# Chapter I-6 CMS and CMS Contractor Roles

## **Table of Contents**

Section	Title
I-6-1	CMS Contractors and Related Entities
I-6-2	CMS and CMS Contractor Involvement in ALJ Hearings—In General
I-6-3	Role of CMS and CMS Contractors in ALJ Hearings

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### I-6-1 CMS Contractors and Related Entities

**NOTE:** CMS contractors described in the regulations at 42 C.F.R. Part 422, Subpart M and Part 423, Subparts M and U as Independent Review Entities (IREs) or Independent Outside Entities are commonly referred to as Part C QICs or Part D QICs. Usage of these terms has also been adopted in this manual.

**NOTE:** For purposes of the chart below and provisions of this manual regarding CMS and CMS contractor participation, entities that contract with CMS to administer benefits under Medicare Part C and Part D (MAOs and Part D plan sponsors, respectively) are included in the definition of CMS contractors.

CMS contractors administer program benefits, identify and prevent improper payments, protect beneficiaries and their due process rights, and/or conduct lower-level appeals. The following table lists the various types of CMS contractors, the types of appeals they review, a general summary of the contractor's responsibility, and provides a resource to obtain additional information, including the names of the current contractors.

Contractor Type	Appeal Type	Responsibilities	Website
Medicare Administrative Contractor (MAC)	Parts A & B	Processes claims submitted under Medicare Parts A and B. This includes identifying and correcting underpayments and overpayments and effectuating Medically Unlikely Edits (MUEs) and conducting the initial determination and redetermination (except in Part A inpatient claims denied by a Quality Improvement Organization (QIO)).	<u>CMS Medicare</u> <u>Administrative</u> <u>Contractors</u> <u>website</u>
Zone Program Integrity Contractor (ZPIC).	Parts A & B	Replaces Program Safeguard Contractor (PSC). Identifies and develops cases of suspected fraud, waste, and abuse; makes referrals to law enforcement; and takes appropriate administrative corrective actions.	<u>CMS CPI website</u>

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Supplemental Medical Review Contractor (SMRC)	Parts A & B	Conducts medical review as directed by CMS and provides support for a variety of tasks aimed at lowering the improper payment rates and increasing efficiencies of the medical review functions CMS.	<u>CMS SMRC</u> <u>website</u>
Comprehensive Error Rate Testing (CERT) Contractor	Parts A & B	Collects documentation and performs reviews on statistically-valid random samples of Medicare Fee-For-Service (FFS) claims to produce an annual improper payment rate.	<u>CMS CERT</u> <u>website</u>
Recovery Auditor	Parts A & B*	Identifies and recovers Parts A and B overpayments and identifies underpayments, as part of the Recovery Audit Program.	<u>Recovery Audit</u> <u>Program</u>
Benefits Coordination and Recovery Center (BCRC)	Parts A & B	Consolidates functions previously performed by the Medicare Secondary Recovery Contractor (MSPRC) and the Coordination of Benefits Contractor (COBC). The BCRC initiates Medicare Secondary Payer (MSP) claim recoveries from beneficiaries.	<u>CMS</u> <u>Coordination of</u> <u>Benefits and</u> <u>Recovery</u> ( <u>COB&amp;R</u> ) <u>website</u> .
Qualified Independent Contractor (QIC)	Parts A & B	Responsible for conducting the second-level appeal (reconsideration) and expedited reconsiderations for FFS appeals. There are 5 QICs that perform reconsiderations, as well as 1 administrative QIC (AdQIC) that performs various program support functions.	<u>Review</u> <u>Contractor</u> <u>Directory</u>

