Chapter 3 PROCEDURAL SCREENING

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NOTE: The CMS contractors described in the regulations as Independent Review Entities (IREs) or Independent Outside Entities are commonly referred to as "Part D QICs." This manual adopts this common usage and uses these terms for ease of identification only.

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IV-3-1 Procedural Screening, Generally

An initial screening of the case file and request for hearing must be conducted to determine whether:

- The request for hearing involves an appealable decision (see IV-3-2, Appealable Decision);
- The individual filing the request for hearing has standing to appeal (see IV-3-3, Standing);
- The amount in controversy threshold is met (see IV-3-4, Amount in Controversy);
- The request for hearing is timely filed (see IV-3-5, Timely Request for Hearing);
- The request for hearing is complete for a standard Part D appeal, if applicable (see IV-3-6, Complete Request for Hearing–Standard);
- The request for hearing is complete for an expedited Part D appeal, if applicable (see IV-3-7, Complete Request for Hearing–Expedited).

IV-3-2 Appealable Decision

A. Jurisdiction

When reviewing a request for hearing, there must be an appealable action.

An ALJ has jurisdiction over certain actions, including:

- Part D QIC reconsideration involving:
  - Decision not to provide or pay for a Part D drug;
  - Failure to provide a coverage determination in a timely manner if the delay would adversely affect the health of the enrollee;
  - Decision concerning an exception for a plan's tiered cost-sharing structure or non-formulary Part D drug; or
  - Decision on the amount of cost-sharing.
- Part D QIC dismissal of a request for reconsideration.

An ALJ does not have jurisdiction over certain actions, including:

- Grievances between an enrollee and PDPS or any other entity or individual through whom the PDPS provides covered benefits under any Part D plan it offers. § 423.564.
- Part D subsidy determination. § 423.774©.
- Part D late enrollment penalty determination. § 423.46©.

  NOTE: Under the regulation, while CMS or a CMS contractor conducts the reconsideration for a Part D late enrollment penalty, such review is not subject to appeal. See also 74 Fed. Reg. 1494, 1502–03 (Jan. 12, 2009).

B. If No Appealable Action

If there is no appealable action, the request for hearing is dismissed for no right to a hearing.

IV-3-3 Standing

Citations: § 423.2008.

A. Part D QIC Reconsideration

Only the enrollee (or the enrollee's representative) may request a hearing. § 423.2008.

NOTE: While a prescribing physician or other prescriber can request a redetermination under § 423.580 and reconsideration under § 423.600, with only providing simple notice to the enrollee, only the enrollee can request a hearing. The prescribing physician or other prescriber would have to execute an appointment of representation and request a hearing as a representative of the enrollee (compare above rules with § 423.1972(a)).

B. If No Enrollee with Standing

If there is no enrollee with standing, the request for hearing is dismissed for no right to a hearing.

IV-3-4 Amount in Controversy

Citations: §§ 1860D–4(h), 1852(g)(5), § 1869 of the Act; § 423.1970.

A. Generally

An enrollee is entitled to a hearing only if the amount remaining in controversy meets the threshold amount in controversy (AIC) established annually by the Secretary. § 423.1970(a).

The minimum AIC is revised annually based on a formula prescribed by Congress:

Calendar Year	Minimum AIC	Federal Register Publication
2017	$160	81 Fed. Reg. 65651 (Sep. 23, 2016)
2016	$150	80 Fed. Reg. 57827 (Sep. 25, 2015)
2015	$150	79 Fed. Reg. 57933 (Sep. 26, 2014)
2014	$140	78 Fed. Reg. 59702 (Sep. 27, 2013)
2013	$140	77 Fed. Reg. 59618 (Sep. 28, 2012)
2012	$130	76 Fed. Reg. 59138 (Sep. 23, 2011)
2011	$130	75 Fed. Reg. 58407 (Sep. 24, 2010)
2010	$130	74 Fed. Reg. 48976 (Sep. 25, 2009)
2009	$120	73 Fed. Reg. 55847 (Sep. 26, 2008)
2008	$120	72 Fed. Reg. 73348 (Dec. 27, 2007)
2007	$110	71 Fed. Reg. 75250 (Dec. 14, 2006)
2006	$110	71 Fed. Reg. 2247 (Jan. 13, 2006)

B. Determination of Appropriate Calendar Year for Minimum AIC

The date OMHA receives a request for hearing determines the minimum AIC to be used.

