Significant Regulatory Changes and OMHA Initiatives Impacting the Medicare Appeals Process

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HCCA Compliance Conference; April 15, 2018 1

Agenda

1. Overview of Medicare Appeals Process
2. OMHA Workload Updates
3. 2017 Medicare Appeals Final Rule (Selected Provisions)
   - Precedential Decisions
   - Attorney Adjudicators
   - New Evidence
   - CMS and CMS Contractor Participation
   - Remands and Review of Remands
   - Miscellaneous Provisions to Streamline Appeals Process
4. OMHA Initiatives
5. CMS Initiatives
Five Level Appeal Process

1. Redetermination ("MAC" Medicare Administrative Contractor)
2. Reconsideration ("QIC" Qualified Independent Contractor)
3. Administrative Law Judge "ALJ" ("OMHA" Office of Medicare Hearings and Appeals)
4. Medicare Appeals Council (Departmental Appeals Board)
5. Federal District Court

Before the Appeal, Record Requests

- Pre-Payment Audit
- Post-Payment Audit—typically a reopening of an initial determination
- Responding to Record Request
  - Generally have 45 calendar days to submit the requested documentation, except ZPICs/UPICs may require submission within 30 days.
- Review Determinations
  - MACs – 60 days
  - RACs – 30 days
**Record Request Practice Tips**

- Request an extension in advance of deadline
- Records maintained by third parties
- Revocation concerns:
  - 42 C.F.R 424.525 and 42 C.F.R 424.516: A provider or supplier that furnishes covered ordered items of DMEPOS, clinical laboratory, imaging services or covered ordered/certified home health services is required to maintain documentation for 7 years from the date of service and, upon request, provide CMS or a Medicare contractor access to that documentation. Failure to comply with this documentation requirement is a basis for revocation.

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**Before the Appeal**

- Medical Review Decision Letter v. Demand Letter
- Demand Letter
  - Triggers Appeal Deadlines
  - Reconcile Against Decision Letter
- Multiple Demand Letters
- Notification of Secondary Payors
- Discussion Period for RACs
**Before the Appeal, Rebuttals**

- The provider may submit a rebuttal statement to the demand letter within 15 calendar days from the *date* of the demand letter
- The rebuttal will lay out why Medicare should not initiate recoupment
  - The reasons should be other than a disagreement over the overpayment assessment
- A rebuttal statement is *not* an appeal

**Level I: Redetermination**

- An “initial determination” or “reopening determination” must exist
- The contractor’s decision on a claim is the “initial determination”
- An initial determination that is revised in a reopening by the MAC (as typically happens in post-payment audits) becomes a “revised” or “reopened” determination
- Form v. Letter
  - File within 120 days of receipt of the initial determination
    - presumed to be five days after date of notice
    - but for stay of recoupment, file within 30 days
- Appointment of representation; duration of validity
Level I: Redetermination

- 95% of redeterminations should be decided by the MAC within 60 days of the filing
  - Submitting additional evidence extends deadline fourteen (14) days for each such submission
- No right to escalate to next level if MAC does not issue decision within 60-day (or as extended) time frame
- Desk review must be conducted by a different individual(s) than the one(s) who made the initial or reopened determination
- Qualifications of reviewers