Quality	<b>D</b> · · · -	010 activities are performed under	CMC Quality
Quality	Parts A, B	QIO activities are performed under	CMS Quality
Improvement	& C	two separate contract types.	Improvement
Organization		Beneficiary and Family Centered Care	Organizations
(QIO)		(BFCC)-QIOs are responsible for case	<u>website</u>
		review to evaluate medical necessity	
		and appropriateness of services and	
		setting. All BFCC-QIO appeals of claim	
		denials, hospital discharge reviews,	
		and provider service terminations that	
		reach OMHA have undergone review	
		by a BFCC-QIO. Quality Innovation	
		Network (QIN)-QIOs provide a vast	
		range of quality improvement services	
		across the spectrum of the health care	
		delivery system; however, QIN-QIO	
		activities do not result in appeals	
		subject to the Medicare claims and	
		coverage appeals process.	
Medicare	Part C	Private companies contract with	Medicare
Advantage	Part C	Medicare to provide enrollees with	
Organization		their Part A and Part B benefits.	Advantage
Organization			<u>Website</u>
		Medicare Advantage Organizations	
		(MAOs) may also provide	
		supplemental benefits for items and	
		services not generally covered under	
		Original (Fee-For-Service) Medicare,	
		subject to the provisions of the plan's	
		evidence of coverage (EOC). The MAO	
		is also responsible for conducting first-	
		level appeals and forwarding	
		unfavorable determinations to the Part	
		C Independent Review Entity (IRE) for	
		reconsideration.	
Independent	Parts C &	Performs level 2 reconsiderations and	Reconsideration
Review Entity	D	expedited reconsiderations in Part C	by Part C
		and D appeals. The Part C and D IREs	Independent
		are also commonly referred to as Part	Review Entity

		C QICs or Part D QICs.	(Part C QIC) <u>Reconsideration</u> <u>by the</u> <u>Independent</u> <u>Review Entity</u> (Part D)
Part D Plan Sponsor	Part D	Private companies contract with Medicare to provide Part D prescription drug benefits for enrollees. Stand-alone prescription drug plans and Medicare Advantage plans that offer Part D coverage (MA- PDs) conducts the first level of appeal.	<u>PDP Plan</u> <u>Directory</u>

\*The concept of Recovery Auditing in Parts C and D is distinct from the role of a Recovery Auditor in Part A and Part B claim appeals. In Parts C and D, the focus of recovery is improper payments made by Medicare to the MAO or Part D plan sponsor, not payments made to providers or enrollees. Part C and D Recovery Audit determinations are not subject to the appeals processes in <u>42 C.F.R. Part 422</u>, <u>Subpart M</u> or <u>Part 423 Subparts M</u> and <u>U</u>; therefore, Part C and Part D Recovery Auditors are not parties to an ALJ hearing. In addition, Part C MAOs may subcontract post-payment review and auditing functions to an entity that also holds a Part A/B Recovery Audit contract. In these circumstances, the work performed by the entity is distinct from the work performed under its Part A/B contract with CMS.

## I-6-2 CMS and CMS Contractor Involvement in ALJ Hearings—In General

**Citations:** §§ 405.904, 405.1010, 405.1012, 405.1020, 405.1024, 405.1036, 405.1040, 405.1042, 405.1044, 405.1046, 405.1052, 405.1102, 405.1104, 422.562, 422.602, 423.2010, 423.2020, 423.2024, 423.2040, 405.2042, 423.2044, 478.40(c); 20 C.F.R. §§ 404.908, 404.921, 418.1350, 418.2350

Subject to the provisions and limitations set forth below, CMS or its contractors may elect or request to join, or be requested to join, a hearing as a party or as a non-party participant. In Part C appeals, the MAO is always a party to the hearing.

**NOTE:** The Social Security Administration (SSA) makes initial determinations and reconsiderations on applications for Medicare benefits, entitlement of an individual to receive Medicare benefits, Income Related Monthly Adjustment Amounts (IRMAAs), and Part B late enrolment penalties. Only beneficiaries/applicants and (for non-IRMAA appeals) persons whose rights are adversely affected are entitled to request an ALJ hearing. § 405.904(a); 20 C.F.R. §§ 404.908(b), 404.921(a), 418.1350, 418.2350. CMS and SSA are not parties or non-party participants to these appeals.

#### A. Party Status

#### 1. Definition.

"Party," in the context of CMS and CMS contractor involvement in ALJ hearings, refers to CMS or a CMS contractor that elects party status under § 405.1012, and also refers to the MAO in Part C appeals, which is always a party to the hearing. § 422.602.