Example: If a request for hearing is sent on December 30, 2012, and received by OMHA on January 2, 2013, the AIC for calendar year 2013 applies to the request.

C. When to Calculate AIC

The exact AIC must be calculated if the record does not clearly establish whether the minimum AIC is met for the appeal(s) at issue.

D. How to Calculate AIC

The AIC is calculated based on what is appealed (§ 423.1970, CMS, *Medicare Prescription Drug Manual*, Pub. 100-18, Ch. 18, § 90.2 (MPDM, Ch. 18, § 90.2)):

1. **Part D plan's refusal to provide prescription drug benefits.**

   Step One. Find the projected value of the drug benefits in dispute, including any costs the enrollee could incur based on the number of refills prescribed for the drug(s) in dispute for the plan year, as well as enrollee co-payments, all expenditures incurred after an enrollee's expenditures exceed the initial coverage limit, and expenditures paid by other entities.

   Step Two. Subtract any allowed amount under Part D by the plan sponsor.

   Step Three. Subtract any deductible, co-payments, and coinsurance amounts applicable to the Part D drug at issue.

2. **Reimbursement for out-of-pocket costs incurred in obtaining a disputed Part D drug.**

   Step One. Find the actual amount charged the enrollee or third party for the Part D drug.

   Step Two. Subtract any allowed amount under Part D by the plan sponsor.

   Step Three. Subtract any deductible, co-payments, and coinsurance amounts applicable to the Part D drug at issue.

3. **The amount of cost-sharing.**

   Find the amount contested by the enrollee or third party for cost-sharing, including any deductible, co-payment, or coinsurance.

NOTE: When necessary, the PDPS is expected to cooperate with the ALJ in computing the AIC (for example, the PDPS may need to provide the amount an enrollee was required to pay at the time of the coverage determination).

E. Aggregation to Meet the Minimum AIC

1. **Generally.**

   Appeals may be considered together (aggregated) to meet the minimum AIC, when any of the appeals involved in the request for aggregation do not individually meet the AIC. Either an individual enrollee or multiple enrollees may aggregate two or more claims to meet the minimum AIC.

   NOTE: Aggregation is only used to meet the minimum AIC. Aggregation is not a mechanism to request consideration of multiple appeals together for a party's convenience or administrative efficiency.

2. **Aggregation Request with Previously Filed Requests for Hearing**.

   A request seeking to aggregate appeals with appeals specified in a previously filed request is not permitted.

   i. If a new request for hearing includes appeals that individually meet the AIC threshold, the request will be processed separately as a regular request for hearing, and the request for aggregation disregarded.

   ii. If a new request for hearing includes appeals that together meet the AIC threshold, the request will be processed separately as a potential aggregation.

   iii. If a new request for hearing includes appeals that individually or together do not meet the AIC threshold, the request will be dismissed for failing to meet the minimum AIC, as provided at § 423.1972(c)(1).

F. Reviewing a Request for Aggregation

1. The ALJ must review a request for aggregation, and determine whether the following requirements have all been met (§ 423.1970(c)):

   a. The request lists all of the appeals to be aggregated.

      NOTE: A request does not have to use the term "aggregate" or specifically mention meeting the AIC requirement.

   b. The appeals to be aggregated were reconsidered by the Part D QIC.

   c. The request was filed within 60 calendar days after receipt of all of the reconsiderations being appealed.

   d. The appeals involve the delivery of prescription drugs to a single enrollee (if single enrollee requesting) or the appeals that multiple enrollees seek to aggregate involve the same prescription drug (if multiple enrollees requesting).

2. If the ALJ determines the requirements for aggregation are met, and the minimum AIC is satisfied, staff continues processing the case. The granting of the request for aggregation must be explicitly stated in the decision.