<table>
<thead>
<tr>
<th>Appeal Category</th>
<th>Decided Claims</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient</td>
<td>163,661</td>
<td>39%</td>
</tr>
<tr>
<td>Home Health</td>
<td>72,710</td>
<td>17%</td>
</tr>
<tr>
<td>Other (Hospice, etc.)</td>
<td>78,230</td>
<td>19%</td>
</tr>
<tr>
<td>Inpatient</td>
<td>31,180</td>
<td>7%</td>
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<tr>
<td>Skilled Nursing Facility (SNF)</td>
<td>14,194</td>
<td>3%</td>
</tr>
<tr>
<td>Lab</td>
<td>52,891</td>
<td>13%</td>
</tr>
<tr>
<td>Ambulance</td>
<td>3,994</td>
<td>1%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>417,160</td>
<td>100%</td>
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<thead>
<tr>
<th>Appeal Category</th>
<th>Decided Claims</th>
<th>Percent</th>
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<tbody>
<tr>
<td>Physician</td>
<td>1,502,178</td>
<td>49%</td>
</tr>
<tr>
<td>Durable Medical Equipment (DME)</td>
<td>1,109,356</td>
<td>36%</td>
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<tr>
<td>Lab</td>
<td>143,746</td>
<td>5%</td>
</tr>
<tr>
<td>Ambulance</td>
<td>134,126</td>
<td>4%</td>
</tr>
<tr>
<td>Other (Rehabilitation Services, Vision, etc.)</td>
<td>166,274</td>
<td>5%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>3,055,680</td>
<td>100%</td>
</tr>
</tbody>
</table>
**Level I: Redetermination**

**Redetermination Practice Tips**

- CMS’s 60 Day Overpayment Final Rule: In the absence of an appeal, a provider may be considered to be put on notice to look back and report potential overpayments for the previous six years.

  [T]he contractor or government audit may be for a limited time period. If the provider or supplier confirms the audit’s findings, then the provider and supplier may have credible information of receiving a potential overpayment beyond the scope of the audit if the practice that resulted in the overpayment also occurred outside of the audited timeframe. In such situations, providers and suppliers will need to conduct reasonable diligence within the lookback period of this rule . . . 81 Fed. Reg. 7654 at 7667 (Feb. 12, 2016)

  RAC audit findings, as well as other Medicare contractor and OIG audit findings, are credible information of at least a potential overpayment. Providers and suppliers need to review the audit findings and determine whether they have received an overpayment. As part of this review, providers and suppliers need to determine whether they have received overpayments going back 6 years as stated in this rule. Id. at 7672.
Level I: Redetermination

Redetermination Practice Tips (cont’d)

- CMS’s 60 Day Overpayment Final Rule (cont’d)
  
  The provisions of this final rule establish that a person has the responsibility to conduct an investigation in good faith and a timely manner in response to obtaining credible information of a potential overpayment and to return identified overpayments by the deadline set forth in § 401.305(b). This responsibility exists independent of the appeals process for contractors’ overpayment determinations. 81 Fed. Reg. 7654 at 7667 (Feb. 12, 2016)

  If the provider appeals the contractor identified overpayment, the provider may reasonably assess that it is premature to initiate a reasonably diligent investigation into the nearly identical conduct in an additional time period until such time as the contractor identified overpayment has worked its way through the administrative appeals process. Id.

  If the MAC notifies a provider of an improper cost report payment, the provider has received credible information of a potential overpayment and must conduct reasonable diligence on other cost reports within the lookback period to determine if it has received an overpayment. Id. at 7670


Level I: Redetermination

Redetermination Practice Tips (cont’d)

- Risk of Revocation: Providers and suppliers may consider appealing claims to avoid a determination that the provider or supplier has a pattern or practice of noncompliance with billing practices.

  - Standard language in ZPIC Notices of Medical Review Results: “Per 42 C.F.R. § 424.535(a)(8)(ii), CMS has the authority to revoke a currently enrolled provider or supplier’s Medicare billing privileges and any corresponding provider agreement based on a pattern or practice of submitting claims that fail to meet Medicare requirements. Should you continue to fail to meet these requirements as described in this letter, your billing privileges may be revoked on this basis or any of the bases articulated in 42 C.F.R § 424.535(a).”
Level I: Redetermination

Redetermination Practice Tips (cont’d)

- Scope of Review: For redeterminations and reconsiderations of claims denied following a complex prepayment review, CMS has instructed MACs and QICs to limit their review to the reason(s) the claim or line item at issue was initially denied.


