) Under circumstances set forth in §§ 405.1016 and 405.1108, 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.

(c) When the Council reviews an ALJ's or attorney adjudicator's decision, it undertakes a *de novo* review. The Council issues a final decision or dismissal order or remands a case to the ALJ or attorney adjudicator within 90 calendar days of receipt of the appellant's request for review, unless the 90 calendar day period is extended as provided in this subpart.

(d) When deciding an appeal that was escalated from the OMHA level to the Council, the Council will issue a final decision or dismissal order or remand the case to the OMHA Chief ALJ within 180 calendar days of receipt of the appellant's request for escalation, unless the 180 calendar day period is extended as provided in this subpart.

■ 57. Section 405.1102 is revised to read as follows:

§ 405.1102 Request for Council review when ALJ or attorney adjudicator issues decision or dismissal.

(a)(1) A party to a decision or dismissal issued by an ALJ or attorney adjudicator may request a Council review if the party 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.

(2) For purposes of this section, the date of receipt of the ALJ's or attorney adjudicator's decision or dismissal is presumed to be 5 calendar days after the date of the notice of the decision or dismissal, unless there is evidence to the contrary.

(3) The request is considered as filed on the date it is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action.

(b) A party requesting a review may ask that the time for filing a request for Council review be extended if—

(1) The request for an extension of time is in writing;

(2) It is filed with the Council; and

(3) It explains why the request for review was not filed within the stated time period. If the Council finds that there is good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the Council uses the standards outlined at § 405.942(b)(2) and (3).

(c) A party does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to a QIC, affirmation of a QIC's dismissal of a request for reconsideration, or dismissal of a request for review of a QIC dismissal.

(d) For purposes of requesting Council review (§§ 405.1100 through 405.1140), unless specifically excepted, the term ''party'', includes CMS where CMS has entered into a case as a party according to § 405.1012. The term, ''appellant,'' does not include CMS, where CMS has entered into a case as a party according to § 405.1012.

§ 405.1104 [Removed]

■ 58. Section 405.1104 is removed.

■ 59. Section 405.1106 is revised to read as follows:

§ 405.1106 Where a request for review or escalation may be filed.

(a) When a request for a Council review is filed after an ALJ or attorney adjudicator has issued a decision or dismissal, the request for review must

be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action. The appellant must also send a copy of the request for review to the other parties to the ALJ or attorney adjudicator decision or dismissal who received notice of the decision or dismissal. Failure to copy the other parties tolls the Council's adjudication deadline set forth in § 405.1100 until all parties to the ALJ or attorney adjudicator decision or dismissal receive notice of the request for Council review. If the request for review is timely filed with an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council 's adjudication period to conduct a review begins on the date the request for review is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action. Upon receipt of a request for review from an entity other than the entity specified in the notice of the ALJ's or attorney adjudicator's action, the Council sends written notice to the appellant of the date of receipt of the request and commencement of the adjudication timeframe.

(b) 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 under § 405.1016, the request for escalation must be filed with OMHA and the appellant must also send a copy of the request for escalation to the other parties who were sent a copy of the QIC reconsideration. Failure to copy the other parties tolls the Council's adjudication deadline set forth in § 405.1100 until all parties who were sent a copy of the QIC reconsideration receive notice of the request for escalation. In a case that has been escalated from OMHA, the Council's 180 calendar day period to issue a final decision, dismissal order, or remand order begins on the date the request for escalation is received by the Council.

§ 405.1108 [Amended]

■ 60. Section 405.1108 is amended by—

■ a. Amending the section heading and paragraphs (a), (b), (c), (d) introductory text, (d)(2), and (4) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ b. Amending paragraphs (a), (b), (c), (d)(1), and (5) by removing the term ''ALJ'' each time it appears and adding ''ALJ or attorney adjudicator'' in its place.

■ c. Amending paragraphs (a) and (b) by removing the term ''ALJ's'' each time it appears and adding ''ALJ's or attorney adjudicator's'' in its place.

■ d. Amending paragraph (b) by removing the first use of ''dismissal'' in the paragraph and adding ''dismissal of a request for a hearing'' in its place.

■ e. Amending paragraph (d) introductory text by removing the term ''ALJ level'' and adding ''OMHA level'' in its place.

■ f. Amending paragraph (d)(3) by removing the phrase ''to an ALJ'' and adding ''to OMHA'' in its place.

■ 61. Section 405.1110 is revised to read as follows:

§ 405.1110 Council reviews on its own motion.

(a) *General rule.* The Council may decide on its own motion to review a decision or dismissal issued by an ALJ or attorney adjudicator. CMS or any of its contractors may refer a case to the Council for it to consider reviewing under this authority anytime within 60 calendar days after the date of an ALJ's or attorney adjudicator's decision or dismissal.

(b) *Referral of cases.* (1) CMS or any of its contractors may refer a case to the Council if, in their view, the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest. CMS may also request that the Council take own motion review of a case if—

(i) CMS or its contractor participated in the appeal at the OMHA level; and

(ii) In CMS' view, the ALJ's or attorney adjudicator's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ or attorney adjudicator abused his or her discretion.

(2) CMS' referral to the Council is made in writing and must be filed with the Council no later than 60 calendar days after the ALJ's or attorney adjudicator's decision or dismissal is issued. The written referral will state the reasons why CMS believes the Council must review the case on its own motion. CMS will send a copy of its referral to all parties to the ALJ's or attorney adjudicator's action who received a copy of the hearing decision under § 405.1046(a) or the notice of dismissal under § 405.1052(d), and to the OMHA Chief ALJ. Parties to the ALJ's or attorney adjudicator's action may file exceptions to the referral by submitting written comments to the Council within 20 calendar days of the referral notice. A party submitting comments to the Council must send such comments to CMS and all other parties to the ALJ's or attorney adjudicator's action who received a copy of the hearing decision under § 405.1046(a) or the notice of dismissal under § 405.1052(d).

(c) *Standard of review*—(1) *Referral by CMS after participation at the OMHA level.* If CMS or its contractor participated in an appeal at the OMHA level, the Council exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ or attorney adjudicator, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS.

(2) *Referral by CMS when CMS did not participate in the OMHA proceedings or appear as a party.* The Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS.

(d) *Council's action.* If the Council decides to review a decision or dismissal on its own motion, it will mail the results of its action to all the parties to the hearing and to CMS if it is not already a party to the hearing. The Council may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ or attorney adjudicator for further proceedings or may dismiss a hearing request. The Council must issue its action no later than 90 calendar days after receipt of the CMS referral, unless the 90 calendar day period has been extended as provided in this subpart. The Council may not, however, issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case. If the Council does not act within the applicable adjudication deadline, the ALJ's or attorney adjudicator's decision or dismissal is binding on the parties to the ALJ's or attorney adjudicator's action.

■ 62. Section 405.1112 is revised to read as follows:

§ 405.1112 Content of request for review.

(a) The request for Council review must be filed with the entity specified in the notice of the ALJ's or attorney adjudicator's action. The request for

review must be in writing and may be made on a standard form. A written request that is not made on a standard form is accepted if it contains the beneficiary's name; Medicare health insurance claim number; the specific service(s) or item(s) for which the review is requested; the specific date(s) of service; the date of the ALJ's or attorney adjudicator's decision or dismissal order, if any; and the name and signature of the party or the representative of the party; and any other information CMS may decide.

(b) The request for review must identify the parts of the ALJ's or attorney adjudicator's action with which the party requesting review disagrees and explain why he or she disagrees with the ALJ's or attorney adjudicator's decision, dismissal, or other determination being appealed. For example, if the party requesting review believes that the ALJ's or attorney adjudicator's action is inconsistent with a statute, regulation, CMS Ruling, or other authority, the request for review should explain why the appellant believes the action is inconsistent with that authority.

(c) The Council will limit its review of an ALJ's or attorney adjudicator's actions to those exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary. For purposes of this section only, we define a representative as anyone who has accepted an appointment as the beneficiary's representative, except a member of the beneficiary's family, a legal guardian, or an individual who routinely acts on behalf of the beneficiary, such as a family member or friend who has a power of attorney.

§ 405.1114 [Amended]

■ 63. Section 405.1114 is amended by—

■ a. Amending the introductory text and paragraphs (b) and (c)(1) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ b. Amending paragraph (c)(3) by removing the phrase ''ALJ hearing'' and adding ''ALJ's or attorney adjudicator's action'' in its place.

§ 405.1116 [Amended]

■ 64. Section 405.1116 is amended by—

■ a. Removing the term ''MAC'' each time it appears in the heading and text and adding ''Council'' in its place.

■ b. Removing the term ''MAC's'' and adding ''Council's'' in its place.

■ c. Removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.

§ 405.1118 [Amended]

■ 65. Section 405.1118 is amended by—

■ a. Removing the term ''MAC'' each time it appears in the heading and text and adding ''Council'' in its place.

■ b. Removing the phrase ''ALJ hearing'' and adding ''ALJ's or attorney adjudicator's action'' in its place.

■ c. Removing the phrase ''the exhibits list'' and adding ''any index of the administrative record'' in its place.

■ d. Removing the term ''tape'' and adding ''audio recording'' in its place.

■ e. Removing the term ''MAC's'' and adding ''Council's'' in its place.

§ 405.1120 [Amended]

■ 66. Section 405.1120 is amended in the heading and text by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

§ 405.1122 [Amended]

■ 67. Section 405.1122 is amended by—

■ a. Amending the section heading and paragraphs (a) paragraph heading, (a)(1) and (2), (b) paragraph heading, (b)(1) and (2), (c)(1), (2), and (3) introductory text, (c)(3)(ii), (d)(1) and (3), (e)(1), (2), (3), and (4), and (f)(1), (2), and (3) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ b. Amending paragraphs (e)(5) and (6), and (f)(2) by removing the term ''MAC's'' and adding ''Council's'' in its place.

■ c. Amending paragraph (a)(1) by removing the term ''hearing decision'' and adding ''ALJ's or attorney adjudicator's decision'' in its place.

■ d. Amending paragraphs (a)(1) and (b)(1) by removing the term ''ALJ level'' and adding ''OMHA level'' in its place.

■ e. Amending paragraphs (a)(1) and (2), (b)(1) and (2), (c)(2), (c)(3) introductory text, and (c)(3)(i) and (ii) by removing the term ''ALJ'' each time it appears and adding ''ALJ or attorney adjudicator'' in its place.

■ f. Amending paragraphs (a) paragraph heading and (a)(1) by removing the term ''ALJ's'' and adding ''ALJ's or attorney adjudicator's'' in its place.

■ g. Amending paragraph (a)(2) by removing the term ''hearing record'' and adding ''administrative record'' in its place.

§ 405.1124 [Amended]

■ 68. Section 405.1124 is amended by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

§ 405.1126 [Amended]

■ 69. Section 405.1126 is amended by—

■ a. Amending the section heading and paragraphs (a), (b), (c), (d) paragraph heading, (d)(1) and (2), (e) paragraph heading, and (e)(1) and (2) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ b. Amending paragraph (b) by removing the term ''MAC's'' and adding ''Council's'' in its place.

■ c. Amending paragraphs (a), (b), (c), (d) paragraph heading, and (e)(2) by removing the term ''ALJ'' each time it appears and adding ''ALJ or attorney adjudicator'' in its place.

