CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-08 Medicare Program Integrity	Centers for Medicare & Medicaid Services (CMS)
Transmittal 543	Date: September 26, 2014
	Change Request 8501

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

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to instruct the Medicare Administrative Contractors to support their medical review decisions through the ALJ level of appeal, whether by taking participant or party status at the hearings, as well as to coordinate with the Qualified Independent Contractors (QICs) to receive the notice of hearing.

EFFECTIVE DATE: October 27, 2014

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

IMPLEMENTATION DATE: October 27, 2014

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.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	3/Table of Contents
N	3/3.9 Defending Medical Review Decisions at Administrative Law Judge (ALJ) Hearings
N	3/3.9.1 Collaboration
N	3/3.9.2 Participation in the ALJ Hearing
N	3/3.9.3 Party in the ALJ Hearing
N	3/3.9.4 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 obliged 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

Pub. 100-08 Transmittal: 543 Date: September 26, 2014 Change Request: 8501

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EFFECTIVE DATE: October 27, 2014

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I. GENERAL INFORMATION

- A. Background: Medicare Administrative Contractors (MACs), Recovery Auditors, Zone Program Integrity Contractors (ZPICs), the Comprehensive Error Rate Testing (CERT) contractor, and the Supplemental Medical Review Contractor (SMRC) conduct reviews in accordance with CMS instructions and apply the statute, regulations, rulings, national coverage determinations, local coverage determinations, and CMS manuals to guide their decisions. A significant time and effort is spent by CMS and its contractors to ensure that review staff are making quality decisions. It is important for contractors to support and defend their medical review decisions throughout the appeals process, including at Administrative Law Judge (ALJ) hearings. This CR instructs the MACs, Recovery Auditors, ZPICs, CERT, and the SMRC on how they should coordinate with the Qualified Independent Contractor (QIC) to receive the notice of hearing, the differences between being a participant and taking party status in a hearing, and other general information about the hearing process.
- **B. Policy:** Medicare Review Authorities are found in the Social Security Act.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility								
			A/E MA(D M E	,	Sys	red- tem aine		Other
		A	В	H H H		F I S S	M C S	V M S	C W F	
8501.1	The MAC shall assign a physician to participate or take party status at Administrative Law Judge (ALJ) hearings, and oversee the ALJ hearing support process established in this section. This applies only to their own claim determinations or claim determinations over which they have responsibility.	X	X	X	X					
8501.1.1	The MAC should participate only in a supporting role for claims that are reviewed by other entities.	X	X	X	X					
8501.1.2	Physicians with oversight of the ALJ hearings process shall be a current CMD, a MAC 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	X	X	X	X					

Number	mber Requirement Responsibility									
			А/В ИА(D M E		Sha Sys	tem		Other
		A	В	H H H	M A C	F	M C S		С	
	generally the primary individual overseeing and/or taking party/participant status, a contractor may elect to have an attorney or clinician take party or participant status, or another qualified individual if approved by the COR.									
8501.1.3	The MAC shall establish a process for assessing the notices of hearing received to determine which cases should be selected for participation at the ALJ level of appeal.	X	X	X	X					
8501.1.3.1	Factors to be examined should include, but not be limited to policy implications, dollars at issue, source of the denial, program integrity matters, and the extent to which a particular issue is, or has been, a recurring issue at the ALJ level of appeal.	X	X	X	X					
8501.1.4	MACs should be proactive in evaluating potential participation cases, and redetermination cases that are expected to continue through to an ALJ hearing and in some cases, should prepare a letter to include in the case file to indicate that they intend on participating if the case goes to a hearing.	X	X	X	X					
8501.2	The MACs shall capture and report the ALJ participation and party data in their monthly status report to CMS.	X	X	X	X					
8501.3	The MAC shall coordinate with the QIC to ensure timely notification of all ALJ hearings, as the election to participate as a party or participant must be made no later than 10 days after receipt of the notice of hearing by the QIC.	X	X	X	X					
8501.3.1	The MAC shall add procedural details involved with the coordination of representation at ALJ hearings into the existing joint operating agreement with the QIC.	X	X	X	X					
8501.3.2	Since the QIC may also elect to participate in the ALJ hearing process, the MAC shall also collaborate with the QIC regarding 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.	X	X	X	X					

