August 29, 2016

Office of Medicare Hearings and Appeals
Department of Health & Human Services
Attention: HHS-2015-49
5201 Leesberg Pike, Suite 1300
Falls Church, VA 22041

Submitted electronically to: www.regulations.gov

Re: HHS-2015-49

To Whom It May Concern:

The Center for Medicare Advocacy (the Center) is pleased to provide the Centers for Medicare & Medicaid Services (CMS) comments on the proposed rule on the Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures (HHS-2015-49). We also submit these comments on behalf of the undersigned organizations.

The Center, founded in 1986, is a national, non-partisan law organization that works to ensure fair access to Medicare and quality health care. We draw upon our direct experience with thousands of individuals to educate policy makers about how decisions affect the lives of real people. Additionally, we provide legal representation to ensure that people receive the Medicare coverage for which they qualify, and the quality health care they need.

Introduction to Comments

Over the last three decades, the Center has represented thousands of Medicare beneficiaries seeking coverage of health care and services through the Medicare administrative appeals process. We have extensive experience with each level of review, and have advocated for our clients in individual appeals, policy discussions1, and, selectively, through strategic litigation

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aimed at enforcing due process and other rights.\(^2\)

Based upon our broad experience, we have witnessed significant trends in appeals that negatively affect beneficiaries, and have policy solutions and suggestions for addressing many of these problems. Many of these issues, however, are beyond the scope of issues raised in this proposed rule. For example, legislative and administrative proposals have been introduced elsewhere that would seek to increase decision making consistency among the levels of appeal. Our experience shows that the high rate of coverage denials upheld at the first two levels of appeal often amount to “rubberstamp” decisions, and any reforms that drive the more independent and thorough review at the ALJ level to be more consistent with the lower levels of review – rather than the opposite – could further infringe on beneficiaries’ ability to obtain due process.

In the Preamble to this proposed rule, HHS notes that an “unprecedented and sustained increase in the number of appeals” in recent years has resulted in a tremendous backlog of cases pending hearing at the Office of Medicare Hearings and Appeals (OMHA). While proposals here and elsewhere have largely been aimed at easing OMHA’s backlog, in our view, scant attention has been paid by policymakers to addressing the primary causes of the backlog, including the “rubberstamp” decisions at the lower levels described above along with increasing provider audits and resulting provider appeals, mostly related to CMS’ hospital observation status policies. We urge this process take place before major changes are made that will further complicate and fragment the Medicare appeals process.

In the Preamble, HHS states that it is “pursuing [a] 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” (p. 43792).

On the one hand, we recognize the need to streamline certain rules, terminology and processes in order to make the broader appeals system function better, and we support many of the proposals herein to do so. For example, we generally support the proposals to update regulatory language to clearly reflect the role of OMHA in administering ALJ appeals, and replace “Medicare Appeals Council”, “MAC” or “Board” with “Council.” In addition, the alignment of many of the proposed procedural provisions across the appeals rules will clearly ease confusion and reduce administrative burdens.

On the other hand, we strongly object to other proposals which, on their face, might appear to make things easier for both appellants and adjudicators, but in practice would likely severely dilute the rights of beneficiaries pursuing appeals. It is clear that these rules reflect concerns raised by OMHA. We implore HHS to listen to and incorporate the concerns of beneficiaries and those who represent them. The burden of obtaining fair and timely appeals should not shift from adjudicators to appellants.

In particular, and as discussed further below, we express strong concerns with proposals to:

- Permit the Medicare Appeals Council Chair to decide that certain Council decisions will have precedential value;
- Restrict application of Part 405 to all Parts of Medicare when alternative provisions are not articulated;
- Increase the burden on beneficiaries requesting ALJ hearings;
- Remove the requirement that ALJ hearings “must” be conducted within 90 days;
- Change the default mode of hearing from Video Teleconference (VTC) to telephone.

**Comments to Proposed Rule**

We offer the following comments to the proposed rule, organized by where provisions appear in the Preamble, and under Parts II. General Provisions of Proposed Regulations and III. Specific Provisions of the Proposed Rule.

**II. General Provisions of Proposed Regulations**

**A. Precedential Final Decisions of the Secretary**

CMS proposes to allow select Appeals Council decisions, to be made precedential and designated as a “final decision of the Secretary” at the sole discretion of the Council Chair. Such decisions would, according to CMS, provide “clear direction on repetitive legal and policy questions, and in limited circumstances, factual questions” (p. 43793). These decisions would be binding as long as the same authority or provision is applied and still in effect, unless CMS revises the authority or provision. The Center strongly objects to this proposal as it could result in restrictions in coverage for medically necessary care and services to which Medicare enrollees are entitled by law.

**Rationale Against Granting Authority**

The preamble to the proposed rule cites the March 2004 report by HHS and SSA entitled “Report to Congress: Plan for the Transfer of Responsibility for Medicare Appeals.” The Report recommends against granting the Appeals Council precedential authority. This conclusion is based, in part, on the fact that CMS is not a party to Council appeals:

As a result, it is often difficult for the agency to ensure that all relevant issues and authorities are presented to the MAC (Council) for consideration before it makes a final determination in a particular case. Moreover, the agency is not able to appeal adverse or erroneous rulings by the MAC. Affording precedential authority to decisions where a particular legal argument has not been raised or thoroughly considered may result in an inaccurate or incomplete interpretation of an agency regulation or ruling, and may ultimately result in greater problems and uncertainty in subsequent cases when the issue is raised more clearly or in different factual circumstances. (Pp. 12-13)

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3 Available at: [https://www.ssa.gov/legislation/medicare/medicare_appeal_transfer.pdf](https://www.ssa.gov/legislation/medicare/medicare_appeal_transfer.pdf).
In addition to the growth of online resources, including the ability to post key Council decisions online, the Report went on to state:

In addition, other changes mandated by BIPA and MMA are expected to help improve the uniformity and consistency of decision-making at the lower levels of the administrative appeals process. Accordingly, HHS has determined that, at this time, any problems that may arise from the possibility of inconsistent ALJ rulings are outweighed by the difficulties that could result from conferring binding, precedential authority upon decisions of the MAC (Council). (p. 13)

In the proposed rule, CMS argues that BIPA and MMA changes to the appeals process have now been fully implemented, and therefore it is now appropriate that select Council decisions be made precedential to increase consistency in decisions at all levels of appeal for appellants. We believe, however, that the HHS and SSA report’s logic against affording precedential authority to Council decisions is still correct, and has not been weakened in the intervening years since the Report’s release.

In particular, since beneficiaries are often unrepresented by counsel during the administrative appeals process, it is very likely that beneficiary-specific legal arguments, to use the language of the Report, do not get raised “or thoroughly considered [which] may result in an inaccurate or incomplete interpretation of an agency regulation or ruling, and may ultimately result in greater problems and uncertainty in subsequent cases when the issue is raised more clearly or in different factual circumstances.”

Further, the limited scope of review at the Council level - a review almost exclusively on paper, with no hearings, additional evidence, or required briefing of issues before it – weighs against giving Council decisions any precedential value. Certainly, the determination to grant precedential value to a decision should not be in the sole decision of the Council’s chair.

**Danger of Bad Precedent**

As an organization that serves Medicare beneficiaries, we have extensive experience with the Medicare administrative appeals process, including cases that reach the Council level of review. We have represented clients who have received Council decisions that, on their face, defy Medicare coverage guidelines apply erroneous logic, and misstate the facts. If such decisions were given precedential effect, it would seriously degrade the rights of beneficiaries to obtain coverage for care and services to which they are entitled under statute, regulation and policy.

Below are two of our clients’ examples of similar, substantively narrow issues where, among other things, the Council found against coverage for a per se skilled service – intramuscular injections – which, by definition regulatory, should be covered in these instances.

- The Center recently appealed to federal court a case challenging a Council decision upholding the denial of Medicare home health coverage for a beneficiary who required monthly Vitamin B-12 intramuscular injections. Intramuscular injections are, by regulation, a per se skilled service, and the beneficiary in this case has a condition (Total Gastrectomy) for which Medicare policy expressly recognizes B-12 injections to be a medically necessary treatment. The court granted the government’s motion to remand the case to the Appeals Council, which issued a new decision, favorable to the beneficiary. It decided that the monthly Vitamin B-12 injections should be covered, however its
rationale was questionable. The Appeals Council stated that the medical records did not “clearly indicate the purpose for giving” the B-12 injections, “nor do most of the skilled nursing visit notes specifically reference the beneficiary’s gastrectomy.” It found coverage as warranted nonetheless because the beneficiary’s plans of care referenced the total gastrectomy. The decision made no reference to the determinative regulation, or to the serious problems with the original Appeals Council decision, which theorized that the beneficiary could have performed the intra-muscular injections herself.