■ d. Amending paragraph (e)(2) by adding ''if applicable'' after the word ''rehearing''.

§ 405.1128 [Amended]

■ 70. Section 405.1128 is amended by—

■ a. Amending the section heading and paragraphs (a), (b), and (c) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ b. Amending paragraph (a) by removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.

■ c. Amending paragraph (b) by removing the term ''ALJ hearing decision'' and adding ''ALJ's or attorney adjudicator's decision'' in its place.

§ 405.1130 [Amended]

■ 71. Section 405.1130 is amended in the section heading and text by removing the term ''MAC's'' each time it appears and adding ''Council's'' in its place.

§ 405.1132 [Amended]

■ 72. Section 405.1132 is amended by—

■ a. Amending paragraphs (a) introductory text, (a)(2), and (b) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ b. Amending paragraph (b) by removing the term ''MAC's'' and adding ''Council's'' in its place.

■ c. Amending paragraphs (a) introductory text, (a)(1), and (b) by removing the term ''ALJ'' each time it appears and adding ''ALJ or attorney adjudicator'' in its place.

§ 405.1134 [Amended]

■ 73. Section 405.1134 is amended by—

■ a. Amending paragraph (a) by removing the term ''MAC's'' and adding ''Council's'' in its place.

■ b. Amending paragraphs (b)(3) and (c) by removing the term ''MAC'' and adding ''Council'' in its place.

§ 405.1136 [Amended]

■ 74. Section 405.1136 is amended by—

■ a. Amending paragraphs (a)(1) and (2), and (c)(3) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ b. Amending paragraph (a)(1) by removing the term ''ALJ's'' and adding

''ALJ's or attorney adjudicator's'' in its place.

■ c. Amending paragraphs (a)(2) and (c)(2) by removing the term ''MAC's'' each time it appears and adding ''Council's'' in its place.

■ d. Amending paragraph (c)(3) by removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.

§ 405.1138 [Amended]

■ 75. Section 405.1138 is amended by—

■ a. Removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ b. Removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.

§ 405.1140 [Amended]

■ 76. Section 405.1140 is amended by—

■ a. Amending the section heading and paragraphs (a)(1), (2), and (3), (b)(1), (2), and (3), (c) paragraph heading, (c)(1), (3), and (4), and (d) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ b. Amending the section heading and paragraphs (a)(1), (2), and (3), (b) paragraph heading, (b)(1), (2), and (3), (c)(1) and (4), and (d) by removing the term ''ALJ'' each time it appears and adding ''ALJ or attorney adjudicator'' in its place.

■ c. Amending paragraph (d) by removing the term ''ALJ's'' and adding ''ALJ's or attorney adjudicator's'' in its place.

■ 77. Section 405.1204 is amended by revising paragraphs (c)(4)(iii) and (c)(5) to read as follows:

§ 405.1204 Expedited reconsiderations.

* * * * *

(c) * * *

(4) * * *

(iii) Information about the beneficiary's right to appeal the QIC's reconsideration decision to OMHA for an ALJ hearing in accordance with subpart I of this part, including how to request an appeal and the time period for doing so.

(5) Unless the beneficiary requests an extension in accordance with paragraph (c)(6) of this section, if the QIC does not issue a decision within 72 hours of receipt of the request, the QIC must notify the beneficiary of his or her right to have the case escalated to OMHA for an ALJ hearing in accordance with subpart I of this part, if the amount remaining in controversy after the QIO determination meets the requirements for an ALJ hearing under § 405.1006.

* * * * *

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 78. The authority citation for part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 422.561 [Amended]

■ 79. Section 422.561 is amended, in the definition of ''Appeal,'' by removing the phrase ''Medicare Appeals Council (MAC)'' and adding ''Medicare Appeals Council (Council)'' in its place.

■ 80. Section 422.562 is amended by—

■ a. Amending paragraph (b)(4)(v) by removing the term ''MAC'' and adding ''Council'' in its place.

■ b. Revising paragraphs (c)(1) and (d) to read as follows:

§ 422.562 General provisions.

* * * * *

(c) * * *

(1) If an enrollee receives immediate QIO review (as provided in § 422.622) of a determination of noncoverage of inpatient hospital care the enrollee is not entitled to review of that issue by the MA organization.

* * * * *

(d) *When other regulations apply.* Unless this subpart provides otherwise, the regulations in part 405 of this chapter (concerning the administrative review and hearing processes and representation of parties under titles II and XVIII of the Act) apply under this subpart to the extent they are appropriate, unless the part 405 regulation implements a provision of section 1869 of the Act that is not also in section 1852(g)(5) of the Act.

■ 81. Section 422.594 is amended by revising paragraph (b)(2) to read as follows:

§ 422.594 Notice of reconsidered determination by the independent entity.

* * * * *

(b) * * *

(2) If the reconsidered determination is adverse (that is, does not completely reverse the MA organization's adverse organization determination), inform the parties of their right to an ALJ hearing if the amount in controversy meets the requirements of § 422.600;

* * * * *

■ 82. Section 422.602 is amended by revising paragraph (b) to read as follows:

§ 422.602 Request for an ALJ hearing.

* * * * *

(b) *When to file a request.* (1) Except when an ALJ or attorney adjudicator extends the time frame as provided in part 405 of this chapter, a party must file a request for a hearing within 60 calendar days of receipt of the notice of a reconsidered determination. The time and place for a hearing before an ALJ will be set in accordance with § 405.1020.

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

* * * * *

■ 83. Section 422.608 is revised to read as follows:

§ 422.608 Medicare Appeals Council (Council) review.

Any party to the ALJ's or attorney adjudicator's decision or dismissal, including the MA organization, who is dissatisfied with the decision or dismissal, may request that the Council review the decision or dismissal. The regulations under part 405 of this chapter regarding Council review apply to matters addressed by this subpart to the extent that they are appropriate, unless the part 405 regulation implements a provision of section 1869 of the Act that is not also in section 1852(g)(5) of the Act.

§ 422.612 [Amended]

■ 84. Section 422.612 is amended by—

■ a. Amending paragraph (a) paragraph heading and introductory text by removing the term ''ALJ's'' and adding ''ALJ's or attorney adjudicator's'' in its place.

■ b. Amending paragraph (a)(1) by removing the term ''Board'' and adding ''Council'' in its place.

■ c. Amending paragraph (b) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

§ 422.616 [Amended]

■ 85. Section 422.616 is amended in paragraph (a) by removing the terms ''ALJ'' and ''MAC'' and adding in their place ''ALJ or attorney adjudicator'' and ''Council'' respectively.

§ 422.618 [Amended]

■ 86. Section 422.618 is amended by—

■ a. Amending paragraph (c)(1) by removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.

■ b. Amending paragraph (c)(2) by removing the terms ''Medicare Appeals Council'', ''Medicare Appeals Council (the Board)'', and ''Board'' and adding ''Council'' in their place.

§ 422.619 [Amended]

■ 87. Section 422.619 is amended by—

■ a. Amending paragraph (c)(1) by removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.
■ b. Amending paragraph (c)(2) by removing the terms ''Medicare Appeals Council'', ''Medicare Appeals Council (the Board)'', and ''Board'' and adding ''Council'' in their place.

§ 422.622 [Amended]

■ 88. Section 422.622 (g)(2) is amended by removing the phrase ''may appeal to an ALJ, the MAC, or a federal court'' and adding ''may appeal to OMHA for an ALJ hearing, the Council, or a federal court'' in its place.

§ 422.626 [Amended]

■ 89. Section 422.626(g)(3) is amended by removing the phrase ''to an ALJ, the MAC, or a Federal court'' and adding ''to OMHA for an ALJ hearing, the Council, or a Federal court'' in its place.

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 90. The authority citation for part 423 continues to read as follows:

Authority: Sections 1102, 1106, 1860D–1 through 1860D–42, and 1871 of the Social Security Act (42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh).

§ 423.560 [Amended]

■ 91. Section 423.560 is amended by amending the definition of ''Appeal'' by removing the term ''Medicare Appeals Council (MAC)'' and adding ''Medicare Appeals Council (Council) in its place.
■ 92. Section 423.562 is amended by revising paragraphs (b)(4)(v) and (vi) to read as follows:

§ 423.562 General provisions.

* * * * *

(b) * * *

(4) * * *

(v) If the ALJ or attorney adjudicator affirms the IRE's adverse coverage determination, in whole or in part, the right to request Council review of the ALJ's or attorney adjudicator's decision, as specified in § 423.1974.

(vi) If the Council affirms the ALJ's or attorney adjudicator's adverse coverage determination, in whole or in part, the right to judicial review of the decision if the amount in controversy meets the requirements in § 423.1976.

* * * * *

Subpart U—Reopening, ALJ Hearings and ALJ and Attorney Adjudicator Decisions, MAC Review, and Judicial Review

■ 93. The heading of subpart U is revised to read as set forth above.

■ 94. Section 423.1968 is revised to read as follows:

§ 423.1968 Scope.

This subpart sets forth the requirements relating to the following:

(a) Part D sponsors, the Part D IRE, ALJs and attorney adjudicators, and the Council with respect to reopenings.

(b) ALJs with respect to hearings and decisions or decisions of attorney adjudicators if no hearing is conducted.

(c) The Council with respect to review of Part D appeals.

(d) Part D enrollees' rights with respect to reopenings, ALJ hearings and ALJ or attorney adjudicator reviews, Council reviews, and judicial review by a Federal District Court.

■ 95. Section 423.1970 is amended by revising paragraphs (c)(1)(ii) and (iii), and (c)(2)(ii) and (iii) to read as follows:

§ 423.1970 Right to an ALJ hearing.

* * * * *

(c) * * *

(1) * * *

(ii) The enrollee requests aggregation at the same time the requests for hearing are filed, and the request for aggregation and requests for hearing are filed within 60 calendar days after receipt of the notice of reconsideration for each of the reconsiderations being appealed, unless the deadline to file one or more of the requests for hearing has been extended in accordance with § 423.2014(d); and

(iii) The appeals the enrollee seeks to aggregate involve the delivery of prescription drugs to a single enrollee, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the appeals the enrollee seeks to aggregate do not involve the delivery of prescription drugs to a single enrollee.

(2) * * *

(ii) The enrollees request aggregation at the same time the requests for hearing are filed, and the request for aggregation and requests for hearing are filed within 60 calendar days after receipt of the notice of reconsideration for each of the reconsiderations being appealed, unless the deadline to file one or more of the requests for hearing has been extended in accordance with § 423.2014(d); and

(iii) The appeals the enrollees seek to aggregate involve the same prescription drugs, as determined by an ALJ or attorney adjudicator. Only an ALJ may determine the appeals the enrollees seek to aggregate do not involve the same prescription drugs.

■ 96. Section 423.1972 is amended by revising paragraphs (a), (b), and (c)(1) to read as follows:

§ 423.1972 Request for an ALJ hearing.

(a) *How and where to file a request.* The enrollee must file a written request for a hearing with the OMHA office specified in the IRE's reconsideration notice.

