

## **Chapter IV-4 Administrative Record**

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## **IV-4-1 Administrative Record, Generally**

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

**Citations:** [§ 423.2042](#).

### **A. Overview**

The administrative record is the complete record of the administrative proceedings, including the evidence used in making decisions at all levels of review and recordings of any conference and hearing proceedings. The administrative record is created at the OMHA level based on records provided from lower-level reviews and records submitted or created at OMHA. Where an enrollee pursues further appeals, the administrative record created at OMHA is forwarded to the Council, and then to Federal district court.

### **B. Materials Included in the Administrative Record**

All materials forwarded to OMHA in the case file must be maintained in the record unless otherwise specified in this Manual. Removal or disposal of materials in the case file (for example, removing and disposing of duplicative records filed by the enrollee) is not permitted.

The administrative record includes both exhibited and not exhibited materials.

#### **1. Materials marked as exhibits.**

Exhibited materials include, but are not limited to, the following:

- All documents used in making the decision under review (for example, the Part D QIC reconsideration and all prior procedural and substantive documents related to the reconsideration and lower-level appeals);
- Submissions by the enrollee, and possible participants including CMS, the Part D QIC and PDP sponsor(see, [I-4](#), [I-5](#) and [1-6](#) for information on parties, representatives and roles of CMS and CMS contractors);
- Correspondence or documentation issued by OMHA, except final disposition documents and audio recording of hearings as detailed in [IV-4-1 B.2](#);

**NOTE:** The originals of any OMHA-produced materials (for example, notices, letters, or orders) must be included in the administrative record, with copies sent to the parties;

- Reports of contact by OMHA staff with the enrollee, and possible participants.

**NOTE:** As set forth in IV-4-5 B, no marks (for example, writing, highlighting, or notations) may be made on the record materials, other than the page numbering required for exhibiting, in accordance with IV-4-3 D.2).

## **2. Materials not marked as exhibits.**

The following materials must be kept with the administrative record, but are not exhibited:

- Final disposition documents, including any orders, the notice of decision, decision, and final exhibit list;
- The audio record of the hearing and any pre-hearing or post-hearing conferences;
- Duplicates.
- New evidence.

**NOTE:** See IV-4-3 D.4 for instructions on separating the new evidence and adding it to the record.

## **C. Materials not Included in the Administrative Record**

### **1. Generally.**

The following materials are never part of the administrative record and must be removed from the file:

- Case file requests;
- Case file transmittal sheets;
- Internal OMHA deliberative (working) documents (for example, ALJ hearing notes, drafts, research, and communications within the ALJ team);
- Blank pages; and
- Materials for the incorrect enrollee inadvertently included in the case file at the lower levels and forwarded to OMHA.

*Example.* The Part D QIC accidentally places medical records for Enrollee 1 in the case file for Enrollee 2, which has a separate Part D QIC Medicare Appeal Number. OMHA receives a request for hearing for Enrollee 2 and requests the file. The contractor forwards the file for Enrollee 2 (that also contains medical records for Enrollee 1). Because the case file forwarded by the contractor includes PII for Enrollee 1, OMHA must remove the Enrollee 1 materials from the case file for Enrollee 2 to limit any further PII breach, and follow the applicable OMHA policy on PII.

**NOTE:** The incorrectly associated materials must be forwarded to the designated field office contact, who will notify CMS so that CMS may take appropriate action to resolve the error, and provide direction to OMHA (for example, to dispose of the materials, in accordance with OMHA's policy on PII).

**2. Pre-paginated sequence.**

Although non-probative materials are generally not retained, if a page has a page number that is part of a pre-paginated sequence (for example, a page received by fax is blank but contains the fax header) the non-probative page must be kept in the record.

*Example.* An enrollee faxes 10 pages of evidence prior to the hearing. The last page received is blank; however, it contains the fax header and shows a page count of 10/10. The last page must be exhibited and kept with the remaining pages of the fax in the record.

## IV-4-2 Organizing the Administrative Record

Citations: §§ 423.2014; 423.2022; 423.2042.

### A. Generally

1. Formal organizing and exhibiting of the record is not required in the following appeals (if known at the time the case file is organized):
  - Remands to the Part D QIC;
  - Removals to the Council;
  - Requests for Expedited Access to Judicial Review where the request and case file are forwarded to the DAB (the reviewing entity); or
  - Procedural dismissals if there is no right to judicial review (for example, dismissals for amount in controversy.)
2. For appeals where formal organizing and exhibiting of the record is not required, place any documentation received with the request for hearing on top of the documentation received from the lower levels of review. Any disposition documents generated for these appeals will be placed on top of the Request for Hearing documents. See [IV-4-3 A](#) for instructions on processing appeals that do not require organization.