- Earlier this year the Center received an unfavorable Council decision wherein coverage for intramuscular injections (IM) in a skilled nursing facility — a per se skilled service under federal regulations – was denied. Our client was in the hospital prior to the period in question for aspiration pneumonia. Upon discharge from the hospital all of the documentation indicated that she was to be monitored for further respiratory distress and was to remain on aspiration precautions. It was documented that she suffered from chronic urinary tract infections. During the period, again while she was being further monitored for respiratory issues, she was found to have pseudomonas aeruginosa for which she was prescribed IM injections.

The ALJ denied coverage of the per se skilled IM injections because treatment was not for a condition for which she was treated in the hospital. While acknowledging that IM injections do qualify as per se skilled services, the MAC found that “the present injections are not covered because they were not furnished for a condition for which the beneficiary was hospitalized – aspiration pneumonia - and did not arise during SNF treatment for the aspiration pneumonia” (citing to 42 C.F.R. §409.31(b)(1)). Because the individual had a history of UTIs prior to her hospitalization, the Council concluded that the condition was “chronic” and therefore could not be something that “arose” in the SNF. In essence, applying a narrow and illegal interpretation of the regulations, the Council asserted that the condition that arose can’t be something that this person ever experienced before. In this instance, the beneficiary suffered from UTIs before her hospital stay but she was UTI-free when she was discharged from the hospital. A new UTI arose during the period which required per se skilled services. Any reasonable interpretation of the regulations can’t possibly mean that any condition that an individual had suffered from prior to a hospital stay can never be a “condition which arose” during a subsequent SNF stay.

Giving sole discretion to a single person at the Council to determine whether these or similar cases – including ones in which the Council simply “gets the law wrong” – will have precedent effect, is unacceptable. The Council can and does make mistakes, which should not inure to the detriment of all beneficiaries.

Unanswered Questions/Issues

In addition to the objections raised above, the proposal lacks specificity in several key areas. For example, the rule lacks clear criteria governing the selection of decisions, a necessary prerequisite particularly when one individual has sole discretion. There is no articulation of a
timeframe within which decisions about precedent would be made, nor are means proposed for challenging which decisions are chosen.

What effect would this proposal have on federal court decisions in appeals that reverse a Council decision chosen to have precedential value? Presumably if a federal court reversed a Council decision, the decision would, in effect, cease to exist and lose its precedential value. But this is not discussed.

Despite attention paid to potential findings of fact, the proposal remains too ambiguous concerning such findings. Proposed § 401.109(d)(2) states “[f]actual 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.” We appreciate, as noted in the Preamble, that CMS recognizes “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” (p. 43794). As drafted, however, the language of the proposed rule would not preclude such review.

How will determinations be made as to whether, in a given appeal, there has been a change in “the underlying factual circumstances”? If a subsequent appeal involves, for instance, the same home health agency and same Medicare beneficiary, what criteria will be used to determine if an individual’s medical condition has changed enough to warrant a new review of the underlying factual circumstances?

If Proposal Proceeds, Must Only Apply to Decisions Fully Favorable to Beneficiaries

Despite these objections, if HHS chooses to proceed with this proposal to allow the Chair of the Council to elect which decisions have precedential value, we urge this authority to be limited only to decisions which are fully favorable to the Medicare beneficiary. Rather than shackle beneficiaries with narrow interpretations of Medicare rules, only decisions in the light most favorable to those for whom the program is meant to serve should have a precedential bearing on future decisions.4

### B. Attorney Adjudicators

CMS proposes to allow attorney adjudicators, rather than Administrative Law Judges (ALJs), to perform a portion of OMHA’s workload that “does not require a hearing.” While ALJs would continue to be responsible for making findings of fact and conclusions of law, CMS articulates

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4 See *Friedman v. Secretary of U.S. Department of Health and Human Services*, 819 F.2d 42 (2d Cir. 1987) "A determination of a Medicare claimant's need for skilled nursing care as opposed to custodial care should be guided by two principles. First, the decision should be based upon a common sense, non-technical consideration of the patient's condition as a whole. E.g., *Gartmann*, 633 F.Supp. at 679; *Howard v. Heckler*, 618 F.Supp. 1333 (E.D.N.Y. 1985). Second, the *Social Security Act is to be liberally construed in favor of beneficiaries*, E.g., *Rivera v. Schweiker*, 717 F.2d 719, 723 (2d Cir. 1983); *See also Ridgely v. Secretary*, 345 F.Supp. 983, 993 (D. Md.1972) (*"the purpose of the custodial care disqualification ... was not to disentitle old, chronically ill and basically helpless, bewildered and confused people ... from the broad remedy which Congress intended to provide for our senior citizens"*), aff'd, 475 F.2d 1222 (4th Cir.1973)" [emphasis added].
scenarios in which “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 on the appealed matter” (p. 43794).

There may be logic in allowing well-trained attorneys to perform certain of the articulated tasks, including issuing dismissals when an appellant withdraws a request for hearing, remands for information that can only be supplied by CMS or contractors and, in certain instances, issuing decisions that are fully favorable to the appellant. We are concerned, however, that conducting reviews of QIC and IRE dismissals – one of the proposed tasks that attorney adjudicators could perform – may sometimes require a hearing to determine findings of fact or conclusions of law. Unless a decision is fully favorable to a beneficiary appellant, for example, a determination of whether good cause exists for reopening (e.g., pursuant to 42 C.F.R. § 405.986) could require a hearing. These cases should be assigned to an ALJ. Further, neither 42 C.F.R. § 405.1004 nor § 423.2004 preclude a hearing being held for review of a QIC or IRE dismissal, respectively.

Further, we appreciate that CMS proposes to allow requests for hearings initially assigned to Attorney Adjudicators to be reassigned to an ALJ for an oral hearing if the Attorney Adjudicator determined that a hearing could be necessary to render a decision. However, this transfer from an Attorney Adjudicator to an ALJ should be required in all instances in which a hearing could be necessary, based upon clearer guidance and thresholds established by CMS.

If the proposal to incorporate Attorney Adjudicators into OMHA is adopted, we do support revising 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, and an extension of rights associated with an appeal adjudicated by an ALJ would extend to any appeal adjudicated by an Attorney Adjudicator. We appreciate that, as articulated in the Preamble, Attorney Adjudicators would receive the same training as OMHA ALJs.

C. Application of 405 Rules to Parts of Medicare Coverage Besides A and B

Given certain gaps among and misalignments between various statutory provisions relating to the spectrum of Medicare appeals, from Parts A through D, including expedited and independent reviews, “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 hearings procedures” relating to Medicare Advantage and QIO appeals. As noted by CMS, such rules “are often helpful in filling in procedural rules when there is no rule on point in the respective part” (p. 43795).

CMS states, however, that “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” (p. 43795).

Thus, to clarify the application of Part 405 rules concerning Medicare Part A and B appeals to other rules relating to Medicare appeals, CMS is proposing revisions to Medicare Advantage appeal rules under part 422 (specifically, §§ 422.562(d) and 422.608) to 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, CMS proposes to revise §478.40(c) to 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, which concerns QIO reconsiderations and appeals. CMS states that “[t]he 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” (p. 43796).

The Center strongly objects to CMS’ proposed approach to aligning appeals rules by limiting the application of Part 405 to other parts of the Medicare program. Despite articulated intentions, this proposal would not clear up existing ambiguity relating to the application of Part 405 to other parts of the rules; it will create confusion. Further, it is very likely to have the unintended consequence of stripping away important safeguards that currently provide consistency in application of beneficiary rights across the appeals spectrum, and provides answers, in absence of specific applicable provisions.

Based upon the proposed regulatory language, read along with existing statutory language, ambiguity would remain. For example, proposed rule §422.562(d) states that Part 405 rules apply to administrative reviews, hearings processes and representation of parties “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.” Reviewing the language in section 1852(g)(5) of the Act, however, shows that the only sections of 1869 that are referenced are §§ 1869(b)(1)(E)(i) and (iii) which relate to amounts in controversy. Would this proposed rule, then, preclude the application of any provisions of 1869 other than amounts in controversy to MA appeals? Would sections of Part 405 – other than those relating to amounts in controversy – be unavailable to fill in the gaps of Part 422?