3. If the ALJ determines the aggregation requirements are not met and denies the request for aggregation, resulting in insufficient AIC, see the instructions in subsection **G**, below.

G. Addressing Insufficient AIC

If the minimum AIC is not met, the request for hearing is dismissed for no right to a hearing.

- If the minimum AIC is not met because the request for aggregation is invalid, the reason must be included in the dismissal.

IV-3-5 Timely Request for Hearing

Citations: §§ 405.942, 423.1972(b), 423.2002, 423.2014.

A. When the Request for Hearing Must be Filed

1. An enrollee must file a written request for hearing within 60 calendar days after receiving the notice of reconsideration. § 423.2014(c).
2. The request for hearing is considered filed on the date when it is received by the entity specified in the reconsideration (but see subsection **B,** below). § 423.2002(e).
3. When the last day for filing a request for hearing falls on a weekend, Federal holiday, or any other day that the receiving OMHA office is closed for business (for example, due to weather), the time frame for filing is automatically extended to the next business day that the OMHA office is open for business.
4. An enrollee is presumed to have received the reconsideration notice 5 calendar days after the date of the notice, unless the record contains evidence to the contrary. § 423.2002(d).

   NOTE: If the enrollee introduces evidence that the reconsideration was not received within the 5-day mailing presumption, thereby making the request for hearing timely filed, this is not a good cause determination. Rather, it is an issue that affects when the time period to request a hearing began.

Example. The Part D QIC issues a reconsideration notice on Tuesday, September 23, 2014. The record does not show the date the enrollee actually received it, so the 5-calendar day regulatory presumption applies and the 60-calendar day time period for filing the request for hearing begins on Sunday, September 28, 2014. Applying the 60-calendar day period for timely filing, the request for hearing should be filed no later than November 27, 2014. However, November 27, 2014, is a Federal holiday, so the time frame is automatically extended to the next business day that the OMHA office is open for business, on Friday, November 28, 2014.

B. Where the Request for Hearing Must be Filed

1. An enrollee must file a request for hearing with the entity specified in the notice of reconsideration. § 423.2014. However, if a request for hearing is received by an entity other than the entity specified in the notice of reconsideration (for example, an incorrect OMHA entity or an entity outside OMHA, such as SSA or CMS), the date that the incorrect entity received the request must be used to determine timeliness.

Example. Using the example in paragraph A, the Part D QIC's reconsideration notice identified OMHA Central Operations as the entity where appeals should be filed. If the OMHA Miami Field Office received the request on Friday, November 28, 2014, the Miami Field Office date stamps the request for hearing as received on that date and forwards it to OMHA Central Operations for further processing. However, the November 28, 2014, received date will be used to assess the timeliness of the request, regardless of when OMHA Central Operations receives the request.

2. If the request for hearing is timely filed with an entity other than the entity specified in the QIC's reconsideration, the adjudication period begins on the date the entity specified in the QIC's reconsideration receives the request for hearing. § 423.2014(c)(2). In this situation, OMHA Central Operations issues an acknowledgement letter that notifies the appellant of the date of receipt of the request, and the start of the adjudication period.

C. Requesting an Extension of Time

Any enrollee who has a right to a hearing but does not file a timely request, may ask for an extension of time to make the request. The request for an extension must be in writing (form HHS-727 may be used, but is not required) and must give the reasons why the request was not filed within the required time period, and must be filed with the entity specified in the notice of reconsideration. § 423.2014(d).

NOTE: Any explanation for a late filing is deemed a request for an extension of time to request a hearing.

D. Addressing Untimely Requests

1. Considerations when evaluating good cause. 405.942(b)(2)–(3).

When evaluating whether an enrollee has shown good cause for missing a deadline to request a hearing, an ALJ considers:

- The circumstances that kept the party from making the request on time;
- If the contractor's or OMHA's action(s) misled the party; and
- If the party had or has any physical, mental, educational, or linguistic limitations, including any lack of facility with the English language, that prevented the party from filing a timely request or from understanding or knowing about the need to file a timely request.