### B. Categories of Record Materials

The administrative record is organized into the following categories, or groups of record materials, which establishes the minimum exhibiting structure.

- Duplicates, if any;
  - Excluded evidence, if any.
1. **Category 1– Initial, Redetermination and Reconsideration procedural documents**

The documents in this category may include, but are not limited to, the following:

- Appointment of representative;
- Documentation of authorized representative;
- Part D Plan Formulary;
- Part D Plan Evidence of Coverage (EOC);
- Coverage determination;
- Request for redetermination and materials submitted with the request (other than evidence);

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- Redetermination decision;
- Request for Reconsideration;
- Reconsideration decision;
- Any other correspondence with the Part D Plan Sponsor (PDP) or Part D QIC.

### **2. Category 2 – Medical Records/Evidence received by the PDP or CMS Contractors**

The materials in this category may include, but are not limited to, the following:

- Medical records;
- Letters of medical necessity;
- Progress, treatment, evaluation, or visit notes;
- Physician orders;
- Prescriptions;
- Peer reviewed journal articles;

### **3. Category 3–Request for ALJ Hearing**

The documents in this category include the following:

- The request for hearing, whether oral or in writing. [§ 423.2014](#).

**NOTE:** An oral request for hearing must be documented by OMHA in writing. [§ 423.2014\(b\)](#). Include the written documentation of the oral request, and the audio CD, if available, in this category. The audio CD must be processed in accordance with the electronic media provisions in [IV-4-3 D.4](#).

- Documents received with the request for hearing, except verified duplicates and any new evidence.

See [IV-4-3 D.4](#) for further instructions on processing new evidence. See [IV-4-3 C.1.b](#) for further instructions on processing duplicate documents.

### **4. Category 4– OMHA Proceedings**

The documents in this category may include, but are not limited to, the following:

- OMHA Notice and Order Denying Expedited Hearing Request
- OMHA Notice of Hearing;
- Responses to the notice of hearing or other documentation to confirm the enrollee received the notice (for example, a report of contact made pursuant to [§ 423.2022\(c\)\(1\)](#));

- Pre-hearing or post-hearing conference notices or orders;
- Hearing or supplemental hearing notices;
- PDP and CMS contractor submissions (for example, position papers), or documentation sent in response to a request for information or evidence;
- Requests for an expert by OMHA, and any communication between OMHA, the expert, and the enrollee.

#### **5. Category 5—Documents received after the Request for ALJ Hearing**

The documents in this category may include, but are not limited to, the following:

- Post-hearing briefs or memoranda submitted by a party or participant;  
**NOTE:** Materials included with a brief or memorandum, for example, exhibits, must remain with the brief or memorandum in the order submitted.
- Pre-hearing briefs or memoranda submitted by a party or participant, if not submitted with the request for hearing;  
**NOTE:** Materials included with a brief or memorandum, for example, exhibits, must remain with the brief or memorandum in the order submitted.
- Evidence received after the request for hearing is filed but prior to the hearing;
- Evidence received after the hearing, but prior to the issuance of the disposition.

*Example.* The case file received from the Part D QIC did not include the evidence of coverage. Prior to the hearing, staff obtained the EOC. The EOC is added to category 5.

#### **6. Category 6—Disposition Documents**

The documents in category 6 are not exhibited unless the file is returned to OMHA on remand or otherwise reopened. The documents in this category may include, but are not limited to, the following:

- Audio record of hearing the hearing and any pre-hearing or post-hearing conferences;  
**NOTE:** See [IV-4-3 D.3](#) for additional information on placement of audio records in the file.
- Notice of decision;
- Decision; and
- Final exhibit list.

## 7. Category 7—Post-disposition Proceedings

The documents in category 7 are not exhibited unless the file is returned to OMHA on remand or otherwise reopened. The documents in this category may include, but are not limited to, the following:

- Reopening requests;
- Submissions to the Council, including any request for review or CMS memorandum in support of own motion review and attachments;
- Notice and order of remand from the Council;
- Information furnished by the Part D QIC after remand from OMHA to the Part D QIC;
- Court orders.

**NOTE:** If there are additional proceedings, categories are added as applicable.

*Example.* OMHA receives a remand from Council. The Council materials are included in the record as category 7. The documents and evidence obtained in the OMHA proceedings after remand are added as a new category (for example, “Category 8—OMHA Proceedings after Remand from Council”). The categories are then exhibited as appropriate in accordance with the provisions of IV-4-3.

## C. Organization of Documents

Within each category, documents are organized in reverse chronological order based on the date they were filed by the enrollee or produced by an adjudicator (that is, newer documents are above older documents).