Level II: Reconsideration

- Form v. Letter
- File within 180 days of receipt of the redetermination
  - But for stay of recoupment, file within 60 days of date of redetermination
- Early presentation of evidence: New evidence cannot be considered at subsequent levels of appeal, unless “good cause” is shown
  - If the QIC issues a decision before submission of all evidence, you can request the QIC to reopen its decision, but the decision to do so is discretionary.
- Evidence may be presented to the QIC at any time before its decision
  - Each submission extends the QIC’s deadline fourteen (14) days
- Decision within 60 days (plus extensions)
  - If QIC does not issue a decision within 60 days, then appellant can, upon request to the QIC, “escalate” to the ALJ level. However, due to the backlog of pending appeals at the ALJ level, this is not a practical option at this time.
**Level II: Reconsideration**

- Once the QIC issues its decision, stay of recoupment ends
- QIC may obtain evidence on its own
  - QICs are not bound by contractor Local Coverage Decisions or CMS program guidance “such as program memoranda or manual instructions, but [must] give substantial deference to these”
  - On questions of medical necessity, the QIC must use panels of physicians or other “appropriate health care professionals”
- No hearing at the QIC level (desk review)
- Consider request to reopen for clear error

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### Top 10 Part A Reconsideration Categories for 2016

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<thead>
<tr>
<th>Appeal Category</th>
<th>Decided Claims</th>
<th>% of Total</th>
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<tbody>
<tr>
<td>Home Health</td>
<td>40,871</td>
<td>27%</td>
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<tr>
<td>Outpatient Therapies / CORF</td>
<td>24,228</td>
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<tr>
<td>Skilled Nursing Facility</td>
<td>14,626</td>
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<td>Acute Inpatient Hospital</td>
<td>14,448</td>
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<tr>
<td>MSP</td>
<td>11,237</td>
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<tr>
<td>Hospice</td>
<td>8,288</td>
<td>5%</td>
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<tr>
<td>Outpatient Hospital / ASC</td>
<td>7,907</td>
<td>5%</td>
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<tr>
<td>Drugs</td>
<td>5,017</td>
<td>3%</td>
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<tr>
<td>Acute Inpatient Rehab.</td>
<td>4,908</td>
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<tr>
<td>AC Dismissal</td>
<td>3,449</td>
<td>2%</td>
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Level II: Reconsideration


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<thead>
<tr>
<th>Appeal Category</th>
<th>Decided Claims</th>
<th>% of Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pathology/Laboratory</td>
<td>115,417</td>
<td>29%</td>
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<tr>
<td>Ground Transportation</td>
<td>44,547</td>
<td>11%</td>
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<tr>
<td>Other</td>
<td>44,185</td>
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<tr>
<td>Office E/M Services</td>
<td>25,604</td>
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<tr>
<td>Integum/Muscular-skeletal Surgery</td>
<td>22,771</td>
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<tr>
<td>Imaging/Radiology</td>
<td>18,036</td>
<td>4%</td>
</tr>
<tr>
<td>Outpatient Therapies / CORF</td>
<td>18,031</td>
<td>4%</td>
</tr>
<tr>
<td>Hospital E/M Services</td>
<td>17,110</td>
<td>4%</td>
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<tr>
<td>Drugs</td>
<td>13,461</td>
<td>3%</td>
</tr>
<tr>
<td>AC Dismissal</td>
<td>11,846</td>
<td>3%</td>
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Reconsideration Dispositions for 2016

- **Part A Reconsiderations**
  - Unfavorable: 77%
  - Partially Favorable: 22%
  - Favorable: 2%

- **Part B Reconsiderations**
  - Unfavorable: 76%
  - Partially Favorable: 23%
  - Favorable: 2%
Level II: Reconsideration

Reconsideration Practice Tips:

- **Issue preservation:** If you haven’t already done so at redetermination, ensure that your request for reconsideration includes all issues that you wish to raise.

- **Submission of evidence:**
  - To the extent possible, submit all evidence at reconsideration. Absent good cause, the evidence is excluded from the record.
  - If reconsideration request is submitted early to avoid recoupment and not all documentation is included, note that you expect to submit additional documentation in appeal letter.
  - If there is evidence you have tried unsuccessfully to obtain, include this in your appeal letter to help establish good cause.