An ALJ must evaluate whether an enrollee has shown good cause based on the circumstances of the case. Examples of when good cause for late filing may be found to exist include, but are not limited to, the following circumstances:

- The enrollee was prevented by serious illness from contacting OMHA in person, in writing, or through a friend, relative, or other person;
- The enrollee had a death or serious illness in his or her immediate family;
- Important records of the enrollee were destroyed or damaged by fire or other accidental cause;
- The contractor gave the enrollee incorrect or incomplete information about when and how to request a hearing;
- The enrollee did not receive notice of the reconsideration; or
- The enrollee sent the request to a Government agency in good faith within the time limit, and the request did not reach the appropriate entity until after the time period to file a request expired.

2. Developing good cause.

If there is no evidence in the file indicating that the enrollee has provided a reason for the late filing, an interim letter requesting the enrollee show cause (OMHA-110 Interim Letter, available in MATS) must be sent to the enrollee.

The notice provides 60 calendar days from the date of the interim letter for an enrollee to provide a reason for the late filing. The original interim letter must be placed in the file, and a copy sent to the enrollee.

3. Good cause is found.

If a request for hearing is untimely, but the ALJ determines that the enrollee established good cause for missing the filing deadline, the ALJ grants an extension for filing the request for hearing.

NOTE: The adjudication period begins on the date the ALJ grants the request to extend the filing deadline, which must be explicitly stated in the decision.

4. Good cause is not found.

If a request for hearing is untimely and there is no good cause for extending the filing deadline, the request is dismissed.

- If the enrollee did not respond to the interim letter requesting good cause for untimely filing, the dismissal will include a summary statement relating this fact (for

example, “The enrollee has not provided any explanation for its late filing; thus, I find that there is no good cause to extend the period for timely filing in this case.”)

- If the enrollee provided a reason for the untimely filing, the dismissal must explain why the reason does not constitute good cause.

IV-3-6 Complete Request for Hearing — Standard

Citations: § 423.2014.

A. Generally

1. The request for hearing must be in writing, but may be in any format that contains all required information.
   - There are no standard forms for requesting a hearing in Part D appeals.
2. Although OMHA does not encourage submission of a request for hearing via fax, filing by fax is acceptable.
3. Whether a request for hearing meets the content requirements for a hearing request will be determined by taking into consideration all of the information submitted with the request.

   Example. An enrollee submits a request for hearing that attaches a Part D QIC reconsideration. The hearing request is considered complete if these documents together contain all of the content information required for a request for hearing.

B. Required Elements for a Complete Request for Hearing

The request for hearing must be reviewed to determine whether the request includes the required elements (§ 423.2014(a)):

1. The name, address, telephone number, and Medicare health insurance claim number of the enrollee.

   NOTE: Only the enrollee (or the enrollee's appointed representative) may request a hearing before an ALJ. The enrollee is the only party to a Part D appeal.
2. If a representative is involved, the name, address, and telephone number of the appointed representative, as defined at § 423.560.
   - If a representative is listed on the request for hearing, staff must confirm there is a valid appointment of representative or evidence of an authorized representative.
3. The appeals case number assigned to the appeal by the Part D QIC, if any.
   - This is the "Medicare Appeal Number" listed on the first page of the reconsideration.
4. The prescription drug in dispute.
5. The plan name.
6. The reasons the enrollee disagrees with the Part D QIC's reconsideration.

NOTE: This does not require a detailed explanation. Any reason for disagreement satisfies the requirement (for example, "I need a different drug" or "I need more than they will let me have").

7. A statement of any additional evidence to be submitted and the date it will be submitted.

   NOTE: If no evidence is submitted, it is not necessary for an enrollee to include a statement, and the enrollee may not be required to provide this information. Further, failure to indicate in the request for hearing that additional evidence will be submitted does not preclude the evidence from being submitted at a later date, in accordance with the regulations (for example, in response to the notice of hearing).

C. Addressing Incomplete Requests for Hearing

If the request for hearing is incomplete, the enrollee must be given an opportunity to cure the defects to perfect the request for hearing.