We offer one example here that highlights both the ambiguity of CMS’ proposal along with a potential unintended consequence. In the Preamble, CMS cites, as proof of unaligned statutory provisions, an example regarding the ability of providers and suppliers to introduce new evidence in an appeal at the hearing stage (according to CMS, section 1869 of the Act prohibits this in Part A and B appeals absent good cause but section 1852(g) concerning MA appeals does not incorporate this provision of 1869). While CMS does not articulate what its desired outcome would be from aligning these provisions (would the prohibition still not apply in MA appeals?), the introduction of evidence by a beneficiary is unmentioned. 42 C.F.R. § 405.1018, which relates to appeals under Parts A and B, states that limitations on submitting written evidence prior to an ALJ hearing does not apply to a beneficiary unrepresented by a provider or supplier. Part 422, subpart M, which includes rules applicable to ALJ hearings in MA appeals, is silent on this issue. What would the outcome be if an MA enrollee can no longer look to Part 405 to fill in the gaps in procedural rules in Part 422?

Instead of stripping away rights and subjecting any reinstatement of such rights to future rulemaking, CMS should further articulate what regulations it believes do not apply and in what instance, with an opportunity for public comment on each provision. This proposal is overly broad by assuming that a better approach to alignment than the one currently used would be to
later backfill any lost rights through rulemaking. In short, CMS must articulate exactly what it wants to do, rule by rule and provision by provision. Until CMS does so, the current approach—applying in procedural rules from Part 405 when there is nothing on point in other Parts—should remain in force.

III. Specific Provisions of Proposed Rule


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

e. Medicaid State Agencies (§405.908)

We appreciate the apparent intent to clarify that the same review options are to be available whether a case is decided by an Attorney Adjudicator or an ALJ. However, while most provisions in the proposed rule spell this out, this section subsumes Attorney Adjudicator and ALJ reviews under the term “OMHA level of review.” This is not a term currently in common parlance.

In order to avoid any possible confusion, we ask that this term be replaced with the phrase “and Attorney Adjudicator or ALJ review.” If the term “OMHA level of review” is to be used, we ask that it be defined as the level of review that includes both Attorney Adjudicators and ALJs and that it then then be used consistently throughout the regulations.

3. ALJ Hearings

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

We commend the agency’s proposal to amend §§ 405.1002(a) and 423.2002(a) to clearly state that a party to a QIC reconsideration or an enrollee who receives an IRE reconsideration has a right to a hearing, which is stronger than stating that they “may request” one. We also appreciate that the agency aims to further reinforce the right to a hearing by emphasizing that escalations are “for a hearing before an ALJ.” This language provides greater assurance that due process rights will be honored.

To address the current uncertainty about which “entity” to send one’s hearing request, CMS proposes revising §§ 405.1002(a)(4) and 423.2002(e) to replace the word “entity” with “office”. We value the agency’s effort to reduce confusion, but wonder if this wording change will make things clearer, since there is still a risk that a beneficiary would mail a hearing request to the QIC, IRE, or wrong OMHA field “office”. Thus, we urge the agency to continue its policy of accepting timely-filed requests even if they are timely-filed with the wrong office/entity; this should be incorporated into the regulation. Because beneficiaries have a right to request a hearing, it is important that there be no wrong entry point for their filing.

We agree with the proposal to amend this provision to require that OMHA (rather than ALJs) document all oral requests for expedited hearings, since an ALJ may not yet have been assigned to the matter. We recommend that, for practical purposes, such documentation be standardized if it is not already so.
Amount in Controversy Required for an ALJ Hearing (§§ 405.1006, 405.976(b)(7), 423.1970, 422.600(b) and 478.44(a))

We commend the agency’s intent and effort to reduce confusion by laying out precisely how to calculate the amount in controversy for the particular type of claim/dispute being appealed (i.e., coinsurance/deductible challenges, overpayments, fee schedule challenges, service terminations, etc.). Although it makes for a substantially longer regulatory provision, it nonetheless offers greater clarity. With that said, we recommend that the agency create a user-friendly online resource(s) that explains these calculations in a more basic way for beneficiaries and their advocates, because the regulatory language may not be readily understood by most laypersons.

The Center agrees with the proposed revision that the jurisdictional amount in controversy requirement must be met for an ALJ hearing, rather than to request an ALJ hearing. The original wording may have hindered beneficiaries from even requesting a hearing if they were confused or unsure about whether they met the amount in controversy. We commend the new language for being less restrictive and more respecting of a party’s right to request a hearing.

The Center opposes changing the amount in controversy from the actual amount charged to a beneficiary to the Medicare allowable amount for the items and/or services being appealed. What would happen in the event that the amount charged to the individual met the amount in controversy but the Medicare allowable amount for the item or service did not? Would the individual be prohibited from appealing the claim? We ask that in the event the amount charged to a beneficiary and the Medicare allowable amount do not match that the individual be able to use the higher amount in order to meet the amount in controversy and not be precluded from appealing if the amount charged meets the amount in controversy requirement but the Medicare allowable amount does not.

The Center strongly supports the agency’s proposal to require that QICs specify in reconsideration decisions issued to unrepresented beneficiary and Medicaid state agency appellants whether the amount remaining in controversy is estimated to meet the amount in controversy for an ALJ hearing. We think this is imperative especially if CMS intends to make this information a required element on hearing requests.

The calculated amount remaining in controversy should be boldly designated in the QIC decision, along with a clear instruction that this amount may be inputted on the hearing request form. There also must be safeguards for beneficiaries in the event that a QIC decision omits to indicate the amount remaining in controversy or misstates the amount. Not infrequently in our practice we have received QIC decisions that misstated the dates of service or omitted entire pages (e.g., the page containing the analysis or conclusion). We ask that QIC decisions give clear instructions that regardless of the calculated amount appellants still have the right to request an ALJ hearing and to contest the amount in controversy as it appears in the QIC decision if they feel that it is inaccurate.

Further, as is current practice, OMHA should continue to ascertain the amount in controversy. Timely hearing requests should not be dismissed if this information is missing. It is more reasonable to expect OMHA than beneficiaries and appellants to provide this information. Among other reasons, OMHA and the MACs have access to claims data not available to
beneficiaries or the public.

The Center recommends continued use of the current provision (42 C.F.R. § 405.1006(d)(2)) concerning calculation of the amount in controversy when liability has been limited, payment made, or the beneficiary has been indemnified. It is more straightforward and easier to understand than the proposed 42 C.F.R. § 405.1006(d)(3). We appreciate, however, the agency’s affirmation and reinforcement of this exception in the comments to the proposed rule.

We are pleased by the proposed new § 405.1006(d)(4), which addresses how to calculate the amount in controversy in circumstances where a provider or supplier terminates a Medicare-covered item or service and the beneficiary does not elect to continue receiving the item or service due to potential liability. The provision clearly establishes that the basis is the amount that would have been charged had the beneficiary received the items/services and Medicare payment were not made for them. However, this raises an important related issue which the proposed appeals rules do not address: What relief can be obtained in this scenario.

As an advocacy organization we continually hear from beneficiaries who are appealing terminations of services or items and are surprised when the ALJ addresses only whether the provider’s termination of the service/item was appropriate, but:

- Is then unable to require that the provider furnish or reinstate the terminated service/item; and/or
- Lacks jurisdiction to rule on whether Medicare payment should be made for those items/services that the beneficiary did continue to receive and pay for, because a claim was never submitted for those items/services.

To illustrate - we frequently hear from skilled nursing facility (SNF) residents who received notice that their stay will no longer be covered by Medicare because they are being discharged from skilled therapy services. Some assume liability for their SNF stay while simultaneously seeking expedited review by the BFCC-QIO to challenge the termination of therapy, and then proceed with their appeal up through the administrative process. The vast majority of beneficiaries (and their caregivers) who get to the ALJ review stage do not understand that the ALJ will only rule on whether the termination was proper and not rule on whether their continued stay, for which they have assumed liability, is coverable by Medicare. They are duly shocked when, after the time and energy they invested in their appeal, the ALJ claims no jurisdiction to even address the services/items they paid for after the provider termination.

This confusion is very common and it highlights the lack of information provided to beneficiaries regarding the scope of review in expedited versus regular appeals. Misunderstandings in this regard also takes extra time and work for OMHA. In cases we hear about, beneficiaries’ family members go to the trouble of obtaining and submitting post-termination medical documentation and supporting letters, arranging for witnesses, researching Medicare law and policy for their arguments, which they present at hearings. At the same time, ALJs and their staff have to process this documentation, facilitate the hearings, and ultimately explain in writing (and sometimes orally, as well) why they only have authority to rule on the termination. Frustrated but undeterred, some of these families will then rightfully submit a claim for the post-termination services and proceed all over again through the administrative appeals process. However, in many instances, because it takes so long to reach the ALJ level of appeal,
the deadline for submitting a claim to Medicare for the services in question has expired and the family is prevented from pursuing a standard or regular appeal.