OMHA Workload Updates

**OMHA Current Status**

- **As of Jan. 26, 2018,** OMHA had about 502,000 appeals pending
  - **Down** from over 880,000 appeals pending at end of FY 2015
- **In FY 2017,** OMHA received about 113,000 appeals
  - **Down** from prior years (e.g., over 470,000 were filed in FY 2014)
  - OMHA disposition capacity in FY 2017 was approximately 77,000 appeals—in FY 2018 it will be approximately 93,500
- **Average processing time frame at OMHA is 1216 days***

* As of February 19, 2018
OMHA by the Numbers

Average Receipts per Team per Day

Average Dispositions per Team per Day

Average Agency Dispositions per Day (Including Special Initiatives)

Average Processing Time


OMHA Updates

Appeals Received and Decided by Fiscal Year

*Data current as of September 30, 2017
OMHA Workload Updates

**FY 2017 Receipts by Medicare Type**

![Pie chart showing receipt distribution by Medicare Type]

- Part A
- Part B
- Part C
- Part D
- Entitlement
- IRMAA

Run date: Dec 18, 2017

Office of Medicare Hearings and Appeals

**Organizational Chart**

- Chief Administrative law Judge
- Deputy Chief Administrative Law Judge

**Office of Programs**
- Budget & Financial Management Division
- Executive Support and Resources Division
- Information Management and Systems Division
- Program Evaluation and Policy Division

**Field Offices**
- Arlington, VA
- Cleveland, OH
- Irvine, CA
- Kansas City, MO
- Miami, FL
- Seattle, WA

**Office of Operations**
- Field Operations Division
- Central Operations Division
2017 Final Rule


- Became Effective March 20, 2017
- **Stated Goals include:**
  - Streamline the administrative appeals process
  - Increase consistency in decision-making across appeal levels
  - Improve efficiency for both appellants and adjudicators
  - Expand the available pool of adjudicators at the third level of appeal
- Read the fact sheet on the OMHA website at

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**2017 Final Rule**

**Precedential Decisions (§401.109)**

- DAB Chair may designate a Medicare Appeals Council decision as precedential
  - Decisions that address, resolve, or clarify recurring legal issues, rules or policies, or that may have broad application or impact, or involve issues of public interest
- Notice of precedential decision published in Federal Register and on Council website
- Binding on CMS and HHS components, SSA
2017 Final Rule

**Precedential Decisions (cont’d)**

- **Legal analysis and interpretation** of Medicare authority or provision is binding in future appeals where same authority or provision applies and is still in effect
- **Factual findings** are binding in future appeals involving the same parties if the relevant facts are the same and evidence is presented that underlying factual circumstances are unchanged

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**OMHA Attorney Adjudicators (§405.902)**

- Licensed attorney with knowledge of Medicare coverage and payment laws and guidance, and authorized to take the actions provided for in the regulations on requests for ALJ hearing and requests for reviews of QIC dismissals
- Currently limited to OMHA senior and supervisory attorneys
  - First round of designations made September 14, 2017 (18 part-time attorney adjudicators)

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OMHA Attorney Adjudicators (cont’d)

- Authorized to:
  - Decide cases that do not require a hearing
  - Issue remands
  - Dismiss a request for hearing when the appellant withdraws
  - Dismiss a request for review for any reason

- Appellants can send requests to reaffirm waivers of oral hearing filed prior to March 20, 2017 to:
  OMGHA Central Operations
  200 Public Square, Suite 1260
  Cleveland, OH 44114-2316

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<table>
<thead>
<tr>
<th>Action</th>
<th>ALJ</th>
<th>Attorney Adjudicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conduct a conference and/or hearing</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Decide a case that does not require a hearing</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Decide or dismiss a request for review of a dismissal</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Dismiss a request for hearing when appellant withdraws</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Dismiss a request for hearing for any other reason</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Issue remands</td>
<td>YES</td>
<td>YES</td>
</tr>
</tbody>
</table>
### 2017 Final Rule