(b) *When to file a request.* (1) Except when an ALJ or attorney adjudicator extends the timeframe as provided in § 423.2014(d), the enrollee must file a request for a hearing within 60 calendar days of receipt of the notice of an IRE reconsideration determination. The time and place for a hearing before an ALJ will be set in accordance with § 423.2020

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

(c) * * *

(1) If a request for a hearing clearly shows that the amount in controversy is less than that required under § 423.1970, the ALJ or attorney adjudicator dismisses the request.

* * * * *

■ 97. Section 423.1974 is revised to read as follows:

§ 423.1974 Council review.

An enrollee who is dissatisfied with an ALJ's or attorney adjudicator's decision or dismissal may request that the Council review the ALJ's or attorney adjudicator's decision or dismissal as provided in § 423.2102.

§ 423.1976 [Amended]

■ 98. Section 423.1976 is amended by—
■ a. Amending paragraph (a) paragraph heading and introductory text by removing the term ''ALJ's'' and adding ''ALJ's or attorney adjudicator's'' in its place.
■ b. Amending paragraphs (a)(1) and (b) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

§ 423.1978 [Amended]

■ 99. Section 423.1978(a) is amended by removing the phrase ''ALJ or the MAC'' and adding ''ALJ or attorney adjudicator or the Council'' in its place.
■ 100. Section 423.1980 is amended by revising the section heading and paragraphs (a)(1)(iii) and (iv), (a)(2) and (4), (d) paragraph heading, (d)(2) and (3), (e) paragraph heading, and (e)(2) and (3) to read as follows:

§ 423.1980 Reopening of coverage determinations, redeterminations, reconsiderations, decisions, and reviews.

(a) * * *

(1) * * *

(iii) An ALJ or attorney adjudicator to revise his or her decision; or

(iv) The Council to revise the ALJ or attorney adjudicator decision, or its review decision.

(2) When an enrollee has filed a valid request for an appeal of a coverage determination, redetermination, reconsideration, ALJ or attorney adjudicator decision, or Council review, no adjudicator has jurisdiction to reopen an issue that is under appeal until all appeal rights for that issue are exhausted. Once the appeal rights for the issue have been exhausted, the Part D plan sponsor, IRE, ALJ or attorney adjudicator, or Council may reopen as set forth in this section.

* * * * *

(4) Consistent with § 423.1978(d), the Part D plan sponsor's, IRE's, ALJ's or attorney adjudicator's, or Council's decision on whether to reopen is binding and not subject to appeal.

* * * * *

(d) *Time frame and requirements for reopening reconsiderations, decisions and reviews initiated by an IRE, ALJ or attorney adjudicator, or the Council.*

* * * * *

(2) An ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision on its own motion within 180 calendar days from the date of the decision for good cause in accordance with § 423.1986. If the decision was procured by fraud or similar fault, then the ALJ or attorney adjudicator may reopen his or her decision, or the Council may reopen an ALJ or attorney adjudicator decision at any time.

(3) The Council may reopen its review decision on its own motion within 180 calendar days from the date of the review decision for good cause in accordance with § 423.1986. If the Council's decision was procured by fraud or similar fault, then the Council may reopen at any time.

(e) *Time frames and requirements for reopening reconsiderations, decisions, and reviews requested by an enrollee or a Part D plan sponsor.*

* * * * *

(2) An enrollee who received an ALJ's or attorney adjudicator's decision or a Part D plan sponsor may request that an ALJ or attorney adjudicator reopen his or her decision, or the Council reopen an ALJ or attorney adjudicator decision, within 180 calendar days from the date of the decision for good cause in accordance with § 423.1986.

(3) An enrollee who received a Council decision or a Part D plan sponsor may request that the Council reopen its decision within 180 calendar days from the date of the review decision for good cause in accordance with § 423.1986.

§ 423.1982 [Amended]

■ 101. Section 423.1982 is amended by—

■ a. Amending paragraphs (a)(1) and (2), and (b)(1) and (2) by removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.

■ b. Amending paragraphs (a)(1) and (2) and (b)(1) and (2) by removing the term ''MAC'' and adding ''Council'' in its place.

■ 102. Section 423.1984 is amended by revising paragraphs (d) and (e) to read as follows:

§ 423.1984 Effect of a revised determination or decision.

* * * * *

(d) *ALJ or attorney adjudicator decisions.* The revision of an ALJ or attorney adjudicator decision is binding unless an enrollee submits a request for a Council review that is accepted and processed as specified in § 423.1974 and § 423.2100 through § 423.2130.

(e) *Council review.* The revision of a Council determination or decision is binding unless an enrollee files a civil action in which a Federal District Court accepts jurisdiction and issues a decision.

* * * * *

■ 103. Section 423.1990 is amended by—

■ a. Amending paragraphs (a)(2), (b)(1) introductory text, (b)(1)(ii), and (b)(4) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place

■ b. Amending paragraph (d)(2)(ii) by removing the term ''MAC's'' and adding ''Council's'' in its place.

■ c. Amending paragraph (b)(1)(i) by removing the phrase ''final decision'' and adding ''decision'' in its place and by removing the phrase ''order of the ALJ'' and adding ''order of the ALJ or an attorney adjudicator'' in its place.

■ d. Amending paragraph (b)(1)(ii) by removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.

■ e. Amending paragraphs (c)(3), (4), and (5) by removing the term ''ALJ hearing decision'' and adding ''ALJ or attorney adjudicator decision'' in its place.

■ f. Revising paragraph (d)(1).

■ g. Amending paragraph (d)(2)(i) by removing the term ''ALJ's'' and adding ''ALJ's or attorney adjudicator's'' in its place.

■ h. Revising paragraph (h).

The revisions read as follows:

§ 423.1990 Expedited access to judicial review.

* * * * *

(d) * * *

(1) *Method and place for filing request.* The enrollee may—

(i) If a request for ALJ hearing or Council review is not pending, file a written EAJR request with the HHS Departmental Appeals Board, with his or her request for an ALJ hearing or Council review; or

(ii) If an appeal is already pending for an ALJ hearing or otherwise before OMHA or the Council, file a written EAJR request with the HHS Departmental Appeals Board.

* * * * *

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

(2) Whenever a review entity forwards a rejected EAJR request to OMHA or the Council, the appeal is considered timely filed and, if an adjudication time frame applies to the appeal, the adjudication time frame begins on the day the request is received by OMHA or the Council from the review entity.

■ 104. Section 423.2000 is amended by revising the section heading and paragraphs (a), (b), (c), (d), (e), and (g) to read as follows:

§ 423.2000 Hearing before an ALJ and decision by an ALJ or attorney adjudicator: General rule.

(a) If an enrollee is dissatisfied with an IRE's reconsideration, the enrollee may request a hearing before an ALJ.

(b) A hearing before an ALJ may be conducted in-person, by video-teleconference, or by telephone. At the hearing, the enrollee may submit evidence subject to the restrictions in § 423.2018, examine the evidence used in making the determination under review, and present and/or question witnesses.

(c) In some circumstances, the Part D plan sponsor, CMS, or the IRE may participate in the proceedings on a request for an ALJ hearing as specified in § 423.2010.

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

(e) If an enrollee waives his or her right to appear at the hearing in person

or by telephone or video-teleconference, the ALJ or an attorney adjudicator may make a decision based on the evidence that is in the file and any new evidence that is submitted for consideration.

* * * * *

(g) An ALJ or attorney adjudicator may also issue a decision on the record on his or her own initiative if the evidence in the administrative record supports a fully favorable finding.

§ 423.2002 [Amended]

■ 105. Section 423.2002 is amended by—

■ a. Amending paragraph (a) introductory text by removing the phrase ''may request'' and adding ''has a right to'' in its place.

■ b. Amending paragraph (c) by removing the phrase ''The ALJ'' and adding ''OMHA'' in its place.

■ c. Amending paragraph (e) by removing the word ''entity'' and adding ''office'' in its place.

■ 106. Section 423.2004 is amended by revising the section heading and paragraphs (a) introductory text, (a)(1) and (4), (b), and (c) and adding paragraph (d) to read as follows:

§ 423.2004 Right to a review of IRE notice of dismissal.

(a) An enrollee has a right to have an IRE's dismissal of a request for reconsideration reviewed by an ALJ or attorney adjudicator if—

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

* * * * *

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

(b) If the ALJ or attorney adjudicator determines that the IRE's dismissal was in error, he or she vacates the dismissal and remands the case to the IRE for a reconsideration in accordance with § 423.2056.

(c) If the ALJ or attorney adjudicator affirms the IRE's dismissal of a reconsideration request, he or she issues a notice of decision affirming the IRE's dismissal in accordance with § 423.2046(b).

(d) The ALJ or attorney adjudicator may dismiss the request for review of an IRE's dismissal in accordance with § 423.2052(b).

■ 107. Section 423.2008 is revised to read as follows:

§ 423.2008 Parties to the proceedings on a request for an ALJ hearing.

The enrollee (or the enrollee's representative) who filed the request for hearing is the only party to the proceedings on a request for an ALJ hearing.

■ 108. Section 423.2010 is revised to read as follows:

§ 423.2010 When CMS, the IRE, or Part D plan sponsors may participate in the proceedings on a request for an ALJ hearing.

(a) *When CMS, the IRE, or the Part D plan sponsor may participate.* (1) CMS, the IRE, and/or the Part D plan sponsor may request to participate in the proceedings on a request for an ALJ hearing upon filing a request to participate in accordance with paragraph (b) of this section.

(2) An ALJ may request, but may not require, CMS, the IRE, and/or the Part D plan sponsor to participate in any proceedings before the ALJ, including the oral hearing, if any. The ALJ cannot draw any adverse inferences if CMS, the IRE, and/or the Part D plan sponsor decide not to participate in any proceedings before an ALJ, including the hearing.

(b) *How a request to participate is made*—(1) *No notice of hearing.* If CMS, the IRE, and/or the Part D plan sponsor requests participation before it receives a notice of hearing, or when no notice is required, it must send written notice of its request to participate to the assigned ALJ or attorney adjudicator, or a designee of the Chief ALJ if the request is not yet assigned to an ALJ or attorney adjudicator, and the enrollee, except that the request may be made orally if a request for an expedited hearing was filed and OMHA will notify the enrollee of the request to participate.

(2) *Notice of hearing.* If CMS, the IRE, and/or the Part D plan sponsor requests participation after the IRE and Part D plan sponsor receive a notice of hearing, it must send written notice of its request to participate to the ALJ and the enrollee, except that the request to participate may be made orally for an expedited hearing and OMHA will notify the enrollee of the request to participate.

(3) *Timing of request.* CMS, the IRE, and/or the Part D plan sponsor must send its request to participate—

(i) If a standard request for hearing was filed, if no hearing is scheduled, within 30 calendar days after notification that a standard request for hearing was filed;

(ii) If an expedited hearing is requested, but no hearing has been scheduled, within 2 calendar days after notification that a request for an expedited hearing was filed.

(iii) If a non-expedited hearing is scheduled, within 5 calendar days after receiving the notice of hearing; or

(iv) If an expedited hearing is scheduled, within 1 calendar day after receiving the notice of hearing. Requests may be made orally or submitted by facsimile to the hearing office.