More effective notice and communication to beneficiaries earlier on about the scope of expedited appeals could help avoid these situations at the OMHA level. Beneficiaries must be informed that they must simultaneously request a demand bill to obtain an appealable Medicare determination for any services they continue to receive. The expedited decision from the BFCC-QIO, conveyed verbally and/or in writing, should reinforce that information, letting beneficiaries know that by appealing the expedited decision they are only appealing the termination decision.

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

We commend the proposed specification that even though CMS or its contractor is not subject to examination or cross-examination by the parties, 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.” However, we urge more protective language (e.g., “the parties must be (or will be) given the opportunity to provide testimony…”) to ensure that beneficiaries are made aware of this option. We also ask CMS to provide advocate education about this.

We support the proposal to require that CMS or its Contractor’s position papers and written testimony be submitted within 14 calendar days of election to participate if no hearing is scheduled and at least 5 calendar days prior to a hearing unless the ALJ grants additional time, and that a copy be sent to the parties. We also agree that these items should not be considered in deciding the appeal if these requirements aren’t met. However, the language should expressly apply the 5/14-day timeframe when a copy must be sent to the other parties. The proposed language permits CMS and its contractors to send the parties copies of their position papers/written testimony as late as the date of the hearing. Our concern about this applies particularly to appeals brought by unrepresented beneficiaries, who may need more time to sufficiently understand and prepare a response to the agency/contractor’s arguments.

The Center wholeheartedly supports the agency’s proposed plan to limit the number of CMS/contractor entities that may elect to participate at the hearing. We also support authorizing ALJs to deem such an election invalid if not timely filed or sent to the correct parties.

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

Similar to § 405.1010 above, we support the proposed specification that even though CMS or its contractor is not subject to examination or cross-exam by the parties, 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.” However, we recommend more protective language (e.g., “the parties must be (or will be) given the opportunity to provide testimony…”) to ensure that beneficiaries are made aware of this option.
Similar to § 405.1010 above, we support the proposed requirements for position papers and written testimony submitted by CMS and its contractors. However, we recommend that the language definitively apply the timeframe requirements to when a copy must be sent to other parties.

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

The Center supports the proposal to only allow either CMS or one of its contractors to be a party to a hearing.

We do have concerns regarding the proposed wording of Section 405.1012, however. Although 405.1012(a)(1) precludes CMS or its contractors from electing to be a party when a hearing request is filed by an unrepresented beneficiary, the phrase “and unless otherwise provided in this section,” along with proposed 405.1012(a)(2), suggest that an ALJ may request that CMS and/or one or more of its contractors be a party to a hearing, including a hearing requested by an unrepresented beneficiary. We recommend clarification in 405.1012(a)(2) to expressly exclude this possibility when the request for hearing is filed by an unrepresented beneficiary. Similar to 405.1010 and 423.2010 above, we support the proposed requirements for position papers and written testimony submitted by CMS and its contractors. However, we recommend the language definitively apply the timeframe requirements to when a copy must be sent to other parties.

**Requirements for a Request for Hearing or Review of a QIC or IRE Dismissal**

We have concerns about the proposal to require that unrepresented beneficiaries indicate a telephone number on their requests for hearing. While we appreciate the intention to ensure that OMHA is able to make timely contact with appellants, we know from our experience that many beneficiaries do not have telephone accounts or immediate/consistent access to a phone. A hearing request should not be considered incomplete if this requirement is not met. We suggest allowing a beneficiary to additionally, or alternatively, furnish an e-mail address. And we encourage the Secretary to evaluate if other options are available for contacting beneficiaries that are respectful of their privacy.

The Center does not object to the proposal to ask for the “dates of service of the claim[s] being appealed, if applicable” instead of the “dates of service” on the hearing request. However, we feel that latitude should be afforded to appellants (particularly, unrepresented beneficiaries) who may not have input the correct dates or who wish to amend those dates prior to or during the hearing. Various developments (e.g., new evidence, understanding of the relevant law, policy, etc.) may trigger an appellant to change the dates being appealed. In general we strongly request rules that prohibit OMHA from dismissing a timely filed hearing request because some bit of information is missing.

We have one concern regarding the proposal to require additional information from appellants who appeal a statistical sampling and/or extrapolation. We worry that if this section appears on the face of the regular hearing request form, it may confound unrepresented beneficiaries who may not understand that it does not apply to their appeal. We have spoken to beneficiaries who were confused about and daunted by the requirements on the current version of hearing request form. Thus, we hope that any changes made to the form take into account the need for simplification so that it will not deter individuals from pursuing their appeal.
The agency proposes to require all of the information in (a)(1) in order for a hearing request to be complete, but allows that individuals will be given an opportunity to cure an incomplete request, tolling the adjudication timeframe. We ask that the agency afford unrepresented beneficiaries as much flexibility and leniency as possible when applying this requirement. We are glad that the agency will deem a request complete if supporting materials submitted with request clearly provide the required information. For example, a copy of the QIC decision would satisfy a lot of the required information. However, most unrepresented beneficiaries are not aware of this, as it is not mentioned on the form. At the very least, when offering a beneficiary a second opportunity to complete their request, OMHA should also offer guidance as to where to locate the missing information. As the agency notes, the changes in § 405.1014(b) are meant to provide clearer standards and to reduce confusion surrounding information needed in a request for hearing.

In order to provide more clarification in this process and to further reduce confusion we ask that the ALJ be required to inform the appellant exactly what information is missing from the request. We recommend that the wording of § 405.1014(b) be changed to read in part “If a request is not complete, the ALJ will inform the Appellant of what information is missing from the request and will provide the appellant with an opportunity to complete the request…” We also ask that a reasonable timeframe be established for how long an Appellant has to cure any defect with a request for hearing so that there is uniformity and consistency among the ALJs. We are pleased that the agency is proposing to align the filing deadline for requesting review of an IRE’s reconsideration with the filing deadline for requests for hearing under Parts A and B. We agree that consistency may reduce confusion.

We have concerns that the proposed copy requirements at § 405.1014(d) will result in deterring more unrepresented beneficiaries from appealing, or rendering more of their hearing requests incomplete. We don’t disagree with the proposed amendment to clarify that the appellant must send a copy of request for ALJ hearing or review of a QIC dismissal to the other parties who were sent a copy of the QIC’s reconsideration or dismissal. However, with respect to the proposed rules about sending copies of additional materials and satisfying a standard of proof, we believe this will create undue complications, and will also be costly and burdensome to carry out.

Most Medicare beneficiaries simply don’t have the wherewithal to determine whether they must make and send copies of the additional materials because they are necessary to complete the request, or to adequately summarize those materials if they are not necessary to the request. To be sure, many beneficiaries lack the resources, ability, and access to make copies and go to the post office. It may not be enough that appellants are provided with an opportunity to cure defects within a certain timeframe before a request for review is dismissed. The fact that the adjudication timeframe will be tolled if an appellant doesn’t satisfy the copy requirements means that many hearing requests will be delayed or abandoned altogether. If this proposed rule is finalized, we request leniency be afforded to unrepresented beneficiaries and OMHA should be directed to guide or assist them with this requirement. A designated beneficiary ombudsman and an OMHA clerk function would be useful in this regard.

We also ask that the agency and OMHA understand that sending a copy of the hearing request and additional materials to other parties is not always easily accomplished. Health care
providers especially are apt to go out of business, change their contact information, etc. This is increasingly occurring throughout the health system. Thus, appellants are not always successfully contacted at their last known address. If the duty to provide this information is finalized, we ask that the QIC reconsideration or dismissal be required to include the full name and address of all the other parties so that an appellant could simply copy that information.

As stated above, in order to provide more clarification to this process and to further reduce confusion we ask that the ALJ be required to inform the appellant with specificity what is wrong with the hearing request and what must be done to cure the defect with the request. OMHA and ALJs should be reminded not to frivolously dismiss timely filed hearing requests. We recommend that the wording of § 405.1014(d)(3) be changed to read in part “[i]f 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 summary thereof, as described in paragraph (d)(1) of this section, the ALJ will inform the appellant what copy requirement has not been met, and the appellant will be provided with an additional opportunity to send the request, materials, and/or evidence or summary thereof…” We also ask that a reasonable timeframe be established for how long an Appellant has to cure any defect with a request for hearing so that there is uniformity and consistency among the ALJs.

We agree with incorporating the rule for extending the time to file a hearing request to reviews of QIC and IRE dismissals. The proposal would ask filers to file both requests (for hearing and extension) at the same time. We ask that the agency and OMHA continue to recognize requests that may not be filed simultaneously, especially those made by unrepresented beneficiaries. We concur that only an ALJ should be authorized to deny good cause for missing the deadline to file a request for review.