#### Action ALJ Attorney Adjudicator

<table>
<thead>
<tr>
<th>Action</th>
<th>ALJ</th>
<th>Attorney Adjudicator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Request information from CMS or CMS contractor</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Make a good cause determination on submission of new evidence</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Determine AIC was met for a request for hearing</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Determine AIC not met for a request for hearing</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Review fee petition</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>Call an OMHA expert</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>Raise new issue</td>
<td>YES</td>
<td>NO</td>
</tr>
</tbody>
</table>

**New Evidence (§§405.1018, 405.1028)**

- Requirement to show good cause for the introduction of new evidence does NOT apply to:
  - An unrepresented beneficiary, or a beneficiary represented by someone other than a provider or supplier
  - CMS or any of its contractors
  - A Medicaid State agency
  - An applicable plan

- If good cause is required, statement **must** be included with request for hearing
2017 Final Rule

New Evidence (cont’d)

For new evidence submitted by a provider, supplier, or beneficiary represented by a provider or supplier, §405.1028 provides 4 new examples of when good cause may be found:

- Material to a new issue identified after QIC decision
- Unable to be obtained prior to QIC’s decision, and evidence that reasonable attempts were made
- Previously submitted but missing evidence
- Any other circumstance where party could not have obtained evidence before the QIC issued its reconsideration

New Evidence Practice Tip

- Early presentation of evidence: Providers should gather all evidence and retain experts as early as possible.
  - Providers should obtain documentation of the methodology used for statistical sampling and extrapolation so the provider can timely submit evidence challenging the methodology used, such as a statistician review report.
- Relevant additional medical records
- Waiver of liability/provider without fault
### CMS and CMS Contractor Participation

#### 2 types of participation:
- **Party (§405.1012)**
  - All the same rights and responsibilities of any other party
  - Not permitted when appellant is an unrepresented beneficiary
- **Non-party participant (§405.1010)**
  - Limited scope of participation

#### 2 opportunities to elect:
- Within 30 calendar days after notification that a request for hearing was filed (non-party participant elections only)
- Within 10 calendar days of receipt of notice of hearing

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### CMS and CMS Contractor Participation (cont’d)

- New limits on the number of CMS or CMS contractor entities permitted to attend oral hearing
  - 1st entity to file party status election; OR
  - If no entity elects to be a party, 1st contractor to respond to notice of hearing
- Additional entities may be non-party participants; may not attend oral hearing, but may:
  - File position papers/written testimony
  - Be called as a witness by CMS or contractor participating as a party
Contractor Participation Practice Tip

- Object if contractor does not timely send written notice of its intent to participate in the ALJ hearing.

- Submission of additional evidence
  - In general, parties must submit all written or other evidence they wish to have considered with the request for hearing by the date specified in the request for hearing, or if a hearing is scheduled, within 10 calendar days of receiving the notice of hearing. If a provider or supplier has new evidence, include a statement of good cause for submitting the evidence for the first time at the ALJ level of appeal.

- Contractor participation impacts the scope of review by the Council:
  - If CMS or its contractor participated in the hearing, the Council exercises its own motion review if there is an error of law material to the outcome of the decision, an abuse of discretion, the conclusions are not supported by a preponderance of the evidence, or there are issues of broad public policy.
  - If CMS or its contractor did not appear as a party, the Council will accept review only if there is an error material to the decision or there are issues of broad public policy.

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2017 Final Rule

Remands (§§405.1056, 405.1058)

**Old Rule**

Remands and Requests for Information

§405.1034

**New Rule**

Requests for Remands

Information §§405.1056 and 405.1058

§405.1034
Remands (cont’d)

Requested Remands—§405.1056(c)

- CMS or CMS contractor and appellant jointly request a remand to the QIC that issued the reconsideration, and a remand is likely to resolve the matter(s) in dispute.
- If the ALJ or attorney adjudicator believes the remand will resolve the issues on appeal, the adjudicator may remand to the QIC to reopen decision and take further action.