(c) *The ALJ's or attorney adjudicator's decision on a request to participate.* The assigned ALJ or attorney adjudicator has discretion not to allow CMS, the IRE, and/or the Part D plan sponsor to participate. The ALJ or attorney adjudicator must notify the entity requesting participation, the Part D plan sponsor, if applicable, and the enrollee of his or her decision on the request to participate within the following time frames—

(1) If no hearing is scheduled, at least 20 calendar days before the ALJ or attorney adjudicator issues a decision, dismissal, or remand;

(2) If a non-expedited hearing is scheduled, within 5 calendar days of receipt of a request to participate; or

(3) If an expedited hearing is scheduled, within 1 calendar of receipt of a request to participate.

(d) *Roles and responsibilities of CMS, the IRE, and/or the Part D plan sponsor as a participant.* (1) Participation may include filing position papers and/or providing testimony to clarify factual or policy issues in a case, but it does not include calling witnesses or cross-examining the witnesses of an enrollee to the hearing.

(2) When CMS, the IRE, and/or the Part D plan sponsor participates in an ALJ hearing, CMS, the IRE, and/or the Part D plan sponsor may not be called as a witness during the hearing and is not subject to examination or cross-examination by the enrollee, but the enrollee may provide testimony to rebut factual or policy statements made by a participant and the ALJ may question the participant about its testimony.

(3) CMS, IRE, and/or Part D plan sponsor positon papers and written testimony are subject to the following:

(i) Unless the ALJ or attorney adjudicator grants additional time to submit a position paper or written testimony, a position paper and written testimony must be submitted—

(A) Within 14 calendar days for a standard appeal, or 1 calendar day for an expedited appeal, after receipt of the ALJ's or attorney adjudicator's decision on a request to participate if no hearing has been scheduled; or

(B) No later than 5 calendar days prior to the hearing if a non-expedited hearing is scheduled, or 1 calendar day prior to the hearing if an expedited hearing is scheduled.

(ii) A copy of any position paper and written testimony that CMS, the IRE, or

the Part D plan sponsor submits to OMHA must be sent to the enrollee.

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

(e) *Invalid requests to participate.* (1) An ALJ or attorney adjudicator may determine that a CMS, IRE, and/or Part D plan sponsor request to participate is invalid under this section if the request to participate was not timely filed or the request to participate was not sent to the enrollee.

(2) If the request to participate is determined to be invalid, the written notice of an invalid request to participate must be sent to the entity that made the request to participate and the enrollee.

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

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

(iii) If an expedited hearing is scheduled, oral notice of an invalid request to participate must be provided to the entity that submitted the request, and the written notice must be sent as soon as possible after the oral notice is provided.

■ 109. Section 423.2014 is revised to read as follows:

§ 423.2014 Request for an ALJ hearing or a review of an IRE dismissal.

(a) *Content of the request.* (1) The request for an ALJ hearing or a review of an IRE dismissal must be made in writing, except as set forth in paragraph (b) of this section. The request, including any oral request, must include all of the following—

(i) The name, address, telephone number, and Medicare health insurance claim number of the enrollee.

(ii) The name, address, and telephone number of the appointed representative, as defined at § 423.560, if any.

(iii) The Medicare appeal number, if any, assigned to the IRE reconsideration or dismissal being appealed.

(iv) The prescription drug in dispute.

(v) The plan name.

(vi) The reasons the enrollee disagrees with the IRE's reconsideration or dismissal being appealed.

(vii) A statement of whether the enrollee is aware that he or she, or the prescription for the drug being appealed, is the subject of an investigation or proceeding by the HHS Office of Inspector General or other law enforcement agencies.

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

(3) The enrollee must submit a statement that the enrollee is requesting an expedited hearing, if applicable.

(b) *Request for expedited hearing.* If an enrollee is requesting that the hearing be expedited, the enrollee may make the request for an ALJ hearing orally, but only after receipt of the written IRE reconsideration notice. OMHA must document all oral requests in writing and maintain the documentation in the case files. A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for expedited review.

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

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

(d) *When and where to file.* Consistent with §§ 423.1972(a) and (b), the request for an ALJ hearing after an IRE reconsideration or request for review of an IRE dismissal must be filed:

(1) Within 60 calendar days from the date the enrollee receives written notice of the IRE's reconsideration or dismissal being appealed.

(2) With the office specified in the IRE's reconsideration or dismissal.

(i) If the request for hearing is timely filed with an office other than the office specified in the IRE's reconsideration, any applicable time frame specified in § 423.2016 for deciding the appeal begins on the date the office specified in the IRE's reconsideration or dismissal receives the request for hearing.

(ii) If the request for hearing is filed with an office, other than the office specified in the IRE's reconsideration or dismissal, OMHA must notify the enrollee of the date the request was received in the correct office and the commencement of any applicable adjudication timeframe.

(e) *Extension of time to request a hearing or review.* (1) Consistent with § 423.1972(b), if the request for hearing or review is not filed within 60 calendar days of receipt of the written IRE's reconsideration or dismissal, an enrollee may request an extension for good cause.

(2) Any request for an extension of time must be in writing or, for expedited reviews, in writing or oral. OMHA must document all oral requests in writing and maintain the documentation in the case file.

(3) The request must give the reasons why the request for a hearing or review was not filed within the stated time period, and must be filed with the request for hearing or review of an IRE dismissal with the office specified in the notice of reconsideration or dismissal.

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

(5) If a request for hearing is not timely filed, any applicable adjudication period in § 423.2016 begins the date the ALJ or attorney adjudicator grants the request to extend the filing deadline.

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

■ 110. Section 423.2016 is revised to read as follows:

§ 423.2016 Timeframes for deciding an appeal of an IRE reconsideration.

(a) *Standard appeals.* (1) When a request for an ALJ hearing is filed after an IRE has issued a written

reconsideration, an ALJ or attorney adjudicator issues a decision, dismissal order, or remand, as appropriate, no later than the end of the 90 calendar day period beginning on the date the request for hearing is received by the office specified in the IRE's notice of reconsideration, unless the 90 calendar day period has been extended as provided in this subpart.

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

(3) If the Council remands a case and the case was subject to an adjudication time frame under paragraph (a)(1) of this section, the remanded appeal will be subject to the same adjudication time frame beginning on the date that OMHA receives the Council remand.

(b) *Expedited appeals*—(1) *Standard for expedited appeal.* An ALJ or attorney adjudicator issues an expedited decision if the appeal involves an issue specified in § 423.566(b), but is not solely a request for payment of Part D drugs already furnished, and the enrollee's prescribing physician or other prescriber indicates, or an ALJ or attorney adjudicator determines that applying the standard timeframe for making a decision may seriously jeopardize the enrollee's life, health or ability to regain maximum function. An ALJ or attorney adjudicator may consider this standard as met if a lower level adjudicator has granted a request for an expedited hearing.

(2) *Grant of a request.* If an ALJ or attorney adjudicator grants a request for expedited hearing, an ALJ or attorney adjudicator must—

(i) Make the decision to grant an expedited appeal within 5 calendar days of receipt of the request for an expedited hearing;

(ii) Give the enrollee prompt oral notice of this decision; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor written notice of the decision. This notice may be provided within the written notice of hearing.

(3) *Denial of a request.* If an ALJ or attorney adjudicator denies a request for expedited hearing, an ALJ or attorney adjudicator must—

(i) Make this decision within 5 calendar days of receipt of the request for expedited hearing;

(ii) Give the enrollee prompt oral notice of the denial that informs the enrollee of the denial and explains that an ALJ or attorney adjudicator will process the enrollee's request using the 90 calendar day timeframe for non-expedited appeals; and

(iii) Subsequently send to the enrollee at his or her last known address and to the Part D plan sponsor an equivalent written notice of the decision within 3 calendar days after the oral notice.

(4) *Decision not appealable.* A decision on a request for expedited hearing may not be appealed.

(5) *Time frame for adjudication.* (i) If an ALJ or attorney adjudicator accepts a request for expedited hearing, an ALJ or attorney adjudicator issues a written decision, dismissal order, or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for hearing is received by the office specified in the IRE's written notice of reconsideration, unless the 10 calendar day period has been extended as provided in this subpart.

(ii) The adjudication period specified in paragraph (b)(5)(i) of this section begins on the date that a timely provided request for hearing is received by the office specified in the IRE's reconsideration, or, if it is not timely provided, the date that an ALJ or attorney adjudicator grants any extension to the filing deadline.

(6) *Time frame for Council remands.* If the Council remands a case and the case was subject to an adjudication time frame under paragraph (b)(5) of this section, the remanded appeal will be subject to the same adjudication timeframe beginning on the date that OMHA receives the Council remand, if the standards for an expedited appeal continue to be met. If the standards for an expedited appeal are no longer met, the appeal will be subject to the adjudication time frame for a standard appeal.

(c) *Waivers and extensions of adjudication period.* (1) At any time during the adjudication process, the enrollee may waive the adjudication period specified in paragraphs (a)(1) and (b)(5) of this section. The waiver may be for a specific period of time agreed upon by the ALJ or attorney adjudicator and the enrollee.

(2) The adjudication periods specified in paragraphs (a)(1) and (b)(5) of this section are extended as otherwise specified in this subpart, and for the following events—

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

(ii) The duration of a stay of proceedings granted by an ALJ or attorney adjudicator on a motion by an enrollee.

■ 111. Section 423.2018 is revised to read as follows:

§ 423.2018 Submitting evidence.

(a) *All appeals.* An enrollee must submit any written or other evidence that he or she wishes to have considered.

(1) An ALJ or attorney adjudicator will not consider any evidence submitted regarding a change in condition of an enrollee after the appealed coverage determination was made.

(2) An ALJ or attorney adjudicator will remand a case to the Part D IRE where an enrollee wishes evidence on his or her change in condition after the coverage determination to be considered.

(b) *Non-expedited appeals.* (1) Except as provided in this paragraph, a represented enrollee must submit all written or other evidence he or she wishes to have considered with the request for hearing by the date specified in the request for hearing in accordance with § 423.2014(a)(2), or, if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing.

(2) If a represented enrollee submits written or other evidence later than 10 calendar days after receiving the notice of hearing, any applicable adjudication period specified in § 423.2016 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.

(3) The requirements of paragraph (b) of this section do not apply to unrepresented enrollees.

(c) *Expedited appeals.* (1) Except as provided in this section, an enrollee must submit all written or other evidence he or she wishes to have considered with the request for hearing by the date specified in the request for hearing pursuant to § 423.2014(a)(2), or, if an expedited hearing is scheduled, within 2 calendar days of receiving the notice of the expedited hearing.

(2) If an enrollee submits written or other evidence later than 2 calendar days after receiving the notice of expedited hearing, any applicable adjudication period specified in § 423.2016 is extended by the number of calendar days in the period between 2 calendar days after receipt of the notice of expedited hearing and the day the evidence is received.

(d) *When this section does not apply.* The requirements of paragraphs (b) and (c) of this section do not apply to oral testimony given at a hearing.

■ 112. Section 423.2020 is amended by
■ a. Revising paragraphs (b), (c), (d), and (e)(3) and (4).
■ b. Adding paragraphs (g)(3)(vii) and (viii).
■ c. Revising paragraphs (h), (i) paragraph heading, and (i)(1), (2), (4), and (5).
■ d. Adding paragraph (j).