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: Timeframes for Deciding an Appeal of a QIC or an Escalated Request for a QIC Reconsideration

CMS proposes to revise the regulation at 42 C.F.R. § 405.1016(a) to remove the word “must” from the provision establishing the timeframe for ALJ decisions. Currently, the regulation states that “the ALJ must issue 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.”5 CMS proposes to revise this to state that the “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 . . . .”6 This proposal is contrary to the plain language of the statute and a recent decision by the D.C. Circuit Court of Appeals.7

5 42 C.F.R. § 405.1016(a) (emphasis added).
The Medicare statute requires an ALJ to schedule a hearing and issue a written decision within 90 days of the date that an appeal is filed: “an administrative law judge shall conduct and conclude a hearing on a decision of a qualified independent contractor . . . and render a decision on such hearing by not later than the end of the 90-day period beginning on the date a request for hearing is timely filed.” The only exception to this deadline is if the appellant expressly waives it.

In the Preamble to the Proposed Rule, however, CMS argues that the word “must” should be removed because the deadline is not an absolute requirement:

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.

CMS’s proposed interpretation of the statutory deadline is contrary to the plain language and intent of the statute. The statute requires that ALJs “shall” issue decisions in 90 days. The D.C. Circuit recently held that this creates a mandatory obligation to decide appeals in 90 days:

To begin with, as to clear duty, the statute uses the typically mandatory “shall.” E.g., 42 U.S.C. §1395ff(d)(1)(A) (“[A]n administrative law judge shall conduct and conclude a hearing ... and render a decision on such hearing” within ninety days. (Emphasis added.) ) To be sure, as the Secretary points out, context can dictate that “shall” take a directory rather than a mandatory meaning. But here, context only reinforces a mandatory reading. The statute itself repeatedly refers to the time frames as “deadlines.” E.g., id. §1395ff(d)(1)(B).

Moreover, the reference to escalation in the preamble implies that the option of escalation dilutes the mandatory nature of the deadline, which was also rejected by the D.C. Circuit because “providing a consequence for noncompliance does not necessarily undermine the force of a command” to decide appeals in 90 days. The fact that providers have the option to escalate their case(s) to the next level of administrative review when the ALJ fails to meet the statutory deadline is irrelevant to whether the decision must be rendered by the ALJ within 90 days.

The D.C. Circuit remanded the AHA case to the U.S. District Court for the District of Columbia to decide whether to order the Secretary to comply with the statutory deadline. The case is still pending in the D.C. District Court. Due to this unique set of circumstances, the timing and content of the Proposed Rule raise serious questions about its intent. The proposed change is not a minor clarification or technical modification. The Center is concerned that CMS is attempting to weaken the statutory requirement through the rulemaking process, thus attempting an “end run” around the issues currently pending before the court.

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10 AHA, 812 F.3d at 190.
11 Id.
The current regulation’s use of “must” correctly implements the mandatory statutory deadline. CMS has no interpretive authority to alter Congress’s directive that ALJs “shall” decide ALJ appeals in 90 days: “If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.” Therefore, the Center strongly opposes the proposed removal of the word “must” from 42 C.F.R. § 405.1016(a) as it pertains to the adjudication time frames imposed on ALJs, and we urge CMS to take all necessary steps to comply with the binding statutory requirement to decide ALJ decisions in 90 days.

This is not simply a matter of whether or not CMS has the authority to finalize this regulation as proposed. The implications on providers and beneficiaries are profound. CMS has failed to recognize the gravity of the problem it currently has with the ALJ backlog which numbers approximately 750,000 cases. With its current ALJ capacity to decide approximately ten percent of these cases per year, the backlog could be as long as ten years, and every month the backlog grows longer as more appeals enter the OMHA than are decided. Removing the requirement to decide these cases within 90 days removes any remaining pressure on CMS to finally address this intractable problem in a meaningful way. Medicare beneficiaries and providers alike are being harmed by the backlog problem every day. The Center strongly urges CMS and the OMHA to fix it now.

The agency’s justification for removing the absolute requirement is that the statute affords appellants the option of escalating their appeal to the next level of review when the 90-day adjudication timeframe is not met. The Center strongly objects to removing this requirement with respect to appeals brought by Medicare beneficiaries and Medicaid state agencies.

Our extensive experience with Medicare appeals has shown us that the success rates at the initial levels of administrative review are remarkably dismal (roughly 2%), but that beneficiaries have high rates reversal at the ALJ level of appeal. It is therefore absolutely imperative that beneficiaries maintain a right to timely determinations by ALJs (and now, Attorney Adjudicators). This is especially so in light of the enormous appeals backlog caused by Medicare’s auditing practices, which has already resulted in beneficiaries having to wait far beyond the 90-day statutory time frame for a hearing and decision. Although beneficiaries can, in theory, seek to escalate their appeal to the Council in such instances of delay, this is neither a fair nor adequate antidote. It means foregoing an ALJ (or attorney adjudicator) review, wherein beneficiaries have the greatest likelihood of success, and limiting their chances to one final level of administrative review. In addition, they face similar lengthy delays before the Council issues a decision. We therefore adjure the agency not to remove the word “must” from the adjudication timeframe provisions. It would be highly detrimental to remove the final protection that beneficiaries have against the difficult problems currently affecting the Medicare appeals system.

We support the proposals to add titles addressing when an adjudication period begins, waivers and extensions of that period, application of the adjudication timeframe to Council remanded appeals, and circumstances in which the appellant requests a stay of action on an appeal while related matters are addressed by another court or tribunal or investigators. We believe these new titles will provide guidance and clarity.

We support the proposal to only require appellants to file a single request for escalation with OMHA. We agree with the protocol that if OMHA does not issue a decision, remand, or dismissal within 5 days of receiving the escalation request, it must notify the appellant that the QIC reconsideration will be escalated for Council review and forward the file to the Council. This one-step process is much better than the current rule requiring the appellant to file a separate request for Council review if OMHA does not act within 5 days of the escalation request.

However, with respect to the proposal to require that the escalation request be sent to other parties on the QIC reconsideration that unrepresented beneficiaries should be exempted from this requirement. Since OMHA must take action on the request within 5 days or issue notice of escalation to the beneficiary-appellant, we see no reason why OMHA could not also send notice of its action or escalation to the other parties on the QIC reconsideration. We support the new language addressing invalid escalation requests in § 405.1016(f)(3) that states if an escalation request is determined to be invalid by the ALJ or the Attorney Adjudicator because it does not meet certain requirements then “OMHA will send a notice to the appellant explaining why the request is invalid…” As noted above, we ask that this same standard be written in to § 405.1014(b) and § 405.1014(d)(3) so that the ALJ or Attorney Adjudicator be required to give an explanation as to why a request for hearing may be invalid so that the appellant can cure the defect.

Section 423.2016: Timeframes for Deciding an Appeal of an IRE reconsideration

Similar to the proposed change in § 405.1016, we strongly object to the proposal to remove the requirement that an ALJ or Attorney Adjudicator must issue a decision, dismissal, or remand to the IRE within the statutory timeframe. This change would be very detrimental to beneficiaries given the current state of the appeals system. The agency anticipates that the instances in which the adjudication timeframe would not be met would “be rare because beneficiary and enrollee appeals are generally prioritized by OMHA.” If this is in fact the case, then there is no compelling reason to alter the requirement that ALJs and attorneys must adhere to the timeframe for beneficiary appeals.

We support the proposal to subject Council-remanded appeals to the same adjudication timeframe as other appeal requests received by OMHA, with the timeframe beginning on the date that OMHA receives the remand. However, it raises the question of how will the appellant know when OMHA receives the remand in order to know when the timeframe begins and expires? We request clarification on this issue.

Submitting Evidence (§§ 405.1018 and 423.2018)

We ask for further clarification regarding the ability to submit additional evidence. The current regulations at § 405.1018(c) states that “[a]ny 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…” The revised regulation does not propose to change this language. The Center for Medicare Advocacy has
participated in thousands of ALJ hearings.

In a number of cases where we represented a state Medicaid agency we were told by the ALJ that we were required to submit a statement explaining why the evidence was not previously submitted. Some ALJs, even after reading the language in § 405.1018(c), stated that they interpreted this language to require a state Medicaid agency to show good cause for evidence that was not submitted prior to the QIC decision. Because this language has become a source of confusion in many ALJ hearings we ask that the following language be added to the regulation: “This requirement does not apply to state Medicaid agencies or beneficiaries not represented by a provider or supplier.”

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

Under the proposed rule, video-teleconferencing (VTC) would be retained as the default method of conducting hearings for unrepresented beneficiaries, unless good cause for an in-person appearance exists. The Center strongly urges retaining VTC as the default for any appellant who requests a VTC hearing.