Review of Remands—§405.1056(e)

- Previously, no procedure for requesting review of a remand.
- Under the final rule, parties, CMS, and CMS contractors may request that the OMHA Chief ALJ (or designee) review a remand they believe was not authorized by § 405.1056.
  - If the remand is found to have been unauthorized, the order is vacated and the case resumes at OMHA.
  - If the remand is found to have been authorized, the finding of the Chief ALJ or designee is binding and not subject to further review.
2017 Final Rule

Stipulated Decisions (§405.1038(c))

CMS or a contractor can stipulate in writing or orally at a hearing that a claim should be paid. The statement:

- Indicates the item or service at issue is covered or payment may be made
- If the amount of payment is at issue, agrees to the amount of payment the parties believe should be made

The ALJ or attorney adjudicator may issue a stipulated decision finding in favor of appellant or other liable parties without making findings of fact, conclusions of law, or further explaining the reasons for the decision.

Stipulated Decisions Practice Tips

- Limit the scope of cases
- Another settlement opportunity
- Allowable payment/reimbursement for procedure
2017 Final Rule

Escalation (OMHA → Council) (§405.1016(f))

- Appeals of Part A and Part B QIC reconsiderations pending more than 90 days at OMHA
  - 180 days for escalated requests for QIC reconsiderations
- Now a 1-step process: File escalation request with OMHA and send a copy to the other parties who were sent a copy of the QIC reconsideration
  - If OMHA time frame has elapsed and an ALJ or Attorney Adjudicator is unable to issue a decision, dismissal, or remand within 5 days, the appeal is sent to the Council for review
  - If escalation request is invalid, OMHA sends notice to appellant
- Council review is conducted on a 180-day time frame

Final Rule Takeaways

- Provides clarity to reduce delays
  - Establish precedential decisions from the Council
  - Clarify the need for good cause to submit new evidence at OMHA level
  - Clarify CMS contractor participation at OMHA level
- Streamlines processes
  - Add attorney adjudicators to increase case-processing capacity
  - Reduce remands back to CMS contractors for information requests
  - Provide for stipulated decisions at ALJ level
  - Simplify OMHA-to-Council escalation process
**ALJ Level Practice Tips**

- Position paper
- Retain experts
- Witnesses
- Statistical sampling
- Challenges to contractors
- Waiver of interest/provider without fault

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**Medical Necessity**

**Medicare Program Integrity Manual – Chapter 13**

- Section 13.3 – Individual Claim Determinations
  - When making individual claim determinations, the contractor shall determine whether the item or service in question is covered based on an LCD or the clinical judgment of the medical reviewer.
  - An item or service may be covered by a contractor if it meets all of the conditions listed § 13.5.1, Reasonable and Necessary Provisions in LCDs
- Section 13.5.1 – Reasonable and Necessary Provisions in LCD.
  - An item or service may be covered by a contractor LCD if:
  - It is reasonable and necessary under 1862(a)(1)(A) of The Act. Only reasonable and necessary provisions are considered part of the LCD.
Medical Necessity

Medicare Program Integrity Manual – Chapter 13

• Section 13.5.1 – Reasonable and Necessary Provisions in LCDs
  – Reasonable and Necessary
  – Contractors shall describe in the draft LCD the circumstances under which the item or service is reasonable and necessary under 1862(a)(1)(A). Contractors shall consider a service to be reasonable and necessary if the contractor determines that the service is:
    • Safe and Effective
    • Not experimental or investigational (exception: routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary); and
    • Appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
      – Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient’s condition or to improve the function of a malformed body member;
      – Furnished in a setting appropriate to the patient’s medical needs and condition;
      – Ordered and furnished by qualified personnel;
      – One that meets, but does not exceed, the patient’s medical need; and
      – At least as beneficial as an existing and available medically appropriate alternative.