The revisions and additions read as follows:

§ 423.2020 Time and place for a hearing before an ALJ.

* * * * *

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

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

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

(A) The video-teleconferencing or telephone technology is not available; or

(B) Special or extraordinary circumstances exist.

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

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

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

(A) The video-teleconferencing or telephone technology is not available; or

(B) Special or extraordinary circumstances exist.

(c) *Notice of hearing.* (1) A notice of hearing is sent to the enrollee, the Part D plan sponsor that issued the coverage determination, and the IRE that issued the reconsideration, advising them of the proposed time and place of the hearing.

(2) The notice of hearing will require the enrollee to reply to the notice by:

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

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

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

(3) The notice of hearing will require CMS, the IRE, or the Part D plan sponsor that requests to attend the hearing as a participant to reply to the notice by:

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

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

(d) *An enrollee's right to waive a hearing.* An enrollee may also waive the right to a hearing and request a decision based on the written evidence in the record in accordance with § 423.2038(b).

(1) As specified in § 423.2000, an ALJ may require the enrollee to attend a hearing if it is necessary to decide the case.

(2) If an ALJ determines that it is necessary to obtain testimony from a person other than the enrollee, he or she may still hold a hearing to obtain that testimony, even if the enrollee has waived the right to appear. In those cases, the ALJ would give the enrollee the opportunity to appear when the testimony is given but may hold the hearing even if the enrollee decides not to appear.

* * * * *

(e) * * *

(3) The objection must be in writing except for an expedited hearing when the objection may be provided orally, and except that the enrollee may orally request that a non-expedited hearing be rescheduled in an emergency circumstance the day prior to or day of the hearing. The ALJ must document all oral objections to the time and place of a hearing in writing and maintain the documentation in the case files.

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

* * * * *

(g) * * *

(3) * * *

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

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

(h) *Effect of rescheduling hearing.* If a hearing is postponed at the request of the enrollee for any of the above reasons, the time between the originally scheduled hearing date and the new hearing date is not counted toward the adjudication period specified in § 423.2016.

(i) *An enrollee's request for an in-person or video-teleconferencing hearing.* (1) If an unrepresented enrollee objects to a video-teleconferencing hearing or to the ALJ's offer to conduct a hearing by telephone, or a represented enrollee who filed the request for hearing objects to a telephone or video-teleconferencing hearing, the enrollee or the enrollee's representative must notify the ALJ at the earliest possible opportunity before the time set for the hearing and request a video-teleconferencing or an in-person hearing.

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

* * * * *

(4) When an enrollee's request for an in-person or video-teleconferencing hearing is granted and an adjudication time frame applies in accordance with § 423.2016, the ALJ issues a decision, dismissal, or remand to the IRE within the adjudication time frame specified in § 423.2016 (including any applicable extensions provided in this subpart), unless the enrollee requesting the hearing agrees to waive such adjudication timeframe in writing.

(5) The ALJ may grant the request, with the concurrence of the Chief ALJ or designee, upon a finding of good cause and will reschedule the hearing for a time and place when the enrollee may appear in person or by video-teleconference before the ALJ.

(j) *Amended notice of hearing.* If the ALJ changes or will change the time and/or place of the hearing, an amended notice of hearing must be sent to the enrollee and CMS, the IRE, and/or the Part D plan sponsor in accordance with § 423.2022(a)(2).

■ 113. Section 423.2022 is revised to read as follows:

§ 423.2022 Notice of a hearing before an ALJ.

(a) *Issuing the notice.* (1) After the ALJ sets the time and place of the hearing, the notice of the hearing will be mailed or otherwise transmitted in accordance with OMHA procedures to the enrollee and other potential participants, as provided in § 423.2020(c) at their last

known addresses, or given by personal service, except to an enrollee or other potential participant who indicates in writing that he or she does not wish to receive this notice.

(2) The notice is mailed, transmitted, or served at least 20 calendar days before the hearing, except for expedited hearings where written notice is mailed, transmitted, or served at least 3 calendar days before the hearing, unless the enrollee or other potential participant agrees in writing to the notice being mailed, transmitted, or served fewer than 20 calendar days before the non-expedited hearing or 3 calendar days before the expedited hearing. For expedited hearings, the ALJ may orally provide notice of the hearing to the enrollee and other potential participants but oral notice must be followed by an equivalent written notice within 1 calendar day of the oral notice.

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

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

(ii) A statement of any specific new issues the ALJ will consider in accordance with § 423.2032.

(2) The notice will inform the enrollee that he or she may designate a person to represent him or her during the proceedings.

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

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

(5) The notice advises the enrollee that if he or she objects to appearing by video-teleconferencing or telephone, and wishes instead to have his or her hearing at a time and place where he or she may appear in person before the ALJ, he or she must follow the procedures set forth at § 423.2020(i) for notifying the ALJ of his or her objections and for requesting an in-person hearing.

(c) *Acknowledging the notice of hearing.* (1) If the enrollee or his or her representative does not acknowledge receipt of the notice of hearing, OMHA attempts to contact the enrollee for an explanation.

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

(3) The enrollee may request that the ALJ reschedule the hearing in accordance with § 423.2020(e).

■ 114. Section 423.2024 is amended by—

■ a. Amending paragraph (a) by removing the phrase ''The ALJ hearing office'' and adding ''OMHA'' in its place.

■ b. Revising paragraph (c) to read as follows:

§ 423.2024 Objections to the issues.

* * * * *

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

■ 115. Section 423.2026 is revised to read as follows:

§ 423.2026 Disqualification of the ALJ or attorney adjudicator.

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

(b) If an enrollee objects to the ALJ or attorney adjudicator assigned to adjudicate the appeal, the enrollee must notify the ALJ within 10 calendar days of the date of the notice of hearing if a non-expedited hearing is scheduled, except for expedited hearings in which the enrollee must submit written or oral notice no later than 2 calendar days after the date of the notice of hearing, or the ALJ or attorney adjudicator at any time before a decision, dismissal order, or remand order is issued if no hearing is scheduled. The ALJ or attorney adjudicator must document all oral objections in writing and maintain the documentation in the case files. The ALJ or attorney adjudicator considers the enrollee's objections and decides whether to proceed with the appeal or withdraw.

(c) If the ALJ or attorney adjudicator withdraws, another ALJ or attorney adjudicator will be assigned to adjudicate the appeal. If the ALJ or attorney adjudicator does not withdraw, the enrollee may, after the ALJ or attorney adjudicator has issued an action in the case, present his or her objections to the Council in accordance with § 423.2100 through § 423.2130. The Council will then consider whether the decision or dismissal should be revised or, if applicable, a new hearing held before another ALJ.

(d) If the enrollee objects to the ALJ or attorney adjudicator and the ALJ or attorney adjudicator subsequently withdraws from the appeal, any adjudication period that applies to the appeal in accordance with § 423.2016 is extended by 14 calendar days for a standard appeal, or 2 calendar days for an expedited appeal.

■ 116. Section 423.2030 is revised to read as follows:

§ 423.2030 ALJ hearing procedures.

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

(b) *At the hearing.* (1) The ALJ fully examines the issues, questions the enrollee and other witnesses, and may accept evidence that is material to the issues consistent with § 423.2018.

(2) The ALJ may limit testimony and argument at the hearing that are not relevant to an issue before the ALJ, or that address an issue before the ALJ for which the ALJ determines he or she has sufficient information or on which the ALJ has already ruled. The ALJ may, but is not required to, provide the enrollee or representative with an opportunity to submit additional written statements and affidavits on the matter in lieu of testimony and/or argument at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(3) If the ALJ determines that the enrollee or enrollee's representative is uncooperative, disruptive to the hearing, or abusive during the course of the hearing, the ALJ may excuse the enrollee or representative from the hearing and continue with the hearing to provide the participants with an opportunity to offer testimony and/or argument. If an enrollee or representative was excused from the hearing, the ALJ will provide the enrollee or representative with an opportunity to submit written statements and affidavits in lieu of testimony and/or argument at the hearing, and the enrollee or representative may request a recording of the hearing in accordance with § 423.2042 and respond in writing to any statements made by participants and/or testimony of the witnesses at the hearing. The written statements and affidavits must be submitted within the time frame designated by the ALJ.

(c) *Missing evidence.* The ALJ may also stop the hearing temporarily and continue it at a later date if he or she believes that there is material evidence missing at the hearing.

(d) *Effect of new evidence on adjudication period.* If an enrollee, other than an unrepresented enrollee in a standard appeal, submits evidence pursuant to paragraph (b) or (c), and an adjudication period applies to the appeal, the adjudication period specified in § 423.2016 is extended in accordance with § 423.2018(b) or (c), as applicable.

(e) *Continued hearing.* (1) A hearing may be continued to a later date. Notice of the continued hearing must be sent in accordance with § 423.2022, except that a waiver of notice of the hearing may be made in writing or on the record, and the notice is sent to the enrollee and participants who attended the hearing, and any additional potential participants the ALJ determines are appropriate.

(2) If the enrollee requests the continuance and an adjudication time frame applies to the appeal in accordance with § 423.2016, the adjudication period is extended by the period between the initial hearing date and the continued hearing date.

(f) *Supplemental hearing.* (1) The ALJ may conduct a supplemental hearing at any time before he or she mails a notice of the decision in order to receive new and material evidence, obtain additional testimony, or address a procedural matter. The ALJ determines whether a supplemental hearing is necessary and if one is held, the scope of the hearing, including when evidence is presented and what issues are discussed. Notice of the supplemental hearing must be sent in accordance with § 423.2022, except that the notice is sent to the enrollee and participants who attended the hearing, and any additional potential participants the ALJ determines are appropriate.

(2) If the enrollee requests the supplemental hearing and an adjudication period applies to the appeal in accordance with § 423.2016, the adjudication period is extended by the period between the initial hearing date and the supplemental hearing date.

■ 117. Section 423.2032 is revised to read as follows:

§ 423.2032 Issues before an ALJ or attorney adjudicator.

(a) *General rule.* The issues before the ALJ or attorney adjudicator include all the issues for the appealed matter specified in the request for hearing that were brought out in the coverage determination, redetermination, or reconsideration that were not decided entirely in an enrollee's favor.

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

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

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

(2) *Notice of the new issue.* The ALJ may consider a new issue at the hearing if he or she notifies the enrollee about the new issue before the start of the hearing.

(3) *Opportunity to submit evidence.* If notice of the new issue is sent after the notice of hearing, the enrollee will have at least 10 calendar days in standard appeals or 2 calendar days in expedited appeals after receiving notice of the new issue to submit evidence regarding the issue, and without affecting any applicable adjudication period. If a hearing is conducted before the time to submit evidence regarding the issue expires, the record will remain open until the opportunity to submit evidence expires.

(c) *Adding coverage determinations to a pending appeal.* A coverage determination on a drug that was not specified in a request for hearing may only be added to pending appeal if the coverage determination was adjudicated in the same reconsideration that is appealed, and the period to request an ALJ hearing for that reconsideration has not expired, or an ALJ or attorney adjudicator extends the time to request an ALJ hearing on the reconsideration in accordance with § 423.2014(e).

■ 118. Section 423.2034 is revised to read as follows:

§ 423.2034 Requesting information from the IRE.