Notwithstanding, we do get calls from beneficiaries who, for various reasons (e.g., severe anxiety disorder, pain, immobility, lack of access to transportation), would much prefer a phone hearing but are hesitant to request it because they believe the ALJ expects to conduct the hearing by VTC. Although the proposed rule permits the ALJ to offer to conduct a phone hearing if the hearing request or administrative record suggests that a phone hearing may be more convenient for the unrepresented beneficiary, nowhere does the hearing request form elicit this information from the beneficiary. The agency should add a section or checkboxes to that effect on the Hearing Request form. We recommend a solution that preserves and facilitates the beneficiary’s preference, but does not inadvertently suggest that the ALJ favors a particular method.

Related to this, we oppose proposed § 405.1020(i)(1) and (2), which provide that an unrepresented beneficiary must file their objection to the hearing method in writing, and must include the reasons for their objection. This could prove difficult for many beneficiaries. Unrepresented beneficiaries should be afforded the convenience of being allowed to call the ALJ’s contact listed on the hearing notice to orally request a change in the hearing method. The proposed provision also seems to leave out the possibility that the beneficiary may request a phone hearing when a different type of hearing has already been scheduled.

The Center strongly opposes the proposal to make phone hearings the default for hearings sought by all others, unless an ALJ finds good cause for a VTC or in-person appearance. There is no reasonable justification for this change and it will create a significant reduction in due process. Phone hearings do not take appreciably less time than VTC hearings and do not afford the same level of communication. Moreover, OMHA is budgeted to provide VTC hearings and there is no evidence that the volume of VTC hearings in past years have exceeded this line item on OMHA’s operational budget. Thus, there is no reason to anticipate that VTC will be over-utilized in the future. Most importantly, whatever the advantage to OMHA, a phone hearing does not outweigh the value of VTC hearings. When parties can see one another and exhibits, communication is far better.
The Center has found that appearance by VTC affords greater assurance that ALJs fulfill their duty to provide a full and fair hearing. VTC has allowed us to gauge the ALJs’ reaction to arguments, and better ascertain whether there was understanding, confusion or lingering questions. With VTC, we have some awareness when an ALJ is tired, disinterested, talking to someone else in the room, thumbing through the file or not referring to the file at all. This is not readily witnessed on a phone call.

We have participated in phone hearings that resulted in tremendous waste of time and resources for all involved. In one particular phone hearing that lasted over an hour, both sides argued over coverage of physical therapy services, extensively referencing the PT notes, only to later find out *in the decision* that the claims file did not even contain the relevant documentation. The decision was then appealed to the MAC, then remanded back to the ALJ for a re-hearing. This would all have been avoided via VTC. We have also called in late to phone hearings (because the hearing notice indicated that OMHA would call us at the designated time) and been shocked to find the ALJ engaging in ex parte conversation with a Medicare Advantage plan representatives and witnesses for who knows how long. VTC hearings afford our clients a measure of protection against these kinds of procedural improprieties. In addition, VTC hearings have allowed us to show and discuss images of injuries, wounds, and other important visual evidence.

Typically with the third-party liability claims we bring on behalf of a Medicaid state agency, an ALJ will decide to schedule between 7 and 15 hearings to be heard consecutively. The hearings can last upwards of two hours and may involve different types of claims, participation by different providers, testimony from their witnesses, and several reams of documentation. Some ALJs have told us afterwards that it was beneficial to them that these lengthy hearing sessions were conducted by VTC due to the volume of appeals, issues, documentation, and complexity of the arguments being conveyed. Just listening for long periods of time requires great mental energy and focus and can prove exhausting. One’s ability to comprehend what a person is saying is significantly enhanced by being able to watch the person. This is all the more relevant if the listener is experiencing any degree of fatigue or hearing loss. Thus, the face-to-face aspect of VTC hearings offers more assurance that ALJs will really hear and understand the testimony and arguments being presented, which is an asset to everyone involved.

Appellants must retain the ability to choose a VTC hearing without having to establish good cause, as the proposed rule would require. In our experience, giving ALJs the discretion to find good cause for an appearance by VTC will almost never result in a VTC hearing. Many ALJs have already quite adamantly expressed to us that there is no good cause for a VTC hearing if the requesting party does not plan to present a witness and that there is never an instance when they would determine that a VTC is necessary to examine facts and issues, regardless of any potential benefit the appellant might allege. Therefore, in practice, this “good cause” protection will likely be almost meaningless.

The Center objects to the wording of the proposed revision to § 405.1020(c)(1), which suggests that a notice of hearing will, as a rule, be sent to “CMS or a contractor that the ALJ believes would be beneficial to the hearing.” The language should reflect that notice will only issue to CMS or a contractor *if* the ALJ believes they would be beneficial to the hearing.
While we don’t object to the additional requirement that an entity or organization specify in response to the notice of hearing the individuals who plan to attend the hearing and the witnesses who will be providing testimony, this requirement should not restrict them from modifying this information prior to the hearing. We support the specification that non-parties may not object to the proposed time and place of hearing, or present witnesses. Further, we commend the proposal to allow parties to orally request that a hearing be rescheduled in an emergency the day of or prior to the hearing.

Also with respect to proposed § 405.1020(j), CMS proposes to add a new requirement that if an ALJ changes the time and place of the hearing they need to send out an amended notice of hearing. However, there is no requirement that an ALJ notify the parties if they refuse to grant a request for a change in time and/or place of a hearing. We ask that the language be changed so that not only must a request for a change to the time and place of a hearing, or the type of hearing, be in writing but that the ALJ be required to respond to the request in writing, even if the ALJ is refusing to change the time and place of a hearing. The Center for Medicare Advocacy has spent much time following up on requests for a change in the time, place or type of hearing conducted when we do not receive a response from the ALJ. Sometimes it is not clear to us until the day of the hearing whether the ALJ has decided to grant or deny our request. Clear guidelines should be put in place requiring an ALJ to inform the appellant of their decision in advance of the ALJ hearing.

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

We are in accord with the proposed change to require the notice to include a general (rather than specific) statement of the issues before the ALJ, including all issues brought out in earlier decisions that were not decided entirely in a party’s favor. We also agree with requiring that the notice include a statement of any specific new issues that the ALJ is aware of at time notice is sent and will consider. While we do not object to the requirement that a copy of one’s objection to the issues be sent to the other parties, we believe this requirement should be waived for unrepresented beneficiaries. They should be exempted from procedural rules that add to the cost and burden of maintaining their appeal.

The Center for Medicare Advocacy has appeals for beneficiaries with more than one claim. For example, the Center may have three appeals for the same beneficiary who had three different skilled nursing facility stays with three different dates of service. If the dates of service or QIC number are not included with the Notice of Hearing then we have to go on OMHA’s website, type in the ALJ number, get the QIC number and match it up with the correct claim. On occasion OMHA’s website did not have the QIC number so we had to call the ALJ’s legal assistant to find out which claim was being scheduled for hearing. This same scenario could easily apply to an unrepresented beneficiary who is appealing multiple claims. Therefore, we request that the Notice of Hearing be required to include the dates of service and/or the QIC number so that an appellant is made aware of which claim is being scheduled for hearing.

We also request that § 405.1022(b)(1) be amended to include a requirement that the Notice of Hearing include the name, address, telephone number and fax number of the person to whom the ALJ would like the appellant to address questions. Just as CMS is requiring in 405.1014(a)(1)(i)
that a beneficiary’s telephone number be included in the request for hearing to “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 ask that the same courtesy of including specific contact information be given to all appellants.

**Review of Evidence Submitted by the Parties (§ 405.1028)**

The Center does not comment on the proposed additional examples of circumstances in which an ALJ could find good cause to accept new evidence. However, we urge the agency and OMHA to firmly reinforce with all ALJs, Attorney Adjudicators, and staff that the statutory limitation on submitting new evidence after a QIC review at 1869(b)(3) and 5 USC 556(c)(3) does not apply to unrepresented beneficiaries and Medicaid state agencies. We still occasionally encounter ALJs who improperly try to require these latter parties to establish good cause for submitting new evidence at the ALJ review stage.

**ALJ Hearing Procedures (§§ 405.1030 and 423.2030)**

We strongly object to the new § 405.1030(b)(2) that provides “the ALJ with the clear authority to limit testimony and/or argument during the hearing.” The new regulation says that “[t]he 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.” (Emphasis added.) Further the ALJ may “but is not required” to provide the party or representative with an opportunity to submit additional written statements on the matter. This essentially gives the ALJs discretion to decide when they have heard enough and further discretion to decide whether an appellant can continue their argument with a written statement after the hearing. Appellants should be given the right to a full and fair hearing and be allowed to provide as much testimony and argument as they want.