D. Providing the Opportunity to Cure

Staff must take the following steps:

1. Issue an interim letter (OMHA-110 Interim Letter, available in MATS) to the enrollee:
   a. Notifying the enrollee that the request is incomplete, and specifying the exact information that must be provided;
   b. Providing 60 calendar days from the date the letter is mailed for the enrollee to provide the specified information;

      NOTE: The letter must be mailed on the date stated on the interim letter.

   c. Notifying the enrollee that the request for hearing may be dismissed if the information is not provided within the specified time period; and
   d. Informing the enrollee that the date of receipt of the initial request protects the filing date, and the adjudication period will begin upon receipt of the missing information.
2. Upon receipt, review the information submitted by the enrollee and determine whether it satisfies the information detailed in the interim letter.

   a. Defects cured.

   If the enrollee provides the information missing from the request for hearing within the 60-calendar day period, the adjudication period begins on the date the information provided completes the request for hearing.

b. Defects not cured.

If the enrollee does not cure the defects and perfect the request for hearing, the request for hearing is dismissed for no right to a hearing.

IV-3-7 Complete Request for Hearing — Expedited

Citations: § 423.2014

A. Generally

1. The request for hearing may be made orally or in writing (mail or fax), but must contain all required information. If a request is made orally, the request must be documented in writing and made part of the administrative record. § 423.2014(b).

   - There are no standard forms for requesting a hearing in expedited Part D appeals.

2. Although OMHA does not encourage submission of a request for hearing via fax, filing by fax is acceptable.

3. Whether a request for hearing meets the content requirements for a hearing request will be determined by taking into consideration all of the information submitted with the request.

   Example. An enrollee submits a request for hearing that attaches a Part D QIC reconsideration. The hearing request is considered complete if these documents together contain all of the content information required for a request for hearing.

   NOTE: If an oral request for hearing is made, the recording of the phone call and documentation thereof constitutes the request.

B. Required Elements for a Complete Request for Hearing

Immediately upon receipt, Central Operations reviews the request for hearing and determines if the request includes the required elements (§ 423.2014(a)):

1. The name, address, telephone number, and Medicare health insurance claim number of the enrollee.

   NOTE: Only the enrollee (or the enrollee's appointed representative) may request a hearing before an ALJ. The enrollee is the only party to a Part D appeal.

2. If a representative is involved, the name, address, and telephone number of the appointed representative, as defined at § 423.560.

   - If a representative is listed on the request for hearing, staff must confirm there is a valid appointment of representative or evidence of an authorized representative.

3. The appeals case number assigned to the appeal by the Part D QIC, if any.

   - This is the Medicare Appeal Number located on the first page of the reconsideration.

4. The prescription drug in dispute.

5. The plan name.
6. The reasons the enrollee disagrees with the Part D QIC's reconsideration.

   NOTE: This does not require a detailed explanation. Any reason for disagreement satisfies the requirement (for example, "I need a different drug" or "I need more than they will let me have").
7. A statement of any additional evidence to be submitted and the date it will be submitted.

NOTE: If no evidence is submitted, it is not necessary for an enrollee to include a statement, and the enrollee may not be required to provide this information. Further, failure to indicate in the request for hearing that additional evidence will be submitted does not preclude the evidence from being submitted at a later date, if in accordance with the regulations (for example, in response to the notice of hearing).

8. A statement or indication that the enrollee is requesting an expedited hearing.

C. Addressing Incomplete Requests for Hearing

Due to the expedited nature of these appeals, the cure process outlined in IV-3-6 for standard Part D appeals is not applicable to expedited Part D appeals.

1. If the request for hearing is missing information that is necessary for identifying the Part D QIC reconsideration being appealed, Central Operations contacts the enrollee/representative via telephone and documents the missing information via a Report of Contact (form OMHA-101).
   - Once the information is obtained, Central Operations immediately forwards the request and report(s) of contact to the assigned ALJ.
2. If the request for hearing as received is sufficient to identify the Part D QIC reconsideration being appealed, Central Operations immediately forwards the request to the assigned ALJ.