*Example 1.* Procedural documentation received for category 1 includes the plan evidence of coverage, coverage determination, the request for redetermination filed with the PDP, the redetermination decision, request for reconsideration filed with the Part D QIC and the Part D QIC reconsideration decision. The documents will be placed in the following order, with the first on the bottom:

1. Evidence of Coverage
2. Coverage determination
3. Request for Redetermination
4. Redetermination decision
5. Request for reconsideration
6. Reconsideration decision

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*Example 2.* Evidence received for category 2 includes medical evidence received with the request for redetermination and duplicative medical evidence, new medical evidence and peer reviewed articles submitted with the request for reconsideration. The documents are arranged as follows, with the first on the bottom:

1. The medical evidence received with the redetermination.
2. The new medical evidence and peer reviewed articles submitted to the Part D QIC with the request for reconsideration.

**NOTE:** The duplicative documents are removed from the categories and the duplicative records coversheet is placed on top. The duplicative records will remain in the administrative record at the bottom of the file as detailed in [IV-4-3](#)

## IV-4-3 Exhibiting the Record

### A. Generally

1. As noted in IV-4-2 A, above, exhibiting is not required for the following appeal dispositions (if known at the time record is being exhibited):
  - Remands to the Part D QIC;
  - Removals to the Council;
  - Requests for Expedited Access to Judicial Review where the request and case file are forwarded to the reviewing entity (DAB); or
  - Procedural dismissals, if there is no right to judicial review as discussed in IV-4-2 A, above.
2. Documents should be kept in the order received by the lower levels of review, with documents received or generated by OMHA on top, in accordance with IV-4-2 A.

**NOTE:** Where no exhibiting is required, the record must be two-hole punched and affixed (pronged) to the case file folder.

### B. Exhibited Record Materials

#### 1. Single enrollee.

##### a. Generally.

The record is exhibited based on the categories identified with IV-4-2. Categories containing documents become exhibits that are numbered sequentially.

*Example.*

- Category 1 (Coverage determination and Reconsideration Procedural Documents) becomes Exhibit 1.
- Category 2 (Medical Records/Evidence received by the PDP and CMS contractors) becomes Exhibit 2.
- Category 3 (Request for ALJ Hearing) becomes Exhibit 3.
- Category 4 (OMHA Proceedings) becomes Exhibit 4.
- Category 5 (Evidence received after the Request for ALJ Hearing) becomes Exhibit 5.

**b. Categories without documentation.**

If a category does not contain any documents, the exhibit numbers are adjusted so they are sequential for the categories that contain documents.

*Example.*

- Category 1 (Coverage determination, Redetermination and Reconsideration Procedural Documents) becomes Exhibit 1.
- No medical records or other evidence was submitted. There are no documents in category 2 so Exhibit 2 will be used for the next category with documentation.
- Category 3 (Request for ALJ Hearing, including any evidence received) becomes Exhibit 2.
- Category 4 (OMHA Notice & Response to Notice of Hearing) becomes Exhibit 3.
- Category 5 (Evidence received after the Request for ALJ Hearing) becomes Exhibit 4.

**c. New evidence.**

All new evidence received shall be affixed to the left side of the file folder with the Part D New Evidence Coversheet on top. If there are multiple folders, the new evidence shall be placed on the left side of the first file folder.

- i. Evidence the ALJ determines to be admissible shall be placed in the appropriate category and exhibited in accordance with IV-4-3 B.1.
- ii. Evidence the ALJ determines to be excluded from the administrative record is marked as “excluded” on the Part D New Evidence coversheet, is added to the end of the record, and is not exhibited.

**2. Multiple enrollees.**

For request for hearings filed under the aggregation provisions of [§ 423.1970](#) to reach the amount in controversy requirement, the individual appeals should be exhibited under the provisions of **B.1**, above. If a single request for hearing is filed seeking aggregation, the request must be copied and placed in each of the appeal files. See IV-3-4 F for additional information on aggregation.

**C. Non-exhibited Materials**

1. Review the record materials in each category and remove the following:

**a. Non-Probative materials.**

Non-Probative materials are administrative in nature, and not relevant to the disposition of an appeal; therefore, these documents do not need to be retained or otherwise kept associated with the administrative record. Examples of non-probative materials include:

- Case file transmittal sheets;
- Checklists between the PDP and CMS contractors and OMHA;
- CMS contractor divider sheets;
- Blank pages that have not been paginated.

**NOTE:** If the materials are referenced in lower level procedural or substantive documentation, the materials must be retained and exhibited.

**b. Duplicates**

Duplicates are exact copies of information. Duplicates must be kept with the administrative record.

