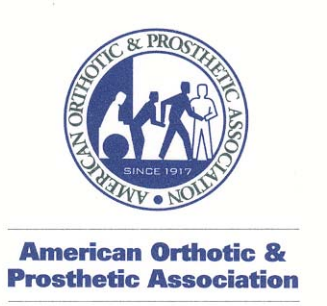

Submitted Electronically via Regulations.gov

August 29, 2016

Office of Medicare Hearings and Appeals
U.S. Department of Health and Human Services
Attention: HHS–2015–49
5201 Leesburg Pike, Suite 1300
Falls Church, Virginia 22041

RE: HHS-2015-49 "Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures"

Dear Office of Medicare Hearings and Appeals:

We are writing to provide comments on the proposed rule entitled: *HHS-2015-49 "Medicare Program: Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures"* which was published in the *Federal Register* on July 5, 2016.

The American Orthotic & Prosthetic Association (AOPA), founded in 1917, is the largest national orthotic and prosthetic trade association with a membership that draws from all segments of the field of artificial limbs and customized bracing for the benefit of patients who have experienced limb loss, or limb impairment resulting from a trauma, chronic disease or health condition. These include patient care facilities, manufacturers and distributors of prostheses, orthoses and related products, and educational and research institutions.

AOPA's comments are presented in summary below and followed by specific comments relative to specific provisions of the proposed rule.

1. AOPA opposes the proposal to remove the word "must" from the regulatory language of 42 C.F.R. 405.1016(a). This proposal appears to circumvent the intent of the original statutory requirement that Administrative Law Judge (ALJ) decisions must be issued within 90 days of the appeal of a decision issued by a Qualified Independent Contractor (QIC).

2. AOPA supports the proposal to authorize the Chair of the Departmental Appeals Board (DAB) to declare that certain decisions of the Medicare Appeals Council as precedential for purposes of application to future cases. AOPA is concerned, however, about the grant of authority to a single person, the DAB chair, in determining which decisions are considered precedential. In addition, AOPA is also concerned that the proposed rule lacks specific criteria to determine whether a decision is precedential, does not provide any guidance on timeframes for this decision, and provides no pathway to challenge a precedential determination.

3. AOPA supports the concept of the creation of non-judicial (attorney) adjudicators as a means to address and reduce the growing backlog of cases that are awaiting adjudication but believes that the final rule must contain provisions that require the consent of the appellant to have their case decided by an attorney adjudicator rather than an ALJ. In addition, AOPA believes that the final rule must clearly outline the required qualifications of attorney adjudicators as well as the types of cases for which they will be allowed to render decisions.

4. AOPA generally supports the proposed changes to the regulations that address the ability of CMS and/or its contractors to enter an appeal as a participant or party provided that their inclusion does not lead to further delay in the appeals process. AOPA will provide additional comment on this proposal later in its comments.

5. AOPA generally supports the proposed clarifications regarding "on the record" and stipulated decisions but has concerns regarding the foreclosure of "on the record" decisions when CMS and/or it contractor(s) enter as a party to the appeal.

6. AOPA supports the proposed changes regarding ALJ hearings that involve statistical sampling or extrapolation. The proposed changes will allow for the consolidation of similar claims into a single hearing and decision, saving appellants and OMHA valuable time by eliminating duplicative and redundant hearings.

7. AOPA believes that the final rule should include provisions that allow for the re-scheduling of ALJ hearings when the appellant's witnesses are unavailable to provide testimony due to direct patient care duties.

8. AOPA recommends that the final rule contain provisions that prevent recoupment of funds for services that remain under appeal until an ALJ decision has been rendered.

General Comments

AOPA applauds the recognition by the Office of Medicare Hearings and Appeals (OMHA) that the current backlog in adjudication of pending appeals before an ALJ is unacceptable and essentially unfair to Medicare beneficiaries and providers who have a reasonable expectation for access to a hearing in a timely manner. As OMHA has reported, despite recent increases in funding, the addition of several ALJs, and the creation of a new ALJ field office in Kansas City, Missouri, the exponential increase in new requests for ALJ hearings continues to

contribute to unprecedented delays in the average time it takes to schedule ALJ hearings. Federal statute requires decisions in ALJ hearings to be rendered within 90 days of the filing of a request for hearing after a decision is issued by a QIC. The increase in the number of pending requests, coupled with the failure of HHS, CMS, and OMHA to provide the necessary resources to keep pace with the increased demand, has resulted in delays of several years between the filing for a hearing request and the actual hearing and subsequent decision. The recognition by OMHA that the current backlog is unacceptable and must be addressed, is a positive step toward reducing these delays and creating an environment where Medicare beneficiaries and providers can have a reasonable expectation for due process.