• Section 13.7.1 – Evidence Supporting LCDs
  – Contractor LCDs shall be based on the strongest evidence available. The extent and quality of supporting evidence is key to defending challenges to LCDs. The initial action in gathering evidence to support LCDs shall always be a search of published scientific literature for any available evidence pertaining to the item or service in question. In order of preference, LCDs should be based on:
    • Published authoritative evidence derived from definitive randomized clinical trials or other definitive studies, and
    • General acceptance by the medical community (standard of practice), as supported by sound medical evidence based on:
      – Scientific data or research studies published in peer-reviewed medical journals;
      – Consensus of expert medical opinion (i.e., recognized authorities in the field); or
      – Medical opinion derived from consultations with medical associations or other health care experts;
    – Acceptance by individual health care providers, or even a limited group of health care providers, normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with financial interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality shall be evaluated before a conclusion is reached.
    – LCDs which challenge the standard of practice in a community and specify that an item or service is never reasonable and necessary shall be based on sufficient evidence to convincingly refute evidence presented in support of coverage.
    – Less stringent evidence is needed when allowing for individual consideration.
**Level IV: Medicare Appeals Council**

- Within sixty (60) days of receipt of notice of ALJ decision
- Form v. Letter
- The Medicare Appeals Council may initiate a review of an ALJ decision on its own motion within sixty (60) days
- Medicare Appeals Council must implement its own motion review within the sixty (60) days
- Similar backlog issues

- If CMS or its contractor participated in an appeal at the ALJ level, the Council exercises its own motion review if (i) there is an error material to the decision, (ii) abuse of discretion, (iii) the conclusions not supported by the preponderance of the evidence, and (iv) there are issues of broad public policy.
  - If CMS did not participate in the ALJ proceeding, the Council will accept review of the decision only if there is an error material to the decision or there are issues of broad public policy.
- The Administrative QIC ("AdQIC") serves as a *de facto* appellant arm of CMS.
  - If the AdQIC finds a newly issued ALJ decision that CMS views as wrong as a matter of law or contravenes an important policy, then the AdQIC files a "referral" to ask the Medicare Appeals Council to redecide the ALJ decision.
  - The Medicare Appeals Council has unfettered discretion within 60 days to exercise its “Own Motion” jurisdiction to reopen an ALJ decision, and is required to reopen if there is an error of law.
**Level IV: Medicare Appeals Council**

- Review is usually on the record. A party to the appeal can file briefs.
- May remand a case to the ALJ for further consideration or action
- If the Medicare Appeal Council fails to decide within 90 days, then appellant can request escalation to federal court review
- Standard of review is *de novo*

**Level V: Federal District Court**

- Sixty (60) days of Medicare Appeals Council’s decision
- Defendant: the Secretary of HHS in his/her official capacity
- Standards of review are “substantial evidence” as to findings of fact; arbitrary, capricious or an abuse of discretion as to procedural matters; and *de novo* as to matters of law.
- Government motion for remand. The court retains jurisdiction and essentially decides the case, although the formal outcome may be a remand for implementation of the court’s decision.
  - In contrast, under a “Sentence 6” remand, the court relinquishes jurisdiction so that the merits of the case (most likely based on additional evidence) are decided on remand by the Medicare Appeals Council or, most likely, by the ALJ to whom the Medicare Appeals Council will likely further remand.
OMHA Initiatives

Settlement Conference Facilitation

Alternative dispute resolution process

- OMHA trained mediators act as a neutral facilitator in conference to discuss possible settlement of pending appeals between provider and CMS
- If an agreement is reached, appealed claims are paid under settlement terms and appeals are dismissed

Appeals resolved since June 2014: 70,785*

*Data current as of Dec. 31, 2017

Settlement Conference Facilitation (cont’d)

April 2018 Expansion:

- Available for requests for hearing filed on or before November 3, 2017, by Part A or Part B providers or suppliers with:
  - 500 or more appeals pending at OMHA and Council, combined; or
  - Any number of appeals pending at OMHA and the Council that each have more than $9,000 in billed charges