(a) If an ALJ or attorney adjudicator believes that the written record is missing information that is essential to resolving the issues on appeal and that information can be provided only by CMS, the IRE, and/or the Part D plan sponsor, the information may be requested from the IRE that conducted the reconsideration or its successor.

(1) Official copies of redeterminations and reconsiderations that were conducted on the appealed issues can only be provided by CMS, the IRE, and/or the Part D plan sponsor.

(2) ''Can be provided only by CMS, the IRE, and/or the Part D plan sponsor'' means the information is not publicly available, is not in the possession of the enrollee, and cannot be requested and obtained by the enrollee. Information that is publicly available is information that is available to the general public via the Internet or in a printed publication. Information that is publicly available includes, but is not limited to, information available on a CMS, IRE or Part D Plan sponsor Web site or information in an official CMS or HHS publication.

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

(c) The IRE has 15 calendar days for standard appeals, or 2 calendar days for expedited appeals, after receiving the request for information to furnish the information or otherwise respond to the information request directly or through CMS or the Part D plan sponsor.

(d) If an adjudication period applies to the appeal in accordance with § 423.2016, the adjudication period is extended by the period between the date of the request for information and the date the IRE responds to the request or 20 calendar days after the date of the request for standard appeals, or 3 calendar days after the date of the request for expedited appeals, whichever occurs first.

§ 423.2036 [Amended]

■ 119. Section 423.2036 is amended by—

■ a. Amending paragraph (b)(1) introductory text by removing the phrase ''send the ALJ'' and adding ''submit to OMHA'' in its place.

■ b. Amending paragraph (b)(1)(ii) by removing the phrase ''The ALJ hearing office'' and adding ''OMHA'' in its place.

■ c. Removing paragraph (d).

■ d. Redesignating paragraph (g) as new paragraph (d).

■ e. Amending paragraphs (f)(2), (f)(3) introductory text, and (f)(3) (i), (ii), and (iii) by removing the term ''MAC'' and adding ''Council'' in its place.

■ f. Amending paragraph (f)(2) by removing the term ''MAC's'' and adding ''Council's'' in its place.

■ 120. Section 423.2038 is revised to read as follows:

§ 423.2038 Deciding a case without a hearing before an ALJ.

(a) *Decision fully favorable.* If the evidence in the administrative record supports a finding fully in favor of the enrollee(s) on every issue, the ALJ or attorney adjudicator may issue a decision without giving the enrollee(s) prior notice and without an ALJ conducting a hearing. The notice of the decision informs the enrollee(s) that he or she has the right to a hearing and a right to examine the evidence on which the decision is based.

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

(i) The enrollee indicates in writing or, for expedited hearings orally or in writing, that he or she does not wish to appear before an ALJ at a hearing, including a hearing conducted by telephone or video-teleconferencing, if available. OMHA must document all oral requests not to appear at a hearing in writing and maintain the documentation in the case files; or

(ii) The enrollee lives outside the United States and does not inform OMHA that he or she wants to appear at a hearing before an ALJ.

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

(c) *Stipulated decision.* If CMS, the IRE, and/or the Part D plan sponsor submits a written statement or makes an oral statement at a hearing indicating the drug should be covered or payment may be made, an ALJ or attorney adjudicator may issue a stipulated decision finding in favor of the enrollee on the basis of the statement, and without making findings of fact, conclusions of law, or further explaining the reasons for the decision.

■ 121. Section 423.2040 is revised to read as follows:

§ 423.2040 Prehearing and posthearing conferences.

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

(b) For non-expedited hearings, the ALJ informs the enrollee, and CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant to the hearing at the time the notice of conference is sent, of the time, place, and purpose of the conference at least 7 calendar days before the conference date, unless the enrollee indicates in writing that he or she does not wish to receive a written notice of the conference.

(c) For expedited hearings, the ALJ informs the enrollee, and CMS, the IRE, and/or the Part D plan sponsor if the ALJ has granted their request(s) to be a participant to the hearing, of the time, place, and purpose of the conference at least 2 calendar days before the conference date, unless the enrollee indicates orally or in writing that he or she does not wish to receive a written notice of the conference.

(d) All oral requests not to receive written notice of the conference must be documented in writing and the documentation must be made part of the administrative record.

(e) At the conference—

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

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

(f) The ALJ issues an order to the enrollee and all participants who attended the conference stating all agreements and actions resulting from the conference. If the enrollee does not object within 10 calendar days of receiving the order for non-expedited hearings or 1 calendar day for expedited hearings, or any additional time granted by the ALJ, the agreements and actions become part of the administrative record and are binding on the enrollee.

■ 122. Section 423.2042 is revised to read as follows:

§ 423.2042 The administrative record.

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

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

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

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

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

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

(2) If an enrollee requests a copy of all or part of the record from OMHA or the ALJ or attorney adjudicator and an opportunity to comment on the record, any adjudication period that applies in accordance with § 423.2016 is extended by the time beginning with the receipt of the request through the expiration of the time granted for the enrollee's response.

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

■ 123. Section 423.2044 is revised to read as follows:

§ 423.2044 Consolidated proceedings.

(a) *Consolidated hearing.* (1) A consolidated hearing may be held if one or more of the issues to be considered at the hearing are the same issues that are involved in one or more other appeals pending before the same ALJ.

(2) It is within the discretion of the ALJ to grant or deny an enrollee's request for consolidation. In considering an enrollee's request, the ALJ may consider factors such as whether the

issue(s) may be more efficiently decided if the appeals are consolidated for hearing. In considering the enrollee's request for consolidation, the ALJ must take into account any adjudication deadlines for each appeal and may require an enrollee to waive the adjudication deadline associated with one or more appeals if consolidation otherwise prevents the ALJ from deciding all of the appeals at issue within their respective deadlines.

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

(4) Notice of a consolidated hearing must be included in the notice of hearing issued in accordance with §§ 423.2020 and 423.2022.

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

(i) A consolidated decision and record; or

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

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

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

(c) *Limitation on consolidated proceedings.* Consolidated proceedings may only be conducted for appeals filed by the same enrollee, unless multiple enrollees aggregated appeals to meet the amount in controversy requirement in accordance with § 423.1970 and the enrollees have all authorized disclosure of information to the other enrollees.

■ 124. Section 423.2046 is revised to read as follows:

§ 423.2046 Notice of an ALJ or attorney adjudicator decision.

(a) *Decisions on requests for hearing*—(1) *General rule.* Unless the ALJ or attorney adjudicator dismisses or remands the request for hearing, the ALJ or attorney adjudicator will issue a written decision that gives the findings of fact, conclusions of law, and the reasons for the decision.

(i) The decision must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions.

(ii) A copy of the decision should be mailed or otherwise transmitted to the enrollee at his or her last known address.

(iii) A copy of the written decision should also be provided to the IRE that issued the reconsideration determination, and to the Part D plan sponsor that issued the coverage determination.

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

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

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

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

(3) *Limitation on decision.* When the amount of payment for the Part D drug is an issue before the ALJ or attorney adjudicator, the ALJ or attorney adjudicator may make a finding as to the amount of payment due. If the ALJ or attorney adjudicator makes a finding concerning payment when the amount of payment was not an issue before the ALJ or attorney adjudicator, the Part D plan sponsor may independently determine the payment amount. In either of the aforementioned situations, an ALJ's or attorney adjudicator's decision is not binding on the Part D plan sponsor for purposes of determining the amount of payment due. The amount of payment determined by the Part D plan sponsor in effectuating the ALJ's or attorney adjudicator's decision is a new coverage determination under § 423.566.

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

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

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

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

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

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

■ 125. Section 423.2048 is revised to read as follows:

§ 423.2048 The effect of an ALJ's or attorney adjudicator's decision.

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

(1) An enrollee requests a review of the decision by the Council within the stated time period or the Council reviews the decision issued by an ALJ or attorney adjudicator under the procedures set forth in § 423.2110, and the Council issues a final decision or remand order;

(2) The decision is reopened and revised by an ALJ or attorney adjudicator or the Council under the procedures explained in § 423.1980;

(3) The expedited access to judicial review process at § 423.1990 is used;

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

(5) In a case remanded by a Federal district court, the Council assumes jurisdiction under the procedures in § 423.2138 and the Council issues a decision.

(b) The decision of the ALJ or attorney adjudicator on a request for review of an IRE dismissal is binding on the enrollee unless the decision is reopened and revised by the ALJ or attorney adjudicator under the procedures explained in § 423.1980.

§ 423.2050 [Amended]

■ 126. Section 423.2050 is amended by—

■ a. Amending the section heading by removing the phrase ''an ALJ'' and adding ''OMHA'' in its place.

■ b. Amending the text of the section by removing the phrase ''pending before an ALJ'' and adding ''pending before OMHA'' in its place, and by removing the term ''the ALJ'' and adding ''OMHA'' in its place.

■ c. Amending the section heading and the text of the section by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ 127. Section 423.2052 is revised to read as follows:

§ 423.2052 Dismissal of a request for a hearing before an ALJ or request for review of an IRE dismissal.

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

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

(i) The enrollee was notified before the time set for the hearing that the request for hearing might be dismissed for failure to appear, the record contains documentation that the enrollee acknowledged the notice of hearing, and the enrollee does not contact the ALJ within 10 calendar days after the hearing for non-expedited hearings and 2 calendar days after the hearing for expedited hearings, or does contact the ALJ but the ALJ determines the enrollee did not demonstrate good cause for not appearing; or

(ii) The record does not contain documentation that the enrollee acknowledged the notice of hearing, the ALJ sends a notice to the enrollee at his or her last known address asking why the enrollee did not appear, and the enrollee does not respond to the ALJ's notice within 10 calendar days for non-expedited hearings or within 2 calendar days for expedited hearings after receiving the notice, or does contact the ALJ but the ALJ determines the enrollee did not demonstrate good cause for not appearing. For expedited hearings, an enrollee may submit his or her response orally to the ALJ.

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

(2) The person requesting a hearing has no right to it under § 423.2002.

(3) The enrollee did not request a hearing within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in § 423.2014(e).

(4) The enrollee died while the request for hearing is pending and the request for hearing was filed by the enrollee or the enrollee's representative, and the enrollee's surviving spouse or estate has no remaining financial interest in the case and the enrollee's representative, if any, does not wish to continue the appeal.

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

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

(7) The enrollee's request is not complete in accordance with § 423.2014(a)(1), even after the enrollee is provided with an opportunity to complete the request.

(b) *Dismissal of request for review of IRE dismissal.* An ALJ or attorney adjudicator dismisses a request for review of an IRE dismissal under any of the following conditions:

(1) The enrollee has no right to a review of the IRE dismissal under § 423.2004.

(2) The enrollee did not request a review within the stated time period and the ALJ or attorney adjudicator has not found good cause for extending the deadline, as provided in § 423.2014(e).

(3) The enrollee died while the request for review was pending and the request was filed by the enrollee or the enrollee's representative, and the enrollee's surviving spouse or estate has no remaining financial interest in the case and the enrollee's representative, if any, does not wish to continue the appeal.

(4) The enrollee's request is not complete in accordance with § 423.2014(a)(1), even after the enrollee is provided with an opportunity to complete the request.

