

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-08 Medicare Program Integrity</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 748</b>	<b>Date: October 13, 2017</b>
	<b>Change Request 10226</b>

**SUBJECT: Defending Medical Review Decisions at Administrative Law Judge (ALJ) Hearings**

**I. SUMMARY OF CHANGES:** The purpose of this change Request (CR) is to update Chapter 3, Section 3.9 of Pub.100-08, to reflect the recent regulatory changes in the Office of Medicare Hearings and Appeals process.

**EFFECTIVE DATE: November 14, 2017**

*\*Unless otherwise specified, the effective date is the date of service.*

**IMPLEMENTATION DATE: November 14, 2017**

*Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.*

**II. CHANGES IN MANUAL INSTRUCTIONS:** (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	3/Table of Contents
R	3/3.9/Defending Medical Review Decisions at Administrative Law Judge (ALJ) Hearings
R	3/3.9/3.9.1/Election of Status
R	3/3.9/3.9.2/Coordination of the ALJ Hearing
D	3/3.9/3.9.3/Party in the ALJ Hearing
D	3/3.9/3.9.4/The ALJ Hearing

**III. FUNDING:**

**For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**IV. ATTACHMENTS:**

**Business Requirements**  
**Manual Instruction Attachment - Business Requirements**

<b>Pub. 100-08</b>	<b>Transmittal: 748</b>	<b>Date: October 13, 2017</b>	<b>Change Request: 10226</b>
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**I. GENERAL INFORMATION**

**A. Background:** This CR updates Chapter 3, Section 3.9 of Pub. 100-08, to reflect recent changes in the Office of Medicare Hearings and Appeals process. These changes include, but are not limited to, restrictions on the number of contractors able to participate during oral testimony and the adoption of the witness role for those cases in which additional support may be sought.

**B. Policy:** This CR does not contain any legislative or regulatory policies.

**II. BUSINESS REQUIREMENTS TABLE**

*"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.*

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
10226.1	Contractors shall support medical review decisions appealed to ALJs in accordance with Ch. 3, Section 3.9 of Pub. 100-08, as indicated in their statements of work.	X	X	X	X					RACs, SMRC, ZPICs
10226.1.1	Contractors shall note the changes in process related to the number of contractors able to participate during oral testimony and the adoption of the witness role for those cases in which additional support may be sought.	X	X	X	X					RACs, SMRC, ZPICs

**III. PROVIDER EDUCATION TABLE**

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

**IV. SUPPORTING INFORMATION**

**Section A: Recommendations and supporting information associated with listed requirements: N/A**

*"Should" denotes a recommendation.*

X-Ref Requirement Number	Recommendations or other supporting information:

**Section B: All other recommendations and supporting information: N/A**

**V. CONTACTS**

**Pre-Implementation Contact(s):** Olufemi Shodeke, 410-786-1649 or Olufemi.Shodeke@cms.hhs.gov , Jennifer Phillips, 410-786-1023 or Jennifer.Phillips@cms.hhs.gov

**Post-Implementation Contact(s):** Contact your Contracting Officer's Representative (COR).

**VI. FUNDING**

**Section A: For Medicare Administrative Contractors (MACs):**

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

**ATTACHMENTS: 0**

# Medicare Program Integrity Manual

## **Chapter 3 - Verifying Potential Errors and Taking Corrective Actions**

### Table of Contents

*(Rev.748, Issued: 10-13-17)*

#### Transmittals for Chapter 3

*3.9.1 – Election of Status*

*3.9.2 – Coordination of the ALJ Hearing*

### **3.9 - Defending Medical Review Decisions at Administrative Law Judge (ALJ) Hearings**

*(Rev. 748, Issued: 10-13-17; Effective: 11-14-17; Implementation: 11-14-17)*

This section in its entirety applies to MACs. This section applies to Recovery Auditors, CERT, ZPICs/UPICs, and the SMRC as indicated in their SOWs.