**NOTE:** If there is any difference in the materials, they are not considered duplicates. For example, if there are two copies of the same prescription, but one has handwritten initials in the top corner, the orders are not duplicates, and both prescriptions must be included in the exhibited record.

2. For materials that must be kept with the administrative record, place the appropriate cover separator sheet corresponding to each type of non-exhibited materials (for example, "Duplicates,"), and place on top of the corresponding materials.
3. For non-probative material that is not required to be kept with the administrative record, dispose of the records as appropriate.

**NOTE:** Generally, non-probative materials should not include PII. If PII is present on non-probative materials, the materials must be handled in accordance with OMHA's PII policy.

**D. Preparing the Exhibits**

Prepare the exhibits as follows:

**1. Exhibit identifiers.**

Purple exhibit number slip sheets are inserted above each exhibit as identified in C.2 above.

*Exception:* Field offices may continue to utilize any remaining supplies, for example exhibiting tabs, until such time that the supplies are exhausted.

## 2. Page numbering.

- a. OMHA automated print paginators must be used to paginate paper case file exhibits, or OMHA-approved software must be used to paginate electronic files, with each exhibit separately paginated (that is, pagination restarts for each exhibit).
- b. Handwritten page numbers are not permitted.

*Exception.* In the following circumstances, handwriting or labels may be used for page numbering paper case files, in lieu of the automated print paginators:

- One or more pages were skipped in the middle of the exhibit.

*Example.* Exhibit 1 contains 300 pages, and it is discovered that the device skipped four pages between pages 70 and 71. It is permissible to use the preceding page number (“70”) and add a handwritten letter, in ink, to differentiate the page for citing within a decision or other documentation. For example, the four pages would be labeled “Exhibit 1, page 70a,” Exhibit 1, page 70b,” etc.

- If there are no paginators in the office that are in operating order, typed labels may be used.
- c. Paginate each exhibit from 1 through the last page in a category with page 1 as the first page of each exhibit.

*Example.* A case file includes the following: Exhibit 1, pages 1–10; Exhibit 2, pages 1–35; Exhibit 3, pages 1–5; and Exhibit 4, pages 1–16.

- d. Place page numbers at the bottom center of each page, in the following format: “Exhibit X, Page X.” An abbreviated convention of “Ex. X, p. X” is also acceptable. If there is text in the bottom center of the documents that would make placement of page numbers there unreadable, the page numbers may be placed to the right side of the text.

**NOTE:** If the record contains dual-sided materials, only one side requires pagination. In the decision or other OMHA produced materials, when citing the back/reverse side of the page, include the exhibit and page number, and indicate it is on the reverse side. For example, use “Ex. 1, p. 1 (reverse)”. As discussed in IV-4-4, the exhibit list must include a footnote indicating that the materials are dual-sided; however, the second side is not counted in the page range.

**3. Non-Standard materials.**

**a. Electronic media submissions (for example, compact disc (CD), digital video disc (DVD), or flash/thumb drive).**

- i. Attach electronic media to the administrative record by affixing (for example, using a media jacket with adhesive on the back, staples, and/or tape) directly to the media template, ensuring the item will not come loose or fall out.
- ii. Label the media with the ALJ Appeal Number and identify the information (for example, a summary or index of the contents), directly on the media (if possible) and on the media template. If password protected, the location of the password must be included (for example, "password located in MAS, under the "Notes" tab).

*Example.* After receiving the notice of hearing, the enrollee submits a brief. The brief consists of 10 standard pages and a CD containing exhibits referenced in the brief. The paper portion of the brief is marked as Exhibit 5, pages 1-10. The CD is affixed to the media template which is numbered and added as Exhibit 5, page 11. The page includes a summary of the contents (for example, "ALJ Appeal # 1-999999999, exhibits submitted in support of the enrollee's brief").

**NOTE:** If the material is something other than a CD or DVD (for example, a thumb drive), the material may be labelled and placed at the front of the file or in a separate location (such as a padded envelope), if necessary. A copy of the media template must be placed in the appropriate exhibited portion of the record.

**b. Materials stored separately.**

Materials that are maintained separately from other exhibits within the record must be identified and referenced. Assign these materials exhibit and/or page numbers as appropriate and include them in the exhibit list, just as you would with standard paper documents.

*Example.* After receiving the notice of hearing, the enrollee submits a brief. The brief consists of two oversized three-ring binders. The exhibit list identifies the two binders collectively as part of Exhibit 5. In addition to the ALJ Appeal Number, label the binders as "Exhibit 5, Part 1 of 2" and "Exhibit 5, Part 2 of 2" respectively.