#### 2. Rights.

Generally, when CMS or its contractors join an ALJ hearing as a party, they have the same rights and responsibilities as any other party to the hearing. However, rights that extend only to the appellant, and not to other parties, (for example, the option to escalate an appeal from the ALJ to the Council in appeals of Part A and Part B QIC reconsiderations) do not extend to CMS or its contractors. §§ 405.1102, 405.1104; 67 Fed. Reg. 69312, 69329 (Nov. 15, 2002).

#### **B. Non-Party Participant Status**

#### 1. Definition.

"Non-party participant" means CMS or a CMS contractor who joins a hearing as a participant under § 405.1010 or § 423.2010.

A non-party participant's scope of participation in an ALJ hearing includes filing position papers and providing testimony to clarify factual or policy issues, but it does not include calling witnesses or cross-examining the witnesses of a party to the hearing. §§ 405.1010, 423.2010(d).

#### 2. Provisions that do not apply to non-party participants.

In addition to the limitations described above, certain rights set forth in 42 C.F.R. Part 405, Subpart I specifically apply only to parties, and to the extent equivalent rights exist in Part 423, Subpart U, they apply only to enrollees. Therefore, when CMS or a CMS contractor has joined a hearing as a non-party participant, CMS or the CMS contractor is not entitled to:

- Object to the time, place, or method of hearing under § 405.1020(e) or § 423.2020(e);
- Object to the issues described in the notice of hearing under § 405.1024 or § 423.2024;
- Request a subpoena § 405.1036(f);
- Participate in, or receive notice of, a prehearing or post-hearing conference under § 405.1040 or § 423.2040;
- Obtain a copy of the administrative record under § 405.1042 or § 405.2042; or
- Receive notice of the ALJ's decision under §§ 405.1046, unless the non-party participant is the QIC or the entity that made the initial determination, or notice of the ALJ's dismissal under § 405.1052(b).

**NOTE:** For Part D appeals, a copy of the ALJ's decision must be sent to both the Part D QIC and the Part D plan sponsor under § 423.2046(a)(4). However, it is not necessary to send a copy of a dismissal of the request for hearing to the Part D QIC or the Part D plan sponsor. § 423.2052(b).

#### C. Notice of Consolidated Hearings

1. Before consolidating a hearing, the ALJ must notify CMS of his or her intention to do so. CMS may then elect to join the consolidated hearing as a party (for a Part A or Part B consolidated hearing) or as a non-party participant (for a Part D consolidated hearing) by sending written notice to the ALJ within the time frames specified in §§ 405.1044(d) and 423.2044(d). The ALJ's notification of the intent to consolidate and the corresponding election by CMS may be incorporated into the Notice of Hearing and response to the Notice of Hearing, respectively, or may be by separate written instrument.

### I-6-3 Role of CMS and CMS Contractors in ALJ Hearings

**Citations:** §§ 405.904, 405.1028, 405.1010, 405.1012, 405.1018, 405.1022, § 405.1028, 405.1036, 405.1042, 405.1037, 422.562, 422.600, 422.602, §§ 423.2000, 423.2008, 423.2010, 423.2018, 423.2020, 423.2036, 423.2042, 478.40(c); 20 C.F.R. §§ 418.1350, 418.2350; 20 C.F.R. §§ 404.908, 404.921, 418.1350, 418.2350

**NOTE:** The Social Security Administration (SSA) makes initial determinations and reconsiderations on applications for Medicare benefits, entitlement of an individual to receive Medicare benefits, Income Related Monthly Adjustment Amounts (IRMAAs), and Part B late enrolment penalties. Only beneficiaries/applicants and (for non-IRMAA appeals) persons whose rights are adversely affected are entitled to request an ALJ hearing. § 405.904(a); 20 C.F.R. §§ 404.908(b), 404.921(a), 418.1350, 418.2350. CMS and SSA are not parties or non-party participants to these appeals.

#### A. Types of Involvement Permitted

- 1. When CMS or its contractors may be a party.
  - a. Part A or B Appeals.
    - i. Non-QIO appeals.