Details and how to request SCF:

- OMHA Website: https://www.hhs.gov/about/agencies/omha/about/special-initiatives/settlement-conference-facilitation/index.html
- Email: OMHA.SCF@hhs.gov
Settlement Conference Facilitation Practice Tips

- Position Paper
  - Timing of submission (early submission for CMS decision makers)
  - Big-picture discussion
    - Trends
      - Patterns of initial denials/approvals
    - Appeal strategy (selective vs. 100%)
    - Previous approvals (at earlier levels of appeal and ALJ)
- Expert participation
- Sampling of claims
  - Who picks the sample
  - When are the claims sampled

Statistical Sampling Initiative

Alternative method for resolving large numbers of appealed claims

- OMHA-procured independent statistician pulls a random sample of appealed claims
- ALJs adjudicate the sample claims
  - Lead ALJ decides issues related to sampling and extrapolation, and hears and decides a portion of the sampled claims
  - Cadre or 2–4 additional ALJs, depending on sample size, hears and decides remaining sampled claims
- Outcomes are extrapolated to the universe of appealed claims
Currently available for providers with at least 250 claims pending at OMHA, all of which fall into only one of the following categories:

- Pre-payment claim denials; or
- Post-payment (overpayment) non-RAC claim denials; or
- Post-payment (overpayment) RAC claim denials from a single RAC

Appeals for which the appellant selected statistical sampling since June 2014: 14,360*

Details and how to request statistical sampling:

- OMHA Special Initiatives Website:
  https://www.hhs.gov/about/agencies/omha/about/special-initiatives/statistical-sampling/index.html
- Email: OMHA.Stat.Sampling@hhs.gov

*Data current as of February 1, 2018
**Statistical Sampling Practice Tips**

- Initial statistics
- Prehearing conference
- **Number of judges**
  - If the universe size is 250-750 claims, a cadre of 2 additional Administrative Law Judges will be assigned. Each Administrative Law Judge will hear and decide one third of the statistical sample claims.
  - If the universe size is 750 claims or greater, a cadre of 3-4 additional ALJs will be assigned. Each Administrative Law Judge will hear and decide one quarter to one fifth of the statistical sample claims.
- **Interplay with SCF**

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**CMS Initiatives**

**Low Volume Appeals (LVA) Settlement Option**

- Available from Feb. 5 through April 11, 2018
- Providers and suppliers with fewer than 500 appeals pending at OMHA and DAB can resolve eligible appeals with total billed amount of $9,000 or less for 62% of net allowable amount
CMS Initiatives

QIC Formal Telephone Discussion Demo

- DME QIC conducts voluntary telephone discussions with DME suppliers in MAC Jurisdictions C & D
- DME suppliers given opportunity to present facts of case and provide additional documentation
- Demonstration includes all DME claim types, except appeals already subject to another CMS initiative
- QIC also reviews closed reconsiderations pending with OMHA to identify cases that can be resolved favorably via QIC reopening in light of discussion

QIC Formal Telephone Discussion Demo (cont’d)

- 5-year demonstration project designed to improve claim submission to DME MACs from suppliers participating in the discussion process
- Results so far:
  - 26,567 appeals* have been resolved favorably via demonstration process prior to reaching OMHA
  - 25,025 appeals* have been remanded from OMHA for QIC to process reopening/resolve claim favorably

*Data current as of Jan. 1, 2018
**OMHA and CMS Initiatives Practice Tips**

- Be proactive about assessing eligibility under the current programs and monitoring for new initiatives.
- Incorporate initiatives into appeal strategy.

**Contacts**

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**OMHA Appeals**

For cases assigned to an ALJ, contact the ALJ team:
OMHA Field Office phone numbers available at:
http://www.hhs.gov/about/agencies/omha/contact/index.html

For cases not yet assigned or other issues:
OMHA Customer Service Line: (855) 556-8475 (toll free)
Medicare.Appeals@hhs.gov (OMHA-level appeals only)