(c) *Withdrawal of request.* At any time before notice of the decision, dismissal, or remand is mailed, if the enrollee asks to withdraw the request, an ALJ or attorney adjudicator may dismiss the request for hearing or request for review of an IRE dismissal. This request for withdrawal may be submitted in writing, or a request to withdraw a request for hearing may be made orally at a hearing before the ALJ. The request for withdrawal must include a clear statement that the enrollee is withdrawing the request for hearing or review of the IRE dismissal and does not intend to further proceed with the appeal. If an attorney or other legal professional on behalf of an enrollee files the request for withdrawal, the ALJ or attorney adjudicator may presume that the representative has advised the enrollee of the consequences of the withdrawal and dismissal.

(d) *Notice of dismissal.* OMHA mails or otherwise transmits a written notice of the dismissal of the hearing or review request to the enrollee at his or her last known address. The written notice provides that there is a right to request that the ALJ or attorney adjudicator vacate the dismissal action.

(e) *Vacating a dismissal.* If good and sufficient cause is established, the ALJ or attorney adjudicator may vacate his or her dismissal of a request for hearing or review within 6 months of the date of the notice of dismissal.

■ 128. Section 423.2054 is revised to read as follows:

§ 423.2054 Effect of dismissal of a request for a hearing or request for review of an IRE's dismissal.

(a) The dismissal of a request for a hearing is binding, unless it is vacated by the Council under § 423.2108(b), or vacated by the ALJ or attorney adjudicator under § 423.2052(e).

(b) The dismissal of a request for review of an IRE dismissal of a request for reconsideration is binding and not subject to further review unless vacated by the ALJ or attorney adjudicator under § 423.2052(e).

■ 129. Section 423.2056 is added to read as follows:

§ 423.2056 Remands of requests for hearing and requests for review.

(a) *Missing appeal determination or case record.* (1) If an ALJ or attorney adjudicator requests an official copy of a missing redetermination or reconsideration for an appealed coverage determination in accordance with § 423.2034, and the IRE, CMS, or Part D plan sponsor does not furnish the copy within the time frame specified in § 423.2034, an ALJ or attorney adjudicator may issue a remand directing the IRE or Part D plan sponsor to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(2) If the IRE does not furnish the case file for an appealed reconsideration, an ALJ or attorney adjudicator may issue a

remand directing the IRE to reconstruct the record or, if it is not able to do so, initiate a new appeal adjudication.

(3) If the IRE or Part D plan sponsor is able to reconstruct the record for a remanded case and returns the case to OMHA, the case is no longer remanded and the reconsideration is no longer vacated, and any adjudication period that applies to the appeal in accordance with § 423.2016 is extended by the period between the date of the remand and the date that case is returned to OMHA.

(b) *No redetermination.* If an ALJ or attorney adjudicator finds that the IRE issued a reconsideration and no redetermination was made with respect to the issue under appeal or the request for redetermination was dismissed, the reconsideration will be remanded to the IRE, or its successor, to re-adjudicate the request for reconsideration.

(c) *Requested remand*—(1) *Request contents and timing.* At any time prior to an ALJ or attorney adjudicator issuing a decision or dismissal, the enrollee and CMS, the IRE, or the Part D plan sponsor may jointly request a remand of the appeal to the IRE. The request must include the reasons why the appeal should be remanded, and indicate whether remanding the case will likely resolve the matter in dispute.

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

(d) *Remanding an IRE's dismissal of a request for reconsideration.* Consistent with § 423.2004(b), an ALJ or attorney adjudicator will remand a case to the appropriate IRE if the ALJ or attorney adjudicator determines that an IRE's dismissal of a request for reconsideration was in error.

(e) *Consideration of change in condition.* The ALJ or attorney adjudicator will remand a case to the appropriate IRE if the ALJ or attorney adjudicator determines that the enrollee wants evidence on his or her change in condition after the coverage determination to be considered in the appeal.

(f) *Notice of a remand.* OMHA mails or otherwise transmits a written notice of the remand of the request for hearing or request for review to the enrollee at his or her last known address, and CMS, the IRE, and/or the Part D plan sponsor if a request to be a participant was granted by the ALJ or attorney adjudicator. The notice states that there is a right to request that the Chief ALJ or a designee review the remand.

(g) *Review of remand.* Upon a request by the enrollee or CMS, the IRE, or the Part D plan sponsor filed within 30 calendar days of receiving a notice of remand, the Chief ALJ or designee will review the remand, and if the remand is not authorized by this section, vacate the remand order. The determination on a request to review a remand order is binding and not subject to further review.

■ 130. Section 423.2058 is added to read as follows:

§ 423.2058 Effect of a remand.

A remand of a request for hearing or request for review is binding unless vacated by the Chief ALJ or a designee in accordance with § 423.2056(g).

§ 423.2062 [Amended]

■ 131. Section 423.2062 is amended by—

■ a. Amending the section heading and paragraphs (a) and (b) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ b. Amending paragraph (a) by removing the term ''ALJs'' and adding ''ALJs and attorney adjudicators'' in its place.

■ c. Amending paragraph (b) by removing the term ''ALJ'' each time it appears and adding ''ALJ or attorney adjudicator'' in its place.

■ 132. Section 423.2063 is revised to read as follows:

§ 423.2063 Applicability of laws, regulations, CMS Rulings, and precedential decisions.

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

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

(c) Precedential decisions designated by the Chair of the Departmental Appeals Board in accordance with § 401.109 of this chapter are binding on all CMS components, and all HHS components that adjudicate matters under the jurisdiction of CMS.

■ 133. Section 423.2100 is revised to read as follows:

§ 423.2100 Medicare Appeals Council review: general.

(a) Consistent with § 423.1974, the enrollee may request that the Council review an ALJ's or attorney adjudicator's decision or dismissal.

(b) When the Council reviews an ALJ's or attorney adjudicator's written decision, it undertakes a de novo review.

(c) The Council issues a final decision, dismissal order, or remands a case to the ALJ or attorney adjudicator no later than the end of the 90 calendar day period beginning on the date the request for review is received (by the entity specified in the ALJ's or attorney adjudicator's written notice of decision), unless the 90 calendar day period is extended as provided in this subpart or the enrollee requests expedited Council review.

(d) If an enrollee requests expedited Council review, the Council issues a final decision, dismissal order or remand as expeditiously as the enrollee's health condition requires, but no later than the end of the 10 calendar day period beginning on the date the request for review is received (by the entity specified in the ALJ's or attorney adjudicator's written notice of decision), unless the 10 calendar day period is extended as provided in this subpart.

■ 134. Section 423.2102 is revised to read as follows:

§ 423.2102 Request for Council review when ALJ or attorney adjudicator issues decision or dismissal.

(a)(1) An enrollee may request Council review of a decision or dismissal issued by an ALJ or attorney adjudicator if the enrollee files a written request for a Council review within 60 calendar days after receipt of the ALJ's or attorney adjudicator's written decision or dismissal.

(2) An enrollee may request that Council review be expedited if the appeal involves an issue specified in § 423.566(b) but does not include solely a request for payment of Part D drugs already furnished.

(i) If an enrollee is requesting that the Council review be expedited, the enrollee submits an oral or written request within 60 calendar days after the receipt of the ALJ's or attorney adjudicator's written decision or dismissal. A prescribing physician or other prescriber may provide oral or written support for an enrollee's request for expedited review.

(ii) The Council must document all oral requests for expedited review in writing and maintain the documentation in the case files.

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

(4) The request is considered as filed on the date it is received by the entity specified in the notice of the ALJ's or attorney adjudicator's action.

(b) An enrollee requesting a review may ask that the time for filing a request for Council review be extended if—

(1) The request for an extension of time is in writing or, for expedited reviews, in writing or oral. The Council must document all oral requests in writing and maintain the documentation in the case file.

(2) The request explains why the request for review was not filed within the stated time period. If the Council finds that there is good cause for missing the deadline, the time period will be extended. To determine whether good cause exists, the Council uses the standards outlined at § 405.942(b)(2) and (3) of this chapter.

(c) An enrollee does not have the right to seek Council review of an ALJ's or attorney adjudicator's remand to an IRE, or an ALJ's or attorney adjudicator's affirmation of an IRE's dismissal of a request for reconsideration, or dismissal of a request to review an IRE dismissal.

§ 423.2106 [Amended]

■ 135. Section 423.2106 is amended by—

■ a. Removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.

■ b. Removing the term ''ALJ's'' each time it appears and adding ''ALJ's or attorney adjudicator's'' in its place.

■ c. Removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ d. Removing the term ''MAC's'' and adding ''Council's'' in its place.

§ 423.2108 [Amended]

■ 136. Section 423.2108 is amended by—

■ a. Amending paragraphs (a), (b), and (c) by removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.

■ b. Amending paragraphs (a) and (d)(2)(iii) by removing the term ''ALJ's'' each time it appears and adding ''ALJ's or attorney adjudicator's'' in its place.

■ c. Amending the section heading and paragraphs (a), (b), (c), (d)(1), (d)(2) introductory text, (d)(3) introductory text, and (d)(3)(ii) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

■ d. Amending paragraph (a) by removing the term ''MAC's'' and adding ''Council's'' in its place.

■ e. Amending the paragraph heading and text of paragraph (b) by removing the phrase ''ALJ's dismissal'' and adding ''ALJ's or attorney adjudicator's dismissal of a request for a hearing'' in its place.

■ 137. Section 423.2110 is revised to read as follows:

§ 423.2110 Council reviews on its own motion.

(a) *General rule.* The Council may decide on its own motion to review a decision or dismissal issued by an ALJ or attorney adjudicator. CMS or the IRE may refer a case to the Council for it to consider reviewing under this authority any time within 60 calendar days after the date of an ALJ's or attorney adjudicator's written decision or dismissal.

(b) *Referral of cases.* (1) CMS or the IRE may refer a case to the Council if, in the view of CMS or the IRE, the decision or dismissal contains an error of law material to the outcome of the appeal or presents a broad policy or procedural issue that may affect the public interest. CMS or the IRE may also request that the Council take own motion review of a case if—

(i) CMS or the IRE participated or requested to participate in the appeal at the OMHA level; and

(ii) In CMS' or the IRE's view, the ALJ's or attorney adjudicator's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ or attorney adjudicator abused his or her discretion.

(2) CMS' or the IRE's referral to the Council is made in writing and must be filed with the Council no later than 60 calendar days after the ALJ's or attorney adjudicator's written decision or dismissal is issued.

(i) The written referral will state the reasons why CMS or the IRE believes that the Council should review the case on its own motion.

(ii) CMS or the IRE will send a copy of its referral to the enrollee and to the OMHA Chief ALJ.

(iii) The enrollee may file exceptions to the referral by submitting written comments to the Council within 20 calendar days of the referral notice.

(iv) An enrollee submitting comments to the Council must send the comments to CMS or the IRE.

(c) *Standard of review*—(1) *Referral by CMS or the IRE when CMS or the IRE participated or requested to participate in the OMHA level.* If CMS or the IRE participated or requested to participate in an appeal at the OMHA level, the Council exercises its own motion authority if there is an error of law material to the outcome of the case, an abuse of discretion by the ALJ or attorney adjudicator, the decision is not consistent with the preponderance of the evidence of record, or there is a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review under this standard, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS or the IRE.