CMS or a CMS contractor (other than a ZPIC or a PSC) may join any hearing as a party, unless the request for hearing was filed by an unrepresented beneficiary. § 405.1012. ZPICs and PSCs are only permitted to join ALJ hearings as a non-party participant. CMS, *Medicare Program Integrity Manual (MPIM) (Internet-Only Manual Publ'n 100-08*), ch. 4, § 4.8.2 (June 13, 2008).

#### ii. QIO appeals.

A QIO may join any hearing as a party, unless the request for hearing was filed by an unrepresented beneficiary. § 405.1012.

#### b. Part C Appeals.

The Medicare Advantage Organization (MAO) is always a party to a Part C hearing. § 422.602.

#### c. Part D Appeals.

Only the enrollee (or the enrollee's representative) may be a party to an ALJ hearing § 423.2008. Therefore, CMS, the Part D QIC, or the Part D plan sponsor may not elect party status and may not be requested to join the hearing as a party. *See* 74 Fed. Reg. 65340, 65353 (Dec. 9, 2009).

#### 2. When CMS or its contractors may not be a party.

CMS or its contractors may not be a party to a hearing under the following circumstances:

- In Part A and B appeals, including QIO cases, if the request for hearing was filed by an unrepresented beneficiary. § 405.1012.
- In Part D appeals, only the enrollee (or the enrollee's representative) may be a party to an ALJ hearing § 423.2008. Therefore, CMS, the Part D QIC, or the Part D plan sponsor may not elect party status and may not be requested to join the hearing as a party. See 74 Fed. Reg. 65340, 65353 (Dec. 9, 2009).

#### 3. When CMS or its contractors may be a non-party participant.

#### a. Part A and B appeals.

CMS or a CMS contractor, including QIOs, may be a non-party participant in any hearing. Because the role of a non-party participant, as opposed to that of a party, is non-adversarial, CMS or a CMS contractor may join a hearing as a non-party participant even where the appellant is an unrepresented beneficiary. § 405.1010; 70 Fed. Reg. 11420, 11459 (Mar. 8, 2005)

#### b. Part C appeals.

Because the MAO is always a party to a Part C hearing, the MAO may never be a non-party participant.

#### c. Part D appeals.

The enrollee (or the enrollee's representative) is the only party to a hearing. Under certain circumstances, CMS, the Part D QIC, or the Part D plan sponsor may be able to join a hearing as a non-party participant.

#### B. ALJ Requests for CMS or CMS Contractor Involvement

#### 1. In general.

The ALJ may request that CMS or a CMS contractor join the hearing as a party or as a non-party participant, except in the case of an MAO (which is always a party to the ALJ hearing), and Part D appeals, where CMS and CMS contractors are permitted to join the ALJ hearing as a non-party participant only. As explained in subsection **D** below, an ALJ may not draw adverse inferences if CMS or a CMS contractor declines to join the hearing following an ALJ's request.

#### 2. Form of the request.

The ALJ may request CMS or CMS contractor involvement prior to, or at the same time as issuing the Notice of Hearing. All parties must be sent a copy of the ALJ's request for CMS involvement.

#### 3. Subpoenas.

An ALJ may not issue a subpoena to compel the appearance or testimony of CMS or a CMS contractor. § 405.1036(f), § 423.2036(f). An ALJ also may not issue a subpoena to compel the production of evidence, except to a Part D plan sponsor. § 423.2036(f)(1).

#### C. CMS or CMS Contractor Elections or Requests

CMS or a CMS contractor may also elect or request to join a hearing on its own initiative.

#### 1. Requirements for valid election or request.

a. Part A and B appeals, including QIO. (§ 405.1010(b) or 405.1012(b))

When CMS or a CMS contractor elects to join a hearing, it must advise the following individuals and entities of its intent to participate no later than 10 days after receipt of the Notice of Hearing:

- The ALJ;
- The appellant; and
- All other parties identified in the Notice of Hearing.

#### b. Part C appeals.

As the MAO is always a party to the ALJ hearing, it need only respond to the Notice of Hearing with its intent to attend the hearing.

#### c. Part D appeals.

CMS, the Part D QIC, or the Part D plan sponsor may request to join a hearing as a non-party participant by sending a request to participate to the ALJ within the following time frames: (§ 423.2010(b))

- For expedited hearings, within 1 calendar day of receipt of the Notice of Hearing;
- For non-expedited hearings (both requests for drug benefits and requests for payment), within 5 calendar days of receipt of the Notice of Hearing.