Number Requirement Responsibility																					
1,000			A/B		D	ľ	Sha	red-		Other											
		N	MAC		MAC M				Sys	tem											
					E			E			E				E			aint			
		Α	В	Н		F	M	V	С												
				Н	M	I	C	M	W												
				Н	A	S	S	S	F												
					C	S															
8501.4	MACs should obtain all relevant case file	X	X	X	X																
	information, including information from other																				
	MACs regarding the claims at issue, when electing to participate in the hearing as a participant or as a																				
	party.																				
	party.																				
8501.4.1	There may be cases in which testimony from	X	X	X	X																
	another contractor is necessary. The MAC should																				
	call those entities as a witness only if the MAC has																				
	declared party status.																				
0501.4.2	TO 1 MAC 1 11	37	37	37	37																
8501.4.2	If the MAC submits a position paper as a	X	X	X	X																
	participant, the MAC should collaborate with other contractors and document their views on the case in																				
	the paper.																				
	the paper.																				
8501.5	The MAC shall establish a single point of contact	X	X	X	X																
	for ALJ offices on administrative matters involving																				
	notifications, scheduling, information sharing, and																				
	other coordination necessary between the ALJ, the																				
	appellant, and other MACs.																				
8501.5.1	The MAC shall provide contact information and	X	X	X	X																
0301.3.1	updates to the AdQIC for dissemination to CMS,	1	21	1	71																
	OMHA Headquarters, and OMHA ALJ field																				
	offices.																				
8501.5.2	The MAC shall copy all other relevant CMS	X	X	X	X																
	entities and parties to the hearing (i.e., Recovery																				
	Auditor, ZPIC, QIC) when sending their response																				
	to the notice of hearing.																				
8501.6	If multiple CMS entities intend to participate and	X	X	X	X																
	the QIC is not participating, the MAC shall																				
	coordinate the roles and responsibilities of the																				
	participants.																				
0501.5																					
8501.7	The MAC shall make the election to participate in	X	X	X	X																
	the hearing consistent with the rules at 42 CFR 405.1010.																				
	100.1010.																				
8501.7.1	The MAC shall provide such notice of their intent	X	X	X	X																
	to participate as a party or a participant in writing to																				
	the ALJ, appellant, and all parties identified, within																				
	10 calendar days of receipt of the notice of hearing																				
	(by the QIC).																				

Number Requirement Responsibility												
		A/B			D		Sha			Other		
		N	ИA	С	M E	•						
		A						F	M		C	
		11		Н	M		C	M	_			
				Н	A C	S S	S	S	F			
8501.8	The MAC shall be adequately prepared to respond to questioning by the ALJ (and by the appellant if the contractor is willing) regarding all issues related to the claims under appeal.	X	X	X	X							
8501.9	The MAC shall coordinate with other contractors in advance to solicit their participation should testimony from the other contractors be necessary.	X	X	X	X							
8501.10	The MAC shall obtain approval from CMS prior to electing party status in an ALJ hearing and advising the ALJ and other parties of the intention to participate as a party	X	X	X	X							
8501.11	The MAC shall make the election for party status consistent with the rules at 42 CFR 405.1012.	X	X	X	X							
8501.12	The MAC shall submit any position paper or additional evidence requested by the ALJ within timeframes established by the ALJ, and provide copies of any written statements to the other parties to the hearing at the same time they are submitted to the ALJ.	X	X	X	X							
8501.13	The MAC shall actively participate in the ALJ hearing as appropriate based on participation status (participant or party).	X	X	X	X							
8501.13.1	In either situation, the MAC shall 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.	X	X	X	X							
8501.14	For extrapolation cases, the MAC shall 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 process.	X	X	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility

		A/B MA(D	С
	1	MAC	\mathbb{C}	M	Е
				Е	D
	Α	В	Н		I
			Н	M	
			Н	Α	
				C	
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): Amy Cinquegrani, 410-786-8627 or amy.cinquegrani@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR) or Contractor Manager, as applicable.

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

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(Rev.543, Issued: 09-26-14)

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3.9.2 - Participation in the ALJ Hearing

3.9.3 - Party in the ALJ Hearing

3.9.4 - The ALJ Hearing

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

(Rev.543, Issued: 09-26-14, Effective: 10-27-14, Implementation: 10-27-14)

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

The MAC shall assign a physician to participate or take party status at Administrative Law Judge (ALJ) hearings, and oversee the ALJ hearing support process established in this section. This applies only to their own claim determinations or claim determinations over which they have responsibility. For claims that are reviewed by other entities, the MAC should participate only in a supporting role. Further rules and procedures related to the ALJ hearing process begin at 42 CFR 405.1000. Physicians overseeing and/or taking party or participant status shall be a current CMD, a MAC employed physician or any combination thereof.