**c. Over-sized materials.**

- i. For materials larger than 8.5"x11" (for example, a mailing envelope), make a photocopy and reduce the size of the material to an 8.5"x11" paper. Ensure all information is included on the reduced size copy. The original may then be discarded.

- ii. For large, bulky, or unwieldy items (for example, an x-ray or sample of a prescription bottle), the ALJ may request that the enrollee submit an image or video of the item. Alternatively, the ALJ may consider the item and
  - (1) reduce the size of the material to an 8.5"x11" photocopy, where possible; or
  - (2) include a picture of the item in the record. Staff must document any necessary information (for example, ALJ Appeal Number, date received, postmark date, sender, addressee, and a description of the item), and return the original item to the enrollee; or
  - (3) If original oversized materials (for example, x-ray films that cannot be reduced in size), are kept in the record, they may be labelled and placed at the front of the file or in a separate location (such as a padded envelope), if necessary.

*Example.* Evidence received by OMHA included oversized x-ray films along with 14 pages of medical records. The exhibit list identifies the medical records as Exhibit 2, pages 1-15. The x-rays are affixed to the media template, which is numbered Exhibit 2, page 15. The page includes a summary of the contents (for example, "ALJ Appeal # 1-999999999, X-rays"). The x-rays are placed at the front of the file. The media template is affixed to the x-rays and a copy of the media template is placed at Exhibit 2, page 15, with a note that the x-rays are attached to the front of the file.

**d. Undersized materials.**

For materials smaller than 8.5"x11," such as a photograph, attach to the administrative record by affixing (for example, using staples and/or tape) directly to an 8.5"x11" sheet of paper or in an envelope secured to an 8.5"x11" sheet of paper, ensuring that the item will not come loose or fall out. The sheet of paper must be labeled with the appropriate exhibit and page number.

**e. Audio Recordings.**

**i. Generally.**

Audio recordings of conferences and hearings must be copied on a CD in accordance with OMHA PII policy, labeled with the ALJ Appeal Number, type of conference or hearing, and the date:

*Example.* ALJ Appeal # 1-999999999, Hearing, September 30, 2014.

**ii. Placement in the administrative record.**

Attach audio recordings to the administrative record by affixing (for example, using a media jacket with adhesive on the back, staples, and/or tape) on the left side of the folder containing the administrative record, ensuring the audio recording(s) will not come loose and fall out. If there is more than one folder, place the recording on the left side of the last folder.

**iii. Recordings of consolidated hearings when record is not also consolidated.**

For appeals filed under the provisions of [§ 423.1970](#) that involve consolidated hearings, affix the audio of the entire consolidated hearing to each enrollee file, specifying the end time stamp for the general portion of the hearing and the start and stop time stamp for the individual enrollee using the consolidated record label template.

**NOTE:** If the record (including the hearing recording) is requested by the enrollee, the enrollee must only be given the portion that applies to the appeal requested to prevent unauthorized disclosure of PII.

**NOTE:** This provision may not be used to combine hearings by representative. If multiple enrollees are represented by the same representative and grouped for hearing on the same day for administrative efficiency, an individual audio record must be created for each enrollee. Similarly, this provision may not be used to combine an entire day of hearings with multiple enrollees.

**4. Evidence submitted for the first time at the OMHA level.**

- a. Evidence submitted to OMHA (for example, with the request for hearing) must be reviewed to determine whether the evidence is duplicative of evidence already in the administrative record, or new evidence submitted for the first time at the OMHA level.
- b. New evidence submitted to OMHA must be removed and affixed to the left side of the case file folder for review by the ALJ.

**NOTE:** The ALJ need not find good cause to admit new evidence submitted by the enrollee.

*Example.* The Appellant, an enrollee, submits 15 pages of evidence with the request for hearing. A review of the evidence shows 5 pages are new medical records and 10 pages are duplicates of medical records that have been marked as Exhibit 2. The duplicate records are placed at the end of the record behind duplicative records coversheet. A Part D New Evidence Coversheet is added on top of the 5 pages of new records, which are then affixed to the left side of the folder. The ALJ does not

need to find good cause to admit the new documentation submitted by the enrollee as part of Exhibit 3. Ultimately these 5 pages of new records must be added to Exhibit 3 and the exhibit list updated to reflect the new page range.

**NOTE:** An ALJ will not consider any evidence submitted regarding a change in condition of an enrollee after the appealed coverage determination was made. § 423.2018(a)(1). An ALJ will remand a case to the Part D QIC where an enrollee wishes evidence of a change in condition after the coverage determination to be considered. [§ 423.2018\(a\)\(2\)](#).