#### 2. Form of election or request.

**a.** The election or request need not take any specific form. Use of form HHS-732 (Centers for Medicare and Medicaid Services (CMS) or CMS Contractor Participation

as a Non-Party or as a Party to an Administrative Law Judge (ALJ) Hearing) is encouraged, but is not required. The election should clearly indicate whether CMS or the CMS contractor is electing to join the hearing as a party or as a non-party participant.

**NOTE:** CMS and CMS contractors may, but are not required to, send an election using regular or expedited mail. CMS and CMS contractors may make an election by fax; however other forms of electronic transmission (for example, e-mail) are currently prohibited.

b. If the election provided by CMS or the CMS Contractor does not specify whether CMS or the CMS Contractor is electing party or non-party participant status, staff will contact CMS or the CMS Contractor upon receipt of the election to clarify. Upon receiving clarification, the ALJ will notify all parties of the status CMS or the CMS contractor has elected using form OMHA-110, Clarification of CMS or CMS Contractor Status.

#### 3. Notification to other parties.

#### a. Part A and B appeals, including QIOs.

CMS or the CMS contractor must indicate in its election that it notified the appellant and all other parties identified in the Notice of Hearing of its intent to join the hearing. Indication may be accomplished in any manner the ALJ deems sufficient. The following list, though not exhaustive, provides examples of how CMS or a CMS contractor may demonstrate compliance with this requirement:

- An indication on CMS or the CMS contractor's election of the parties to whom a carbon/courtesy copy (cc) was sent, along with their addresses;
- Certified mail receipt;
- Delivery confirmation obtained from a carrier;
- Facsimile or email confirmation; or
- A written statement made by CMS or the CMS contractor that it notified the appellant and all parties identified in the Notice of Hearing of its intent to join the hearing, if the statement also includes the names of the parties and the address, facsimile number, or email address where notice was sent.

#### b. Part C appeals.

As the MAO is already a party, the MAO is not required to notify the other parties of its intent to attend the hearing; the Notice of Hearing will indicate that the ALJ sent a copy of the Notice to the MAO.

#### c. Part D appeals.

As detailed in **C.5.c** below, the ALJ will send notification to the entity requesting to join the hearing, the enrollee, and the Part D plan sponsor (if the Part D plan sponsor is not the entity requesting to join) of the ALJ's decision on whether to allow CMS or the CMS contractor's involvement. Therefore, CMS, the Part D QIC, or the Part D plan sponsor is not required to provide the enrollee (or the enrollee's representative) with notice of its request to join the hearing.

#### 4. Calculating timeliness.

#### a. Part A and B appeals, non-QIO.

For purposes of determining whether an election is timely, CMS or a CMS contractor will be deemed to have received the Notice of Hearing on the date it was received by the QIC. *Cf.* CMS, Medicare Program Integrity Manual, Pub. 100-08 (MPIM), Ch. 3, §§ 3.9, 3.9.2 (MPIM, Ch. 3, §§ 3.9, 3.9.2).

#### b. QIO appeals.

For reconsiderations issued by a QIO, CMS will be deemed to have received the Notice of Hearing on the date it was received by the QIO.

#### c. Part C appeals.

As the MAO is already a party to the hearing and does not need to file an election (only indicate its intent to attend the hearing after receiving a Notice of Hearing), it is not necessary to determine when the MAO received the Notice of Hearing.

#### d. Part D appeals.

Under § 423.2020(c), the Notice of Hearing must be sent to the Part D QIC and to the Part D plan sponsor. For purposes of determining whether a request for non-party participant status is timely, CMS will be deemed to have received the Notice of Hearing on the same date it was received, or presumed received, by the Part D QIC and the Part D plan sponsor.

