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VIA ELECTRONIC SUBMISSION

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Office of Medicare Hearings and Appeals
Department of Health & Human Services
5201 Leesburg Pike Suite 1300
Falls Church, VA 22042

RE: 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 Medicare Rights Center (Medicare Rights) is pleased to submit comments in response to the proposed rule “Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination and Medicare Prescription Drug Coverage Determination Appeals Procedures.” Medicare Rights is a national, nonprofit organization that works to ensure access to affordable health care for older adults and people with disabilities through counseling and advocacy, educational programs, and public policy initiatives. Medicare Rights provides services and resources to over two million Medicare beneficiaries, family caregivers, and professionals annually.

The following comments are informed by our experience working with beneficiaries and their families, particularly those pursuing appeals after denials of coverage. For additional information, please contact Casey Schwarz, Senior Counsel for Education and Federal Policy, CSchwarz@medicarerights.org or 212-204-6271 and Stacy Sanders, Federal Policy Director at SSanders@medicarerights.org or 202-637-0961.

II. General Provisions of the Proposed Regulations

A. Precedential Final Decisions of the Secretary

The rule proposes to allow certain Appeals Council decisions to be made precedential and designated as a “final decision of the Secretary” at the sole discretion of the Council Chair. According to the Centers for Medicare and Medicaid Services (CMS), such decisions would provide “clear direction on repetitive legal and policy questions, and in limited circumstances, factual questions”¹ and would be binding on future decision makers as long as the same authority or provision is applied and still in effect. Medicare Rights does not support this proposal, and we encourage CMS to make modifications.

¹ 81 Fed. Reg. 43793.

-We appreciate the goal of the proposed change, namely to increase predictability and consistency among agency decisions. Nevertheless, we believe CMS should institute more stringent safeguards to ensure that the decisions afforded precedential authority are accurate and fair and that the process for identifying such decisions is transparent. In particular, in situations where there is significant dispute as to a question of Medicare law and where administrative decision makers as well as Federal Court review are divided, we do not believe the Secretary should be able to forgo notice and comment rulemaking to alter or clarify Medicare regulation by this mechanism.

The preamble to the proposed rule cites the March 2004 “Report to Congress: Plan for the Transfer of Responsibility for Medicare Appeals”² which recommends *against* granting the Appeals Council precedential authority in part because CMS is not a party to Council decisions and beneficiaries are often unrepresented, which can result in decisions where a particular legal argument was not raised or thoroughly considered. According to the report, giving precedential authority to such decisions 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.”³

The proposed rule does not adequately address how these concerns have been addressed in the intervening years. Furthermore, the proposal seeks to give blanket authority to one person on the Council to designate those decisions that are to be treated as precedential without providing clear criteria on the selection of decisions. In addition, the proposed rule lacks detail on the timeframe within which decisions about precedent would be made, the public availability of those decisions, or how such decisions could be challenged.

Further, the proposed rule does not address the effect this proposal would have on a federal court decision that reverses a Council decision which was chosen to have precedential value, or whether a Council decision implicating a question of law which differs from a prior federal court decision in a separate appeal could be designated. Presumably if a federal court reversed a Council decision, the decision would, in effect, cease to exist and lose its precedential value. Yet, this is not discussed and CMS has not previously given blanket precedential authority to federal court decisions that overturn Council determinations.

Despite attention paid to potential findings of fact, the proposal remains ambiguous concerning such findings. Proposed §401.109(d)(2) states that “[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.”⁴ As drafted, however, the proposed rule would not preclude such review.

If CMS 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 through clear regulatory requirements – created through public notice and comment as well as more complete guidance with regard to the open questions identified above. One possible limitation would be to only allow decisions which are fully favorable to the Medicare beneficiary and achieve the broad remedial purpose of the statute to have precedential authority. Thereby, actions that narrow Medicare rules would only be undertaken with the full procedural protections of notice and comment rulemaking;

² Available at: https://www.ssa.gov/legislation/medicare/medicare_appeal_transfer.pdf.

³ *Id.* at 12-13.