#### **Overview:**

*Effective March 20, 2017 several changes were made to the regulations that outline the activities related to contractor participation in ALJ hearings. Under the new regulations, CMS contractors are limited to 3 roles in an ALJ hearing: a Participant, a Party, or a Witness (defined in detail below). These changes are outlined in 42 CFR §405.1010 and 42 CFR §405.1012.*

*A physician overseeing participation shall be a current Contractor Medical Director (CMD), a contractor employed physician or any combination thereof. Nurses and other staff may assist the physician with the tasks described in this section. While the physician is generally the primary individual overseeing and/or taking party or participant status, a contractor may elect to have an attorney or clinician take party or participant status, or another experienced qualified individual if approved by their COR. In either situation, the contractor must be prepared to discuss details related to the facts of each claim under appeal, the relevant coverage policies and payment requirements, including any clarification required on decisions made earlier in the appeals process. For post-pay audit/overpayment cases, the contractor must be prepared to discuss the background on how the provider/supplier was selected for review, results of the sample case adjudications, as well as matters related to the extrapolation methodology and/or processes.*

*This section establishes expectations related to the contractor's participation and associated coordination activities, although CMS may provide additional guidance and direction as needed. Further rules and procedures related to the ALJ hearing process are contained in 42 CFR §405.1000.*

*The MAC shall capture and report the ALJ participation and party data in their monthly status report to CMS. Contractors shall record the frequency of their support as a witness in the narrative field of the monthly status reports. Contractors shall ensure that JOAs are sufficient to support the ALJ hearing process and related coordination activities.*

#### **Role of the Participant:**

*In accordance with the revised regulation under 42 CFR Part §405.1010(c) and (d), all contractors' participation as a participant (i.e., non-party) shall be limited to submitting written testimony and/or position papers (except in those instances when non-party participants are able to provide testimony to clarify factual or policy issues in the case—as noted in the scenario below).*

*The regulations do not prohibit multiple CMS contractors and/or related entities from participating in the ALJ hearing as a participant. However, if no contractor or CMS invokes party status, then the first entity to submit their election to participate as a non-party participant to the ALJ may participate in the oral hearing (limited to clarification of factual or policy issues, as requested by the ALJ). All other entities may participate, but are precluded from the hearing and may only submit written testimony and/or position papers as indicated in 42 CFR §405.1010(d)(1) and (2). If the contractor is able to participate in the hearing, they shall be adequately prepared to respond to questioning by the ALJ regarding all issues related to the claims under appeal. Because participation status does not include the same rights as full party status, the contractor may not call witnesses or cross-examine witnesses of another party, as indicated in 42 CFR §405.1010(c)(1).*

*(Note: At this time, CMS would not expect contractors to be responsible for clarifying factual or policy issues for cases/claims outside of their jurisdiction.)*

### ***Role of the Party:***

*Contractors shall invoke party status in ALJ hearings in accordance with the regulatory provisions in 42 CFR § 405.1012 and the CMS-prescribed QIC prioritization process, described below, for cases or items/services of interest to CMS. Under 42 CFR §405.1012(d)(1), the first contractor to invoke party status with the ALJ is made the party to the hearing. All other contractors who invoke party status for that particular hearing are made participants and are precluded from the hearing (See Role of the Participant section above).*

*Note: At this time, CMS would not expect contractors to be responsible for representing cases/claims outside of their jurisdiction.)*

*If the contractor is interested in a particular case, but is precluded from invoking party status based on the CMS-prescribed QIC prioritization of cases or otherwise, the contractor may request 'leave' from the ALJ in accordance with 42 CFR §405.1012(d)(2). In submitting a request for 'leave' to the ALJ, the contractor is formally requesting that the ALJ grant the contractor the right to be a secondary party to the hearing. Requests for 'leave' to the ALJ shall also include the reason(s) why the contractor believes that their presence as a secondary party in the ALJ Hearing is necessary. The ALJ shall make the determination as to whether or not the contractor is granted 'leave.' If this is approved, the contractor shall become a secondary party to the hearing. Alternatively, the contractor may participate as a witness, based on the circumstance. (See Role of Witness section for additional information).*

*As a party, the contractor is able to orally participate in the hearing and may file position papers, call witnesses, and/or cross-examine witnesses of other parties. The contractor shall submit any position paper or additional evidence requested by the ALJ in accordance with 42 CFR §405.1012(c)(2)(i) and (ii). The contractor shall be adequately prepared to respond to questioning by the ALJ or other parties regarding all issues related to the claims under appeal. As a party to the hearing, contractors are subject to discovery by the other party to the hearing in accordance with 42 CFR §405.1037.*

*For Notice of Hearings (NOHs) received that include issues deemed significant by CMS or the contractor, the contractor shall, at a minimum:*