## **E. Non-exhibited Record Materials**

Move non-exhibited record materials (for example, duplicates, or information relating to enrollees not at issue) to the end of the exhibited portion of the record (after Exhibit 1), separated by the purple slip sheets indicating the type of non-exhibited materials (see subsection **C.2**, above).

## **F. Securing the Exhibited and Non-exhibited Record Materials**

### **1. Organize materials.**

The records are organized with the non-exhibited records on the bottom, then in reverse sequence starting with Exhibit 1.

*Example.* The administrative record includes 4 exhibits and duplicative records. The duplicative records are placed at the bottom with the duplicative records coversheet on top. Exhibit 1, with the corresponding coversheet, is placed on top of the duplicative records. Exhibit 2, with the corresponding coversheet, is placed on top of Exhibit 1. Exhibit 3, with the corresponding coversheet, is placed on top of Exhibit 2. Exhibit 4, with the corresponding coversheet, is placed on top of Exhibit 3 and is the first exhibit visible when the file folder is opened.

### **2. Hole Punching.**

Two-hole punch both the exhibited and non-exhibited materials so that the file is bound on the side, and opens like a book.

### **3. Labeling the folder(s) containing the record materials.**

- a. Label the front of the folder(s) that contains the administrative record with the ALJ Appeal Number.

*Example.* "ALJ Appeal # 1-999999999."

- b. If there are multiple folders, indicate the folder number and the total folders included with the administrative record.

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*Example.* For an appeal with two folders, place “ALJ Appeal # 1-999999999, 1 of 2” on the top front of first folder and “ALJ Appeal # 1-999999999, 2 of 2” on the top front of the second folder.

**NOTE:** If an appeal requires the use of one or more boxes to house the folders, label each box with the ALJ Appeal number. If there is more than one box, indicate the box number and the total number of boxes containing the administrative record (for example, “ALJ Appeal 1-999999999, Box 1 of 2.” Boxes should only contain appropriately bound files and not loose papers.

## **IV-4-4 Exhibit List**

**Citations:** [§ 423.2042](#).

### **A. Preparing the Exhibit List**

1. A typed exhibit list must be created using form OMHA-156.

**NOTE:** No handwriting is permitted on the exhibit list.

2. The exhibit list identifies the following:

#### **a. Exhibit number.**

The exhibit number on the exhibit list corresponds to the exhibit number in the administrative record, based on the categories in [IV-4-3 B](#).

#### **b. Description.**

- The minimum description on the exhibit list corresponds to the categories in [IV-4-3 B](#).
- Additional descriptions of materials within an exhibit may be listed as bulleted items in the exhibit list under the description, with page ranges.

#### **c. Page range.**

The pages on the exhibit list refer to the page range of the materials within each exhibit.

**NOTE:** If the exhibited materials are dual sided, the exhibit list must include the following footnote: “Some materials in the exhibited record are dual sided. References to the second side include a notation of (reverse). For example, “Ex. 1, p. 1 (reverse).” The second side of a dual sided page is not included in the page count for the page number range.”

#### **d. Date.**

This is the date of the most recent revision to the exhibit list. The date on the exhibit list ensures the most recent exhibit list is maintained in the administrative record.

*Example.*

**EXHIBIT LIST**

<b>Exhibit</b>	<b>Description</b>	<b>Pages</b>
1	Coverage determination, Redetermination and Reconsideration procedural documents	1–25
2	Medical Records/Evidence received by PDP and CMS contractors	1–110
3	Request for ALJ Hearing	1–30
4	OMHA Proceedings	1–10

Dated: [September 30, 2014]

*Example.* Exhibit list highlighting certain materials within the exhibit.

**EXHIBIT LIST**

<b>Exhibit</b>	<b>Description</b>	<b>Pages</b>
1	Coverage determination, Redetermination and Reconsideration procedural documents	1–25
2	Medical Records/Evidence received by PDP and CMS contractors <ul style="list-style-type: none"> <li>• Office visit notes</li> <li>• Letters of medical necessity</li> </ul>	1–30 32–40
3	Request for ALJ Hearing	1
4	OMHA Proceedings <ul style="list-style-type: none"> <li>• Notice of Hearing</li> <li>• Response to Notice of Hearing</li> <li>• Report of contact</li> </ul>	1–4 5–9 10

Dated: [September 30, 2014]

3. The current exhibit list must be maintained on the top of the record on the left side of the file. Exhibit lists are not exhibited in the administrative record, unless included as an attachment to information added to the record (for example, attached to the notice of hearing or an updated exhibit list sent prior to hearing, when required under subsection C, below).