#### e. Determining the date of receipt (Part A, B, and D appeals, including QIO).

The QIC, QIO, Part D plan sponsor, and any other direct recipient of the Notice of Hearing will be presumed to have received the Notice of Hearing 5 calendar days after the date the Notice of Hearing was mailed, unless there is evidence to the contrary. If an alternate means of transmitting the Notice of Hearing is authorized (for example, fax), it is presumed that the CMS contractor received the Notice of Hearing on the date transmitted, unless there is evidence to the contrary.

#### 5. Denying elections or requests.

#### a. Part A and B appeals.

Generally, if CMS or a CMS contractor has filed a valid election to join an ALJ hearing, an ALJ may not deny the election without cause. However, if the contractor' election does not meet the requirements in **C.1** and **C.3** above, it will be rejected by the ALJ. The ALJ must notify CMS or the contractor and all parties that received the Notice of Hearing that the election was invalid, including the reason(s) it was determined to be invalid, within a reasonable period of time.

#### b. Part C appeals.

Because the MAO is a party to the appeal, the ALJ may not deny the MAO the opportunity to appear.

#### c. Part D appeals.

The ALJ has the discretion to allow or deny non-party participant status requested by CMS, the Part D QIC, or the Part D plan sponsor. § 423.2010(c). The ALJ may deny the request to join the hearing if it was not received within the applicable time frames described in **C.1.c** above, or for any other reason if the ALJ deems the denial necessary to balance the interests of the enrollee with the interests of CMS, the Part D QIC, or the Part D plan sponsor.

The ALJ must notify the entity requesting to join the hearing, the enrollee, and the Part D plan sponsor (if the Part D plan sponsor is not the entity requesting to join) of the ALJ's decision on the request to join the hearing within the following time frames:

- For expedited hearings, within 1 calendar day of receipt of the request to join the hearing;
- For non-expedited hearings (both requests for drug benefits and requests for payment), within 5 calendar days of receipt of the request to join the hearing.

#### 6. Elections made before a notice of hearing is issued.

#### a. Part A and B appeals.

CMS or a CMS contractor may elect to join a hearing no later than 10-calendar days after receiving notice of hearing. §§ 405.1010(b); 405.1012(b). Any request made by CMS or a CMS contractor to join a hearing prior to issuance of the Notice of Hearing will be included in the administrative record for completeness. However, to be considered valid, CMS or the CMS contractor must resubmit its election after a Notice of Hearing has been issued, or after an ALJ requests its involvement.

#### b. Part C appeals.

Although the MAO may not request an ALJ hearing under § 422.600, as a party it is always entitled to receive notice of the ALJ hearing, and need not separately indicate its intent to join the ALJ hearing.

#### c. Part D appeals.

#### i. Standard.

Any request from CMS, the Part D QIC, or the Part D plan sponsor to join a hearing, must be made within 5-calendar days of receipt of the notice of hearing. § 423.2010(b)(1). Any request to join a hearing made by CMS, the Part D QIC, or the Part D plan sponsor prior to issuance of the Notice of Hearing will be documented in the administrative record, and the enrollee will be notified of the request. However, the request will be rejected as premature, and the entity requesting to join the hearing will be advised to resubmit its election after a Notice of Hearing has been issued, or after an ALJ requests its involvement.

#### ii. Expedited.

Any request from CMS, the Part D QIC, or the Part D plan sponsor to join a hearing, must be made within 1-calendar day of receipt of the notice of hearing. § 423.2010(b)(2). Any request to join a hearing made by CMS, the Part D QIC, or the Part D plan sponsor prior to issuance of the Notice of Hearing will be documented in the administrative record, and the enrollee will be notified of the request. However, the request will be rejected as premature, and the entity requesting to join the hearing will be advised to resubmit its election after a Notice of Hearing has been issued, or after an ALJ requests its involvement.

#### 7. Effect of waivers of 20-day (or 3-day) advance notice requirement.

Unless waived, notice of an ALJ hearing must be mailed or served 20 calendar days before the scheduled date of the hearing (or 3 calendar days for an expedited Part D hearing). A waiver of the 20-day (or 3-day) notice made by the appellant and other parties to the appeal does not affect the 10-, 5-, or 1-day period following receipt of the Notice of Hearing during which CMS or a CMS contractor may elect to participate in the hearing. § 405.1022.