The MAC shall establish a process for assessing the notices of hearing received to determine which cases should be selected for participation at the ALJ level of appeal. Factors to be examined should include, but not be limited to policy implications, dollars at issue, source of the denial, program integrity matters, and the extent to which a particular issue is, or has been, a recurring issue at the ALJ level of appeal. MACs should be proactive in evaluating potential participation cases and redetermination cases that are expected to continue through to an ALJ hearing and, in some cases, should prepare a letter to include in the case file to indicate that they intend on participating if the case goes to a hearing.

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/participant status, a contractor may elect to have an attorney or clinician take party or participant status, or another qualified individual if approved by the COR.

The MACs shall capture and report the ALJ participation and party data in their monthly status report to CMS.

3.9.1 - Collaboration

(Rev. 543, Issued: 09-26-14, Effective: 10-27-14, Implementation: 10-27-14)

A notice of an ALJ hearing issued by Office of Medicare Hearings and Appeals (OMHA) will be sent to the appropriate QIC. The MAC shall coordinate with the QIC to ensure timely notification of all ALJ hearings, as the election to participate must be made no later than 10 calendar days after QIC receipt of the notice of hearing. The MAC shall add procedural details involved with the coordination of representation at ALJ hearings into the existing joint operating agreement with the QIC.

Since the QIC may also elect to participate in the ALJ hearing process, the MAC shall also collaborate with the QIC regarding 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. MACs should obtain all relevant case file information, including information from other MACs regarding the claims at issue, when electing to participate in the hearing as a participant or as a party. There may be cases in which testimony from another contractor is necessary. The MAC should call those entities as a witness only if the MAC has declared party status. However, if the MAC submits a position paper as a participant, the MAC should collaborate with other contractors and document their views on the case in the paper.

The MAC 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 MACs. The MAC shall provide contact information and updates to the AdQIC for dissemination to CMS, OMHA Headquarters, and OMHA ALJ field offices.

The MAC shall copy all other relevant CMS entities and parties to the hearing (i.e., Recovery Auditor, ZPIC, QIC) when sending their response to the notice of hearing. If multiple CMS entities intend to participate and the QIC is not participating, the MAC shall coordinate the roles and responsibilities of the participants.

3.9.2 - Participation in the ALJ Hearing

(Rev. 543, Issued: 09-26-14, Effective: 10-27-14, Implementation: 10-27-14)

The MAC shall make the election to participate in the hearing consistent with the rules at 42 CFR 405.1010, and shall provide such notice in writing to the ALJ, appellant, and all parties identified, within 10 calendar days of receipt of the notice of hearing (by the QIC). Participation may include filing position papers and providing testimony to clarify factual and policy issues involved in a case. The MAC shall be adequately prepared to respond to questioning by the ALJ (and by the appellant if the contractor is willing) regarding all issues related to the claims under appeal.

Because participation status does not include the same rights as full party status, the MAC may not call witnesses, or cross-examine witnesses, of another party. The MAC shall coordinate with other contractors in advance to solicit their participation should testimony from the other contractors be necessary.

3.9.3 - Party in the ALJ Hearing

(Rev. 543, Issued: 09-26-14, Effective: 10-27-14, Implementation: 10-27-14)

The MAC shall obtain approval from CMS prior to electing party status in an ALJ hearing. High priority will be given to cases involving program integrity matters and/or overpayment cases involving significant dollar amounts. The MAC shall obtain approval from CMS prior to advising the ALJ and other parties of the intention to participate as a party. In the event that CMS does not approve the MAC's request for party status, the MAC may elect to proceed as a participant.

The MAC shall make the election for party status consistent with the rules at 42 CFR 405.1012, and shall provide such notice in writing to the ALJ, appellant, and all parties identified, within 10 calendar days of receipt of the notice of hearing (by the QIC). As a party, the MAC can file position papers, call witnesses, and/or cross-examine witnesses of other parties, and/or request discovery, subject to the limitations of 42 CFR 405.1037(b). The MAC shall submit any position paper or additional evidence requested by the ALJ within timeframes established by the ALJ, and provide copies of any written statements to the other parties to the hearing at the same time they are submitted to the ALJ. The MAC shall be adequately prepared to respond to questioning by the ALJ or other parties regarding all issues related to the claims under appeal.

3.9.4 The ALJ Hearing

(Rev. 543, Issued: 09-26-14, Effective: 10-27-14, Implementation: 10-27-14)

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.

Notice of the hearing will be sent to all parties and to the QIC. If the MAC intends to be either a participant or a party, the MAC shall send the acknowledgement notice to the ALJ, the appellant, and all other parties identified in the notice of hearing within 10 calendar days of the date that the QIC received the notice of

hearing. 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).

The MAC shall actively participate in the ALJ hearing as appropriate based on participation status (participant or party). In either situation, the MAC shall 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 extrapolation cases, the MAC shall 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 process.