While AOPA supports OMHA efforts to take necessary action to reduce the backlog of pending hearing requests, there must be reasonable assurances that any regulatory action that is taken to accomplish this goal does not compromise, in any way, the right to a fair and impartial decision on claim appeals that are adjudicated through the OMHA process, including the appellant's right to a timely ALJ decision.
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AOPA is pleased to offer the following expanded comments that were outlined in summary above.

1. **Section 405.1016: Timeline for Deciding an Appeal of a QIC or Escalated Request for a QIC Reconsideration**

   The proposed rule would revise the regulations at 42 C.F.R. 405.1016(a) by removing the word "must" when discussing the timeframe in which an ALJ decision is rendered. While on the surface, this might appear to be a minor change, AOPA believes that the removal of the term "must" is contrary to the original statute which states, "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." The proposed revision to the regulatory language states, "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." The removal of the word "must" from the regulatory language implies that the 90 day response requirement is a goal as opposed to a requirement. AOPA understands that the current backlog has not resulted in adjudication of ALJ hearings within the mandated 90 calendar day period, but instead routinely violates the requirements of the statute. AOPA cannot support any proposed change to the regulatory language that dilutes the legal obligation of OMHA to hold hearings and issue decisions or other actions within the legally required 90 day timeframe. The HHS/OMHA argument presented in the preamble of the proposed rule that the deadline is not an absolute requirement is an errant attempt at revisionist history—just because HHS/CMS/OMHA have routinely violated the statute enacted by Congress does not serve to revise that statute which is clear and absolute—any ALJ hearing as well as a final decision must occur within 90 days of the hearing request.

2. Precedential Final Decisions of the Secretary

AOPA supports the provision of the proposed rule that will establish previous DAB decisions as precedential, therefore allowing them to be referenced in the adjudication of future appeals. This provision could lead to significant increases in efficiency and eliminate redundant appeals involving the same issues in the future. While AOPA supports this concept in theory, it remains concerned that failure to further clarify this provision in the final rule will lead to unnecessary delays in the appeal process.

AOPA's specific concerns include the lack of a clear deadline in determining the precedential status of a DAB decision. Current regulations state that a decision of the DAB must be appealed to federal district court within 60 days of the DAB decision. Failure to create a definitive timeline for a DAB decision to be declared as precedential may lead to the expiration of a provider's ability to appeal to the federal district court before a precedential decision has been made. AOPA believes that the final rule must allow sufficient time to continue the appeal process once a precedential decision has been made regarding a DAB decision. Additionally, AOPA is concerned that the proposed rule provides sole discretion regarding the precedential nature of a DAB decision to the Chair of the DAB, with no mechanism to appeal those decisions. AOPA believes that the final rule must expand the authority to declare DAB decisions as precedential beyond that of only the DAB chair and must also develop a mechanism in which appellants may challenge precedential decisions.

3. Attorney Adjudicators

AOPA generally supports the use of qualified and independent attorney adjudicators to issue hearing decisions on behalf of an ALJ but believes that additional clarification regarding their role and authority must be included in the final rule. While the use of non-judicial attorney adjudicators will certainly have an impact on the desired reduction of the backlog in hearing requests, the rights of the appellant must remain intact in this circumstance. First, AOPA believes that there must be specific regulation that outlines the required qualifications necessary to serve as an attorney adjudicator. Second, the right of the appellant to demand a decision from an ALJ must be maintained. In other words, attorney adjudicators should only be allowed to render decisions when the appellant has not only been notified of the proposal to have their case reviewed by an attorney adjudicator, but has also consented to the use of the attorney adjudicator to render the decision.