- Invoke party status in ALJ cases per volume of ALJ cases funded for this activity;*
- Participate in any pre-ALJ hearing conference calls, as needed, with other contractors (as facilitated by the appropriate QIC);*
- Coordinate with Medical Director(s) or related personnel from other contractors intending to participate as consultants/expert witnesses, as necessary, in accordance with 42 CFR §405.1010(d)(3). In addition, the MAC shall coordinate with other contractors for those hearings in which they do not invoke party status, but decide to participate as a consultant/expert witness; and/or,*
- Participate in the hearings as a party via telephone, video conferencing, or in-person.*

### ***Role of the Witness:***

*If the ALJ declines the request for contractor 'leave' on a particular hearing, the contractor may be called as a 'witness' by CMS or another CMS contractor that is a party to the hearing. A determination regarding the need for a 'witness' by the participating party shall be determined by the party and communicated to the contractor prior to the hearing. Contractors should, at their discretion, participate as a 'witness' in any case in which another CMS contractor and/or CMS has requested their support in a hearing. Contractors shall notify the requesting party no later than 10 days prior to the scheduled hearing in those instances in which contractors are unable to support the hearing as a 'witness.' As a 'witness,' contractors shall be*

*tasked with supporting the party to the hearing in responding to policy or factual issues related to a particular case through direct examination and is subject to cross examination by the opposing party.*

### **3.9.1-- Election of Status**

*(Rev. 748, Issued: 10-13-17; Effective: 11-14-17; Implementation: 11-14-17)*

*The contractor shall establish a process for assessing the notices of hearing received to determine which cases should be selected for participation, as well as the type of participation (participant, party, or witness) to be employed. Factors to be examined should include, but not be limited to: originator of initial denial, policy implications, dollars at issue, program integrity matters, and the extent to which a particular issue is, or has been, a recurring issue at the ALJ level of appeal.*

*Contractors shall, for those cases in which they were the medical reviewer issuing the denial subject to appeal, have a prioritized ability to invoke party status (in lieu of other appeals support contractors). Contractors who did not perform the original review and denial shall only invoke party status after confirmation that the entity that initially denied the claim does not wish to invoke party status. This process is further described below.*

#### **A. Election of Participation Status Prior to Receipt of a Formal NOH:**

*The election to participate as a participant shall be made consistent with 42 CFR §405.1010 and can be done either prior to receipt of a formal NOH or after the receipt of a formal NOH.*

*The regulations allow CMS contractors to elect to participate as a participant before issuance and/or receipt of the formal NOH. If no hearing is scheduled, a contractor must send its notice of intent to participate no later than 30 calendar days after notification that a request for hearing was filed. See section of 42 CFR §405.1010(b)(1) for additional information. If the contractor elects to participate before the receipt of the NOH, it shall send written notice of its intent to the assigned ALJ or attorney adjudicator, or the designee of the Chief ALJ, if no contact assigned yet, and to all parties on the reconsideration (per the prescribed OMHA process) within 30 calendar days after notification that a request for hearing had been filed. In accordance with the regulations, a position paper or written testimony must either be submitted within 14 calendar days of an election to participate, if no hearing has been scheduled, or no later than 5 calendar days prior to the hearing, if a hearing is scheduled, unless the ALJ grants additional time to submit the position paper or written testimony.*

#### **B. Election of Participation or Party Status Following Receipt of the Formal NOH**

*The election to be a participant or a party to a hearing after receipt of the formal NOH shall be made consistent with 42 CFR §405.1010(b) or 42 CFR §405.1012, respectively, and the CMS-prescribed QIC prioritization process, described below. If through the CMS-prescribed QIC Prioritization process it is determined that the contractor may act as either the party or a participant to a hearing, elections of participation must be sent by the Contractor within 10 calendar days of receipt of the NOH at the QIC to all parties listed on the NOH. Submission of a position paper, written testimony, and/or evidence must be submitted no later than five calendar days before the date of the scheduled hearing. Copies of these items must also be sent to those parties listed on the NOH in accordance with 42 CFR §405.1010(c)(3)(ii) and 42 CFR §405.1012(c)(2)(ii).*

#### **C. CMS-prescribed QIC Prioritization Process and Providing a Response to the Formal NOH:**

*Upon receipt of the formal NOH, the QIC will send written notice to the appropriate CMS contractors (e.g., DME MAC, A/B MAC, ZPIC/UPIC, SMRC and/or RACs) involved with the claim denial and/or redetermination. The QIC will send the NOH to the contractors within 2 calendar days of receipt of the notice. This communication shall occur via secure electronic notice.*

The CMS Contractor Participation form, a form generated to express contractor interest and assist the QIC with the prioritization process, shall be distributed with the formal NOH. Contractors shall use this form to indicate their interest in a particular ALJ hearing and any supporting discussion. Contractors shall provide the completed participation form to the QIC within 2 calendar days of receipt (or next applicable business day). NOTE: The QIC will consider non-responses by contractors, within the prescribed timeframe, an indication that the respective contractor(s) does not wish to participate in the respective hearing.