(2) *Referral by CMS or the IRE when CMS or the IRE did not participate or request to participate in the OMHA proceedings.* The Council will accept review if the decision or dismissal contains an error of law material to the outcome of the case or presents a broad policy or procedural issue that may affect the general public interest. In deciding whether to accept review, the Council will limit its consideration of the ALJ's or attorney adjudicator's action to those exceptions raised by CMS or the IRE.

(d) *Council's action.* (1) If the Council decides to review a decision or dismissal on its own motion, it will mail the results of its action to the enrollee and to CMS or the IRE, as appropriate.

(2) The Council may adopt, modify, or reverse the decision or dismissal, may remand the case to an ALJ or attorney adjudicator for further proceedings, or may dismiss a hearing request.

(3) The Council must issue its action no later than 90 calendar days after receipt of the CMS or the IRE referral, unless the 90 calendar day period has been extended as provided in this subpart.

(4) The Council may not issue its action before the 20 calendar day comment period has expired, unless it determines that the agency's referral does not provide a basis for reviewing the case.

(5) If the Council declines to review a decision or dismissal on its own motion, the ALJ's or attorney adjudicator's decision or dismissal is binding.

§ 423.2112 [Amended]

■ 138. Section 423.2112 is amended by—

■ a. Amending paragraphs (a)(1), (b), and (c) by removing the term ''ALJ's'' and adding ''ALJ's or attorney adjudicator's'' in its place.

■ b. Amending paragraph (b) by removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.

■ c. Amending paragraphs (a)(1) and (3), and (c) by removing the term ''MAC'' and adding ''Council'' in its place.

§ 423.2114 [Amended]

■ 139. Section 423.2114 is amended in the introductory text and paragraph (b) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

§ 423.2116 [Amended]

■ 140. Section 423.2116 is amended by—
■ a. Removing the term ''MAC'' each time it appears and adding ''Council'' in its place.
■ b. Removing the term ''MAC's'' and adding ''Council's'' in its place.
■ c. Removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.

§ 423.2118 [Amended]

■ 141. Section 423.2118 is amended by—
■ a. Removing the term ''MAC'' each time it appears and adding ''Council'' in its place.
■ b. Removing the term ''MAC's'' and adding ''Council's'' in its place.
■ c. Removing the phrase ''ALJ hearing'' and adding ''ALJ's or attorney adjudicator's action'' in its place.
■ d. Removing the phrase ''the exhibits list'' and adding ''any index of the administrative record'' in its place.
■ e. Removing the term ''CD'' and adding ''audio recording'' in its place.

§ 423.2120 [Amended]

■ 142. Section 423.2120 is amended by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

§ 423.2122 [Amended]

■ 143. Section 423.2122 is amended by—
■ a. Amending the section heading and paragraphs (a) paragraph heading, (a)(1), (2), and (3), (b) introductory text, (b)(1) and (2), and (c)(1), (2), (3), and (4) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.
■ b. Amending paragraphs (a) paragraph heading and (a)(1) by removing the term ''ALJ's'' and adding ''ALJ's or attorney adjudicator's'' in its place.
■ c. Amending paragraph (a)(1) by removing the term ''ALJ level'' and adding ''OMHA level'' in its place.
■ d. Amending paragraph (a)(1) by removing the term ''hearing decision'' and adding ''ALJ's or attorney adjudicator's decision'' in its place.
■ e. Amending paragraphs (a)(1) and (2) by removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.
■ f. Amending paragraph (a)(2) by removing the term ''hearing record'' and adding ''administrative record'' in its place.
■ g. Amending paragraph (c)(3) by removing the term ''MAC's'' and adding ''Council's'' in its place.

§ 423.2124 [Amended]

■ 144. Section 423.2124 is amended in the introductory text and paragraphs (a), (b), (c), (d), and (e) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.

§ 423.2126 [Amended]

■ 145. Section 423.2126 is amended by—
■ a. Amending the section heading and paragraphs (a) paragraph heading, (a)(1), (2), and (3), (a)(4) paragraph heading, (a)(4)(i) and (ii), (a)(5) paragraph heading, (a)(5)(i) and (ii), and (b) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.
■ b. Amending paragraphs (a) paragraph heading, (a)(1), (2), and (3), (a)(4) paragraph heading, and (a)(5)(ii) by removing the term ''ALJ'' each time it appears and adding ''ALJ or attorney adjudicator'' in its place.
■ c. Amending paragraph (a)(2) by removing the term ''MAC's and adding ''Council's'' in its place.
■ d. Amending paragraph (a)(5)(ii) by adding ''if applicable'' after the word ''rehearing''.

§ 423.2128 [Amended]

■ 146. Section 423.2128 is amended by—
■ a. Amending the section heading and paragraphs (a), (b), and (c) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.
■ b. Amending paragraph (a) by removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.
■ c. Amending paragraph (b) by removing the phrase ''ALJ hearing decision'' and adding ''ALJ or attorney adjudicator decision'' in its place.

§ 423.2130 [Amended]

■ 147. Section 423.2130 is amended in the section heading and text by removing the term ''MAC's'' each time it appears and adding ''Council's'' in its place.

§ 423.2134 [Amended]

■ 148. Section 423.2134 is amended in paragraphs (b)(3) and (c) by removing the term ''MAC'' and adding ''Council'' in its place.

§ 423.2136 [Amended]

■ 149. Section 423.2136 is amended by—
■ a. Amending paragraphs (a) and (c)(3) by removing the term ''MAC'' and adding ''Council'' in its place.
■ b. Amending paragraph (c)(2) by removing the term ''MAC's'' and adding ''Council's'' in its place.
■ c. Amending paragraph (c)(3) by removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.

§ 423.2138 [Amended]

■ 150. Section 423.2138 is amended by—
■ a. Removing the term ''MAC'' each time it appears and adding ''Council'' in its place.
■ b. Removing the term ''ALJ'' and adding ''ALJ or attorney adjudicator'' in its place.

§ 423.2140 [Amended]

■ 151. Section 423.2140 is amended by—
■ a. Amending the section heading and paragraphs (a)(1), (2), and (3), (b)(1), (b)(2) introductory text, (b)(2)(ii), (b)(3) and (4), (c) paragraph heading, (c)(1), (3), and (4), and (d) by removing the term ''MAC'' each time it appears and adding ''Council'' in its place.
■ b. Amending the section heading and paragraphs (a)(1), (2), and (3), (b) paragraph heading, (b)(1), (b)(2) introductory text, (b)(2)(i), (b)(3) and (4), (c)(1) and (4), and (d) by removing the term ''ALJ'' each time it appears and adding ''ALJ or attorney adjudicator'' in its place.
■ c. Amending paragraph (d) by removing the term ''ALJ's'' and adding ''ALJ's or attorney adjudicator's'' in its place.

PART 478—RECONSIDERATIONS AND APPEALS

■ 152. The authority citation for part 478 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 153. Section 478.14(c)(2) is amended by removing the phrase ''part 405, subpart G of this chapter for determinations under Medicare Part A, and part 405, subpart H of this chapter for determinations under Medicare Part B'' and adding ''part 405, subpart I of this chapter for determinations under Medicare Part A and Part B'' in its place.
■ 154. Section 478.40 is amended by revising paragraphs (a) and (c) to read as follows:

§ 478.40 Beneficiary's right to a hearing.

(a) *Amount in controversy.* If the amount in controversy is at least $200, a beneficiary (but not a provider or practitioner) who is dissatisfied with a QIO reconsidered determination may request a hearing by an administrative law judge (ALJ) of the Office of Medicare Hearings and Appeals (OMHA).

* * * * *

(c) *Governing provisions.* The provisions of subpart I of part 405 of this chapter apply to hearings and appeals under this subpart unless they

are inconsistent with specific provisions in this subpart or implement statutory provisions that are not also applicable under section 1155 of the Social Security Act. References in subpart I to initial determinations made by a Medicare contractor and reconsiderations made by a QIC should be read to mean initial determinations and reconsidered determinations made by a QIO.

■ 155. Section 478.42 is revised to read as follows:

§ 478.42 Submitting a request for a hearing.

(a) *Where to submit the written request.* A beneficiary who wants to obtain a hearing under § 478.40 must submit a written request to the OMHA office identified in the notice of the QIO reconsidered determination.

(b) *Time limit for submitting a request for a hearing.* (1) The request for a hearing must be filed within 60 calendar days of receipt of the notice of the QIO reconsidered determination, unless the time is extended for good cause as provided in § 478.22.

(2) The date of receipt of the notice of the reconsidered determination is presumed to be 5 calendar days after the date on the notice, unless there is evidence to the contrary.

(3) A request is considered filed on the date it is received by OMHA.

■ 156. Section 478.44 is revised to read as follows:

§ 478.44 Determining the amount in controversy for a hearing.

(a) After an individual appellant has submitted a request for a hearing, the ALJ or attorney adjudicator determines the amount in controversy in accordance with § 405.1006(d) and (e) of this chapter. When two or more appellants submit a request for hearing, the ALJ or attorney adjudicator determines the amount in controversy in accordance with § 405.1006(d) and (e) of this chapter.

(b) If the ALJ or attorney adjudicator determines that the amount in controversy is less than $200, the ALJ, without holding a hearing, or attorney adjudicator notifies the parties that the parties have 15 calendar days to submit additional evidence to prove that the amount in controversy is at least $200.

(c) At the end of the 15-day period, if an ALJ determines that the amount in controversy is less than $200, the ALJ, without holding a hearing dismisses the request for a hearing without ruling on the substantive issues involved in the appeal and notifies the parties and the QIO that the QIO reconsidered determination is conclusive for Medicare payment purposes.

■ 157. Section 478.46 is revised to read as follows:

§ 478.46 Medicare Appeals Council and judicial review.

(a) The circumstances under which the Medicare Appeals Council (Council) will review an ALJ's or attorney adjudicator's decision or dismissal are the same as those set forth at §§ 405.1102 (''Request for Council review when ALJ or attorney adjudicator issues decision or dismissal'') and 405.1110 (''Council reviews on its own motion'') of this chapter.

(b) If $2,000 or more is in controversy, a party may obtain judicial review of a Council decision, or an ALJ's or attorney adjudicator's decision if a request for review by the Council was denied, by filing a civil action under the Federal Rules of Civil Procedure within 60 days after the date the party received notice of the Council decision or denial.

■ 158. Section 478.48 is amended by revising the section heading and paragraphs (b) and (c) to read as follows:

§ 478.48 Reopening and revision of a reconsidered determination or a decision.

* * * * *

(b) *ALJ or attorney adjudicator and Council Reopening—Applicable procedures.* The ALJ or attorney adjudicator, or the Council, whichever made the decision, may reopen and revise the decision in accordance with the procedures set forth in § 405.980 of this chapter, which concerns reopenings and revised decisions under subpart I of part 405 of this chapter.

(c) *Fraud or similar abusive practice.* A reconsidered determination, a review of a DRG change, or a decision of an ALJ or attorney adjudicator, or the Council may be reopened and revised at any time, if the reconsidered determination, review, or decision was obtained through fraud or a similar abusive practice that does not support a formal finding of fraud.

Approved: June 8, 2016.

Sylvia Burwell,

Secretary, Department of Health and Human Services.

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