4. Provisions that address the ability of CMS and/or its contractors to enter an appeal as a participant or party

AOPA supports the significant clarification in the proposed rule that determines when CMS or its contractors may participate in an ALJ hearing as well as those that clarify when CMS or its contractors may be considered a party to a hearing. In particular, AOPA believes that the clarifications in the proposed rule will help appellants to better prepare their arguments if they are aware, through required notification that CMS or its contractor(s) will be

participating in the hearing process. AOPA also believes that the proposed limitation on the number of contractors that can be considered participants or parties to a hearing will eliminate unnecessary delays that occur when multiple contractors request inclusion as a participant or a party and subsequently provide duplicative or redundant testimony.

5. On the Record and Stipulated Decisions

AOPA supports the proposed clarifications in the proposed rule regarding "on the record" decisions by ALJs and attorney adjudicators with the exception of the proposal that would disallow an "on the record" decision should CMS or its contractor(s) request standing as a participant in or party to a hearing. AOPA believes that by the time a case has reached the ALJ stage of the Medicare appeal process, CMS has had ample opportunity to develop its reasons for denial of the initial claim. This information should be incorporated into the record during previous levels of the appeal process and should allow an ALJ or attorney adjudicator to render an "on the record" decision. The decision by CMS or its contractor(s) to be added as a participant in or party to an ALJ hearing should not, in and of itself, preclude the ability of an ALJ or attorney adjudicator to render an "on the record" decision when the relevant facts are clear.

AOPA fully supports the proposal to allow stipulated decisions when CMS or its contractors acknowledge that a claim should have been paid. In this scenario, both the appellant and CMS or its contractor(s) are in agreement that the claim was valid and should not have been denied in the first place. Allowing for stipulated decisions will further serve to reduce the administrative burden faced by ALJs and attorney adjudicators and will help to reduce the hearing backlog.

6. Requests for Hearing Involving Statistical Sampling and extrapolation

AOPA supports the proposed changes regarding requests for hearings on appeals involving statistical sampling and extrapolation. The ability to consolidate hearings that involve identical issues into a single hearing before one ALJ (by the nature of the decision, it should be recorded by the ALJ) will allow for more efficient use of the limited OMHA resources and reduce undue burden on appellants. The provisions in the proposed rule will also contribute to reduced case load management and is in the best interest of all involved parties.

7. Re-Scheduling of ALJ Hearings

Orthotic and Prosthetic providers, like all healthcare providers, offer direct patient care services to patients. When developing a list of witnesses that will provide essential testimony to support the appellant during the hearing, schedule conflicts may occur where vital witnesses are unavailable to provide testimony during the scheduled hearing time. AOPA respectfully requests that the final rule contain provisions that allow for reasonable re-scheduling of ALJ hearings as a result of the unavailability of witnesses as a direct result of patient care responsibilities.

8. Recoupment of Reimbursement for Claims Subject to an ALJ Hearing

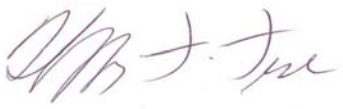
The largest impact on healthcare providers resulting from the multi-year backlog for the scheduling of ALJ hearings has been the impact that it has had on cash flow. This impact is especially significant for O&P providers who must purchase expensive componentry from manufacturers in order to create and assemble a complete prosthesis. Current regulations suspend recoupment activity for claims in the appeal process until after the reconsideration decision has been made by the QIC. While this reduces the immediate financial impact of denied claim, recoupment of funds with no recourse for potentially several years has literally led to the bankruptcy of many O&P businesses long before an ALJ hearing, and decision, delayed well beyond the statutory limit of 90 days, takes place.

AOPA strongly believes that a provision in the final rule that will further delay recoupment of funds for denied claims until the ALJ or attorney adjudicator has rendered a decision will allow O&P providers to maintain appropriate cash flow to sustain their business during the extensive appeal process.

AOPA appreciates the opportunity to provide its comments on the OMHA proposed rule, applauds the efforts of OMHA to acknowledge that the current delays are illegal and unacceptable, and supports any efforts to reduce the extensive delays as long as the rights of the appellants and beneficiaries remain intact.

If AOPA can be of any further assistance on this subject, please feel free to contact me at (571) 431-0876 or via e-mail at tfise@aopanet.org.

Sincerely,



Thomas F. Fise, JD
Executive Director