## B. Providing the Exhibit List

An initial copy of the exhibit list is sent:

1. With the notice of hearing, to the enrollee and participants who receive the notice; or
2. At the first available opportunity before the hearing to the enrollee and participants who responded to the notice of hearing.

**NOTE:** The enrollee may review the record at the hearing, or if no hearing is held, at any time prior to issuance of the decision. [§ 423.2042\(a\)\(3\)](#).

## C. Updating the Exhibit List

The exhibit list must be updated with materials added to the administrative record prior to issuance of the decision, including any post-hearing submissions, if applicable.

*Example.*

### EXHIBIT LIST

<b>Exhibit</b>	<b>Description</b>	<b>Pages</b>
1	Coverage determination, Redetermination and Reconsideration procedural documents	1–25
2	Medical Records/Evidence Received by PDP and CMS Contractors	1–110
3	Request for ALJ Hearing	1-30
4	OMHA Proceedings	1–10
5	Evidence received after the Request for ALJ Hearing	1–15

Dated: [October 1, 2014]

**NOTE:** The current exhibit list is maintained on the top of the record. When an exhibit list is updated, all prior exhibit lists are discarded, in accordance with OMHA’s policy for disposal of PII.

## D. Finalizing the Exhibit List

A copy of the final exhibit list must be sent to the enrollee with the notice of decision.

**NOTE:** The exhibit list is finalized on the date the notice of decision is mailed.

## **IV-4-5 Finalizing the Administrative Record**

**Citations:** [§ 423.2042](#).

### **A. Overview**

The original disposition documents must be hole punched and placed on the top of the complete administrative record. If there is more than one folder, the disposition documents must be placed in the last folder. If there are master folders, the disposition documents must be placed in the last master folder.

The materials must be placed in the folder in the following order, from top to bottom:

1. Notice of disposition (for example, escalation, remand, dismissal, or decision);
2. Disposition document;
3. Attachments, if any; and

**NOTE:** Do not include form DAB-101.

4. Final exhibit list.

### **B. Ensuring the record is clean**

No marks (for example, writing, highlighting, or notations) may be made on the record materials, other than the page numbering required for exhibiting made in accordance with [IV-4-3 D.2](#)). Any self-adhesive notes that may be used in reviewing the case or conducting the hearing must be removed prior to the closing and forwarding of the case file from OMHA.

## **IV-4-6 Adding Materials to the Record after Issuance of a Decision or Other Disposition**

Citations: [§ 423.2042](#).

### **A. Generally**

Disposition and supporting documents received each time action is taken at a different level following the original ALJ disposition must be given a new category number and added as the next sequential exhibit number.

### **B. Amended Decision or Other Disposition**

For an appeal in which a request for clarification has been received and a clerical edit (for example, correction of the ALJ Appeal Number) is required:

1. If the case file has already been sent to the contractor, provide the amended decision, dismissal, or remand, as requested. Upload the amended document in MAS.
2. If the case file is still with the team, provide the amended decision, dismissal, or remand to the contractor, as requested. Add the amended document on top of the records and finalize processing as appropriate.

### **C. Remand from the Council**

If an appeal is remanded from the Council:

1. Use the existing file as exhibited at OMHA. The OMHA disposition documents are added as a new exhibit for Category 6—OMHA Disposition documents. Add the materials from the Council (for example, Council notice of remand, Council remand order, and exhibits entered into evidence by Council) to a new exhibit for Category 7—Post-disposition Proceedings.
2. Add the materials related to OMHA proceedings after remand to a new exhibit for an additional category (for example, “Category 8—OMHA Proceedings after Remand from the Council”).

*Example.* The ALJ issues a decision based on the following 5 exhibits:

- Exhibit 1— Coverage determination, Redetermination and Reconsideration procedural documents
- Exhibit 2—Medical Records/Evidence received by CMS Contractors
- Exhibit 3—Request for ALJ Hearing
- Exhibit 4—OMHA Proceedings

- Exhibit 5—Evidence received after the Request for ALJ Hearing

The Council remands the file to OMHA and additional documentation received by Council is included in the remanded file. The ALJ holds a new hearing and issues a new decision. Upon review, the Council remands to OMHA a second time. The exhibited administrative record now includes the following exhibits:

- Exhibit 6—January 1, 2013 OMHA Disposition documents
- Exhibit 7—Post-disposition Proceedings, April 1, 2013 Remand from Council with additional evidence
- Exhibit 8—OMHA Proceedings after Remand from Council
- Exhibit 9—August 1, 2013 OMHA Disposition documents
- Exhibit 10— Post-disposition Proceedings, December 1, 2013 Remand from Council with additional evidence

#### **D. Return after remand to the Part D QIC**

For appeals returned to OMHA after remand to the Part D QIC:

- If the record was not exhibited prior to remand to the Part D QIC, organize and exhibit the administrative record as detailed in IV-4-2 A. Place the remand order in Exhibit 1.
- If the file was exhibited prior to remand to the Part D QIC, use the existing file as exhibited and add any additional materials provided by the QIC under the exhibit for Category 7—Post-disposition Proceedings.
- Add the materials related to OMHA proceedings after return of remand to the Part D QIC as a new exhibit for an additional category (for example, “Category 8—OMHA Proceedings after Remand to the Part D QIC”).