An ALJ hearing is the first, and in most appeals only time, where an appellant has the right to provide oral argument and under no circumstances should they be prevented from presenting what they deem to be a full argument to the ALJ. In addition, according to § 405.1122 the Medicare Appeals Council limits its review of the evidence to the evidence contained in the record of the proceedings before the ALJ. Limiting an appellant’s testimony and argument during the hearing could therefore negatively impact their appeal to the Medicare Appeals Council.

It is our experience that ALJs will occasionally schedule up to 20 hearings, and sometimes more, at a time within a very short period of time. In the interest of getting all the hearings done in that amount of time they may improperly use the discretion they are afforded in this regulation to speed the hearings. Again, we strongly object to this discretion and ask that it be deleted.

The regulations also give ALJs the clear ability to excuse a party if they think they are being “uncooperative, disruptive to the hearing, or abusive during the course of a hearing”. Although we agree that an ALJ should be given the authority to excuse a parties if they are being disruptive or abusive during the course of a hearing we ask for more clarification regarding what it means to be “uncooperative.” On occasion we have disagreed with an ALJ’s interpretation of the law. Will this be seen as “uncooperative” if we disagree with an ALJ?
Concerning the proposed provisions that give ALJs the authority and parameters to handle “difficult parties,” we hope that CMS intends to prepare basic informational documents that may be furnished to or accessed by any party whose testimony has been limited or who has been excused from a hearing, explaining their rights and options under the regulation.

With respect to the proposed revision of § 405.1030(d) to extend the adjudication period if new evidence submitted at hearing by appellant other than unrepresented beneficiary, we believe that the exemption should also apply to appellant Medicaid state agencies which, like unrepresented beneficiaries, do not have direct access to relevant medical, claims, and billing information. To penalize Medicaid state agencies with further delay in adjudication for submitting new evidence is entirely inconsistent with the statute’s affirmative recognition that they, like unrepresented beneficiaries, are permitted to submit new evidence at the ALJ review stage.

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

There are numerous significant modifications proposed in this subpart concerning standards for ALJs to consider new issues, notice requirements for new issues, the submission and admissibility of evidence related to new issues, and rules governing whether claims may be added to a pending appeal. If these rules are finalized, we urge the agency to publish an expanded beneficiary handbook (online and elsewhere) that explains these provisions in practical, understandable terms for the layperson.

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

Regarding section § 405.1034(a), the Center questions why, when the record is missing an “official copy” of the redetermination or reconsideration, must the ALJ or Attorney Adjudicator request the same from the contractor, even though the appellant has already furnished or could readily furnish a copy of the same. Because it seems unnecessary and unfair to extend the adjudication period upwards of 15 days to obtain an “official copy” from the QIC, we seek clarification from the agency on this point.

We support the proposed new sections 405.1056 and 405.1068 that describe when hearing or review requests of a QIC dismissal may be remanded, and the effect of remand. We value the specification that when a record has been reconstructed by the QIC on remand, it would be returned to OMHA. This helps to ensure that appellants are not required to restart the entire review process.

However, proposed § 405.1056(b) is concerning. It provides that if a QIC issues a reconsideration that addresses coverage or payment for which no redetermination was made or the redetermination request was dismissed, the ALJ or Attorney Adjudicator must remand the matter to the QIC for re-adjudication. This essentially means that the appellant has to start all over at the first level of appeal, which is not generally necessary or appropriate.

For example, consider the scenario in which a redetermination decision upholds a technical denial (and therefore does not reach the question of coverage and payment), the appellant submits evidence at the reconsideration level that cures the technical defect, and so the QIC proceeds to address availability of coverage and payment. In that situation, it would be a waste of
time and resources for the ALJ to remand the matter back to the QIC to be remanded back to the initial contractor to address the issue of coverage and payment. The ALJ should be able to conduct a de novo review of the QIC’s determination. We seek clarification from the agency regarding the application of this proposed rule, as well as examples of how it might affect appeals brought on behalf of Medicare beneficiaries and Medicaid state agencies.

The Center also has reservations about proposed § 405.1056(c) which would allow the appellant and CMS/contractor to jointly request remand to the QIC/IRE at any time before the ALJ or attorney adjudicator issues a decision or dismissal. Although the request must indicate the reasons the appeal should be remanded and whether it would likely resolve the matter in dispute, we are concerned that this measure alone will not be sufficient to safeguard the interests of unrepresented beneficiary appellants. Such a “joint request” would mostly likely be initiated and facilitated by CMS or its contractor, who would have greater knowledge and bargaining power than appellants. At a minimum, ALJs should be required to hold pre-hearing conferences to confirm both parties’ understanding of the possible ramifications if the remand is granted. We seek further agency input as to how the beneficiaries’ interests may be protected in such situations.

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

The agency proposes to impose two new limitations upon an ALJ’s ability to issue a decision “on the record” (i.e., without holding a hearing) when the evidence supports a finding in favor of the appellant on every issue. The agency would disallow an “on the record” decision if another party to the appeal is liable for the claims at issue or if CMS or a contractor elected to be a party to the hearing. We object to both limitations. If another party who is liable for the claims waives its appearance at a hearing, the ALJ should be allowed to issue a favorable decision to the appellant on the record. Furthermore, the position of CMS and/or its contractor will be well-established in the administrative record by the time the ALJ reviews the claim. The mere “election” to be a party to the appeal should not stand in the way of fairness and expediency if the record supports a finding in favor of the appellant on every issue. Time is often of essence in these cases. **ALJs should retain all rights to issue favorable decisions.**

The Center has reservations about proposed § 405.1038(c), which provides new authority for stipulated decisions when CMS or its contractor submits a written statement or makes an oral statement at hearing indicating that an item or service should be covered or paid. The ALJ or Attorney Adjudicator would be able to issue the stipulation without making findings of fact, conclusions of law, or further explaining the reasons for the decision. We have concerns about how to protect the interests of unrepresented beneficiary appellants in these situations. A stipulated decision could potentially have an impact or future ramifications that the beneficiary may not be aware of. There may be circumstances in which it would be in the beneficiary’s interests to actually obtain a finding of fact or conclusion of law by an ALJ regarding the application of a regulation or policy, eligibility for benefits, or criteria for coverage.

**Pre-hearing & Posthearing Conferences** (§§ 405.1040 and 423.2040)

In theory, the Center does not oppose authorizing an ALJ or an OMHA attorney designated by an ALJ to conduct conferences, so long as uniform policies and procedures are established to
govern the scope and proper handling of conferences, and ALJs and OMHA attorneys receive mandatory training about these matters. We agree that only an ALJ may consider matters in addition to those stated in the conference notice and that the parties must consent in writing to consideration of the additional matters.

In the past, we have participated in pre-hearing conferences that were essentially treated as or converted into hearings, in order to forego a later hearing. This was justified by the fact that the other parties had already waived their appearances, no taking of testimony or receiving of additional evidence was required, only argument would be presented, and the conference was being recorded. We respectfully request clarification about whether this is an acceptable practice. Our concern is that unrepresented beneficiaries are not apprised in advance, will not be prepared, and may go along with simply because they think the ALJ wants to proceed in this fashion. We ask that the agency publish information (e.g., in an online appeals handbook) that explains what can and can’t be expected at a conference.

The Administrative Record (§§ 405.1042 and 423.2042)

The Center supports the proposal to vest OMHA (rather than ALJs) with the responsibility of making a complete record of the evidence and administrative proceedings, which allows OMHA to develop policies and uniform procedures to this end. We also support authorizing Attorney Adjudicators to mark exhibits and advising them to indicate the portions of the record they considered in making a decision, in the same manner as expected of an ALJ. We appreciate the proposed clarification as to what, at a minimum, must be marked as exhibits, and what the record would also include (though perhaps not marked as exhibits).

We have one caveat, however. In our experience, we frequently receive ALJ decisions that do not reflect whatsoever that the ALJ considered the evidence that was submitted (e.g., treating physician statements). That is to say, there is no mention of the submitted evidence in the findings of fact or analysis. The agency should clarify in the regulation that just because evidence is marked as an exhibit does not create a legal presumption that the adjudicator actually considered it in rendering the decision.

Concerning the proposal to require adjudicators to discuss in their decisions whether good cause was found for submission of new evidence, we ask the agency and OMHA to reinforce to adjudicators (e.g., in education sessions and materials) that the good cause requirement does not apply to new evidence submitted by unrepresented beneficiaries and Medicaid state agencies.

We support the revision of § 405.1042(a)(3) to indicate that a party may request and review the record prior to or at the hearing, or any time before the notice of decision is issued, as well as the revision of § 405.1042(b)(1) to allow a party to request and receive a copy of the record from OMHA while the appeal is pending at OMHA.