The QIC will review all Contractor Participation forms received and utilize the prioritization guidelines below to determine which entity shall have the primary opportunity to participate as a 'party' and which entities can participate as 'participants' or 'witnesses.'

The anticipated prioritization for the role of party status is as follows:

- 1) Primary opportunity for the 'party' role in an ALJ hearing will be granted to the entity that conducted the initial claim denial (e.g., ZPIC/UPIC, RAC, SMRC or medical review unit within the MAC).
- 2) If the entity that issued the initial claim denial does not have interest in participating as a party (due to workload considerations or otherwise) the QIC will have the primary opportunity to participate as a party.
- 3) If no CMS contractors and/or CMS wish to invoke 'party' status in a hearing and multiple entities wish to be a participant, the primary participant shall be the entity that conducted the initial claim denial (e.g., ZPIC/UPIC, RAC, SMRC, or medical review unit within the MAC).
- 4) If the entity that identified/conducted the initial claim denial does not wish to be the 'primary' participant on the case, the QIC will have the next opportunity to assume this role.

The QIC will complete the review and prioritization of the roles in a respective ALJ hearing (i.e., which contractor shall be the 'party', 'participants,' etc.), and notify all related contractors, via secure email, regarding the determination of roles within 2 calendar days of receipt of the Contractor Participation forms. On rare occasion, the QIC may need to facilitate a call with the CMS and the related contractors to determine the roles and/or responsibilities on a particular hearing.

Within 1 calendar day (or the next applicable business day) of receipt of the QIC's notice of the prioritization of participation/party status on an ALJ hearing, contractors shall reply to the OMHA/the formal NOH with their formal notice of election. Contractors have 10 calendar days from the date that the QIC originally received the NOH to provide the ALJ with notice of their intent to participate. The acknowledgement notice shall be sent to the ALJ, the appellant, and all other parties identified in the NOH.

Note: NOHs/participation forms received after standard business hours (e.g. 4:30 p.m.) and/or during weekends or business holidays, as defined by the respective entity, will be considered as being received on the next applicable business day (e.g., if the QIC receives the formal NOH on a Friday at 4:30 pm, the 2 calendar day timeframe begins on Monday).

The ALJ sets the hearing date, time, and method by video teleconferencing (VTC), telephone, or in-person if VTC is not available or special circumstances exist. A party may object in writing to the time and place of the hearing, as soon as possible before the originally scheduled time, and include the reason for the objection along with a proposed alternative date and time. In addition, a party may request an in-person hearing by notifying the ALJ in writing and following the same procedures noted above for an objection to the time/place of the hearing. The ALJ may reschedule if good cause is established per 42 CFR §405.1020(f) or (g).

### **3.9.2—Coordination of the ALJ Hearing**

(Rev. 748, Issued: 10-13-17; Effective: 11-14-17; Implementation: 11-14-17)



*As needed, if multiple entities are participating in a hearing as a party, participant, or witness, the QIC will set up a brief pre-hearing conference call to discuss the respective entity's participation in the case, roles and responsibilities, etc. Examples in which this may be necessary include high dollar cases, extrapolated overpayments, policy implications, and/or fraud related cases, etc.*

*Pre-hearing briefing topics may include: coordination with OMHA on scheduling matters, the manner of participation, coordination on position papers or other written testimony submitted, and lessons learned from participation in the ALJ process.*

*There may be cases in which testimony from another contractor is necessary. The contractor may call those entities as a witness only if the contractor has declared party status. However, if the contractor submits a position paper as a participant, the contractor may collaborate with other contractors and document their views on the case in the paper—although only one contractor may typically participate via the hearing.*

*The contractor shall establish a single point of contact for ALJ offices on administrative matters involving notifications, scheduling, information sharing, and other coordination necessary between the ALJ, the appellant, and other contractors.*