**NOTE:** Where an ALJ requests information from the QIC but retains jurisdiction of the appeal, the case file remains with the ALJ. Record materials furnished by the Part D QIC are added to the exhibit for the appropriate category (for example, if the ALJ requests a copy of a document referenced in the Part D QIC decision that is not included in the record received, add the document to Category 2—Medical Records/Evidence received).

#### **E. Requests for Reopening**

An enrollee may request a reopening of an ALJ hearing decision within 180 calendar days of the decision for good cause, in accordance with [§ 423.1986](#).

**1. Good cause exists.**

For appeals that are reopened, upon receiving the file, use the existing file as exhibited and add any additional materials relating to the request, reopening, and revised decision to a new exhibit for the appropriate category (for example, Category 7–Post-disposition Proceedings).

**2. Good cause does not exist or the request for reopening was untimely.**

For appeals that are not reopened, forward the request from the enrollee, response from OMHA indicating the ALJ determined good cause did not exist to reopen the appeal, and any other relevant materials to the contractor.

**NOTE:** Only decisions can be reopened. An ALJ may not reopen a dismissal or remand.

**F. Return to the ALJ after Rejection of Expedited Access to Judicial Review (EAJR) by the review entity (DAB)**

Upon receipt of the file, add any additional materials forwarded by the review entity to the exhibit for the appropriate category (for example, Category 4–OMHA Proceedings).

**NOTE:** The returned file is treated as a timely request for hearing, and the adjudication period begins on the day the request is received by OMHA.

## IV-4-7 Requests for Copies of the Record

Citations: [§ 423.2042](#).

### A. Generally

The enrollee may request a copy of all or part of the administrative record, including the recording of any conferences or hearings.

**NOTE:** Upon receipt of a request, staff may contact the enrollee and clarify the records that the enrollee is seeking or requested. Staff may ask whether the enrollee will accept a scan of voluminous materials on CD; however, electronic transmission of PII may only be made in accordance with OMHA's PII policy.

**NOTE:** If a request for a copy of the administrative record is made after OMHA has transferred the record to CMS or a CMS contractor, the requesting party must contact CMS to obtain a copy of the record.

### B. Submission of a Request for a Copy of the Record

The enrollee may request a copy of all or part of the record (including a copy of any audio recordings) in one of the following ways:

#### 1. In writing.

##### a. Request made by the enrollee or representative.

A written request by the enrollee, or the enrollee's representative, may take any form. [Form HHS-719](#), Request for Copy of the Record(s) in the Case File, may be used.

**NOTE:** Although [Form HHS-719](#) provides instructions for making a Freedom of Information Act (FOIA) request, a FOIA request is not needed where the enrollee requests records for an open appeal. If a request for a copy of the administrative record is made after OMHA has transferred the record to CMS or a CMS contractor, the requesting party must contact CMS to obtain a copy of the record.

##### b. Request made by a third party.

If the request is made by the third party, both [Form HHS-720](#), Request for Copy of Record(s): Third Party with the Individual Appellant's Consent, and [Form HHS-721](#), Individual Appellant's Consent to Third Party for Copies of the Individual Appellant's Record(s), should be used. If these forms are not used, the request must include all of the elements contained in the two forms, including a written, signed and dated consent of the party to release the record to the requestor. If individual consents to

only a portion of the record being released, the consent must specify which documents may be released and which documents must be removed or redacted.

**NOTE:** If a request for a copy of the administrative record is made after OMHA has transferred the record to CMS or a CMS contractor, the requesting party must contact CMS to obtain a copy of the record.

**2. Orally.**

If the enrollee makes an oral request for a copy of all or part of the record, the request must be documented in a report of contact and report of contact added to the record.

**C. Reserved.**

**D. Requests for an Opportunity to Comment**

If the enrollee requests an opportunity to comment on the record, the ALJ must provide the enrollee with a reasonable time to review the record and provide a response, depending on the volume and nature of the materials.

**NOTE:** The adjudication period is tolled from receipt of the request through the expiration of the comment period. [§ 423.2042\(b\)\(1\)](#).