⁴ 81 Fed. Reg. at 43794.

whereas, needless appeals to conform initial determinations to decisions that interpret Medicare rules in the light most favorable to those for whom the program is meant to serve would be avoided.⁵

B. Attorney Adjudicators

The proposed rule would allow attorney adjudicators, rather than Administrative Law Judges (ALJs), to perform a portion of the Department of Health and Human Services (HHS) Office of Medicare Hearing and Appeals' (OMHA) workload that “does not require a hearing.”⁶ While ALJs would continue to be responsible for making findings of fact and conclusions of law, CMS articulates 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.”⁷

Medicare Rights agrees with the proposal to allow 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 Qualified Independent Contractor (QIC) and Independent Review Entity (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 CFR §405.986) could require a hearing. These cases should be assigned to an ALJ.

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. Still, we encourage HHS to go further and require such a transfer in all instances in which a hearing could be necessary, based upon clearer guidance and standards established by CMS.

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

Because of certain gaps among and misalignments between various statutory provisions relating to different Medicare appeals, “Part 405 rules are used, to the extent appropriate, for administrative review and hearing procedures in the absence of specific provisions” relating to Medicare Advantage and Quality Improvement Organization (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.”⁸ The proposed rule, however, goes on to note 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 Medicare Advantage (MA), QIO and cost plan appeals programs].”⁹

To clarify the application of Part 405 rules concerning Medicare Part A and B appeals to other rules relating to Medicare appeals, the rule proposes revisions to MA and QIO appeal rules to provide that the Part 405 rules do *not*

⁵See *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. . . **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).

⁶ 81 Fed. Reg. at 43794

⁷ *Id.*

⁸ 81 Fed. Reg at 43795.

⁹ *Id.*

apply when the Part 405 rule implements a statutory provision that is not also applicable to section 1852 or section 1155 of the Act.

Medicare Rights Center urges CMS to reconsider this approach to aligning appeals rules. While well intentioned, we do not believe this proposal will clear up existing ambiguity relating to the application of Part 405 to other parts of the rules; instead, we are concerned it will create confusion. Further, it is likely to have the unintended consequence of stripping away important safeguards that currently provide consistency in application of beneficiary rights and relative simplicity in beneficiary messaging across the appeals spectrum.

For example, under the proposed rule, 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.” However, the only sections of 1869 that are referenced in 1852(g)(5) relate to amounts in controversy. This might mean that all sections of Part 405—other than those relating to amounts in controversy—are unavailable to fill in the gaps of Part 422. This will not solve the problem of inconsistent appeals rules identified by CMS.

Indeed, CMS cites, as proof of unaligned statutory provisions, the ability of providers and suppliers to introduce new evidence in an appeal at the hearing stage (section 1869 requires good cause for supplemental submissions but section 1852(g) is silent). CMS does not articulate how the proposed rule would align the provisions. In fact, a plain reading would prohibit the use of regulation interpreting section to fill in this gap and would preserve the disparate treatment. More critically, the introduction of evidence by a beneficiary is left aside. Part 405 states that limitations on submitting evidence prior to a hearing do not apply to a beneficiary unrepresented by a provider or supplier.¹⁰ Part 422 is silent. If an MA enrollee can no longer look to Part 405 to fill in the gaps in procedural rules in Part 422, that could constitute a severe curtailment of important protections for beneficiaries who are not represented in their appeal by their supplier or provider.

Instead of the blanket rollback of reasonable cross references to fill gaps in otherwise similar processes, we ask that CMS articulate which specific regulations it believes should not apply when other parts are silent and to regulate to fill in those gaps, with an opportunity for public comment on each provision. Until CMS does so, the current approach—applying procedural rules from Part 405 when other Parts are silent—should remain.

D & E. OMHA References and Medicare Appeals Council References

Medicare Rights supports the proposals to update regulatory language to clearly reflect the role of OMHA in administering ALJ appeals, and replace “MAC” or “Board” with “Council” when referring to the Medicare Appeals Counsel.

III. Specific Provisions of the Proposed Rule

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

3. ALJ Hearings

B. Right to an ALJ Hearing

¹⁰ 42 CFR §405.1018.

We support the 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, strengthening the current statement 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 because there is still a risk that a beneficiary would mail a hearing request to the QIC, IRE, or wrong OMHA field “office,” we urge the agency to continue its policy of accepting timely-filed requests even if they are timely-filed with the wrong office/entity and to incorporate this policy in the final regulation.

D. Amount in Controversy Required for an ALJ Hearing

We support the 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.). To further aid in beneficiary understanding, we encourage HHS to create a user-friendly online resource that explains these calculations in a more basic way for beneficiaries and their advocates.