#### a. Part A and B appeals.

When all parties to the hearing have waived the 20-day notice requirement, the ALJ will notify the QIC or QIO as soon as practicable and request that CMS or any CMS

contractor interested in electing a role submit its election as soon as possible. However, the ALJ may not require CMS or a CMS contractor to submit its election sooner than 10 days after the QIC or QIO received the Notice of Hearing. If CMS or the CMS contractor elects party status, the 20-day notice requirement cannot be waived unless CMS or the CMS contractor also waives the notice period and agrees to an earlier hearing date.

#### b. Part C appeals.

The MAO is always a party to the hearing and is not subject to any specific time frame for responding to the Notice of Hearing. Furthermore, the 20-day advance notice requirement cannot be waived unless the MAO also waives the notice period and agrees to an earlier hearing date.

#### c. Part D appeals.

When an enrollee waives the 20-day notice requirement (or 3-day notice requirement for expedited hearings), the ALJ will notify the Part D QIC and the Part D plan sponsor as soon as practicable and request that, if CMS, the Part D QIC, or the Part D plan sponsor is interested in joining the hearing, it must submit the request as soon as possible. However, the ALJ may not require CMS, the Part D QIC, or the Part D plan sponsor to submit its request sooner than 5 days (or 1 day for expedited hearings) after the Part D QIC and the Part D plan sponsor received the Notice of Hearing.

#### **D.** Prohibition on Adverse Inferences

An ALJ may not draw adverse inferences if CMS or a CMS contractor decides not to join the hearing as a party or participant. Similarly, if CMS or a CMS contractor elects to join a hearing as a non-party participant and refuses to respond to cross examination, the ALJ may not draw an adverse inference because CMS or the CMS contractor has declined to extend the scope of its involvement in the hearing beyond that of a non-party participant. §§ 405.1010(f), 405.1012(d), 423.2010(g); 74 Fed. Reg. 65296, 65318 (Dec. 9, 2009).

#### E. Submission of Evidence and Position Papers

#### 1. Submission of evidence.

a. Part A, B and C appeals, including QIO.

When CMS or a CMS contractor (including the MAO) joins an ALJ hearing as a party, CMS or the CMS contractor may submit written evidence within 10 calendar days after receipt of the Notice of Hearing, or within the time frame designated by the ALJ. §§ 405.1018, 405.1012(c). If additional evidence is submitted later than 10

calendar days after receiving the Notice of Hearing, the time between when the evidence was required to be submitted and the time it is received is not counted toward any applicable adjudication time frame.

CMS and CMS contractors are not required to show good cause for submitting evidence for the first time at the ALJ level, as this requirement only applies to providers, suppliers, and beneficiaries represented by a provider or supplier. § 405.1018(c), 405.1028. To the extent submission of evidence by CMS or a CMS contractor raises new issues in the appeal that were not considered during the earlier levels of appeal, there may be good cause for the introduction of new evidence by other parties at the ALJ level of appeal. 74 Fed. Reg. 65296, 65318 (Dec. 9, 2009).

#### b. Part D

Under § 423.2018, only the enrollee may submit written evidence to be considered at the hearing. Therefore, CMS, the Part D QIC, and the Part D plan sponsor, whose role is limited to that of a non-party participant, may not submit written evidence.

#### 2. Position papers.

When CMS or a CMS contractor elects a party or a non-party participant role in the hearing, it may submit position papers within the time frame designated by the ALJ. §§ 405.1010(e), 405.1012(c), 423.2010(d) and (f).

#### F. Discovery

#### 1. Part A and B appeals.

Discovery is permissible when CMS or a CMS contractor elects party status in a hearing; it is not permissible when CMS or a CMS contractor elects non-party participant status. § 405.1037(a)(1).

#### 2. Part C appeals.

As the MAO is a CMS contractor, and is always a party to the hearing, discovery is always available in Part C hearings.

#### 3. Part D appeals.

Discovery is appropriate in cases where an ALJ hearing is adversarial. Because CMS, the Part D QIC, and the Part D plan sponsor can never be a party to the hearing in a Part D appeal, discovery is not permitted. 74 Fed. Reg. 65340, 65353 (Dec. 9, 2009).