Consolidated Proceedings (§§ 405.1044 and 423.2044)

The proposed rule lays out two mutually exclusive options for handling consolidated hearings. The ALJ may make either (1) a consolidated decision and record or (2) a separate decision and record on each appeal. The Center believes there is a need for clearer guidance, training, and
oversight over protocol, decisions, and record maintenance in consolidated hearings.

It is not always clear when an ALJ is intending to conduct a consolidated hearing in the third-party liability (TPL) appeals we have brought on behalf of Medicaid state agencies or what that will entail. Sometimes in these hearings the ALJ will switch out the audio disk in between each hearing, thus creating separate disks for each appeal. Other times, they will create a pause on the audio disk after each hearing, so there is only one disk which includes all of the appeals. Then, other times, the ALJ will not switch out or pause the disk, and there is no clear way of identifying on the single recording when the hearing on one appeal ends and the next one begins. These practices can impact the ability to readily locate and forward the proper recording(s) to the Council when one or more of the separate decisions is later appealed.

We have also encountered problems when ALJs decide to issue a single written document that includes decisions on multiple (sometimes as many as 6 or 7) TPL appeals. This can be extremely confusing because, although the appellant is the same in each case, the Medicare beneficiaries, providers, issues, and facts are not the same. The cases might even pertain to different health settings and Medicare benefits (e.g., SNF, Home Health), so the legal criteria are different. When decisions on completely separate appeals are combined into one document, it is often hard to separate out the factual findings, legal authority, and analysis for each case. Sometimes in these decisions we have seen a tendency to “cut and paste,” which has resulted in significant errors that are difficult and costly to correct.

We thus urge the agency to provide additional guidance, training, and oversight over consolidated hearings, decisions, and record management. We also request that the agency make information about consolidated hearings available in an online source (e.g., appeals handbook).

We support the addition of § 405.1044(c) to provide that consolidated proceedings may only be conducted for appeals filed by the same appellant, unless multiple appellants have aggregated claims to meet the amount in controversy and the beneficiaries whose claims are at issue have authorized disclosure of protected information to the other parties and any participants.

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

The proposed § 405.1046(a) would add a sentence stating that the decision “must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions.” Since the agency’s intended purpose here is to deter adjudicators from merely incorporating findings and conclusions offered by others (e.g., the QIC or IRE’s decision), we recommend the language should make this point explicit. For instance: “As the ALJ is required to perform a de novo review, the ALJ is prohibited from simply incorporating findings/conclusions offered by others.” Moreover, we strongly urge CMS in future rulemaking to likewise apply this requirement of rendering independent findings and conclusions to the lower levels of review, from which we currently commonly see “rubber-stamp” reviews/denials.

The agency proposes to revise this subpart to require OMHA to mail “or otherwise transmits a copy of decision” to allow for additional options as technologies develop. We feel strongly that
beneficiaries should always also be issued a written decision by regular mail. With respect to beneficiaries, regular mailing can be additional, but should never be optional.

As concerns proposed § 405.1046(b)(2) and § 423.2046(b)(2), which govern decisions affirming QIC and IRE dismissals, we ask that an additional provision (iv) be added, which would read “Notification of the right to appeal the decision to the Council, including instructions on how to initiate an appeal under this section and how to submit a request for a copy of the administrative record.” This is an issue we have come across several times and even the individuals we have contacted at OMHA cannot provide definite information about how to obtain a copy of the administrative record.

**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)**

Proposed § 405.1052(a)(7) would allow a hearing request to be dismissed if not “complete” as per proposed § 405.1014(a)(1) or if the appellant did not send copies to the other parties in accordance with proposed § 405.1014(d) after being provided with a second opportunity to cure both defects. As stated earlier, additional leeway should be allowed to unrepresented beneficiaries with respect to both requirements. **Further, the ability to dismiss hearing requests for these reasons should be used sparingly in order not to deny due process simply because details are missing from a form. This should be required by the final regulation.**

Although the proposed rule would allow OMHA to mail “or otherwise transmit” a notice of dismissal to the required parties, we believe that beneficiaries should always be issued such notice by regular mail in addition to any other method of transmittal utilized.

**5. Council review and judicial review**


We support revised § 405.1100(d) which will state that if the Council remands an escalated appeal, it will be to the OMHA Chief ALJ who is in a better position to provide immediate attention to the remand so as to minimize confusion and delay for the appellant.

We strongly encourage CMS to add language to the regulations requiring that the Council acknowledge receipt of an appellant’s request for review. The regulations state that the Council issues a final decision, dismissal order or remand within 90 calendar days of receipt of the appellant’s request for review. However, by their own admission, the Council has a very considerable backlog and in many circumstances issues a decision after more than two years have passed since the request for review was received.

The Center has spent much time simply writing to the Council and asking whether they received our request for review and repeatedly checking to request the status of our requests for review. Because these appeals can sit with the Council for years, we spend a considerable amount of time trying to track these cases. If we, and other appellant’s, had an acknowledgement that the appeal was received from the Council we would at the very least have evidence that the appeal was received and know that the appeal is pending.
b. Request for Council Review When the ALJ Issues Decision or Dismissal (§§ 405.1102 and 423.2102)

We support the revised language that Council review may be sought even if a hearing before an ALJ is not conducted or if an Attorney Adjudicator issues the decision or dismissal.

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

We oppose the revision in § 405.1110(b)(2) requiring CMS or the IRE to send a copy of its referral for Council review to the OMHA Chief ALJ rather than the ALJ who issued the decision. We particularly do not agree with the logic behind requiring CMS or the IRE to send a copy of its referral for Council review to the OMHA Chief ALJ rather than the ALJ who issued the decision. The reason for this change appears to be so that OMHA can “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.”

This reasoning places too much weight on a referral and assumes that the referral itself is evidence that training or policy clarifications are needed. The logical order of things would be to require that the Council’s final decision from a referral be disseminated to the Chief ALJ, not the mere referral. The Council may decide not to accept review and even if they do accept review they may not agree that the decision or dismissal contained an error of law. Therefore, requiring that a referral be sent to the Chief ALJ and placing that much emphasis on the referral itself is premature; we object to this change in the regulations.

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

We ask that § 405.1118 be changed to clarify exactly where a party should direct their request for the record. We have filed requests for Council review and tried to obtain this information from the ALJ who conducted the hearing. When we contacted OMHA to obtain a copy of the record we were simply told that they no longer had it and had “released custody” of the record. It was not clear where we were supposed to direct our request for the record. Therefore, the regulation should clarify exactly where a request for the record should be directed. It would also be helpful if the language in the ALJ’s decision not only informed the Appellant how to appeal the ALJ decision but also where to send a request for the record of the ALJ proceedings.

B. Part 405, Subpart J Expedited Reconsiderations – 405.1204

We are in accord with the proposed revision of §405.1204(c)(5) to align the amount in controversy with §1869(b)(1)(E) of the Act, and 42 CFR §405.1006.

C. Part 422, Subpart M

We generally support the proposals in this section to replace “ALJ’s” with “ALJ’s or Attorney Adjudicator’s” with the caveat that the Center has some concerns with the proposals surrounding the scope of work of Attorney Adjudicators, as discussed in comments above.
3. **Request for an ALJ Hearing** (§ 422.602)

We strongly support the proposal to align § 422.602(b)(1) with the Part 422 timeframe so that a party has to file a request for an ALJ hearing within 60 days of receiving the notice of a reconsideration instead of within 60 days of the date of the reconsideration. The date of receipt is presumed to be 5 calendar days after the date of the reconsideration. We thank CMS for making this important change as we have seen this deadline discrepancy for filing an ALJ hearing cause problems for beneficiaries, providers and ALJs. It makes sense to make the time frames for requesting an ALJ hearing uniform and clear.

**Conclusion**

The Center for Medicare Advocacy appreciates the opportunity to provide comments about these proposed rules. [The Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures (HHS-2015-49)] The proposed rules will make significant changes to the Medicare appeals system; some of the proposals would increase complexity and decrease fairness. We hope our comments will be seriously considered in the interest of promoting access to a full and fair appeals process.

For additional information, please contact our Senior Policy Attorney, David Lipschutz at 202-293-5760 or DLipschutz@MedicareAdvocacy.org. Thank you.

Sincerely,

Judith Stein
Executive Director/Attorney

Submitted on behalf of the following organizations:

ACCSES
American Congress of Rehabilitation Medicine
American Therapeutic Recreation Association
Brain Injury Association of America
Christopher & Dana Reeve Foundation
Disability Right Education and Defense Fund
Epilepsy Foundation
National Association of State Head Injury Administrators
Uniform Data System for Medical Rehabilitation
United Cerebral Palsy
United Spinal Association