Medicare Rights strongly supports the proposal to require that QICs specify in reconsideration decisions issued to unrepresented beneficiary 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 HHS intends to make this information a required element on hearing requests.

Further, the calculated amount remaining in controversy should be boldly designated in the QIC decision, along with a clear instruction with regard to where this amount may be inputted on the hearing request form. The QIC decisions should also 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 believe that it is inaccurate.

Medicare Rights also supports the proposed rule to 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.

E. CMS and CMS Contractors as Participants or Parties in the Adjudication Process

We support the proposed clarification 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.” We encourage HHS to go further and develop language to ensure that beneficiaries are made aware of this option.

We also 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, 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 are not met. We strongly suggest,

however, that the final rule expressly apply the 5/14-day timeframe to when a copy must be sent to the other parties. This is particularly important for appeals brought by unrepresented beneficiaries, who may need more time to sufficiently understand and prepare a response to the agency/contractor's arguments.

G. Request for an ALJ Hearing or Review of a QIC or IRE Dismissal

The proposed rule would require all of the information in subsection (a)(1) of the request form to be included 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 support the decision to 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.

We encourage HHS to afford unrepresented beneficiaries as much flexibility and leniency as possible when applying the requirement. For example, when offering a beneficiary a second opportunity to complete their request, OMHA should also offer guidance as to where to locate the missing information, and HHS should also require that the ALJ inform the appellant exactly what information is missing from the request. 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.

Medicare Rights supports the alignment of 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 are concerned, however, that the proposed copy requirements at 405.1014(d) may deter unrepresented beneficiaries from appealing, or render more of their hearing requests incomplete.

We appreciate the need for clarification about the appellant's obligation to 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. Yet, other parts of the proposed rule, with regard to sending copies of additional materials and satisfying a standard of proof, will be costly and burdensome. Most Medicare beneficiaries simply do not 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.

Should HHS finalize this proposal, we request that 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 ensure that sending a copy of the hearing request and additional materials to other parties is as easily accomplished as possible, by requiring that QIC reconsiderations or dismissals include the full name and address of all the other parties so that an appellant can simply copy that information.

H. Time Frames 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."¹¹ 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

¹¹ 42 C.F.R. § 405.1016(a) (emphasis added).

calendar day period beginning on the date the request for hearing is received”¹² This proposal is contrary to the plain language of the statute and should not be finalized.

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.”¹³ The only exception to this deadline is if the appellant expressly waives it.¹⁴

In general, Medicare Rights supports the other proposals in this section of the proposed rule, including 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 also 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 significantly improves upon 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.

With respect to the proposal to require that the escalation request be sent to other parties on the QIC reconsideration, however, we recommend that unrepresented beneficiaries 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, there is no reason that OMHA could not also send notice of its action or escalation to the other parties on the QIC reconsideration.

N. ALJ Hearing Procedures

Medicare Rights is concerned that the proposed change to this section may undercut a beneficiary’s ability to obtain a full and fair hearing. The proposed 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.”¹⁵ 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 opportunity 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

¹² 81 Fed. Reg. at 43,864 (emphasis added).

¹³ 42 U.S.C. § 1395ff(d)(1)(A).

¹⁴ *Id.*

¹⁵ 81 Fed. Reg. at 43830.

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.

V. Notice of Decision and Effect of an ALJ or Attorney Adjudicator Decision

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.” Because CMS’ stated 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 final rule 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.”

The proposed rule would revise the notice requirement to permit OMHA to mail “**or** otherwise transmit a copy of decision” to allow for additional options as technologies develop. We urge HHS to ensure that beneficiaries *always* receive a written decision by regular mail. With respect to beneficiaries, regular mailing can be additional, but should not be optional.

5. Council review and judicial review

A. Council Review: General

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. Yet, 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.

B. Request for Council Review When the ALJ Issues Decision or Dismissal

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

We are concerned that 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 puts undue weight on a referral for own motion review. A referral itself is not evidence that training or policy clarifications are needed. Instead, we encourage OMHA to require dissemination of the Council's *final* decision from a referral.

C. Part 422, Subpart M

3. Request for an ALJ Hearing

Medicare Rights supports the proposal to align §422.602(b)(1) with the broader Part 422 timeframes and generally applicable timekeeping conventions 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.

Thank you for the opportunity to provide comments.